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ANNEXES 1 to 19

## ANNEXES

**to the Commission Staff Working Document**

**Proposal for a Regulation of the European Parliament and of the Council**

**Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC**

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# ANNEX 1: PROCEDURAL INFORMATION

## 1 LEAD DG, DECIDE PLANNING/CWP REFERENCES

The revision of REACH and the accompanying impact assessment are under the responsibility of DG Environment (ENV) and co-responsibility of DG Internal Market, Industry, Entrepreneurship and SMEs (GROW). The initiative is included in Decide planning with reference [PLAN/2021/10630](#) and mentioned in the Commission work programme 2022 as one of the follow-up actions on the zero pollution action plan.

## 2 ORGANISATION AND TIMING

The revision of REACH was first announced in the Chemicals Strategy for Sustainability published in October 2020 and the [inception impact assessment](#) was published on 4 May 2021. To support the impact assessment, nine studies were launched (timing) and specific input was requested from the Commission Joint Research Centre and from ECHA.

DG ENV and DG GROW established the Inter-Service Steering Group (ISG) on and the following 16 Services participated: COMM, COMP, ECFIN, EEAS, EMPL, JRC, JUST, MARE, NEAR, OLAF, REGIO, RTD, SANTE, SG, TAXUD and TRADE. In addition, ECHA was invited and participated as observer.

The ISG met in total 8 times, for more details please see Table 1.

Table 1: Overview of ISG meetings

ISG meeting date	Topics discussed
1 <sup>st</sup> ISG – 20 May 2021	<ul style="list-style-type: none"><li>• Options for the revision of REACH</li><li>• Work plan, including technical support studies</li><li>• Consultation strategy</li></ul>
2 <sup>nd</sup> ISG – 20 September 2021	<ul style="list-style-type: none"><li>• Update of the work plan</li><li>• Study to support the Commission impact assessment</li><li>• Study supporting the Commission in developing an essential use concept</li><li>• Study on the extension of the use of the generic risk management approach to further hazard classes and uses, and on authorisation and restriction reform</li></ul>
3 <sup>rd</sup> ISG – 15 November 2021	<ul style="list-style-type: none"><li>• Public consultation: timeline, presentation and discussion of the draft questionnaire</li><li>• Progress overview on problem areas, including the status of the technical support studies</li></ul>
4 <sup>th</sup> ISG – 31 May 2022	<ul style="list-style-type: none"><li>• Public Consultation and SME panel: main statistical highlights</li><li>• Outcome of the upstream meeting with the Regulatory Scrutiny Board on 22 April 2022</li><li>• Intervention logic, including policy options</li><li>• State of play of the technical support studies</li><li>• State of play of the impact assessment and next steps</li></ul>
5 <sup>th</sup> ISG – 23 June 2022	<ul style="list-style-type: none"><li>• Update on the timeline and status of the technical supporting studies</li></ul>

ISG meeting date	Topics discussed
	<ul style="list-style-type: none"> <li>• Presentation of the first draft of sections 1-4 of the Staff Working Document</li> </ul>
6 <sup>th</sup> ISG – 1 September 2022	<ul style="list-style-type: none"> <li>• Update on the progress with the Staff Working Document (and Annexes)</li> <li>• Presentation of the overview of options and preliminary expected impacts</li> </ul>
7 <sup>th</sup> ISG – 28 September 2022	<ul style="list-style-type: none"> <li>• Presentation of the Staff Working Document (and Annexes), shared with the ISG ahead of the meeting</li> <li>• Discussion and comments</li> </ul>
8 <sup>th</sup> ISG – 6 October 2022	<ul style="list-style-type: none"> <li>• Final meeting to explain how the comments from the ISG have been addressed.</li> <li>• Services agreed on the draft impact assessment report, and sent final comments in writing after the meeting, which were integrated in the documents.</li> </ul>

In addition to the ISG meetings, interested Services and ECHA were involved in regular discussions on specific topics of the REACH revision in the format of working groups. For example, for the development of the essential use concept, other units in ENV and GROW as well as other Services such as SANTE, CLIMA, EMPL and SG were involved closely in following the supporting study and in internal discussions about the concept.

### 3 CONSULTATION OF THE RSB

To be drafted after RSB meeting on 14 September 2022.

### 4 EVIDENCE, SOURCES AND QUALITY

The evidence collected for the impact assessment is based on a wide range of sources, which can be summarised as follows:

- Ex-post evaluations of REACH, with the [latest in 2018](#) (European Commission, 2018)
- Fitness check on chemicals legislation other than REACH
- ECHA reports on the operation of REACH: [latest in 2021](#)
- Data on substances registered under REACH collected by ECHA
- Technical and scientific support to the Commission's impact assessment for the revision of REACH
- [Scientific and technical support for the development of criteria to identify and group polymers for registration/evaluation under REACH and their impact assessment](#)
- Study to gather Further Information to be Used in Support of an Impact Assessment of Potential Options, for the Update of REACH Annexes for Inclusion of Data Requirements on Endocrine Disruption
- Study supporting the Commission's proposal for introducing a Mixtures Assessment Factor in REACH
- Study to support to the possible introduction of the concept of Derived Minimal Effect Level (DMEL) for non-threshold substances in REACH

- Study supporting the possible introduction of additional information requirements on uses and exposure in REACH
- Study to support the impact assessment for potential amendments of the REACH Regulation, to extend the use of the generic risk management approach to further hazard classes and uses, and to reform the REACH authorisations and restrictions
- Study supporting the Commission in developing an essential use concept
- [Study on the establishment of a European Audit capacity to ensure compliance and effective national control and enforcement of the REACH regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC regulations](#)
- [Study to support the integration of REACH aspects into custom legislation and procedures](#)
- A comprehensive stakeholders consultation (inception impact assessment, public consultation, SME panel, multiple targeted consultations as part of the supporting studies)
- Ad-hoc support from JRC and ECHA

# ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

## 1 CONSULTATION'S OBJECTIVES AND MAPPING OF STAKEHOLDERS

The stakeholder consultation aimed at:

- Collecting factual information and data on the application of REACH, thus adding to the specification of the current baseline, to the existence of the problems and of their scale;
- Obtaining views on the options for the revision of REACH, as initially set out in the Inception Impact Assessment<sup>1</sup> and further refined during the process and on their possible impacts.

Since REACH affects all members of society, including citizens, workers, and businesses, as well as the environment, the main groups of stakeholders that were identified to be relevant for this initiative are the following:

- **Business associations and companies**, with special focus on SMEs, representing the interests of manufacturers, downstream users, distributors and retailers of chemical substances. These include the chemical sector but also a large number of 'downstream' sectors that rely on the use of chemical substances for their production processes (e.g. textile, automotive, detergents sectors).
- **General population** representing their own interest as consumers and citizens;
- **Civil society** representing public health, environmental and animal welfare interests;
- **Social partners**, representing the interests of employers and employees (trade unions);
- **Research and innovation community (academia)**, representing the public interest in scientific research on chemical substance and their effects;
- **Member State Competent Authorities**, representing national interests;
- EU Agencies: the **European Chemicals Agency (ECHA)** is the most impacted as it is tasked to support the implementation of REACH. Other agencies can be indirectly interested, such as the European Food Safety Authority (EFSA), the European Agency for Safety and Health at Work (EU-OSHA) and the European Environment Agency (EEA).
- International organisations (e.g. OECD) and third countries, representing the interests of the international community.

While the stakeholder consultation does not cover inter-institutional consultations, the importance of the European Parliament should be noted as Members of the European Parliament have demonstrated an increasing interest in the topic.

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<sup>1</sup> <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Revision-of-EU-legislation-on-registration-evaluation-authorisation-and-restriction-of-chemicals->



## 2 CONSULTATION ACTIVITIES

A combination of tools and methods were used to gather views and data from the stakeholder groups listed in section 1. The consultation tools used are listed and described in sub-sections 2.1 to 2.5 below, together with a summary of the main results.

### 2.1 Inception impact assessment (IIA)

An **Inception Impact Assessment (IIA)**<sup>2</sup> was published and was open for feedback over a four-week period from 4 May to 1 June 2021. All stakeholders, including EU citizens, were invited to provide written feedback on the IIA.

The IIA aimed to inform citizens and stakeholders about the European Commission's plans to revise REACH and provided an initial overview of the problems identified and ways to address them. Feedback on the IIA was received from 325 respondents (valid contributions). These were mostly from business associations and companies (48%), followed by EU citizens (29%), NGOs (8%), public authorities (4%) and academic/research institutions (3%). A large number of responses were received from Belgium (27%), followed by Germany (20%), France (8%), and Italy (6%). Statistics are provided and visualised on 'Have your say' website<sup>3</sup>.

The table below provides an overview of the analysis of stakeholders' feedback by problem area.

Table 2: Summary of feedback to the inception impact assessment

Area	Summary of feedback
Existing knowledge gaps (on hazards and uses of substances)	<ul style="list-style-type: none"><li>• <b>About 20% of companies/business organisations and associations, as well as all research institutions, NGO, environmental organisations, trade unions, and the majority of public authorities, support the review of REACH and the revision of information requirements.</b></li><li>• However, <b>the majority of companies/business organisations and associations</b> agree that REACH is already comprehensive in this respect, and further tightening would only add pressure to all interested parties. <b>Additional information and data requirements should be proportionate</b> and based on a tiered approach. Consistent with the requirements of Article 13 of REACH, this should not lead to an increase in animal testing.</li></ul>
Mixture assessment factor (combination effects)	<ul style="list-style-type: none"><li>• <b>All NGOs, environmental organisations, trade unions, and the majority of public authorities support the introduction of a generic Mixture Assessment Factor (MAF), as an effective and pragmatic tool to take combination effects into account in the chemical safety assessment.</b></li><li>• Differently, <b>all companies/business organisations and associations</b></li></ul>

<sup>2</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en)

<sup>3</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/feedback\\_en?p\\_id=24337369](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/feedback_en?p_id=24337369)

	<p><b>and a few public authorities (around 10% of respondents) do not support</b> the introduction of a <b>generic MAF</b> as they believe that substances or uses without relevant detectable combination effects would be discontinued without improving the protection of humans and the environment.</p> <ul style="list-style-type: none"> <li>• Due to the infinite number of combinations of chemicals currently on the market and the complexity of combined exposure, the effects of combined exposure cannot be identified in a simple way by introducing a generic MAF.</li> </ul>
Efficiency of communication in the supply chain	<ul style="list-style-type: none"> <li>• <b>The great majority of companies/ business organisations and associations, as well as all public authorities and NGOs, welcome</b> any improvement towards the simplification of the communication in the supply chain, as well as the <b>digitalisation of Safety Data Sheets (SDS)</b> in a way that is mostly compatible with systems already established in companies.</li> </ul>
Simplified and comprehensive evaluation of registration	<ul style="list-style-type: none"> <li>• <b>Public authorities, NGOs, trade unions, and consumer organisations support</b> the revision of the <b>registration requirements</b>, by including for example information on hazards of concerns, safe use, registration of polymers, and of low volume substances.</li> <li>• A limited number of companies/ business organisations and associations, and academics, as well as all public authorities and trade unions, support the introduction of a <b>revocation process for registration numbers</b>. However, companies and business organisations/associations believe that such revocation should be considered carefully and used as last resort measure, not as default action.</li> <li>• The <b>majority of companies and business organisations/associations</b> promote uniform criteria and <b>targeted requirements</b> for substance registration.</li> <li>• A few <b>companies, NGOs, and trade unions</b> (about 40% of respondents) agree with the idea of defining pragmatic <b>grouping criteria</b> and registration requirements, as this would reduce repeating registration for different substances, belonging to the same group of hazardous substances.</li> </ul>
Simplified authorisation	<ul style="list-style-type: none"> <li>• <b>All stakeholders welcome</b> the effort to <b>clarify and simplify</b> the authorisation process.</li> <li>• <b>All companies and business organisations/associations</b> agree that the <b>multi-stage authorisation</b> processes are extremely <b>lengthy and expensive</b>, putting European companies at a competitive disadvantage on the world market.</li> <li>• <b>The majority of companies and business organisations/associations, NGOs, and public authorities disagree with authorisations granted at national level</b>, as these would undermine harmonisation and jeopardise the functioning of the Union's internal market.</li> <li>• The majority of companies and business organisations/ associations call for a targeted ban of substances based on science and data on their risk (i.e. following specific risk assessment), rather than banning substances based on their hazardous properties regardless of whether they can be handled safely (i.e. a generic approach to risk management).</li> <li>• <b>Many companies and business organisations, public authorities,</b></li> </ul>

	<p><b>NGOS, and consumer organisations</b> sustain that the interface between authorisation and restriction needs to be clarified and both processes need to be better aligned. <b>Merging authorisations and restrictions is a very challenging</b> objective, especially because authorisation only applies to the use of the substance in the EU, whereas restrictions also apply to imports of substances, mixtures and articles.</p> <ul style="list-style-type: none"> <li>• <b>Around 50% of companies support</b> the concept of ‘one substance one assessment’.</li> <li>• <b>Academics, public authorities, consumer organisations, trade unions, and very few business associations</b> agree that the authorisation process should be aligned with the <b>concept of essential use</b>.</li> </ul>
<p><b>Simplified restriction</b></p>	<ul style="list-style-type: none"> <li>• <b>All academics, public authorities, citizens, NGOs, environmental organisations, and a limited number of companies and business associations support</b> the ambition in the Chemicals Strategy for Sustainability to <b>introduce endocrine disruptors</b>, persistent, mobile and toxic and very persistent and very mobile substances as categories of Substances of Very High Concern (SVHC) within the REACH restriction process.</li> <li>• <b>All companies and business organisations/ associations reject</b> a restriction process based on <b>potential hazard</b>, while support a regulatory approach based on risk assessment.</li> <li>• <b>Most companies and business organisations/ associations</b> disagree with the extension of the generic approach to risk management. They argue that the equal treatment of consumer uses, and professional uses is not appropriate, as employees already receive training and apply risk management measures. Differently, public authorities, NGOs and a few companies (about 10%) believe that a group approach could contribute to an efficient procedure and fair decision-making.</li> <li>• <b>Around 80% of companies and business organisations/ associations reject the "essential-use-concept"</b>, as they believe that decisions would be made for all Europe in a centralised regulatory process that would not consider regional, cultural, economic, and social factors. The <b>remaining companies and business organisations/ associations, and trade unions</b> believe that the essential use concept could well fit the framework of restriction process, but its implementation must be carefully assessed. A too restrictive definition would strongly limit the innovation capability of the chemical industry, and thus the ability of the European industry to remain globally competitive.</li> </ul>
<p><b>Effectiveness of control and enforcement</b></p>	<ul style="list-style-type: none"> <li>• <b>All companies and business organisations/ associations, public authorities, and trade unions, support consistent enforcement</b> to protect the European Single Market. Support was provided for strengthening cooperation of national enforcement authorities and for improving the monitoring of imports via online sales.</li> </ul>

## 2.2 Public consultation

A **public consultation**<sup>4</sup> (PC) was launched over a 12-week period from 20 January to 15 April 2022. The questionnaire was made available in all EU languages and published on the Have your Say website<sup>5</sup> and the consultation was announced on social media (e.g. via Tweets). A summary report is available in the webpage of the consultation.

The public consultation consisted of a questionnaire split into two sections: one for citizens and organisations with a **general knowledge** on REACH, and another for citizens and organisations with **expert knowledge** on REACH. The latter was targeted at a broad range of stakeholder groups, including public authorities and bodies responsible for implementing and/or enforcing the regulation, as well as industry and sectorial associations representing companies concerned, environmental and consumer NGOs, universities and research institutes, and any other organisations with expert knowledge interested in responding to the questionnaire.

In total, 771 responses were received. Most of the respondents (591 out of 771, 77%) filled in both the general and the expert parts of the questionnaire. The remaining respondents completed only the general part of the questionnaire. The number of each type of stakeholder who responded to the public consultation is shown in the figure below.

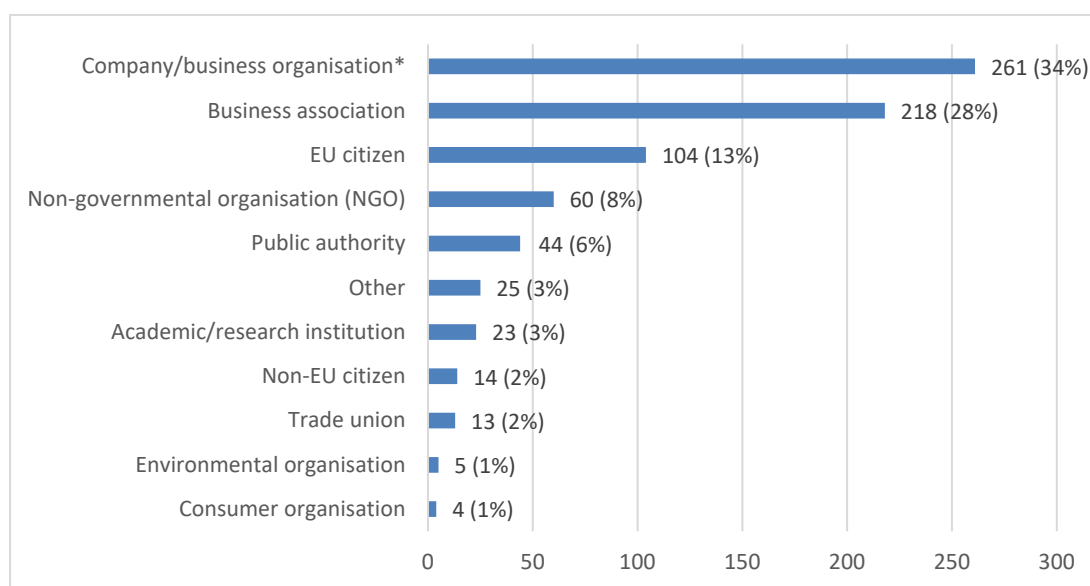


Figure 1: Number of responses by stakeholder type (percentages in brackets)

\* Large (250 or more employees) companies made up the biggest proportion of responses at 185 (71%). Medium (50 to 249 employees) accounted for 30 responses (11%), micro (1 to 9 employees) accounted for 24 (9%), and small (10 to 49 employees) accounted for 22 (8%).

Respondents to the PC came from a total of 33 countries: 25 EU and EEA countries, plus eight from outside the EEA (Australia, Ecuador, Japan, Switzerland, Turkey, United

<sup>4</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/public-consultation\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/public-consultation_en)

<sup>5</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say_en)

Kingdom, United States, Uruguay). The largest number of respondents were from Germany (194), followed by Belgium (140), France (79), and Italy (50).

This section provides a high level summary of the responses to some of the key questions in the public consultation. It shows findings mostly based on averages and percentage responses and therefore does not fully communicate the distribution of responses, although differences between stakeholder types have been drawn out where possible. A more comprehensive description of the results is included in the final report of the supporting study, including an analysis of qualitative responses which has not been presented here, and provides further justification/evidence supporting stakeholder opinions.

Views are presented by stakeholder category, differentiating between academic/research institutions, business associations, company/business organisations, consumer organisations, environmental organisations, EU and non-EU citizens, non-governmental organisations (NGO), public authorities, trade unions, and others. For questions on effectiveness of proposed measures, a similar scale from 0 to 4 was established. For questions with multiple sub-parts, averages have been described qualitatively.

The sub-sections below mirror the structure of the public consultation questionnaire – covering first the results related to registration, followed by evaluation, authorisation and restriction, and enforcement.

Table 3: Summary of results from the public consultation regarding REACH registration

Questionnaire topic	Response summary
<b>Information on critical hazards</b>	<ul style="list-style-type: none"> <li>• <b>Stakeholders were divided</b> whether more information on critical hazards should be provided (with most support from NGOs, environmental organisations, and academia; and most resistance from industry representatives).</li> <li>• Stakeholders supported the introduction of more information on carcinogenicity for all substances registered under REACH. Only industry representatives were neutral on this matter.</li> </ul>
<b>Information on substances marketed at the lowest tonnage level</b>	<ul style="list-style-type: none"> <li>• Most non-industry respondents agreed or strongly agreed that there is sufficient concern regarding the risks from (certain) low tonnage substances (1-10 tonnes) to introduce additional information requirements into REACH. In particular, among respondents from academia, 95% agreed or strongly agreed. This is followed by 87% of responding NGO that agreed or strongly agreed as well as 78% of responding public authorities, 61% of other respondents (which includes consumer and environmental organisations), 58% of responding EU and non-EU citizens, and 50% of responding trade unions. In contrast, only 19% of industry agreed or strongly agreed, while 57% disagreed or strongly disagreed.</li> </ul>
<b>Information requirements to provide information on endocrine disruption</b>	<ul style="list-style-type: none"> <li>• The majority of stakeholders under each stakeholder group except industry agreed or strongly agreed that in order to allow the identification of endocrine disruptors, registrants should be required to provide to authorities sufficient and appropriate standard information requirements on the intrinsic properties of a substance. In particular, 95% of respondents from academia agreed or strongly agreed, as well as 94% of NGOs and of public authorities, 83% of others (which includes consumer and environmental organisations), 81% of EU and non-EU citizens, and 50% of trade unions whereas only 41% of industry respondents agreed or strongly agreed, 43% disagreed or strongly disagreed, and 15% neither agreed nor disagreed.</li> <li>• Stakeholders were divided on whether modifying the standard information</li> </ul>

Questionnaire topic	Response summary
	<p>requirements annexes under REACH (Annex I, VII-X) is the most suitable approach to obtaining information to allow the identification of endocrine-disruptors. NGOs, academia, and public authorities showed high support, while business associations, companies and trade unions tended to disagree.</p> <ul style="list-style-type: none"> <li>• In terms of impacts expected from the introduction of information requirements to provide information on endocrine disruption: <ul style="list-style-type: none"> <li>○ Positive impacts on public health and health systems and environmental protection were predicted by all stakeholder categories.</li> <li>○ Negative impacts on laboratory animals were predicted by all stakeholder categories.</li> <li>○ Consumer and environmental organisations and NGOs predicted positive impacts on all other categories (competitiveness, R&amp;D, compliance etc.). In contrast, companies and business associations expected negative impacts on the same categories.</li> </ul> </li> <li>• Public authorities expected negative impacts on: compliance and administration costs for the chemicals industry, laboratory animals, laboratory capacity and associated costs, and public authorities' resources.</li> </ul>
<p><b>Information requirements for polymers</b></p>	<ul style="list-style-type: none"> <li>• The majority of stakeholders under all categories except for industry agreed or strongly agreed that certain polymers should be registered under REACH. This is the case in particular for 95% of responding academia, 78% of EU and non-EU citizens, 98% of NGOs, 97% of public authorities, 50% of trade unions, and 79% of other respondents (which includes consumer and environmental organisations) while in comparison, only 34% of industry representatives agreed or strongly agreed.</li> <li>• On average, all stakeholder categories agreed that registering certain polymers under REACH would lead to environmental and health benefits.</li> <li>• Academia, environmental organisations, and NGOs generally agreed that registration of certain polymers would lead to socio-economic benefits and economic benefits for industry, while industry disagreed. Responses from other stakeholder types were near neutral.</li> <li>• There was support from all categories of stakeholders except NGOs with regards to aligning future requirements on polymer registration under REACH with similar international polymer registration schemes (e.g. US, Canada, Australia) as much as possible. In particular, 70% of academia responding to the PC agreed or strongly agreed with such an alignment, as well as 92% of industry representatives, 77% of EU and non-EU citizens, 61% of public authorities, 70% of trade unions, and 69% of other respondents (which includes consumer and environmental organisations). A lower share of NGOs (41%) agreed or strongly agreed.</li> <li>• There was support for introducing information requirements for the following polymer types (with number of suggestions in parentheses): <ul style="list-style-type: none"> <li>○ Polymers classified for certain severe hazards (320)</li> <li>○ Polymers having reactive functional groups of concern (256)</li> <li>○ Polymers with low molecular weight expected to behave similarly to non-</li> </ul> </li> </ul>

Questionnaire topic	Response summary
	<p>polymeric substances (253)</p> <ul style="list-style-type: none"> <li>○ Polymers suspected to form hazardous components during degradation (193)</li> <li>○ Cationic polymers or polymers that can be reasonably expected to become cationic in a natural environment (180)</li> <li>○ Fluoropolymers and perfluorinated polymers (171)</li> <li>○ Polymers with higher molecular weight even if they might behave differently than non-polymeric substances (68)</li> </ul>
<b>Information on environmental footprint</b>	<ul style="list-style-type: none"> <li>• The majority of stakeholder categories – 65% of academia respondents, 73% of EU and non-EU citizens respondents, 71% of NGOs respondents, 73% of public authorities respondents, and 64% of other respondents – strongly agreed or agreed that registrants should provide information on the environmental footprint of their substances. In contrast, 59% of industry respondents and 58% trade union respondents disagreed or strongly disagreed.</li> <li>• On average academic, industries, and citizens, responded (even if to different extent) that information on environmental footprint should <u>not</u> only relate to the substance as produced.</li> <li>• There was support from all categories of stakeholders except companies and trade unions for information on environmental footprint to cover the whole lifecycle of the substance. Support came from 92% of academia, 63% of citizens, 60% of NGOs, 73% of public authorities, and 63% of other respondents. On the other hand, 74% of companies disagreed or strongly disagreed.</li> </ul>
<b>Information requirements on use and exposure</b>	<ul style="list-style-type: none"> <li>• Respondents suggested the following stakeholders should be responsible for informing ECHA about the uses of chemicals (with number of suggestions in parentheses):</li> <li>• Registrants (manufacturers and importers of substances) (626)</li> <li>• Downstream users (end users) of substances (361)</li> <li>• Companies placing products (including articles) on the market (including importers of products) (321)</li> <li>• Authorities (based on information from surveys) (214)</li> <li>• 55% of respondents across all categories suggested that registrants should update the information in the registration dossiers whenever new information becomes available, while 15% of (all) respondents suggested every year, and 11% of (all) respondents suggested every 3 years.</li> <li>• Academia, consumer organisations, environmental organisations, NGOs, public authorities, and trade unions agreed or strongly agreed that insufficient or incomplete information on uses and/or exposure has limited the effectiveness of all reported processes on average (demonstrating safe use in chemical safety reports (CSRs), substance evaluation, authorities' prioritisation of substances that require regulatory management, drafting restriction proposals, prioritisation of SVHCs, and granting authorisations). Industry, citizens, and other stakeholders had opposite views on average.</li> <li>• One question asked to what extent respondents agree that certain issues<sup>6</sup> are hindering the correct implementation of REACH. For all issues listed, NGOs,</li> </ul>

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<sup>6</sup> Data gaps with regard to tonnage allocation to uses, insufficient or incomplete data on dispersive consumer and professional uses, lack of information on the specific product category or article category that the substance is used in

Questionnaire topic	Response summary
	<p>consumer and environmental organisations, public authorities, and academia agreed or strongly agreed. Other stakeholders, including industry representatives, generally disagreed or were neutral. The results did not reveal whether any issue is of greater concern.</p> <ul style="list-style-type: none"> <li>• Most respondents indicated that information on use patterns, volumes and exposures from structurally similar substances (expected to have the same or similar technical function) should only be used to inform regulatory risk management measures for the whole group if fully justified on a case-by-case basis. Many non-industry respondents (particularly NGOs and academia) were more supportive of implementing this approach in all cases.</li> </ul>
<p><b>Derived Minimal Effect Level (DMEL) for non-threshold substances</b></p>	<ul style="list-style-type: none"> <li>• Most respondents agreed that the existing approach for the assessment of non-threshold risks (DMELs in certain situations or a qualitative approach) is appropriate and effective. Only NGOs and academia showed strong disagreement (72% and 55% strongly disagreed respectively).</li> <li>• Respondents were divided on whether a more extensive use of a quantitative approach to Chemical Safety Assessments for non-threshold substances should be introduced. Most of NGOs and academia (65% and 73% respectively) strongly disagreed. Half of industry representatives disagreed or strongly disagreed, while only a quarter agreed or strongly agreed. Public authorities mostly agreed.</li> <li>• Most respondents suggested a threshold of 1 in 1 000 000 as a politically acceptable risk level for both workers and the general public. For workers there was nearly as much support for a level of 1 in 100 000.</li> </ul>
<p><b>Introduction of a Mixture Assessment Factor</b></p>	<ul style="list-style-type: none"> <li>• Respondents were polarised on whether a MAF is the most suitable approach to reduce the risks associated with the unintentional exposure to chemical mixtures, in the short- and medium-term. There was high support from NGOs and academia, and strong resistance from industry. Citizens and public authorities generally agreed that a MAF is the most suitable approach.</li> <li>• Of the relatively low number of respondents who answered this question, most respondents (65) supported a single MAF for both the environment and human health. Differentiation between MAF values for the general public and occupational settings was supported by 47 respondents, and 46 supported differentiation based on effects/hazards.</li> </ul>
<p><b>Simplifying communication in the supply chain (options for improving SDS, including harmonised electronic formats)</b></p>	<ul style="list-style-type: none"> <li>• All categories of respondents on average agreed or strongly agreed that the introduction of harmonised electronic tools for the preparation and exchange of (extended) safety data sheets would improve the supply chain communication on chemical substances.</li> </ul>

Table 4: Summary of results from the public consultation regarding REACH evaluation

Questionnaire topic	Response summary
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Inconsistent use information from different registrants, insufficient/vague information on the technical function of the substance, outdated registration tonnage data in registration dossiers, outdated use tonnage data in registration dossiers, unclear conditions of use and exposure levels in chemical safety reports.



Questionnaire topic	Response summary
<b>Changes to the provisions on the evaluation process</b>	<ul style="list-style-type: none"> <li>• All stakeholder categories agreed or strongly agreed on average that dossiers should be fully compliant with all REACH provisions at the time of submission and that they should be kept updated.</li> <li>• All stakeholder categories on average agreed or strongly agreed that when a registrant fails to bring a registration dossier into compliance, the substance should no longer be manufactured or placed on the market. Compared to other categories, a higher share of industry representatives (26% of industry respondents) disagreed or strongly disagreed.</li> <li>• Respondents were asked to rate the effectiveness of a range of measures to improve the evaluation process. <ul style="list-style-type: none"> <li>○ Overall, most support was received for the option to clarify requirements for the registrants in case manufacturing is ceased or the registered volume changed during the evaluation procedure or in any follow-up re-registration. This was the only option supported (on average) by industry representatives.</li> <li>○ NGOs, public authorities, and academia were, on average, supportive of all options. These stakeholder groups showed the most support for the option to empower ECHA to assess compliance (not just completeness) during dossier submission.</li> </ul> </li> <li>• Where standard information requirements for higher-volume registrations require higher-tier testing via animal studies, stakeholders responded that tests should not be performed by default (some stakeholder categories were neutral). Stakeholders were divided regarding higher-tier testing via non-animal studies. Industry weakly disagreed that tests should be performed by default, while other stakeholder types tended to agree.</li> </ul>

Table 5: Summary of results from the public consultation regarding REACH **authorisation and restriction**

Questionnaire topic	Response summary
<b>Reform of authorisation and restriction</b>	<ul style="list-style-type: none"> <li>• Of all options for reforming authorisation and restriction<sup>7</sup>, most support was demonstrated for option 1 (keeping the authorisation process, with clarifications and simplifications). On average, respondents showed neutral to positive views on this option, while other options were perceived neutrally or negatively in terms of impacts on administrative burden, health, the environment, competitiveness, innovation and research, and legal certainty for companies.</li> <li>• Academia preferred option 2 (merging authorisation and restriction) (negatively perceived by industry and by NGOs).</li> </ul>
<b>The essential use concept</b>	<ul style="list-style-type: none"> <li>• Stakeholders were polarised whether the essential use concept would lead to environmental, health, and socio-economic benefits, as well as economic benefits for industry. <ul style="list-style-type: none"> <li>○ Academia, consumer organisations, citizens, environmental organisations, public authorities, and NGOs predicted benefits on average.</li> <li>○ Industry representatives, trade unions, and other stakeholders tended to disagree or strongly disagree (for all benefit categories on average).</li> </ul> </li> </ul>

<sup>7</sup> Option 1 – keeping the authorisation process, with clarifications and simplifications; option 2 – merging the authorisation and restriction processes by allowing authorised uses of restricted substances; option 3 – removing the authorisation title from REACH.

Questionnaire topic	Response summary
	<ul style="list-style-type: none"> <li>○ The most positive responses were received for environmental and health benefits, and the most negative for economic benefits for industry.</li> <li>● The same split among stakeholder categories – except for citizens – was observed on average for questions asking whether implementing the essential use concept in restriction and authorisation would make phasing out the most harmful chemicals simpler, more effective, more predictable and faster. There was, on average, very slightly more support for implementation in restriction (in comparison to authorisation). Responses about effectiveness and predictability were more positive than those about simplicity and speed of processes.</li> </ul>
<b>Generic risk management approach (GRA)</b>	<ul style="list-style-type: none"> <li>● Respondents showed a lack of consensus regarding in which products the most harmful chemical substances should be prohibited (even if this may cause the remaining safer products to have lower performance and/or higher price). <ul style="list-style-type: none"> <li>○ Industry representatives disagreed / strongly disagreed with most options, to a greater degree for professional (rather than consumer) uses.</li> <li>○ The only option for which industry presented neutral views was the option to ban uses for consumer products with exceptions for products designed to ensure safety during production, consumption, disposal and recycling.</li> <li>○ NGOs and consumer and environmental organisations were most supportive of bans for all consumer products (without exception). Strong support for bans for professional uses was also shown. Industry disagreed most strongly with these options.</li> <li>○ Public authorities were most supportive of bans for consumer products except for essential uses (academia, and consumer and environmental organisations tended to also agree). A slightly lower level of support was shown for the equivalent option for professional uses.</li> </ul> </li> <li>● Most respondents predicted positive impacts of extending GRA on the environment and human health (only industry expressed neutral views).</li> <li>● On average, respondents predicted negative impacts on administrative burden on companies and competitiveness and neutral impacts on innovation and research and public authority resources. These views varied substantially by stakeholder type. For example, academia, NGOs and public authorities predicted benefits to innovation and research, while industry representatives predicted negative impacts on average across all impact categories.</li> </ul>

Table 6: Summary of results from the public consultation regarding REACH **enforcement**

Questionnaire topic	Response summary
<b>Establishing a European Audit Capacity</b>	<ul style="list-style-type: none"> <li>● Most respondents across all stakeholder types supported the establishment of a European Audit Capacity (EAC).</li> <li>● All stakeholder categories on average responded that the EAC would have a high contribution to more effective enforcement of the REACH Regulation by Member States – except for public authorities which on average assigned a medium contribution.</li> <li>● All stakeholder categories on average agreed or strongly agreed that an EAC should audit Member States’ control systems and their implementation against common EU standards.</li> <li>● All stakeholder categories on average agreed or strongly agreed that an EAC should also carry out audits on EU chemicals legislation other than REACH.</li> </ul>
<b>Establishing minimum requirements for national controls and enforcement, including stricter border controls</b>	<ul style="list-style-type: none"> <li>● Mostly neutral responses were received regarding the potential solutions to address problems related to border controls.</li> <li>● Most support was received for the following measures, for which respondents suggested would be partly effective: <ul style="list-style-type: none"> <li>○ Organising REACH training sessions for importers or their representatives;</li> <li>○ Giving customs authorities access to REACH-IT data through a specific interface;</li> </ul> </li> </ul>

Questionnaire topic	Response summary
	<ul style="list-style-type: none"> <li>○ Creating an interface between the Information and Communication System for Market Surveillance (ICSMS) and national customs systems to provide access to additional data to customs on high-risk goods (e.g. substances of very high concern (SVHC) and articles containing SVHC) encountered in free circulation, allowing for further targeted controls;</li> <li>○ Creation of harmonised operations on certain articles.</li> </ul>

### 2.3 SME panel

An **SME panel questionnaire** was launched over a 5-week period from 31 March to 6 May 2022. This allowed to reach SMEs in a targeted way, with the help of the European Enterprise Network (EEN)'s partners.

The SME panel questionnaire included questions related to REACH registration, supply chain communication, authorisation, and restriction. All questions were targeted towards SMEs, to help consider their views and practical experience.

In total, 193 responses from companies were received, of which 168 responses from SMEs. Amongst SMEs, 29% (48 out of 168) of respondents were from micro companies (0-9 employees), 36% (60 out of 168) were from small companies (10-49 employees), and 36% (60 out of 168) were from medium sized companies (50-249 employees).

Nearly two thirds of SMEs responded that some of the proposed new REACH measures<sup>8</sup> for registration would result in negative or very negative impacts in terms of administrative costs. In contrast, approximately 10% of SMEs expected positive or very positive impacts of the measures on administrative costs. Predictions of impacts on administrative costs were obtained for each measure individually, however, a similar pattern of results was observed for every measure, showing no significant differences in the predicted nature of impacts (positive or negative) between the options.

Micro companies (0 – 9 employees) predicted more negative impacts of new REACH registration measures on administrative costs in comparison to small and medium companies (up to 249 employees). The measure predicted to have the most negative impacts on the administrative costs of micro and small companies was new information requirements for low tonnage substances (1-10 tonnes). The only measure expected to be less severe for micro and small companies in comparison to medium sized companies was additional requirements on use and exposure, which medium companies expected to be the most severely impacting measure.

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<sup>8</sup> Requirements for quantitative methods to demonstrate that risks are controlled for non-threshold substances; introduction of (a) mixtures assessment factor(s) in registration (chemical safety assessment); registration of certain polymers; new information requirements on the overall environmental footprint of chemicals; additional requirements for companies to provide information on use and exposure; new information requirements on the intrinsic properties of a substance to allow the identification of endocrine disruptors; new information requirements for registrants for low-tonnage substances (1 – 10 tonnes per year); new information requirements for registrants on critical hazard properties.

On measures related to authorisation and restriction, more than half of respondents predicted that ‘lighter information requirements for SMEs to apply for authorisation’ would have an overall positive impact on their REACH administrative costs. Further to this, more than half of respondents predicted that ‘simplified procedures for cases where the risk is likely to be more controlled (e.g. use of closed systems), if the use is specific (e.g. legacy spare parts), if exposure/emissions/quantity used are below a certain threshold’ would have an overall positive impact on REACH administrative costs. Conversely, less than half of respondents believed that ‘introducing a completeness check and strengthening conformity check of applications for authorisation by ECHA’ would have an overall negative impact on their REACH administrative costs.

As well as the above-mentioned results, responses to other questions under the SME panel, e.g., related to supply chain communication, have been used to inform the impact assessment.

## 2.4 Targeted consultations

As part of technical support studies (running indicatively from beginning of 2021 until mid-2022), **10 workshops**<sup>9</sup>, **seven targeted surveys** and **164 interviews** were carried out to gather the views and information from stakeholders on specific problems and options. These activities allowed to reach all the stakeholders with a high interest in the revision, such as companies, business associations, civil society, national public authorities and ECHA. The input received on the specific problems and options is synthesised and taken into account in Annexes 5 to 16 of this impact assessment.

In addition, regular meetings of the Competent Authorities for REACH and CLP **expert working group (CARACAL)** have been used to present progress with the impact assessment and gather input from Member State Competent Authorities and accredited stakeholder organisations<sup>10</sup>.

## 2.5 Fit-for-future platform

In addition to the consultation activities described in the previous sections, the Fit-for-future (F4F) platform provided an opinion on REACH<sup>11</sup>, where the problems presented in the IIA were endorsed. The suggestions of the F4F opinion to address these problems, as well as how these are taken into account, are explained below.

1. Suggestion 1 - Improving communication up and down the supply chain, in particular by assessing how and which digital tools – including a harmonised format for safety data sheets - could make communication in the supply chain more efficient and targeted to the audience, and develop such tools. Two options to improve supply chain communication via changes to the safety data sheets have been assessed in Annex 8 but not presented in the main text of the SWD as they are of a more technical

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<sup>9</sup> The workshops revolved around these topics: information requirements on use and exposure, registration of polymers, Derived Minimal Effect Level for non-threshold substances, introduction of Mixtures Assessment Factors, reforming the restriction and authorisation processes, extending the generic approach to risk management, the essential use concept, and integration of REACH into customs legislation and procedures.

<sup>10</sup> A number of industry and civil society organisations are nominated as accredited stakeholders and participate in the open sessions of CARACAL.

<sup>11</sup> To be noted that this text reflects the draft opinion as received in September 2022 – opinion 2022/SBGR2/06.

nature and do not imply major policy choices, although they are important to improve supply chain communication. See Annex 8 for more details.

2. Suggestion 2 - Facilitate registration and evaluation, by establishing a specific fund to support SMEs in complying with REACH registration obligations and by improving the evaluation of registrations. Non-compliance with registration requirements should result in revocation of registration numbers. While the impacts on SMEs are taken into account, the possibility of a specific fund for SMEs under REACH has not been explored further given the existing funding opportunities and the REACH national helpdesks. Improving the evaluation process and introducing the possibility of revoking registration numbers are taken into account in option #23 and further described in Annex 13.
3. Suggestion 3 - Increase data requirements for problematic substances, but decrease data requirements for non-problematic substances, especially those in low tonnages. To reduce testing-costs especially for SMEs, the opinion recommends that obligatory data-sharing should be applied as efficiently as possible, for example by extending it to read-across-data. The Commission is envisaging for several of the actions under the registration chapter to implement the requirements in a step-wise manner as a means to minimising the burden on industry. This is the case for instance for polymers, where registration will likely be staggered over time depending on the tonnage band, as was done for non-polymeric substances. See Annex 7 for more details.
4. Suggestion 4 - Develop IT-tools more adequate for SMEs by making them available in national languages. The Commission considers this a matter of implementation that is not relevant for this impact assessment and that should be addressed by ECHA.
5. Suggestion 5 - Enhance transparency supporting regulatory actions and innovation, by introducing effective sanctions, like the revocation of registration numbers for persistent non-compliance, improving the evaluation process and providing a database for funding opportunities related to R&D for substitution of SVHCs. The Commission has assessed some of these suggestions, see Annex 13.
6. Suggestion 6 - Strengthen enforcement, ensuring compliance with the EU chemicals legislation especially for products sold online and via increased cooperation at different levels (e.g. between Member States, ECHA, the Commission and/or stakeholders). The Commission has assessed several options to strengthen the enforcement of REACH, from the creation of a European Audit Capacity to the increased controls of imports, including online sales – see Annexes 14-16.
7. Suggestion 7 - Streamline authorisation and restriction by exploring existing synergies between the authorisation and restriction systems. The Commission has considered three main options to reform the authorisation and restriction processes and tackle the issue of multiple applications for authorisation for similar uses, where there is a duplication of some information submitted by companies. See Annex 12 for more details.

## ANNEX 3: WHO IS AFFECTED AND HOW?

### 1 MAIN ACTORS UNDER REACH

The **chemicals industry**, manufacturing chemical substances, is directly affected by the legislation and has a strong interest in how the rules evolve. Manufacturers and importers of substances are responsible for obtaining information on their hazards, to assess safety and implement appropriate risk management measures and advise the downstream users of their substances on how to use them safely. This information shall be provided in their registrations with ECHA. The sector is very diverse with some very large companies manufacturing several thousand different substances in large quantities, as well as many small companies. Special focus was placed on SMEs.

**Downstream users**, which include all companies and users of substances in the course of industrial or professional activities, including for formulation of chemical mixtures, production of articles as well as the final use of the substance on its own or in mixtures or articles (e.g. for cleaning).

**Distributors and retailers:** distributors of substances acting as a link between manufacturers or importers and users as well as retailers, including importers, bringing products to the market. Distributors are responsible for communicating information on hazards and safe uses to their customers, while retailers are responsible for ensuring that their products (mixtures and articles) comply with legal requirements.

**General population and consumers:** the EU population is exposed to substances in their surroundings, including in air, water, soil and foodstuff, and as consumers also to substances in products. There is a general concern among citizens and consumers about their safety and possible negative impacts on their health and wellbeing caused by exposure to substances in their daily life.

The figure below provides a graphical explanation of the main actors along the supply chain. However, it should be noted that not all actors are always involved and this may vary from case to case. For example, there might be cases that do not involve distributors and downstream users, or there might be cases that do not involve an industrial user between manufacturer and consumer or professional end user.



Figure 2: Overview of the role of companies, professional users and consumers under REACH

Source: (ECHA, 2015, p. 11)

**Civil society:** a number of civil society organisations, including consumer organisations, environmental and human health NGOs, and animal welfare organisations, are following closely the chemicals policy, all developments and providing input to initiatives.

**Social partners (employers and trade unions):** these stakeholders have an institutional role in setting limit values for chemicals under workers protection legislation. They follow closely all developments in the broader chemicals' agenda and provide input to the various initiatives.

**Research and innovation community (academia):** these stakeholders are indirectly affected as they are involved in developing the scientific methods used in the hazard and risk assessment as well as innovation towards safe and sustainable chemicals, materials and products. This category also includes experts, either from the academia or the private sector, who are subcontracted to develop methodologies or assessments of technologies for industry or public authorities.

**National public authorities:** Member State Competent Authorities act under direction of national governments and serve the national interests. They are also responsible for the control and enforcement of REACH. Member State Competent Authorities participate in the evaluation work via ECHA and can suggest that substances are identified as Substances of Very High Concern (SVHCs) or are restricted. They also act as decision makers in the framework of comitology together with the European Commission. The level of interest, support and influence varies from Member State to Member State.

**EU Agencies:** the European Chemicals Agency (**ECHA**) is the implementing agency for REACH and any change will affect their work. ECHA is responsible for checking and evaluating registrations from manufacturers and importers, identifying SVHCs, assessing applications for authorisation and proposals for restrictions. On request of the Commission, ECHA is preparing proposals for identification on SVHCs and developing restriction dossiers for substances when risks are not adequately controlled. Finally, ECHA is coordinating Member State inspections and enforcement via the Forum. The European Food Safety

Authority (**EFSA**), and the European Agency for Safety and Health at Work (**EU-OSHA**) are responsible for activities in close relationship with REACH and affecting the interface between REACH and other legislation. The European Environment Agency (**EEA**) is tasked to provide sound, independent information on the environment, including the impact of chemicals legislation on the environment.

**International organisations and third countries:** the EU is the global leader when it comes to legislation on chemicals and the EU legislation has a knock-on effect on how global industry is producing their products, as companies often want to produce their products at the highest standard for a global market. A number of countries around the globe are inspired by the REACH Regulation in developing their national chemicals legislation. Some European initiatives are taken up under the Strategic Approach to International Chemicals Management. The OECD Chemicals Programme is coordinating the international development of test methods and assessment methods that are implemented in EU legislation.

**Media:** journalists have demonstrated a strong interest in regulation of chemicals and are informing extensively about possible risks and new initiatives. They may have a high influence on the public and political debate and need to be kept informed.

While the stakeholder consultation does not cover inter-institutional consultations, the importance of the **European Parliament** should be noted as Members of the European Parliament have demonstrated an increasing interest in the topic.

## 2 PRACTICAL IMPLICATIONS OF THE INITIATIVE

[REDACTED]

[REDACTED]

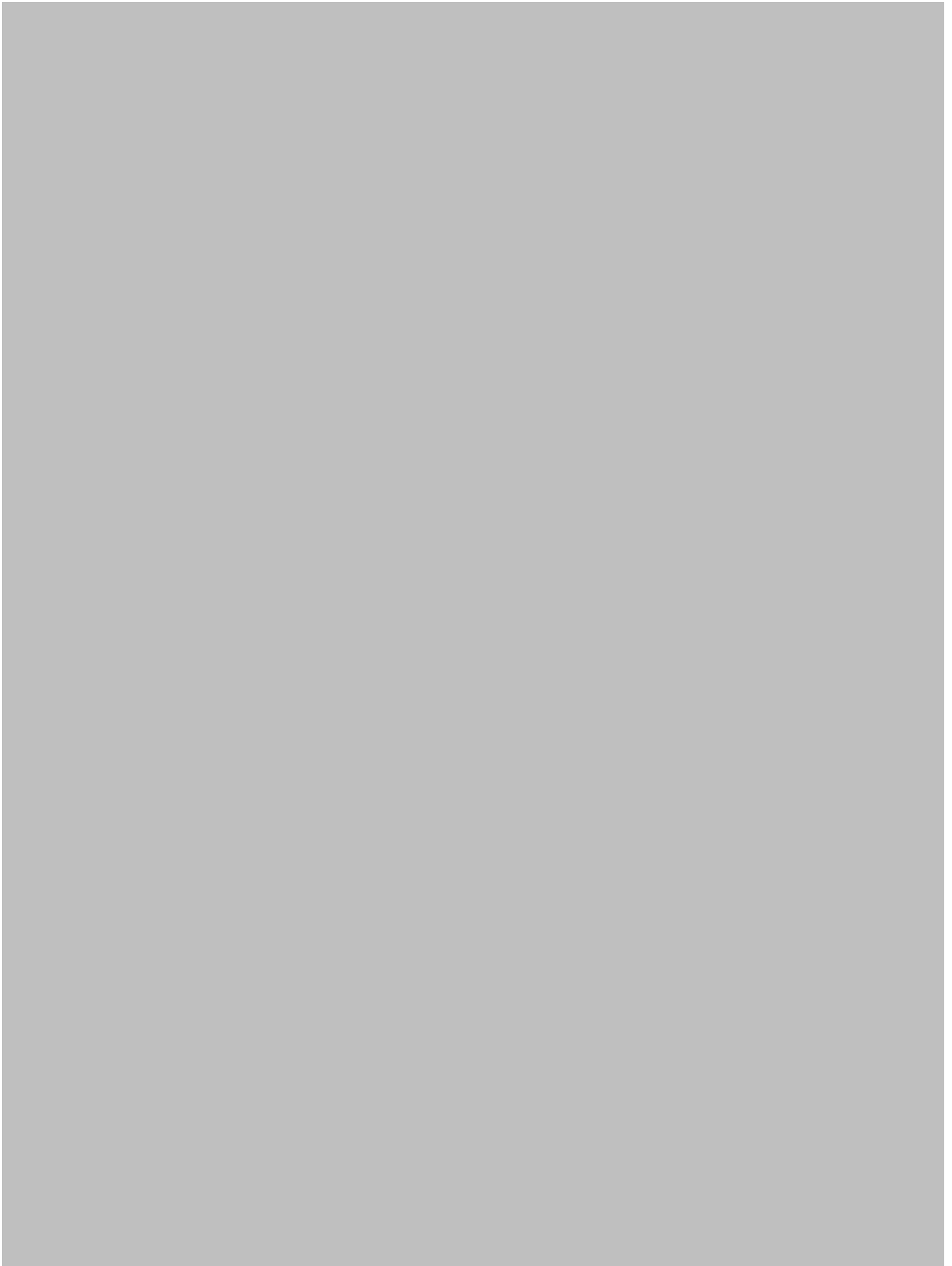
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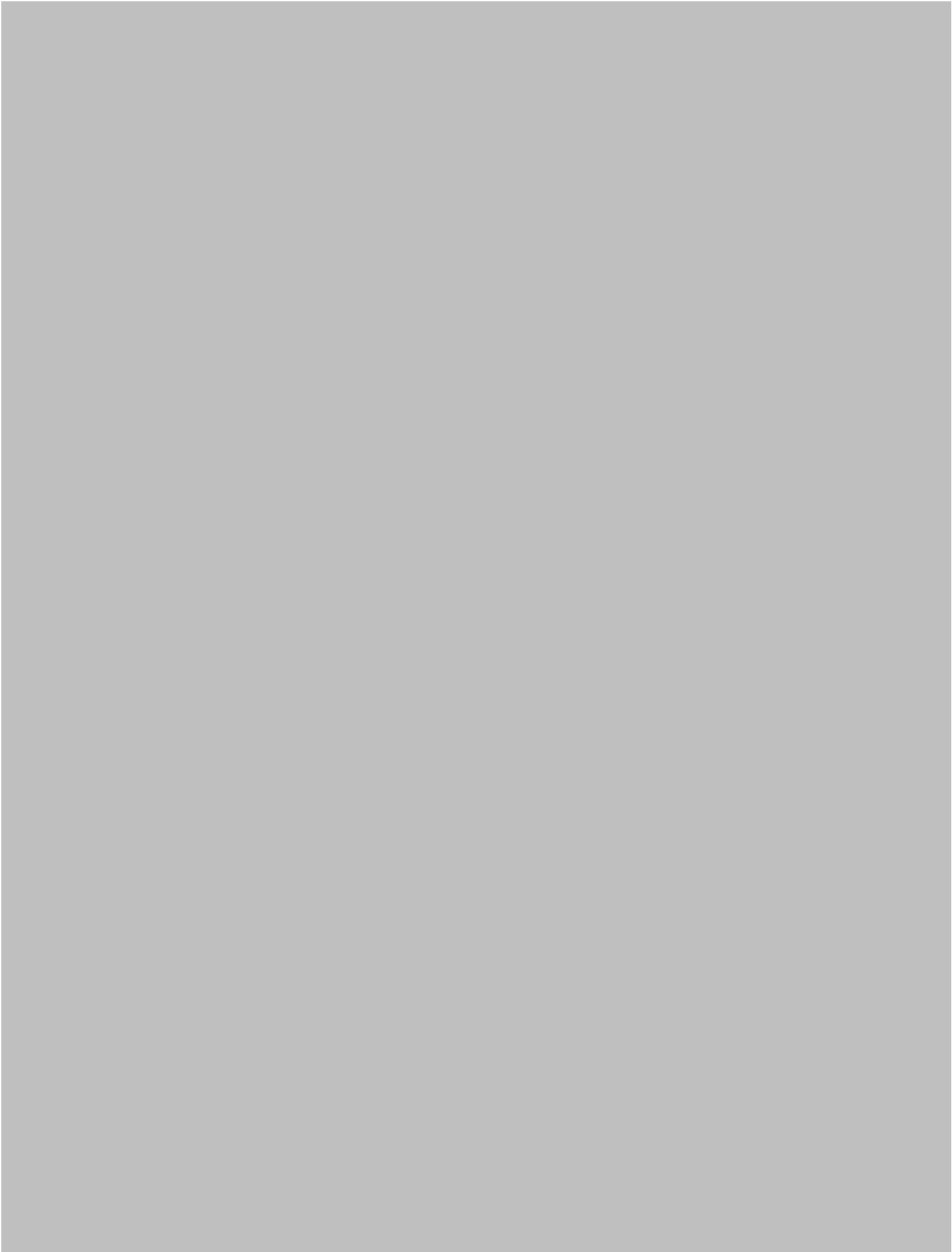




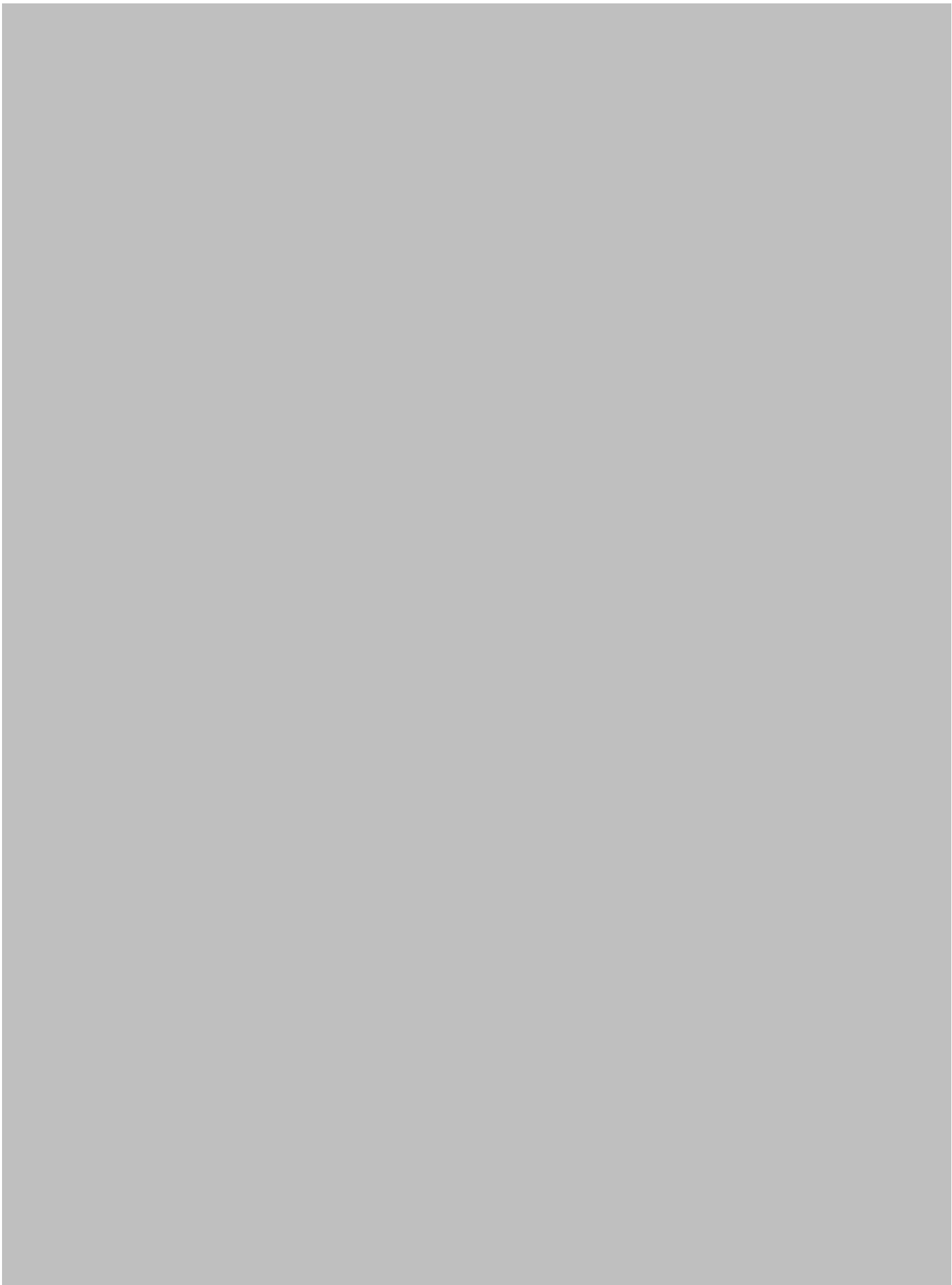


















## ANNEX 4: ANALYTICAL METHODS

### 1 DESIGN OF THE POLICY OPTIONS

The policy options have been constructed to address each specific problem under each of the three main problem/intervention areas presented in section 2 of the SWD. For each specific problem, a few options have been assessed. These options are generally alternative to each other, but in some cases the options are complementary to each other. This is specifically indicated in section 5 of the SWD. The impacts of the options under consideration were assessed in several external studies (see Annex 1 for an overview of all the supporting studies). The choice of the options is based on the outcome of those assessments (see Annexes 5-18 for details). In this manner, we screened-out the options that are not efficient, effective and/or coherent enough to address the identified specific problems, or options that are not legally or politically feasible, including due to the lack of support across all stakeholder groups.

The following table exemplifies how the options were designed to address specific problems. For each problem area, the specific problems are related to each other and so the options are meant to have synergies and reinforce each other in achieving the specific objectives. The preferred package of options would be composed of the preferred option(s) for each specific problem. In the example provided in the table below, the package of preferred options would be composed of option #n, option #n+1, option #n+2 and option #n+5.

*Table 7: Exemplification of the methodology to identify the preferred options*

Problem	Specific problems	Options
Problem area 'x'	Specific problem 'x'1	1. Option #n ✓
		2. Option #n+1 ✓
	Specific problem 'x'2	1. Option #n+2 ✓
		2. Option #n+3 ✗
	Specific problem 'x'3	1. Option #n+4 ✗
		2. Option #n+5 ✓
3. Option #n+6 ✗		

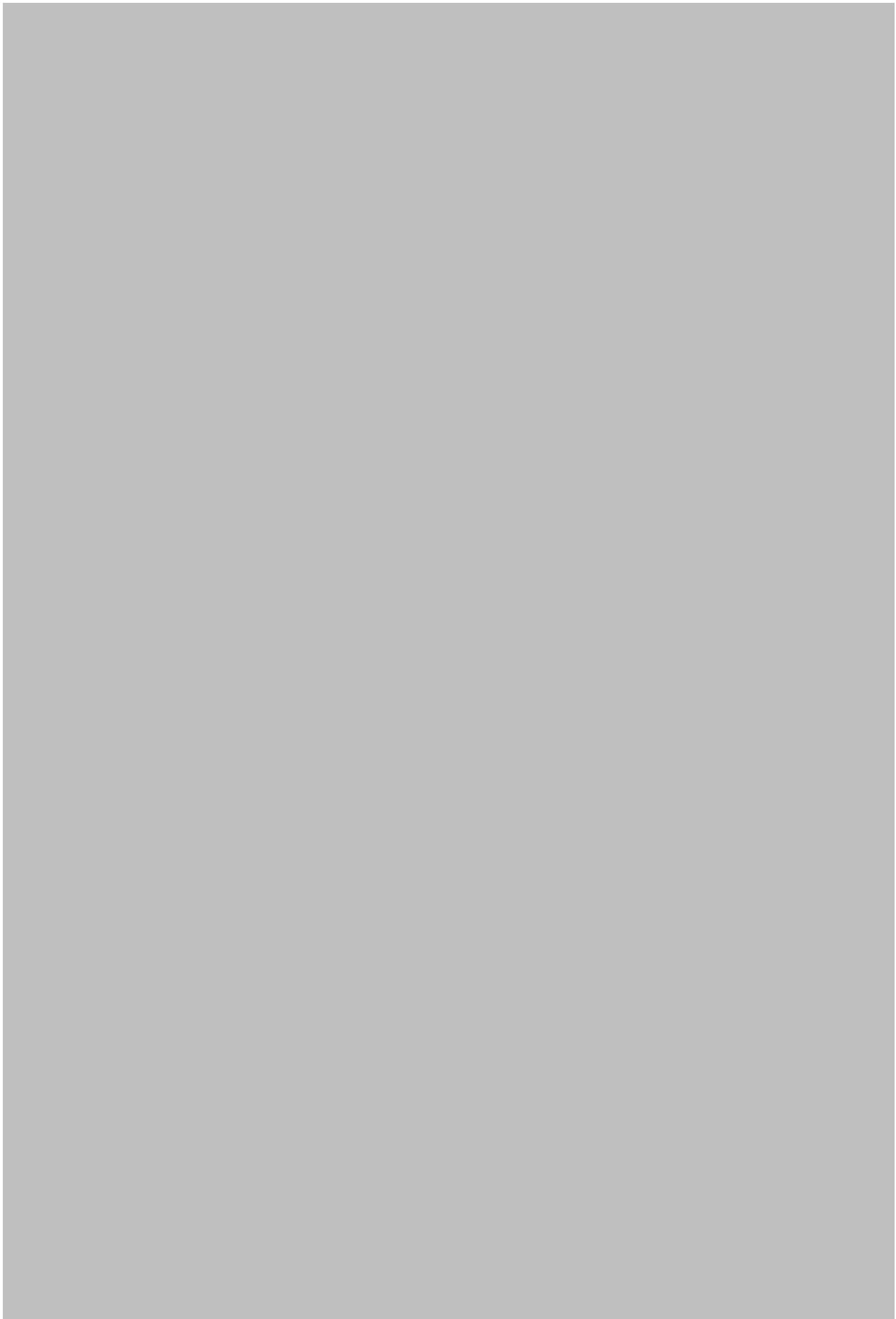
### 2 TEMPORAL AND GEOGRAPHICAL COVERAGE

The assessment period considered in the impact assessment is **30 years** for both costs and benefits. This long assessment period was chosen to take into account that benefits for human health and the environment from reducing the exposure and emissions of hazardous chemicals would occur in the long term in many cases. Also, the full implementation of certain measures, like the introduction of restrictions based on the generic risk management, would take place over a long time frame. Many of the costs linked to registration requirements are likely to occur in the short term after the implementation of the amendments to REACH, with only modest costs (updates of registration dossiers) occurring over the majority of the time period. The costs linked to the extension of the generic risk management

approach, on the contrary, are expected to increase over time as more and more substances would be restricted.

The geographical coverage of the impact assessment includes the **EU 27 Member States** plus the three **EEA countries** (Iceland, Lichtenstein and Norway).











# **ANNEX 5: COMPANIES REQUIRED TO PROVIDE NEW HAZARD INFORMATION IN THE REGISTRATION DOSIERS, INCLUDING ON ENDOCRINE DISRUPTION**

## **1 CONTEXT**

The REACH Regulation aims to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. For a large part, this goal is achieved through information requirements that registered substances need to meet. Those are described in Article 12 and Annexes VII – X of REACH. Companies have to register all substances manufactured or placed on the market in quantities equal to or greater than one tonne per year, per company. Registrations are submitted to the European Chemicals Agency (ECHA) and include information on the hazard properties, uses, exposure and volumes of chemicals that are manufactured or imported. To ensure proportionality, the information requirements depend on the volume of the substance manufactured or imported. For substances registered at >10 tonnes per year, a Chemical Safety Assessment (CSA) is required, but this does not currently apply to the lowest tonnage substances (1-10 tonnes).

During the negotiations on the final text of REACH before it was adopted there was concern that the cost of toxicological and ecotoxicological information could be too onerous for registrants of 1-10 tonnes substances (and particularly small to medium sized enterprises, SMEs). In light of these concerns the final agreed text of REACH limited the number of toxicological and ecotoxicological endpoints for which information was required for these substances by excluding a proportion of them from requiring to provide any toxicological and ecotoxicological information (Article 12 and Annex III) and by excluding all 1-10 tonnes substances from the requirement to complete a CSA. As a consequence, relatively little toxicological and ecotoxicological information is available today for all substances registered at the lowest tonnage level (1-10 tonnes/year, Annex VII).

Furthermore, substances that were previously notified under the Notification of New Substances (NONS) scheme of Directive 67/548/EEC that was in place before REACH, are considered as registered under REACH. The NONS registrations are required to be aligned with the REACH standard information requirements only when the quantity of the substance manufactured or imported reaches the next tonnage threshold. This has happened infrequently and will never happen for those NONS registrations already at the highest REACH tonnage band when REACH entered into force. As a result, most of the NONS registrations are subject to the information requirements of the repealed Directive 67/548/EEC, and not subject to the REACH standard information requirements (ECHA, 2022a).

Over the last 30 years, concerns regarding endocrine disruption<sup>25</sup> have been growing. The information generated according to the current information requirements is not sufficiently addressing these concerns. In 1999, the EU Commission adopted the “Community Strategy for Endocrine Disruptors” (EDs) (European Commission, 1999), which has led to action in the fields of regulation, research, and international cooperation. As noted in Commission Communication “Towards a comprehensive European Union framework on endocrine

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<sup>25</sup> An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations.



disruptors” (European Commission, 2018e), the Commission is currently working towards “*updating data requirements in the different legislative frameworks to improve identification of endocrine disruptors*”. In order to meet the requirements of the Chemicals Strategy for Sustainability (CSS) to “*ensure that sufficient and appropriate information is made available to authorities to allow the identification of endocrine disruptors by reviewing and strengthening the information requirements across legislation*”, the Commission shall “*update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH*” (European Commission, 2020e).

Lastly, the CSS highlighted the need to increase the availability of information on substances registered at all tonnage levels such as to allow the identification of carcinogenic substances (including genotoxic and non-genotoxic modes-of-action) and to amend REACH information requirements to enable an effective identification of substances with *critical hazard* properties, including effects on the nervous and immune systems.

## **2 DESCRIPTION OF THE PROBLEM**

### **2.1 The insufficient level of information for substances at the lowest tonnage level**

Information requirements under REACH are in general tonnage dependent, based on proportionality considerations. Due to that, information requirements in Annex VII are limited and do not provide information that would be necessary to determine all hazard properties. More specifically, no data are available concerning repeated dose or long-term (eco)toxicity. Linked to this, registrants of 1-10 tonnes substances have currently only limited information available for performing a chemical safety assessment (CSA). As outlined in Annex 9 to this SWD, there are benefits in extending the provision for a CSA also to 1-10 tonnes substances, the main benefit being provision of consistent information in the supply chain. In order to make this CSA informative, increased information requirements for low tonnage substances should be considered.

When REACH was adopted, there may have been several reasons to limit the information requirements in Annex VII. In general, the benefits from regulating low tonnage substances are deemed lower compared to high tonnage, so in view of the proportionality considerations of registration efforts, the information required was reduced compared to higher Annex levels. In addition, there was the belief that many SMEs would be manufacturers of low tonnage substances and impacts on their viability and innovation capacity were sought to be minimised. However, this belief was proven wrong by an analysis done in the study by RPA in 2020 (RPA, 2020):

The study showed that only 731 substances at 1-10 tonnes in 930 dossiers were registered by SMEs only (and not by larger companies as well). This represents 7.9% of the 9 264 substances fully registered at 1-10 tonnes and 3.5% of the 26 295 dossiers submitted at this tonnage. The majority of low tonnage substances have hence been registered by larger companies.

Importantly, the impacts on the (non)-detection of substances with hazardous properties appears likely to have been significant. Assuming that the distribution of hazard properties

are the same for high and low tonnage substances, a study by RPA<sup>26</sup> finds that between 99 and 139 substances potentially having a high hazard profile that would meet SVHC criteria remain undetected at the lowest tonnage level. Risks arising from those hazards might not be appropriately managed by registrants.

ECHA undertook a review of the classifications for substances in the 1 – 10 tonnes range in the CLP inventory. The expectation was that substances in the lowest tonnage range can display similar inherent hazards as higher tonnage substances. This was confirmed through the application of predictive methods that ECHA undertook. Therefore, there should be approximately the same share of hazardous substances in the lower tonnage bands compared to higher tonnages, but due to lack of testing requirements together with reluctance to base a classification decision on these requirements, the lower tonnage substances are being classified today to a much lesser extent.

ECHA identified that for Annex VII substances there are about 7-10 times fewer classifications for CMR 1 and STOT RE 1 and about 3-5 times fewer classifications for CMR 2 and STOT RE 2. Even on the basis of the current testing requirements for Annex VII substances, manufacturers/importers should be able to classify for the following hazard classes: mutagenicity cat 2, STOT SE 1-2, skin sensitisation cat 1, acute toxicity, skin and eye corrosion/ irritation, acute aquatic toxicity cat 1 and chronic aquatic toxicity cat 1-4. The CLP inventory entries unfortunately do not reflect this.

This lack of detection of certain hazard properties, may be of concern regarding the REACH objective “to ensure a high level of protection of human health and the environment”. Unless information requirements at Annex VII level would be increased, the problem would persist.

This concern might be mitigated to some extent by the fact that those substances are marketed in the lowest tonnage band, even if market volumes are not a direct proxy of emissions and exposure. In terms of total volume of chemicals on the market, substances at <10 tonnes constitute less than 0.003% of the total volume of chemicals placed on the market per year (see Annex 10).

## **2.2 The insufficient level of information on endocrine disrupting properties**

The current REACH requirements do not sufficiently provide information on endocrine disrupting properties and endocrine mechanisms of action. While current information requirements at higher tonnage levels for repeated dose toxicity, developmental toxicity and reproductive toxicity may give some information or reason for concern about endocrine disrupting properties of a substance, these studies do not provide information about the ED-mechanism of action, and hence do not allow to identify human health EDs for classification and further regulatory action. Information on endocrine disruption for the environment might currently be obtained from fish toxicity studies requested at Annex VIII or IX level, depending on the study provided by the registrant. However, the current information requirements do not allow for a more systematic assessment of endocrine disrupting properties.

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<sup>26</sup> The RPA 2020 study estimated that the limited information requirements possibly has failed to identify 40 substances that might warrant classification as mutagen Cat. 1A/1B and 99 substances that might warrant classification as reprotoxic Cat. 1A/1B. Some substances might be classified for both endpoints.

Unless information requirements for endocrine disrupting properties would be introduced, the problem would persist.

### 2.3 Current information requirements do not allow to address effectively critical hazards

The information requirements currently listed in Annexes VII – X and which are fulfilled in a tiered fashion based on tonnage do not allow - at all tonnage levels – the identification of substances that are carcinogens (incl. genotoxic and non-genotoxic modes-of-action), mutagens and reproductive toxicants, PBT or vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers, and STOT substances.

The current information requirements only allow to identify the following human and environmental health hazards. Note that the information requirements are cumulative and that the table below is a much simplified summary of the requirements:

Table 9: Hazard identified per Annex

Annex level	Hazards identified
Annex VII	<b>Mutagenicity, genotoxicity</b> , skin and eye irritation, skin sensitisation, acute toxicity (oral);  Aquatic toxicity (1 species), aquatic plants growth inhibition, ready biodegradability.
Annex VIII	As in Annex VII plus: <b>Reproductive / developmental toxicity (screening level only), PBT or vPvB substances</b> , acute toxicity (dermal or inhalation), repeated dose toxicity (28-days);  Aquatic toxicity (2nd species), sludge respiration inhibition, degradation (further testing), environmental fate.
Annex IX	As in Annex VII & VIII plus: <b>Reproductive and developmental toxicity (full studies), sub-chronic toxicity (90-days, can identify STOT)</b> ;  Aquatic toxicity long-term, fish developmental toxicity, adsorption to soil or sediment, identification of degradation products, bioaccumulation in fish, effects on terrestrial organisms.
Annex X	As in Annex VII & VIII & IX plus <b>Developmental toxicity (in a 2<sup>nd</sup> species), carcinogenicity*</b> ;  Further degradation and environmental fate hazards, long-term toxicity to all trophic levels.

\*The carcinogenicity study is only rarely conducted because it is not required by default for all substances but only if there is evidence that the substance might induce carcinogenicity and if there is widespread use or long-term human exposure. For substances identified as genotoxicants in other studies, the test is also not required.

Unless information requirements at all Annex levels would be amended, the problem would persist.

### 2.4 Need to balance additional information with the societal expectation that animal testing should end or be reduced

In order to acquire more knowledge on hazard information on substances, traditionally, such knowledge was obtained using animal (in vivo) studies. Today, the expectations of the

society are increasingly against animal testing, and a replacement of the traditional in vivo methods by New Approach Methodologies (NAMs) is advocated. The current system does not take sufficient advantage of the advent of NAMs for hazard and risk assessment, to reduce the extent of animal testing. As is detailed in section *New approach methodologies* below, unfortunately NAMs are not yet sufficiently available to address all information gaps on chemicals and some are not suitable for classification of substances according to the CLP regulation.

### 3 POTENTIAL POLICY OPTIONS

The Commission has derived six possible options amending the general information requirements, and the combinations of these can lead to eight possible options. A technical support study by Wood has assessed the impacts of modifying the information requirements according to these eight options (Wood, 2022).

As regards additional information on endocrine disruptors, the Commission derived two possible sub-options amending the information requirements. A technical support study by Ricardo has assessed the impacts of modifying the information requirements according to these two sub-options (Ricardo, 2022).

#### 3.1 Baseline – current information requirements

The baseline scenario considered in this impact assessment is the situation in which current information requirements would be maintained unchanged (i.e. information requirements in the REACH Annexes including all amendments up until Commission Regulation (EU) 2022/477 of 24 March 2022, amending Annexes VI – X).

#### 3.2 General Information Requirement Options

1. The options cover potential modifications to the information requirements in the following areas: Additional information on Annex VII substances (1-10 t/y) to provide a basis for a Chemical Safety Assessment (CSA), including, where possible, a Derived No Effect Level (DNEL) or a Predicted No Effect Concentration (PNEC). Extension of the information requirements to increase at all tonnage levels information on critical hazards.
2. Information, for example related to toxicokinetic properties and mode of action, to support chemical grouping and the use of read-across to fill data gaps during registration and to support quantitative in vitro to in vivo extrapolation in risk assessment.
3. Replacing, if possible, animal testing with non-animal methods, without lowering the level of information on critical hazards.
4. Extension of the requirement to meet the standard information requirements in Annexes VII to X to substances previously covered by the NONS regime (as well as to develop a CSA).

Table 10: Details of sub-options

Standard information requirements	High testing scenario	Low testing scenario
Three annexes (VII and VIII merged, plus IX and X), with changes to the merged	1A	1B

Standard information requirements	High testing scenario	Low testing scenario
annex		
Four annexes (VII, VIII, IX, X), changes to Annexes VII and VIII	2A	2B
Changes to Annexes IX and X	3A	3B

Note: Sub-options 3A and 3B are to be combined with 1A/1B or 2A/2B.

Some standard information requirements from current Annex VIII (10-100t) and IX (100-1000t) are moved to Annex VII so that they would apply also to 1-10t substances. Given the number of Standard Information Requirements (SIRs) that are proposed to be added to Annex VII, the difference between Annex VII and VIII becomes smaller, therefore sub-options 1A and 1B propose to merge Annex VII and VIII into just one Annex for substances at 1 – 100 tonnes.

A chemical safety assessment would be required at all tonnage levels. Some information requirements are removed under the ‘low testing scenario’ sub-options. A set of NAM-based SIRs is applicable to all sub-options.

The table below summarises the changes<sup>27</sup> in the information requirements that would apply under each of the sub-options, as set out by the Commission.

*Table 11: Details of changes to standard information requirements under sub-options*

Sub-option	Details
All sub-options	NAM-based standard information requirements are added to address ADME/toxicokinetics, bioaccumulation in aquatic species and acute toxicity in fish (see section New Approach Methodologies below).

<sup>27</sup> Note that for reasons of readability, only changes are listed in the table. Existing requirements that are remaining as in the current requirements, e.g. the in vitro gene mutation study in bacteria in Annex VII or the EOGRTS in Annex IX, among many others. For clarity, some studies are called out that are maintained in a given option.

Sub-option	Details
Sub-option 1A Three annexes (VII & VIII merged) – high testing scenario	<p>The following Annex VIII requirements are added also for Annex VII substances:</p> <ul style="list-style-type: none"> <li>• In vitro gene mutation in mammalian cells</li> <li>• In vivo skin irritation</li> <li>• In vivo eye irritation</li> <li>• Acute inhalation (LC50)</li> <li>• Acute dermal (LD50)</li> <li>• Short-term (28 day) repeated dose toxicity (TG 407)</li> <li>• Screening for reproductive/developmental toxicity (TG 421)</li> <li>• Short-term fish toxicity (or long-term fish toxicity instead if substance poorly water soluble)</li> <li>• Activated sludge respiration inhibition test</li> <li>• Degradation - Hydrolysis</li> <li>• Degradation - Inherent biodegradation</li> <li>• Degradation - further biotic testing (if need identified by CSA)</li> <li>• Adsorption/desorption screening</li> </ul> <p>The following Annex IX requirements are added also for Annex VII and VIII substances:</p> <ul style="list-style-type: none"> <li>• Long-term aquatic toxicity in invertebrates</li> <li>• Dissociation constant</li> </ul>
Sub-option 1B Three annexes (VII & VIII merged) – low testing scenario	<p>This sub-option is the same as 1A but with the following removed:</p> <ul style="list-style-type: none"> <li>• In vitro gene mutation in mammalian cells</li> <li>• In vivo skin irritation</li> <li>• In vivo eye irritation</li> <li>• Acute oral (LD50)</li> <li>• Acute inhalation (LC50)</li> <li>• Acute dermal (LD50)</li> <li>• Short-term (28 day) repeated dose toxicity (TG 407)<sup>[Note 1]</sup></li> <li>• Screening for reproductive/developmental toxicity (TG 421)<sup>[Note 1]</sup></li> <li>• Short-term fish toxicity (or long-term fish toxicity instead if substance poorly water soluble): in vivo test replaced with cell line test<sup>28</sup></li> </ul>

<sup>28</sup> Foresee extrapolation from long term daphnia test.

Sub-option	Details
Sub-option 2A Four annexes (changes to annexes VII and VIII) – high testing scenario	<p>The following Annex VIII requirements are added also for Annex VII substances:</p> <ul style="list-style-type: none"> <li>• Short term (28 day) repeated dose toxicity (TG 407)</li> <li>• Screening for reproductive/developmental toxicity (TG 421)</li> <li>• Activated sludge respiration inhibition test</li> <li>• Degradation – Hydrolysis</li> <li>• Degradation – Inherent biodegradation</li> <li>• Degradation – further biotic testing if need identified by CSA</li> <li>• Adsorption/desorption screening</li> </ul> <p>The following Annex IX requirements are added also for Annex VII substances:</p> <ul style="list-style-type: none"> <li>• Long-term aquatic toxicity in invertebrates</li> <li>• Dissociation constant</li> </ul> <p>The following Annex VII in vivo requirements are maintained in 2A:</p> <ul style="list-style-type: none"> <li>- Acute oral (LD50)</li> </ul> <p>The following Annex VIII in vivo requirements are maintained in 2A:</p> <ul style="list-style-type: none"> <li>• In vitro gene mutation in mammalian cells</li> <li>• In vivo skin irritation</li> <li>• In vivo eye irritation</li> <li>• Acute inhalation (LC50)</li> <li>• Acute dermal (LD50)</li> <li>• Short-term fish toxicity (or long-term fish toxicity instead if substance poorly water soluble)</li> </ul>

Sub-option	Details
Sub-option 2B Four annexes (changes to annexes VII and VIII) – low testing scenario	<p>The following Annex VIII requirements are added also for Annex VII substances:</p> <ul style="list-style-type: none"> <li>• Activated sludge respiration inhibition test</li> <li>• Degradation – Hydrolysis</li> <li>• Degradation – Inherent biodegradation</li> <li>• Degradation – further biotic testing if need identified by CSA</li> <li>• Adsorption/desorption screening</li> </ul> <p>The following Annex IX requirements are added also for Annex VII substances currently only covered by:</p> <ul style="list-style-type: none"> <li>• Long-term aquatic toxicity in invertebrates</li> <li>• Dissociation constant</li> </ul> <p>The following Annex VIII requirements are maintained for Annex VIII substances:</p> <ul style="list-style-type: none"> <li>• Combined (28 day) and reproductive/developmental screening test (TG 422)<sup>[Note 1]</sup></li> </ul> <p>Following existing in vivo requirements are removed from Annex VII:</p> <ul style="list-style-type: none"> <li>• Acute oral (LD50)</li> </ul> <p>Following existing in vitro and vivo requirements are removed from Annex VIII:</p> <ul style="list-style-type: none"> <li>• In vitro gene mutation in mammalian cells</li> <li>• In vivo skin irritation</li> <li>• In vivo eye irritation</li> <li>• Acute inhalation (LC50)</li> <li>• Acute dermal (LD50)</li> <li>• Short-term fish toxicity (or long-term fish toxicity instead if substance poorly water soluble)<sup>29</sup></li> </ul>
Sub-option 3A Changes to annexes IX and X combined with 1A/1B or 2A/2B – high testing scenario	<p>The following is added to Annex IX :</p> <ul style="list-style-type: none"> <li>• In vivo toxicokinetics study (TG 417)<sup>[Note 3]</sup></li> </ul>

<sup>29</sup> Foresee extrapolation from long term daphnia test.



Sub-option	Details
Sub-option 3B Changes to annexes IX and X combined with 1A/1B or 2A/2B – low testing scenario	<p>The following is removed from current requirements of Annex IX:</p> <ul style="list-style-type: none"> <li>• Developmental study in second species (trigger)</li> <li>• Long-term fish toxicity (instead, extrapolate from short-term fish or daphnid), unless triggered by ED concern and test enhanced to include ED endpoints <sup>[Note 2]</sup></li> <li>• Bioaccumulation in fish, unless triggered by inability to extrapolate from new in vitro Annex VII requirements for fish clearance (OECD TG 319A or OECD TG 319B, see section New Approach Methodologies below)</li> </ul> <p>The following is removed from current requirements of Annex X:</p> <ul style="list-style-type: none"> <li>• Developmental study in second species (SIR)</li> <li>• Long-term repeated dose toxicity <math>\geq 12</math> months (instead, extrapolate from 90d)</li> <li>• Rodent cancer bioassay</li> </ul>

Notes: (1) Replaced with combined repeated dose toxicity with reproduction/developmental toxicity screening (TG 422); might be waived if 28-day repeated dose toxicity test and reproduction/developmental toxicity screening test (OECD TG 421) is available. (2) See the impact assessment study on information requirements for endocrine disruption. (3) Column 2 adaptation to foresee use of microsampling techniques in in-vivo studies that are already part of the SIRs.

The information in the table above is clearly a simplification of what requirements would in practice be implemented for any given substance. There are several tests, for example, that (already in the current requirements) are conditional upon the results of other tests. Examples include:

- The additional degradation testing applied to substances >1t (Annex VII). This information can help to identify whether substances are likely to be persistent, but additional testing such as biotic simulation testing according to Annex IX would be required to confirm the persistence of a substance.
- In order to confirm mutagenicity of a substance, the test that would newly be applied to Annex VII substances (in vitro gene mutation in mammalian cells) would not be sufficient. Instead, additional in vitro testing and also in vivo testing (e.g. the somatic cell study only otherwise required under Annex IX) would also be needed.

An option is built up in a modular fashion from two sub-options (e.g. 1A+3A, 1A+3B) leading to eight possible options.

The figure below provides an overview of the eight options and the tonnage bands that they apply to.

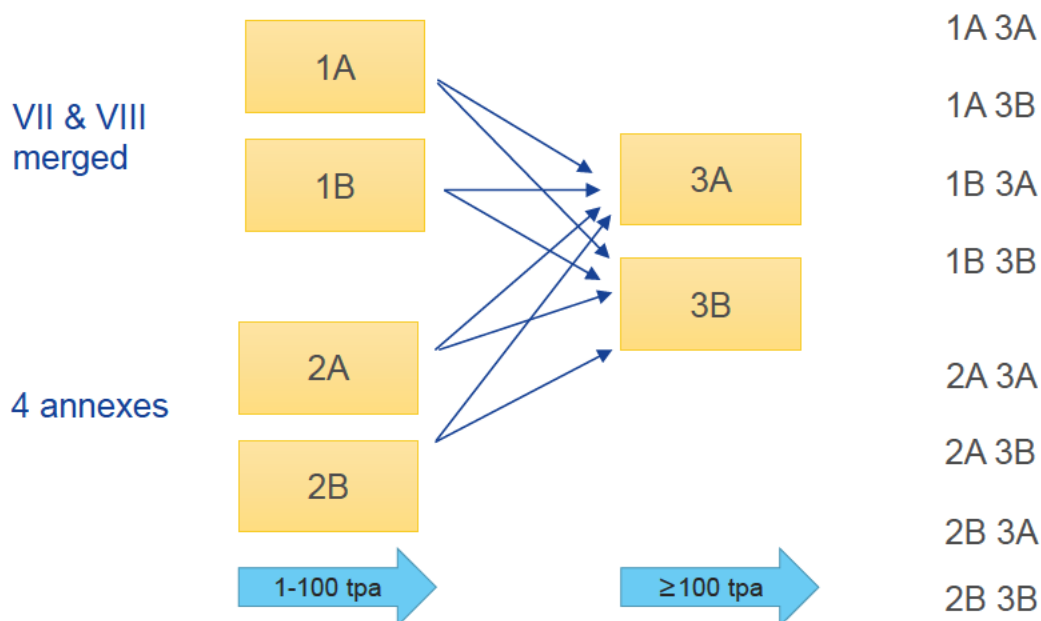


Figure 3: Overview of the eight options

### ***New approach methodologies***

Under all sub-options, NAM-based information requirements would be introduced at Annex VII-level as follows:

- Absorption, distribution, metabolism and excretion (ADME) / toxicokinetics (TK) (NAM battery of three tests): High Throughput data on fraction unbound plasma, in vitro hepatic clearance and in vitro uptake<sup>30</sup>;
- NAM battery for endocrine disruption (covered under a separate supporting study for the impact assessment)<sup>31</sup>;
- Bioaccumulation in aquatic species (NAM battery of two possible tests): Intrinsic clearance in rainbow trout hepatocytes (OECD TG 319A) or S9 fraction (OECD TG 319B);
- Acute fish toxicity (in vitro test in a fish cell line; OECD TG 249).

The methods listed above are considered to be sufficiently standardised and validated to be used for REACH and CLP purposes. Additional NAM-based approaches were considered but evaluated as not being sufficiently ready for introduction as a standard information requirement at this point in time.

<sup>30</sup> OECD Guidance document on the characterisation, validation and reporting of Physiologically Based Kinetic (PBK) models for regulatory purposes. For protein binding and metabolic clearance: Wetmore et al (2012), Paini et al (2020). For cellular uptake: Treyer et al (2018). For Caco-2 permeability: Hubatsch et al (2007).

<sup>31</sup> Ricardo, 2022.

### **3.3 Extension of information requirements for identification of endocrine disruption - Options**

The Commission derived two possible sub-options amending the information requirements for identification of endocrine disruptors. Those are described in full detail by the supporting study on EDCs for this Impact Assessment by Ricardo (Ricardo, 2022).

Sub-option 1 adds in vitro tests for endocrine modes of action to Annex VII. Results from in vitro tests together with all other available information is used in a weight-of-evidence approach to trigger in vivo tests for confirmation of endocrine related mechanisms and adverse effects starting at a tonnage equivalent to Annex VIII level.

In sub-option 2, the same in vitro tests are proposed but the follow-up of positive results with in vivo tests is required already at Annex VII level without taking other information into account in a weight-of-evidence approach.

Further differences exist between the two options in the extent waivers and triggers<sup>32</sup> are introduced, as well as further, although not large, differences in the number and annex levels of required tests.

The requirements for information on endocrine disrupting properties under the policy options are listed in the following table:

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<sup>32</sup> A waiver is an option to forgo testing if conditions described in the waiver are met. A trigger is a requirement to do further testing if conditions described in the trigger are met.

Table 12: Information required for all REACH registered substances at each tonnage band under Policy option 1 and 2

	Policy option 1					Policy option 2				
	Annex	1-10t	10-100t	100-1000t	>1000t	Annex	1-10t	10-100t	100-1000t	>1000t
A weight of evidence determination using expert judgement	VII	All	All	All	All	N/A				
Systematic review of available literature and studies on mammals and non-mammalian vertebrates shall cover EATS modalities.	VII	All	All	All	All	N/A				
Assessment of endocrine disruption from available information, including in silico and in vitro methods and scientific literature – providing adequate and reliable documentation	VII <sup>33</sup>					VII	All	All	All	All
Estrogen receptor transactivation assay (OECD TG 455)	VII	All	All	All	All	VII	All	All	All	All
Androgen receptor transactivation assay (OECD TG 458)	VII	All	All	All	All	VII	All	All	All	All
H295R steroidogenesis assay (OECD TG 456)	VII	All	All	All	All	VII	All	All	All	All
Aromatase assay (OPPTS 890.1200)	VII	All	All	All	All	VII	All	All	All	All

<sup>33</sup> As part of a weight-of-evidence approach

	Policy option 1					Policy option 2				
Thyroid activity in vitro	VII	All	All	All	All	VII	All	All	All	All
Upgrade short-term toxicity testing on fish to long-term testing (See Annex IX) <sup>34</sup>	VIII					VIII				
Uterotrophic Bioassay in Rodents (OECD TG 440)	IX		Triggered (1)	All	All	VIII	Triggered (2)	All	All	All
Hershberger Bioassay in Rats (OECD TG 441)	IX		Triggered (1)	All	All	VIII	Triggered (2)	All	All	All
Fish Short Term Reproduction assay (OECD TG 229)						VIII		Some (3)		
Amphibian Metamorphosis Assay (OECD TG 231)	IX		Triggered (4)	All	All	VIII	Triggered (2)	All	All	All
Fish Sexual Development Test (OECD TG 234)	IX		Triggered (4)	Triggered (4)	Triggered (4)	IX	Triggered (2)		All	All
Medaka Extended One-Generation Reproduction Test (OECD TG 240) OR Zebrafish Extended One-Generation Reproduction Test	X				Note (7)	X		Waived (5)	Waived (5)	Waived (5)
Larval Amphibian Growth and Development Assay (OECD TG 241)	X				Note (7)	X		Waived (6)	Waived (6)	Waived (6)

Standard Information Requirements (SIRs) for ALL substances in black.

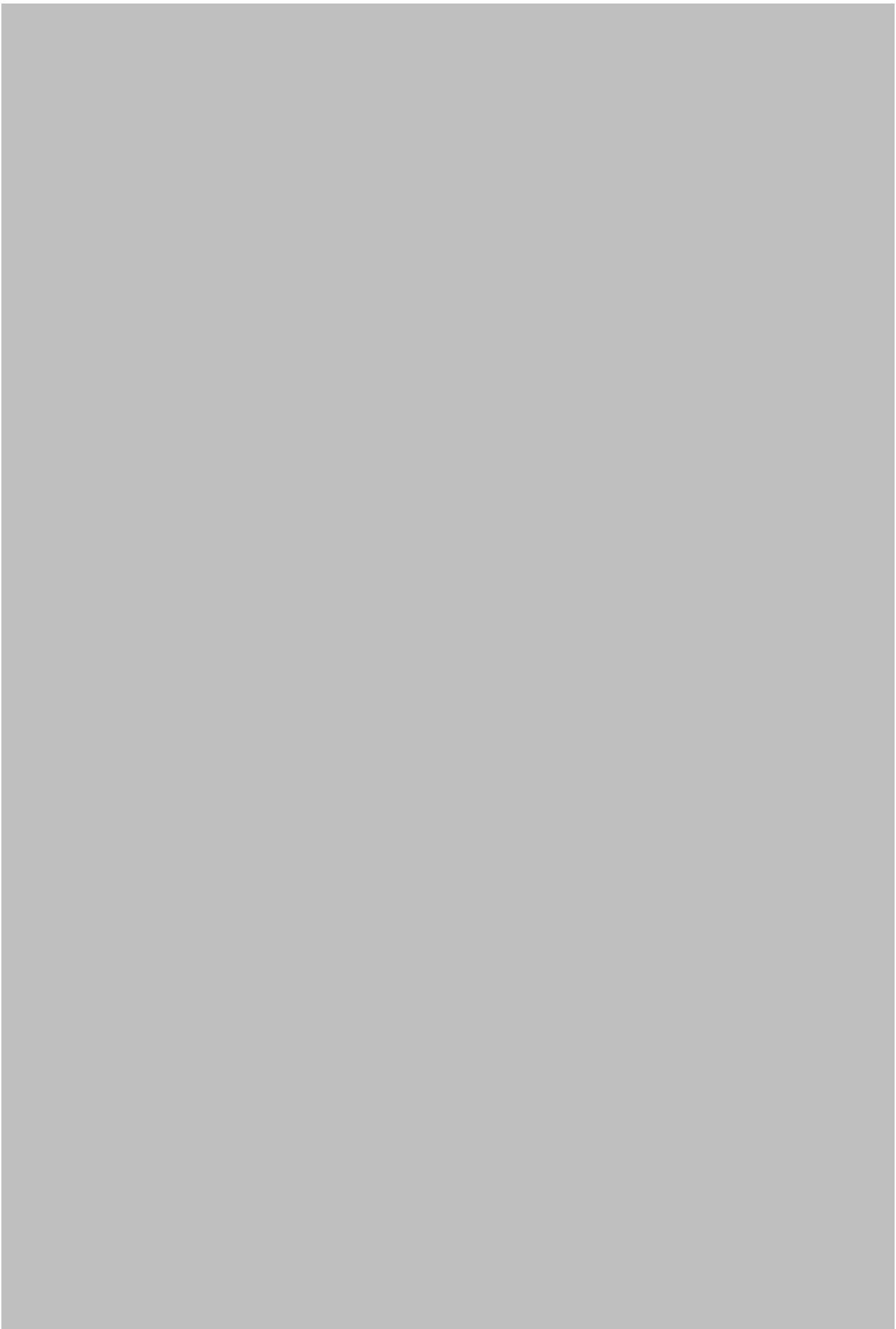
Further Information Requirements (FIRs) for SOME substances in red.

<sup>34</sup> Corresponding to current requirements under Annex VIII

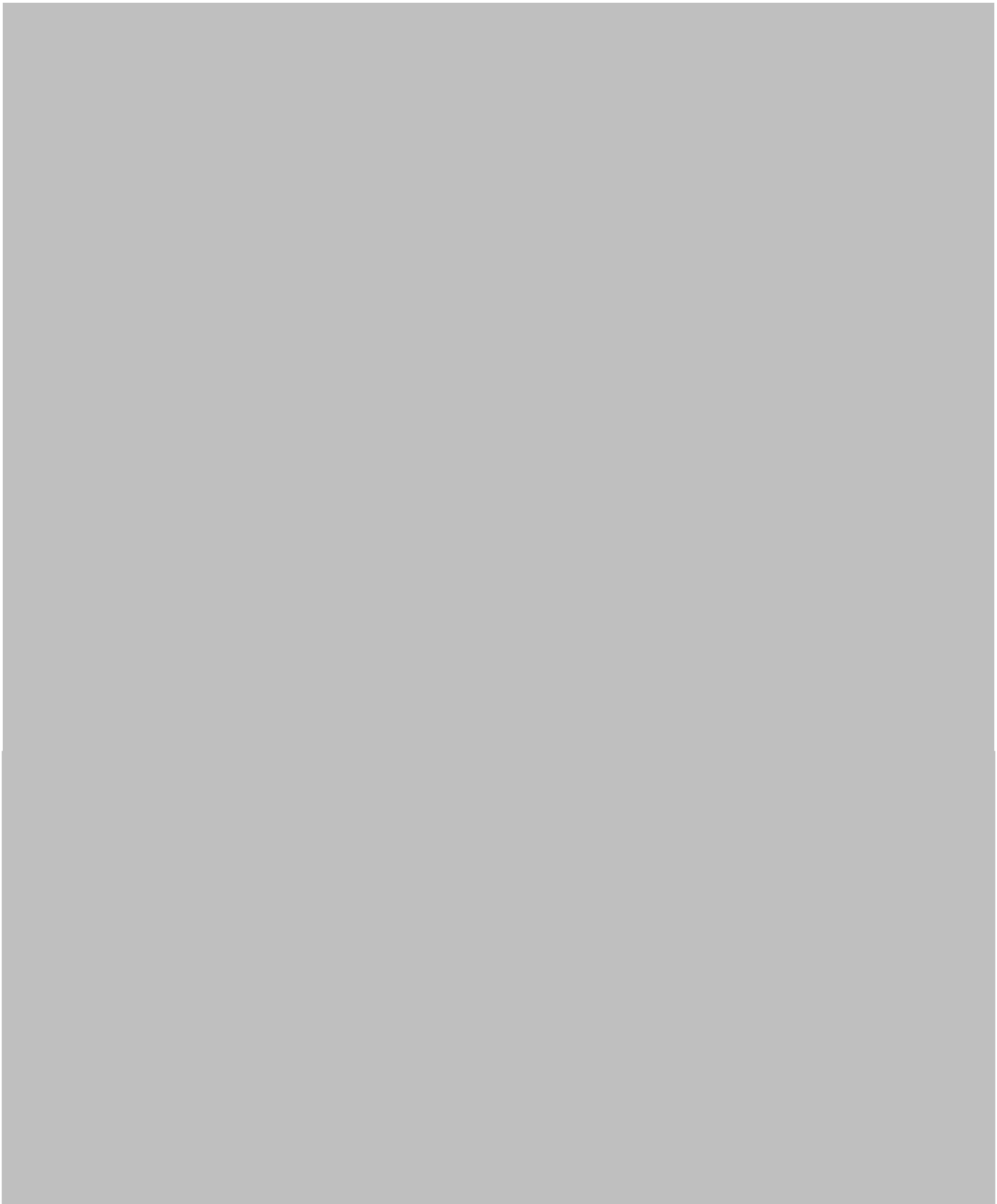
- 1) Triggered for substances in the tonnage range 10-100 tonnes per year by WoE determination AND if relevant human exposure cannot be excluded in accordance with Annex XI Section 3; mandatory for substances in the tonnage range  $\geq 100$  t/y.
- 2) Triggered by a single positive result in any Annex VII in vitro mechanistic study.
- 3) If negative results in all Annex VII in vitro mechanistic studies.
- 4) Triggered by WoE determination.
- 5) Rely on Fish Sexual Development Test (OECD TG 234) instead.
- 6) Rely on Amphibian Metamorphosis Assay (OECD TG 231) instead.
- 7) Certain triggers and waivers apply, see Ricardo study.

The table above shows that the options also foresee certain waiving opportunities for the information requirements as well as triggering of further testing depending on the outcome of the in vitro studies. However, since the identity of substances with endocrine disrupting properties is currently not known, the pragmatic working assumption used in the IA is that, at present, no substances have existing information that enables certain tests for endocrine disruption to be waived/omitted under the policy options. In practice, there may be a few substances where test waiving will be used by registrants as a justification for not performing the test, but it is not possible to predict this with any accuracy. Thus, for the purpose of the IA, no waiving is assumed and the estimates of the costs of testing represent 'worst case' maximum costs of testing.



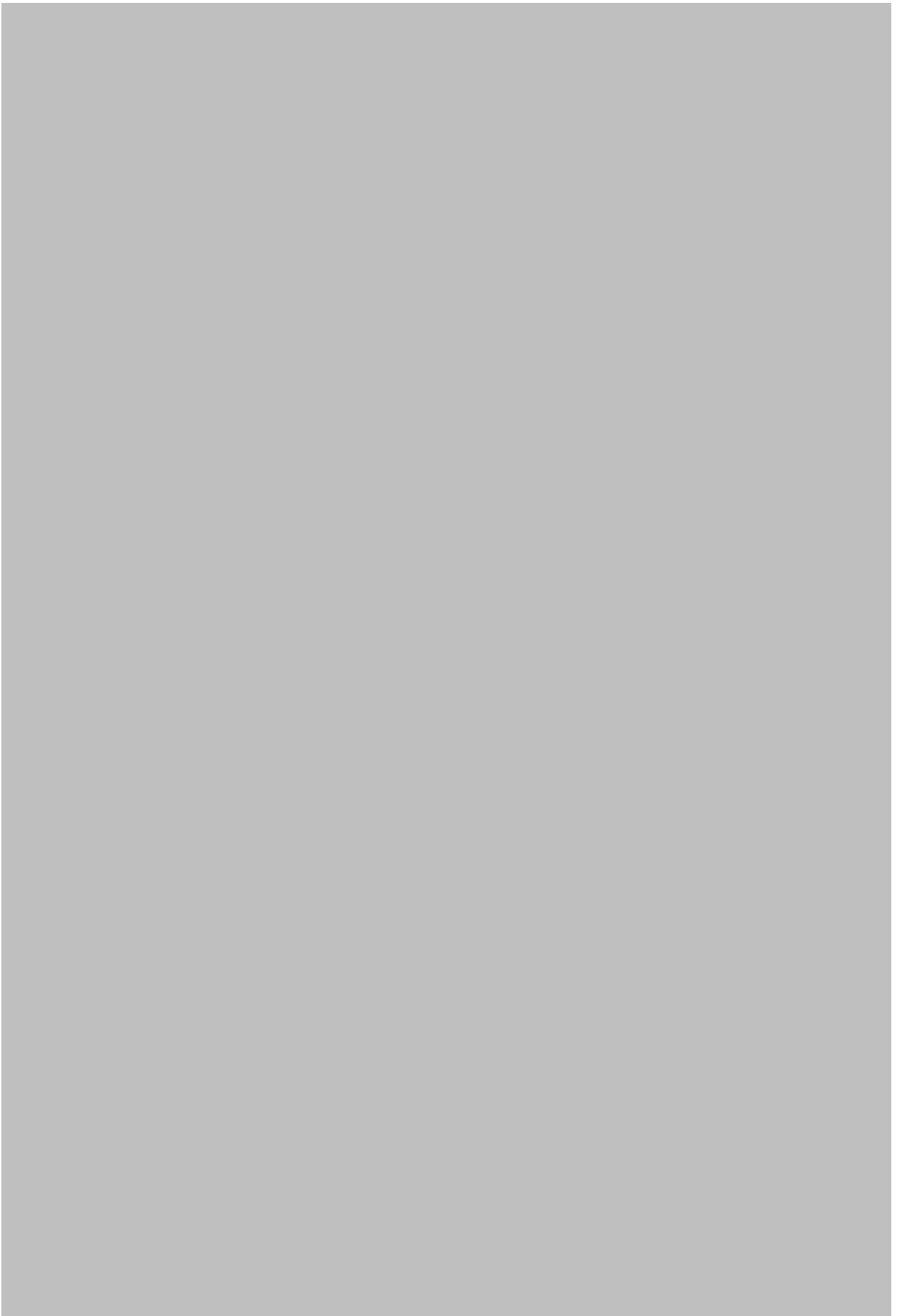




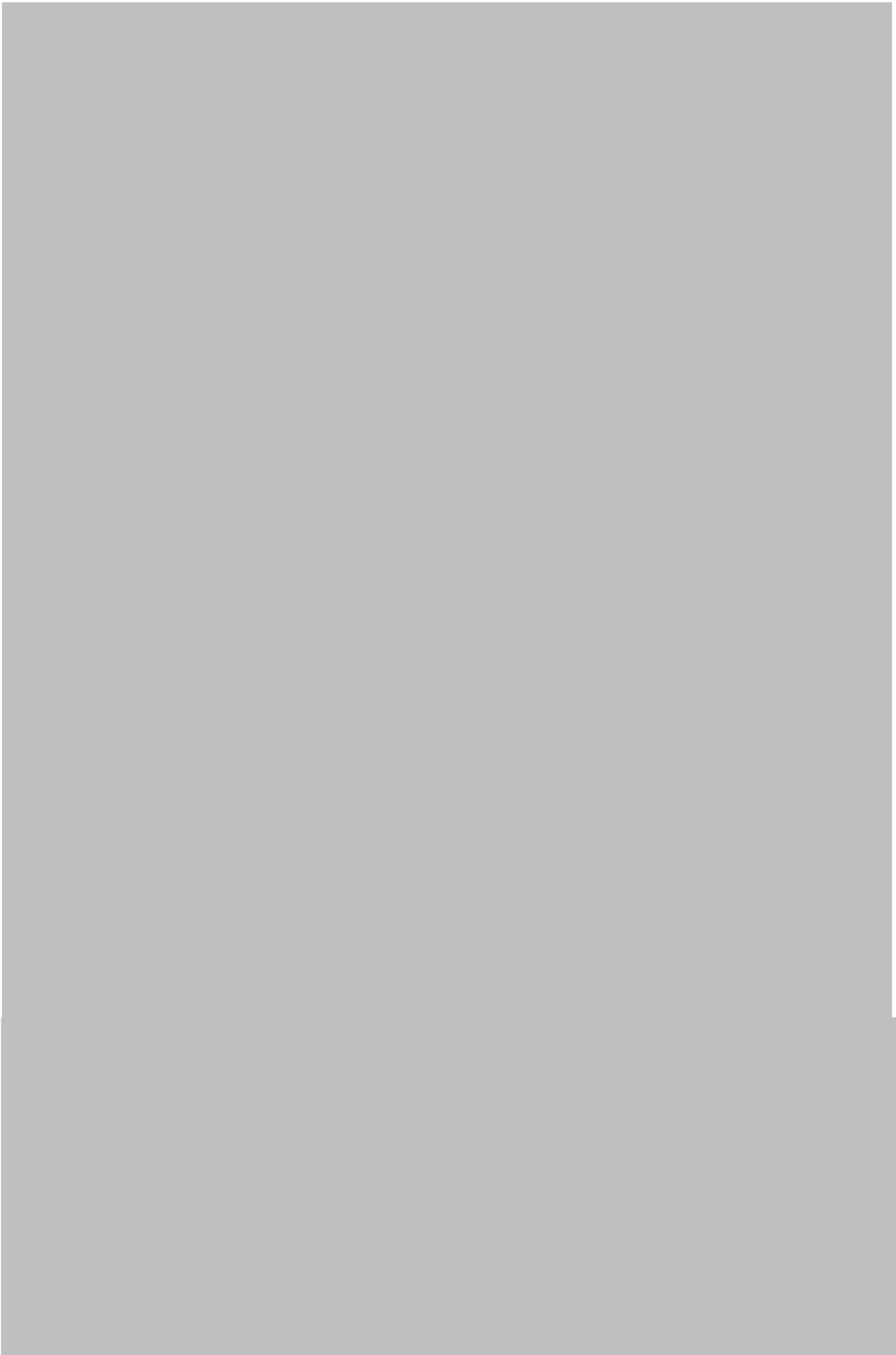


















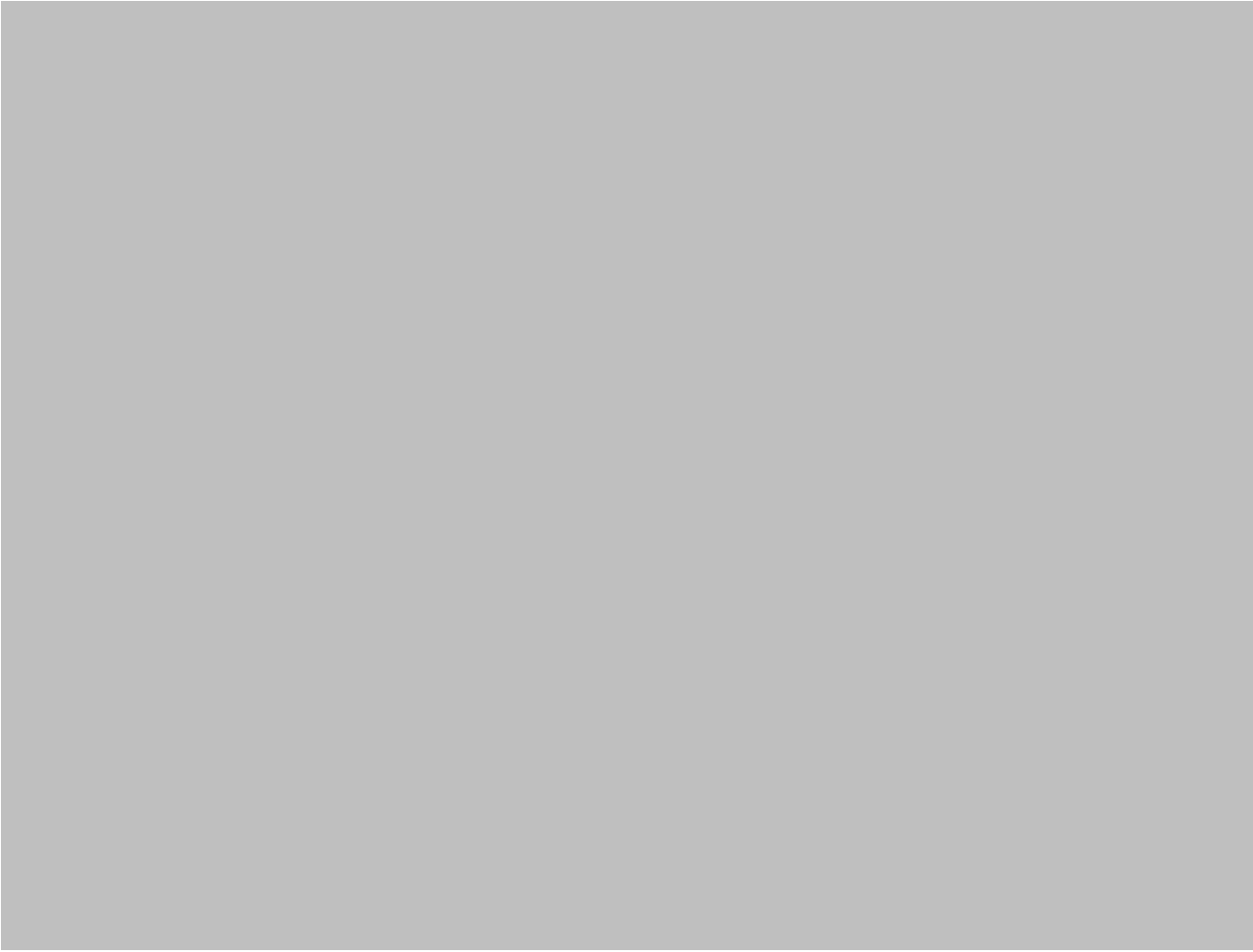








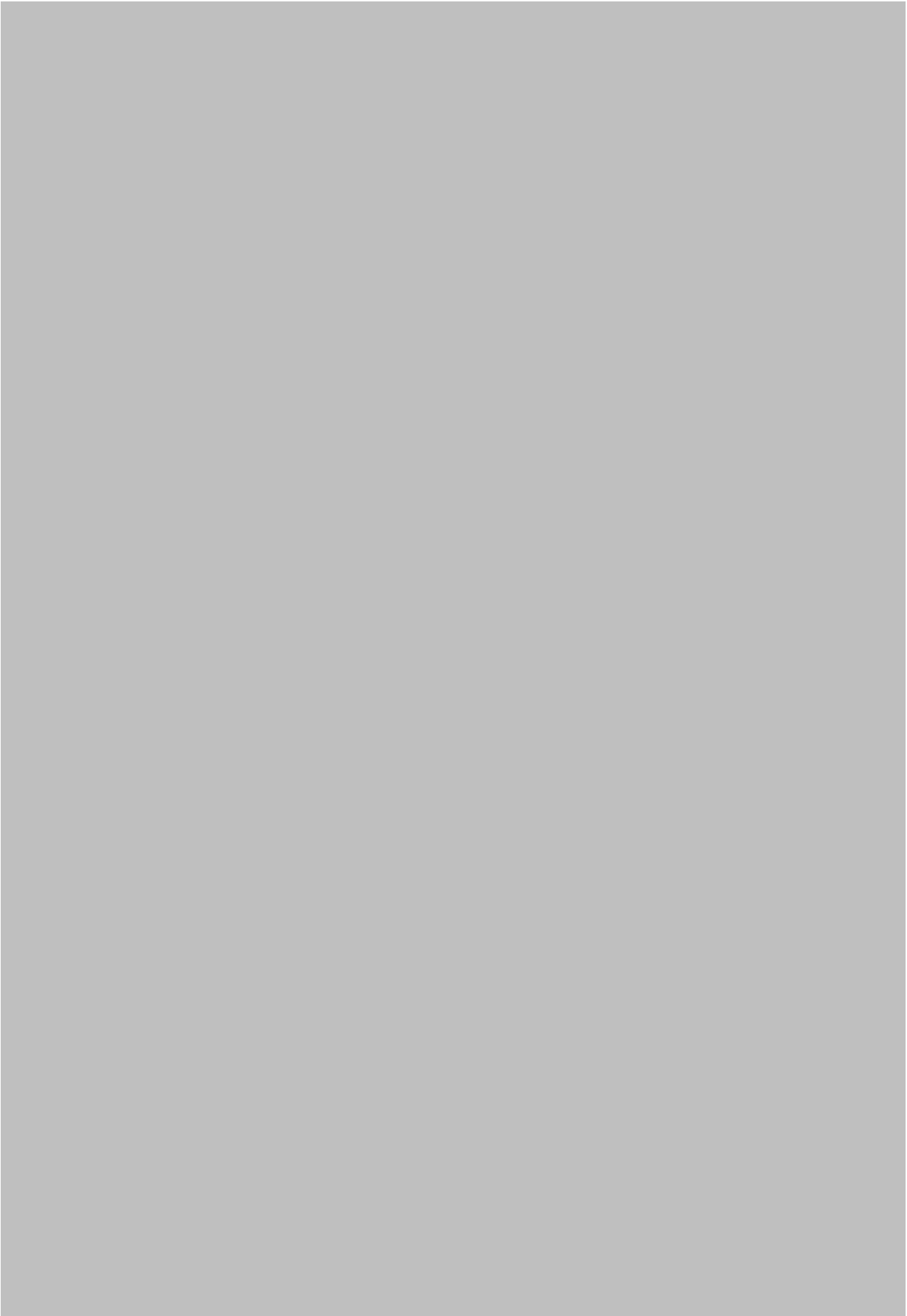






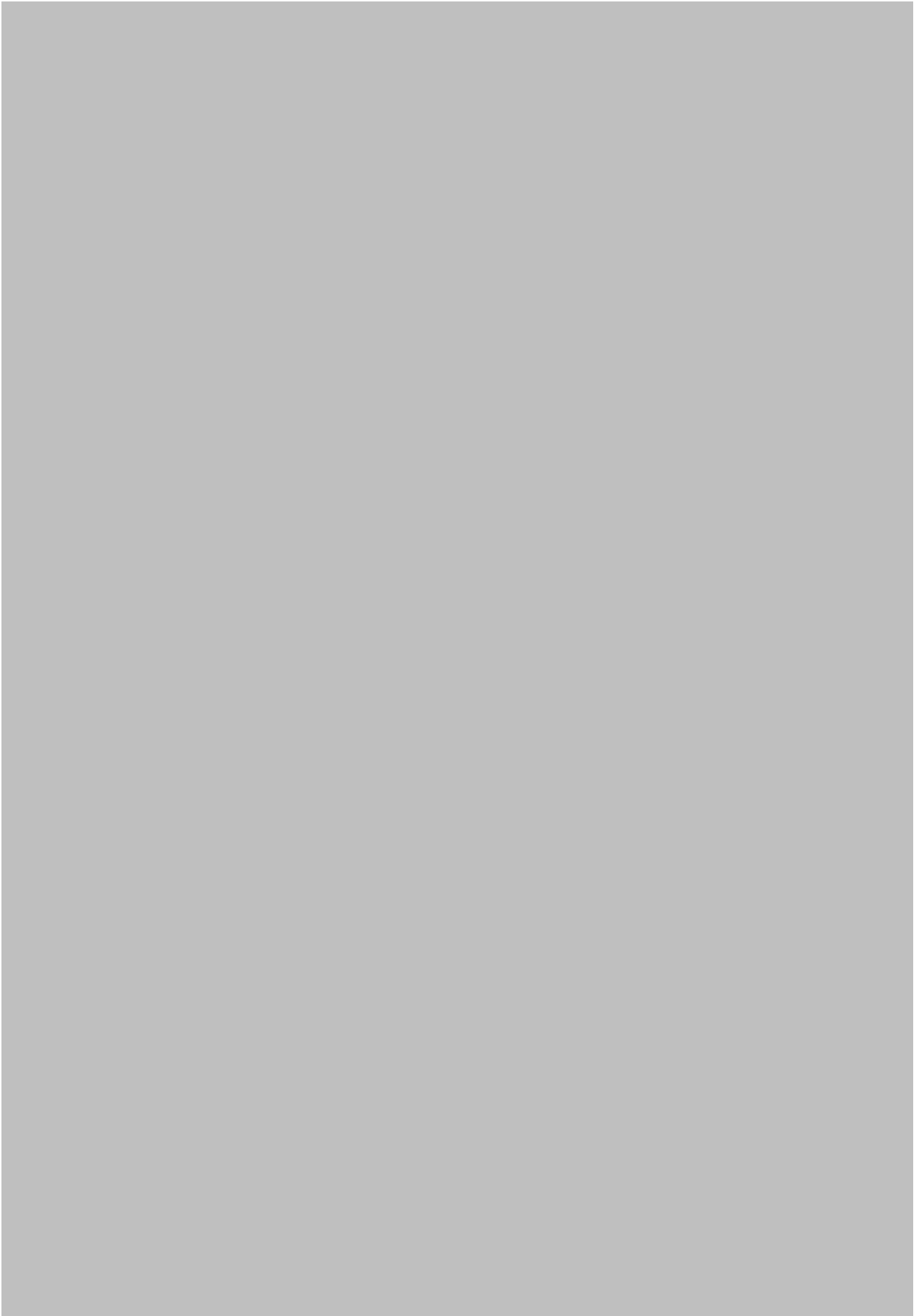




































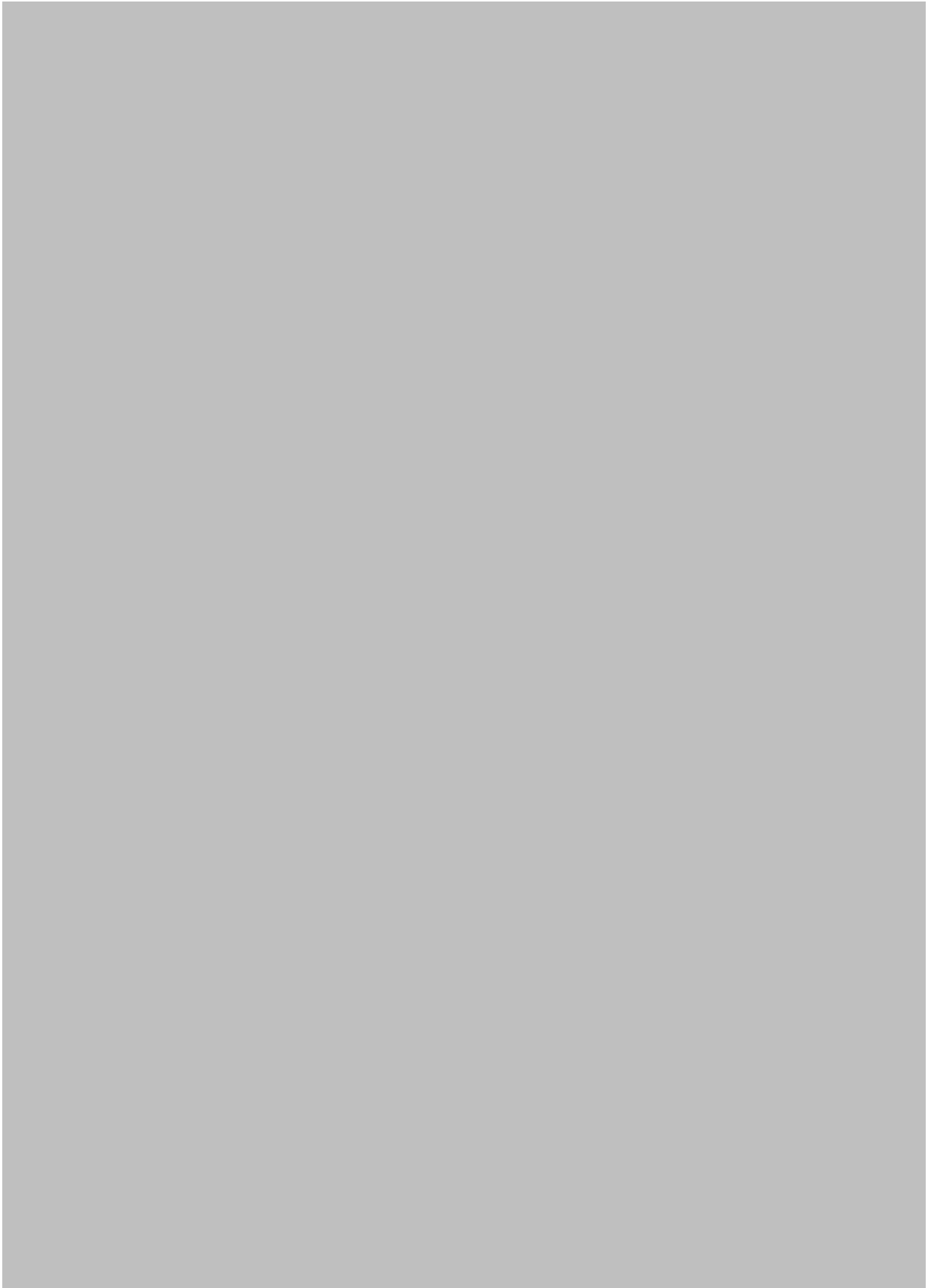


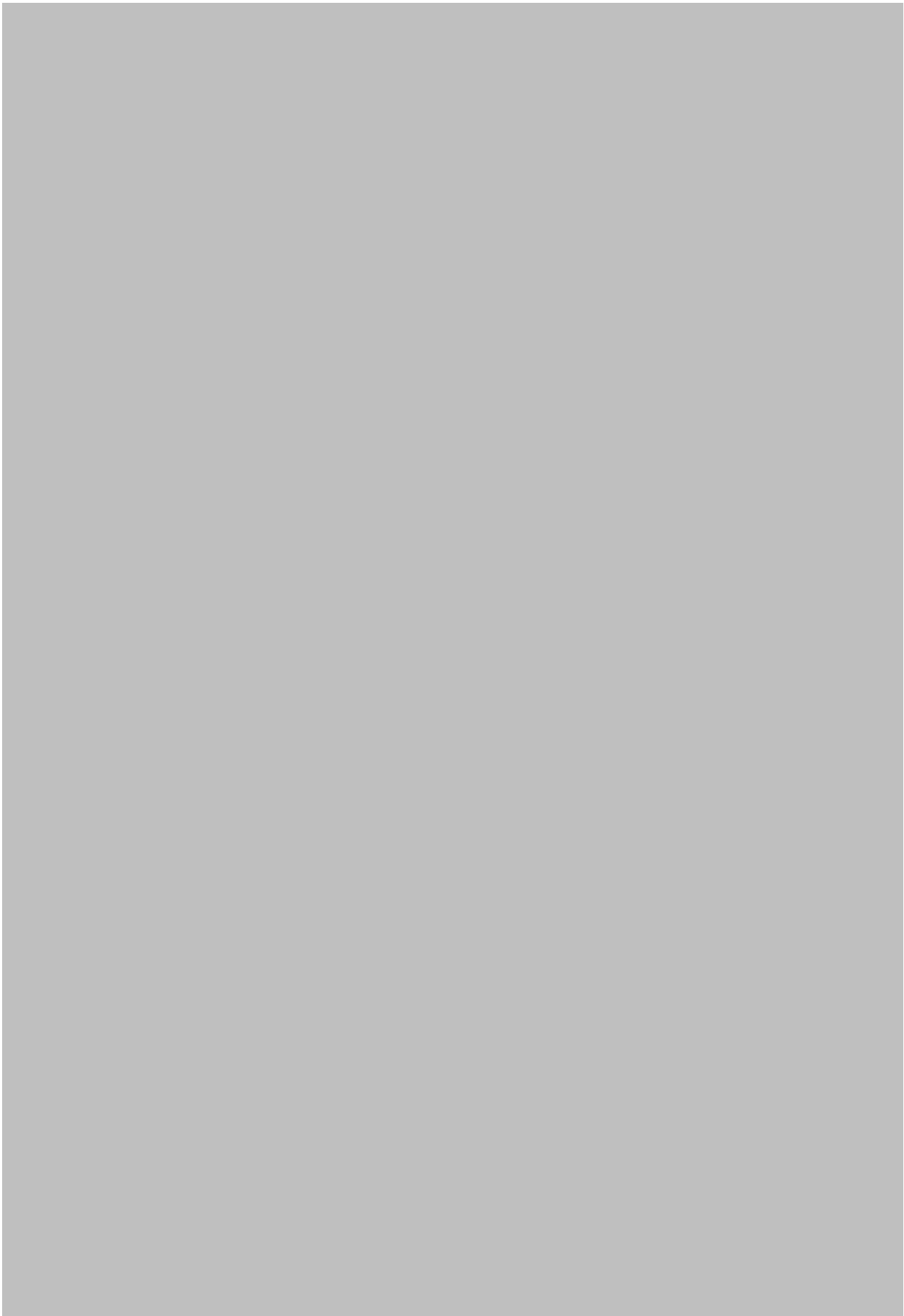














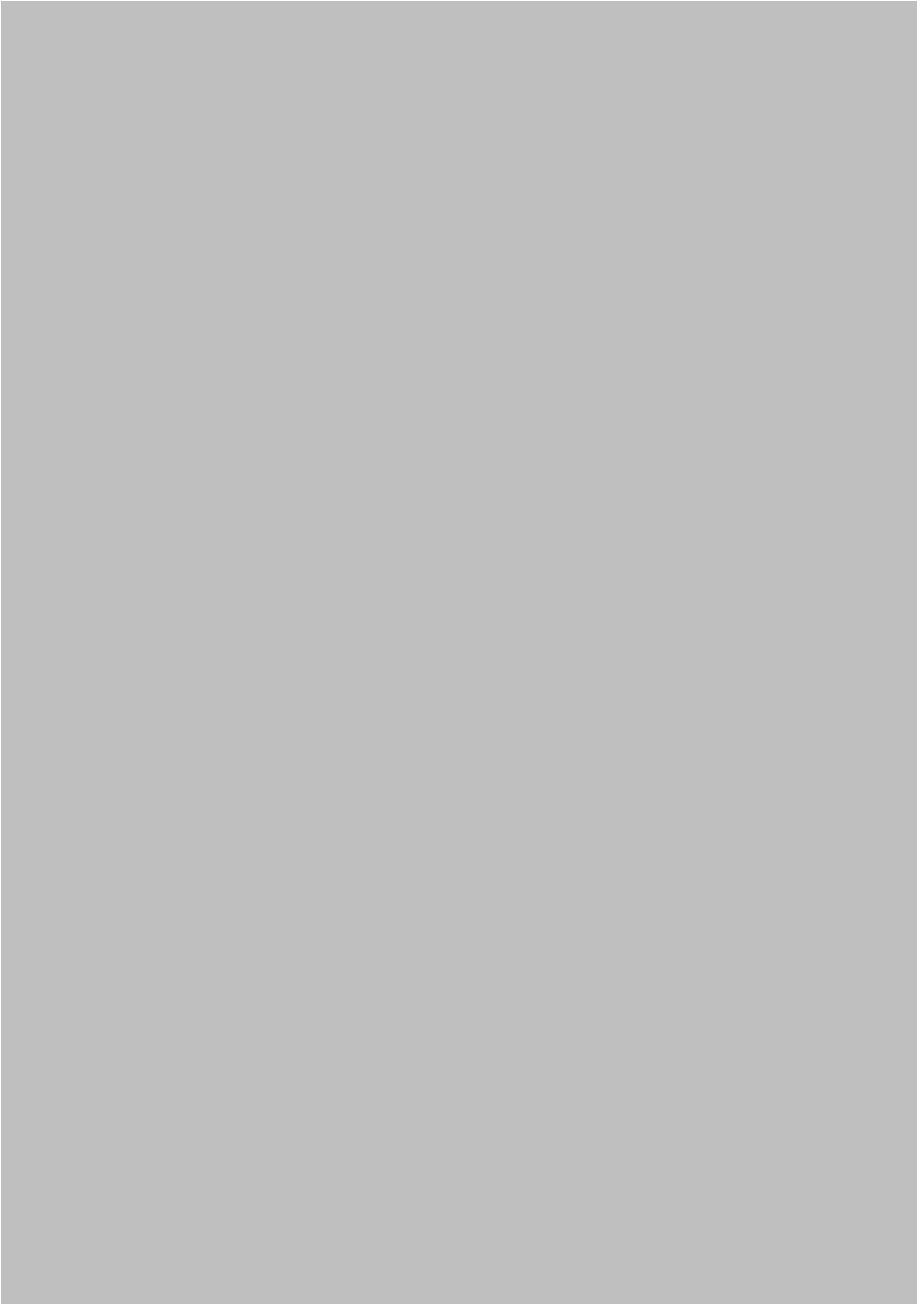


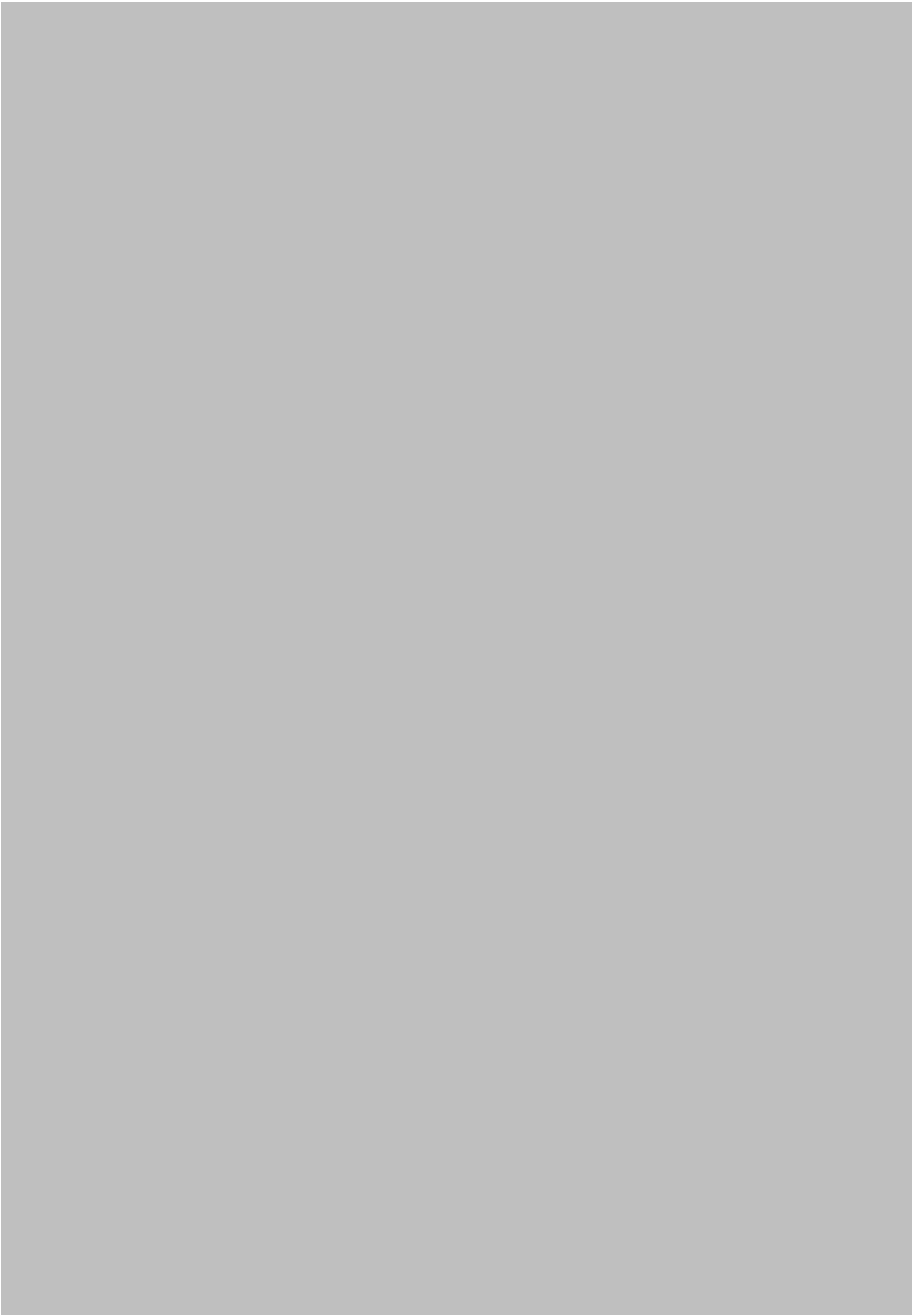




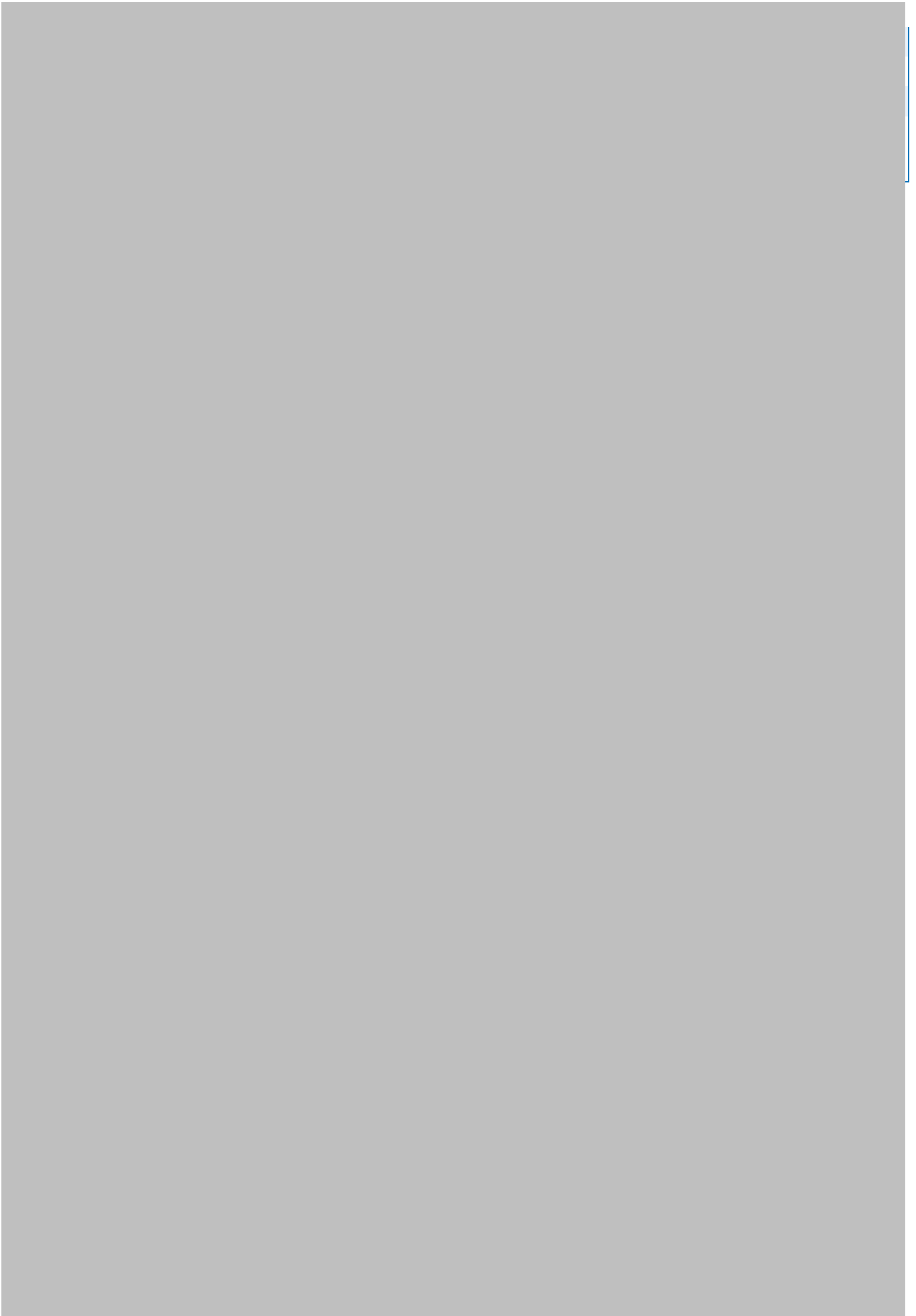


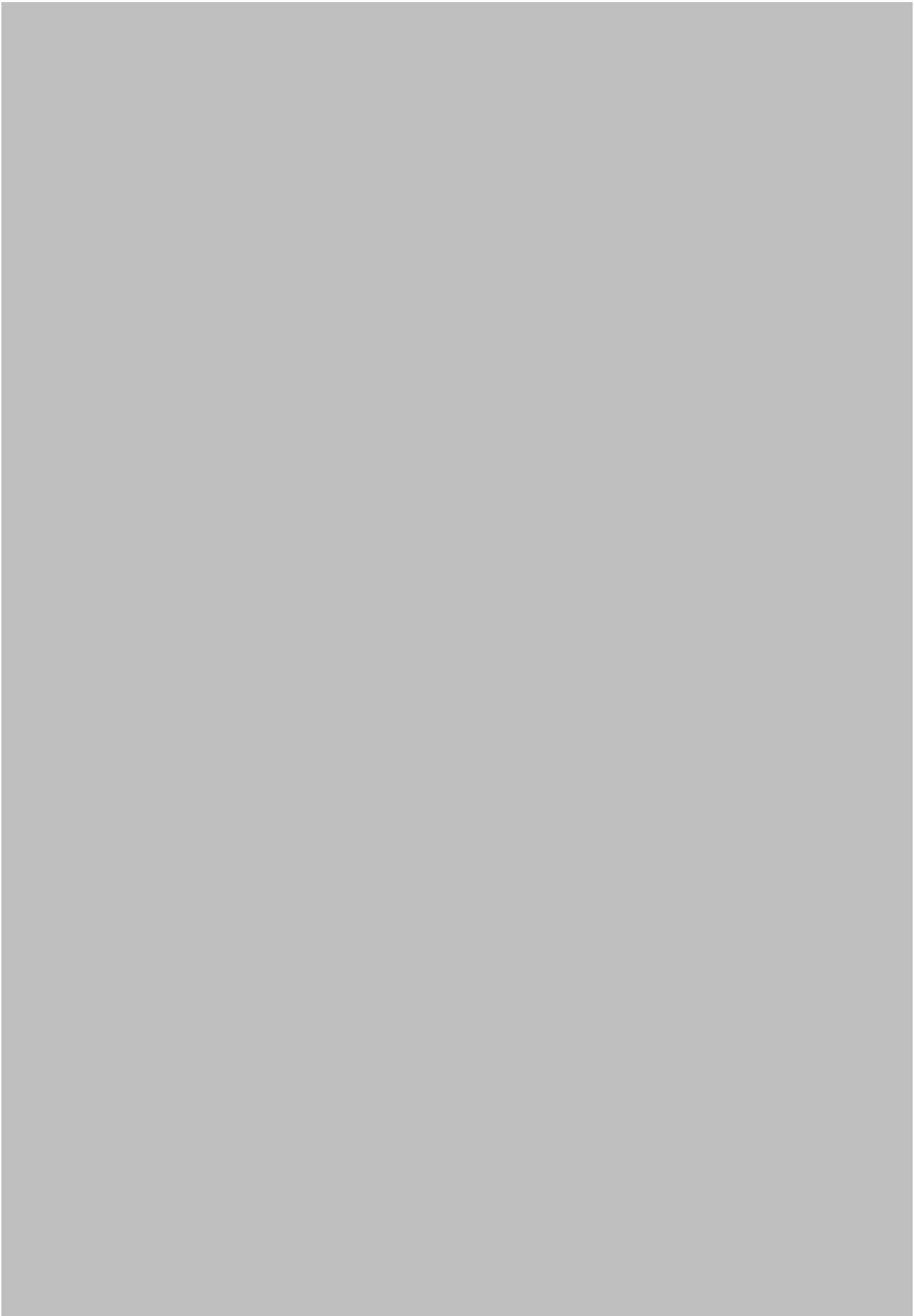


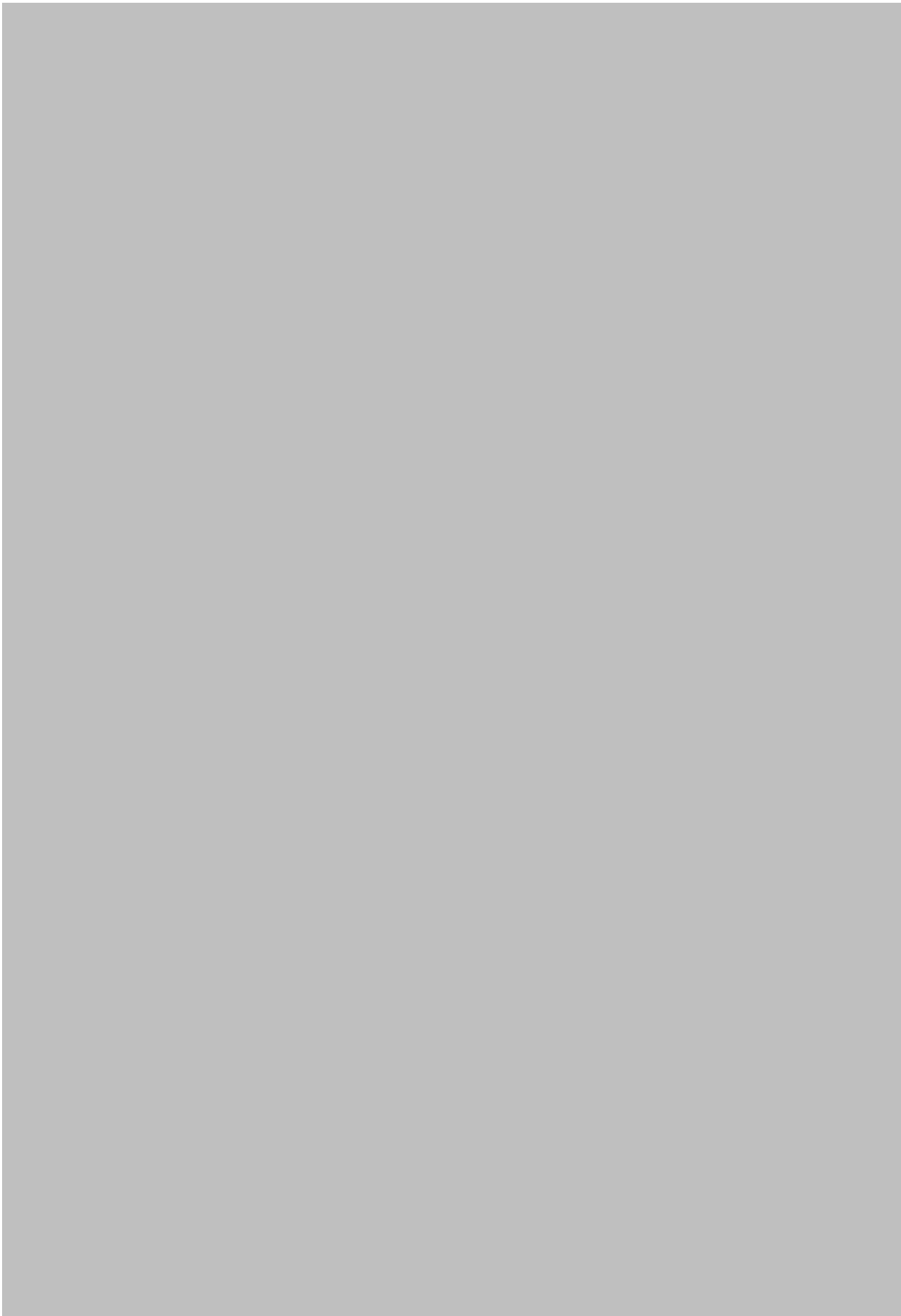




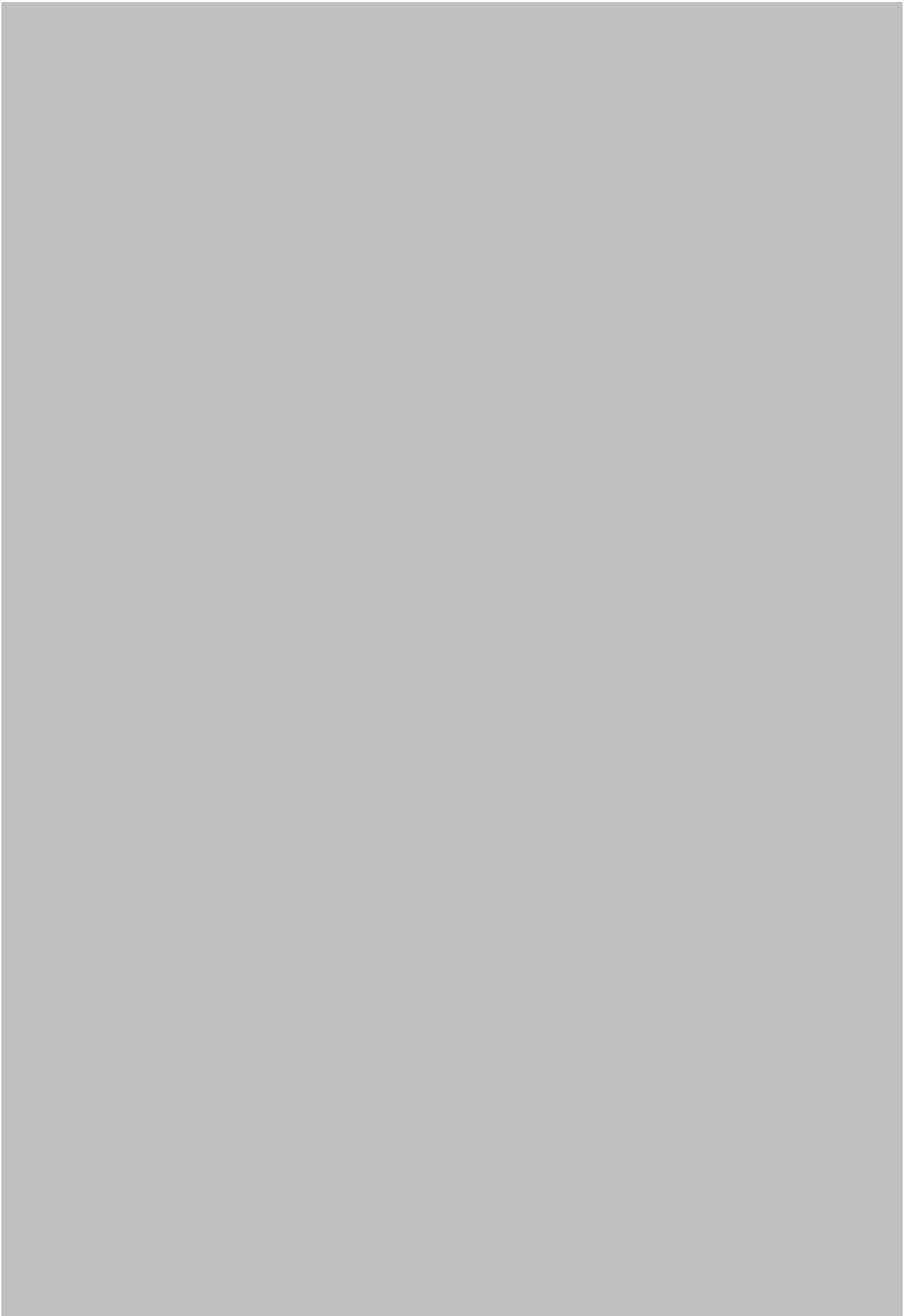


















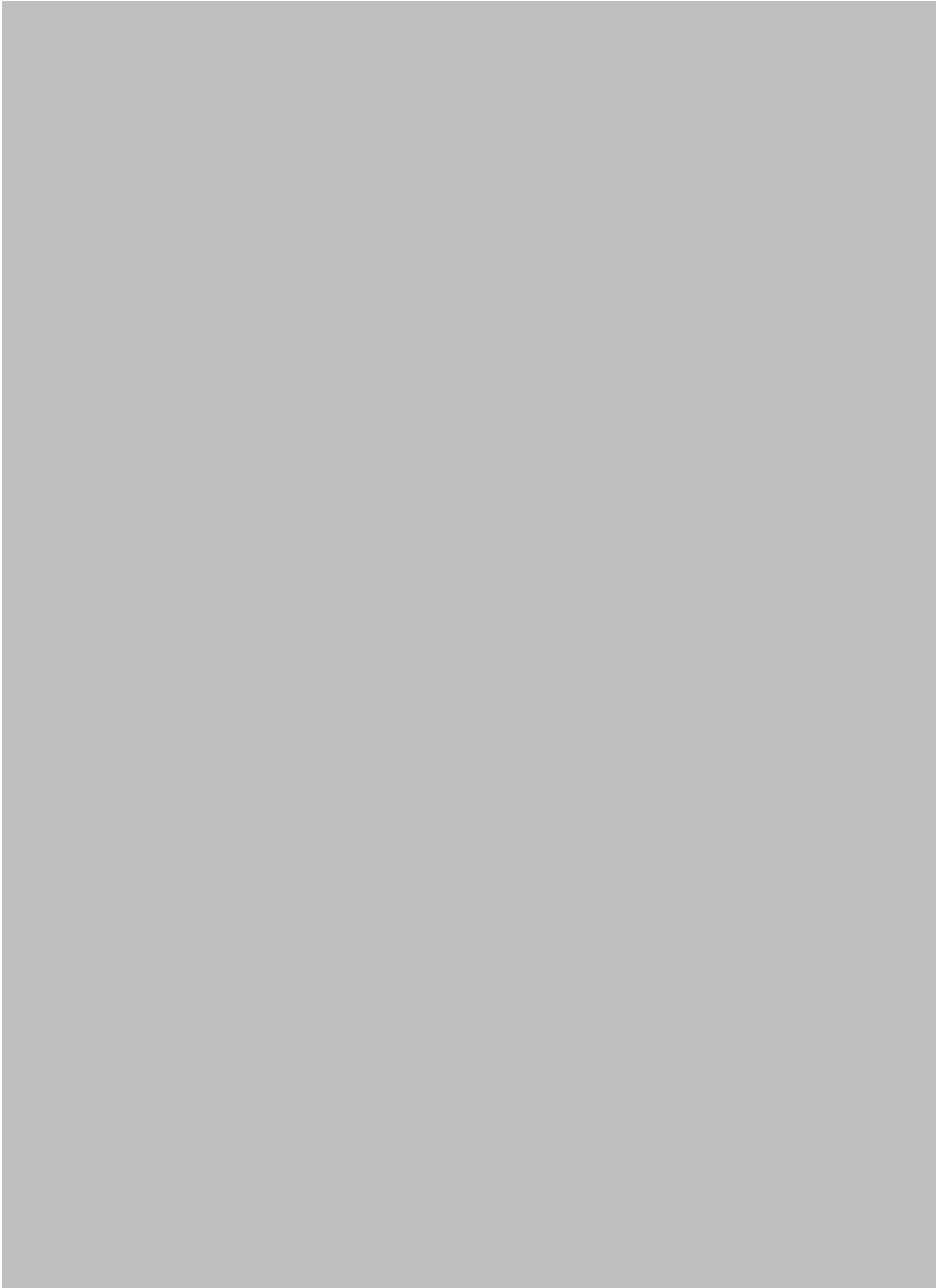


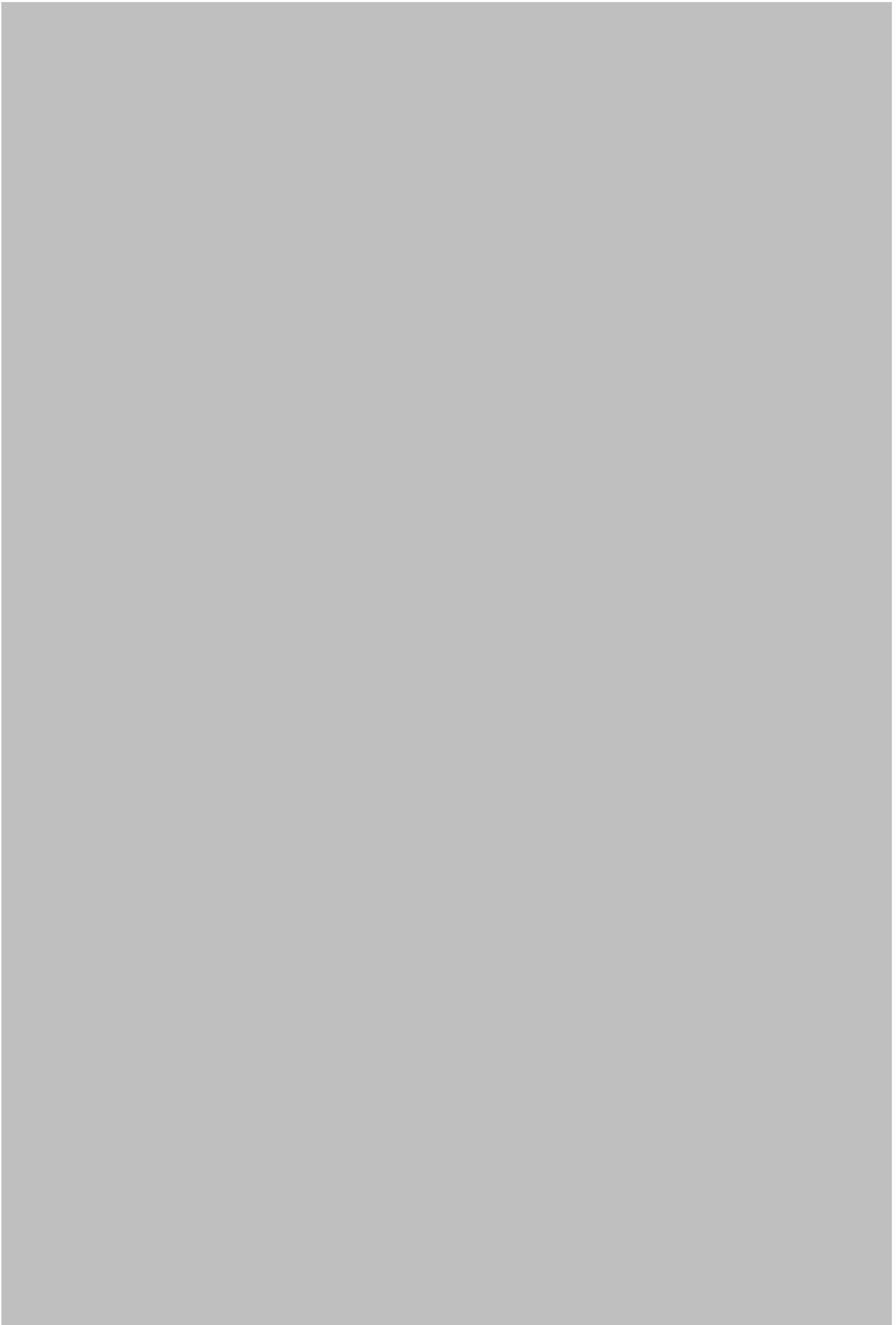




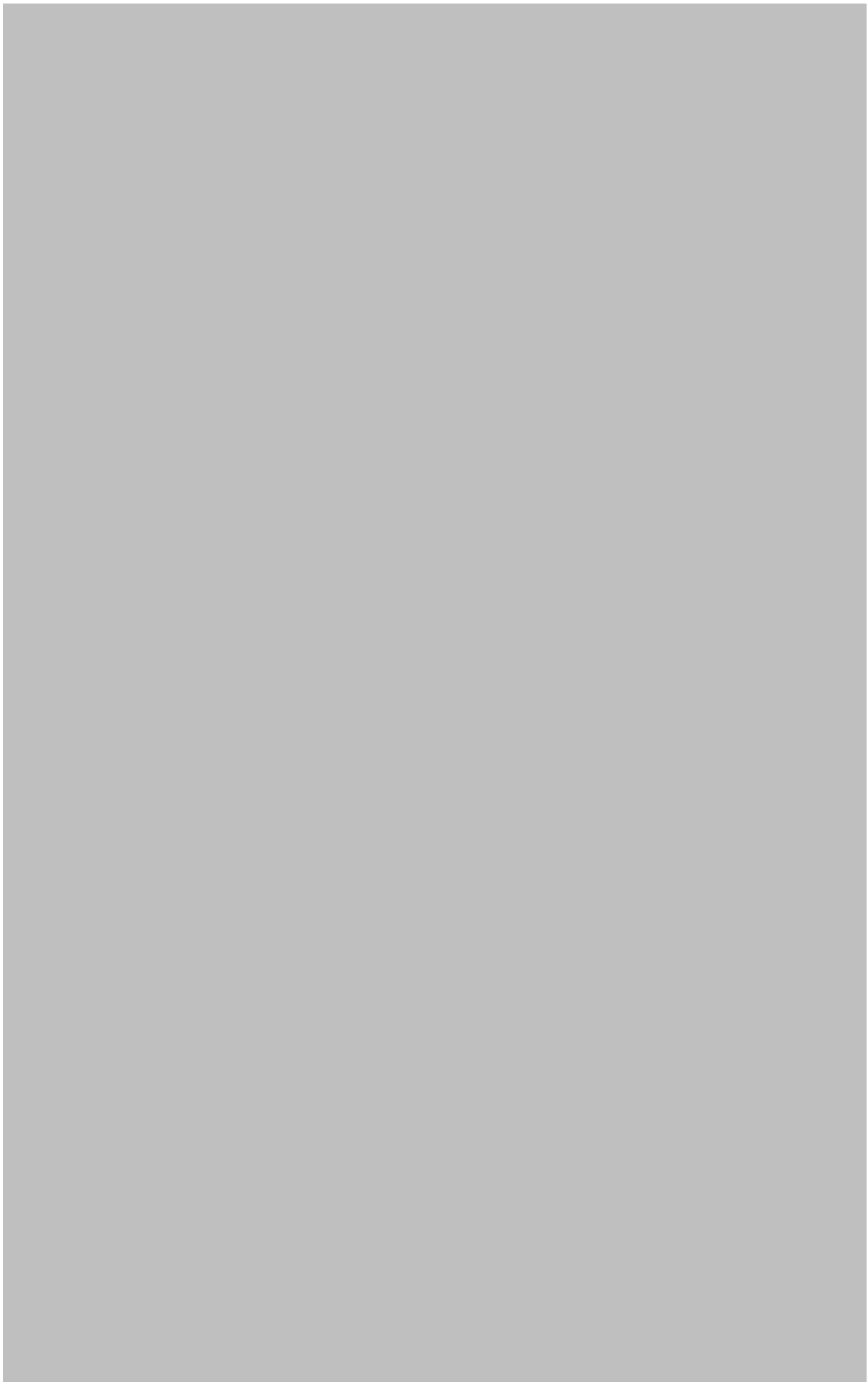




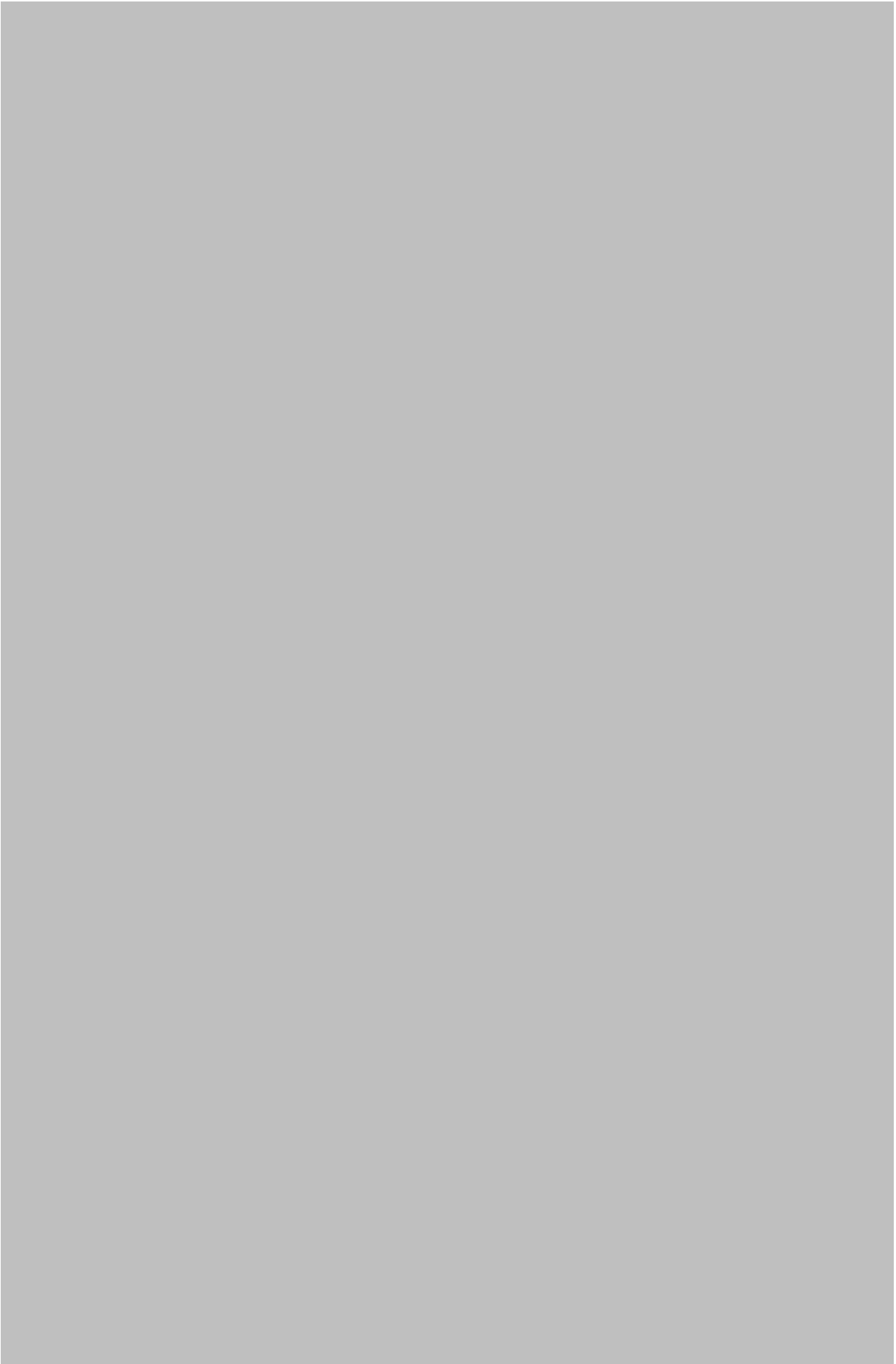


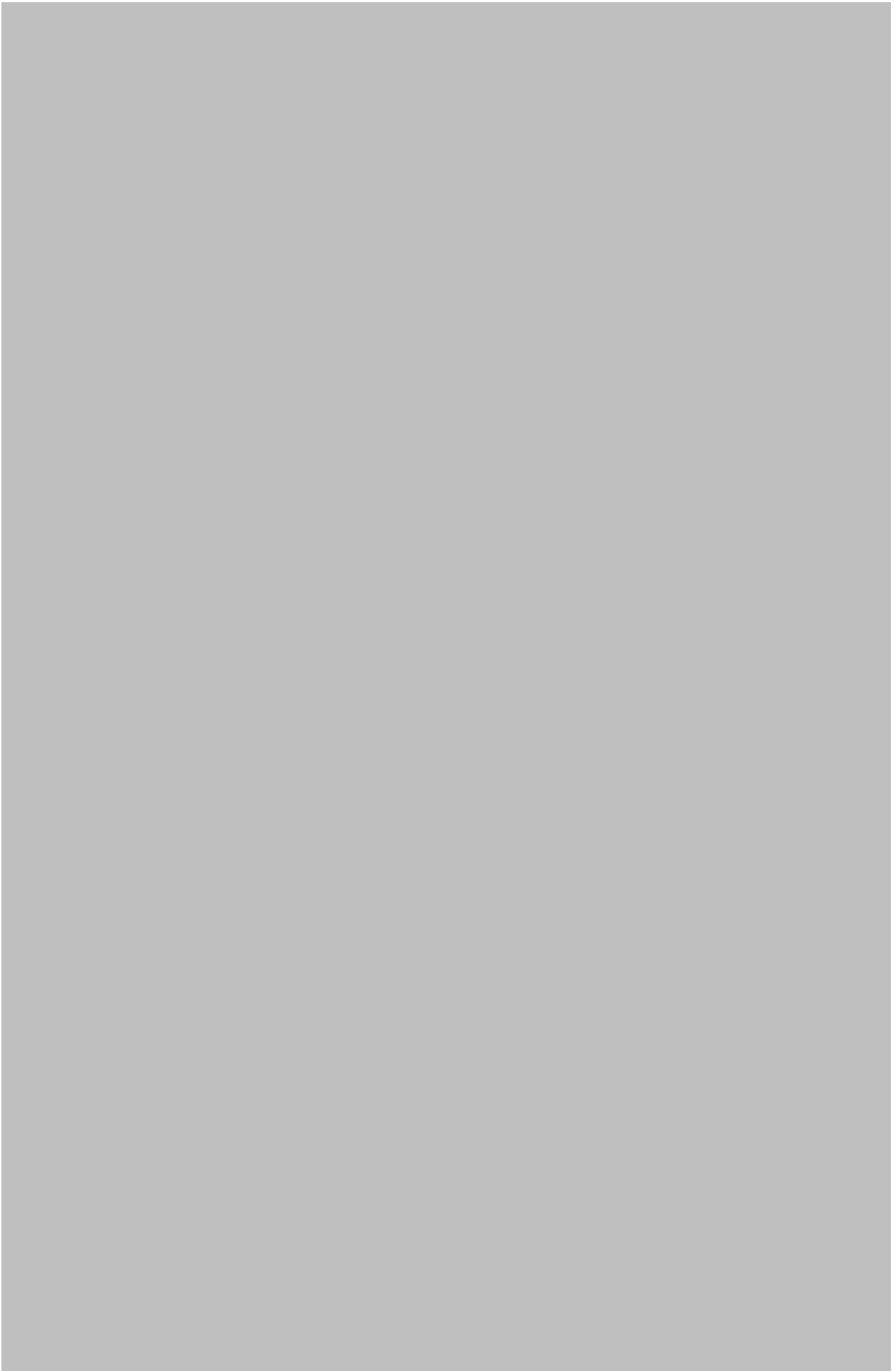














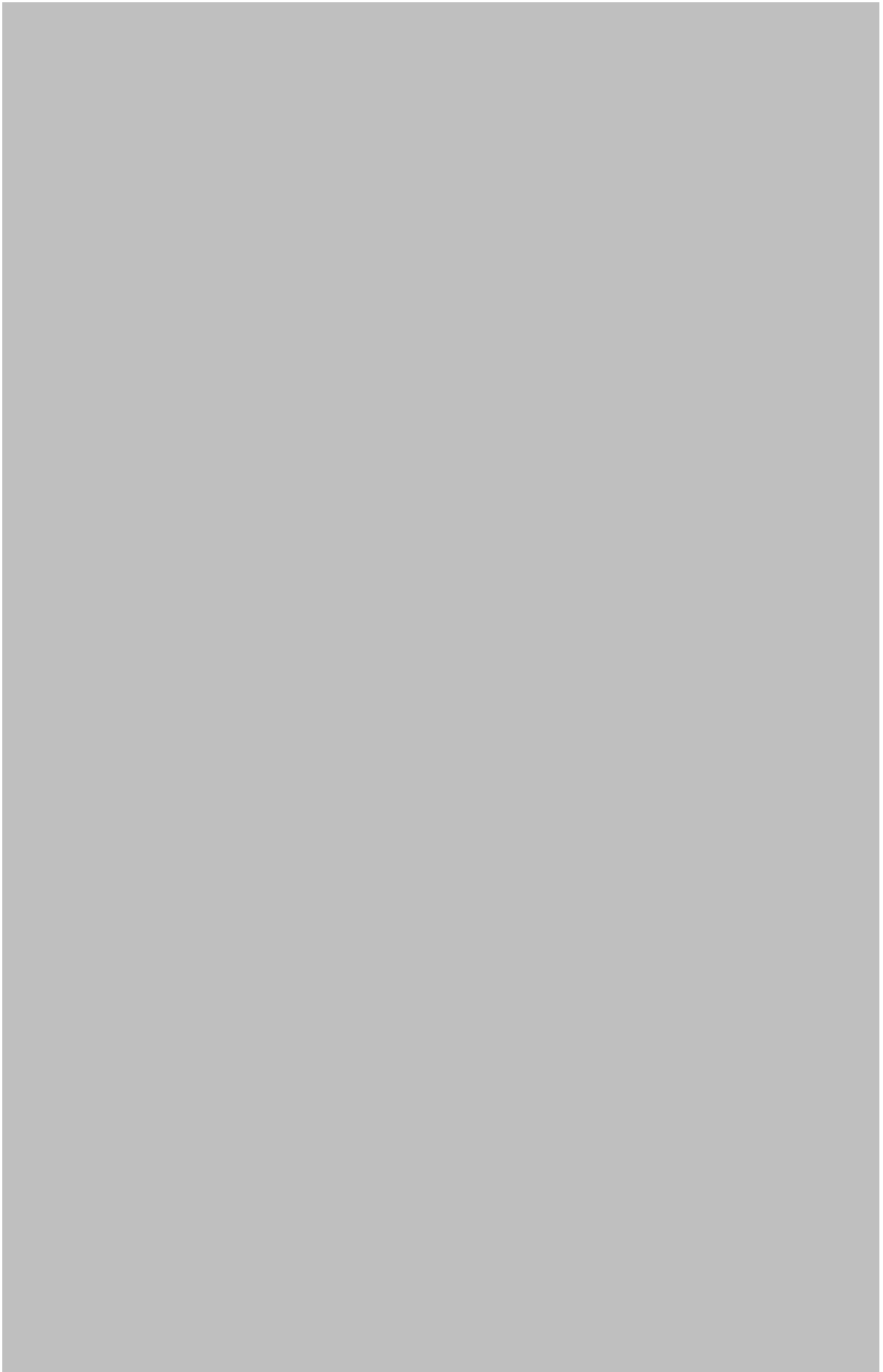










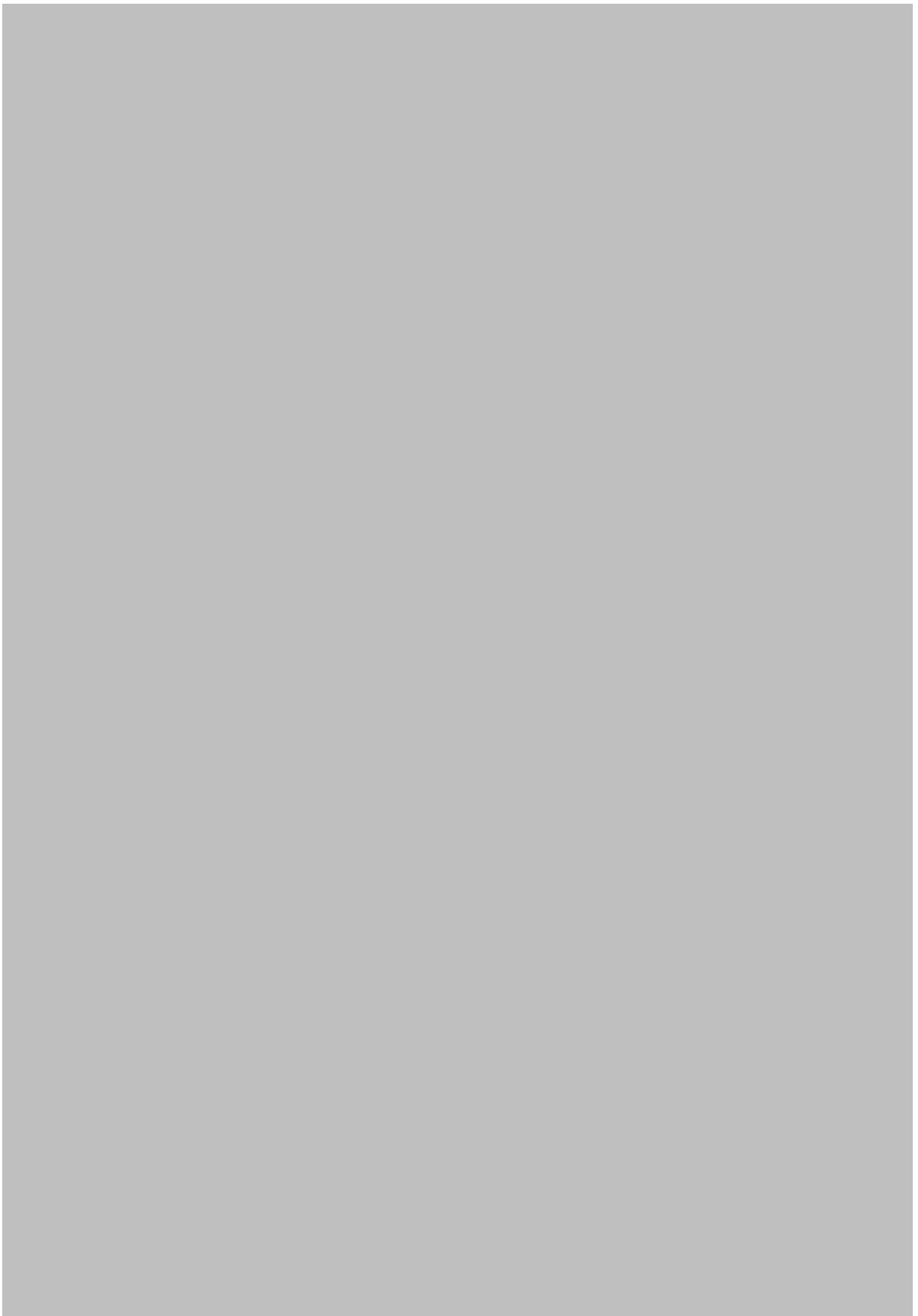


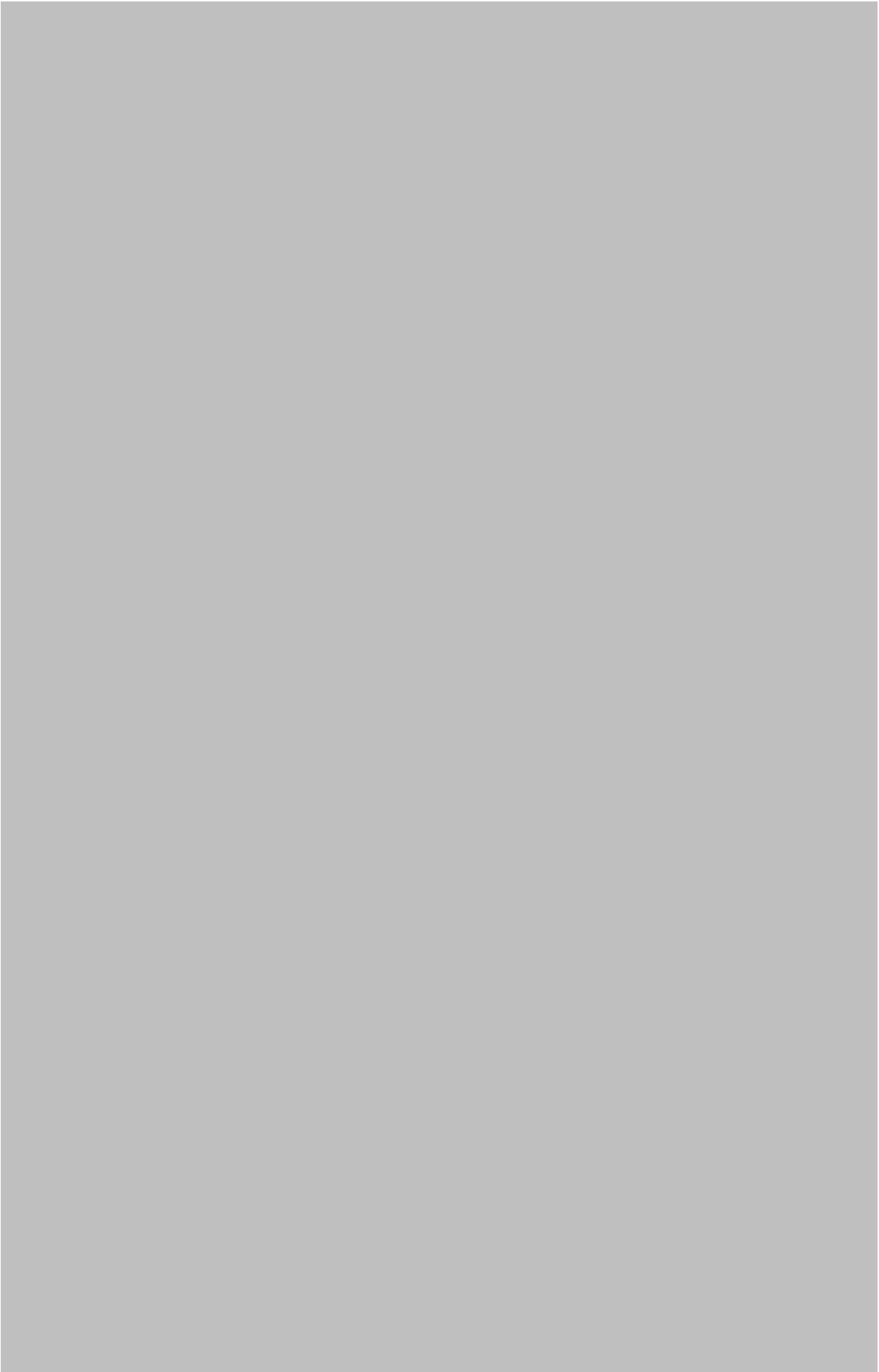


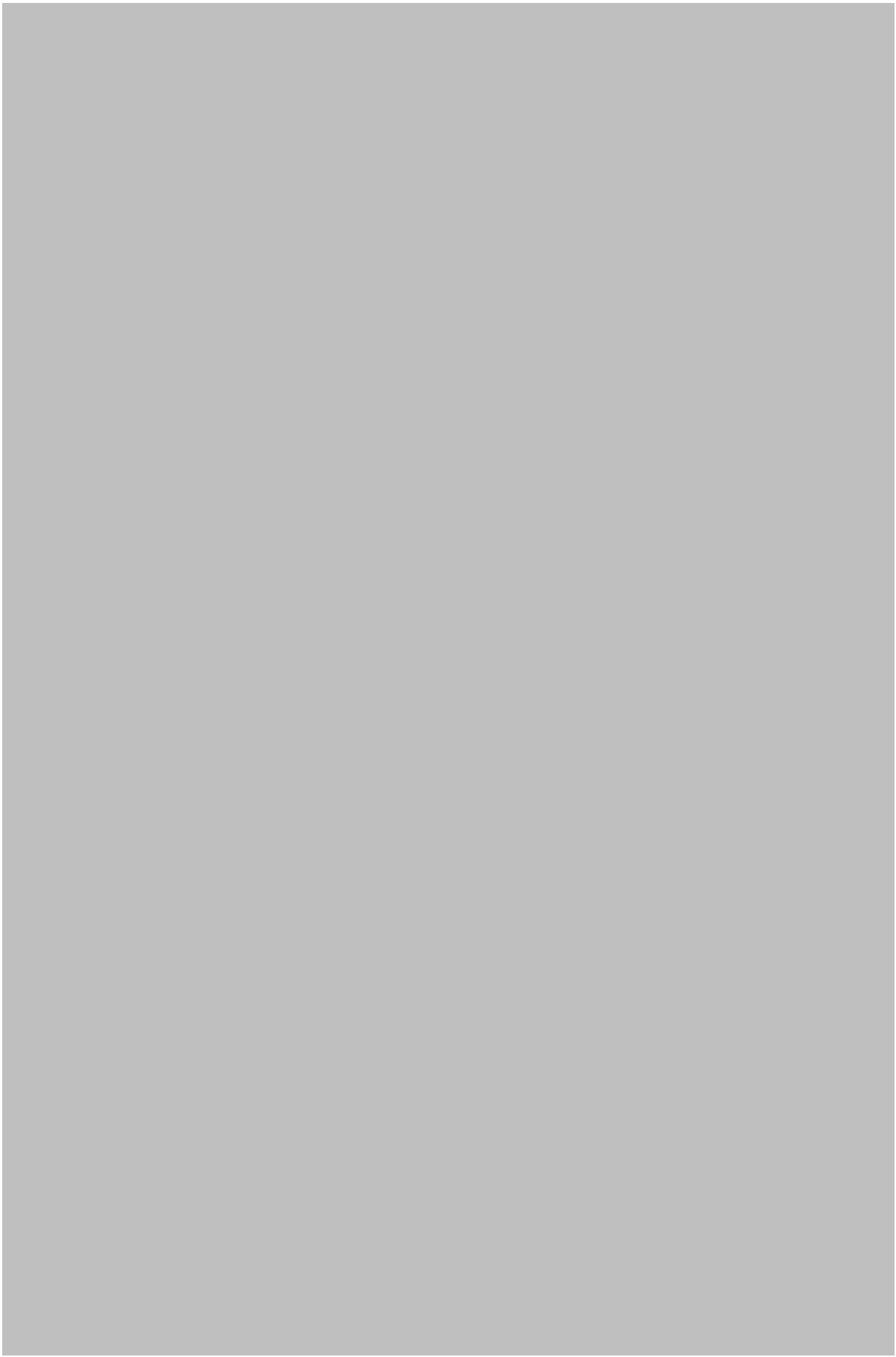


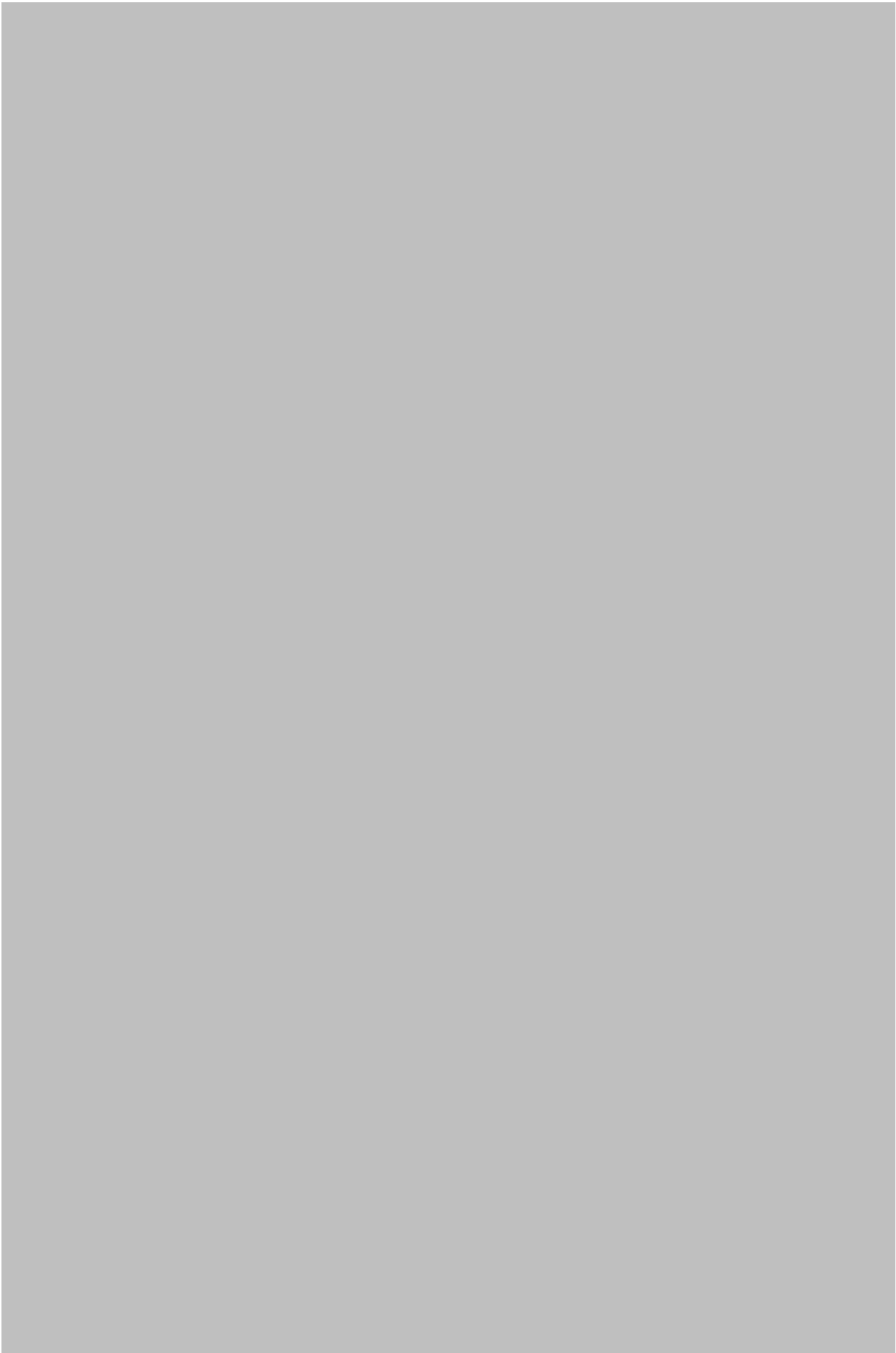
















## **ANNEX 6: COMPANIES REQUIRED TO PROVIDE MORE DETAILED AND/OR ADDITIONAL INFORMATION ON THE USE OF CHEMICALS AND ON EXPOSURE**

### **1 CONTEXT**

Under REACH, registrants shall conduct a chemical safety assessment (CSA) for all substances manufactured or imported in a quantity of more than or equal to 10 tonnes per year. The CSA shall document adequate control of risks. The CSA shall include hazard assessments for all substances and an exposure assessment and a risk characterisation for substances fulfilling the criteria for certain hazard classes according to the CLP Regulation (Article 14(4)) or the criteria for PBT or vPvB substance (Annex XIII). REACH, Annex I describes the approach that a registrant could employ in developing exposure scenarios for the various uses. An exposure scenario (ES) is the set of operational conditions and risk management measures that the manufacturer or importer has implemented or recommends downstream users to implement to ensure adequate control of risks.

Information on uses and resulting exposures is essential not only for the registrant in his documentation that his own uses are safe, but also for ensuring that exposure scenarios submitted to his downstream users are reflecting their uses and securing that risks are adequately controlled for these uses. Moreover, such information is also needed for documenting strictly controlled conditions in case of registering intermediate uses and for supporting exposure-based amendment of information requirements, including triggering of further testing or waiving of further testing.

In a wider perspective, also taking into account current and future product legislation, market actors are expected to better communicate about uses with each other, to enable suppliers to carry out their product safety assessments (for substances, mixtures, materials, articles) and to enable users to introduce appropriate risk management measures at their sites or during their services.

Information on uses at a sufficient level of detail is also beneficial for operators looking for alternatives in the process of phasing out the use of Substances of Very High Concern or for replacing other hazardous substances.

For authorities, such information is essential for checking registration dossiers, in substance evaluations for concluding on whether a given substance constitutes a risk to health or the environment, and in exposure and risk assessment for use in developing proposals for regulatory action, in particular restriction proposals.

One critical aspect in the design of REACH is the dependency of the information flow from registrants to authorities on the functioning of the information mechanisms in the supply chain: Information on uses, use conditions and mass flows is sourced via manufacturers and importers' registration dossiers. Where supply chains are long (distributors, traders and/or multi-stage production) and users have found various applications of substances over time, the registrants' knowledge on uses is naturally limited. The REACH mechanisms for use-reporting from downstream users to ECHA (Article 38) are meant to compensate such malfunctioning to a certain extent.

However, for developing restriction proposals for specific (groups of) hazardous substances, authorities need information going beyond the foreseen content of a registration dossier (e.g. information on alternatives, information on imported articles). Therefore, also other sources of information (beyond registration and supply chain communication) are needed.

With their regulatory measures, authorities aim to protect human health and the environment. Measuring the regulatory impact in terms of health effect and environmental trends is difficult (time delays, complexity). Therefore, monitoring of market trends (change of manufacturing volumes and use patterns) and exposure trends are key instruments to measure and/or predict regulatory impacts.

## **2 DESCRIPTION OF THE PROBLEMS**

### **Use pattern**

#### *Description of the problems*

Knowledge of the use pattern is needed for all regulatory processes, including information on the relevant life cycle stages (LCSs)<sup>63</sup>, the technical function (TF) of a substance and whether it is intended to transform during use, and the types of products (mixtures and articles) in which a substance is used.

For the assessment of regulatory needs, information on the use pattern of a substance (e.g. widespread, localised or specific) supports the identification of exposure potentials and risk management capacities of the substance users. Information on the technical function allows to identify if substances (in particular non-hazardous substances) could be used as an alternative for another (in particular hazardous) substance and hence, supports consistent regulation that prevents regrettable substitution. Furthermore, the use pattern allows understanding of which uses should be addressed under REACH and which uses that are subject to other legislation. Information on the use pattern also helps identifying appropriate regulatory instruments, considering existing legislation and potential exemptions from REACH instruments. Information on the use pattern indicates potential impacts of regulatory actions on the market actors in terms of the number and types of affected products, processes and sectors.

If the assessment of regulatory needs is based on incomplete, missing, or outdated information on the use pattern of a substance, the consequences may be that a high level of protection cannot be ensured due to overlooking substances that are candidate for regulatory measures or due to overlooking relevant uses when designing a regulatory measure. The assessment of regulatory needs is not an in-depth risk assessment and is based mainly on the registration dossiers; thus, information from additional information sources is unlikely to correct inappropriate decisions at this stage.

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<sup>63</sup> The use description should cover the whole life-cycle of the substance, taking into account its degradation/transformation products where applicable. There are four basic steps or stages in the life-cycle of a substance to which a use can be assigned: manufacture, formulation or re-packing, end-use and (article) service life.



For drafting a restriction proposal for a hazardous substance, information on the use pattern (including uses in articles) is necessary to rank the uses that should be regulated. It is needed to scope a restriction and define its conditions (what products and/or processes should be covered and how). For restrictions under Art. 68(1) or 69(2) (specific restrictions), more granular information on uses and exposures is needed for scoping the restriction and documenting an unacceptable risk as well as to support the identification and assessment of alternatives. For generic restrictions of uses in articles according to REACH Art. 68(2), the information as currently provided in registrations is considered not sufficient to prioritise which (specific) article types that should be considered.

As the restriction process is stepwise, usually authorities analyse literature and databases to gather additional information, and (formally) consult stakeholders. Therefore, the registration dossiers are only the starting point for the restriction proposals and hence, the initial understanding of the use pattern may be corrected in the process. However, additional information collection upon the initiative of ECHA or the MSs is less transparent and more time consuming than if sufficient information were available from registration dossiers.

Information on how the use pattern of a regulated substance changes over time is an important indicator for how a regulatory measure impacts the market. This is even more helpful if related to the tonnage applied in a certain use (cf. below). If information on the use pattern is missing, inconsistent and not available as a time trend in the registration dossiers, the impact of a regulatory measure on the uses as identified by the registrants cannot be sufficiently well evaluated. Additional information on use patterns and market data may be available only for some (commodity) substances and would therefore have to be specifically generated.

### *Shortcomings*

Information on the relevant life cycle stages, technical function, and the chemical Product Categories (PCs)<sup>64</sup> and Article Categories (ACs)<sup>65</sup> according to ECHA's guidance R.12 is generally provided in the registration dossiers. Observed deficits concern the completeness of information where data is not subject to the technical completeness check (TCC) (e.g. product categories for industrial and professional uses), inconsistencies and ambiguities in registration dossiers and a lack of relationships between the technical function, product categories and article categories, which hampers the understanding of the use pattern. Furthermore, current information in the registration dossiers is partly outdated.

The following table lists the identified main deficits per information type.

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<sup>64</sup> Chemical Product Category (PC) describes in which types of chemical products (= substances as such or in mixtures) the substance is finally contained when it is supplied to, and used by, end-users e.g. detergents, paints.

<sup>65</sup> Article Category (AC) describes the type of article into which the substance has been processed (e.g. wooden articles, plastic articles). This also includes mixtures in their dried or cured form (e.g. dried printing ink in newspapers; dried coatings on various surfaces).

Table 56: Shortcomings of information on use pattern

Information type	Availability in registration dossier and observed shortcomings
Relevant life cycle stages	Inconsistent within registrations
Name of use	Mostly no added value for understanding of the use provided
Information on relevant product types (Chemical Product Categories (PCs)/Article Categories (ACs) of R12 guidance)	Information inconsistent, over and under reporting of uses PCs for industrial and professional uses not subject to TCC and therefore frequently not provided No clear relation between TFs and PCs / ACs → hampers understanding the use and resulting exposures List of PCs is not fit for purpose, e.g. includes very broad categories, some PCs are overlapping etc.
Affected sectors (sectors of use (SUs) <sup>66</sup> according to R12 guidance)	Information on SU is voluntary → not always provided SU partly very broad, sometimes relation to sector organisation missing (no reflection of formulator industry) Can usually be (better) identified from PCs/ACs but sometimes not
Uses covered by existing legislation (that ensures control of risks)	Can partly be deduced from PCs/ACs but frequently not clear
Uses not covered by (some) regulatory instruments	Can partly be deduced from PCs/ACs but frequently not clear
Technical function (TFs of R12 guidance) <sup>67</sup>	Not available in dossiers not updated since 2016 Partly unclear what the actual function is and/or if the TF has been correctly assigned
Intended transformation due to the technical function	May be obtained from the TF but generally unknown; leads to significant uncertainty as to whether the substance or a reaction product is present in articles (including cured mixtures)
Type of Process and emission /exposure potential (process categories (PROCs) <sup>68</sup> , environmental release categories (ERCs) <sup>69</sup> of R12 guidance)	Provided in the registration dossier but partly inconsistent and unclear whether applied correctly/as intended by the registrants.

<sup>66</sup> Sector of Use (SU) describes in which sector of the economy the substance is used e.g. rubber manufacturing sector, glass manufacturing sector, agriculture, forestry, fishery

<sup>67</sup> Technical Function (TF) defines what the substance actually does in the use (e.g. solvent, pigment).

<sup>68</sup> Process Category (PROC) defines tasks, or process types from the occupational perspective. The PROCs are also differentiated by taking into account the exposure potential for workers during the respective tasks or process types. This descriptor can be assigned to workers' activities contributing to a use. The categories are meant to support harmonised and consistent exposure assessment across sectors and supply chains.

Information type	Availability in registration dossier and observed shortcomings
Number of industrial sites where the substance is used	Not available
Number of exposed workers	Not available
Number of exposed consumers	Not available

In addition to the REACH registration data, information on the article category in which a substance is used is available for SVHCs on the candidate list from Applications for Authorisation, from notifications of substances in articles according to REACH Art. 7(2) and from the database for information on Substances of Concern in Products (SCIP) established under the Waste Framework Directive (SCIP). This data may in particular support restriction proposals under REACH Art. 69(2) but is not relevant for non-candidate list substances.

The use pattern information may be verified and complemented using additional information sources, such as the Substances In Preparations in Nordic Countries (SPIN) database (use of substances in mixtures, partly also articles), positive lists under e.g. biocides or cosmetics legislation (legal coverage), or DU CSR notifications (Art. 38). The Poison Centre Notification (PCN) database contains additional and valuable information on composition of mixtures classified as hazardous on the basis of their health or physical effects. The information is mainly available for medical purposes, including preventive and curative purposes, but can also be used to undertake statistical analysis to identify where improved risk management measures may be needed. It is unclear whether the information can be used directly for drafting restriction proposals.

For the development of restriction proposals and the monitoring of regulatory impacts, information could be further complemented from literature, market surveys, MS product surveys, from websites of companies or sector associations, as well as from formal or informal consultations with the industry and other stakeholders. Time trends may be available from e.g. the SPIN database but the information is not regularly updated. For the assessment of regulatory needs, these options may be of limited use due to the partly high efforts needed to obtain and verify the information.

#### *Drivers of the problem*

The most important reasons for incomplete, outdated, or inconsistent information on the use pattern are:

- The registrants are not sufficiently aware of the downstream uses and frequently base their use description on the generic sector use maps, which may be complemented from the sales statistics. As the communication up the supply chain does not work sufficiently well due to, a.o., downstream users need to keep

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<sup>69</sup> Environmental Release Category (ERC) is designed to label the characteristics of a use based on different aspects relevant from the environmental perspective, e.g. lifecycle stage, technical fate of the substance during use.

their uses confidential or some supply chains are long and complex, registrants do not receive corrective information from their customers.

- The requirements in REACH, Annex I on ESs do not clearly define how broad a use may be described, but it is up to the registrant to define the scope as needed. Frequently, several technical functions and chemical product categories or article categories are covered in one scenario, as broad scenarios are most efficient for registrants. However, this prevents a clear understanding of the use.
- No requirement exists to regularly update the registration dossier, including the use pattern.
- The use descriptors, guidance documents and industry tools (specifically the use maps) are not fully aligned with the regulatory needs and the language in the market.
- Not all legally required information is subject to the TCC.

*What should be achieved?*

As the information on use patterns is crucial at the initial stage of the regulatory risk management processes and relevant for drafting restriction proposals and monitoring impact of restrictions, an improvement of the information is considered as highest priority. Improvement options should therefore ensure that:

- ECHA and the MSs obtain reliable, complete, and up-to-date information in the registration dossiers on the types of users of a substance (industrial, professional and consumers) and the use in mixtures and articles;
- The registration dossiers enable the authorities to get a comprehensive understanding about the PCs and ACs in which a substance may be used, what specific TF it fulfils (in a specific PC or AC), and whether some uses are covered by existing legislation other than REACH;
- The registration dossiers allow understanding if a substance transforms along its life cycle.

## **Information on tonnages**

*Description of the problems*

Information on the tonnage of a substance manufactured or imported and the tonnage breakdown into (groups of) uses is needed for all regulatory processes.

In the assessment of regulatory needs, the tonnage of a substance manufactured or imported is a first but very rough indicator of the maximum overall exposure potential, while the tonnages entering (groups of) uses can be used to weigh the relevance of uses (and their exposure potentials). Consequently, tonnage information supports the prioritisation of substances and uses for regulatory action and helps identifying the most appropriate regulatory instruments that would address the main potential risks.

For drafting restriction proposals, the overall consumption tonnages, and tonnages per (groups of) use are good starting points. For generic restrictions according to REACH Art. 68(2), the available information required according to the current provisions of REACH may be sufficient to prioritise substances and products for which action is needed and to roughly understand the potential regulatory impacts. More granular information may be needed for scoping generic restrictions, in particular for articles.

For specific restrictions under REACH Art. 68(1) or to assess the need for a restriction according to REACH Art. 69(2), more granular information is needed to identify and demonstrate that risks (including from use in articles) are not adequately controlled and to make a socio-economic assessment. Tonnage information may be needed at a higher or lower granularity than the current use descriptors for PCs and ACs, depending on the hazard of a substance, the scope of the restriction and the planned restriction conditions.

Information on how the amounts of a regulated substance applied in (groups of) uses change over time is an important indicator of the market impacts of a regulatory measure, as discussed in relation to the use pattern (cf. above). If information on tonnages is missing or not up-to-date and available as a time trend in the registration dossiers, the impact of regulation on the uses cannot be sufficiently evaluated. Additional information to evaluate the regulatory impacts based on other data sources may be available only for some (commodity) substances and would therefore have to be specifically generated.

### *Shortcomings*

Information on the registration tonnage is provided in the registration dossier. The amounts used as intermediates and the amounts immediately exported by the registrants is sometimes but not always provided. Information on tonnage is available for each Exposure Scenario as part of the environmental exposure assessment present in the Chemical Safety Report. The tonnage used per lifecycle stage can be provided as an aggregated amount from all relevant Exposure Scenarios. The amount per PC or AC is available only if one ES covers only one PC or one AC.

The main shortcomings of tonnage information in the registration dossiers are that specific tonnage data per (groups of) use are missing or inconsistent with the total registration tonnage. In addition, data on exported amounts by the registrants and about uses as intermediates are incomplete.

Information on the manufactured and imported tonnage of substances (as such and in mixtures) is subject to the Technical Completeness Check in IUCLID<sup>70</sup>. The registrants may report the amounts used as an intermediate, the exported amounts and the amounts used in their own uses on a voluntary basis. It is necessary to specify the tonnages per use for the assessment of environmental emissions and exposures in the CSR. Cumulative tonnages per life cycle stage can be derived based on the CSRs and/or provided on a voluntary basis in IUCLID.

*Table 57: Shortcomings of tonnage information in the registration dossiers*

Information type	Availability in registration dossiers and observed shortcomings
Total consumption volume in the European Economic Area	Information not up-to-date Exported amounts not always provided Amounts exported in mixtures and articles as well as imported in

<sup>70</sup> IUCLID (International Uniform Chemical Information Database) is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.

Information type	Availability in registration dossiers and observed shortcomings
	articles unknown to registrant  Inconsistencies with reported amounts per use
Tonnage per lifecycle stage (LCS)	Information not up-to-date  Tonnage per LCS inconsistent with total amounts  Tonnage ending up in articles (service life) and end uses not always available (not subject to TCC); however, filled in automatically if Chesar <sup>71</sup> is used for CSA  Cumulated information from Chesar / CSR is not considered reliable
Tonnage used as intermediate, tonnage covered by other legislation	Reporting of intermediate uses is voluntary (but related to benefits of lower hazard information requirements)  Tonnes not reported according to ACs/PCs that indicate regulatory coverage
Tonnage per use	Information in ESs (environmental assessment) of the CSRs not considered reliable
Tonnage per product category (AC/PC)	Information missing unless ES covers only one PC/AC (then available from environmental assessment)  No information on tonnages in imported articles available
Tonnage per use at higher granularity as AC/PC	No information on amounts used per product at higher granularity than PC/AC available

Information on the total tonnages of substances and allocation to specific uses covered by (product-specific) legislation is not easily available and accessible for the authorities from databases or similar sources. Indeed, it may not be available at all, due to a lack of substance specific reporting systems. While EU production and trade statistics contain information on a few specific commodity chemicals, this information is missing for lower volume and specialty substances. Furthermore, matching the use information reported in e.g. the Production Statistics with the use descriptions in registration dossiers is hardly possible.

#### *Drivers of the problem*

Technical issues is one of the drivers causing insufficient information on tonnages, as there are no plausibility checks highlighting inconsistencies to registrants, and as tonnages used to estimate emissions and exposures in the CSR do not necessarily reflect

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<sup>71</sup> Chesar is an application developed by the European Chemicals Agency (ECHA) to help companies to carry out their chemical safety assessments (CSAs) and to prepare their chemical safety reports (CSRs) and exposure scenarios (ESs) for communication in the supply chain. Chesar enables registrants to carry out their safety assessments in a structured, harmonised, transparent and efficient way.

market reality but are frequently back-calculated so as to ensure safe use; therefore consistency is often lacking between the total tonnage provided in the registration and the amounts specified for different uses in the CSRs.

At present, not all information that registrants are likely to possess or at least are able to obtain based on market knowledge and customer profiles must be provided, such as the own exported amounts or a breakdown of tonnages according to 'main groups of uses'. In addition, there is no requirement to regularly or on demand update tonnage information, except if tonnage bands are exceeded.

The authorities cannot rely on the tonnage information derived from the environmental exposure assessments of the CSR. The lack of reliability is due to the aim of the CSR to demonstrate safe use via an iterative safety assessment starting with default assumptions on the conditions of use (including tonnage). The total tonnage per use as well as the tonnage per installation are important exposure drivers and hence their values are likely to be iterated in the CSR in a way to demonstrate safe use. In addition to that, the ESs frequently cover more than one PC/AC and therefore, the granularity of tonnage information in the CSRs is not sufficient for development of specific restriction proposals.

The downstream users have information on the amounts of substances that they include into their products (mixtures) and, if they use substances in mixtures, they know the tonnages. Similarly, article producers know the amounts included into their products as ranges. However, information on the used tonnages per use and/or per PC/AC is often considered confidential, as it indicates a market potential in a particular application. In most cases, such information is therefore not communicated upstream to registrants.

Tonnage (per use) is an important exposure proxy for the assessment of regulatory needs, including the recommendation of SVHCs for inclusion in the authorisation process. Compared to the use pattern data, tonnage data is considered less important for the assessment of regulatory needs because it is only used to refine the assessment by weighing the relevance of uses against each other based on tonnage. However, specific tonnage data per use is crucial for the development of specific restriction proposals. The ability to monitor policy impacts strongly depends on time trends of the registration and use tonnages of substances. As a minimum, changes in the total tonnage over time are needed. However, to enable a more complete overview of changes in the use pattern, more granular tonnage information per use as time trends is needed.

*What should be achieved?*

The options for improvement should ensure that:

1. ECHA and the MS obtain reliable, complete, and up-to-date information on the consumption volume of substances on the EU market from the registration dossier
2. The registrants specify the tonnage breakdown per (groups of) use based on their market knowledge, in addition to the volumes provided as input to the exposure assessments
3. Authorities get access to more specific tonnage data at a high granularity regarding the products and articles in which a substance is used, including from the DUs, to support the development of specific restriction proposals.

## **Condition of use**

### *Description of the problems*

The conditions of use (CoU) include product-specific information, such as the average concentration of a substance in a mixture or article, or how it is bound to a matrix, process specific information, such as the exposure driving factors including processing temperature and level of containment, as well as information on the overall operational conditions and RMMs applied in a use and during service life.

For generic restrictions according to REACH Art. 68(2), the information on CoU is not necessary. However, also here, information on the average concentration of substances in products/articles and the way they are bound to matrices may influence the prioritisation of types of articles that could be subject to a generic restriction.

For specific restrictions under REACH Art. 68(1) or to assess the need for a restriction according to REACH Art. 69(2), information on the CoU is needed to identify and demonstrate whether risks (from use in articles) are adequately controlled. The information is needed as input to emission and exposure assessments and, where this is relevant, to define specific restriction conditions, such as concentration thresholds in mixtures or articles, risk management measures at workplaces, or migration limits. The granularity of needed information depends on the substance hazard, the restriction scope, and the intended restriction conditions, and is frequently needed at a higher level of granularity than provided in the registration dossiers.

Information on the CoU is not normally needed to monitor the impact of regulatory measures. An exemption are cases, where the regulatory measure aims to change the CoU, e.g. at the workplace. If the measure targets the use of a substance in products, market data are more likely to provide a good picture of the impacts (cf. above).

Information on the CoU is provided per use in the ESs and for all contributing scenarios. In many cases, the registrants apply generic exposure assessment tools, such as the sector use maps, which include process categories (PROCs), environmental release categories (ERCs) and specific environmental release categories (SPERCs) as well as specific workers exposure determinants (SWEDs) and specific consumers exposure determinants (SCEDs) in combination with Chesar and/or the ECETOC TRA exposure model. Where no safe use can be demonstrated, these conditions may be iterated until adequate control of risk can be demonstrated.

### *Shortcomings*

The information on the CoU in the registration dossiers is derived from ECHA's ERCs and/or the more sector specific SWEDs, SCEDs, SPERCs and use maps developed by sector organisations. It is the intention that by using these tools, CoU are defined to cover many uses in few models. However, the downside of this is that specificities of uses are not reflected but 'hidden' under the worst-case emission rates related to a use. Therefore, and as the upstream communication on the CoU does not work well, the authorities cannot rely on the information provided in the CSRs. In addition, only some information on the CoU is available in structured data format in IUCLID.



Information on the (change over time of) CoU is of high relevance for drafting (specific) restriction proposals as part of the justification (demonstration of risks) to scope a restriction, define restriction conditions and to assess impacts of a restriction in the market.

An overview of shortcomings of information on CoU in registration dossiers is listed in the table below.

Table 58: Shortcomings of information on conditions of use in registration dossiers

Information type	Availability in registration dossiers and observed shortcomings
CoU driving exposure that are related to the products (physical state of mixtures, concentration in products, type of matrix binding, containment inside (complex) objects etc.)	<p>Physical state and concentration in products are provided in CSRs (contributing scenarios) but are not obligatory in IUCLID and frequently not imported from Chesar (if used).</p> <p>Information on the type of matrix binding is not explicit in exposure assessment and no data field is available in Chesar/IUCLID</p> <p>Mostly generic information is provided as derived from use descriptors and exposure assessment tools (PROCs, ERCs/SPERCs, ECETOC TRA and others)</p>
Operating conditions driving exposure related to the use process, such as operating temperature, degree of process containment, occurrence of water contact	<p>Information on relevant exposure determinants during use is provided in CSRs (contributing scenarios) but are not obligatory in IUCLID and frequently not imported from Chesar (if used).</p> <p>Mostly generic information is derived from use descriptors and exposure assessment tools (PROCs, ERCs/SPERCs, ECETOC TRA and others)</p>
Exposure drivers related to the service life, such as high temperatures during service life, abrasive conditions, outdoor use of articles	<p>Information on relevant exposure determinants during service life may be provided in CSRs (contributing scenarios on service lives) but are not obligatory in IUCLID and frequently not imported from Chesar (if used).</p> <p>Mostly generic information is derived from use descriptors and exposure assessment tools (ERCs/SPERCs, ECETOC TRA and others)</p>
Operating conditions and RMMs during use and waste processing	<p>Information on operating conditions and RMMs applied during use is provided in CSRs (contributing scenarios) but is not obligatory in IUCLID and frequently not imported from Chesar (if used).</p> <p>Mostly generic information is provided from use descriptors and exposure assessment tools (PROCs, ERCs/SPERCs, ECETOC TRA and others)</p>

Information could be gathered directly from stakeholders via formal consultations but also informal information collection, e.g. Calls for Evidence or in discussions during dossier preparations. Similar to literature research, this type of information gathering is cumbersome and probably only realistic to support restriction proposals.

#### *Drivers of the problem*

Technical issues is a driver for lack of information on CoU:

1. Not all information that is provided in the CSR is available in IUCLID, i.e. in a structured data format.
2. The use descriptors of the PROCs and ERCs are not consistently and sufficiently differentiated according to main exposure drivers.
3. The registrants appear to not fully understand the meaning of the ERCs and PROCs, which leads to inconsistent use descriptions.

Moreover, there is no legal requirement defining the type and granularity of information on the CoU that must be provided in the CSR. Data import from Chesar can be suppressed and there are no data fields on the CoU that are subject to the Technical Completeness Check. Minimum requirements for describing the CoU in Exposure Scenarios do not exist, yet.

The main reason for the lack of specific information on the CoU is that registrants do not have this information and therefore cannot specify it in the registration dossier. The tools to bridge the registrants' lack of knowledge, such as exposure estimation and modelling tools, potentially including default values on the CoU, work sufficiently to enable the CSA. However, authorities do not consider the CoU information as sufficiently reliable for regulatory risk management.

The Downstream Users know the conditions of their own processes and potentially also those of their customers and/or the article service life. While they might not be aware of the exact concentration of a hazardous substance in their products as safety data sheets (SDSs) only specify concentration ranges, they know the physical state of their mixture, the way a substance is bound to a matrix (where relevant) and how they operate their processes. Article producers normally are aware of the type of (end-)products in which their articles are included and can predict which type of exposure driving conditions could exist. In summary, knowledge on the CoU is available at the Downstream Users, but it is currently not provided upstream to the registrants for inclusion in the CSR and/or technical dossier.

*What should be achieved?*

Improvement options regarding the information basis on CoU should ensure that:

- Information on CoU that is useful for the assessment of regulatory needs and the monitoring of policy impacts is made available from the CSRs in a structured data format.
- Information on the average concentration of substances in products (mixtures and articles) is available to the authorities in a structured data format.
- Registrants provide the type of matrix binding of a substance in IUCLID.
- All relevant exposure drivers during use and service life are provided in IUCLID.
- PROCs and ERCs reflect the emission and exposure potential via core exposure drivers related to the processes, such as water contact, process containment etc.
- PROCs and ERCs are refined to better reflect (different) exposure potentials during service life with some core exposure drivers that are relevant to articles.
- Information from the CSR describing the use and the applied Risk Management Measures is available in a structured data format to the authorities.

## Emissions and exposure

### *Description of the problems*

Information on emissions and exposures include quantified emissions and exposures sourced from modelling or based on measurements (environmental and (human) biomonitoring, workplace measurements).

The assessment of regulatory needs does not rely on quantified emission and exposure information. If reliable migration or release rates were available, they might be used to refine the initial understanding of exposure potentials.

Likewise, generic restrictions according to Art. 68(2) do not rely on this information but may use (reliable and relevant) migration or release rates to prioritise uses for regulation.

For specific restrictions under Art. 68(1) or to assess the need for a restriction according to Art. 69(2), mainly information that can be used as input to emission and exposure models is needed, as normally the authorities do not rely on the registrants' CSRs but make their own (more specified) emission estimation and exposure assessment. In addition, reported (measured) emission data as well as measured exposure levels in humans and the environment can be used to substantiate restriction proposals and broaden the evidence basis to justify a restriction as well as to estimate market impacts and improvement (benefit) potentials generated by a restriction.

Due to the iterative nature of the restriction process, wrong initial assumptions may be corrected by additional information from databases, literature and stakeholder consultations. However, as it cannot always be ensured that the relevant stakeholders are involved, have the needed information (e.g. migration rates) and/or provide it to the authorities, such wrong information might remain undetected.

The change of emitted amounts and/or exposure levels of humans and the environment is an indicator of impact of a regulatory action even though it is difficult to relate changes in exposure levels in consumers and the environment to a specific measure if that is not a ban or far-reaching restriction. Thus, if no emission and exposure information is available, it cannot be assessed if regulation improves human health and prevents environmental pollution.

### *Shortcomings*

The main shortcomings regarding emission and exposure information in the registration dossiers are due to the registrants being unaware of the downstream uses and related emission and exposures, except as generically derived in the CSR. Emission and exposure information is not normally provided upstream, and the DUs also frequently do not have this information.

Table 59: Shortcomings of emission information in registration dossiers

Information type	Availability in the registration dossier and observed shortcomings
Release rates from processes	Default values from ERCs are too conservative and the application of the categories is partly inconsistent, SPERCs do not cover all processes, are still conservative and partly not transparently derived

Information type	Availability in the registration dossier and observed shortcomings
	Low release rates other than the defaults may be provided but partly with poor justification
Release rates to the environment per AC	Hardly any defaults are available other than the (worst case) factors in ERCs and refined but still generic factors in SPERCs  Migration or release rates are not normally provided based on measurements  A data field exists in IUCLID but it is not mandatory to fill it
Modelled total emitted amount to the environment	Available in structured data format in IUCLID per compartment (air, water, soil), but not mandatory  As information is based on CSR and the need to demonstrate safe use, information from environmental assessments is not sufficiently reliable
Measured total emitted amount to the environment	Not provided in the registration dossier as not available to the registrant (apart from own use)

Information on releases and release rates from processes may be available for some substances in the grey and scientific literature, best available techniques reference documents (BREFs) or inspection campaigns. Some OECD emission scenario documents provide release rates in relation to (ranges of) substance properties. The European Industrial Emissions Portal (EEA 2021) includes information on releases from large installations. Similarly, information on migration or release rates of specific substances from specific matrices and products may be available in literature. Migration models exist to derive migration rates, e.g. for food contact materials. Information on releases from products and processes can also be gathered through formal and informal consultations with stakeholders using the substance.

Table 60: Shortcomings of exposure information in registration dossiers

Information type	Availability in registration dossiers and observed shortcomings
Modelled exposure levels	Exposure assessments in CSRs are designed to demonstrate safe use, i.e. exposure levels are frequently close to the derived no effect levels or predicted no effect concentrations  A IUCLID data field exists to report modelled exposure levels but is not mandatory
Measured exposure levels	Usually not available, if at all information of workplace exposures in the registrants' use(s)  Frequently, no contextual information is provided with the measurements, making it difficult to interpret the representativity and relevance of data  A IUCLID data field exists to report measured exposures but is not mandatory  Often the reported levels are below the limit of detection or limit of quantification; limit of detection or limit of quantification then reported as conservative estimate of true exposure

Information on emissions and exposures is mainly available in other information sources for substances that are already regulated (e.g. emissions published on the European Industrial Emissions Portal monitoring of surface waters under the Water Framework Directive).

Exposure models exist for different assessment tiers that can be used by the registrants and the authorities. Input information to the models may be emitted amounts.

Measured exposure data is available in the literature and in databases, e.g. the IPCHEM<sup>72</sup> which makes information from human biomonitoring and environmental monitoring accessible to the public. Monitoring data is also generated under environmental legislation, such as the Water Framework Directive. Under OSH legislation, measurements of the workplace air are performed to ensure and document compliance with OELs. Furthermore, human biomonitoring may be performed at the workplace for certain pollutants, but such information is only available at company level and, in some MSs also at the level of occupational health insurance organisations. However, this data is not standardised and its representativeness is unclear.

These data are mostly generated for substances which are already regulated and are missing for unregulated ones. While the IPCHEM is comparably new and does not include information from older studies, the information from workplace measurements is not standardised and accessible to authorities. Exposure levels of the general population rather indicate long-term trends and can hardly be related to a particular use, process or product, which might be needed to justify specific restrictions.

#### *Drivers of the problem*

Except for their own use, registrants mostly perform generic CSAs with the aim of demonstrating safe use. As registrants are not aware of the CoU at the Downstream Users, they are normally also not aware of the emissions from downstream products and processes. Thus, resulting estimated exposure levels of humans and the environment do not necessarily reflect those occurring in practice.

Similarly, migration and release rates of substances from products and processes are usually unknown also to the Downstream Users. However, due to their better knowledge of the products in which a substance is applied and the CoU or type of AC it is included in, they could better determine migration or release rates for their uses. Migration and release rates as well as emitted amounts are sensitive but cannot be claimed to be confidential business information and could be communicated upstream. However, this does not take place in practice.

DUs should model and assess workplace exposures as part of the workplace risk assessment. However, the OSH obligations are not always implemented to a full extent and measured data from OSH are only available, if at all, for substances with EU and/or national OELs. Biomonitoring data should be available for (some) carcinogenic and mutagenic substances handled at workplaces but is not available in a structured and electronic format.

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<sup>72</sup> <https://ipchem.jrc.ec.europa.eu/>

Downstream Users are not normally aware of environmental exposure levels, except in their own wastewater. No requirements exist for the downstream users to determine exposure levels of used substances in the environment.

Some companies may assess potential consumer exposures from articles to ensure product safety under the General Product Safety Directive, which requires products placed on the market to be safe during normal and foreseeable use. However, there is no legally defined methodology under this legislation.

*What should be achieved?*

Improvement options regarding the information basis on emissions and exposures should ensure that:

- ECHA and the MS get access to substance-specific migration and release rates either in the registration dossier (from the CSA, where available), or from reliable and specific emission models
- Available information on measured emissions and exposures is made accessible to the authorities and reviewed regarding future optimised data generation (standardisation, linking to use conditions and/or products) and use.

### **3 POLICY OPTIONS AND SUB-OPTIONS**

#### **Objectives for improving information on use and exposure**

An overall improvement objective is that authorities should have access to up-to-date information on the use pattern, tonnages, conditions of use and emissions and exposures of registered substances so they can base their assessments and decisions on regulatory needs on actual up-to-date information rather than insufficient or obsolete information.

#### **Policy options considered**

The information needs and gap assessment showed that the implementation of risk assessment and management processes, including regulatory ones, would benefit from the availability of better information on uses and exposures in terms of completeness, consistency, reliability and granularity. More specific, relevant and reliable information on the conditions of use, quantified emissions and measured exposure data are mainly needed for screening and priority setting on which uses to regulate, to support the demonstration of risks to justify restriction proposals, and to better understand the impacts of a restriction in the market.

Based on the assessment of information gaps and deficits in the consistency and quality of information as well as the main causes of these, a long list of policy options was developed. The long list includes any possible option that would address the identified shortcomings, regardless of the feasibility, efforts and expected ability to improve the current information availability.

In a second step the long list of improvement options was qualitatively assessed to determine whether an option:

- Is in conflict with existing legal requirements outside REACH, e.g. competition law;

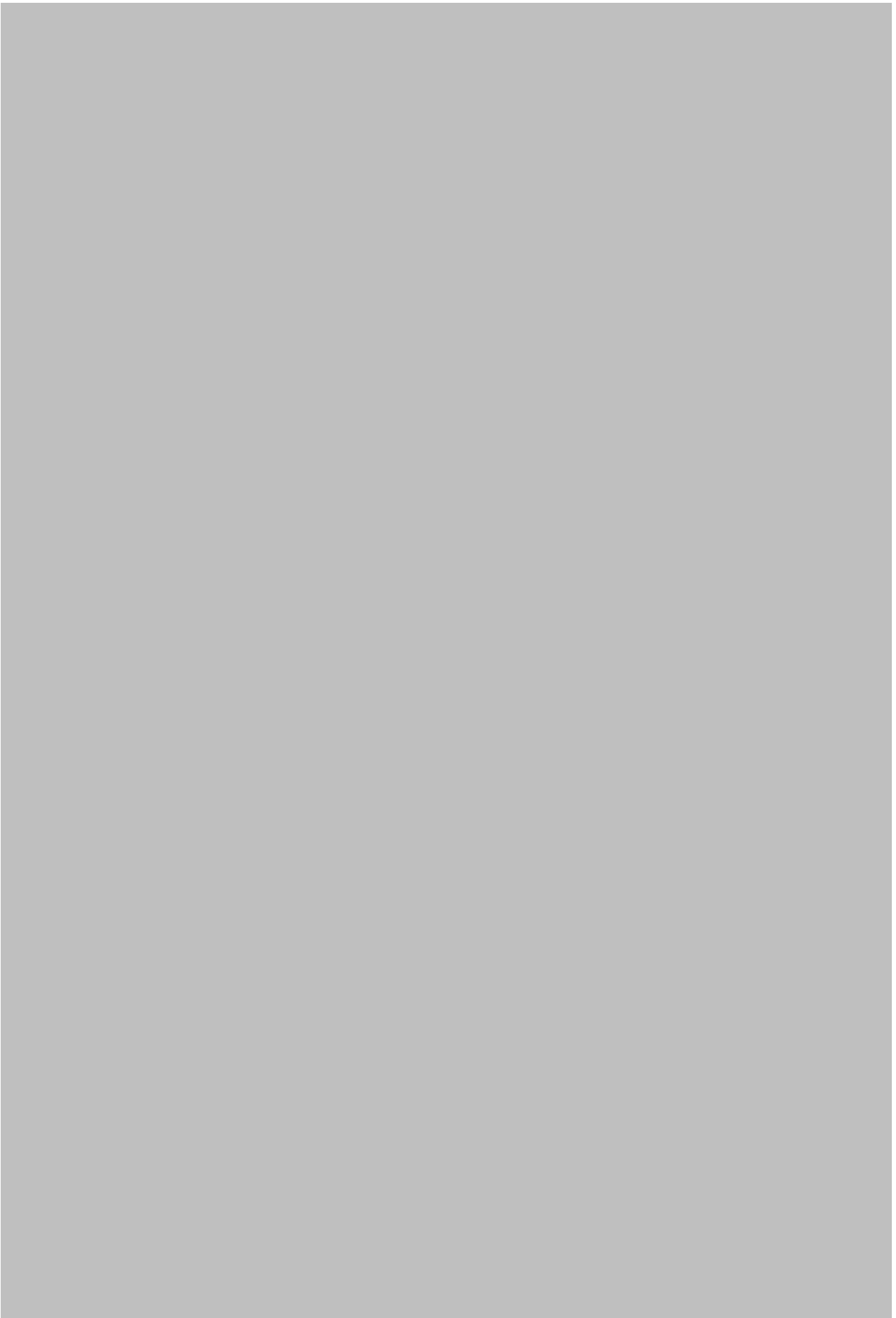
- Would require provision of information from the market that registrants are unlikely to have, e.g., registrants do not normally know the use of their substances in specific articles and could obtain this information only if they and additional actors invest considerable resources;
- Is in line with the aims of the Chemicals Strategy for Sustainability as well as the intended distribution of responsibilities under REACH (i.e. industry responsibilities for ensuring safe use) and are thus expected to get general political justification and support.

Based on this rough evaluation, the options that qualified as ‘potentially feasible’ were compiled and modified so as to derive a set of options that would address all relevant information needs with a focus on information needed for the assessment of regulatory needs. The options in the long list can be assigned to one of the following types of options:

- **Optimisation of implementation tools** (based on Article 111 of REACH) to improve the level of detail, consistency and accessibility of information on use and exposure to the authorities. The technical optimisation includes several aspects **within the current system**, can be implemented without legal changes and are based on improvements of guidance, changes in the IUCLID data structure and the use of IT-instruments, as well as the organisation of information in the IUCLID file.
- Definition of new or change of existing **requirements for the registrants** to provide use and exposure information (including on tonnage) in the registration dossier and to update registration dossiers on a regular basis or upon a regulatory trigger. These options extend **beyond the current system** and hence require changes either to the REACH enacting terms or Annex I or Annex VI.
- Definition of new or change of existing **requirements for Downstream Users** to communicate use and exposure information upstream. These options extend **beyond the current system** and would hence require **changes to the REACH enacting terms**.
- Definition of **obligations for Downstream Users to report use and exposure information to the authorities**. These options go **beyond the current system** and may require the extension of existing or the introduction of new information mechanisms under REACH.
- **Improved use and accessibility of existing information** from ‘other sources’, such as the Poison Centre Notification data, national information sources or monitoring data. These options may **require changes in other legislation** to make the information accessible (e.g. the use of PCN data requires a change of the CLP Regulation) but do **not go beyond the REACH current system**.
- **Change of the design of regulatory processes**, in particular the restriction process, to eliminate the need for information on uses and exposures. These options go **beyond the current system** and would require changes in the REACH enacting terms.







## Policy options taken forward

The table below provides a high-level summary of the policy options and their main components/sub-options that are being considered in the Impact Assessment. The options can be implemented independently of each other or combined in different ways. Most of the options are mutually exclusive but certain elements of Options 6 and 7 overlap.

Table 61: High-level summary of policy options taken forward to assessment

<b>Option 4: Technical optimisations (potentially requiring changes in Annex VI)</b>
<ul style="list-style-type: none"> <li>• Improved guidance, use descriptors and explanation of terms</li> <li>• Additional IUCLID data fields</li> <li>• Obligatory use of Chesar/import of information from the CSR (Chemical Safety Report)</li> <li>• More detailed and unambiguous allocation of TFs (Technical Functions) to PCs/ACs (Product Categories/Article Categories) and of PCs to uses</li> </ul>
<b>Option 5: New requirements to provide more differentiated tonnage information in the registration dossier and new requirements on dossier updates</b>
<ul style="list-style-type: none"> <li>• Provision of tonnage information on a regular basis regarding <ul style="list-style-type: none"> <li>○ Total annual manufacturing and import tonnage (as such or in mixtures)</li> <li>○ Total tonnage exported by the registrant (per year)</li> <li>○ Total tonnage applied as an intermediate</li> </ul> </li> </ul>
<b>Option 6: Regular reporting by downstream users of their use of hazardous substances to ECHA</b>
<ol style="list-style-type: none"> <li>1. Regular notification by DUs on the substances they use, core option: Candidate List substances</li> <li>2. Applies to both mixture and article producers</li> <li>3. Use &amp; tonnage data reported</li> <li>4. Potential variations: greater scope in terms of more substances than the Candidate List, company tonnage use thresholds exempting reporting, etc.</li> </ol>
<b>Option 7: New registrant and downstream users' duty to provide information prior to regulatory action (one-off)</b>
<ol style="list-style-type: none"> <li>1. Update of the full registration dossier prior to regulatory action</li> </ol>

2. Provision of information by downstream users directly to ECHA

All four options aim at obtaining better information on the use pattern, related exposure proxies (such as consumer vs professional vs industrial use) and exposure information inherent to a use, and the registration tonnage and tonnage breakdown per (groups of) uses.

**Option 4 – Technical optimisation**

REACH requires the inclusion of use and exposure information into the registration dossier. Annex VI, ECHA’s guidance documents and the existing IT implementation tools, namely IUCLID and Chesar, specify the information requirements. The assessment of availability of information suggests that there are several improvements that could be implemented either without legal changes or ‘only’ requiring a concretisation of the information requirements in Annex VI (which can be done by comitology). These technical optimisation interventions aim at making more information from the Chemical Safety Reports (CSRs) available for automated extraction and evaluation, obtaining all legally required information from the registrants and decreasing uncertainties about the reliability and meaning of information by removing ambiguities in the guidance and picklists. Thus, the intention of the technical optimisation is to maximise existing reporting tools and data requirements by making changes to IUCLID, Chesar and ECHA guidance, in addition to potentially adding more detail to REACH Annex VI.

In addition to the mainly technical changes, it is suggested to assess the possibility of further differentiating the use description in the CSR and IUCLID by requiring a more specific and unambiguous allocation of use descriptors to specific uses in the CSR, which would be reflected in the life cycle tree. The aim of this option is to provide the authorities with a clearer understanding of the relations between use descriptors.

Seven sub-options make up Option 4, as presented in the table below.

Table 62: Identified sub-options to Option 4 (technical optimisation)

Sub-option	Data gap	New requirement	Implementation method	Implementation frequency
1. Clarification of the terms ‘professional use’, and 2. ‘transformation product’	Overlap in the classification of professional and industrial uses, and of transformation and degradation products	Review and update registration dossiers to remove ambiguity between industrial use and professional use, and between degradation products and transformation product	ECHA update of guidance documents	Preparation of new registration dossier, or update of existing registration dossier
3. Update of use descriptors	Lack of specificity of the use descriptors or uncertain use	Update guidance and IUCLID/Chesar where applicable.  Delete or clarify ambiguous/broad/narrow PCs and ACs	ECHA update of guidance, IUCLID and Chesar	Preparation of new registration dossier, or update of existing registration dossier

Sub-option	Data gap	New requirement	Implementation method	Implementation frequency
		Develop sub- or super categories of PCs  remove superfluous entries and align with industry terminology particularly with TFs		
4. Revision of IUCLID to add more data fields and make them mandatory	Lack of data in IUCLID on transformation products, and use and exposure	Indicate whether the substance is intended to transform during its lifecycle and when;  Indicate which PCs apply to industrial and professional uses;  Make obligatory certain exposure determinants reported in CSR contributing scenarios	ECHA update of IUCLID and Chesar  Annex VI might need revision	Preparation of new registration dossier, or update of existing registration dossier
5. Further differentiation of the lifecycle tree	Lack of clear relationship between a PC/AC and a technical function	Assign one TF per PC (but one TF can have more than one PC);  Assign one TF per AC, but not obligatory	ECHA update of guidance, IUCLID and Chesar	Preparation of new registration dossier, or update of existing registration dossier
6. Make CSR data available in IUCLID	Lack of processable data in IUCLID	Make use of Chesar obligatory and/or  Make reporting of key values in IUCLID obligatory	ECHA update of guidance, IUCLID and IUCLID/Chesar interface	Preparation of new registration dossier, or update of existing registration dossier
7. Introduce consistency checks	Ambiguous use of use descriptors, excessive tonnage reported	Review of notification in IUCLID that highlights inconsistencies in the use pattern and tonnage	ECHA update of IUCLID	Preparation of new registration dossier, or update of existing registration dossier

The objectives of each sub-option are summarised below:

- Sub-option 1: to clarify ambiguities between professional and industrial uses and where there may be overlaps;
- Sub-option 2: to address grey areas (transformation vs. degradation) and aid the provision of data on transformation products;
- Sub-option 3: to increase the granularity of information on use patterns and clarify what the use descriptors are intended to cover;

- Sub-option 4: to report the data required according REACH Annex VI and further specify the reporting format;
- Sub-option 5: to increase the understanding of which function a substance fulfils in each PC or AC, which may further help the scanning of potential alternatives;
- Sub-option 6: to increase accessibility and facilitate processing of data presented in the CSR;
- Sub-option 7: to increase consistency within the registration dossier and ensure that the information provided is consistent and in accordance with its intended meaning, e.g. PROCs within the relevant life cycle stage.

In summary, policy option 4 aims to make it easier for registrants to provide the information required according to REACH, within the constraints of the existing tools and regulations, and to improve enforceability. The instruments used are updates to the guidance, e.g. Guidance R.12, IUCLID, Chesar and the IUCLID/Chesar interface.

***Option 5 – New requirements on more differentiated information on tonnages***

Based on the assessment of information available to the registrants, it is not considered feasible to request much more information from registrants on downstream uses than currently required. As no realistic option was identified to improve the upstream communication so that registrants would receive better information on uses and exposures from their DUs, no additional information requirements are suggested for the impact assessment that would be based on an improved upstream communication.

It is considered possible for the registrants, however, to further specify information on consumption tonnages, as well as on the split of their total production volume according to (groups of) uses. The level of granularity of the information and the grouping of uses depend on whether the current use descriptor system is used or if Option 4 is implemented.

At present, information on the production and/or import tonnage of substances must be updated in the registration dossier only if the tonnage band is changed. Whilst some registrants provide tonnage updates, for many substances the tonnage information has not been revised for a long time and is now outdated. Due to a lack of a ‘coordinated and regular’ updating, no meaningful time trends on the consumption and use volumes can be derived from the registration database.

Therefore, Option 5 suggests that not only more detailed tonnage information is provided but that it is provided on a regular basis, independent of a specific trigger. It proposes the inclusion of additional tonnage information in registration dossiers and regular updates of dossiers independent of any trigger. The option consists of three sub-options (see the table below).

*Table 63: Identified sub-options to Option 5 (additional registration requirements)*

<b>Sub-options:</b>	<b>1a. Inclusion of additional information on tonnages in the registration dossier</b>	<b>1b. Obligatory regular updates of tonnages</b>	<b>2. Provision of tonnages for (groups of) uses</b>
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Sub-options:	1a. Inclusion of additional information on tonnages in the registration dossier	1b. Obligatory regular updates of tonnages	2. Provision of tonnages for (groups of) uses
Data gap	<ul style="list-style-type: none"> <li>• Exported amounts not always provided</li> <li>• Reporting of tonnages for intermediate uses is voluntary</li> </ul>	<ul style="list-style-type: none"> <li>• Tonnage information in registration dossiers is often outdated</li> </ul>	<ul style="list-style-type: none"> <li>• Inconsistencies with reported tonnages per use</li> <li>• Tonnages not reported according to AC/PC that indicate regulatory coverage</li> <li>• Tonnage per LCS inconsistent with total amounts</li> <li>• Tonnage ending up in articles (service life) and end uses not always available (not subject to TCC)</li> <li>• Information in ESs of the CSRs not considered reliable</li> <li>• Information missing unless ES covers only one PC/AC</li> </ul>
New requirement	<p>Provide information on:</p> <ul style="list-style-type: none"> <li>• Tonnages directly exported by the registrant</li> <li>• Tonnages used as intermediates under Article 17/18 (full registrations only)</li> </ul>	<p>Regularly update manufactured/imported, directly exported and intermediate tonnages in registration dossiers.</p> <p>Updating frequency to consider:</p> <ul style="list-style-type: none"> <li>• every 3 or 5 years</li> </ul>	<p>Break down market volume into (groups of) uses based on sales statistics and direct customers.</p> <p>No precise tonnage is required (tonnage bands would be sufficient)</p>
Implementation method	<p>Make the relevant data fields in Section 3.2 of IUCLID (direct export; use as intermediate under Article 17/18) obligatory</p> <p>The change in TCC rules may require updating Annex VI to REACH requirements</p>	<p>Change of REACH enacting terms to implement a requirement for regular tonnage updates in the registration dossier unless changes are 'negligible'</p>	<p>Make relevant data fields in Section 3.5 of IUCLID obligatory</p> <p>The change in TCC rules may require updating Annex VI to REACH requirements</p>

The objective of including additional information on tonnages in registration dossiers (sub-option 1a and sub-option 2) is to better understand the market volume in the EU and the tonnage split of a substance per LCS and PC/AC. More and better information on consumption volumes and tonnage break down per use would benefit the substance screening and prioritisation processes carried out by ECHA and Member State Competent Authorities to identify substances for regulatory risk management and enable distinguishing minor uses from major uses. In addition, it would facilitate the assessment of regulatory needs, the preparation of restriction proposals, the assessment of applications for authorisation and the monitoring of the impacts of regulatory measures.

The objective of obligatory regular updating of tonnages (sub-option 1b) is to ensure that the information on manufactured, imported, immediately exported, and intermediate use tonnages in the registration dossier is always up-to-date. Article 22 of REACH requires registrants to update their registration — without undue delay — with relevant new information on:

- Changes in the annual or total quantities manufactured or imported by them or in the quantities of substances present in articles produced or imported by them if these result in changes of tonnage bands, including cessation of manufacture or import (Article 22(c));
- New identified uses and new uses advised against (Article 22(d)).

However, the regular updates would be independent of whether there are changes in the above information. This sub-option can be implemented by changing the REACH enacting terms to implement a requirement to regularly update tonnage information in the registration dossier unless changes are ‘negligible’.

### ***Option 6 – New requirements for downstream user reporting***

The third option proposes to establish a requirement for DUs to report the use of certain substances to ECHA. A direct reporting to ECHA appears more feasible and realistic than improved information provision via upstream communication and through the registrants. The reporting obligation could either be implemented as an extension of the existing reporting obligations or as an entirely new obligation.

The potential scope of Option 6 can be defined by, for example, the following elements:

- **Categories of companies reporting**, i.e. supply chain roles that would need to report: formulators, distributors, importers of mixtures, article producers, article assemblers; article importers, service providers/construction sector, etc.
- **Substances** that would trigger reporting: the most harmful substances<sup>77</sup>, substances on the candidate list, substances of concern<sup>78</sup>, all hazard classes;
- **Tonnage thresholds** per company for reporting: none, 1 t/a, 0.1 t/a, 0.01 t/a, other
- **Potential other thresholds** exempting certain companies from reporting (e.g. based on the number of employees);
- **Information that would need to be reported**: identification of the notifier, specification of the PCs or ACs in which the substances are included, categorisation of users as professional, industrial, consumer, specification of the sectors of end-use for the PCs/ACs produced, concentration (ranges) of the substance in the produced product or article, tonnage (ranges) for the different product types and end-uses.
- **Reporting frequency**: whenever there is a change, annually, every two years, every five years (one-off reporting is considered under Option 7)

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<sup>77</sup> The term most harmful substance was introduced in the Chemicals Strategy for Sustainability. In this Annex it is defined as all substances meeting the criteria for classification as CMRs, endocrine disruptors, PBTs/vPvBs, neurotoxicants, immunotoxicants, respiratory sensitisers, STOT and classified through harmonised classification or by the registrant (self-classification).

<sup>78</sup> Defined in the Commission proposal for an Ecodesign for Sustainable Products Regulation

Downstream users within the framework of REACH and CLP are defined as entities that use a substance, either on its own or in a mixture, in their industrial or professional activities, with examples including formulators, end users, producers of articles, re-fillers, re-importers and distributors.

The core definition of Option 6 encompasses two sets of two complementary sub-options (four sub-options in total) and is provided in the table below. The first set of sub-options (6A Mixtures and 6A Articles) focuses on the current approach to candidate listing (shaded in blue in the table below), the second set of sub-options (6B Mixtures and 6B Articles) focus on an increased use of generic restrictions (GRA), shaded in green in the table below.

Table 64: Downstream user reporting of uses

Sub-option	Companies reporting	Substances	Tonnage threshold	Information reported	Frequency
6A – Mixtures (6A-M)	Formulators of mixtures Distributors (Importers of mixtures*)	Substances on candidate list (CL) (current CL approach)	None	Notify substances used on their own or in mixtures, together with PC/AC, sectors of end-use, concentrations, tonnages	Every 2 years
6A – Articles (6A-A)	Article producers	Candidate list substances or mixtures including them (current CL approach)			
6B – Mixtures (6B-M)	Formulators of mixtures Distributors (Importers of mixtures*)	The most harmful substances	None	Notify substances used on their own or in mixtures, together with PC/AC, sectors of end-use, concentrations, tonnages	Every 2 years
6B – Articles (6B-A)	Article producers	The most harmful substances or mixtures including them			
*Importers of mixtures are included among formulators and distributors since they import for own use or to place on the market					

Under the core definition, article importers and end users that are not article producers (e.g. service providers, construction sector) do not report. Reporting by article importers is not seen as necessary for establishing an EU use map and the reporting by service providers and companies in the construction sector is not seen as practical due to large number and diffuse nature of these companies. The core definition also takes into account the baseline and the potential for extending the current reporting under PCN and SCIP.



The scope of the information reported is the same for both sub-options and includes identification of the notifier, specification of the PCs and ACs in which the substances are included, categorisation of users as professional, industrial, consumer, specification of the sectors of end-use for the PCs/ACs produced, concentration (ranges) of the substance in the produced mixture or article, tonnage (ranges) for the different product types and end-uses.

As regards the frequency of reporting, annual reporting is not considered necessary – industry input (DUCC) collected for this study suggests that even products that are deemed to be ‘frequently reformulated’ are typically reformulated after a few years rather than a period of less than 1 year. For producers of bespoke products, annual reporting would not be frequent enough in any case and for most formulators, it is unnecessary. A two year interval is selected as the frequency for the Impact Assessment. A five year interval is considered too long given that many formulations are likely to have changed within this five year period. In addition, a number of stakeholders commented on the policy options that regular reporting would be burdensome. In conclusion, annual reporting is not considered in this study.

***Option 7 – New requirements on registrants and downstream users to provide information prior to regulatory action***

This option focuses on ensuring that the authorities have up-to-date information for substances that may be subject to regulatory action - this option focuses on one-off provision of information for substances that are candidates for regulatory action. Option 7 comprises two elements:

- Registrants updating their (full) registration dossiers upon request of the authorities that are considering implementing a particular regulatory process, such as a restriction. This is illustrated by the example of the inclusion of a substance in the Candidate List.
- Downstream users providing information on emissions, exposures and generic information on alternatives for candidates for regulatory action (inclusion of a substance on the Candidate List).

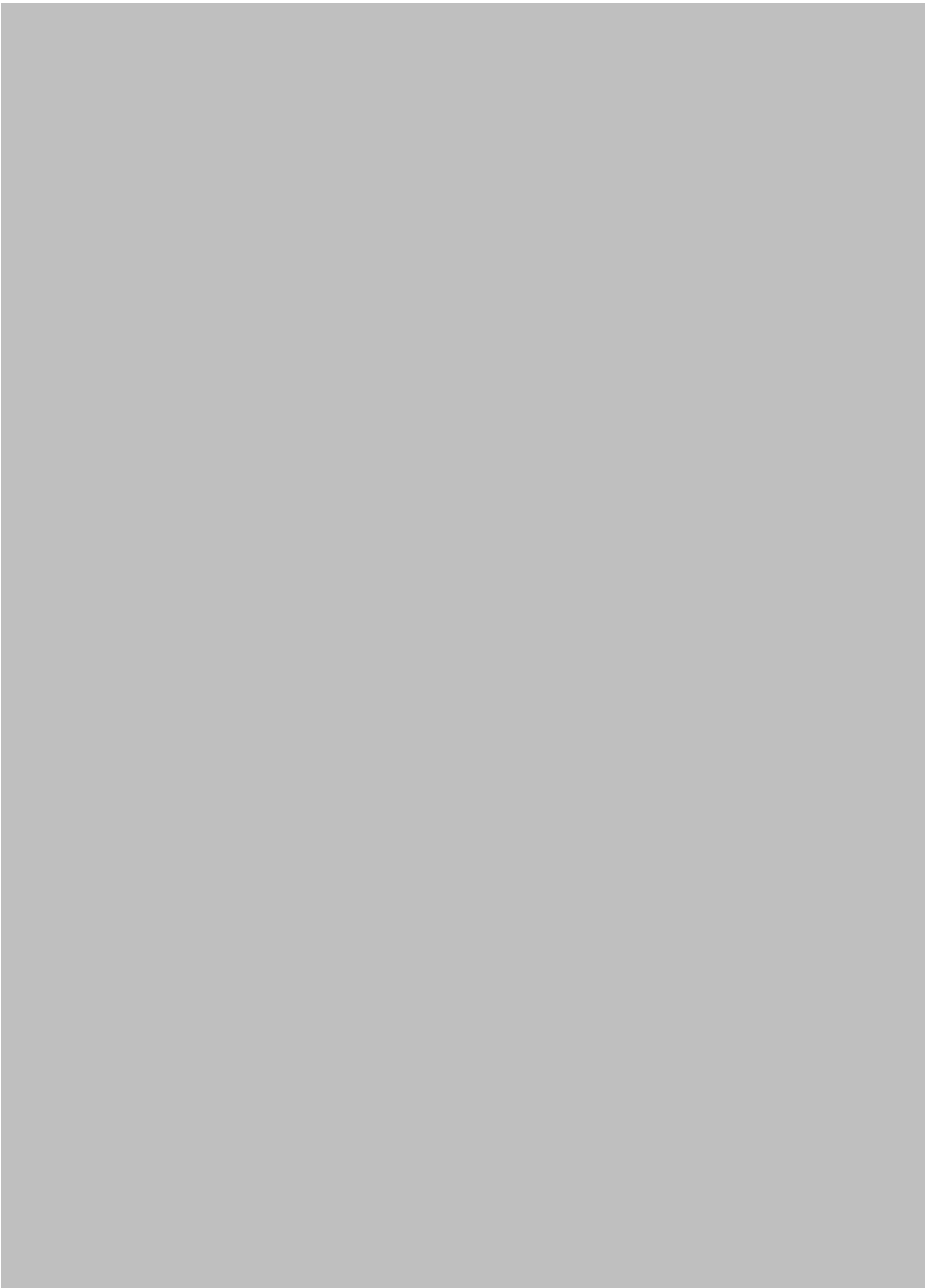
In practice, Option 7 would include in the REACH enacting terms a duty for registrants and DUs to provide information on their uses of substances on the candidate list and emissions and resulting exposure of humans and the environment as well as on possible alternatives.

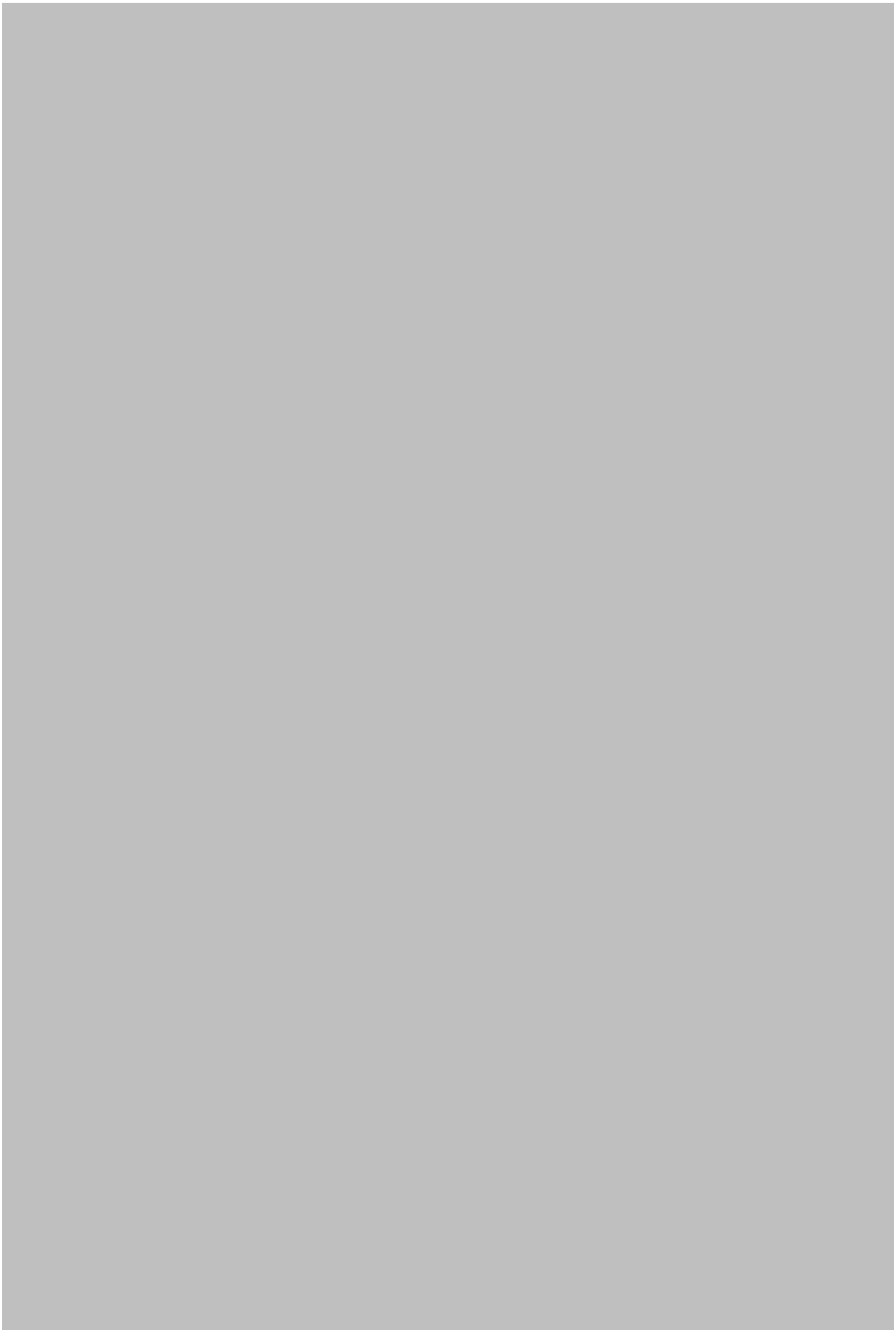
It is expected that a) individual registrants or registration consortia and individual DUs would provide the information, i.e. not DU associations, b) existing data collection tools would be used and c) an enforcement mechanism possibly including penalties for non-compliance would be established.

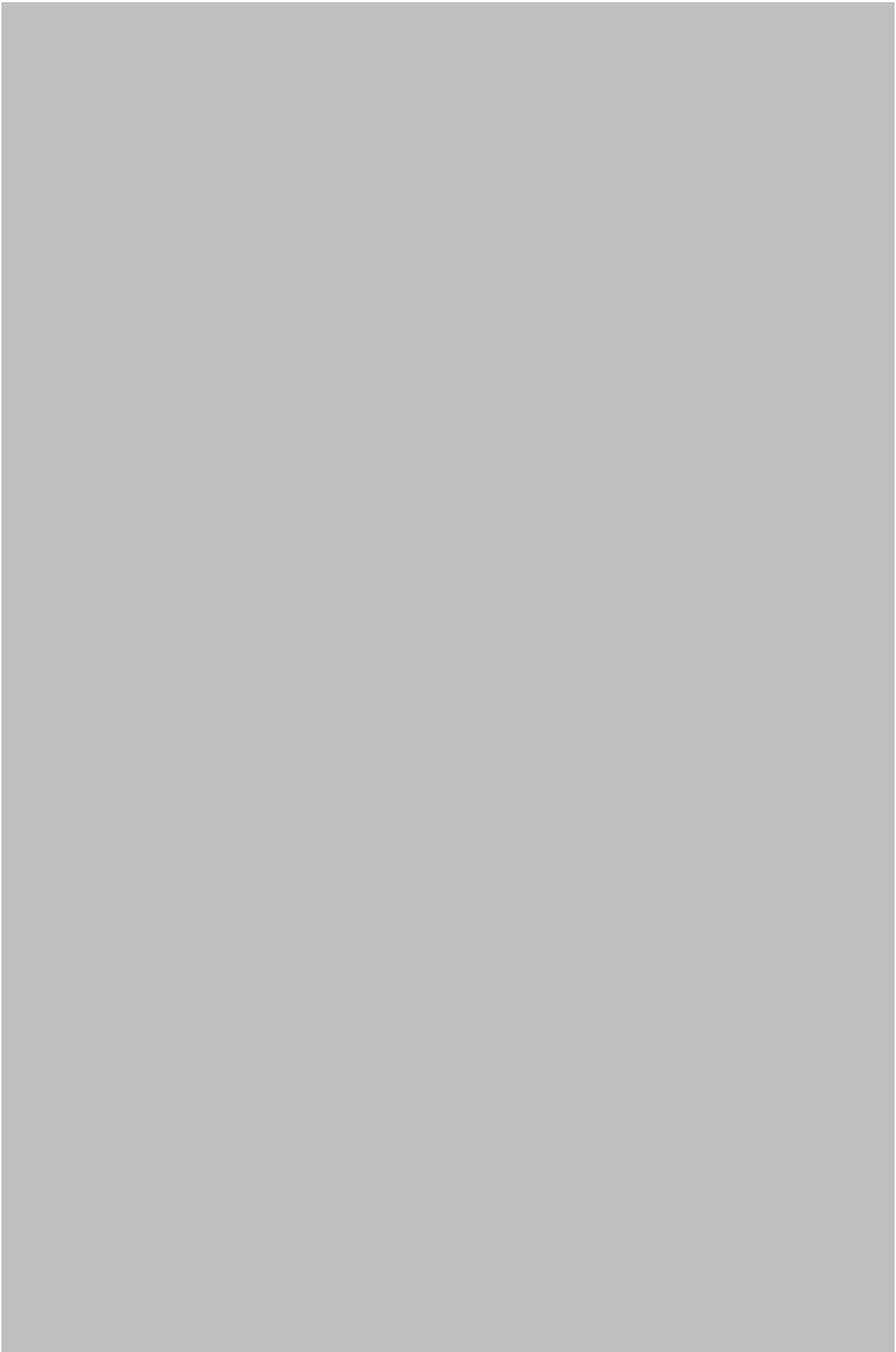








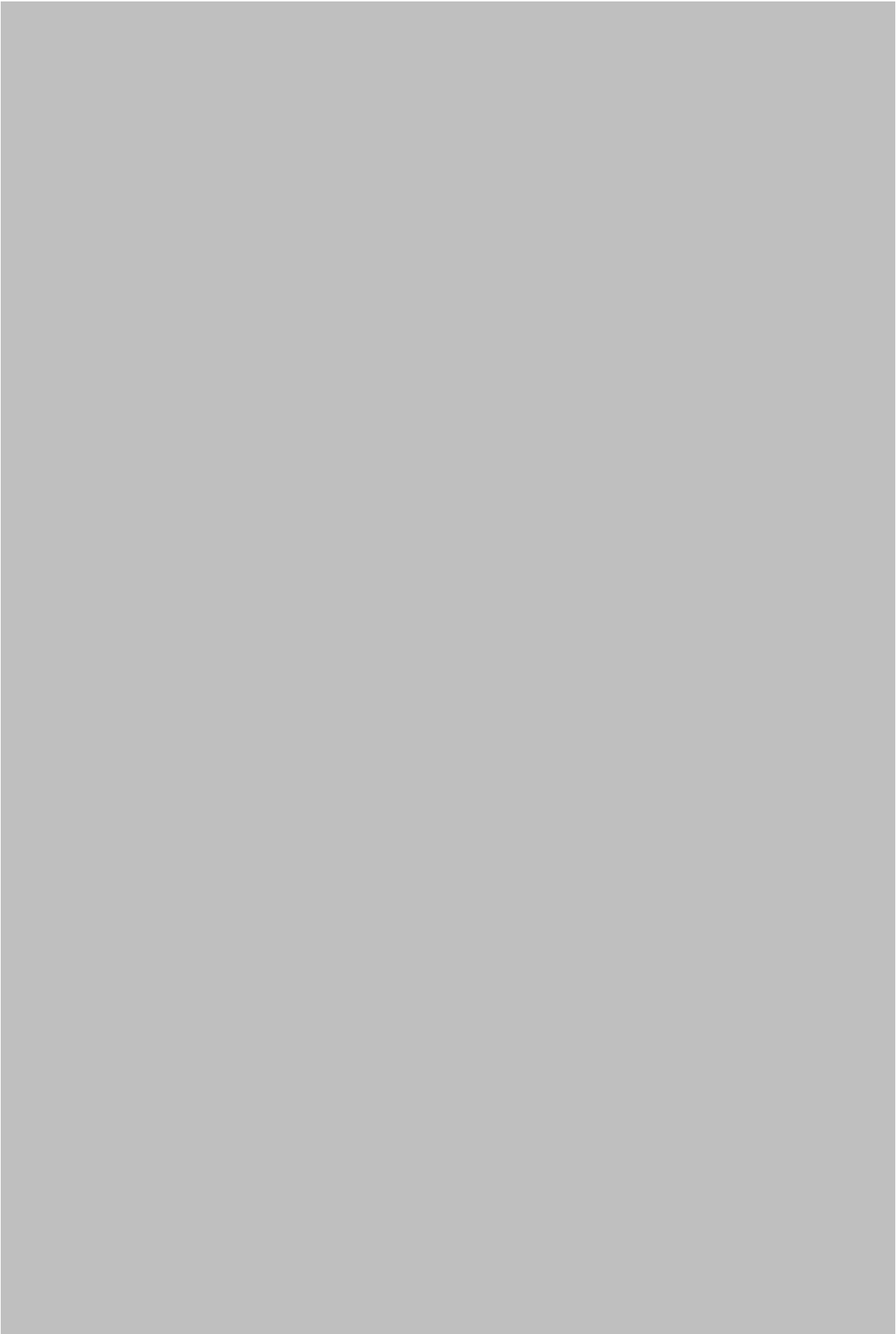








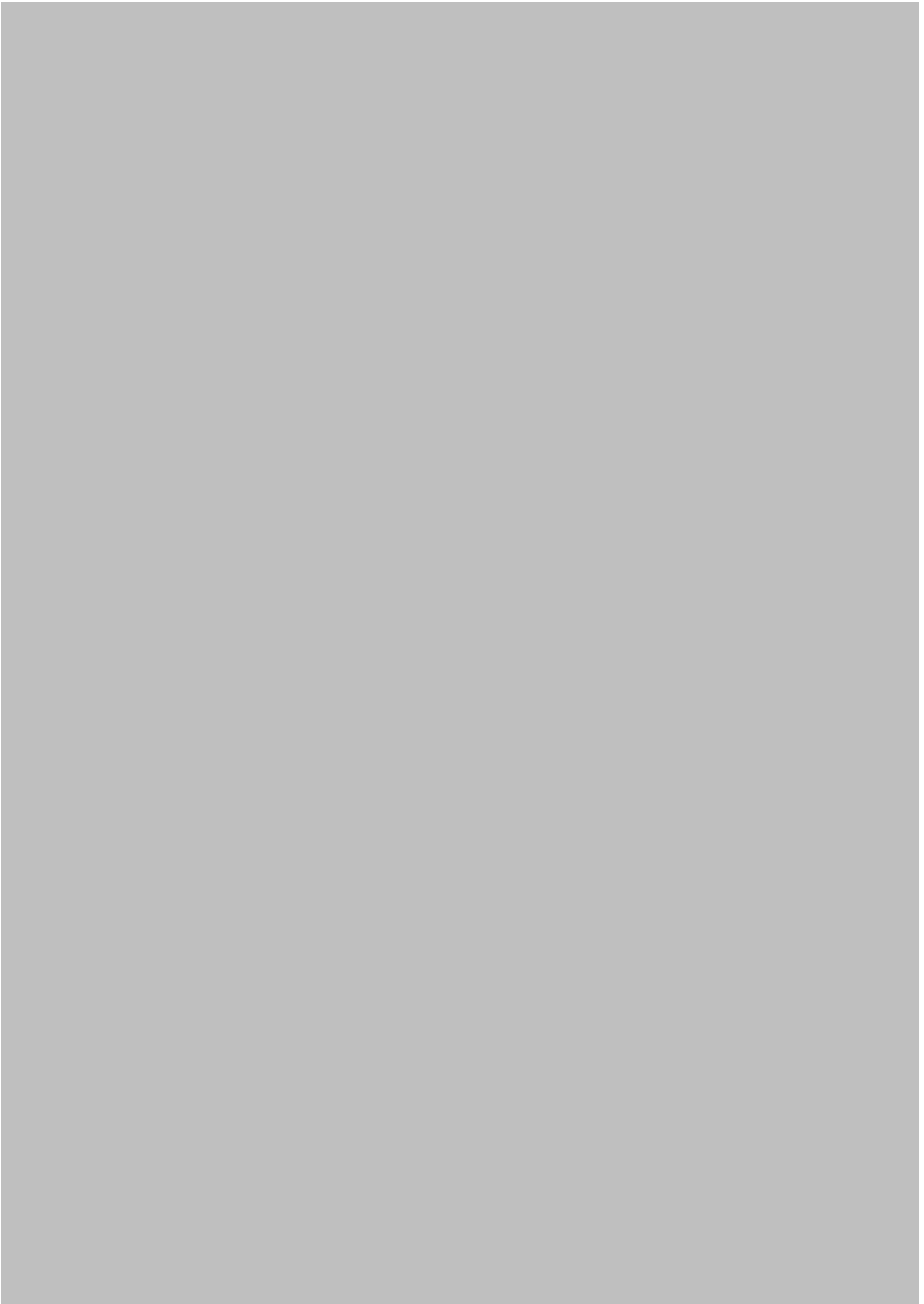












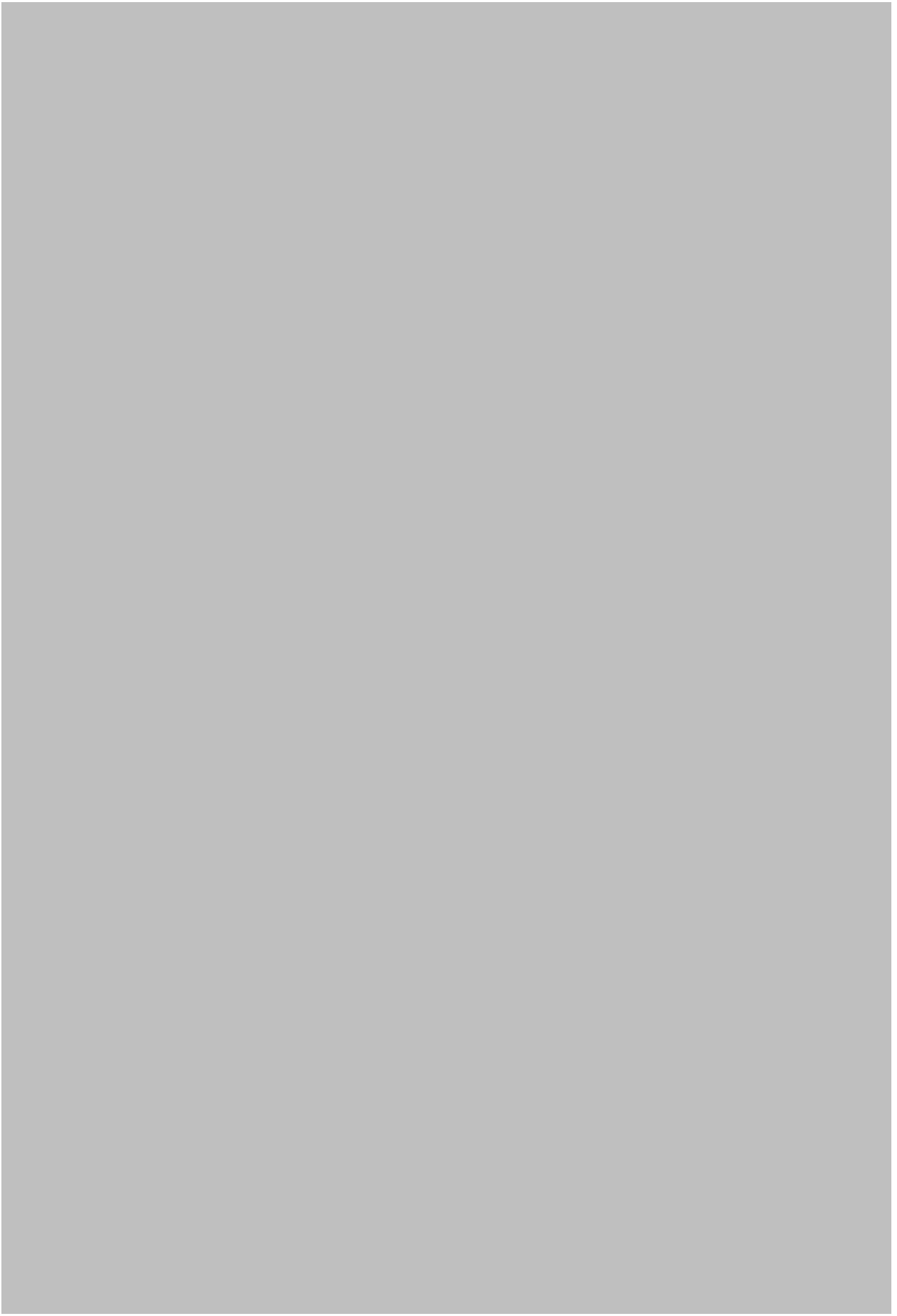


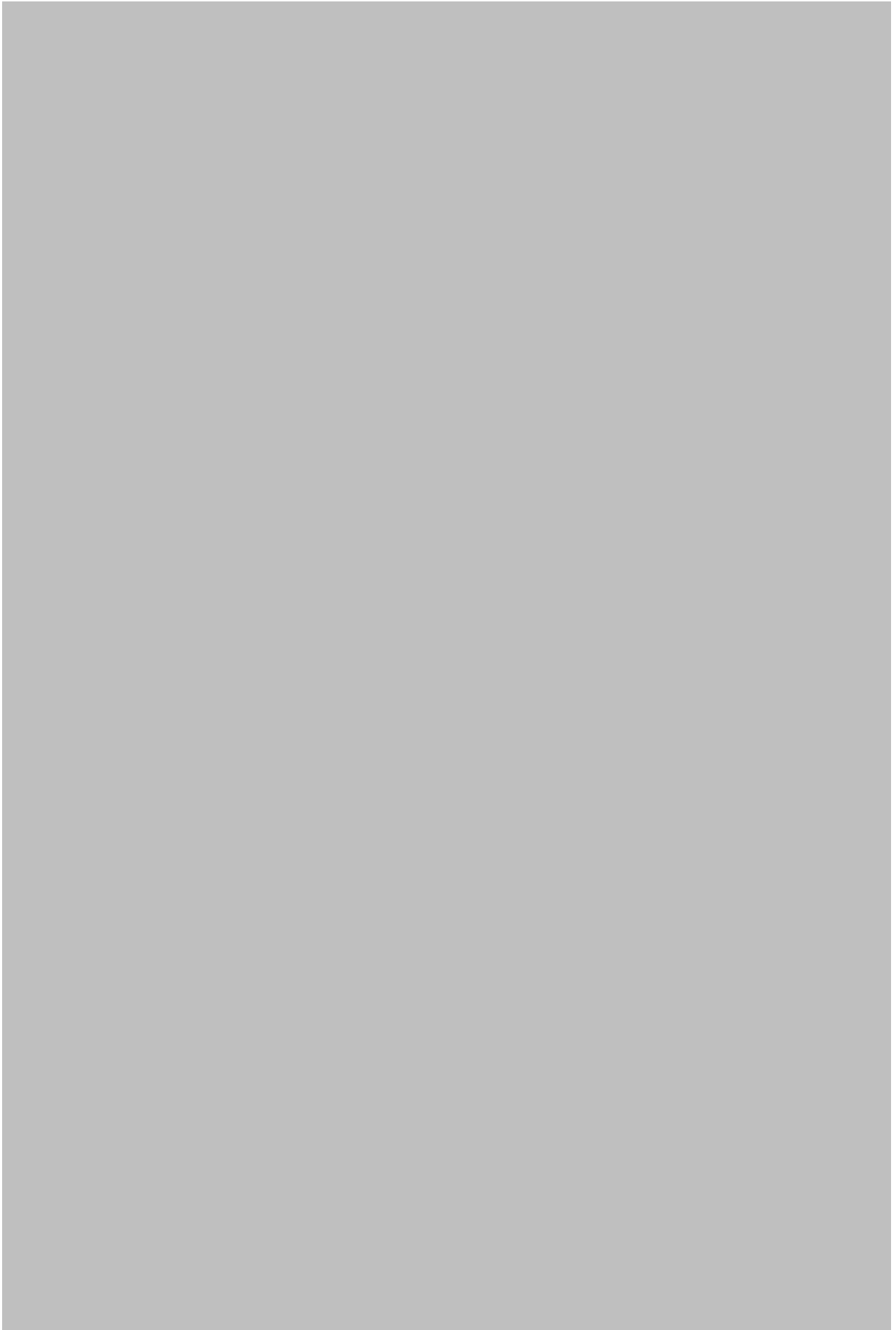


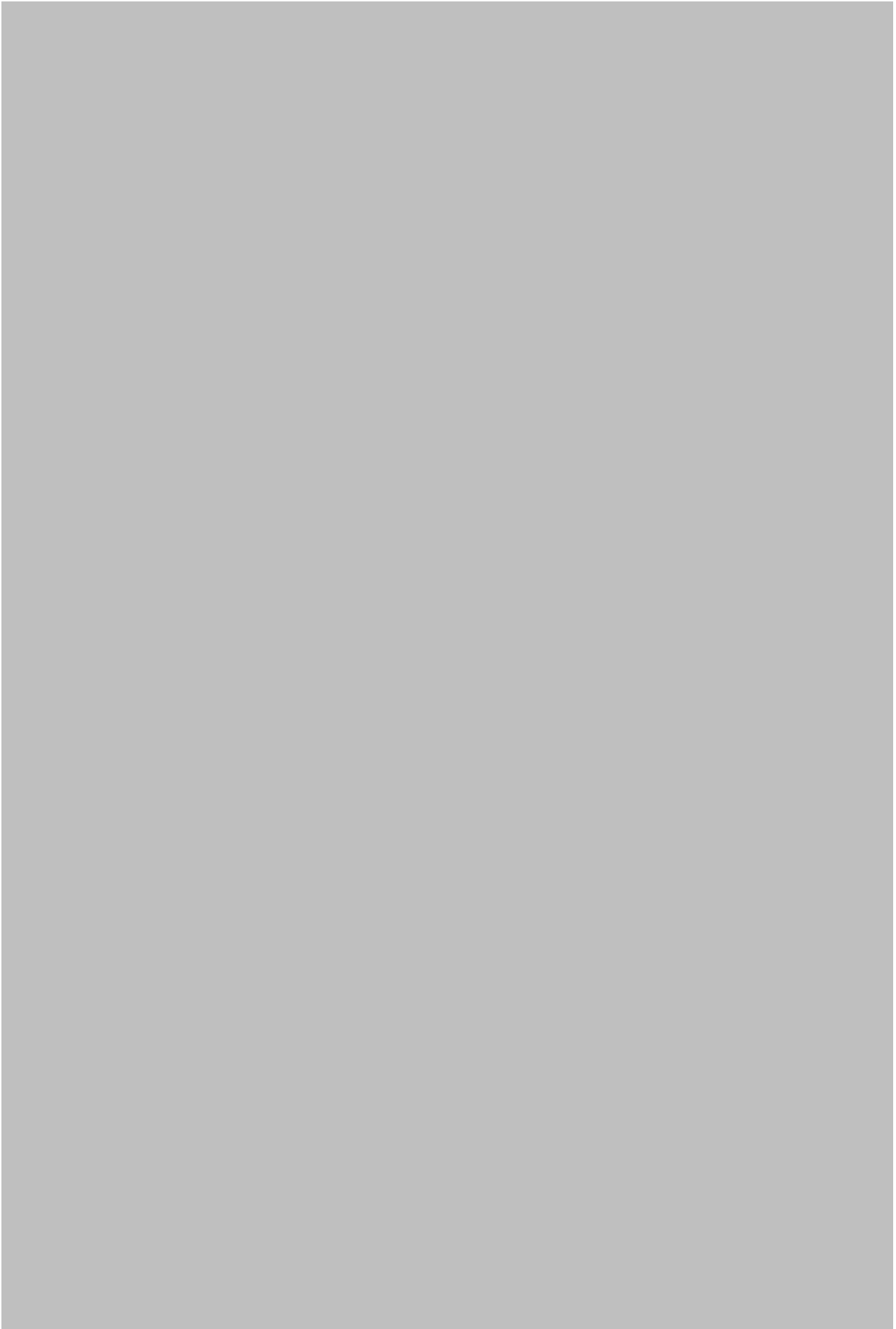


















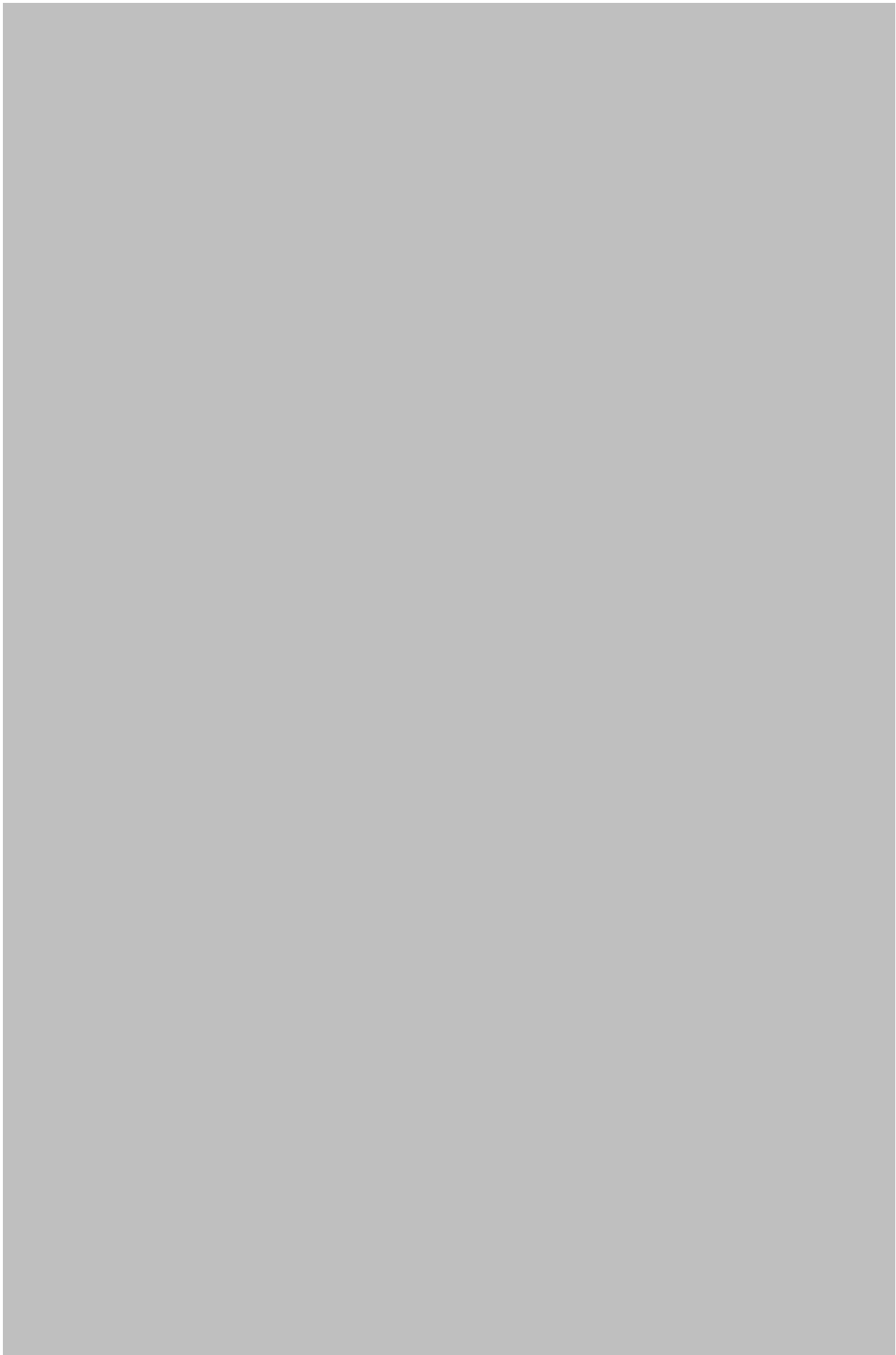












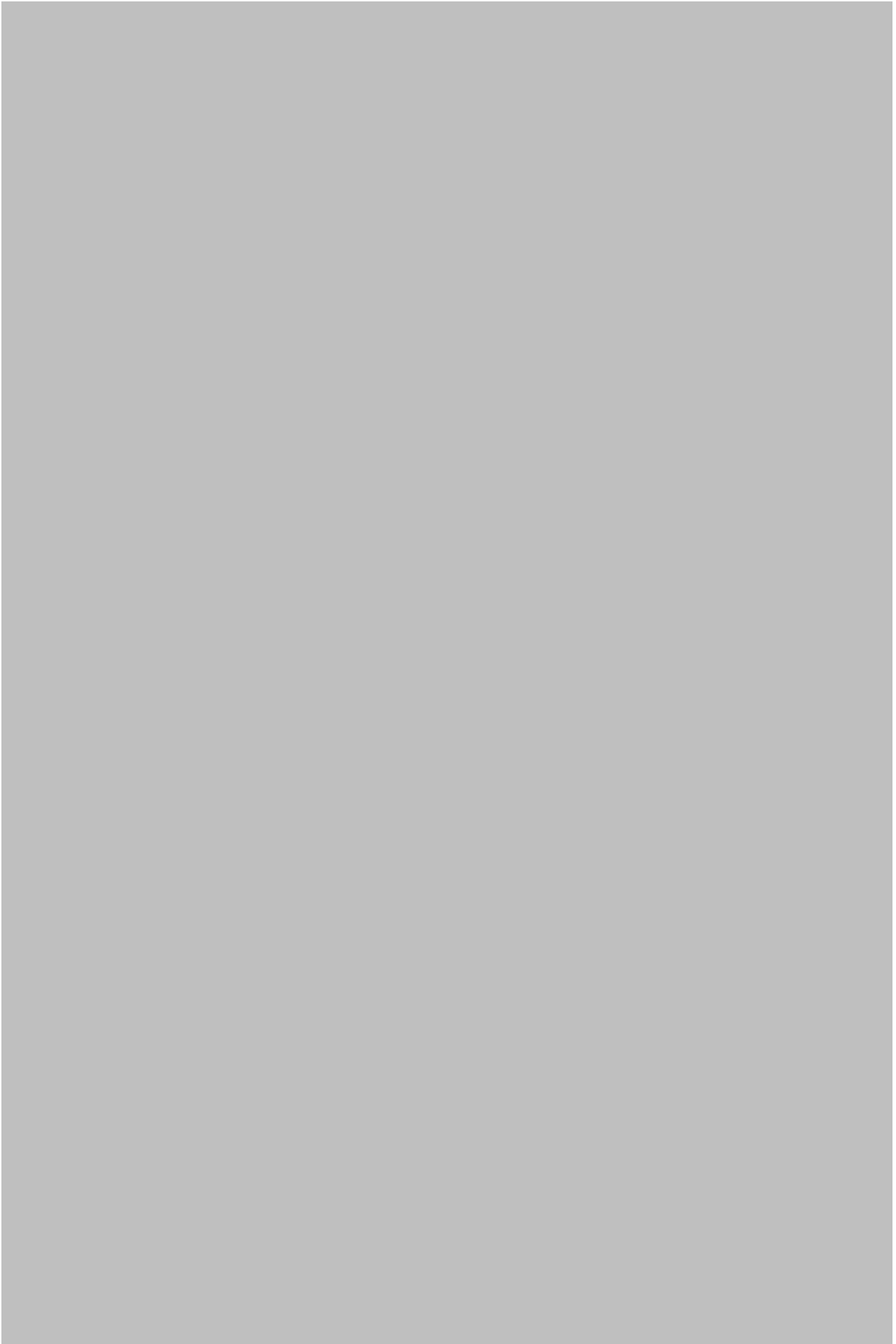


















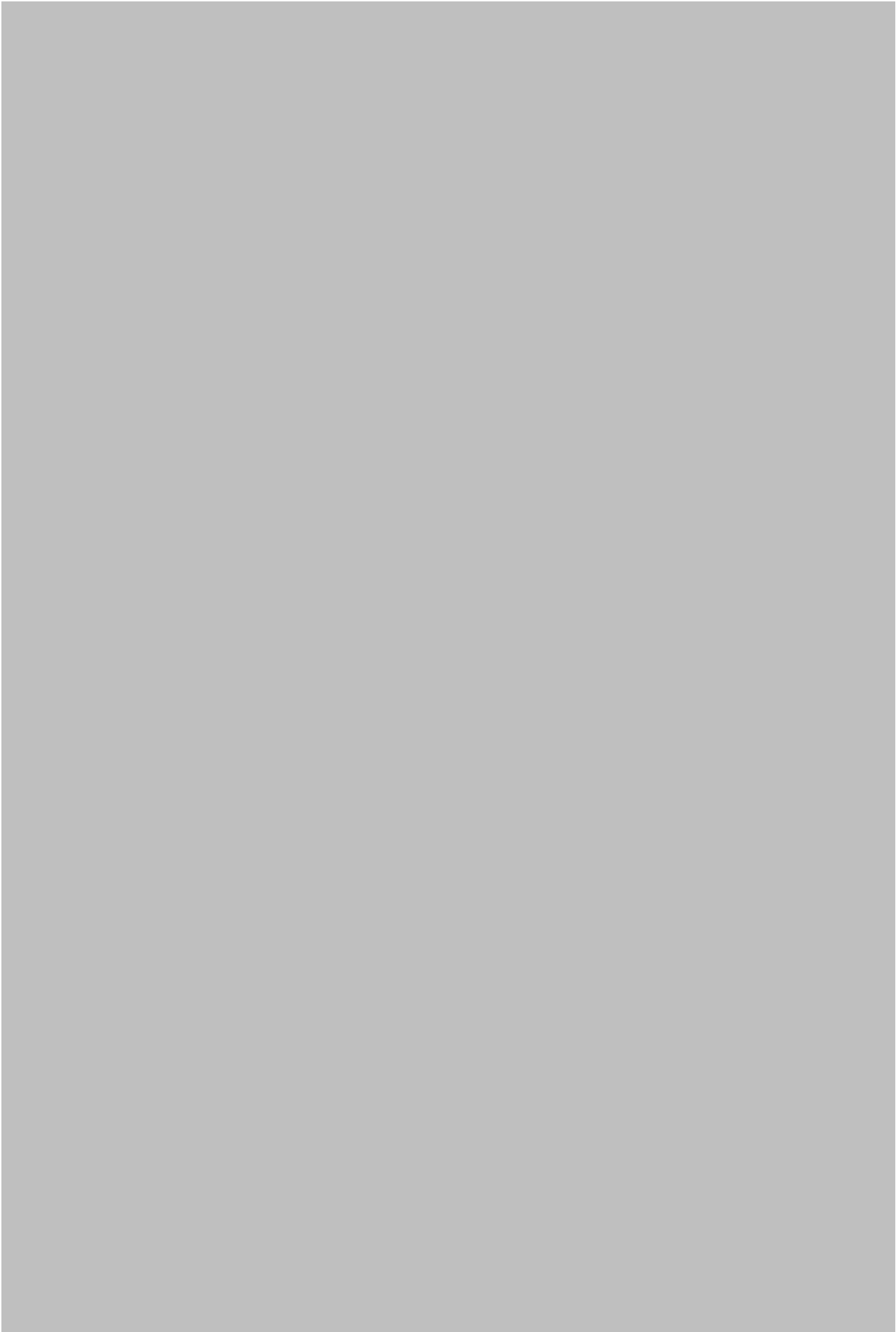


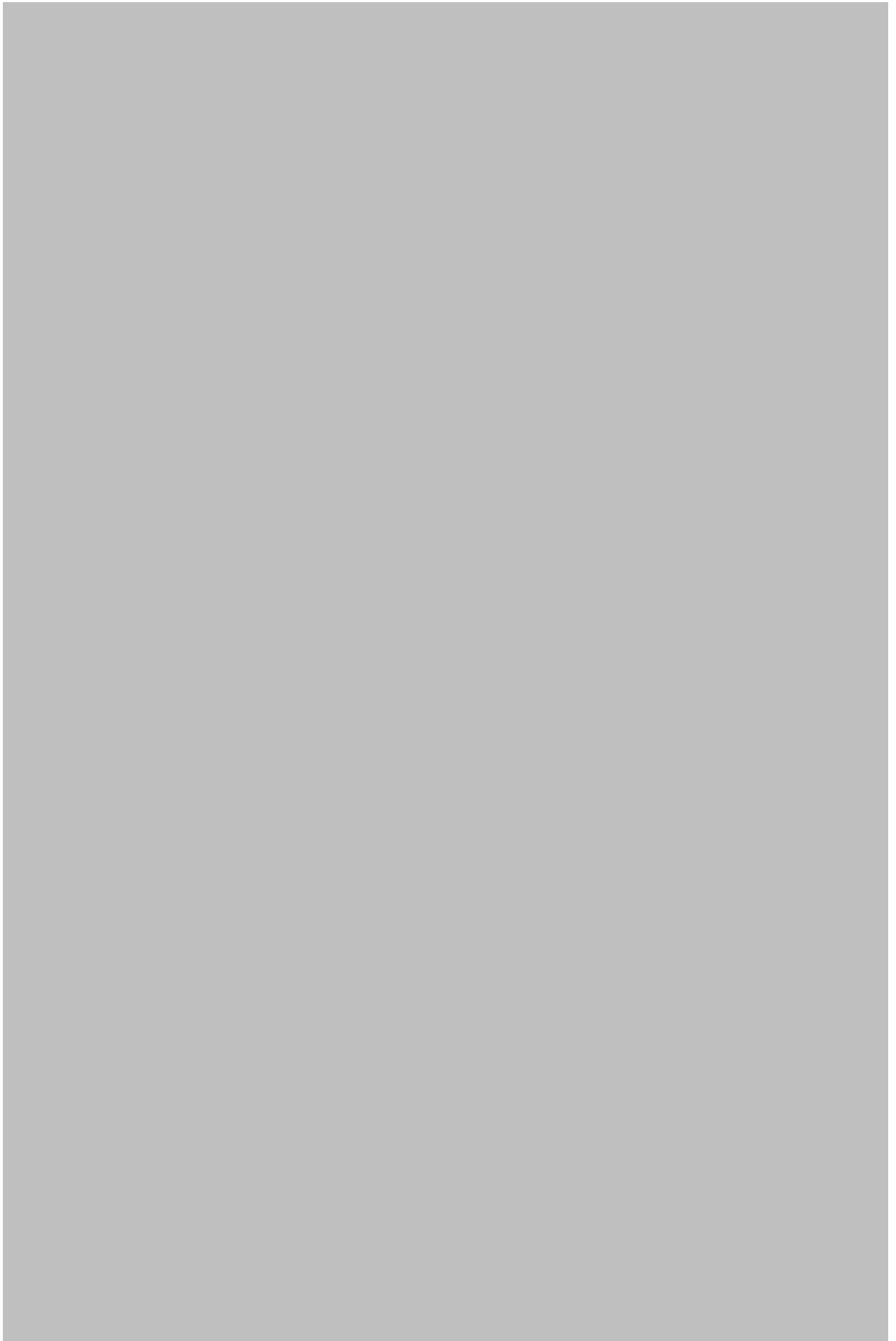


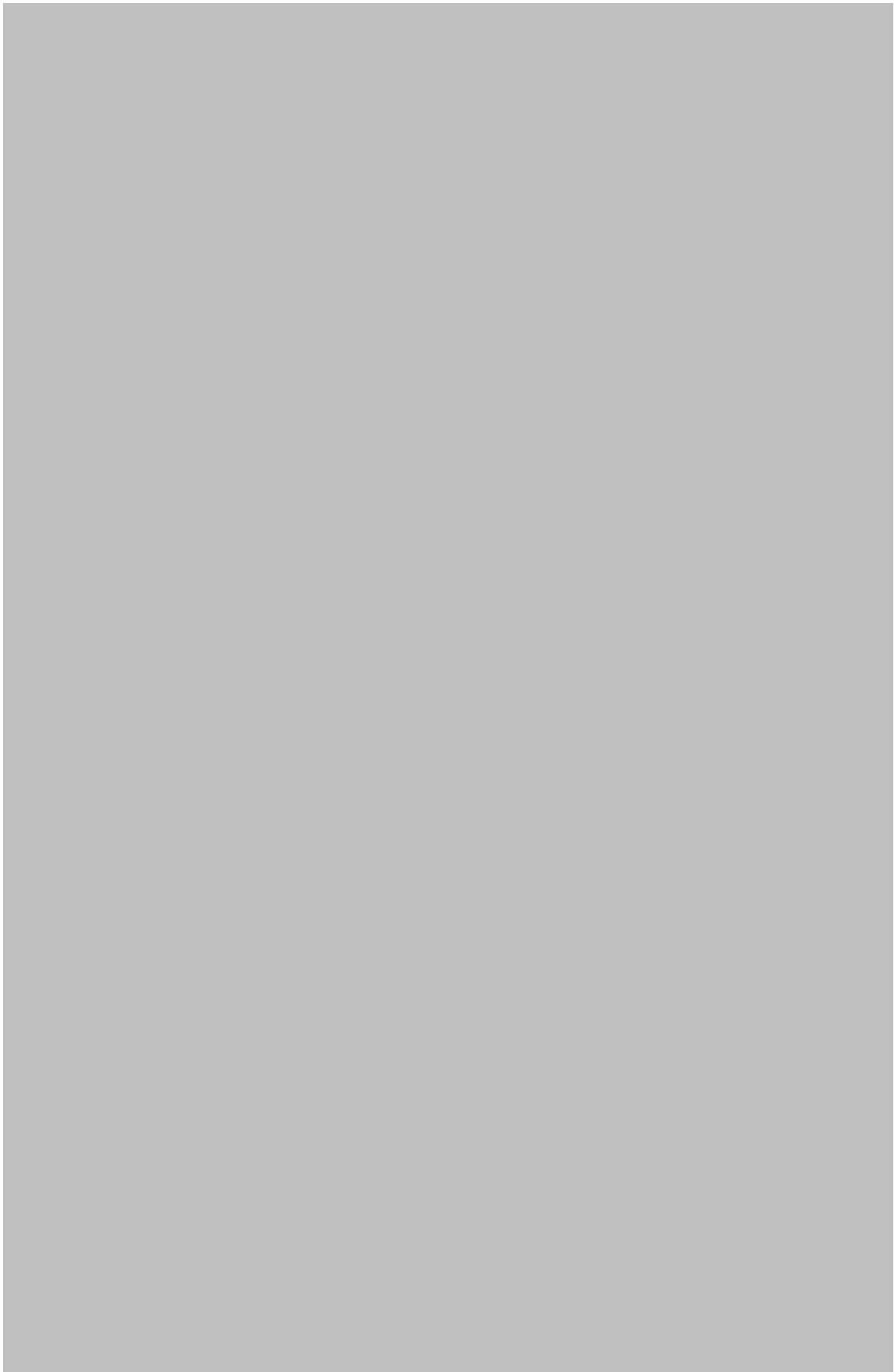




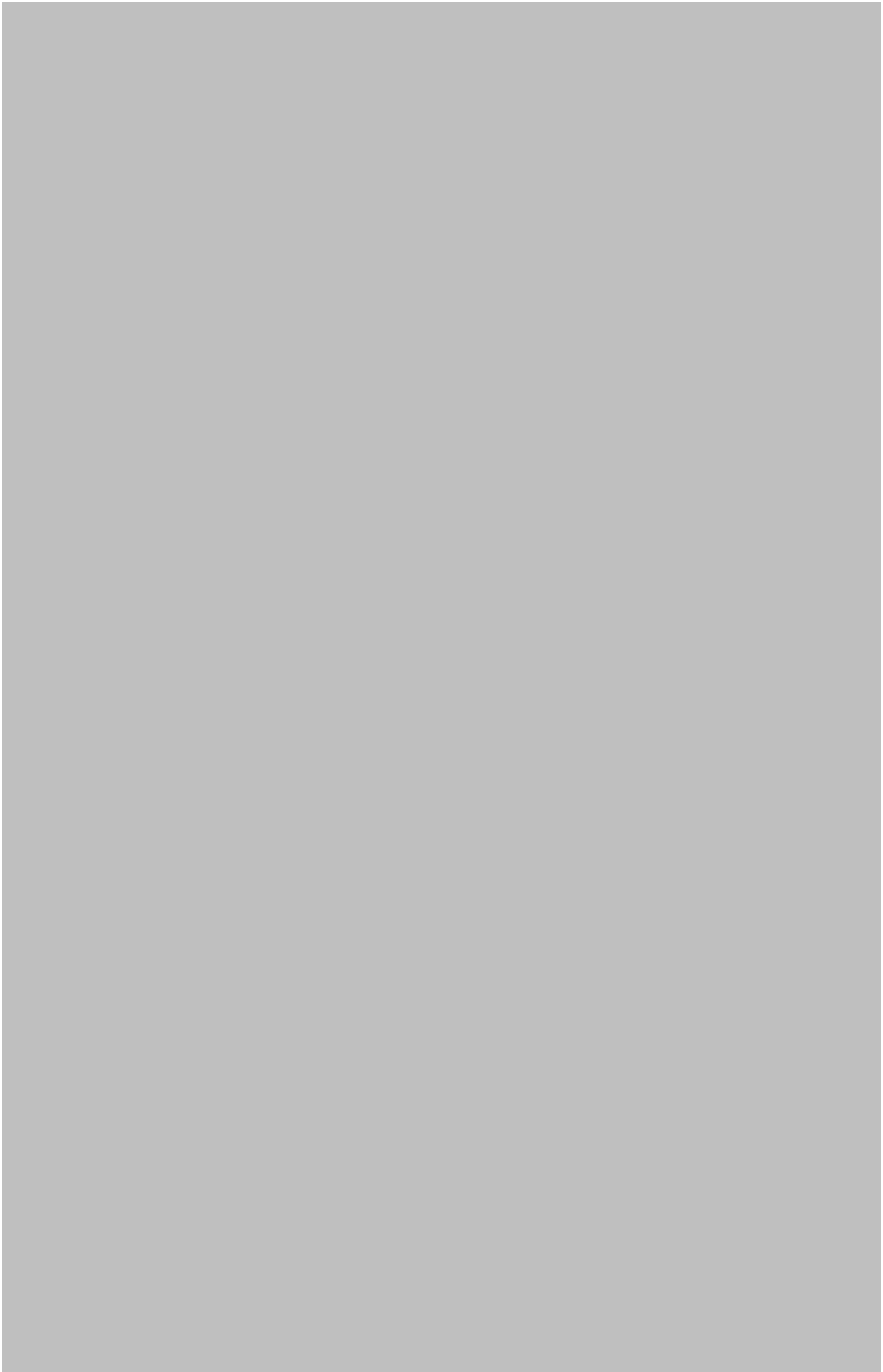


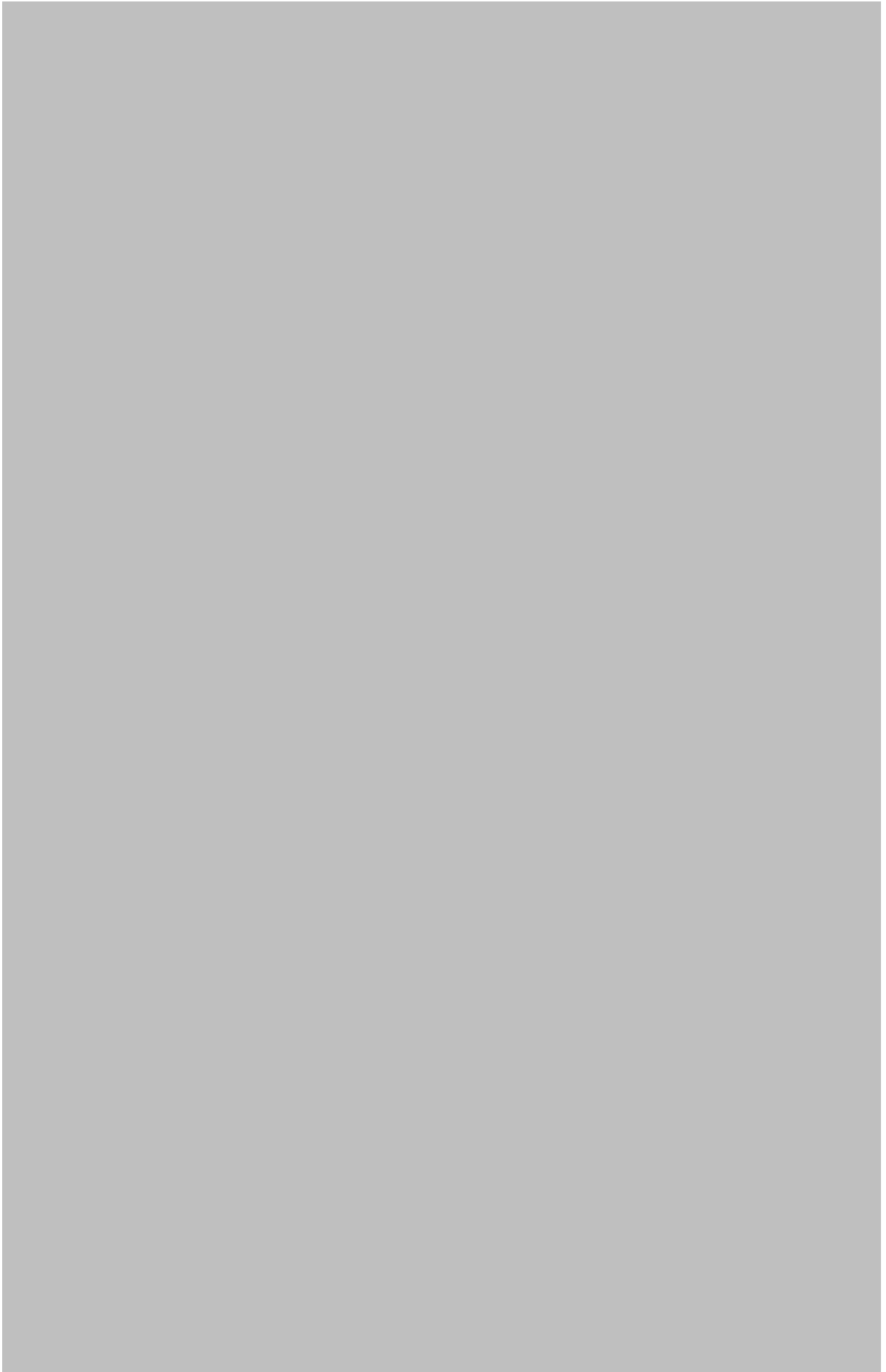
















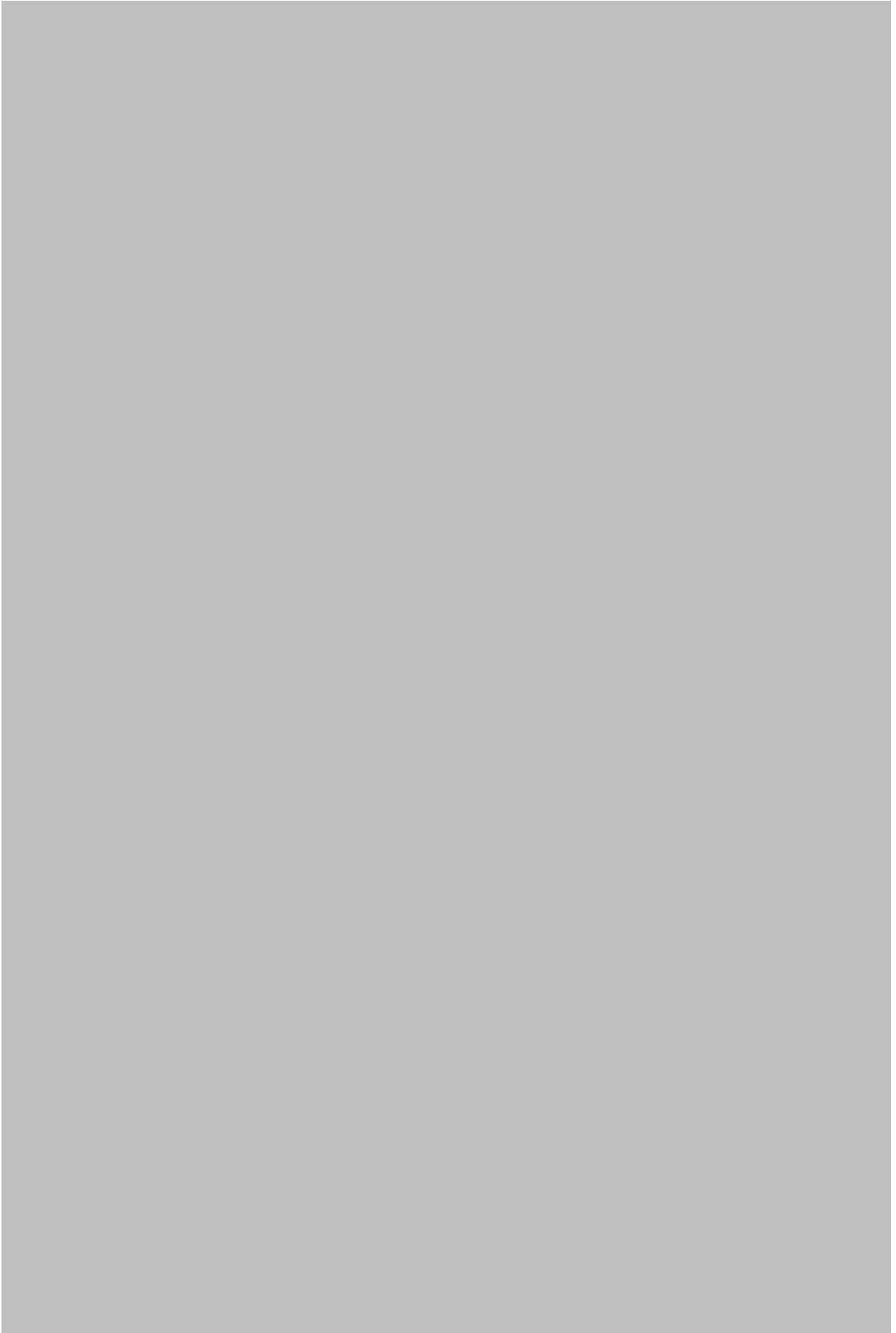




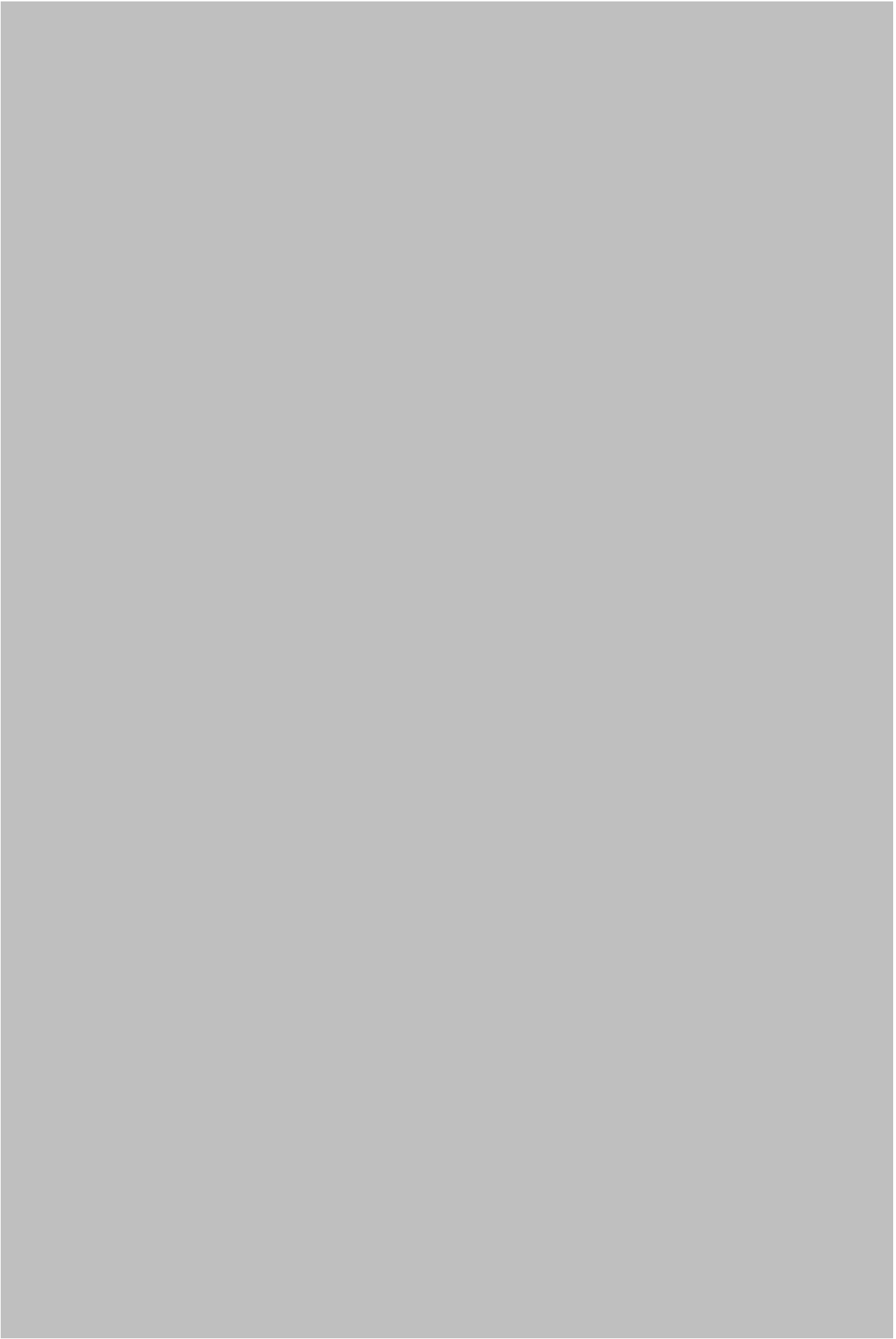




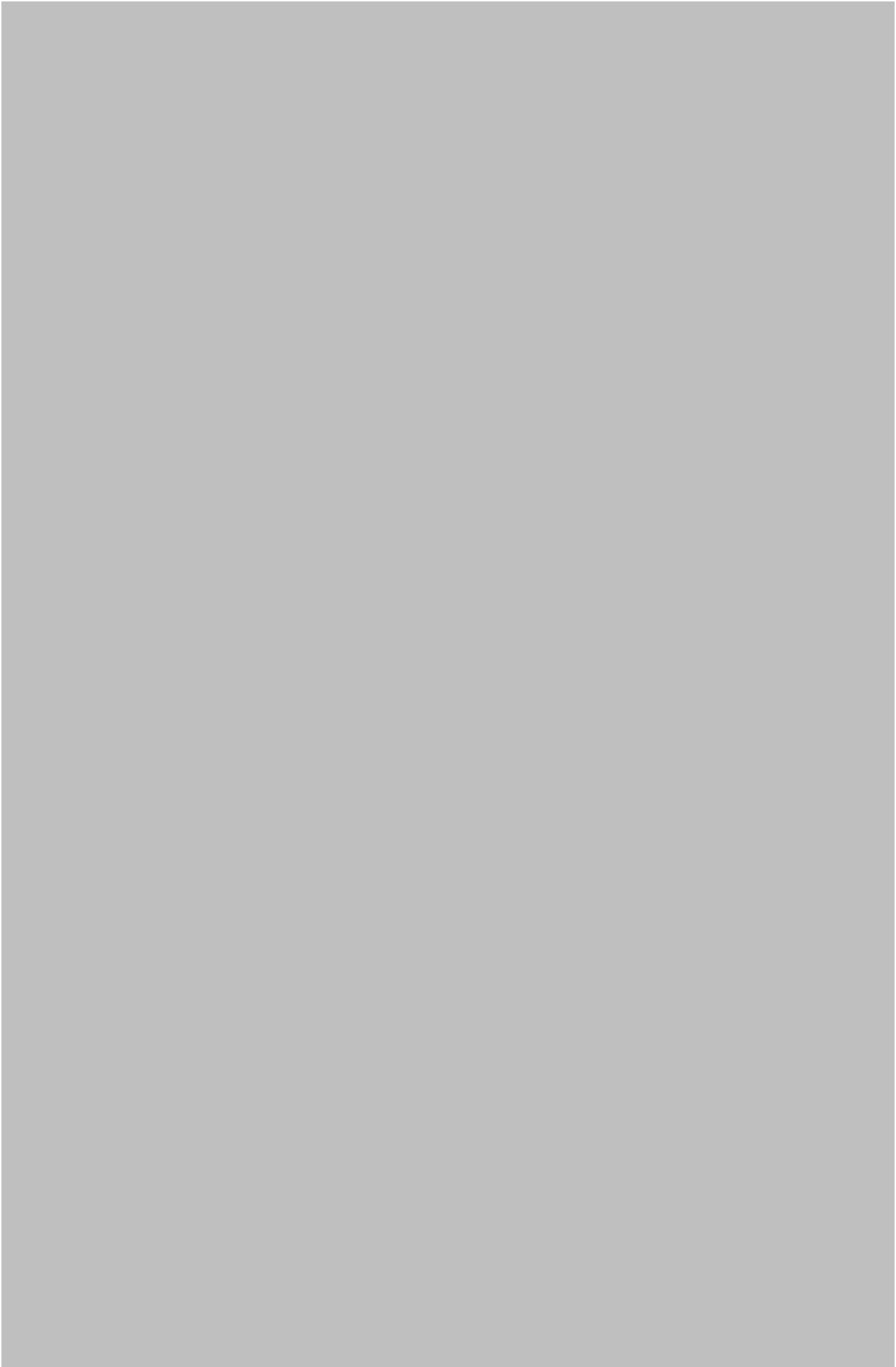




















# ANNEX 7: COMPANIES ARE REQUIRED TO REGISTER POLYMERS

## 1 CONTEXT

Currently, polymers are exempted from the provisions on registration of Title II of REACH (Article 2(9)). However, Article 138(2) of the REACH regulation requires a further review of polymers and comparison of the risks compared to other substances. Linked to this review obligation, the Commission had contracted 3 studies on the topic of polymer registration in 2012, 2015 and 2020.

## 2 DESCRIPTION OF THE PROBLEM

Due to the current exemption from Registration, rather limited information is available to authorities and the public on the identity of polymers on the EU market, their uses as well as their physico-chemical and hazardous properties. At the same time, the number of polymers on the EU market is high, estimated somewhere between 70 000 and 400 000 polymers, where 200 000 is used as a working average. Human and environmental exposures to polymers are expected to be high as well due to polymers being used in almost all aspects of modern life and due to high production volumes of many polymers (e.g., plastic production in Europe was around 49 million tonnes per year in 2020 (PlasticsEurope, 2022)). A key difference between polymers and non-polymeric substances is their potential bioavailability: the molecular size of many final polymers is much larger than that of non-polymeric substances and by consequence, the ability to cross biological membranes and exert hazardous effects may be more limited for high molecular weight polymers. However, low molecular weight polymers that would be able to cross biological membranes are assumed to represent a similar level of concern as non-polymeric substances.

Therefore, there is a need to better understand the intrinsic hazard properties of this large pool of substances and to manage polymers in a cost-effective way that provides a higher level of protection for human health and the environment than today, but which also limits costs and therewith burden on industry where polymeric substances are unlikely to exert any hazards. Due to the large number of polymers on the market, and the fact that several types of polymers are probably unlikely to display significant hazards, there is a need to devise a system that requires registration only for a certain sub-set of polymers, those likely to represent a hazard. However, this prediction of which sub-set of polymers is likely to represent a hazard and should hence be registered is difficult because only very little hazard information on polymers is available today.

Polymers are currently required to be classified under the CLP Regulation and notified to the CLP inventory<sup>126</sup>, if information to do so is available. However, only a low number of polymers has been classified. Wood analysed the inventory in their 2020 study: a search for the term “polymer” resulted in 1 670 results: around 70% of the entries related to health hazards and around 30% of the entries related to environmental hazards. The number of polymers classified based on their physical hazard was <4%. The most numerous classifications related to corrosivity or irritancy. Less than 1 % of the polymers

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<sup>126</sup> <https://echa.europa.eu/regulations/clp/cl-inventory>

in the inventory had a harmonised classification & labelling. It is not clear from the entries within the CLP inventory whether the classification relates to the polymer itself or other constituents present within the polymer (e.g., unreacted monomer or additives added to mixtures).

The classification of polymers notified under the former Dangerous Substances Directive (DSD) was also considered by Wood in 2020. Among the complete data sets for all 117 polymers notified under the DSD, the total number of polymers classified or labelled as hazardous was 40 polymers or ~34%. From that analysis (given the limitations of the data available), the conclusions were that there is a higher incidence of hazardous properties within the following groups:

- Polymers with low number-averaged molecular weight (MWn) (i.e., <1 000 Dalton (Da)) or polymers with substantial amounts of constituents with MWn <1 000 Da);
- Polymers with reactive functional groups;
- Polymers with surface active properties; and
- Cationic polymers.

### 3 POTENTIAL POLICY OPTIONS

#### 3.1 Baseline – no change scenario

The baseline would be the current REACH requirements for polymers, i.e., no obligation to register and hence no evaluation either.

#### 3.2 Alternative options

##### 3.2.1 Overview of options

After the publication of the Wood and PFA 2020 study (PFA, 2020), a CARACAL-subgroup (CASG-polymers) was formed which met eight times until summer 2022. The various exchanges within the CASG – polymers led to a selection of two options for consideration in the Impact Assessment for the revision of REACH. At a high level, the options differ according to the criteria that are used to identify selected polymers for registration, with one option including more strict criteria and a second option including less strict criteria; and according to the notification and registration process including the information requirements, with one option following a proposal by ECHA and a second option following a proposal from industry.

Table 98: Overview of policy options

	Option a	Option b
<b>8. Identification of polymers for registration (PRR)</b>	8a stricter criteria to identify PRRs	8b less strict criteria to identify PRRs
<b>9. Registration process</b>	9a Two step registration process: notification and registration	9b Three step registration process: notification, pre-registration, and

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### 3.2.2 Options for identification of PRR (options 8a and 8b)

Based on the limited ability to predict the hazards of polymers described in Section 2, the proposed approach to identify polymers for registration starts from assessing all polymers against a set of criteria that should allow to identify polymers warranting registration (PRRs, Polymers Requiring Registration). The possible assessment outcomes for a given polymer are:

- polymer requiring registration (PRR);
- polymeric precursor;
- polymer not requiring registration (non-PRR).

It is proposed that the majority of all polymers would be assessed against all the PRR-criteria. It is expected that most polymers that are categorised as polymer of low concern (PLC) in some other jurisdictions (e.g., US, Canada, Australia) would be concluded to be non-PRR.

#### 3.2.2.1 *Only polymers requiring registration (PRR) would need to undergo registration. Option 8a – Stricter criteria for identification of PRR*

Option 8a includes relatively more strict criteria for identification of PRR, including:

- Polymeric precursors used in industrial settings would be exempt from registration only if handled under strictly controlled conditions (SCC)<sup>127</sup>.
- There would be no special rules to exclude certain polyesters (i.e., they would be treated the same as any other polymer).
- Polymers with concerns related to reactive functional groups (RFG) would be considered to be PRR as in the report by Wood and PFA (2020).
- Polymers > 1 000 Dalton (Da) with an oligomer content > 2% of MW <500 Da, > 5% of MW <1 000 Da would be considered to be PRR.

The figure below outlines how this would work in practice.

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<sup>127</sup> Substances registered as intermediates (both on-site and transported), and manufactured and used under strictly controlled conditions, are subject to reduced requirements under REACH. Article 18(4)(a to f) describes the definition of strictly controlled conditions.



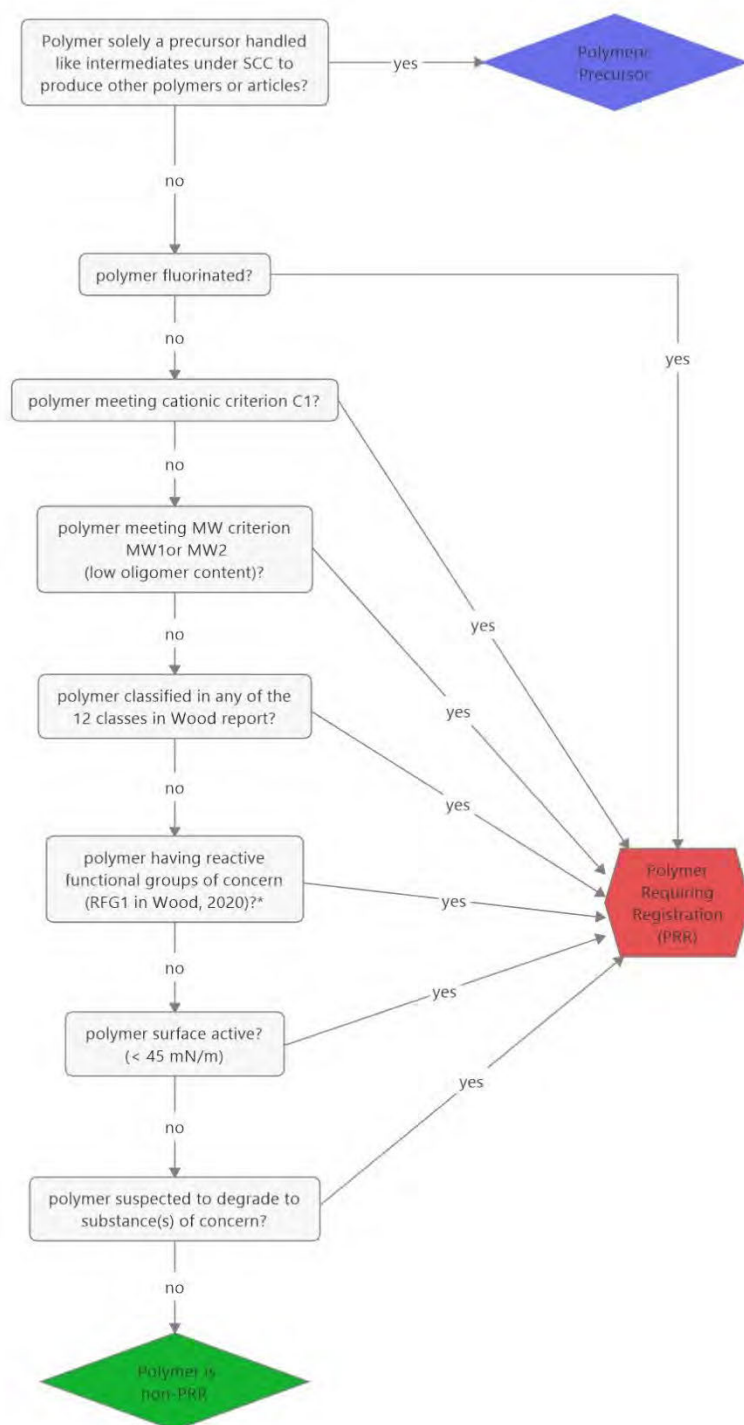


Figure 6: Flowchart for identification of PRR under option 8a

Further detail on interpretation of this flowchart has been set out by the European Commission (2022b), including definition of the acronyms. A brief summary is provided in the following table.

Table 99: Overview of key terms for identification of PRR

Parameter	Explanation
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Parameter	Explanation
Polymeric precursor	Polymeric precursors are transitional polymers, which are typically a component of mixtures including e.g., the polymeric precursor, unreacted monomer, additives and solvents. The polymeric precursor is expected to be transformed in the further reaction to create another polymer, often a polymeric article; it therefore has a finite lifespan defined by the supply chain.
Fluorination	All fluorinated polymers, regardless of whether the fluorine is attached to the carbon backbone or part of a fluorinated sidechain of the polymer are considered polymers requiring registration.
Cationic criterion C1:	Cationic polymers or polymers that can be reasonably expected to become cationic in a natural environment are considered polymers requiring registration, except those whose cationic groups have a combined functional group equivalent weight (FGEW) of > 5 000 Da.
Criterion MW1	Polymers with number average molecular weight (MW <sub>n</sub> ) of ≤ 1 000 Da are considered as polymers requiring registration.
Criterion MW2	Polymers with MW <sub>n</sub> > 1 000 Da are considered polymers requiring registration if containing > 2% oligomer content of molecular weight below 500 Da or > 5% oligomer content of molecular weight below 1 000 Da.
Criterion RFG1	Polymers with 1 000 < MW <sub>n</sub> < 10 000 Da containing reactive functional groups in either the high-concern category and/or moderate-concern category are considered polymers requiring registration unless the following applies: <ol style="list-style-type: none"> <li>2 The combined functional group equivalent weight (FGEW) of these groups is &gt;5 000 Da. Further, each group in the high-concern category has a FGEW &gt;5 000 Da and each group in the moderate-concern category has a FGEW &gt;1 000 Da.</li> <li>3 For polymers containing reactive functional groups in the moderate-concern and/or low-concern category only, each moderate-concern group has a FGEW &gt;1 000 Da and the combined FGEW is &gt;1 000 Da.</li> </ol>
Surface activity	Covers anionic, non-ionic and amphoteric polymers. Surface activity determination may not be possible or meaningful for some polymer classes. It will be specified in ECHA guidance later for which polymer types surface activity should be described.
Degradation into substances of concern:	Substance of concern: substance having one or more defined hazard classifications. Polymers would be assessed against this criterion using available information (i.e., registrants own and publicly available information). If no information is available that the polymer could degrade to a substance of concern, and no other PRR-criteria are met, it is a non- PRR.

Source: European Commission (2022b). See the source document for further explanations.

### 3.2.2.2 Option 8b – Less strict criteria for identification of PRR

Option 8b would have relatively less strict criteria for identification of PRR, including:

- Polymeric precursors used in industrial settings would be exempt from registration if the use is “adequately controlled”.

- Polyesters built from an EU-list of allowed monomers would be exempt from registration.
- Polymers with concerns related to RFG would be considered to be PRR<sup>128</sup>.
- Polymers > 1 000 Da with an oligomer content > 10% of MW <500 Da, > 25% of MW <1000 Da would be considered to be PRR.

The figure below outlines how this would work in practice.

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<sup>128</sup> As discussed at the 8th CASG-polymers meeting. Some RFGs have been moved to a lower presumed hazard as compared to the Wood & PFA 2020 report.

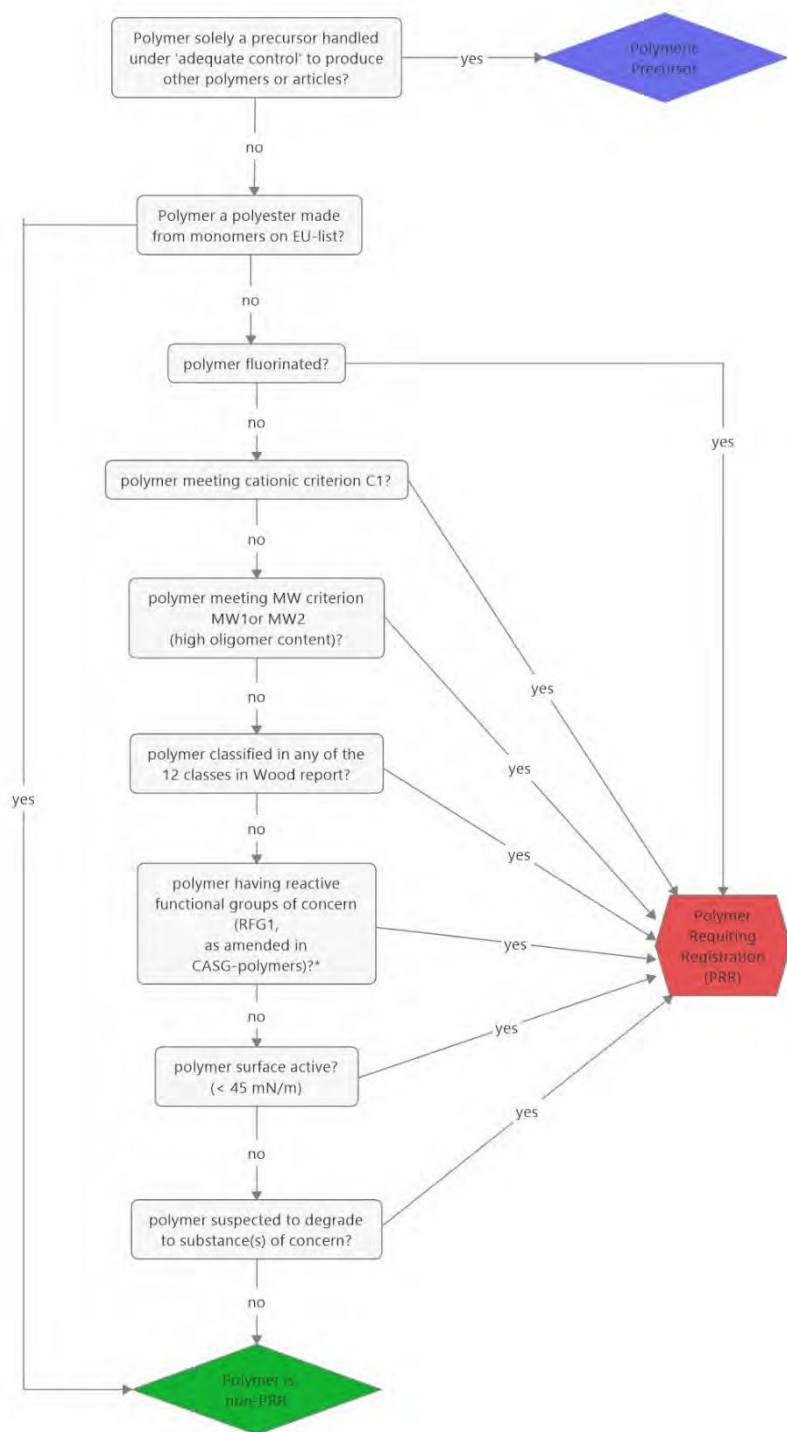


Figure 7: Flowchart for identification of PRR under option 8b

In terms of treatment of **polymeric precursors**, the approach would be to exempt those where use is adequately controlled according to an approach set out by Cefic (2022a). The argument put forward is that it is the hazard profile of the mixture as a whole which dictates the level of control required.

Cefic (2022) set out four scenarios for adequate control influenced by the nature of the polymeric precursor itself, the hazards associated with the mixture as a whole, the length/complexity of the supply-chain and the ultimate use setting.

As opposed to option 8a, the level of control would be less stringent under this option. ‘Adequate control’ can be defined as the handling and/or processing requirements that adequately avoid exposure and emission of a polymeric precursor, dependent on the individual chemical nature, physicochemical properties and hazard potential. The conditions need to be individually defined, based on the chemistry, composition, (expected) hazard profile, and processing/use conditions of the material in use, as opposed to the application of a standard set of conditions.

Under option 8b, **polyesters** built from monomers that ECHA and the European Commission will include in a list of polyester monomers expected to be of low risk and do not need to be registered. ECHA and Commission will define an EU-list of allowed monomers on the basis of lists used in the USA, Canada and Australia, excluding monomers for which concerns are known or suspected. Based on the existing experience with polyesters, it is also assumed that no hazardous degradation products are likely to be formed.

In terms of **reactive functional groups (RFG)**, option 8b would differ from the approach set out in the report by Wood and PFA (2020) in that polymers with molecular weight between 1 000 and 10 000 Da containing reactive functional groups in either the “high” concern category and/or “moderate” concern category are considered polymers requiring registration unless:

- The combined functional group equivalent weight (FGEW) of these groups is > 5 000 Da and each group in the high-concern category has a FGEW > 5 000 Da and each group in the moderate-concern category has a FGEW > 1 000 Da.
- For polymers containing reactive functional groups in the moderate-concern and/or low-concern category only, each moderate-concern group has a FGEW > 1 000 Da and the combined FGEW is > 1 000 Da.

*Data on key parameters for identification of PRR*

## **Overview**

This section outlines the available information on some of the key parameters used to define how PRR are identified, in order to feed into the assessment of impacts. It should be noted that there is relatively little information available to estimate some of these data points accurately, and there has not been sufficient time available since identification of the options to undertake surveys or other research to improve the available data.

## **Total numbers of polymers on the market**

In the report by Wood and PFA (2020), it was estimated that there are between 40 000 and 400 000 polymers on the market, with a best estimate of 200 000 polymers.

Cefic (2022b) have provided updated information suggesting that the total number of polymeric substances placed on the market in the EU-27 is 145 697. However, they highlight that the figures do not include the polymer modifications made by downstream

users and that, once that number is included, the number of polymers on the market would be higher.

The number of polymers clearly depends on how individual polymers are defined, but the Cefic (2022b) estimate seems to be in broad agreement with the central estimate of 200 000 polymers from the Wood and PFA (2020) study, particularly when the point about modifications by downstream users is taken into account. Therefore, a figure of 200 000 is used in the subsequent analysis.

### **Polymeric precursors**

Cefic (2022b) has estimated that there are 1 211 polymeric precursors that are used under strictly controlled conditions (relevant to option 8a) and 23 533 polymers that are used under conditions of “adequate control”.

In a separate estimate, the adhesives and sealants industry (FEICA, 2022a), estimate that adhesives and sealants manufacturers place on the market approximately 13 000 to 26 000 polymeric precursors, of which around 85% are used under conditions of “adequate control”.

While the adhesives and sealants sector is only a subset of the wider chemicals industry, the estimates seem to be in reasonable agreement. The figure from Cefic of 23 533 is used in the remainder of this analysis as an estimate of the number of polymeric precursors.

### **Polyesters**

For the purposes of the impact assessment (option 8b), it is assumed that 75% of monomers allowed in other jurisdictions would also be allowed in the EU, i.e., polyesters made from those would be non-PRR (European Commission, 2022a).

The adhesives and sealants industry (FEICA, 2022a) has estimated that their member companies place on the market approximately 2 500 to 4 350 polyesters and that around 12.5% of the polymers that they place on the market are polyesters.

It is not known how representative of the wider polymers industry the data on adhesives and sealants are. However, no other data is available and so the following is assumed:

- Of the 200 000 polymers assumed to be on the market, 12.5% are polyesters.
- Therefore, around 25 000 polyesters are placed on the market.
- Of these, 75% would be non-PRR based on the above i.e., 18 750 polymers, and the remainder (6 250) would be PRR<sup>129</sup>.

### **Reactive functional groups**

The options differ according to which polymers including certain reactive functional groups would be covered, as described above.

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<sup>129</sup> This assumes that each monomer makes one polyester. In reality, it could be the case that polyesters can be made of both allowed and not allowed monomers, so the approach noted here is a simplification.

Cefic (2022d) has provided an estimate of the difference in the number of polymers requiring registration under the two options. It is estimated that option 8a would lead to around 3-4% more PRR being identified compared to option 8b.

### **Oligomer content**

The downstream user association DUCC (2022) has provided an estimate of the difference in the number of polymers requiring registration under the two options allowing different levels of oligomers in polymers of > 1 000 Da. It is estimated that option 8a would lead to around 25-50% more PRR being identified compared to option 8b.

### **Fluoropolymers**

Several fluoropolymers are known to be very persistent and also toxic, and during the production and use of fluoropolymers, problematic fluorine-containing processing aids, monomers, oligomers, smaller polymer fractions and by-products can be emitted into the environment. In addition, no safe end-of-life treatment is known for all these polymers and they are not recyclable.

The number of polymers that are fluoropolymers is unknown. As an indicative estimate, it is assumed that approximately 0.1% of polymers on the EU market could be fluoropolymers, based on an estimate that there were around 40 000 tonnes of fluoropolymers sold on the EU market in 2020<sup>130</sup> (PlasticsEurope, 2022a) and that plastic demand in the EU27+3 was 49.1 million tonnes in 2020 (PlasticsEurope, 2022b)<sup>131</sup>.

Note that there is no differentiation between options 8a and 8b on whether fluoropolymers would be included in identification of PRR. However, data provided by Cefic (2022b) on numbers of PRR were based on a previous scheme for identification of PRR (as discussed at the December 2021 and February 2022 CASG meetings). Therefore, the numbers of PRR identified in that source may be an underestimate. Given the above assumption on the proportion of all plastics that are fluoropolymers (i.e., a relatively small amount by volume), no change has been made to the underlying estimates of numbers of PRR. However, the fact that the data may be an underestimate should be considered.

### **3.2.3 Options for notification and registration**

Under options 9a and 9b, there are a number of key changes to the registration process for polymers as compared to what was assumed in the report by Wood and PFA (2020). These include:

- An initial ‘notification’ process covering all polymers prior to the requirement for registration.
- Incorporation of defined grouping processes following the work of ECHA and industry undertaken after the Wood and PFA (2020) report was concluded. The

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<sup>130</sup> The figure was approximately 40 000 tonnes for both the European Economic Area (EEA) and for the EU28 (including the UK) for 2020.

<sup>131</sup> 40 000 tonnes is 0.8% of 49.1 million tonnes.

extent to which grouping could reduce the number of submissions was a key uncertainty in the previous analysis.

- Alternative approaches to defining standard information requirements (SIR) for polymers, as compared to other, non-polymeric, substances.

### 3.2.3.1 Option 9a – Two step registration process: notification and registration

Under this option, there would be a **notification** stage for all polymers. This would include detailed information requirements for all polymers. Notification would be required 3 years after entry into force of the revised REACH Regulation.

#### Process proposal Notification – Registration

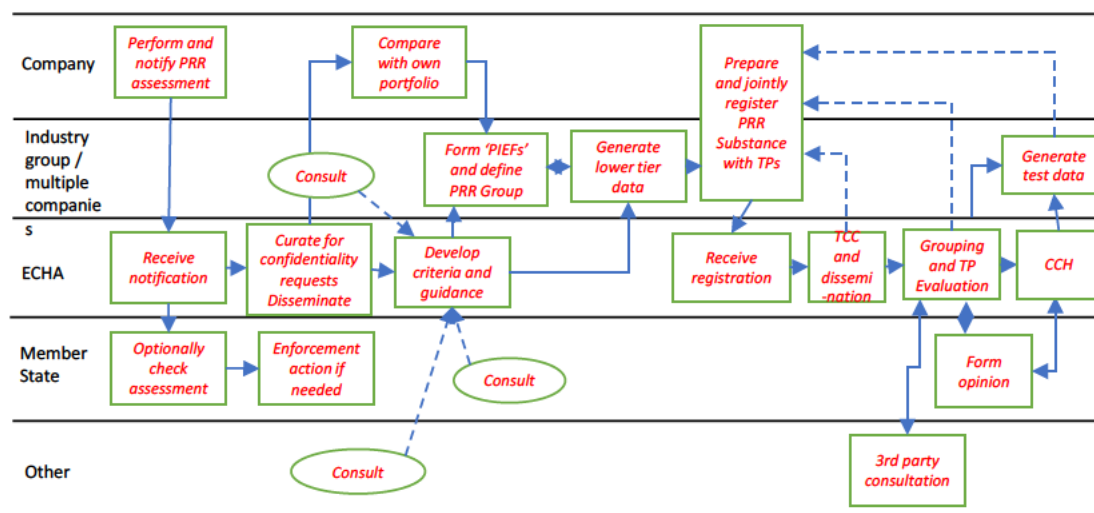


Figure 8: Overview of option 9a, two step registration process: notification and registration

All polymers on the market would need to be notified and this process would lead to the possibility of grouping polymers into one registration. The information required for notification would be assumed to follow REACH Annex VI requirements, including the data that is needed for the PRR assessment.

The notification would be followed by **grouping** of polymers by industry. The essence of a group is that the (hazard) data provided is assumed to be applicable for all individual polymers in the group. As for substance definition under REACH today, grouping would be primarily based on chemical criteria, where possible complemented with physicochemical data. Where hazard data is available prior to registration, this data could be used to justify hazard similarity in the group.

It is estimated that 2 years would be needed following notification for ECHA to set criteria for grouping.



Following grouping, **registration** of PRR would be required 8 years after entry into force for PRRs with MW < 1 000 Da (Type 1 PRR) and 10 years for the remaining PRRs (Types 2 and 3 PRR)<sup>132</sup>.

The **standard information requirements** (SIR) for PRR would for Type 1 polymers be very similar to existing ones for non-polymeric substances, while requirements would be significantly reduced for Type 2 polymers and even less burdensome for Type 3 polymers. A chemical safety assessment would also be required on the basis of the approach followed for non-polymeric substances.

### 3.2.3.2 *Option 9b – Three step registration process: notification, pre-registration, registration*

Also under this option, there would be a **notification** stage for all polymers. Notification would have reduced information requirements compared to option 9a<sup>133</sup>. Notification would be required 1 year after entry into force of the revised REACH regulation.

Under this option, there would be a subsequent **pre-registration** phase for all polymers identified as PRR. Submission would be on the basis of groups of polymers and would be done by a lead registrant and members as joint registration. It would include the rationale for **grouping** and other supporting information (to be defined). In short, the approach to grouping under option 9b consists of using expert judgment to identify key parameters and to determine polymer similarity, where chemical nature, physico-chemical properties and ecological and toxicological properties serve to establish hazard similarity of a group. An initial group is formed based on chemical nature, physico-chemical data and existing toxicological data. Upon generation of further toxicological data, hazard similarity criteria and group boundaries can be refined. In simpler words, this polymer grouping approach is a stepwise narrowing down of a particular group in different iterations until a final group is identified. ECHA would undertake a spot review of groupings (Cefic, 2022c). Pre-registration would take place 5 years after entry into force.

Following pre-registration of PRR, **registration** would be required 8 years after entry into force for PRRs with MW < 1 000 Da (Type 1 PRR) and 10 years after for the remaining PRRs (Types 2 and 3 PRR).

The **standard information requirements** for PRR would be an initial ‘tier 1’ non-animal base set of data submitted, along with a testing strategy, followed by ‘tier 2’ and ‘tier 3’ datasets with additional information for higher-tonnage polymers, if required, based on test proposal decisions and evaluations of PRR status. A chemical safety assessment would also be required on the basis of the approach followed for non-polymeric substances.

- *Summary of timescales under the two options*

The figure below summarises the timescales for the key steps under options 9a and 9b. A key uncertainty with option 9b is the timescale over which information would become available. Under that option, a testing strategy would be submitted with the initial

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<sup>132</sup> PRR Type 1: < 1 000 Da; PRR Type 2: 1 000-10 000 Da; and PRR Type 3: >10 000 Da.

<sup>133</sup> Based on an approach set out by Cefic (2022c).

registration dossier (after 8 or 10 years from entry into force). Tier 2 information would only be submitted if necessary, avoiding unnecessary animal testing.

Tier 2 information, along with a chemical safety assessment, would only be submitted after ECHA decisions on testing proposals. This would be in the form of an update to the registration dossier. Tier 3 information would only be for PRR resulting in high systemic exposures with demonstrated effects in tiers 1 and 2, and for which the risk assessment at the tier 2 stage cannot conclude with sufficient certainty.

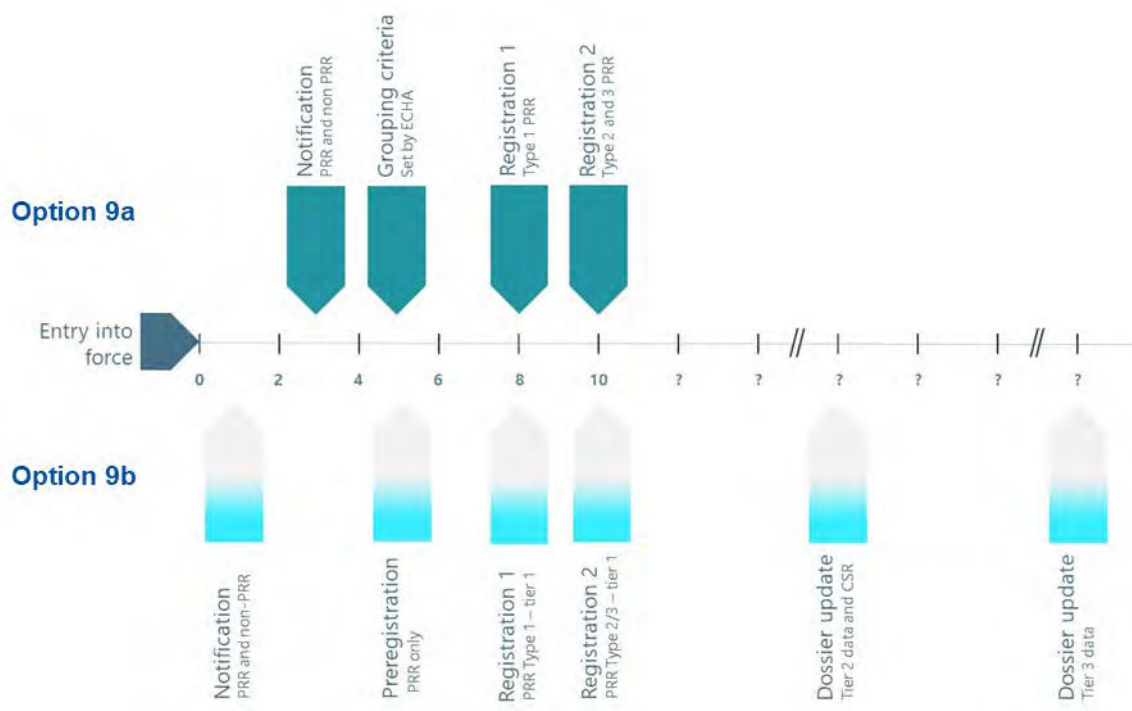


Figure 9: Overview of timescales for options 9a and 9b

Note: Timescales for dossier update under option 9b are not known (the possible delay is represented by the // lines in the figure).

### 3.2.4 Data on key parameters for notification and registration

#### 3.2.4.1 Notification requirements and numbers of polymers covered (options 9a and 9b)

As set out previously, it is assumed that about 200 000 polymers on the EU market could potentially be covered by new requirements for registration of polymers. The notification (and under option 9b, the pre-registration) process would serve to identify those that are PRR and to facilitate grouping of polymers. It is assumed that all of the 200 000 polymers would undergo the notification process under both options 9a and 9b.

The purpose of the notification would be to provide information (to authorities, and the public) on the number of polymers on the market in EU and their PRR/non-PRR status; to offer information to potential registrants for joint submission and grouping; to include information for enforcement authorities that would allow them to check precursor status; to allow authorities to check PRR status; and to provide visibility on existing hazard data. Under option 9a, a quite extensive dataset is needed for notification to fulfil all of these purposes. Similar data would be needed under option 9b, for the PRR assessment, but it would not need to be submitted at the notification stage.

It is expected that certain elements could be claimed as confidential. Once processed, notification data would be disseminated, so that industry is able to find potential registrants of similar polymers. This would require a systematic name to unambiguously identify the polymer. The notification data would also provide information to map the polymer market and possibilities to divide it into logical parts for registration and data generation.

Variability in the composition/structure of a polymer is inevitable as polymers have UVCB<sup>134</sup>-like properties. The expectation is that this variability would be defined at notification stage. The granularity of notifications sets the minimum size of the chemical space a single registration can cover and hence notifications aim at a high level of granularity. Ultimately, it is expected that every PRR would end up in exactly one (grouped) registration.

For the notification stage, most of the information required is expected to be readily available and in line with other jurisdictions. There is an expectation that there could be some waivers possible for non-PRR polymers (ECHA, 2022a).

The table below sets out the information requirements for notification under options 9a and 9b.

Table 100: Assumed information requirements for notification stage

	Option 9a	Option 9b
<b>Name and identifiers</b>		
Chemical name(s) and numerical identifier(s)	IUPAC, CAS, EC, other names	IUPAC, CAS, EC, other names
Weight/number average molecular weight	Range	Range
Polydispersivity index		Included
Manufacturing process description	Starting materials and their ratios, polymerisation type, process conditions, purification steps	
<b>Chemical composition of polymeric part</b>		
Monomer(s) and other reactants	Identity and % (typical, range) (2% rule)	Identity and % (typical, range) Reference to registered monomers
<b>Chemical composition of non-polymeric part</b>		
Constituent(s)	Identity and % (typical, range)	

<sup>134</sup> Unknown or variable composition, complex reaction products or biological materials.

	Option 9a	Option 9b
Additive(s)	Identity and % (typical, range)	
Impurities	Identity	
Oligomer and residual monomer content	Identity and % (typical, range) of oligomer and residual monomer	Identity and % (typical, range) of oligomer content
<b>Structural information</b>		
Polymer backbone	Identity, structure (block, graft, etc.), tacticity	
Branching/Crosslinking	Identity	
Reactive functional groups	Identity and FGEW, combined FGEW	Identity and FGEW, combined FGEW
Fluorination	Identity, location	
Structural identifiers	Repeating unit structure, SMILES <sup>135</sup> , etc.,	
<b>PRR assessment criteria</b>		
PRR assessment outcome	PRR; non-PRR; precursor	PRR; non-PRR; precursor
Other PRR assessment criteria	Precursor control conditions FGEW Fluorination Ionicity Known degradation products	Precursor control conditions
<b>Physico-chemical characterisers</b>	Physical state Surface activity Solubility Viscosity Log Kow	
<b>Hazard information</b>	Any available hazard information	
<b>Tonnage band</b>	Tonnage band	

Sources: ECHA (2022a) for option 9a and Cefic (2022c) for option 9b. For option 9a, the colour coding applies as follows: **Green**: Information requirements for identification, following the current Annex VI section 2 requirements (with the exception of the 2% rule, which is not in Annex VI, but commonly accepted as an identification rule). **Brown**: additional chemical descriptors to specify the polymer. **Blue**:

<sup>135</sup> SMILES (Simplified Molecular Input Line Entry System) is a chemical notation that allows a user to represent a chemical structure in a way that can be used by the computer.

Information needed for assessment against PRR criteria (though the physical state is not strictly a PRR criterion). **Red**: additional physicochemical and hazard data, to be provided if available.

#### 3.2.4.2 *Estimated costs of notification*

##### *Option 9a – notification costs for industry, ECHA and Member States*

No information was available to estimate the costs to industry and authorities associated with the notification stage. On one hand, the requirement would apply to all (200 000) polymers, while on the other hand most of the information needed is expected to be readily available, and would be submitted by individual companies, with no need for interaction with other potential registrants of similar polymers at this stage.

In the absence of better information, it is assumed that there would be a cost of €1 500 per polymer for engaging with internal information<sup>136</sup> and a cost of €2 000 to €3 800 for “dossier submission” depending on company size<sup>137</sup>.

There would also be costs for ECHA associated with set-up for receiving notifications, curating for confidentiality requests, dissemination and development of criteria and guidance. These are described and estimated in section “Costs to ECHA and Member States“.

Similarly, there would be costs for Member States associated with optionally checking assessments (e.g., for PRR status, as above) and enforcement actions. It is not feasible to assign a cost to these actions at this stage, as the details of the requirements have not yet been developed.

##### *Option 9b – notification costs for industry, ECHA and Member States*

The main difference compared to option 9a is that the information requirements would be substantially reduced (see Table 100). However, since most of the information is expected to be readily available, the difference in cost compared to option 9a is assumed to be fairly minimal. It is therefore assumed that the cost to industry associated with engaging with that data would be half the amount as for option 9a (i.e., €750) with other costs remaining the same.

There would be costs for ECHA and Member States which are expected to be of the same type as under option 9a. However, it is worth noting that there is assumed to be less work for ECHA as option 9b does not foresee the establishment of grouping criteria by ECHA, potentially with more of ECHA’s work moved to the pre-registration phase rather than notification phase.

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<sup>136</sup> Based on an assumption that around 40 hours of staff time would be needed per polymer, and an average labour cost of €35.60 per hour for professionals, who would be assumed to undertake the work. €35.60 based on the Commission’s administrative burden calculator estimate, including hourly earnings, plus non-wage labour costs plus 25% overheads (for professionals rather than technicians, given the potential complexity of the analysis for polymers). This gives a figure of just over €1 400, which has been rounded to the nearest €500.

<sup>137</sup> See Table 5.5 in Wood and PFA (2020). Data have been increased from 2017 prices to 2022 prices based on HICP (a factor of 14.8%).

### *Fees payable to ECHA for notification*

It is assumed that no fees would be payable to ECHA for the purposes of notification.

### **3.2.5 Pre-registration requirements and numbers of polymers covered (option 9b only)**

Under option 9b, while all polymers would also be subject to the initial notification stage (with less information required than under option 9a), only polymers identified as PRR would proceed to the pre-registration stage. This is illustrated in the figure below.

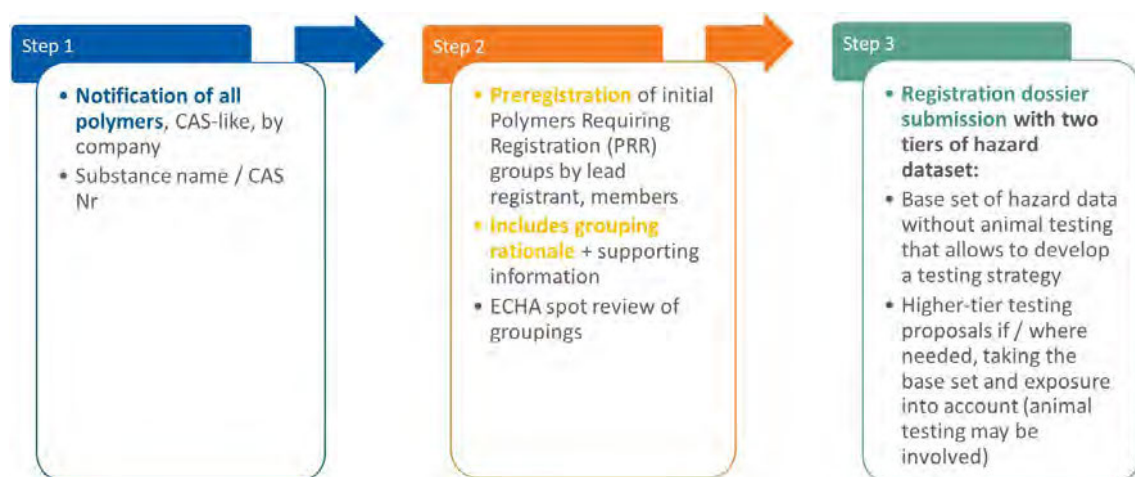


Figure 10: Overview of option 9b: notification, pre-registration and registration (Source: Cefic, 2022c)

It is assumed that pre-registration would take place five years after entry-into-force. It is also assumed that the work associated with developing groups would have been undertaken by this point. It is further assumed that any information that would be submitted at notification stage under option 9a (for all polymers) but which would not be submitted during notification under option 9b, would be submitted at the pre-registration stage (but only for PRR, not for all polymers<sup>138</sup>).

### **3.2.6 Grouping of polymers and effect on numbers of polymers requiring registration**

The approach to grouping of polymers for registration under the two options would be different i.e.:

- Under option 9a, a more detailed dataset would have been required at the notification stage, allowing ECHA to set criteria for grouping, followed by registration of PRR.
- Under option 9b, there would be a more limited dataset for notification, followed by formation of groups for pre-registration (for PRR only), and only then the full registration of PRR.

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<sup>138</sup> See assumed numbers of PRR.

While the process and criteria for grouping under the two approaches differs, and much remains uncertain at this time, there is no information available to say whether one approach or the other would lead to more (grouped) PRR for registration (and pre-registration in the case of option 9b). Option 9a aims to end up with around 10 000 groups of polymers requiring registration, and under option 9a, the criteria for grouping set by ECHA could in principle be set to achieve such a number. Under option 9b there is more uncertainty about how grouping could lead to more or fewer grouped polymers.

In the absence of better data, the costs associated with grouping are assumed to be the same (under both option 9a and option 9b) as in the previous study by Wood and PFA (2020). In practice, the work involved would be different e.g., with ECHA setting grouping criteria under option 9a, and industry deciding upon grouping under option 9b, but it has not been possible to take this into account quantitatively, nor to say which would lead to greater costs.

### 3.2.7 Numbers of polymers requiring registration

In the study by Wood and PFA (2020), the number of polymers that would require registration was estimated as follows:

- It was assumed that there are 200 000 polymers on the market.
- 15% of those polymers would be identified as PRR, i.e., around 30 000.

Following grouping, based on an assumption that 40% of polymers are unique (i.e. similar enough to be registered together as a group), it was estimated that around 12 000 polymers would require registration (or 11 000 based on the outputs of the Monte Carlo analysis run for that study). Such a group of polymers that can be registered together is called a ‘unique PRR’ in the Wood & PFA reports and the remainder of this Annex. Since completion of that study, Cefic (2022b) has undertaken work to estimate the number of polymers that fall into the three main “types” of polymers based on molecular weight<sup>139</sup>. The table below estimates the number of polymers that fulfil the proposed PRR criteria under option 9a (based on the draft version from February 2022), and which can be grouped based on CAS-number, together with the associated tonnage of those polymers. It also includes the number of each type of polymer falling into each tonnage band for the approach to grouping of PRR under option 9b<sup>140</sup>.

Therefore, of the assumed 200 000 polymers, based on the data collected from Cefic members, around 28% (56 000) would be assessed to be PRR and require registration (PRR) under option 9a, and around 11% (23 000) would require registration under option 9b. It is important to note, however, that the data collected by Cefic assumed that, under option 9a, no further grouping would occur beyond grouping by CAS number i.e., polymers with different CAS numbers (no matter how similar) are not assumed to be grouped together in the figures below. In practice, option 9a would allow criteria to be set for grouping that would allow a broader definition of groups (and hence fewer grouped polymers), at least in principle. The criteria are of course not yet known.

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<sup>139</sup> Type 1: < 1000 Da, Type 2: 1000-10,000 Da, Type 3: >10,000 Da.

<sup>140</sup> See details in Cefic (2022c, 2021a) as well as ECETOC (2021a, 2021b).

Table 101: Estimated numbers of PRR based on Cefic survey

	Total	Type 1	Type 2	Type 3
<b>Option 9a (by CAS-number, with no further grouping)</b>				
1-10 tonnes	16 811	9 916	5 928	967
10-100 tonnes	22 499	16 461	5 281	757
100-1000 tonnes	11 107	5 449	4 235	1 422
>1000 tonnes	5 380	1 268	2 491	1 621
All tonnage bands	<b>55 797</b>	33 094	17 935	4 767
<b>Option 9b</b>				
1-10 tonnes	4 389	1 685	2 465	239
10-100 tonnes	6 020	2 157	3 396	467
100-1000 tonnes	8 162	4 526	2 594	1 042
>1000 tonnes	4 118	1 177	2 199	742
All tonnage bands	<b>22 687</b>	9 544	10 653	2 490

Source: Cefic (2022b and 2022d). Based on data from 65 companies, extrapolated by Cefic to the whole market using data from Eurostat. For the extrapolation, Cefic took the number of large and SME enterprises from NACE Rev. 2 Codes C20.16 and C20.17 and compared this to the number of large/SMEs that responded to their survey to estimate the % of the sector that is represented by the survey. The formula  $1/x$  (where  $x$  is the % of the sector represented by the sample) gave the value by which the data should be multiplied by to obtain the extrapolated results at the sectoral level. Note that the original source for these data has not yet been seen.

Taking into account experience from other jurisdictions that the number of polymers that are ultimately identified as unique (i.e. similar) – estimated as 40% based on the Wood and PFA (2020) study – the actual number of unique PRRs that would be registered based on the Cefic (2022b) data could be around 22 300<sup>141</sup> for option 9a, or around 9 100 for option 9b. Note that the data collected by Cefic were based on criteria for identification of PRR that have since been subject to some modifications, such as the inclusion of all fluoropolymers by default (which would increase the number of polymers being PRR and groups). However, they are used in the current analysis in the absence of any other data.

It is important to note that, under option 9a in particular, the number of polymers that will be subject to registration, is very much depending on the criteria set by ECHA for grouping and therefore not possible to be exactly predicted now. For example, the criteria could presumably be set such as to deliberately achieve a certain, lower number of (grouped) polymers requiring registration (e.g., 10 000).

<sup>141</sup> 40% of 55 797 = 22 319, 40% of 22 687 = 9 075



The numbers of PRR identified is clearly driven by the criteria set for identification of PRR under the different options. While there have been some changes to the criteria since the data were collected, the criteria in option 8a are considered to be largely similar, and so provide a reasonable basis for estimating the number of PRR (without further grouping).

Therefore, the following is assumed in terms of numbers of polymers covered under the different options:

- Data in Table 101 are used when estimating impacts under **option 8a**. This covers around 56 000 PRR.
- Data in Table 101 are used when estimating impacts under **option 8b**. This covers around 23 000 PRR.

It is assumed in the subsequent analysis that the proportions of polymers in each tonnage band and each polymer type is the same as under option 8a.

### **3.2.8 Costs for pre-registration**

There is no pre-registration stage assumed under option 9a. Under option 9b, it is assumed that, as a minimum, the information that would be submitted during notification for option 9a but not option 9b would now be submitted at the pre-registration stage. The difference is €750 (i.e., €1 500 for notification under option 9a less €750 for notification under option 9b). However, there would be a saving as, under this option, the costs for pre-registration would only be incurred for PRR, not for all polymers.

In addition, it is assumed there would be costs associated with dossier submission. In the absence of better information, it is assumed that the dossier submission costs would be the same as those for registration (and for notification), as described above (i.e., €2 000 to €3 800).

Costs would also be incurred by industry associated with formation of groups of polymers for pre-registration and for registration. In the absence of better information, it is assumed the costs would be the same for this activity as under option 9a.

### **3.2.9 Standard information requirements for polymers and associated costs**

#### *3.2.9.1 Standard information requirements for option 9a*

The standard information requirements for this option are set out in Table 102. A number of tests would only be required conditional upon the outcome of other test results (as is the case for non-polymeric substances). As a simplifying assumption, it is assumed that 40% of polymers would require such conditional tests. There are additional conditionalities (again 40% is assumed) for type 2 and type 3 polymers.

Appendix A of the Wood 2022 study details the assumed costs per test, where quantitative data were available for this study. It is noted that no estimates of costs are included for various tests on environmental fate and behaviour, e.g., hindered uptake hydrolysis / adsorption screening on leachate, as well as on physicochemical properties e.g., crystallinity, solution/extraction behaviour test, thermal/light stability. These have therefore not been estimated, which tends to underestimate the costs. It is noted that

several of these tests still need to be developed. This represents a key uncertainty in the analysis.

The Section on “Economic impacts” sets out how the total costs associated with undertaking tests to fulfil the information requirements were derived.

Starting with the numbers of polymers of each type assumed to require registration (Table 101) the numbers of polymers of each type requiring each type of standard information were calculated. In summary:

- The standard information requirements for non-polymers were evaluated in order to identify those that are expected to be relevant for polymers.
- Additional information requirements for polymers identified by ECHA were also included<sup>142</sup>.
- An assumption was made on the percentage of polymers expected to have data on that endpoint already.
- Additional ‘conditionality’ factors, typically 40%, were applied to type 2 and 3 polymers, to reflect the expectation that there is a reduced likelihood that these polymers would be prioritised for additional, higher-tier, testing based on the results of initial tests.
- An average weighted price per polymer (for types 1, 2 and 3) for each test was then derived and this was applied to the number of polymers undergoing each type of test, to derive the total costs.
- Separate estimates were derived for (a) type 1, 2 and 3 polymers, (b) company size (large, medium, small, micro) and (c) tonnage band.

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<sup>142</sup> Note that for many of these additional tests, methods still need to be developed, and also cost data are lacking, which means there is a tendency to underestimate the costs.

Table 102: Summary of information requirements under option 9a

<b>Current Annex</b>	<b>Type 1</b>	<b>Type 2</b>	<b>Type 3</b>
VI (all substances)	As for non-polymers but with the following additional tests: <ul style="list-style-type: none"> <li>- GPC for MW distribution: OECD 118</li> <li>- GPC for low MW content: OECD 119</li> <li>- Specific physico-chemical properties necessary for substance identification, e.g., viscosity, crystallinity</li> </ul>	As for Type 1 polymers	As for Type 1 polymers
	<p><b>PHYSICOCHEMICAL PROPERTIES</b></p> <p>As for non-polymers but with the following additional tests:</p> <ul style="list-style-type: none"> <li>- Solution/extraction behaviour of polymers (not applicable to water soluble polymers): test method to be decided, one option is OECD 120 with additional testing at pH 2 and 9</li> <li>- Thermal stability test, including estimate of melting point: OECD 113</li> <li>- Assessment of light-stability if the polymer is not specifically light-stabilised: methodology to be developed</li> </ul> <p>Special considerations for Annex VII to X studies on polymers:</p> <ul style="list-style-type: none"> <li>- Melting point, boiling point, vapour pressure, flash point and self-ignition</li> </ul>	<p><b>PHYSICOCHEMICAL PROPERTIES</b></p> <p>As for type 1 polymers.</p>	<p><b>PHYSICOCHEMICAL PROPERTIES</b></p> <p>As for type 1 polymers.</p>

Current Annex	Type 1	Type 2	Type 3
	<p>temperature: may not be required</p> <ul style="list-style-type: none"> <li>- Kow and Koc may not be reliable in many cases and should not be attempted for surfactants: determination of leachates may be appropriate</li> <li>- Explosivity, flammability and oxidising properties: prediction from composition and experience in use (testing not necessary)</li> </ul>		
VII (1-10t)	<p><b>ENVIRONMENTAL</b></p> <ul style="list-style-type: none"> <li>- As for non-polymers.</li> <li>- Acute and chronic aquatic organism studies in fish, daphnia and algae may have to be performed on the leachate.</li> </ul>	<p><b>ENVIRONMENTAL</b></p> <ul style="list-style-type: none"> <li>- Solution/extraction behaviour of polymers (not applicable to water soluble polymers): test method to be decided, one option is OECD 120 with additional testing at pH 2 and 9 at 37°C and with cyclohexane</li> <li>- Thermal stability test, including estimate of melting point: OECD 113</li> <li>- Assessment of light-stability if the polymer is not specifically light-stabilised: methodology to be developed</li> <li>- Particle size distribution (granulometry)</li> <li>- Surface tension, if applicable (i.e., only if surface activity is predicted from the structure or is a desired property of the polymer)</li> <li>- Biodegradation in water: screening test</li> <li>- Assessment of ‘environmental degradability and release of substances of concern’: methodology to be developed</li> <li>- Assessment of ‘hindered uptake’: methodology to be developed</li> </ul> <p><b>Further testing triggered by the results of the above ‘screening’ tests (these are to be included in the</b></p>	<p><b>ENVIRONMENTAL</b></p> <p>As for Type 2 polymers</p>

Current Annex	Type 1	Type 2	Type 3
		<p><b>registration):</b>            If triggered by the extractability test: the Annex VII and VIII Type 1 polymer ecotoxicity and environmental fate studies:</p> <ul style="list-style-type: none"> <li>- short-term toxicity to fish (only at 10-&lt;100t.p.a.),</li> <li>- short-term toxicity to Daphnia,</li> <li>- toxicity to aquatic algae (or cyanobacteria),</li> <li>- activated sludge respiration test (only at 10-&lt;100t.p.a.),</li> <li>- partition coefficient n-octanol/water on the leachate</li> <li>- hydrolysis on the leachate (only at 10-&lt;100t.p.a.),</li> <li>- adsorption/desorption screening (Koc) on the leachate (only at 10-&lt;100t.p.a.),</li> </ul> <p>If there is an ‘unfavourable’ outcome of the assessment of ‘hindered uptake’, the Annex VII and VIII Type 1 polymer ecotoxicity tests:</p> <ul style="list-style-type: none"> <li>• short-term toxicity to fish (only at 10-&lt;100t.p.a.),</li> <li>• short-term toxicity to Daphnia,</li> <li>• toxicity to aquatic algae (or cyanobacteria),</li> <li>• activated sludge respiration test (only at 10-&lt;100t.p.a.).</li> </ul> <p>If there is an ‘unfavourable’ outcome of the assessment of ‘environmental degradability and release of substances of concern’ forecasting degradation:</p> <ul style="list-style-type: none"> <li>• Testing proposals for PBT assessment, i.e., first simulation test(s) with identification of environmental degradants followed, if appropriate, by a fish bioaccumulation study then long-term fish and Daphnia studies on the identified environmental</li> </ul>	

<b>Current Annex</b>	<b>Type 1</b>	<b>Type 2</b>	<b>Type 3</b>
		degradant(s).	
	<p><b>HUMAN HEALTH</b></p> <p>As for non-polymers.</p>	<p><b>HUMAN HEALTH</b></p> <p>Testing strategy proposed (see figure below). May have to follow the type 1, 2 or 3 SIRs depending on the outcome of the testing strategy. The following remain unchanged:</p> <ul style="list-style-type: none"> <li>• Skin corrosion/irritation</li> <li>• Serious eye damage/eye irritation</li> <li>• Skin sensitisation</li> <li>• Mutagenicity (together with any triggered in vivo follow-up)</li> <li>• Acute toxicity (oral)</li> </ul>	<p><b>HUMAN HEALTH</b></p> <p>As for Type 2 polymers</p>
VIII (10-100t)	<p><b>ENVIRONMENTAL</b></p> <p>As non-polymers but see ‘special considerations’ above</p>	<p><b>ENVIRONMENTAL</b></p> <p>See Annex VII above</p>	<p><b>ENVIRONMENTAL</b></p> <p>See Annex VII above</p>
	<p><b>HUMAN HEALTH</b></p> <p>As non-polymers.</p>	<p><b>HUMAN HEALTH</b></p> <p>Testing strategy proposed (see below)</p> <p>The following remain unchanged:</p> <ul style="list-style-type: none"> <li>• Acute toxicity (dermal, inhalation)</li> </ul> <p>Reproductive and repeated dose toxicity:</p> <ul style="list-style-type: none"> <li>• 28-day repeated dose toxicity</li> <li>• Reproductive toxicity Screening Study</li> </ul>	<p><b>HUMAN HEALTH</b></p> <p>Testing strategy proposed (see below)</p> <p>The following remain unchanged:</p> <ul style="list-style-type: none"> <li>• Acute toxicity (dermal, inhalation)</li> </ul> <p>Reproductive and repeated dose toxicity:</p> <ul style="list-style-type: none"> <li>• Non</li> </ul>
IX (100-1000t)	<p><b>ENVIRONMENTAL</b></p> <p>As non-polymers but see ‘special considerations’ above</p>	<p><b>ENVIRONMENTAL</b></p> <ul style="list-style-type: none"> <li>• Dissociation constant (pKa), if applicable,</li> <li>• If there is an ‘unfavourable’ outcome of the assessment of ‘hindered uptake’ the Annex IX tests:</li> </ul>	<p><b>ENVIRONMENTAL</b></p> <p>As for Type 2 polymers</p>

Current Annex	Type 1	Type 2	Type 3
		<ul style="list-style-type: none"> <li>○ long-term aquatic toxicity to Daphnia and fish</li> <li>○ bioaccumulation in aquatic species: fish</li> <li>• Acute soil organism studies, if necessary, on the appropriate environmental degradants</li> </ul>	
	<p><b>HUMAN HEALTH</b></p> <p>As non-polymers.</p>	<p><b>HUMAN HEALTH</b></p> <p>Reproductive and repeated dose toxicity:</p> <p>3 Repeated dose toxicity (in vivo sub-chronic (90 days) (if triggered by 28d study)</p> <p>4 Pre-natal developmental toxicity 1</p>	<p><b>HUMAN HEALTH</b></p> <p>Reproductive and repeated dose toxicity:</p> <ul style="list-style-type: none"> <li>• 28-day repeated dose toxicity</li> <li>• Reproductive toxicity SS</li> </ul>
X (>1000t)	<p><b>ENVIRONMENTAL</b></p> <p>As non-polymers but see ‘special considerations’ above</p>	<p><b>ENVIRONMENTAL</b></p> <p>5 Chronic soil organism studies, if necessary, on the appropriate environmental degradants</p> <p>6 Sediment organism studies, if necessary, on the appropriate environmental degradants</p>	<p><b>ENVIRONMENTAL</b></p> <p>As for Type 2 polymers</p>
	<p><b>HUMAN HEALTH</b></p> <p>As non-polymers.</p>	<p><b>HUMAN HEALTH</b></p> <p>Reproductive and repeated dose toxicity:</p> <p>7 Pre-natal developmental toxicity 2 (if triggered)</p> <p>8 EOGRTS (if triggered)</p>	<p><b>HUMAN HEALTH</b></p> <p>Reproductive and repeated dose toxicity:</p> <p>9 Repeated dose toxicity (in vivo sub-chronic (90 days)) (if triggered by 28d study)</p> <p>10 Pre-natal developmental toxicity 1 (if triggered)</p> <p>11 Pre-natal developmental toxicity 2 (if triggered)</p> <p>12 EOGRTS (if triggered)</p>

Notes: For Type 2 and 3 polymers, oral and inhalation toxicity testing would be dependent on polymer properties and exposure potential.

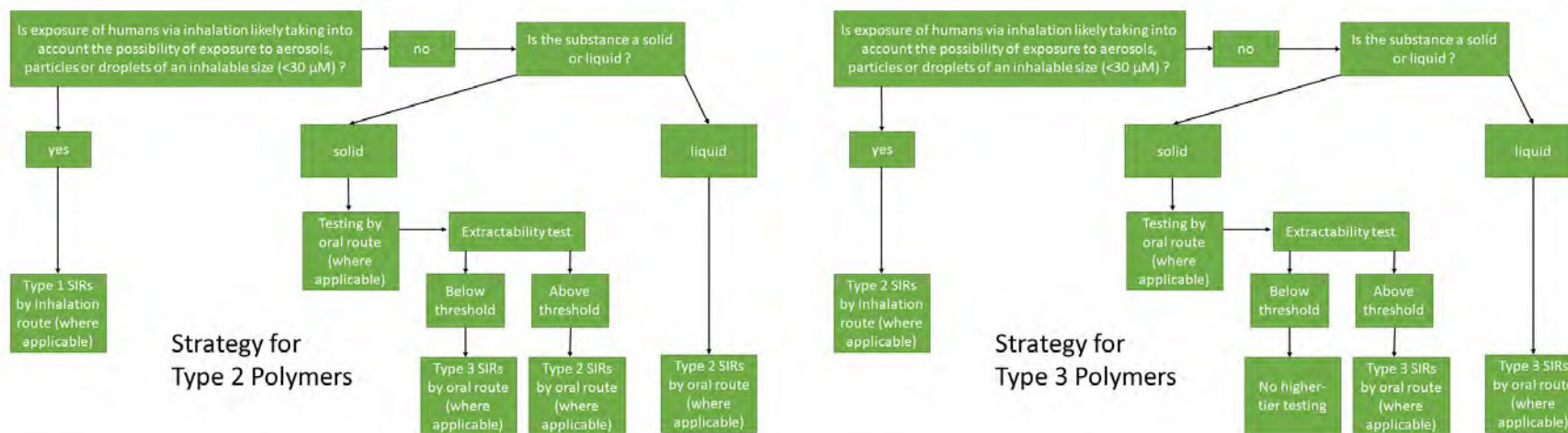


Figure 11: Testing strategies for Type 2 and 3 polymers (ECHA, 2022a)



### 3.2.9.2 Standard information requirements for option 9b

Under this option, basic (tier 1) data would be generated from a representative sample of a group of polymers, with tier 2 data generated from a subset of samples comprising the extremities of the group, as illustrated below. This option therefore does not sub-divide polymers into different types by molecular weight as option 9a does.

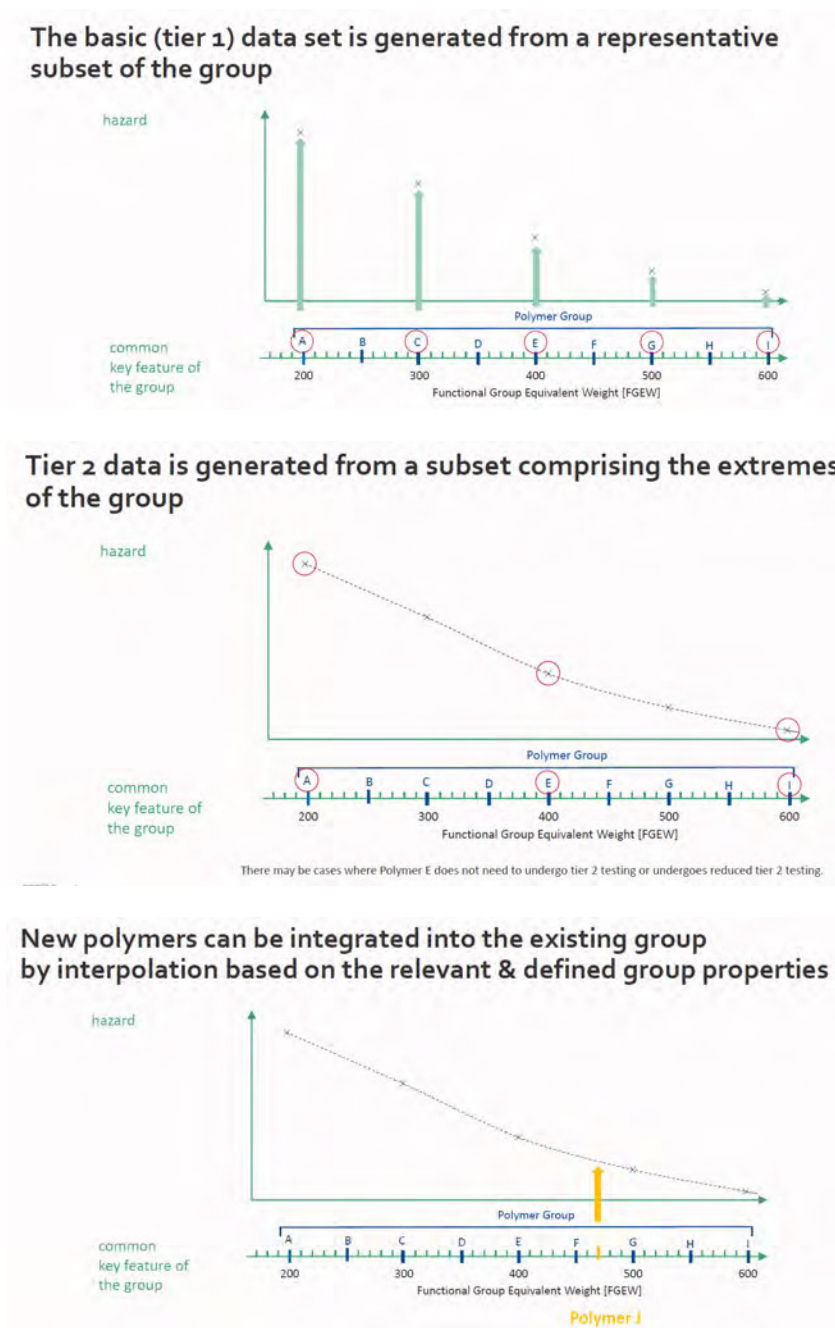


Figure 12: ECETOC bracket testing: (a) tier 1 data, (b) tier 2 data, (c) interpolation for new polymers

In terms of the data required (i.e., information requirements), the approach differs fundamentally to that under option 9a. Under option 9b, there would be three “tiers” of assessment for polymers (tiers 1, 2 and 3). The information requirements per tier are summarised in the figure below.

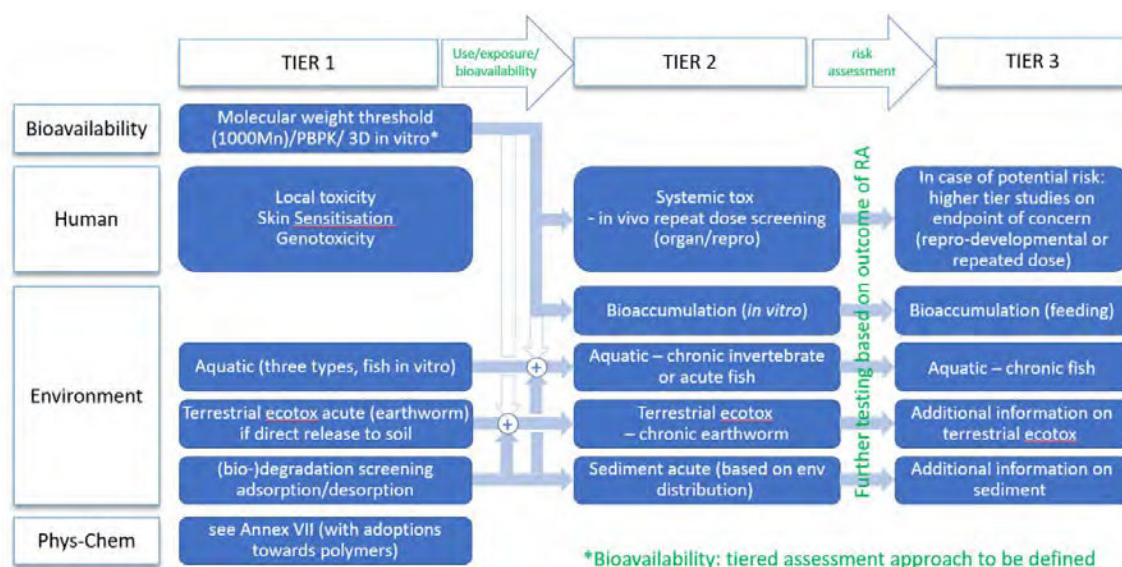


Figure 13: Overview of option 9b PRR Information Requirements. Note: RA = risk assessment. Source: ECETOC (2021b).

Following the pre-registration stage, and subsequent grouping, a registration dossier would be submitted, including tier 1 data. The principles of this tier 1 data submission are as follows (ECETOC, 2021b):

- There would be no animal testing at Tier 1, as this tier addresses local effects for human health and acute effects for relevant environmental species.
- Any animal studies for REACH registration would be routed via testing proposals (submitted as part of the registration).
- Decisions on undertaking further studies would be based on considerations on known properties and effects, combined with systemic bioavailability estimates and use and exposure considerations.

There would be no formal information requirements for physicochemical or fate/hazard data; existing information, along with newly generated data considered meaningful for polymer hazard and risk assessment, would be used to provide an initial hypothesis on grouping (to be addressed by guidance). An initial grouping rationale would be submitted to ECHA.

A key element of this approach is the exclusion of systemic bioavailability based on factors such as molecule size and molecular weight, followed by computational modelling, in combination with 3D epithelium model vitro assays wherever possible. It is assumed that this would have a major impact on animal testing numbers for low molecular weight PRR, taking into account factors other than molecular size affecting systemic bioavailability. In other words, tier 2 or 3 studies would not be conducted on PRR with low systemic bioavailability. Further information would be required in terms of proof-of-concept by performing case studies; definition of cut-offs triggering higher tier studies; and pragmatic approaches to analytical challenges encountered in the in vitro studies.

In broad terms, the information requirements at each of the three tiers would be:

Tier 1 (non-animal base set, initial registration dossier):

- Basic data set for PRR, with data for relevant members of the group (or single polymers if not registered as a group)
- Hazard information avoiding animal testing.

Tier 2 (repeated exposure, systemic toxicity)<sup>143</sup>:

- Provided as a dossier update
- Focused on environmental fate, bioavailability and use considerations from tier 1
- Higher tier hazard assessment for environment
- General systemic, repeated dose and repro-developmental toxicity hazard characterisation and risk assessment for human health

Tier 3 (if undue uncertainty at tier 2) (further characterisation of endpoints of concern)

- Provided as a further dossier update
- In-depth characterisation of potential risks identified in previous tiers, through targeted high-tier studies

A more detailed overview of the information that would be required is set out in Table 103.

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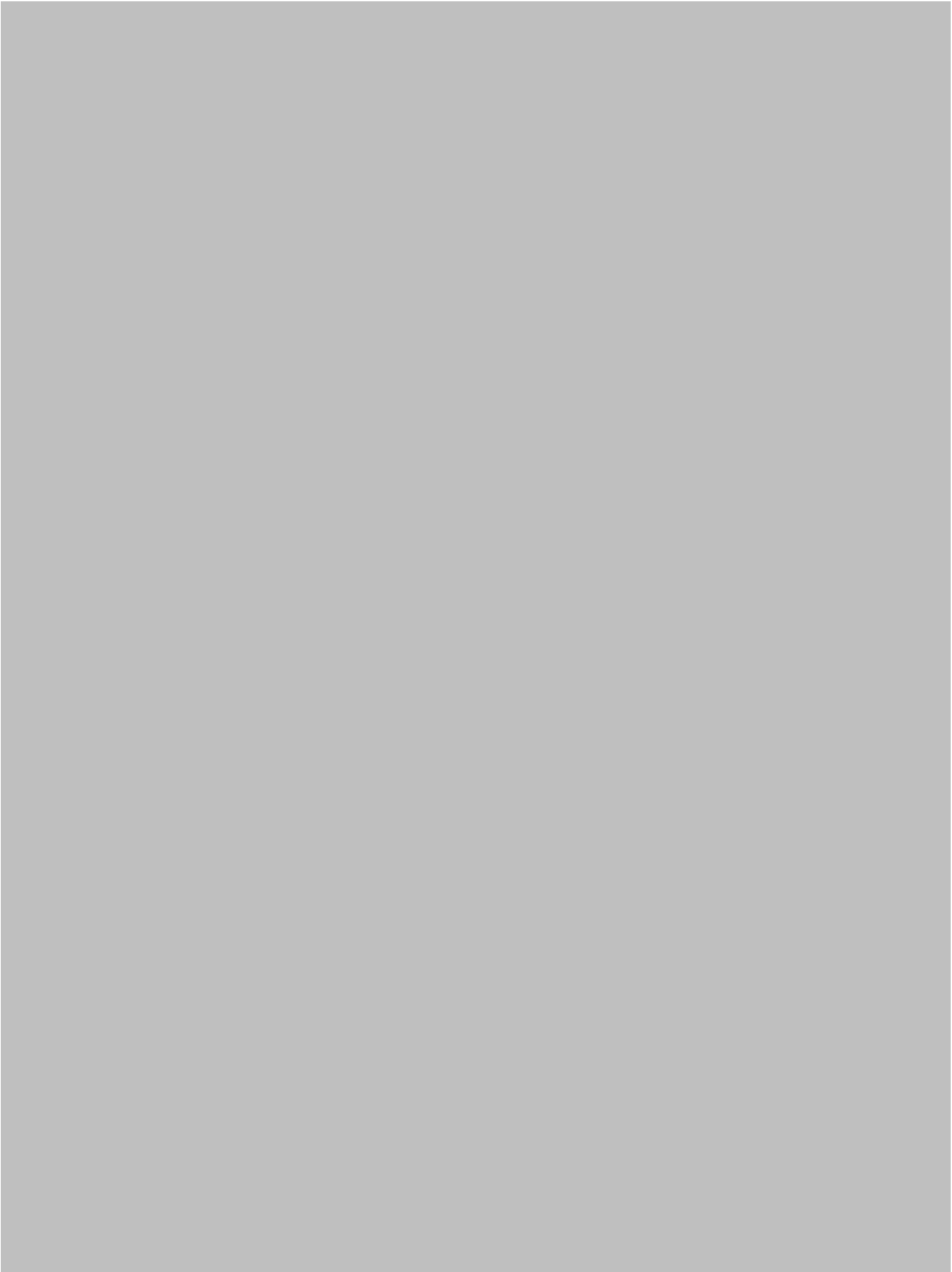
<sup>143</sup> Tier 2 testing would be appropriate if there is ‘undue uncertainty’, largely triggered by environmental fate, bioavailability and use considerations based on assessments made at tier 1.

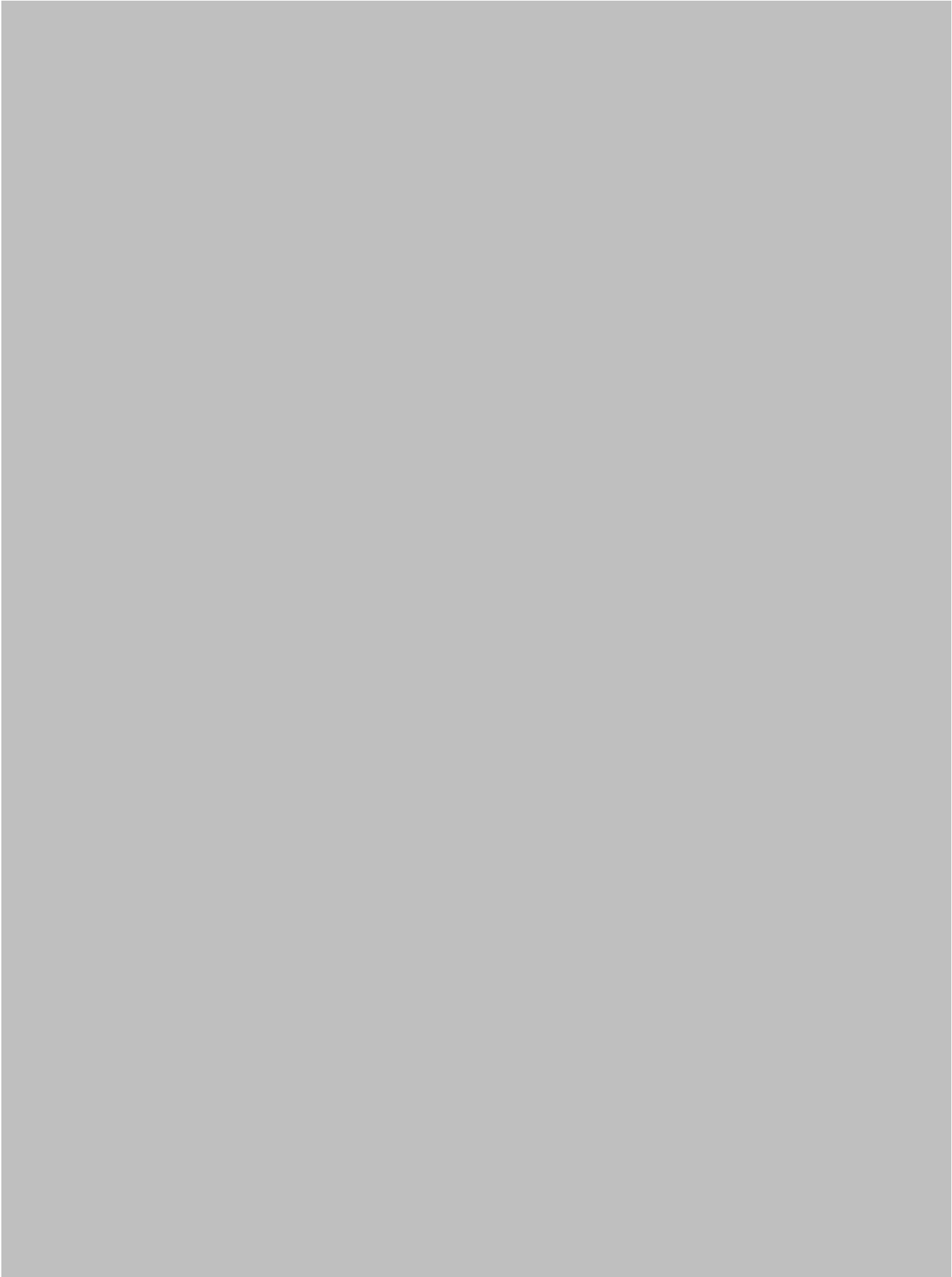
Table 103: Summary of information requirements under option 9b

	<b>Tier 1</b>	<b>Tier 2</b>	<b>Tier 3</b>
<b>Environment</b>			(Only if triggered by risk assessment of effects or accumulation from tier 2)
Degradation	Degradation screening Adsorption/desorption		
Aquatic toxicity	Consider aquatic toxicity (non-animal)	If effect level above threshold based on exposure and systemic bioavailability: <ul style="list-style-type: none"> <li>• Acute fish toxicity</li> <li>• Chronic toxicity to invertebrates</li> </ul>	Chronic toxicity to aquatic vertebrates
Terrestrial toxicity	Consider terrestrial (only when direct release)	If effect level above threshold based on exposure and systemic bioavailability: <ul style="list-style-type: none"> <li>• Acute and chronic toxicity to terrestrial invertebrates</li> </ul>	Chronic toxicity to terrestrial organisms (invertebrates, plants, bacteria)
Sediment toxicity		If justified by environmental distribution: <ul style="list-style-type: none"> <li>• Acute toxicity to sediment-dwelling organisms</li> </ul>	Chronic toxicity to sediment-dwelling organisms
Bioavailability	Bioavailability if number average molecular weight (MW <sub>n</sub> ) <1000 Da Consider systemic bioavailability from HH assessment	If justified by systemic bioavailability: <ul style="list-style-type: none"> <li>• Work on hepatic clearance</li> </ul>	Feeding studies or bioavailability towards invertebrates or vertebrates
<b>Human health</b>		Only if justified by non-industrial use types and systemic bioavailability	
Skin/eye irritation	In vitro skin and eye irritation / corrosion		
Skin sensitisation	Skin sensitivity in vitro (MW <sub>n</sub> <1000 Da or of >1000 Da and high oligomer content and		

	<b>Tier 1</b>	<b>Tier 2</b>	<b>Tier 3</b>
Genotoxicity	<p>RFG present)</p> <p>Genotoxicity in vitro (MWn &lt;1000 Da or of &gt;1000 Da and high oligomer content and RFG present)</p>		
Respiratory effects	In vitro local respiratory effects (only if used in respirable aerosols at >1% or handled as powder containing 1% or more particles with aerodynamic diameter ≤ 10µm).		
Gastrointestinal effects	In vitro gastrointestinal effects only if relevant oral exposure by consumer uses		
Bioavailability	Systemic bioavailability assessment (for MWn <1000 Da or MWn > 1000Da with >10% below 500 Da or > 25% below 1000 Da)		
Systemic toxicity		Acute systemic toxicity	
Repeated dose toxicity / reproductive toxicity		Combined RDT with repro-developmental screening test	Sub-chronic toxicity Developmental toxicity Reproductive toxicity
Other	No risk / chemical safety assessment at this stage Testing strategy submitted to ECHA	CSR with risk assessment and, if triggered, test proposals for animal intense studies.	





















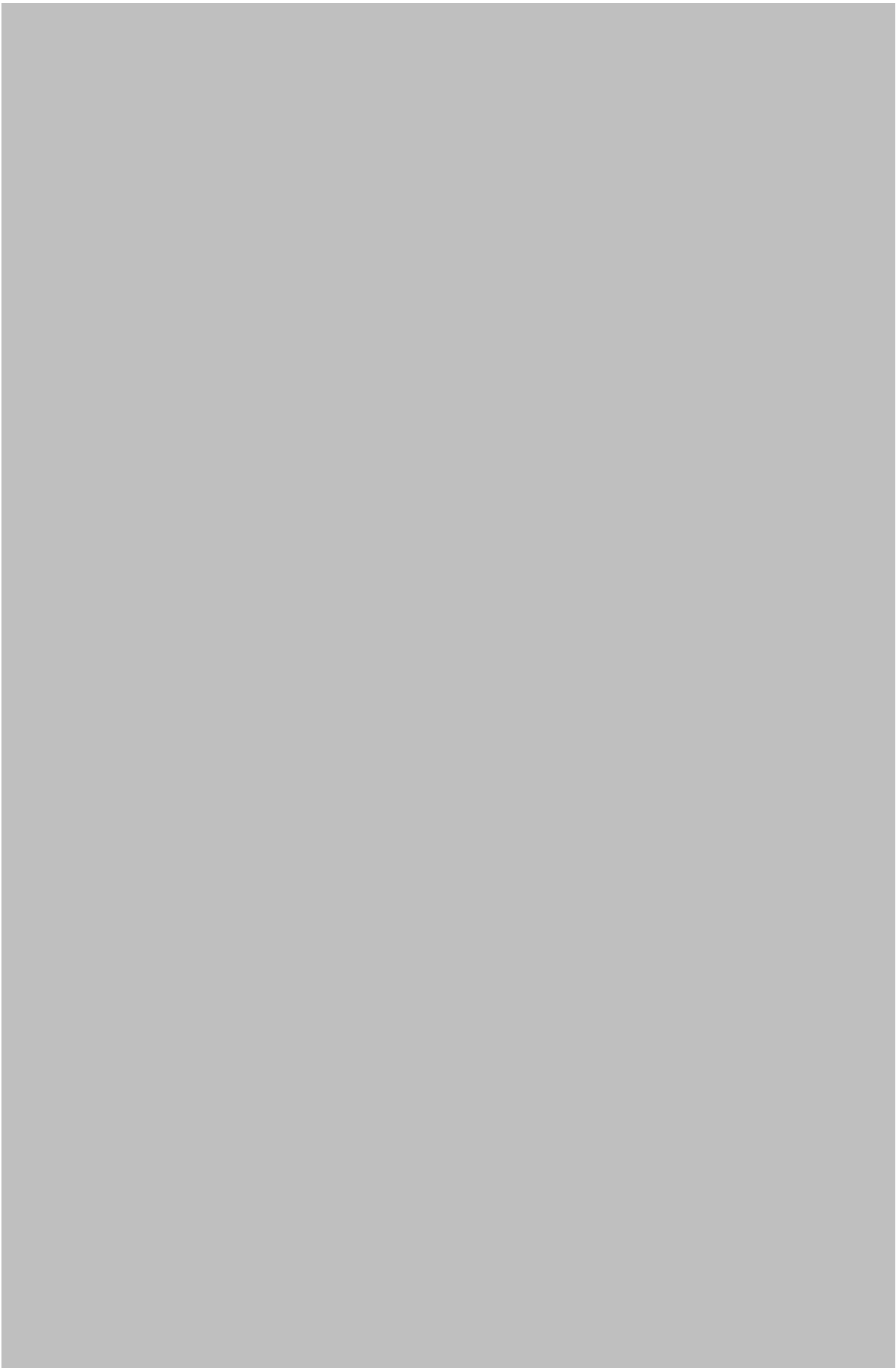










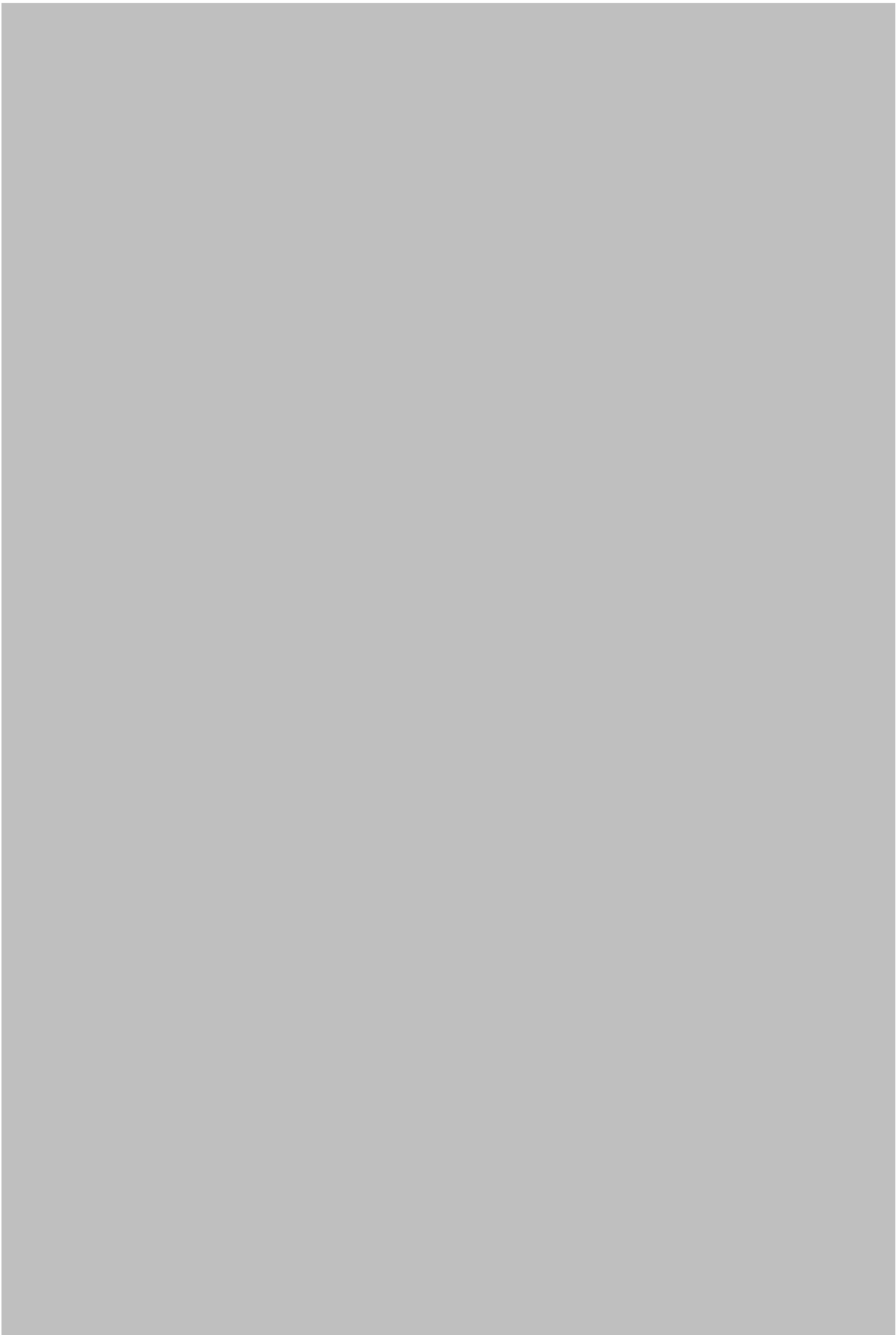






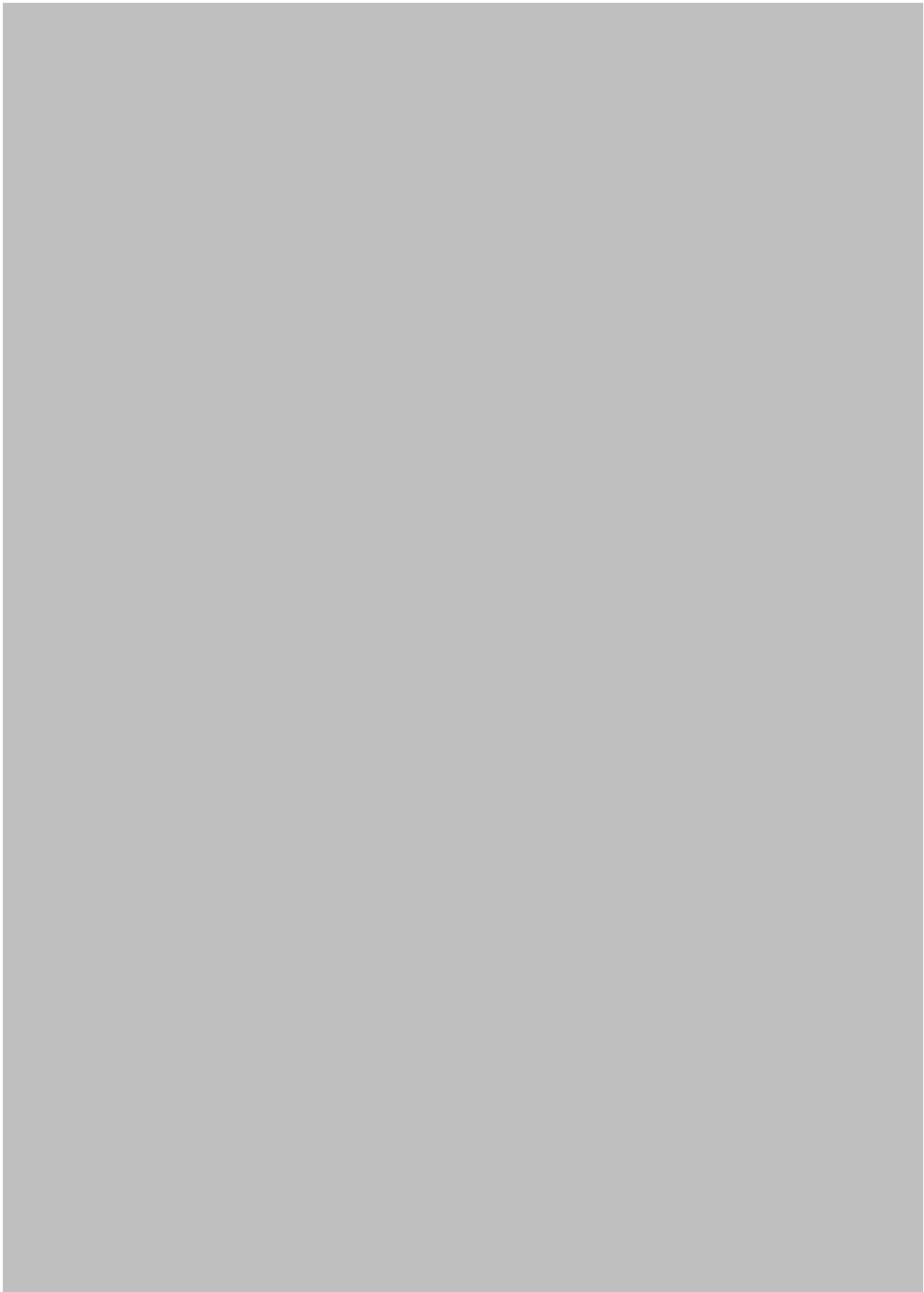




















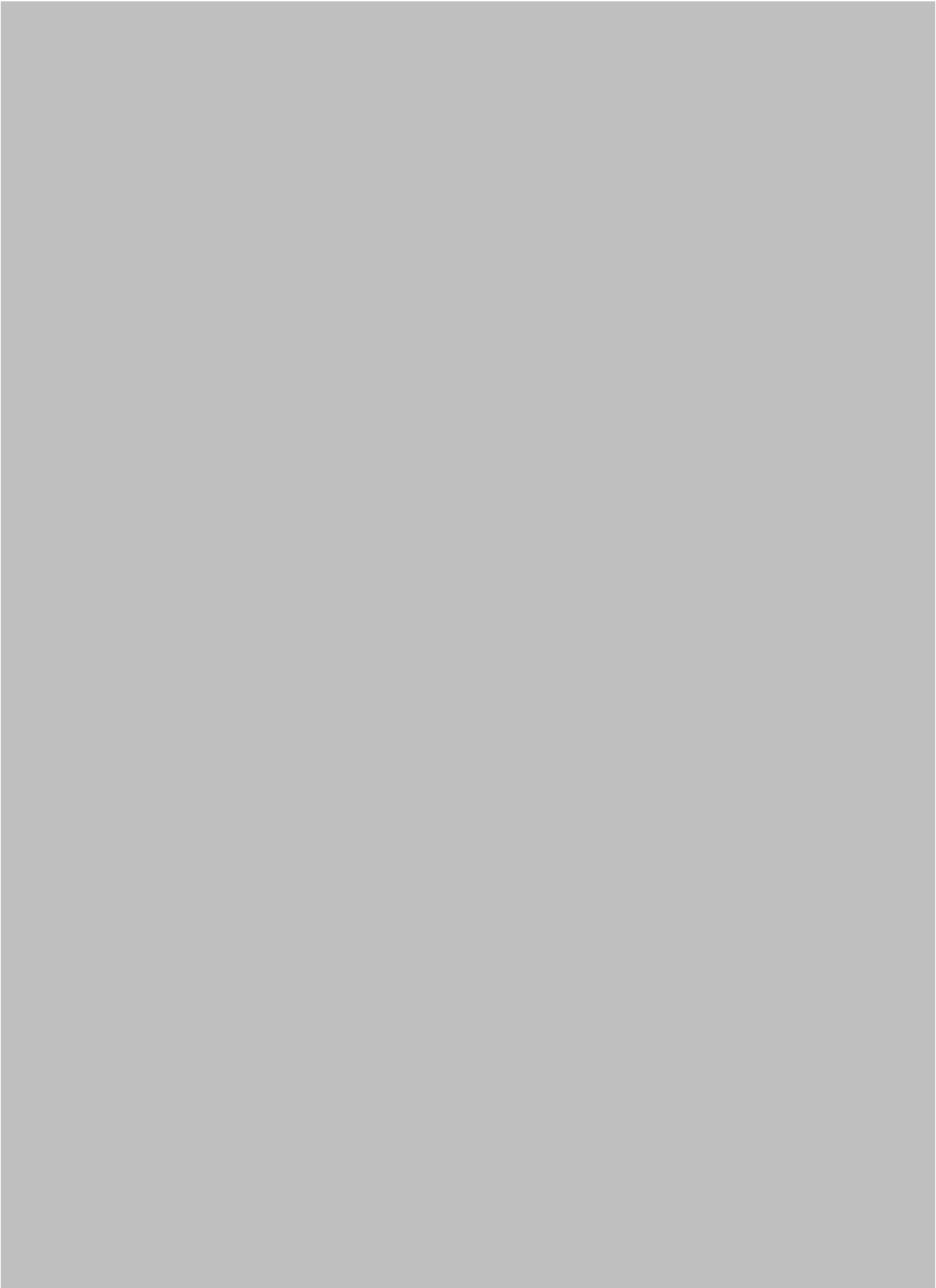


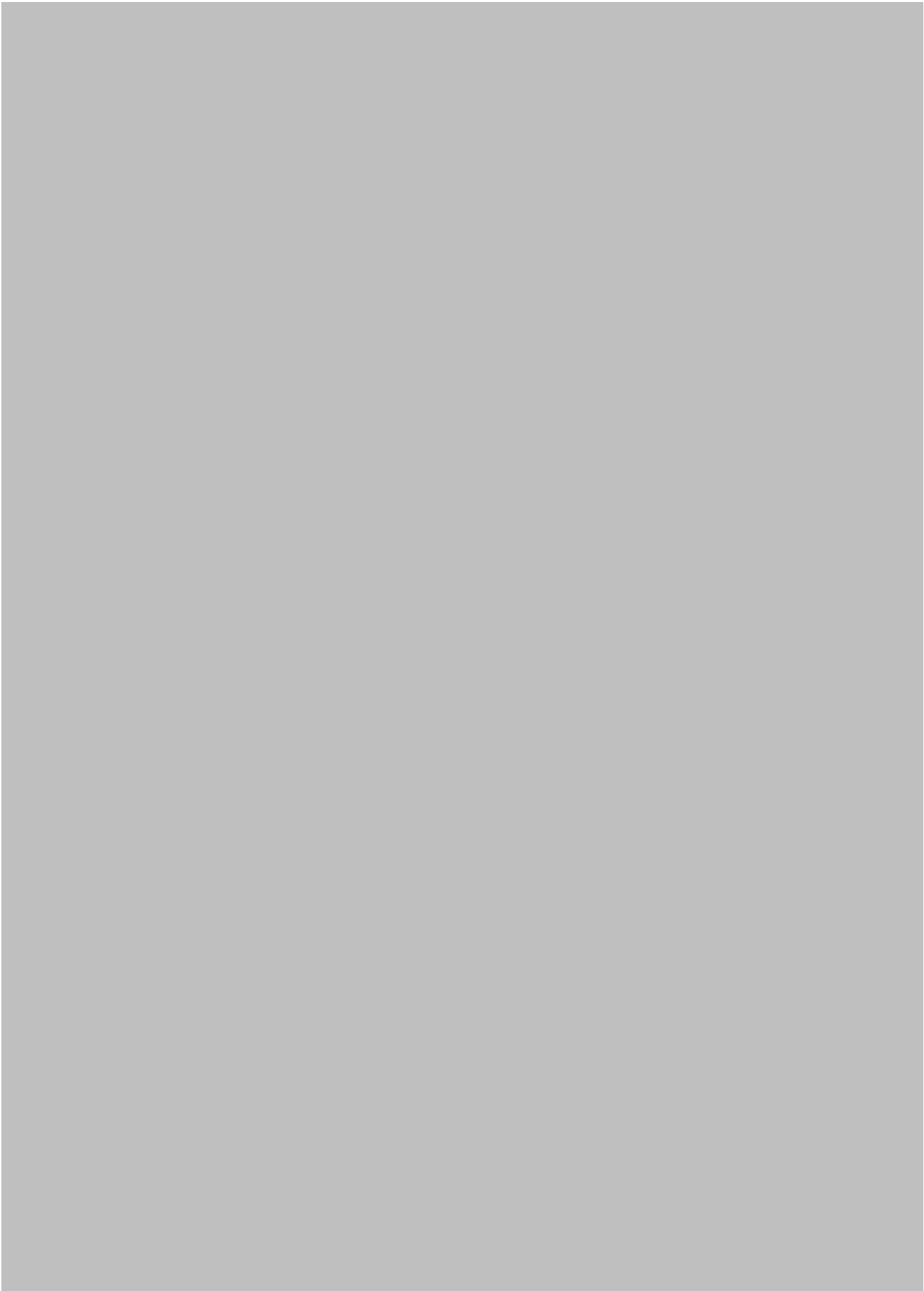


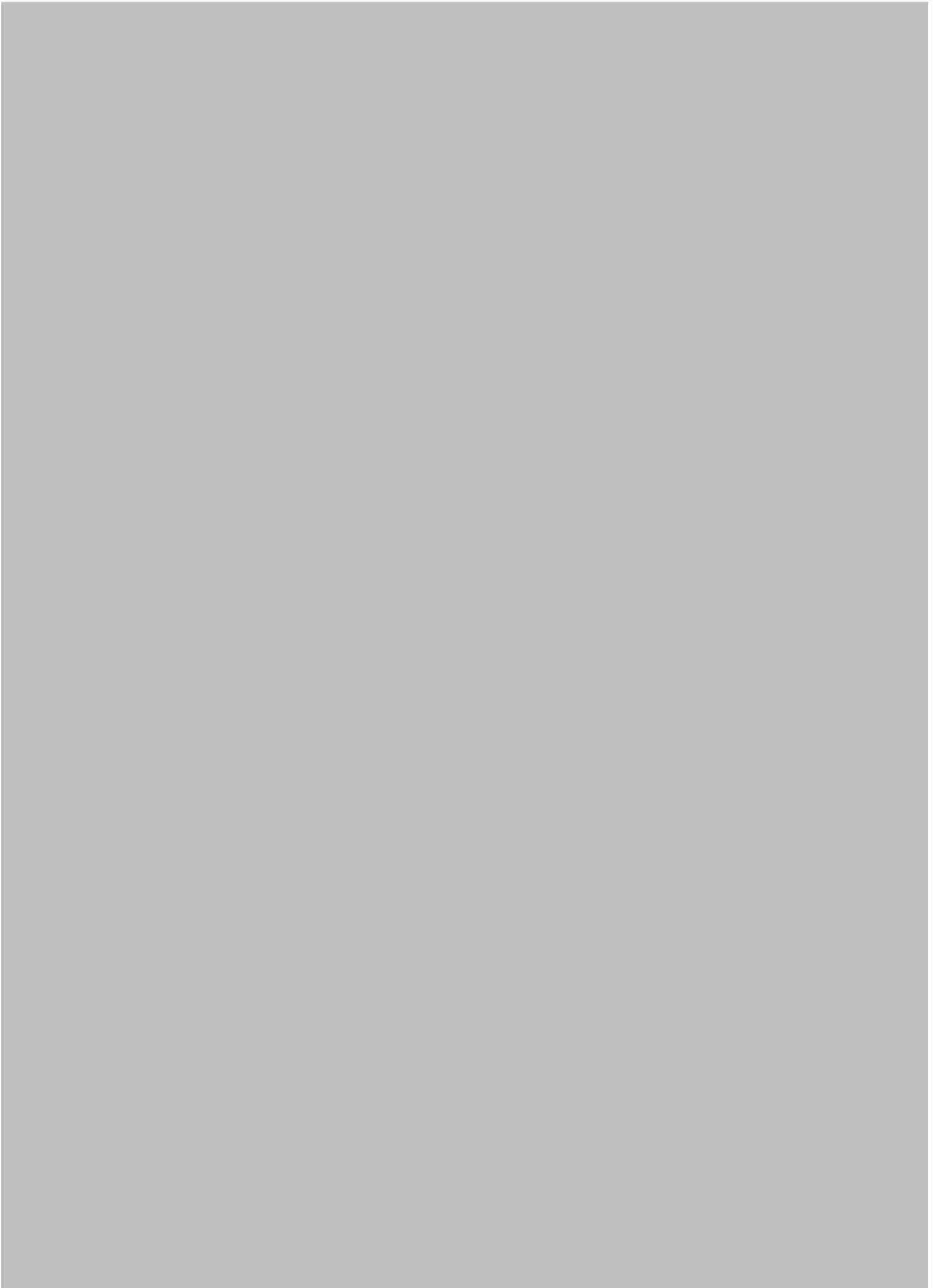




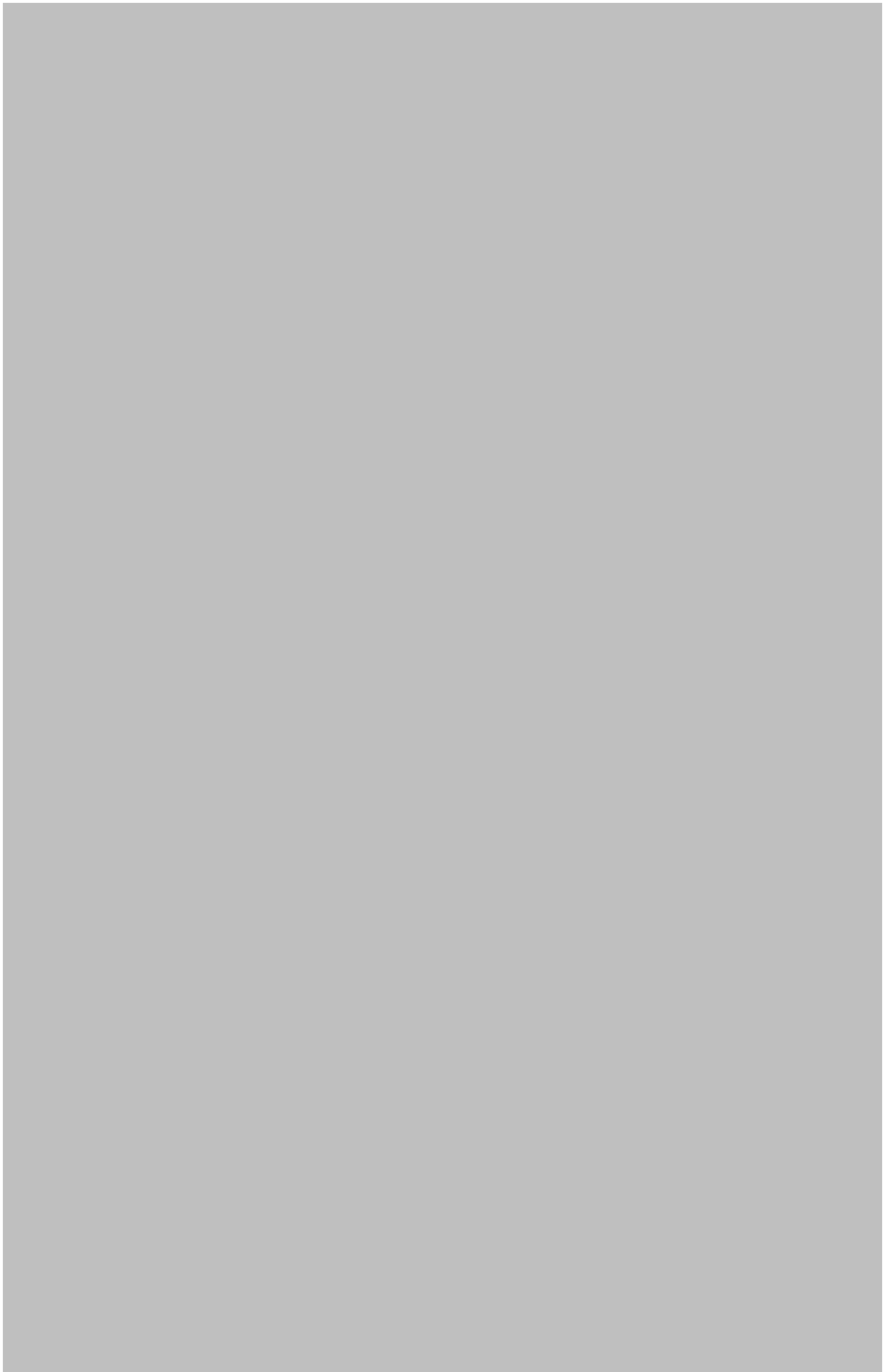


































## **ANNEX 8: IMPROVE THE FORMAT OF THE SAFETY DATA SHEETS**

This Annex presents two measures to improve the communication in the supply chain about chemical properties and their safe use via changes to the safety data sheets. Despite the importance of supply chain communication, these measures are not presented in the main text of the SWD as they are of a more technical nature and do not imply major policy choices.

### **1 CONTEXT**

Safety Data Sheets (SDS) contain the necessary information to allow employers to run a risk assessment as required by law. It describes the hazards, helps employers to assess the probability of risks at the workplace, and is a key tool for employers and workers to take the necessary measures to control the risks, and to identify appropriate steps in case of accidents. They are based on formats developed in the framework of the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS) at UN level but also take into account elements which are specific to EU legislation.

Suppliers of substances and mixtures in the EU are required by REACH Article 31 to compile an SDS and provide it to the recipients of the substance or mixture if it is classified as hazardous, PBT or vPvB, or on the candidate list. Mixtures that are not classified as hazardous still require a SDS to be provided on request if they contain specified concentrations of certain hazardous substances. SDSs should be provided either before or at the time of delivery of the substance. If new information on hazards or risk management measures becomes available, the SDS should be updated without delay. Additionally, the SDS should be updated once an authorisation has been granted or refused, or a restriction has been imposed. Exposure scenarios are required for substances that are sold in quantities of more than 10 tonnes per year and which are classified as hazardous. These exposure scenarios are required to be attached to the SDS to form extended safety data sheets (eSDS) and describe how the substance can be safely handled to control exposure to human health and the environment.

Communication across the supply chain is considered a central theme of REACH, to ensure the safe use of chemicals. Supply chain communication passes information up and down the supply chain on the hazards of substances, the risks of substance use and the risk management measures required to ensure safe use.

In 2018, the Commission's REACH Review noted that there has been a continued increase in the amount of safety data passed down the supply chain over recent years. However, it has also pointed out that that information needs to be communicated in a (more) effective way (delivering useful and relevant safe use advice) and in a more efficient way (reduction of costs of producing, supplying, processing, understanding and using SDS). This is especially a concern for small and medium-sized enterprises (SMEs)<sup>162</sup>.

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<sup>162</sup> See Commission's REACH Review Report 2018 (footnote 4), section 2.2, page 3 at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN>

The REACH review has suggested improving the way in which safety data on hazardous chemicals is generated by a supplier and subsequently communicated to downstream users. An increased use of harmonised formats and IT tools would result in more user-targeted information and simplify the preparation and use of the (extended) SDS, as well as facilitate their electronic distribution (see: REACH Review Action 3(1) aiming to improve the workability and quality of extended SDS). Harmonised electronic formats were identified as an important element to improve supply chain communication.

Subsequently, an extensive dialogue started between the Commission, ECHA, the Member State competent authorities and the relevant stakeholders and services. These discussions and preparatory work resulted in a Development Plan<sup>163</sup> which described in detail the system changes and enhancements required to improve the workability and quality of (extended) SDS necessary to better serve the whole supply chain.

There have been certain improvements to the efficiency of supply chain communication in the past years, with a number of tools introduced to improve effectiveness as well as to cut costs for companies. These relate, in particular, to the harmonisation of use and exposure scenarios. For example, the Exchange Network on Exposure Scenarios (ENES) was set up in 2011. This is a collaborative network established by ECHA together with industry sector organisations, with Member States as active participants. ENES aims to identify good practices with the preparation and implementation of exposure scenarios for SDSs, and to develop effective communication exchanges through the supply chain.<sup>164</sup> Templates for exposure scenarios have already been designed<sup>165</sup>, and through the work of the Chemical Safety Report/Exposure Scenario (CSR/ES) Roadmap between 2013 and 2016 guidance was also produced.<sup>166</sup> The CHEMical Safety Assessment and Reporting tool (Chesar) has also been developed by ECHA and enables safety assessments to be carried out in a structured, harmonised, transparent and effective way<sup>167</sup>.

## 2 DESCRIPTION OF THE PROBLEM

### 2.1 What is the problem and why is the problem?

The 2018 REACH Review report<sup>168</sup> indicates that there have been improvements in communication and greater transparency in the supply chain since the 2013 REACH Review, but it also notes that the communication of this information could be more efficient (e.g. to reduce costs of producing, supplying and processing SDS). Currently, SDS are communicated to downstream users either electronically (mainly in PDF format), or in a paper format. However, neither the PDF, nor the paper format facilitate automated processing of the communicated data by recipients of SDS. In such cases,

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<sup>163</sup> ECHA (2020). REACH Review Action 3: Development Plan. Working draft v.3.2; 03.11.2020

<sup>164</sup> <https://echa.europa.eu/en/about-us/exchange-network-on-exposure-scenarios>

<sup>165</sup> <https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats>

<sup>166</sup> For example, see previous guidance on creating and structuring exposure scenario short titles: <https://cefic.org/app/uploads/2019/01/Structured-Short-Titles-in-Exposure-Scenarios-for-communication-Cefic-DUCC-ECHA-REACHImpl-ES-CSA-CSR.pdf>

<sup>167</sup> <https://chesar.echa.europa.eu/>

<sup>168</sup>

[https://echa.europa.eu/documents/10162/3048539/FINAL\\_MB\\_07\\_2018\\_Reach\\_Review\\_MB49.pdf/25727c6a-eb9b-c533-bdae-eb83e6fc83e](https://echa.europa.eu/documents/10162/3048539/FINAL_MB_07_2018_Reach_Review_MB49.pdf/25727c6a-eb9b-c533-bdae-eb83e6fc83e)

information needs to be manually transferred into the recipients' IT systems. This is not only inefficient but also prone to clerical errors. Modern IT systems should meanwhile be capable to allow the automated integration of information, if it was communicated in a harmonised format. Furthermore, paper and PDF versions do not facilitate automated checks by national enforcement authorities either (e.g., for completeness and consistency), nor easily allow downstream recipients of the SDS to electronically process the safety data of the chemicals they purchase, including targeted extraction for certain tasks at company level, e.g. risk assessment under Occupational Health and Safety (OSH) legislation. Even when SDS are provided electronically, there could still be barriers to the automation of checking and processing the data contained in the SDS, if human-readable formats (e.g., PDF) are used in favour of machine-readable data exchange formats (e.g., XML), and due to a lack of a single standardised exchange format that is used by all supply chain actors. In addition, the paper/PDF approach is not in line with the Digital Strategy that wants digitalisation to improve competitiveness of EU businesses.

Costs and other issues associated with SDSs have been a particular issue for SMEs. In the Wood (2021) report<sup>169</sup>, EU businesses were surveyed on the cost obligations for SDS preparation. It was reported by SMEs<sup>170</sup> that completing SDSs was a significant cost for businesses and SMEs often lack the in-house expertise to complete the SDS.

The lack of accuracy and clarity in the communication of uses and risk management measures, up and down the supply chain, may negatively affect the control of risks associated to the use of chemicals<sup>171</sup>. Therefore, the efficiency of the supply chain communication through SDS needs to be improved<sup>172</sup>.

## 2.2 Drivers to the problem

Current inefficiencies in supply chain communication via SDS are driven by a range of factors. The information contained in the SDSs is not always of appropriate quality to apply the required operational conditions and risk management measures to be implemented in the workplace. Also, the information in the SDSs is not standardised. One driver of this problem is technological development and societal changes. When the existing SDS system, internationally harmonised under UN-GHS, was incorporated into REACH, IT technology was not as advanced and the use of software to manage SDS was not as widespread as today. Furthermore, there was not as much integration into IT systems and the use of electronic devices at the end-user side was only in its infancy.

Costs surrounding the preparation and maintenance of SDSs are reported to be a significant driver for the inefficiency of supply chain communication. The main cost

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<sup>169</sup> European Commission (2021). Study on the impacts of the 2018 REACH registration deadline. Final report. Written by Kastalie Bougas, Leonie Constantine, Caspar Corden, David Tyrer (Wood), Julia Lietzmann, Lise Oulès (Milieu Consulting Sprl) and Oliver Warwick (PFA-Brussels). May – 2021.

<sup>170</sup> This was reported by 60% of medium companies, (30 out of 49 in the survey sample) and 44% of small companies, (10 out of 23 in the survey sample)

<sup>171</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en)

<sup>172</sup> European Commission (2021). Inception Impact Assessment: Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals. [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Revision-of-EU-legislation-on-registration-evaluation-authorisation-and-restriction-of-chemicals\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Revision-of-EU-legislation-on-registration-evaluation-authorisation-and-restriction-of-chemicals_en)

drivers for companies communicating information in the supply chain were: the staff costs for the preparation and/or handling of (extended) SDS; the investment in IT systems; and the time-consuming nature of communication in the supply chain<sup>173</sup>.

### 2.3 Scale of the problem

The 2018 REACH Review referenced findings for the period 2007-2014, of 52% non-compliance for SDS, as seen through enforcement actions<sup>174</sup>. Two Dutch studies, referenced in the 2018 REACH Review reported that 25-50% of Dutch companies that participated in a survey did not have any SDSs, or that those they did have were outdated. Also, 75% of the SDSs examined (in the Dutch studies) were considered to be of poor quality<sup>175</sup>.

Initial costs for SDS preparation have been reported to range from €200 to over €500<sup>176</sup> for an extended version (see the Wood study (2021)<sup>177</sup>, representing the most recent data). However, the REACH review (based on CSES 2015<sup>178</sup>) reported costs of €6 000 for an eSDS and costs as high as €50,000 also for an eSDS have been reported<sup>179</sup>, although such higher figures were less likely to occur, and would be in the case of translation into all European languages and for the preparation of SDS for a portfolio of substances<sup>180</sup>. IT systems are often purchased by firms to support the handling of SDS with costs ranging from a few thousand euros to more than a million depending on the size of the firm<sup>181</sup>. These IT costs should mostly be considered as one off but there are still aspects that will incur on-going costs, as companies will have to update the IT software.

In a survey (sample size: 1,601 companies) (CSES 2012<sup>182</sup> quoted in the Wood study 2021<sup>183</sup>) companies considered costs associated with communication obligations and data requirements as the main drivers for the costs incurred by companies communicating information in the supply chain as required for the first REACH registration deadline. Such issues are complicated data requirements associated with communication

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<sup>173</sup> European Commission (2021). Study on the impacts of the 2018 REACH registration deadline. Final report. Written by Kastalie Bougas, Leonie Constantine, Caspar Corden, David Tyrer (Wood), Julia Lietzmann, Lise Oulès (Milieu Consulting Sprl) and Oliver Warwick (PFA-Brussels). May – 2021.

<sup>174</sup> SWD(2018) 58 final

<sup>175</sup> Impact of REACH on SMEs by Panteia and IVAM (2013) analysing the situation of SDSs and a survey performed by the Dutch Workplace Inspectorate (SWZ) in 2014-2015 in SWD(2018) 58 final

<sup>176</sup> Centre for Strategy & Evaluation Services (CSES). (2012). Interim Evaluation: Functioning of the European chemical market after the introduction of REACH. Sevenoaks: United Kingdom.

<sup>177</sup> European Commission (2021). Study on the impacts of the 2018 REACH registration deadline. Final report. Written by Kastalie Bougas, Leonie Constantine, Caspar Corden, David Tyrer (Wood), Julia Lietzmann, Lise Oulès (Milieu Consulting Sprl) and Oliver Warwick (PFA-Brussels). May – 2021

<sup>178</sup> Centre for Strategy & Evaluation Services (CSES). (2015). Monitoring the impacts of REACH on innovation and competitiveness. Brussels: European Commission

<sup>179</sup> European Commission (2021). Study on the impacts of the 2018 REACH registration deadline. Final report. Written by Kastalie Bougas, Leonie Constantine, Caspar Corden, David Tyrer (Wood), Julia Lietzmann, Lise Oulès (Milieu Consulting Sprl) and Oliver Warwick (PFA-Brussels). May – 2021.

<sup>180</sup> As above

<sup>181</sup> As above

<sup>182</sup> [https://ec.europa.eu/environment/chemicals/reach/pdf/studies\\_review2012/report\\_study7.pdf](https://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study7.pdf)

<sup>183</sup> European Commission (2021). Study on the impacts of the 2018 REACH registration deadline. Final report. Written by Kastalie Bougas, Leonie Constantine, Caspar Corden, David Tyrer (Wood), Julia Lietzmann, Lise Oulès (Milieu Consulting Sprl) and Oliver Warwick (PFA-Brussels). May – 2021.

requirements (79% of respondents agreed strongly or slightly) and understanding the communication obligations (73% of respondents agreed). While 26 % of large companies strongly agreed that this was a major cost, the share was higher the smaller the company was, with micro-companies having 46% of respondents that strongly agreed.

## **2.4 How likely is the problem to persist?**

It is likely that the problems mentioned earlier in this document will persist, if no change occurs on how SDSs are prepared and communicated. Experience showed that without steering at EU level no substantial progress can be made. Without setting up a harmonised set of criteria for exchange formats, it is likely that the market will remain fragmented, and that software will not be fully compatible leading to unnecessary burden and inefficiencies.

## **3 POTENTIAL OPTIONS/ MEASURES**

### **3.1 Baseline – no change scenario**

In a no change scenario (the baseline), an SDS is still mandatorily provided by the supplier in a paper format or electronically (in any electronic form), as required by article 31(8) of REACH. Problems identified earlier, especially as complexity, time-consumption and expensive creation but also maintenance of SDSs, likely continue to occur. The paper format does not allow for easy electronic checks by National Authorities, nor does it allow downstream users to process the necessary data automatically.

In the baseline scenario the currently ongoing non-legislative actions and initiatives (e.g. ENES, REACH2 SDS<sup>184</sup>) will continue. In the event that in future harmonised electronic formats will be developed under an implementing act, the continued possibility to provide SDS alternatively in paper format could undermine the development of more automated exchanges between suppliers and recipients of SDS.

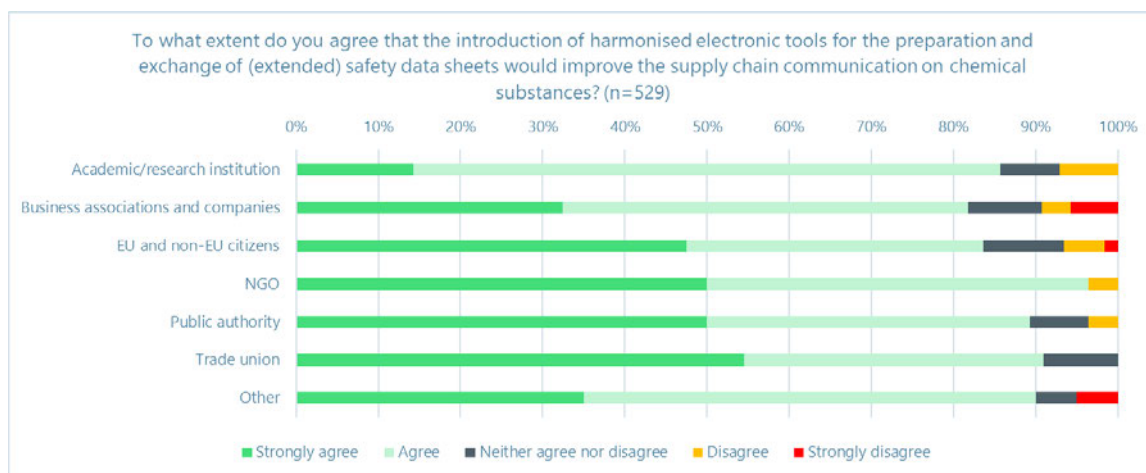
### **3.2 Alternative options**

Results from the public consultation show that a large majority of respondents (close to 85%, across all stakeholder categories) agree or strongly agree that the introduction of harmonised electronic tools for the preparation and exchange of (extended) SDS would improve the supply chain communication on chemical substances. Only around 8% disagree, or strongly disagree.

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<sup>184</sup> <https://www.baua.de/EN/Service/Publications/Report/REACH2SDS-2.html>

Table 134: Results from the public consultation on the introduction of harmonised electronic tools for SDS, Wood



In this context, the following policy options are considered to introduce harmonised electronic tools for supply chain communications:

**Option #10:** Supplier obliged to provide electronic format, with possibility for recipients to request paper version;

**Option #11:** Harmonised format in electronic version only

**Option #10: Supplier obliged to provide electronic format, with possibility for recipients to request paper version**

This option involves amending the current provisions on SDS formats to require the provision of the submission of the SDS by the supplier of an SDS to customers in (any) electronic format. Making the provision of the SDS in (any) electronic format mandatory would require a change to Articles 31(8), 31(9), 32(2) and 32(3) of REACH.

Under this option the dissemination of SDS in an electronic format will become the default option, and there will no longer be the possibility to provide the SDS in paper format only. However, upon request by the recipient of the SDS, it shall also be provided in a paper format free of charge and without unnecessary delay.

Furthermore, Option #10 will include the empowerment of the Commission to establish a harmonised exchange format within Annex II to REACH. This will leave open the possibility to introduce a provision in the future that requires the mandatory use of a harmonised exchange format (extended mark-up language XML or other) when submitting SDSs to customers in an electronic format via an implementing act.

**Option #11: Harmonised format in electronic version only**

Option #11 is identical with Option #10 with the exception that the electronic data exchange format will be mandatory and harmonised (e.g. XML), so other electronic formats (e.g. human readable electronic formats such as PDF) will not be allowed anymore. In this option, providing paper copies by the supplier to the recipients upon request will not be foreseen, so recipients will have to print paper

copies themselves in case they need it. Making the provision of the SDS only in a harmonised electronic format mandatory would require changes to Articles 31(8), 31(9), 32(2) and 32(3) of REACH and an empowerment of the Commission to establish a harmonised exchange format. Under this option, it is assumed that the Commission will use this empowerment.

In doing so, companies would use common data exchange standard (e.g. XML) formats for company-to-company electronic communication of safety data in the supply chain. The aim of the common data exchange standard would be to improve workability (including simplification) of supply chain communication.

The following table summarises the options and their key requirements regarding the obligatory medium (paper/electronic) for submission of SDS and whether there is an obligatory harmonised format for electronic submission.

*Table 135: Comparison of options*

<b>Option</b>	<b>Description</b>	<b>Obligatory medium of submission (paper/electronic)</b>	<b>Obligatory harmonised format for electronic submissions (yes/no)</b>
Baseline		Paper <u>or</u> electronic	No
Option #10	Supplier obliged to provide electronic format, with the possibility for recipients to request paper version.	Electronic (in any form) ( <u>and</u> paper only if so requested by the recipient of the SDS)	No
Option #11	Harmonised format in electronic version only	Electronic (harmonised)	Yes







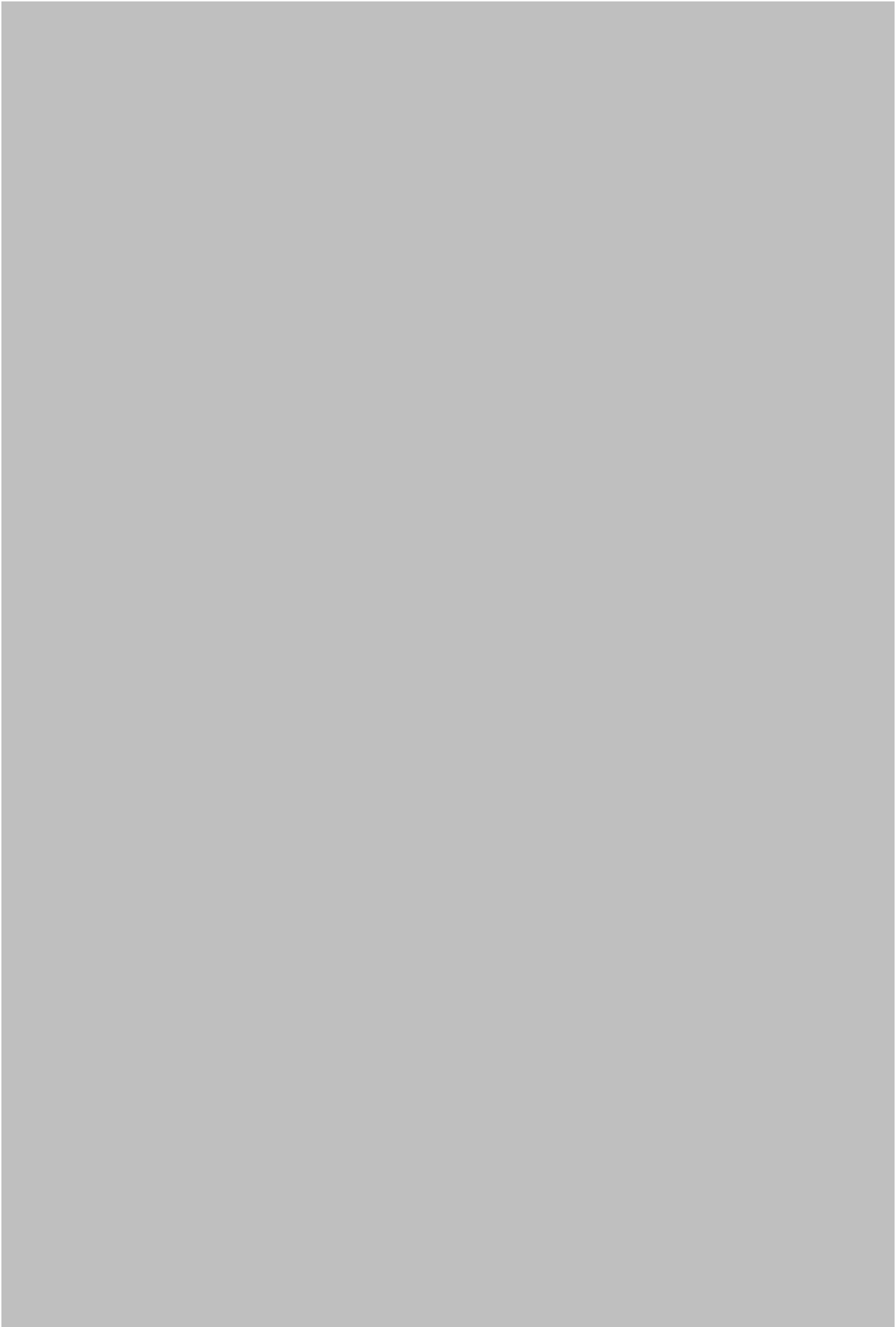


















## ANNEX 9: REQUEST A CHEMICAL SAFETY ASSESSMENT FOR 1-10 TONNES SUBSTANCES

This Annex presents a measure to request a chemical safety assessment for substances registered in quantities of 1-100 tonnes per year. This measure is not presented in the main text of the SWD as it is of a more technical nature and does not imply major policy choices.

### 1 CONTEXT

REACH defines in its Article 14 the duty for manufacturers/importers to perform a chemical safety assessment (CSA), which is documented in a chemical safety report (CSR) and to apply and recommend risk reduction measures in the supply chain. Currently this obligation exists for substances registered at 10 tonnes or more per year per registrant. Article 138 of REACH provides for a number of reviews to be carried out by the European Commission. Article 138 paragraph (1) stipulates a review of this duty, notably *“to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report for substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity, or reproductive toxicity, not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year”*.

For the group of 1-10 tonnes substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity, or reproductive toxicity, the review of this obligation has already been carried out and been published in the Staff Working Document 247 (European Commission, 2020) in 2020 together with the Chemicals Strategy for Sustainability (CSS), and is summarised again here. The review of this obligation for all other (non-CMR) substances manufactured or imported in quantities of less than 10 tonnes per year is reported in this Annex. The review is based upon the Technical Note “Assessment of the impacts of policy options for increased information requirements” by Wood (Wood, Assessment of the impacts of policy options for increased REACH information requirements, 2022).

### 2 DESCRIPTION OF THE PROBLEM

One of the problems identified in the CSS are unaddressed risks for health and the environment from chemicals. More specifically, in problem A5 it is called out that information in the **chemical safety assessment** provided in the registration dossiers does not allow to adequately address the risks from all substances. This is of course especially true for the substances at a tonnage of less than 10 tons/year for which the conduct of a chemical safety assessment and documentation in a chemical safety report is not an obligation based on current REACH provisions.

The CSR is a key instrument in communicating appropriate risk management measures in the supply chain. Where a CSR is not available, the downstream users of a substance only have more general information and advice available from the Safety Data Sheet (SDS).

According to the process established under Article 14 and the corresponding detailed requirements set out in Annex I of REACH, the CSA must include for all substances an

assessment of the human health hazards, physicochemical hazards, environmental hazards and a PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent, very bioaccumulative) assessment. For substances fulfilling the criteria for certain hazard classes as per Article 14(4), or for those assessed as PBT or vPvB, the CSA must in addition include an exposure assessment and a risk characterisation.

When the REACH Regulation went into force, it did not mandate the CSA/CSR for 1-10 tonnes substances in order to limit the burden for registrants of substances at this low tonnage level, many of which were deemed to be SMEs<sup>203</sup> (small to medium sized enterprises). Another side to the problem is that the information that is available for substances in the 1-10 tonnes/year range based on the current standard information requirements is limited and hence the conclusions possible to be drawn in a chemical safety assessment are limited compared to higher tonnage substances. This latter side of the problem is further elaborated in Annex 5 of this SWD.

### **3 POTENTIAL POLICY OPTION AND SUB-OPTIONS**

#### **3.1 Baseline – no change scenario**

The baseline scenario is one in which the current REACH requirements for a chemical safety assessment apply, i.e. that it is only required for substances registered at Annex VIII level and higher but not for those at Annex VII level (1-10 tonnes/year).

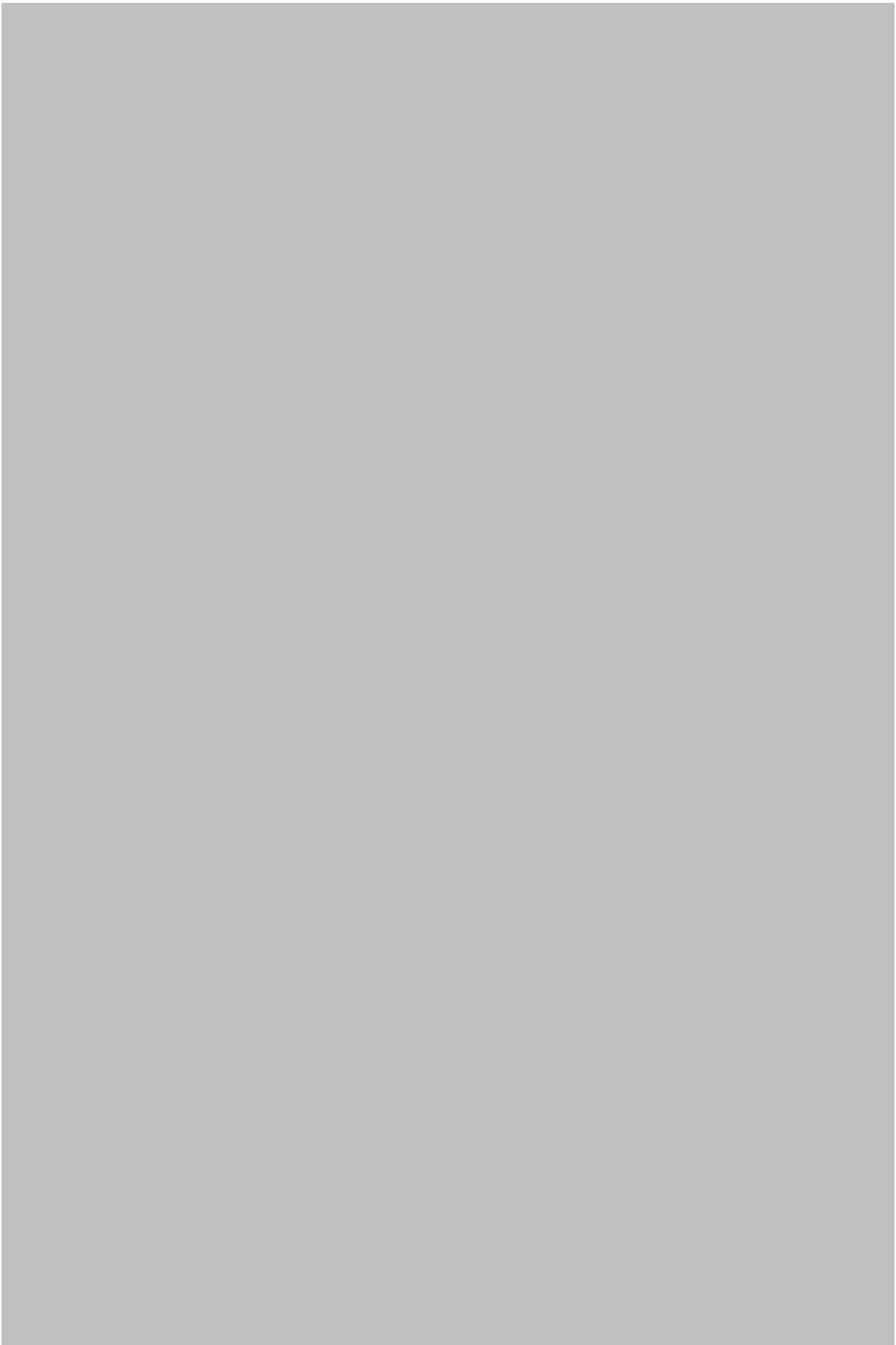
#### **3.2 Policy Option A5 - Sub-option #12: request a chemical safety assessment for all low tonnage substances (1-10t)**

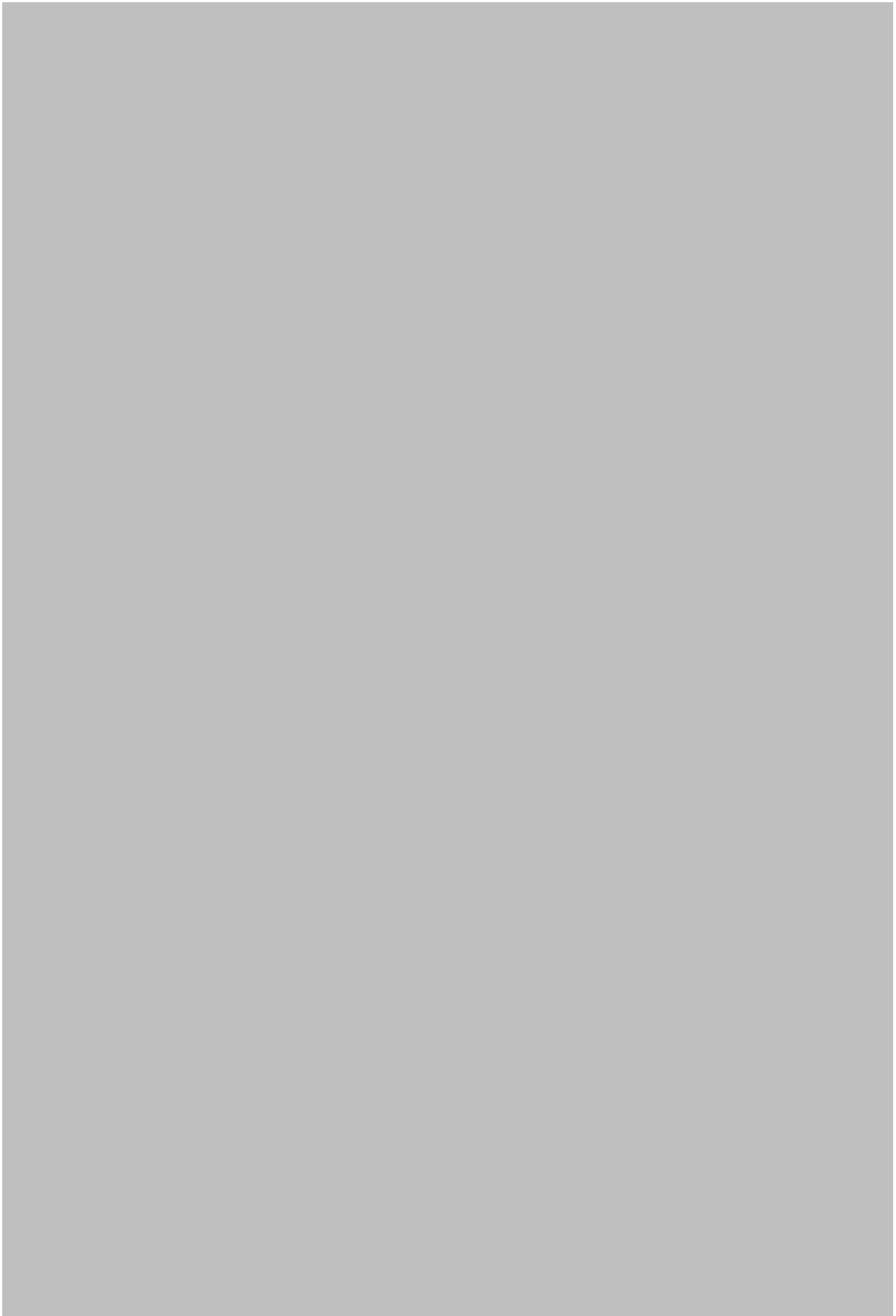
Based on the experience of having a CSA for substances in higher tonnages and the findings in the study by Wood cited above, as well as a previous study considering the costs and benefits of extending the obligation for a CSA/CSR also to the low tonnage substances (RPA, Gather further information to be used in support of an Impact Assessment of potential options, in particular possible amendments of REACH Annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement, 2020), there was only one policy option identified: to request a chemical safety assessment for all 1-10 tonnes substances.

Requesting registrants of these substances to also provide a CSA/CSR would allow for the full achievement of the overall objectives of the REACH registration process by increasing the level of information on substances, on their associated uses and their exposures, and by making this information available to all downstream users.

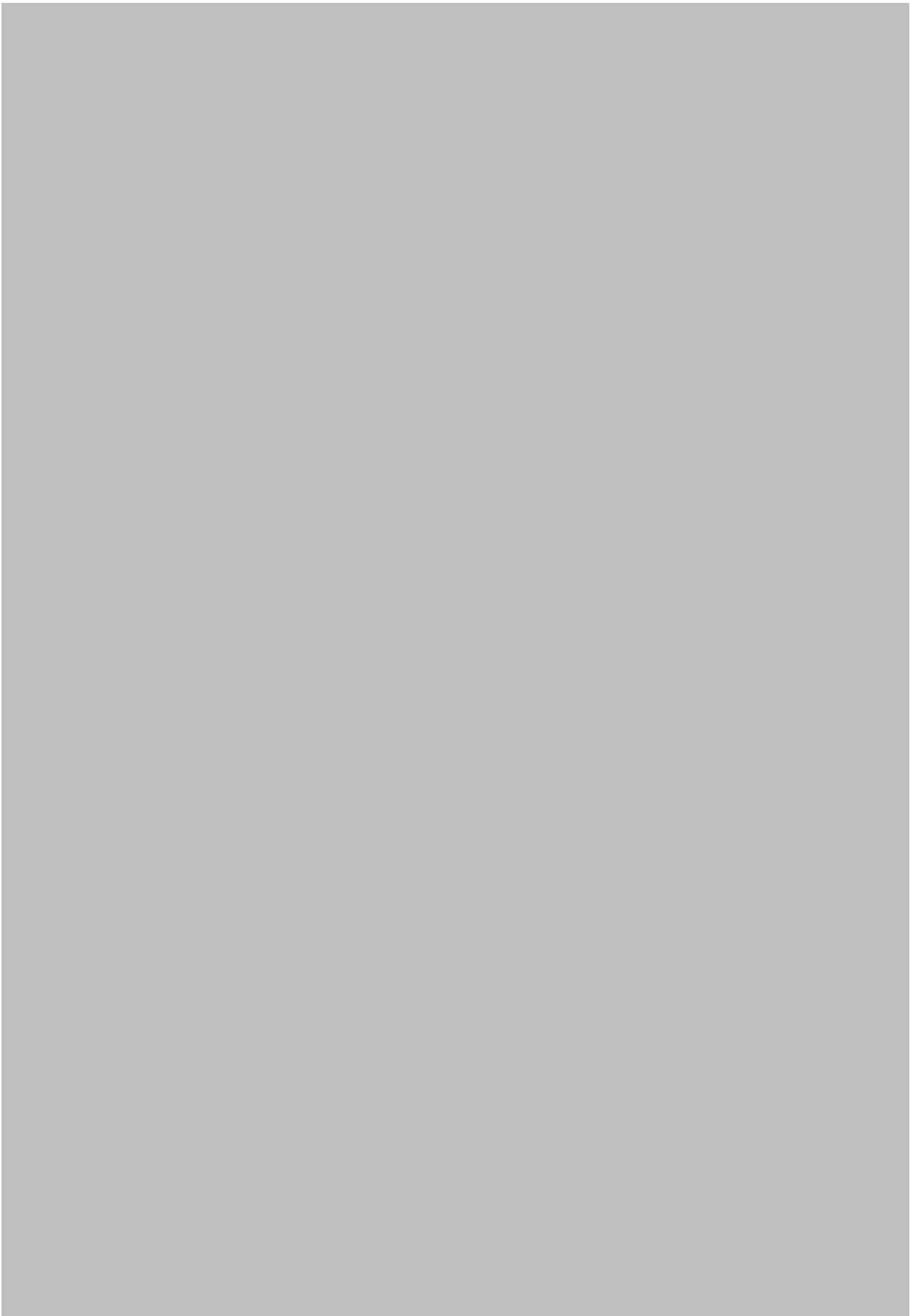
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<sup>203</sup> This assumption from the time REACH went into force has been proven wrong after the last registration deadline of 2018. The majority of 1-10 tonnes substances are registered by large companies.







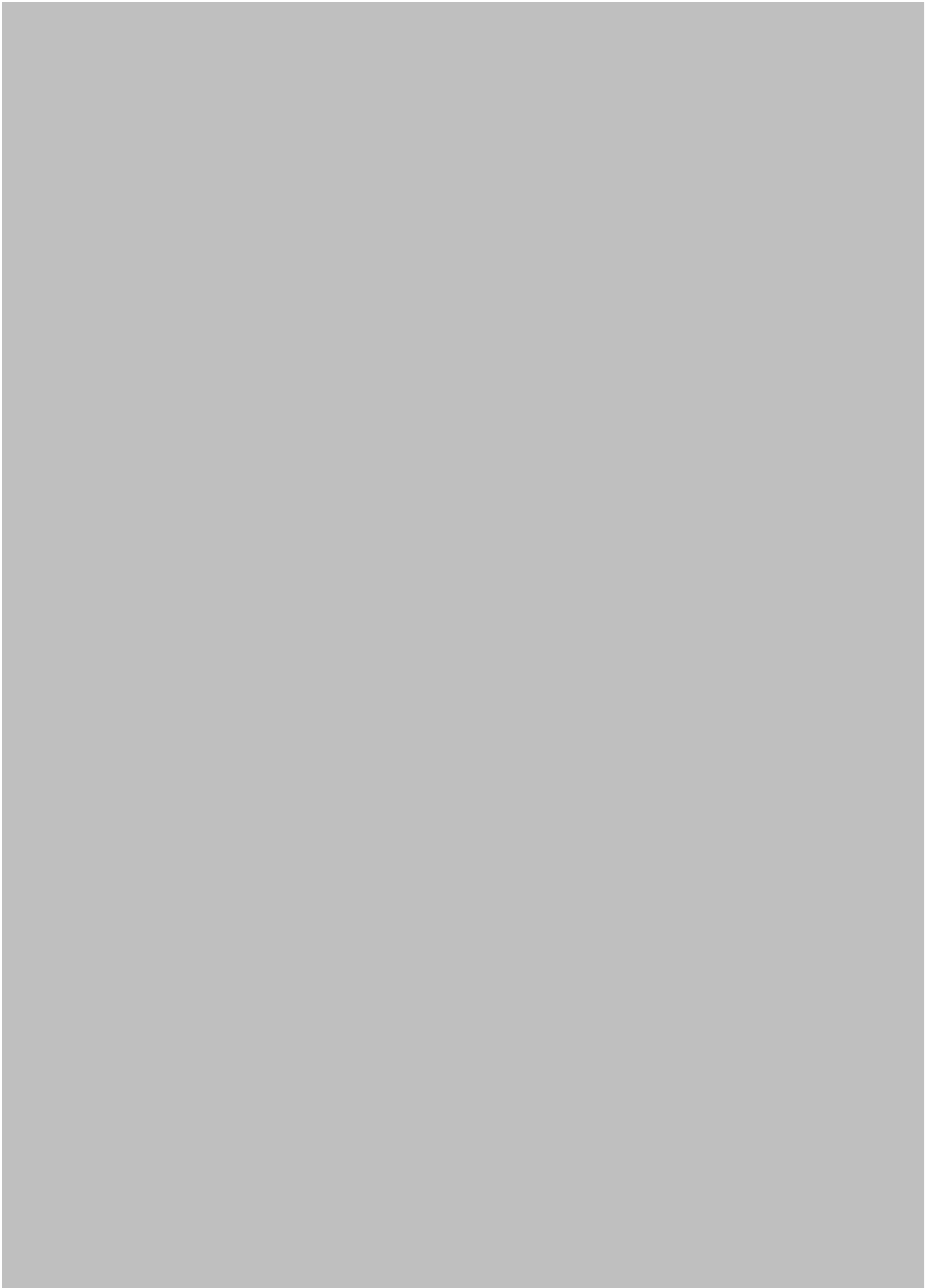




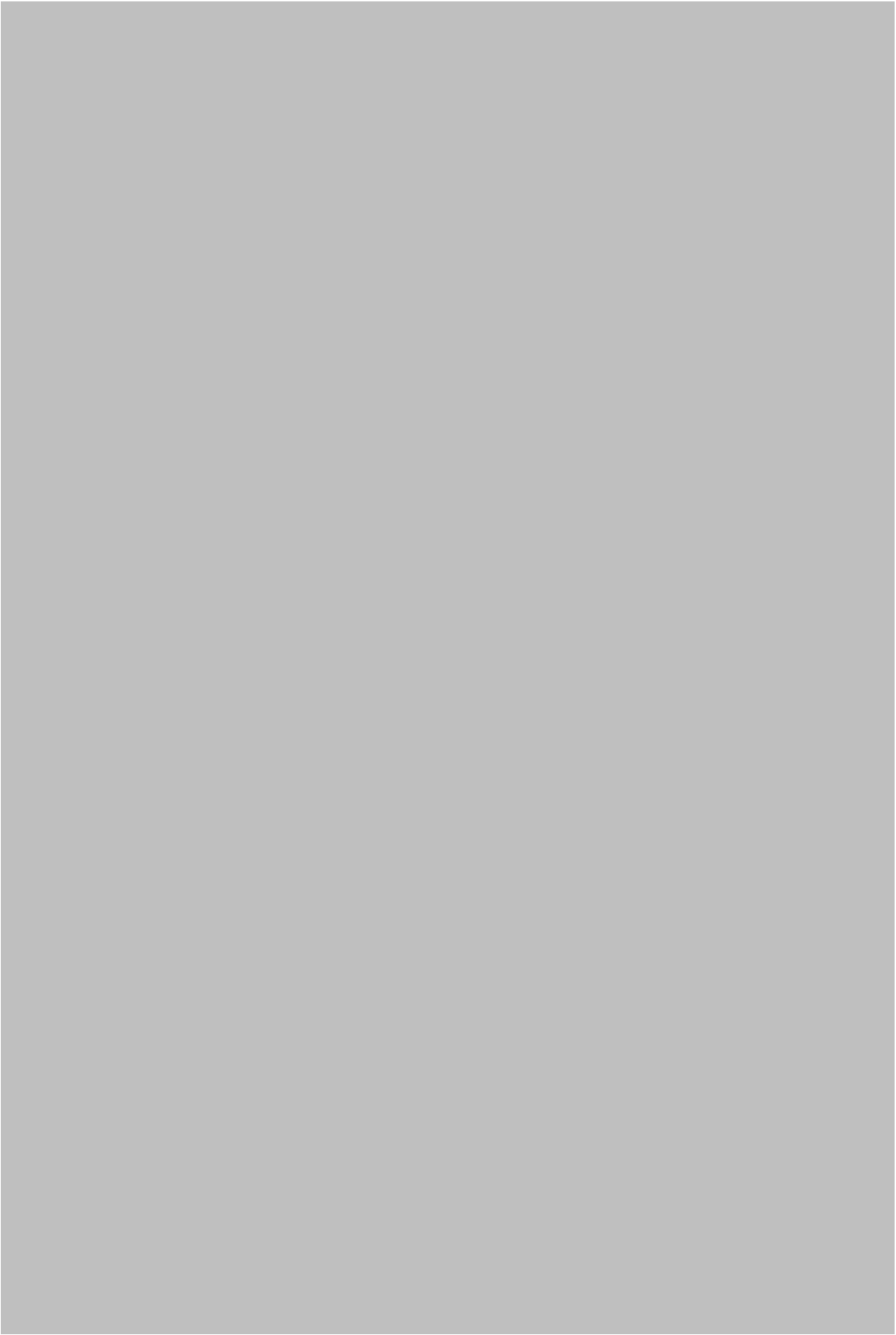


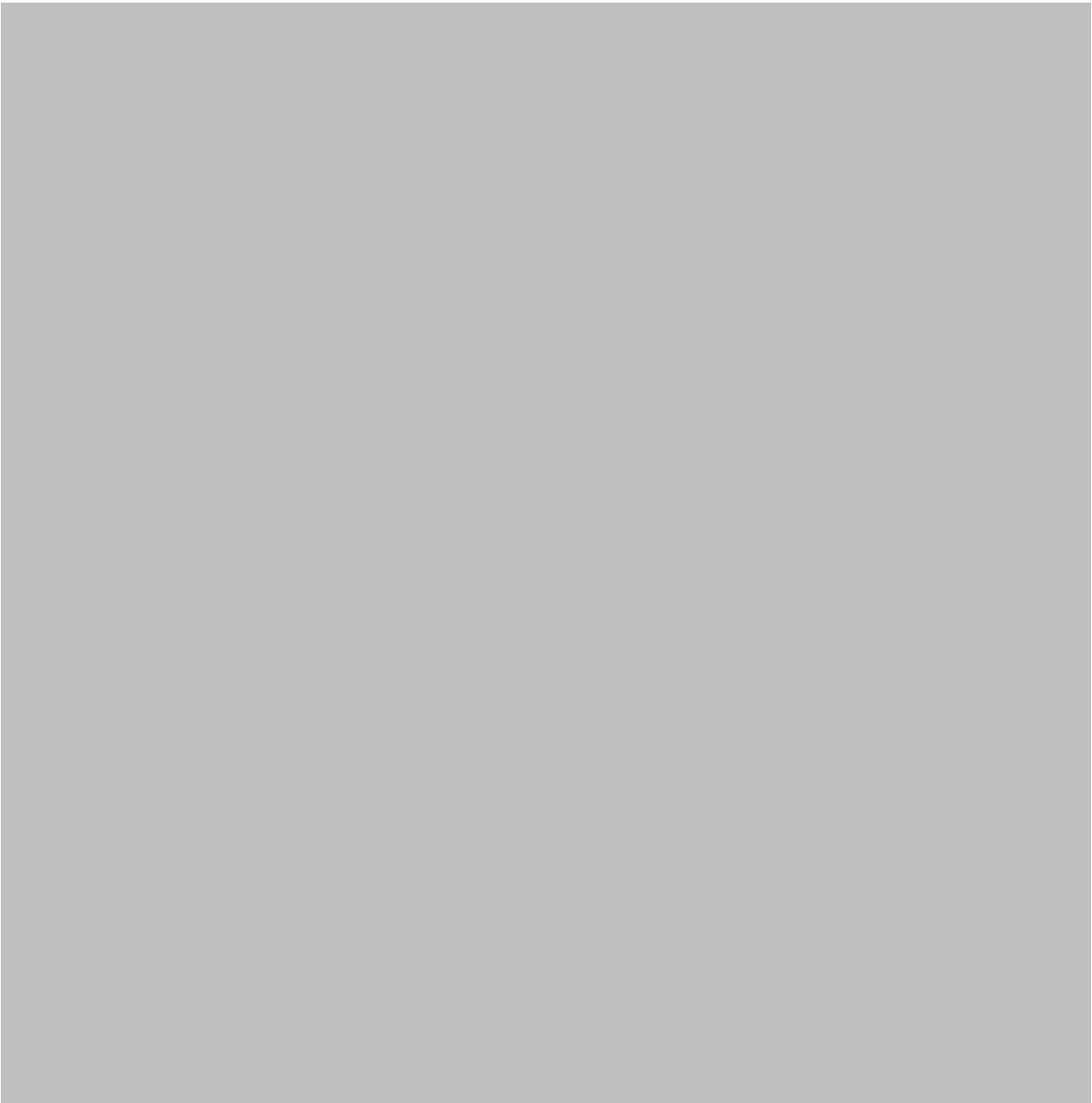












# **ANNEX 10: INTRODUCE MIXTURE ASSESSMENT FACTOR(S) IN THE CHEMICAL SAFETY ASSESSMENT TAKING INTO ACCOUNT THE COMBINATION EFFECT OF CHEMICALS**

## **1 CONTEXT**

Throughout our lives we are exposed simultaneously to a variety of substances, contained in food, water, medicines, the air we breathe, cosmetics and health care products, shoes, clothing and other consumer products. In the natural environment, living organisms are also exposed to a complex cocktail of chemical substances. A growing body of scientific evidence shows that some of these co-exposures represent risks to humans and the environment.

The current regulatory approaches to the assessment of substances are predominantly based on the evaluation of single substances or of so called intentional mixtures (i.e. mixtures of known composition such as cosmetic products). Requirements to consider unintentional mixtures are broadly absent in legislation oriented towards substances and intentional/commercial mixtures. Explicit requirements for the assessment of unintentional mixtures (i.e. cumulative effects) exist only in the directive on the protection of the health and safety of workers from the risks related to chemical agents at work and the regulation on Maximum Residue Levels of pesticides in food and feed, the Plant Protection Products and the Biocidal Products Regulations require to consider cumulative and synergistic effects. Implementation of the requirements in the regulation on Maximum Residue Levels of pesticides in food and feed and in the Plant Protection Products regulation has however not yet started, as the methodology for considering cumulative and synergistic effects is still under development.

In order to adequately address the combination effects of substances in mixtures, legal requirements need to be consistently in place to ensure that risks from simultaneous exposure to multiple substances (unintentional mixtures) are effectively and systematically taken into account across chemicals-related policy areas. In particular, there is a need to introduce or strengthen provisions to take account of unintentional mixtures in relevant pieces of legislation, such as REACH, water, food additives, toys, food contact materials, detergents and cosmetics.

In the current situation, where knowledge and availability of toxicity and exposure information on unintentional mixtures and mixture components is, and possibly will remain for a long time ahead, fragmented and insufficient, there is a need to apply practical and workable approaches. The application of a mixture assessment factor (MAF) seems to be the most pertinent approach for industrial substances under REACH, but it is applicable also to other regulatory areas, where the available data are insufficient to allow an assessment of actual co-exposure situations.

When applying a MAF, exposure levels that are considered sufficiently safe for individual substances are reduced by a certain factor (i.e. by MAF) to safeguard against risk from combined exposure to multiple and largely unknown substances. Hence, the MAF approach takes into account that the individual substance in real-life will be a component of a mixture as soon as it is released into the environment or taken up in the body and that humans and wild organisms will be exposed to such mixtures of different

substances, all contributing to the risk. The application of the MAF in chemicals safety assessment would target those substances and uses that contribute the most to the toxicity of the mixture (i.e. uses of substances with a high toxicity and/or a high exposure, and accordingly a high Risk Quotient). The MAF is proposed to be a pragmatic way of addressing unintentional mixtures where sufficient knowledge or data on co-exposure to largely unknown substances are not available to allow an assessment of actual co-exposure situations. In specific cases where such knowledge or data are available, the MAF can be replaced by scenario- or substance-specific factors or by more specific and targeted methodologies, including for substances with similar or different modes of action.

The appropriate numerical value of the MAF is subject to a scientific discussion and different magnitudes have been proposed for its use in different contexts. Further ongoing discussions relate to whether the value of the MAF can be and should be differentiated. Additional ongoing discussion is related to at what stage of risk assessment should the MAF be applied (to the Derived No-Effect Level (DNEL) and Predicted No-Effect Concentration (PNEC) or to the Risk Quotient). Another question is how to use the MAF for substances for which no dose or concentration threshold below which no toxic response occurs, can be established (so-called ‘non-threshold substances’).

The MAF approach has been already successfully applied for regulatory purposes. In the USA (Congress, 1996), a ‘risk cup’ approach is applied for pesticides under the Food Quality Protection Act. This approach is also the basis for the allocation factors used for the relative source allocation during the setting of drinking water standards by the World Health Organisation (WHO, 2017). An example from the EU is the use of a MAF for the derivation of environmental quality criteria for single substances in the Netherlands (Verbruggen, 2007).

Under REACH, registrants are required to document adequate control of risks for all uses of their substances. REACH Annex I describes the approach that a registrant could employ in developing exposure scenarios for his chemical safety assessment (CSA). A CSA with exposure assessment and risk characterisation is required for all substances registered in a quantity of greater than or equal to 10 tonnes per year and fulfilling the criteria for hazard classification according to the CLP Regulation or for being a PBT or a vPvB substance. This applies to about 20% of the substances registered under REACH (i.e. approx. 4,600 out of more than 21,000 substances). Apart from some carcinogens, mutagens, respiratory sensitizers, endocrine disruptors, PBTs and vPvBs for which no ‘safe levels’ (i.e. Derived No-Effect Level for human health, DNEL, or Predicted No-Effect Concentration, PNEC, for the environment) are currently available, control of risk is demonstrated in a quantitative manner: the exposure estimates for the various uses of a substance are divided by the appropriate DNEL or PNEC. If the quotient (Risk Characterisation Ratio, RCR) is below or equal to 1, risks are considered adequately controlled, and no additional risk management is needed.

If initial assumptions about the operational conditions and risk management measures are not sufficient for demonstrating adequate control, an iterative process may be used with amendment of one or more factors in the hazard and exposure assessment. The refinement of the hazard assessment would typically require additional testing allowing a more precise assessment of the ‘safe level’. The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures



in the exposure scenario, more data on the fate of the substance in the environment or more precise and realistic exposure estimation. The iterative process should be continued until adequate control of risks is demonstrated.

The introduction of a MAF in REACH would lead to re-opening the assessments in the existing chemical safety reports (CSRs) submitted as part of the registrations. Two different scenarios can be considered:

1. The existing assessment demonstrates exposure levels that are far below the DNELs and PNECs for that substance, e.g.  $RCR < 1/MAF$ . For such substances, a MAF could be absorbed within the existing assessment, hence no significant impact is expected.
2. The existing assessment demonstrates control of risk at an RCR level in the interval of  $1/MAF$  to 1, and hence the introduction of a MAF would push the RCR above 1, with the consequence that the registrant would need to re-open his assessment.

The real impact in the latter case in terms of triggering the need to introduce more risk management measures or withdrawal of certain uses by industry, however, depends on the type of assessment that had been carried out and to the extent of risk management that was required (assumed) to arrive at an RCR below or equal to 1. If a 'safe level' has been derived based on few hazard data, additional data may allow the use of lower assessment factors leading to more precise and realistic DNELs or PNECs. If a conservative exposure estimation model had been used (Tier 1 tool), the assessment may be adapted to MAF by switching to a higher tier exposure model or measured exposure data; however, without introducing additional risk management measures. Or as an alternative, operational conditions and risk management measures are adapted within the lower tier assessment and communicated further down the supply chain. The most used tool by registrants (ECETOC TRA) provides refinement options to reduce exposure by a factor of up to 10 000. More than 75% of occupational exposure assessments in REACH CSRs are based on this tool.

If, however, the pre-MAF assessment for documenting that risks are adequately controlled already required the use of DNELs or PNECs based on comprehensive hazard data, higher tier exposure models, measured exposure data and/or stringent risk management, the room for absorbing the MAF without significant impact (i.e. introduction of more stringent risk management measures or even limiting the uses of the substance) is much smaller. In reality, such substances are also those that contribute most to the risk of unintentional mixtures.

Due to the iterative nature of the CSA requiring the registrants to document that risks are adequately controlled, it is assumed that RCR for quite a number of uses in existing registrations, although below a value of 1, are close to 1, e.g. in the range of 0.1 to 1. Even though some registrants could absorb the change by conducting higher tier assessments without having to introduce additional risk management measures, which means that the costs could be relatively limited, some might have to conduct long-term testing, which depending on the type of test may be costly. Other registrants that have already used the option of using higher tier assessment methods based on comprehensive hazard and exposure data would probably have to introduce changes to uses, operational conditions and risk management measures, which might bring additional costs. Thus, the possible impact of introducing a MAF on the costs to registrants will depend on the size

of the MAF, on the number of uses that will no longer be adequately controlled, on the robustness of the current CSAs, and on the number of changes to the uses, the operational conditions and the risk management measures that are required for establishing adequate control.

Finally, the purpose of introducing a MAF is to improve the level of protection of health and the environment by reducing the overall chemical pressure. This is done by reducing the exposure to those substances that are drivers of the risk, i.e. those with risk quotients greater than  $1/MAF$ . Thus, the higher the MAF, the larger the improvement of the protection level.

In this context, substances for which no toxicological threshold can be established (including most carcinogens, endocrine disruptors, PBT/vPvBs), which does not allow the derivation of a DNEL or a PNEC, deserve a special attention. For some of those hazard classes, it might be possible to derive a dose-response relationship allowing for a quantitative risk assessment (e.g. for some carcinogens), while for others no methodology for a quantitative risk assessment has yet been derived (e.g. for PBT/vPvBs). For endocrine disruptors, the presence of a toxicological threshold is disputed. Nevertheless, those hazard classes also contribute to the risks resulting from exposure to unintentional mixtures and options for addressing such effects might be needed.

## **2 DESCRIPTION OF THE PROBLEM**

### **Description of the problems**

Substances co-occur in the environment and in people. Exposure to only a single substance does not exist in the real world, yet this is what is essentially assumed in REACH chemical safety assessments. Dozens or even hundreds of substances may occur in an environmental compartment, in products that we are using, in the indoor environments where we live and could be accumulated in the human body. Chemical composition of the mixtures and their risks are highly dynamic across time and space.

While only a comparatively small number of substances (typically well below 10%) occur at concentrations that exceed their individually “safe” level, in combination, they may still lead to unsafe levels. EFSA’s Scientific Committee (2019)<sup>211</sup> has analysed the available evidence and concluded that dose addition (and concentration addition) usually produces the most conservative prediction, and therefore this approach is preferred in decision-making processes in the context of health or environmental protection, and selected as the default model. In contrast, the use of response addition requires knowledge on the precise effect magnitude that each component would provoke if present individually at the concentration found in the mixture. This information is only accessible through comprehensive dose–response analysis of each mixture component. Such data are not readily available in practice, neither for human nor ecological assessments. Dose addition is therefore adopted as the default assessment approach,

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<sup>211</sup> EFSA Scientific Committee (2019). Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5634>

unless there is evidence that response addition is more appropriate and the necessary data to apply response addition are available or can be easily gathered.

Although the EFSA recommendation applies to risk assessment of mixtures of known composition, this would also apply to the situation under REACH, where individual registrants in practice would have no information on which other substances that might be present together with the registrants' substances. Thus, dose or concentration additivity is used as the basis for developing a MAF for general applicability.

Not every mixture causes an unacceptable risk. However, such risks cannot be ruled out purely on the basis of comparison of individual substance concentrations with the corresponding no-effect thresholds (PNECs, DNELs).

Progress is being made in understanding mixture risks such as through advanced mixture models. However, due to excessive data demands, these are limited to very specific situations, usually involving only a few well characterised and data-rich substances tested in biologically well-known test organisms.

One means of understanding the extent to which risks from mixtures may occur is to consider the sum (across all substances present) of all of the "risk characterisation ratios" (RCR)<sup>212</sup>, i.e. the ratio between the exposure level and the safe level.

Humans and the environment are exposed to substances in a range of unintentional mixtures over time because of the large number of substances on the EU market, their extensive range of uses, and the various emission sources and exposure routes. This is documented by monitoring and modelling studies, which have been carried out across Europe. A few examples of such studies that include large numbers of samples and substances are shown below.

#### ***Environmental risks: Cumulative risk characterisation of substances in European surface water catchments***

The first study describes the co-occurrence of 1 835 substances (industrial substances, pesticides, pharmaceuticals) in 2 223 European surface water catchments, based on an elaborate exposure modeling approach (van Gils, et al., 2020). Only the exposure data for the 1 791 industrial substances included in the paper by van Gils were used for the analysis below. Catchment 9727271 (excessively high exposure estimates) and all catchments with a surface area of less than 1000 km<sup>2</sup> (potentially unreliable exposure estimates) were omitted from the data analysis, resulting in a final pool of 416 catchments that were included in the analysis.

The hazard data that are needed for conducting an environmental risk assessment were retrieved from the study published by Posthuma (Posthuma, 2019) which provides species sensitivity distributions (SSDs) for all the encountered chemicals. These SSDs were used to determine the maximum concentration that does not put more than 5% of the potentially exposed species at risk, even under conditions of chronic exposure, the so-called HC5 concentration. The HC5 estimates from Posthuma (2019) were taken at face value.

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<sup>212</sup> This approach is assuming concentration-additivity.

The case study was selected for the following reasons:

- It provides a basis for a comparative assessment of all major European water bodies, using a consistent and comparable data basis.
- The number of mixture components provides, for the first time, a somewhat realistic approximation of the complexity of chemical exposures. Still, the 1 791 REACH substances included in the study represent less than 10% of the substances registered under REACH (12 785 full registration, including 9 572 substances that are (also) registered as intermediates (ECHA, 2021)).
- As the van Gils study is based on an exposure modeling approach, the exposure data are not censored by analytical detection levels, which allows for a more complete analysis.
- The HC5 concentrations that were used as environmental threshold values allow for a more unbiased analysis, in contrast to e.g. PNECs, which are “tainted” by different data sets and thus different assessment factors.

When interpreting the study results it should also be kept in mind that

- The exposure estimates critically depend on the input data used for the exposure modeling, in particular the assumed tonnage volumes. There is currently no way to estimate the reliability of these confidential data (van Gils, 2020).
- The HC5 estimates are partly based on only a few ecotoxicological data (Posthuma, 2019).
- The HC5 values were taken as direct estimates for the chronic hazard of the substances. That is, no additional assessment factors were applied, in order to avoid any systematic bias between data rich and data poor substances.

As long as issues 1 and 2 do not lead to systematic over or under estimates of the RCR values for a sizeable fraction of the substances included in the assessment, no major impact on the estimated cumulative risk is to be expected. Issue 3 leads to a systematic underestimation of the mixture risk. So does the fact that “only” roughly 10% of the REACH substances are included.

In the analysis, all concentrations for all substances were averaged across all 416 waterbodies by calculating the median concentration per substance. One substance (CAS 7396-58-9) was excluded from the data set due to unrealistically high production volumes used in the underlying exposure modeling. 1 347 substances co-occur in this “average European water body” with median RCR values above zero. The resulting distribution of the 15 substances with the highest risk quotients is presented in the figure below.

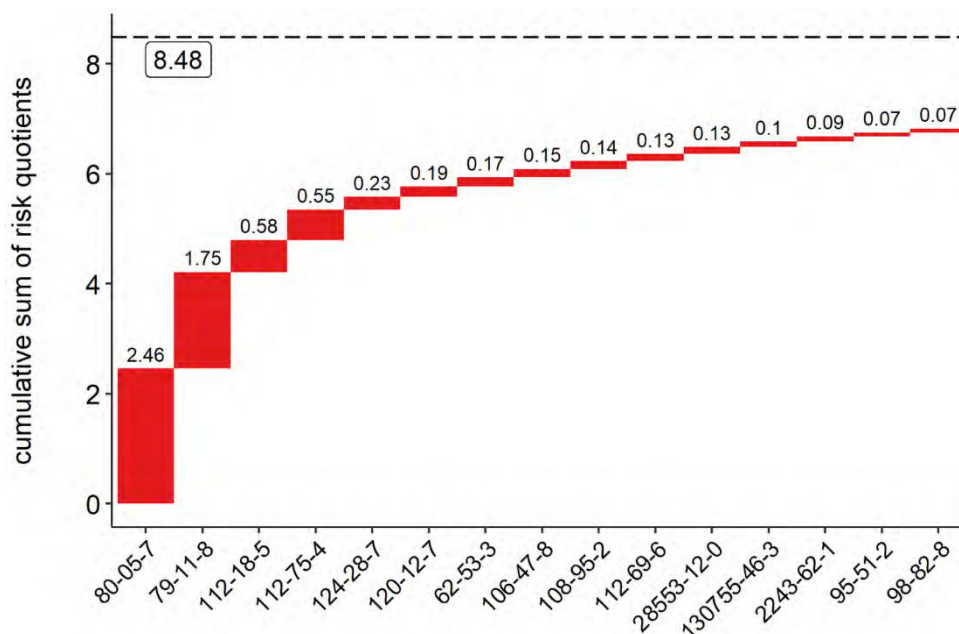


Figure 15: Distribution of RCR values of the top 15 of the 2 347 industrial substances based on the median concentrations found in 2 223 waterbodies. 1 347 substances co-occur in this exposure scenario. Data from van Gils et al. (2020) and Posthuma et al. (2019).

As seen in several previous studies, the contribution of the different substances to the overall mixture risk is quite uneven. The cumulative RCR of 8.5 indicates that on average risks are not adequately controlled, even though the RCR values exceeded 1 for only 2 of the 1 347 substances modelled.

The typical distribution pattern of RCR values shown in the above figure based on exposure modelling is confirmed by environmental monitoring data from various other studies, although with much lower number of substances included in the various monitoring studies.

By zooming in on individual samples, the diversity of estimated cumulative RCR values can be shown. The figures below show two different samples from environmental monitoring in the UK with cumulative RCR values of 0.96 and 128, respectively (Spurgeon, 2021).

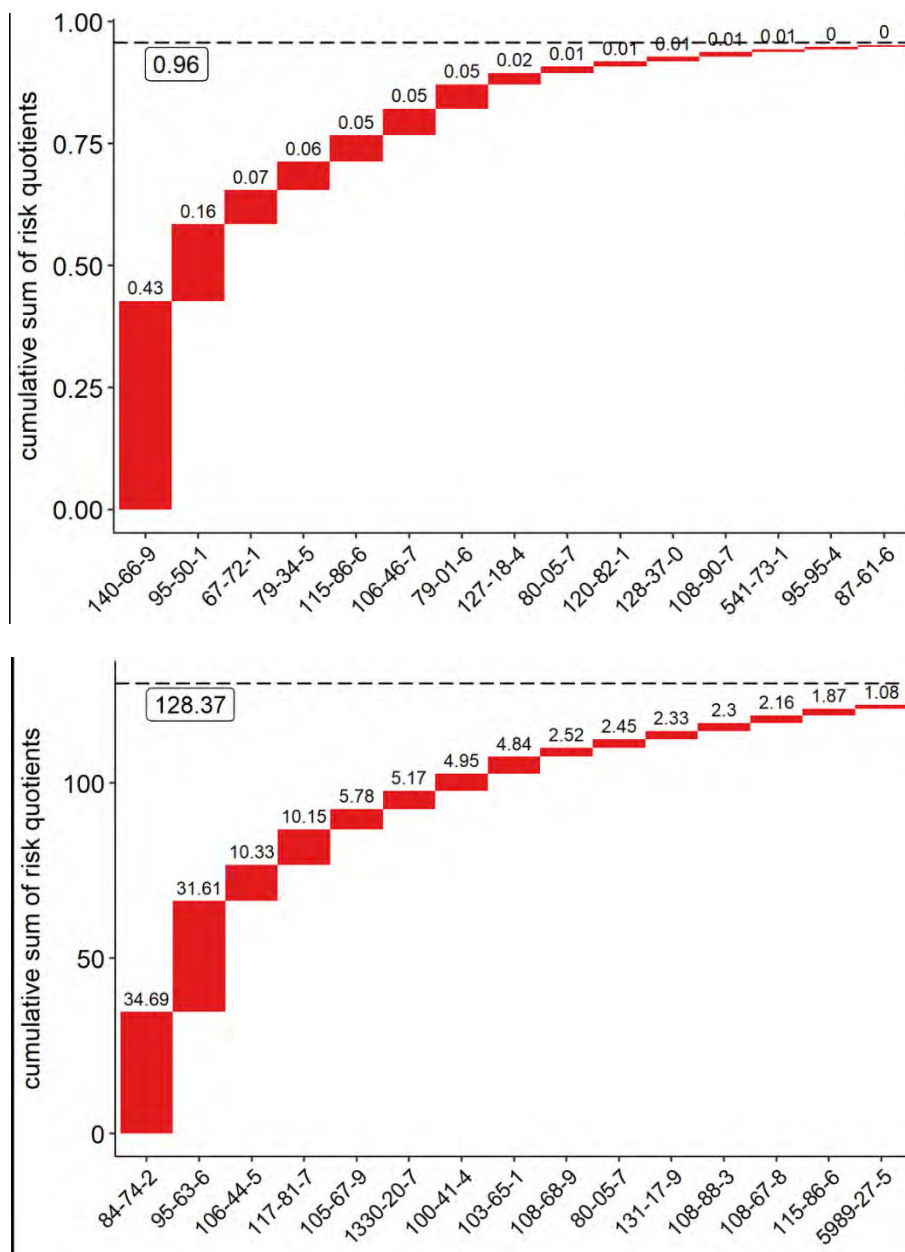


Figure 16: Two examples for the distribution of RCR values as determined for the English environmental monitoring data. The cumulative RCR value for the upper sample containing in total 33 substances is estimated to 0.96, while the similar value for the lower sample containing in total 38 substances is estimated to 128.

Another example is a monitoring study from the river Erft in Germany. The study was published by Markert et al. (Markert, 2020) and is based on 503 samples that were collected between 2016 and 2017. 153 substances were measured consistently at each site, comprising pesticides, industrial substances, personal care products, pharmaceuticals and their degradation products. Threshold values were calculated by the authors in the form of PNECs and per species group, using data collected from “*validated experimental data from toxicity tests following established guidelines*”. Only the PNEC values were used for the present report. An average (median) of 104 substances was found per site, with 457 of the 503 samples exceeding the critical value of 1 for the cumulative RCR (median RCR sum = 7.96). It is noted that the river Erft is located in an industrialised area and that the results might not be representative of rivers in Germany and the EU.

Rorije et al. (Emiel Rorije, 2022) further demonstrate exceedance of protective standards in EU surface waters, using monitoring data to conclude that over 39% of the EU freshwater bodies are currently insufficiently protected from risk due to exposure to 206 detected chemicals and in most of these (31% of the freshwater bodies) this is due to co-exposure to more than one substance in mixtures (rather than individual chemical risks).

A final study referred here on aquatic ecosystems predicted that 65% of European water bodies are “insufficiently protected” based on toxicity data and exposure modelling for 1,760 substances for over 22,000 water bodies (Posthuma et al., 2019).

### ***Health risks: Human biomonitoring samples***

In the first study, aggregated human biomonitoring data from the EU funded HBM4EU project data were analysed by the European Commission Joint Research Centre (JRC) and results have recently been published (Sebastian Socianu, 2022). The underlying data comprise the median risk quotient and the upper 95<sup>th</sup> percentile of the risk quotients for adults (20 substances) and children (17 substances). With the exception of the pyrethroids and chlorpyrifos (which do not contribute to a significant degree) all mixture components are relevant from a REACH perspective.

Safe internal concentration levels were retrieved for 20 substances for the general population on the basis of established regulatory guidance values for the most critical toxicological endpoint, independent of MoA/grouping considerations. For children, biomonitoring data were not available for arsenic compounds, pyrethroids and chlorpyrifos. As arsenic compounds actually contribute quite substantially to the overall risk in the adult population, this might explain the lower cumulative RCR for children and emphasizes how critical it is to include all relevant substances in the mixture risk assessment.

The distribution of estimated RCR values for adults and children, respectively, are shown in the figure below for the upper 95<sup>th</sup> percentile of exposure levels.

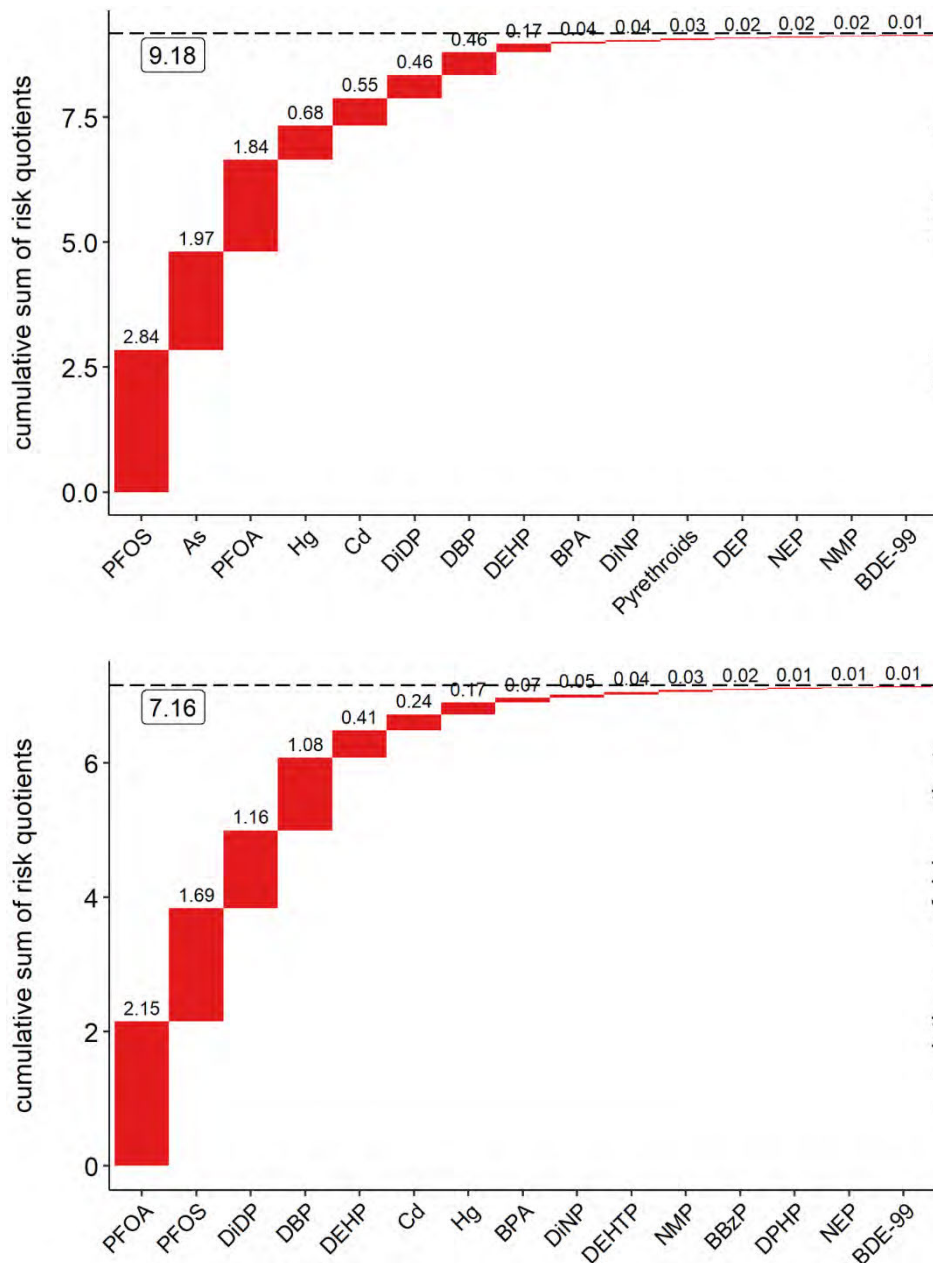


Figure 17: Distribution of estimated average 95<sup>th</sup> percentile RCR values in samples from adults (20 substances) and children (17 substances). Only the 15 substances with the highest RCR values are included in the plots. The data are from the EU HBM4EU project and are published by Socianu et al. (2022).

A second study deals with the impact of chemical mixtures on human health and has recently been published (Kortenkamp, 2022). All 29 substances included in the assessment affect semen quality after prenatal exposures, but via different modes and mechanisms of action (androgen receptor antagonists, substances that disrupt prostaglandin signaling, suppress testosterone synthesis, inhibit steroidogenic enzymes or activate the aryl hydrocarbon receptor). Two exposure scenarios, reflecting the average (median) and maximum (upper 95% percentile) exposure were evaluated. Concentrations were measured in human urine.

The distribution of estimated RCR values in the samples is shown in the figure below.



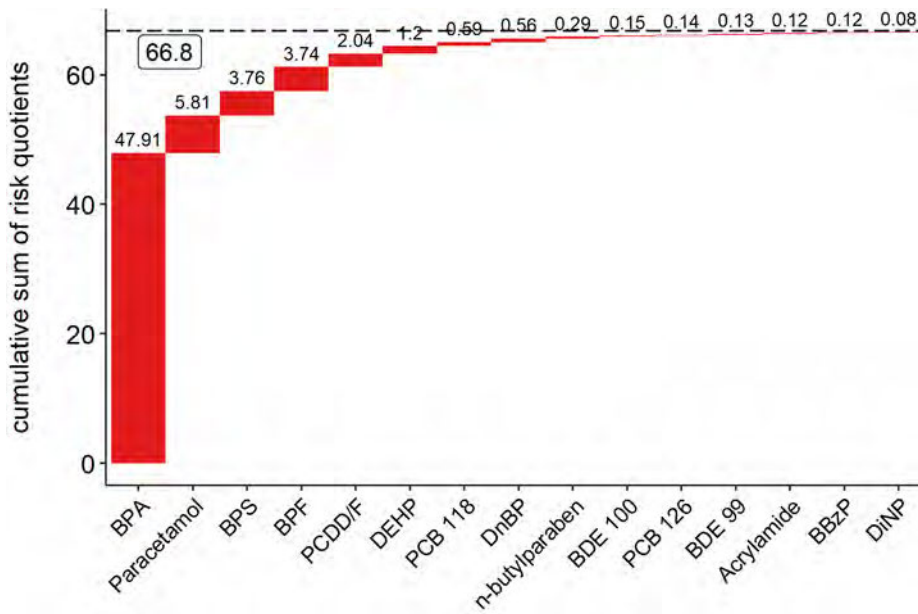


Figure 18: Distribution of estimated 95<sup>th</sup> percentile RCR values for endocrine disruptors in human samples (only the 15 substances with highest RCR values are plotted). Data from Kortenkamp (2022).

The cumulative 95<sup>th</sup> percentile RCR value is estimated to 66.8.

A final example referred here of distribution of RCR values is from indoor air samples (de Brouwere, 2014). The results are shown in the figure below.

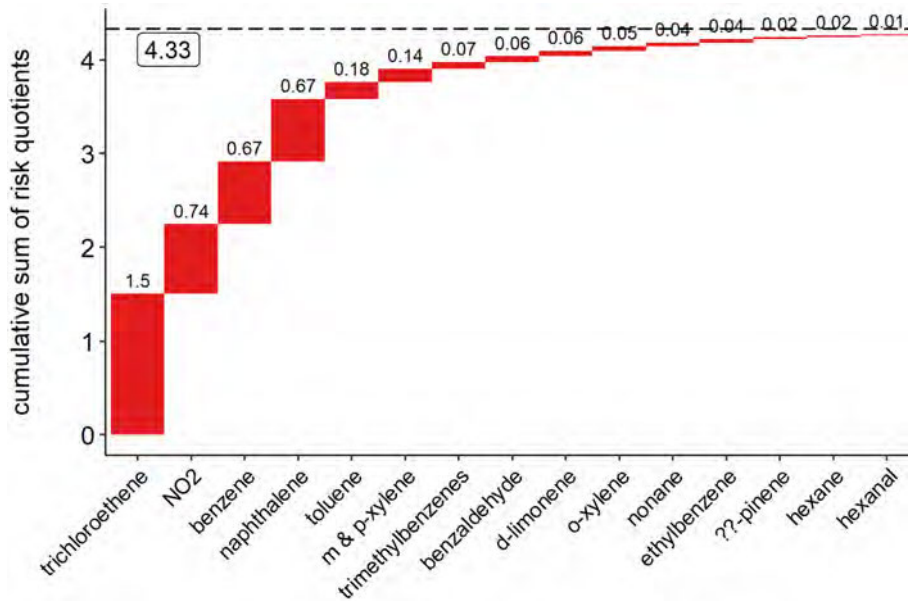


Figure 19: Distribution of RCR values in samples from indoor air (de Brouwere et al., 2014).

Results from the reviewed case studies depend substantially on the mixture composition, the extent of application of the concentration addition assumption (to common vs. multiple modes of action/adverse effects) as well as on the selection of safe thresholds for individual substances.

Supporting evidence of mixture risks includes, for example, exposure monitoring and toxicity modelling by the Danish Environmental Protection Agency showing that

exposure of children under 3 years old to mixtures of endocrine disrupting substances could be of concern.

### ***Conclusions on the problem***

Although the exact nature and magnitude of risks and associated impacts is not fully established, the problem is expected to be widespread given the transboundary nature of chemical transport through the environment and based on the evidence of mixtures of thousands of co-occurring substances. Furthermore, with the increased rate of growth of the chemical industry, the problem is unlikely to desist without intervention.

In conclusion, a significant and increasing number of monitoring and modelling studies show widespread exposure of humans and the environment to a large number of substances and that the estimated cumulative risks, assuming additivity in the lack of detailed knowledge, exceed the protection level established based on the individual substances risk assessment approach used in chemicals legislation.

The lack of provisions to account for unintentional co-exposure in chemical safety assessment is further highlighted as a problem by the growing scientific evidence that exposure to substances in unintentional mixtures can result in adverse toxicological and ecotoxicological effects, even at doses or concentrations regarded as safe (i.e. where no effects are expected) for each individual substance. This reflects the observation that co-occurring substances can have additive risks (or in rare cases, synergisms and antagonisms can occur). This is highlighted in the Commission's progress report on chemical mixtures (European Commission, 2020b), which describes the concerns related to unintentional mixtures.

The evidence that unintentional mixtures can pose significant risks to human health and the environment is a clear driver that action is needed to address the problem, particularly as humans and the environment are continuously exposed to such mixtures. However, it is currently not realistic nor economically feasible to conduct specific risk assessments and regulate an almost infinite number of possible combinations of substances which may occur in unintentional mixtures to which humans and the environment are exposed. In the current situation with a lack of toxicity and exposure data on components of unintentional mixtures, a pragmatic approach which is both proportionate and precautionary is required to address the problem.

### **Drivers of the problems**

REACH currently requires individual registrants to document the safety of their substances, ensuring that they comply with minimum safety requirements to avoid exposure of humans and the environment to substances in doses or concentrations which may cause harm. However, these requirements do not account for the possibility of co-exposure to other substances, representing a shortfall based on the observed reality that substances do not occur in isolation in real real-world exposure scenarios.

Moreover, the individual registrant is not in possession of information on how his substance is used by actors supplied by competing providers, meaning that the registrant would not even be able to take into account other uses of his own substance than those supported by the registrant. Even worse, the individual registrant of a substance would have no knowledge about other substances to which humans or the environment that are

exposed to the registrant's substance might also be exposed to. Thus, the individual registrant would have almost no possibility to take such co-exposures into account in his chemical safety assessment.

### **Current baseline**

The baseline is the 'no-policy-change' scenario, including relevant EU-level and national policies in force and taking into account reasonable projected developments (i.e. a dynamic baseline). The baseline includes the current situation, under which humans and the environment are exposed to substances in unintentional mixtures and where adverse effects can still occur even if use of and exposure to individual substances can be demonstrated to be safe.

The information available to REACH registrants currently does not allow or promote that risks from unintentional mixtures are taken into account in their chemical safety assessments. More than 20 000 substances have now been registered under REACH for manufacture or use in amounts greater than or equal to 1 t/y and continue to be used across the EU. Added to that, each year around 300 additional substances are registered, which adds to the potential for people and the environment to be co-exposed to substances in unintentional mixtures.

Under the baseline, a continuation of the problem associated with human and environmental exposure to unintentional mixtures is expected. It is clear that this is a problem that exists now and could increase in future if no corrective measures are taken, and hence one that would ideally be best tackled in the short term.

### **3 POTENTIAL POLICY OPTION AND SUB-OPTIONS**

The overall objective of the intervention is to prevent risks to humans and the environment from unintentional co-exposure to multiple substances (unintentional mixtures). Specifically, the intention is to introduce one or more mixtures assessment factors (MAFs) into the REACH regulation.

A MAF is a factor which can be applied to the safety assessment of individual chemical substances to account for the potential risks that may arise when humans and the environment are co-exposed to the substance and also to other substances. It therefore elevates risk estimations for individual substances (which typically only consider the risks from exposure to the substance in isolation from other substances). For uses of some substances, this elevation would cause risks to cross the threshold of what is deemed "acceptable".

If implemented in the chemical safety assessments under REACH registration, MAF(s) could have far-reaching consequences, due to the large number of substances which fall under the remit of REACH. For substances with relatively high risks, where introduction of a MAF would indicate a possible risk, this would result in an obligation for registrants to address these risks before registering their substances or updating their registration dossiers. Registrants would be required to implement additional risk management measures or withdraw uses if they cannot demonstrate acceptable risk. These outcomes would result in reduced emissions of substances, therefore decreasing the probability that these substances will contribute to unintentional mixture risks.

Introduction of a MAF(s) would reinforce the preventative approach currently embodied in REACH as it would require registrants to demonstrate adequate control of risks, including unintentional mixture risks. This is in line with the polluter pays principle as set out by the Treaty of the functioning of the European Union.

Introduction of a MAF(s) in REACH is proposed to be a pragmatic way to address the unintentional mixtures problem because it does not rely on knowledge of co-exposures to all substances which may occur in unintentional mixtures. Furthermore, information on the exposure over time and across different sites is usually not available for all relevant substances contributing to mixture effects precluding a more elaborated mixture risk assessment.

A MAF cannot address all potential risks associated with unintentional co-exposure, and other, complementary, approaches may be needed in the future. However, in view of the need to address the associated risks, introducing a MAF could be a pragmatic approach to reduce the contribution that REACH-registered substances make to unintentional mixture risks in the shorter-term, while other methods and approaches are developed.

### Policy options

In addition to the **baseline**, the following options are considered:

- Whether the MAF is **mandatory or not**. Specifically, this covers:
  - Option 1, whereby a MAF would be applied in all chemical safety assessments, with no potential for deviation.
  - Option 2, whereby a MAF would be applied by default, but with the potential for deviation, i.e., to reduce or eliminate the MAF value according to whether a substance is likely to contribute to risks from unintentional mixtures in practice.
- The **target groups** for which the MAF is applied in the CSA, covering:
  - A) The environment;
  - B) The general population (consumers);
  - C) Workers.

Under **Option 1**, REACH registrants would need to revisit their chemical safety assessments/reports to incorporate a MAF (or several MAF values) and provide an updated documentation that the use(s) of the substance is safe. The approach they would be expected to take is to engage in a series of increasingly onerous steps in order to ensure that safe use can still be achieved with the MAF in place.

Under **Option 2**, it would be possible for the registrant to deviate from the ‘blanket’ application of a MAF, and to demonstrate that a lower MAF value, or no MAF at all, should apply. For example, such cases could include:

- Substances used at the workplace where the employer has conducted a specific risk assessment in accordance with Directive 98/24/EC on chemical agents at work<sup>213</sup> and taken into account the potential co-exposure to all relevant

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<sup>213</sup> Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

substances as provided for in Article 4(4) of that directive. If the registrant documents that such a specific risk assessment has been carried out, it might be justified to opt out from the requirement to use a MAF.

- Substances/uses where releases are such that unintentional mixtures are unlikely to pose unacceptable risks. For example, while it has been demonstrated that unintentional mixtures that pose unacceptable risks to the environment can and do form in water bodies, the same cannot be said for mixtures within ambient air (in the environmental assessment). Since the air compartment seems to be of less concern in relation to unintentional mixture risks, it might be argued that a MAF should not apply<sup>214</sup>.
- Substances/uses where the only exposure scenarios are for industrial uses and where it is documented that the substance is not released from the workplace (e.g., through use of largely closed systems or complete destruction/reaction of the substance during its use). For such substances, opening of systems (e.g. for maintenance) can lead to relatively high RCR values, but these are only short-term (e.g. related to intermittent releases). In such cases, it could be argued that there is no, or very limited, potential for the substance to contribute to risks from unintentional mixtures. However, it would be expected that the RCR values for such uses would already be very low and that these uses would not be negatively affected by a MAF except for the need to update the CSA.

Under both options, the application of a MAF would only be relevant for registrations of substances where a full chemical safety assessment is required, i.e. to a subset of the total number of registered substances. In particular, currently only around 18% of registered substances (around 4,000 substances) are understood to both (a) require a chemical safety assessment including exposure assessment and risk characterisation; and (b) have both systemic effects and an identified safe exposure level. For the other substances, a MAF could not be applied as part of the risk characterisation process, because there is no relevant risk characterisation for it to be applied to.

Note that the number of substances affected could be higher if other amendments to REACH are implemented, in particular if a CSR is required for substances registered at 1-10 t/y, if information requirements are increased for substances in the tonnage range 1-10 t/y, if information requirements for certain hazard properties, e.g. endocrine disruption are extended, if polymers are required to be registered and if substances previously included under the past notification of new substances (NONS) regime are required to have equivalent data to other REACH registered substances. Furthermore, the revision of the CLP-Regulation, e.g. inclusion of new hazard classes, could lead to a higher number of substances that will require a CSR and a risk characterisation. All these changes are currently under considerations as part of the targeted REACH revision.

### **Sub-options**

A number of different sub-options and alternative parameters need to be considered in order to define how the options could be implemented in practice. A range of different parameters and sub-options were initially considered, and these were assessed taking into

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<sup>214</sup> Assuming that the substance does not also significantly contribute to concentrations/risks in other environmental compartments, e.g. via deposition from air.

account the key criteria for screening set out in the better regulation toolbox (tool #16). The parameters taken forward for further elaboration and for assessment of impacts are set out in the table below.

Table 143: Overview of sub-options and alternative parameters

Element	Possible sub-options / alternative parameters
a. Which hazard types are covered?	<p>(i) The most harmful chemicals only (CMR 1A/1B, endocrine disrupters, persistent and bioaccumulative chemicals, and chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ)</p> <p>(ii) All chemicals requiring a risk characterisation as part of REACH registration</p>
b. Which tonnage bands are covered?	<p>(i) All &gt; 1000t</p> <p>(ii) All &gt; 100t</p> <p>(iii) All &gt;10t</p> <p>(iv) All &gt; 1t <sup>[Note 1]</sup></p>
c. Differentiation of the value of the MAF <sup>[Note 2]</sup>	<p>(i) One MAF for health and environment</p> <p>(ii) Separate MAFs for health and environment</p> <p>(iii) Separate MAFs for the environment, consumers and occupational settings</p>
d. Value of the MAF <sup>[Note 3]</sup>	<p>(i) MAF = 2</p> <p>(ii) MAF = 5</p> <p>(iii) MAF = 10</p> <p>(iv) MAF = 50</p> <p>(v) MAF = 100</p>
e. Application of the MAF in REACH registration	<p>(i) MAF is applied to the RCR only</p> <p>(ii) MAF is applied to the DNEL/PNEC <sup>[Note 4]</sup></p>
f. Applicability to naturally occurring substances	<p>(i) MAF is applied equally to all substances in scope regardless of whether naturally-occurring or not</p> <p>(ii) Adjustment is made to the MAF in the case of naturally occurring substances.</p>
g. Applicability to non-threshold substances	<p>(i) Non-threshold substances excluded from application of the MAF</p> <p>(ii) Quantitative risk threshold applied for non-threshold substances where dose-response relationship exists or can be derived (e.g. DMEL)</p>

Element	Possible sub-options / alternative parameters
	(iii) Qualitative assessment required to address risks from unintentional mixtures where the registered substance has no threshold for effects

Table notes:

- 1) This would be subject to potential new requirements for conducting a CSA for 1-10t substances as part of the revision of REACH
- 2) The issue here is whether separate values of the MAF should be developed for the different target groups. Main options A, B and C cover whether the target group should be included at all.
- 3) These are indicative values used during the course of the project for assessment of impacts. The outcomes of the derivation of suitable MAF values was expected to possibly lead to different values being justified. However, taking these values as sub-options was intended to allow results to be interpolated.
- 4) Note that the DNEL/PNEC is required for all substances, while the RCR is only needed for substances that meet classification criteria cf. Article 14(4) (around 65% of registered substances, which, however, could change with the revision of REACH and the CLP Regulation)

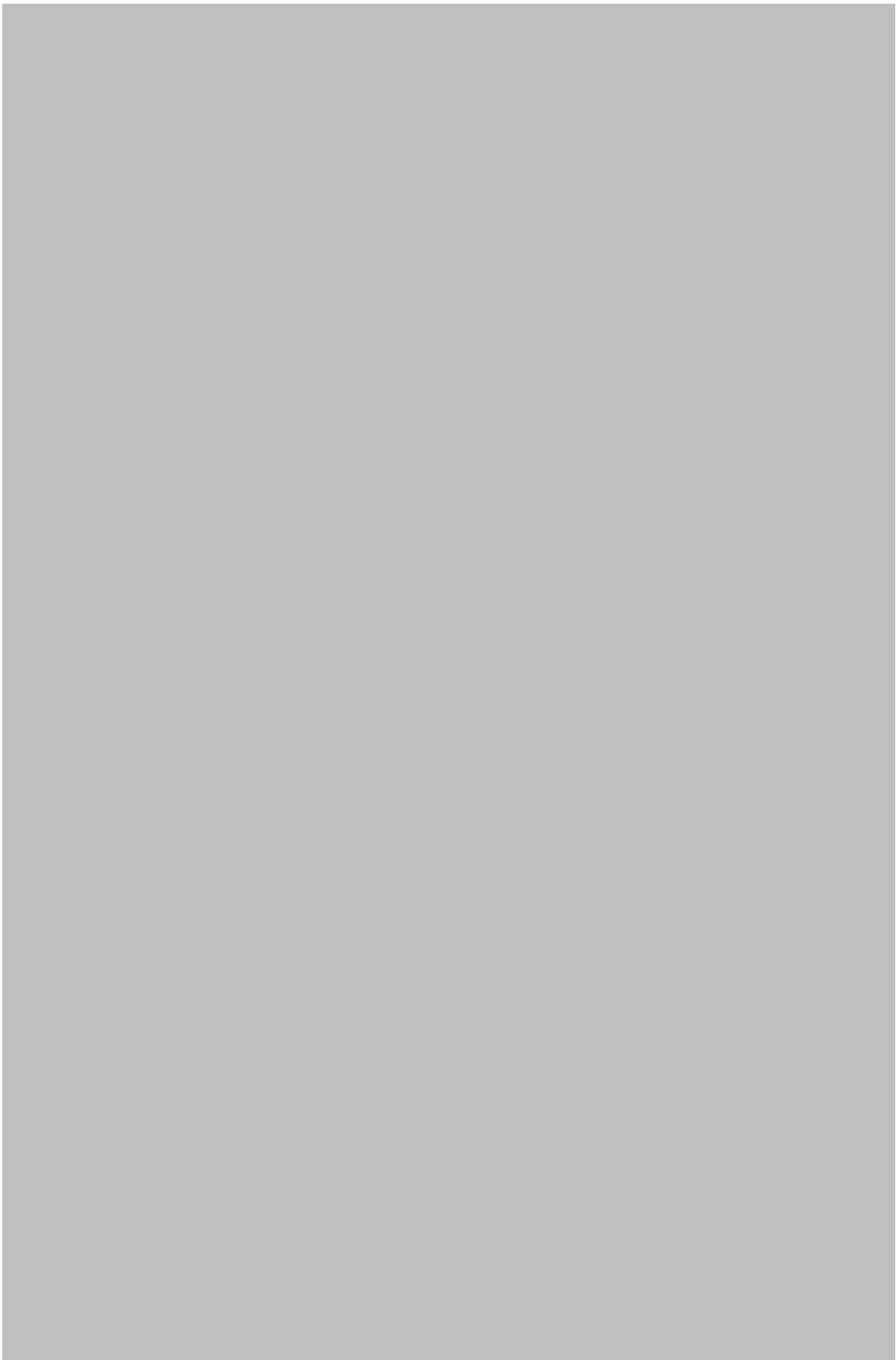






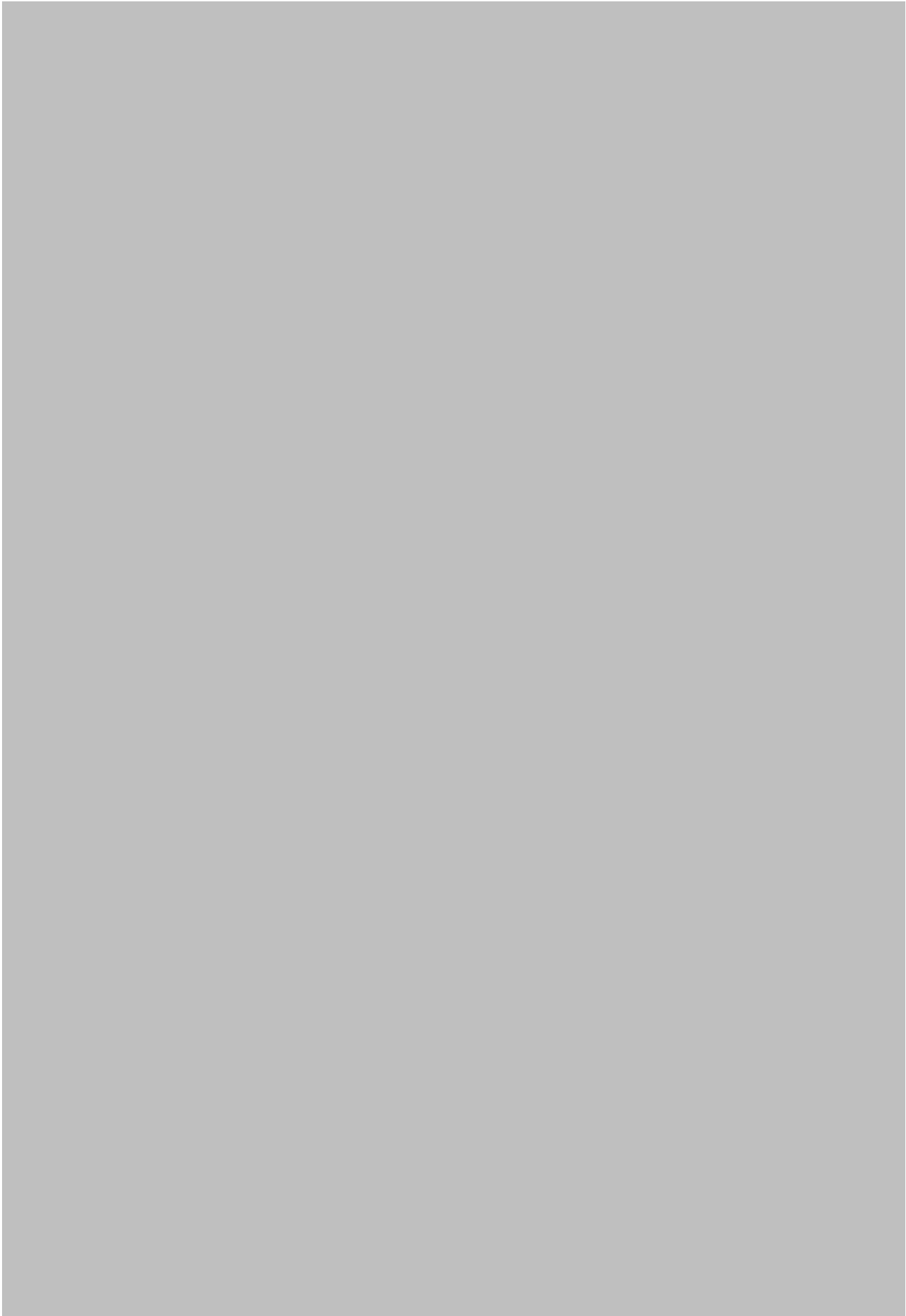














### **Options and parameters taken forward to assessment of impact**

Based on the above, the following options and parameters are considered in the assessment of impacts in the next section of this report:

- Applicability of a MAF to the environment, consumers and/or workers
- Whether a MAF would be mandatory or whether deviation could be allowed according to the likely contribution to risks of unintentional mixtures
- The applicability of a MAF to all those substances requiring a chemical safety assessment.
- Whether all tonnage bands should be covered, or only a selection.
- What value a MAF should take and whether different values should apply to different circumstances (health, environment, etc.).

The above have been considered in terms of impacts.

Other factors that were already concluded above are:

- How a MAF could be applied in the REACH registration process. It is most appropriate to apply the MAF in the risk characterisation as part of the chemical safety assessment required for registration (which would then impact other linked processes such as authorisation, restriction and evaluation).
- That a MAF should be applied to naturally occurring substances if it is applied to other substances, but that additional considerations/guidance should be applied in order to take into account natural background levels of such substances.
- That a MAF should also apply to non-threshold substances where it is possible to define a quantitative threshold for tolerable effects (e.g. DMEL), and that additional considerations (e.g. guidance) might be needed for other substances which can still contribute to mixture risks but where no effects threshold can be identified.



## Stakeholder consultation

Stakeholders have been consulted both as part of the general Public Consultation on the revision of REACH as well as in form of dedicated workshops, targeted consultations and interviews.

### *Public Consultation*

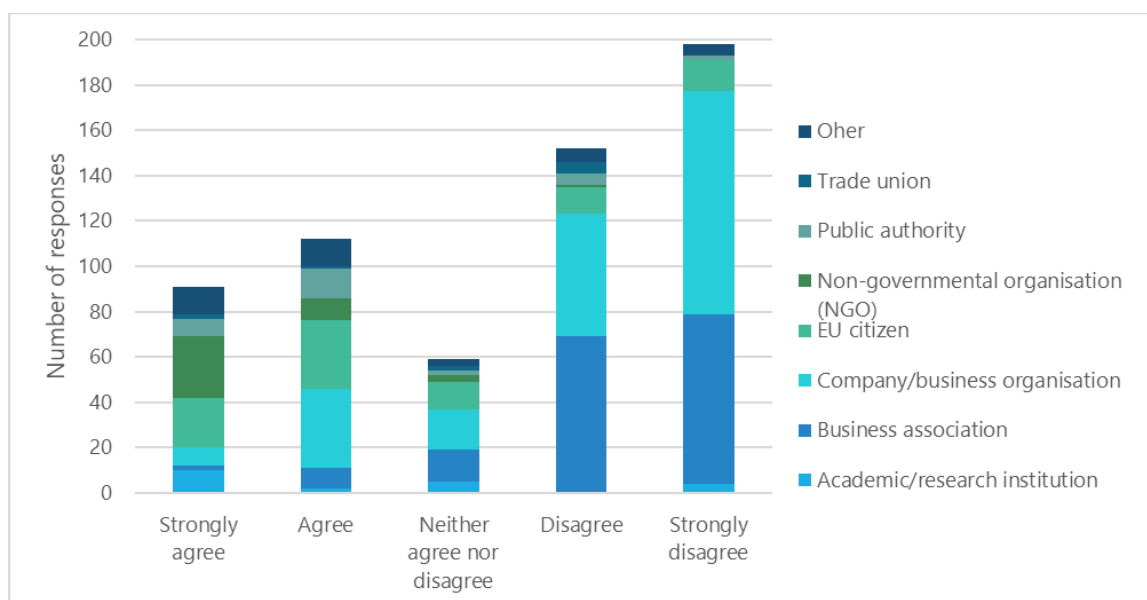
The open public consultation for the targeted revision of REACH invited stakeholders to respond to questions on the revision of REACH, including on specific problem areas and proposed solutions. This document summarises the responses to questions which were asked regarding the proposal to introduce a mixtures assessment factor (MAF) in REACH to address the problem of unintentional mixtures.

**Question 10.** To what extent do you agree that a mixtures assessment factor (MAF) is the most suitable approach to reduce the risks associated with the unintentional exposure to chemical mixtures, in the short- and medium-term?

Responses split by percentage of total respondents, of industry, and of non-industry stakeholders (n = 772, excluding blanks):

	<b>Total</b>	<b>Industry</b>	<b>Non-industry</b>
Strongly agree	13%	2%	31%
Agree	15%	10%	26%
Don't know or no opinion	16%	17%	13%
Neither agree nor disagree	8%	7%	10%
Disagree	21%	27%	11%
Strongly disagree	27%	37%	9%
Total responses	727	463	264

Responses by stakeholder type (n = 612, excluding blanks (6%) and don't know/no opinion (15%):



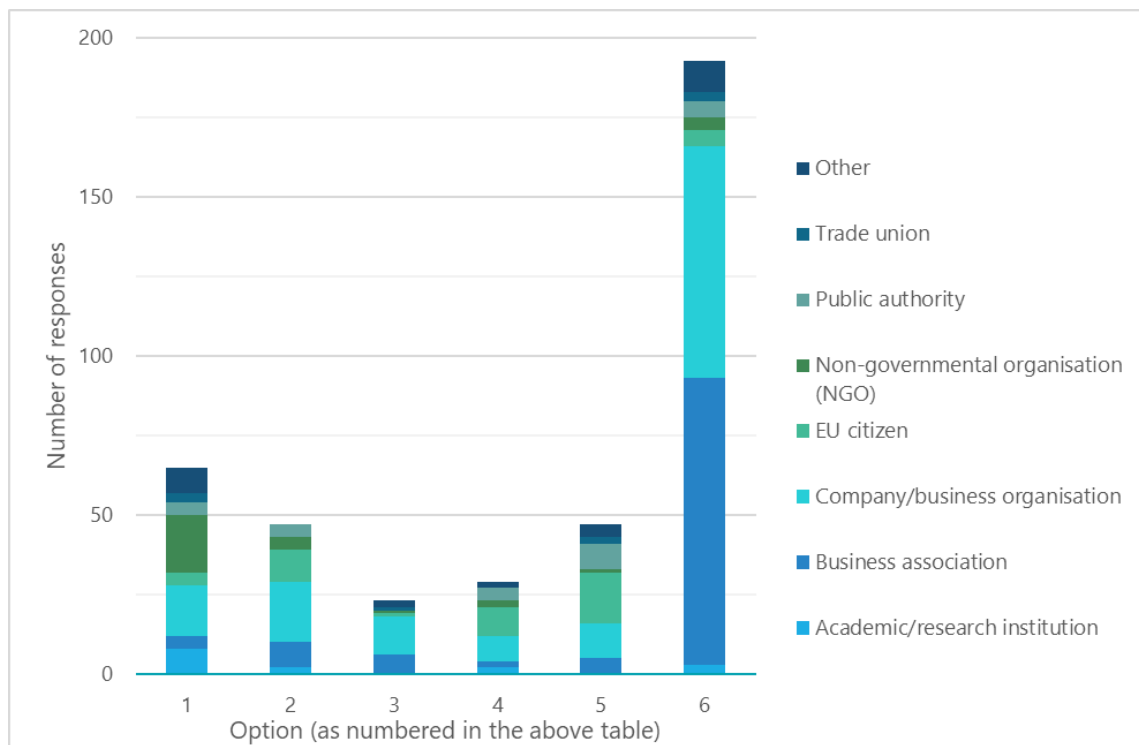
**Question 10a.** If a Mixture Assessment Factor (MAF) were introduced into REACH chemical safety assessments (under the REACH registration process), do you think there should be:

Percentage of responses to each answer (n = 772, excluding blanks):

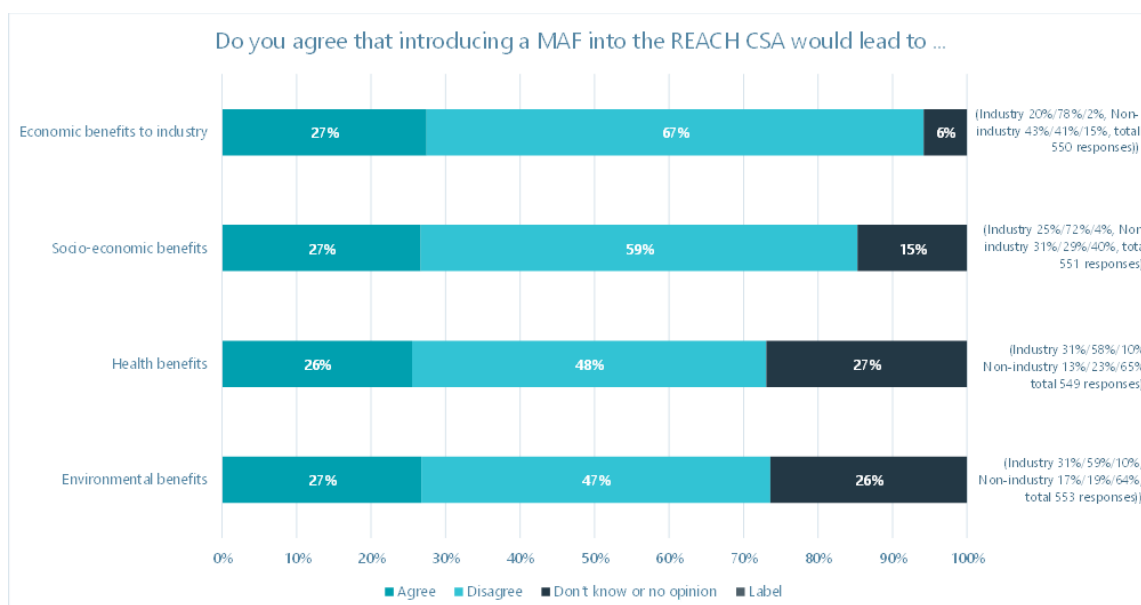
	Total	Industry	Non-industry
1. A single MAF addressing both human health and the environment	31%	24%	42%
2. Different MAFs applied to substances with different types of effects/hazards	25%	34%	10%
3. Different MAFs applied to substances with different types of uses	6%	6%	7%
4. One MAF for human health and another MAF for the environment	17%	23%	7%
5. One MAF for the environment, another MAF for exposure of the general public and a different MAF for human occupational	4%	2%	7%

	Total	Industry	Non-industry
exposure			
6. Another option (please provide details in your response below)	8%	4%	15%
7. Don't know / no opinion	3%	4%	2%
Total responses	772	480	292

Responses by stakeholder type (n = 404, excluding blanks (31%) and don't know/no opinion (17%):



Question 10b. Do you agree that introducing a MAF into the REACH chemical safety assessment (under the REACH registration process) would lead to:



If a MAF were introduced into the REACH chemical safety assessment (under the REACH registration process), do you think this should apply:

	Total	Industry	Non-industry
To cover all currently registered substances	24%	10%	55%
To registered substances that require update of their registration	20%	23%	13%
Only to new registrations	20%	22%	14%
Don't know / no opinion	37%	45%	18%
Total responses	531	365	166

### ***Feedback from the targeted survey***

A targeted survey was launched on 14 February 2022 aiming to support this study through consultation with expert stakeholders to gather insights into the pros and cons of different approaches for introducing the MAF concept into REACH as well as on potential economic, social and environmental impacts of these approaches.

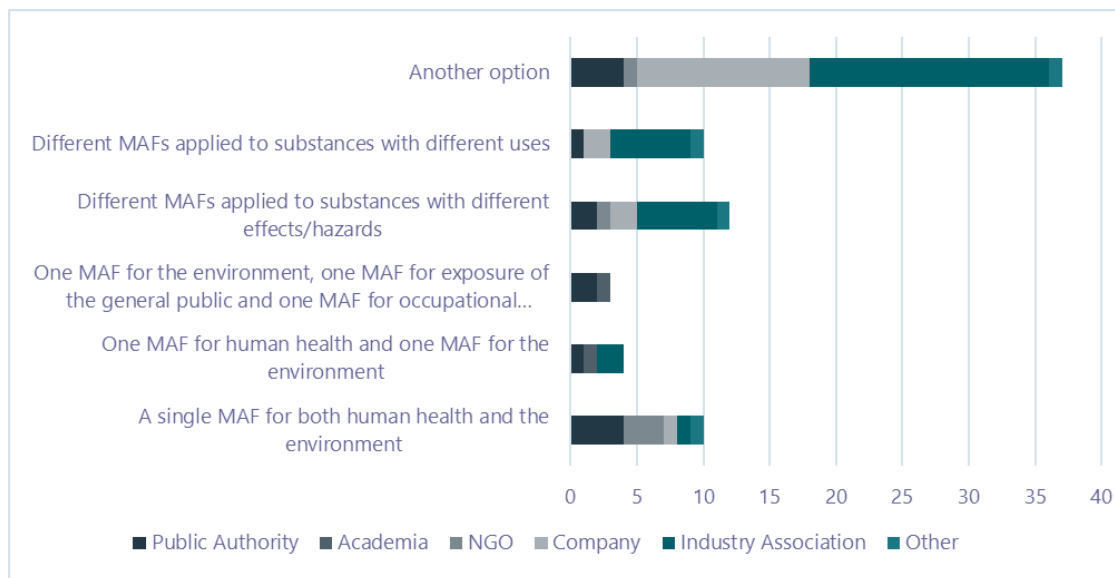
A total of 53 survey contributions were received, with the majority of responses from industry associations (38%), followed by companies (26%), public authorities (19%),

NGOs (8%), and academia (4%). The majority of the participating industry associations and companies were manufacturers of chemicals, downstream users or distributors of chemicals, and importers of chemicals with an average of 467 substances registered under REACH.

The following sections provide an overview of responses to some of the key questions, by topic area.

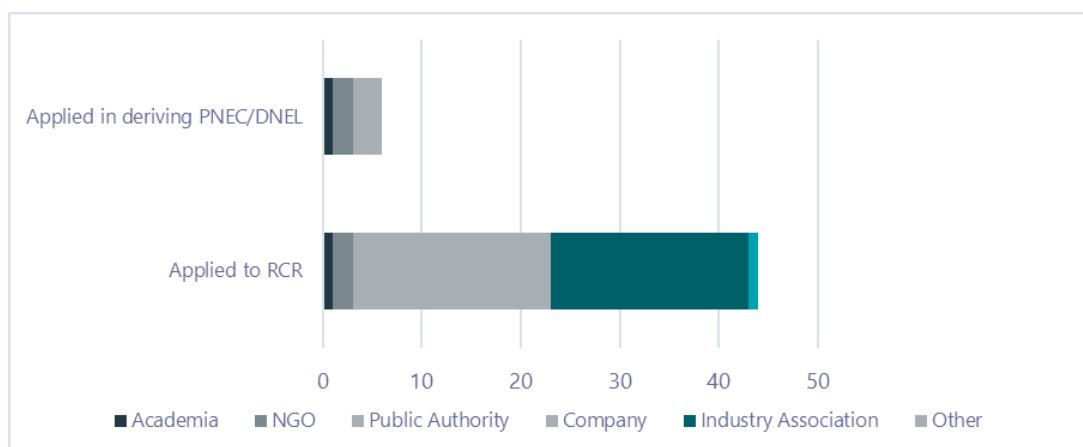
### *Differentiation between MAFs*

If a Mixture Assessment Factor (MAF) were introduced into REACH chemical safety assessments (under the REACH registration process), do you think there should be:



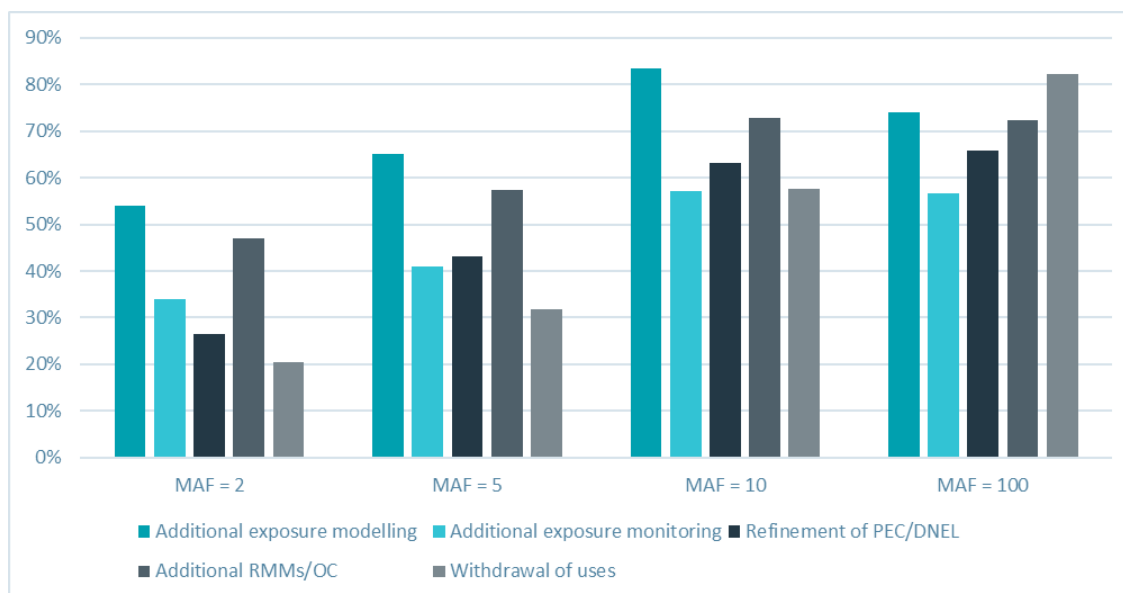
### *Entry points for MAF in chemical safety assessment*

The MAF could be incorporated into Annex I of REACH in two main ways. Which of the following approaches do you favour if a MAF is introduced into REACH?



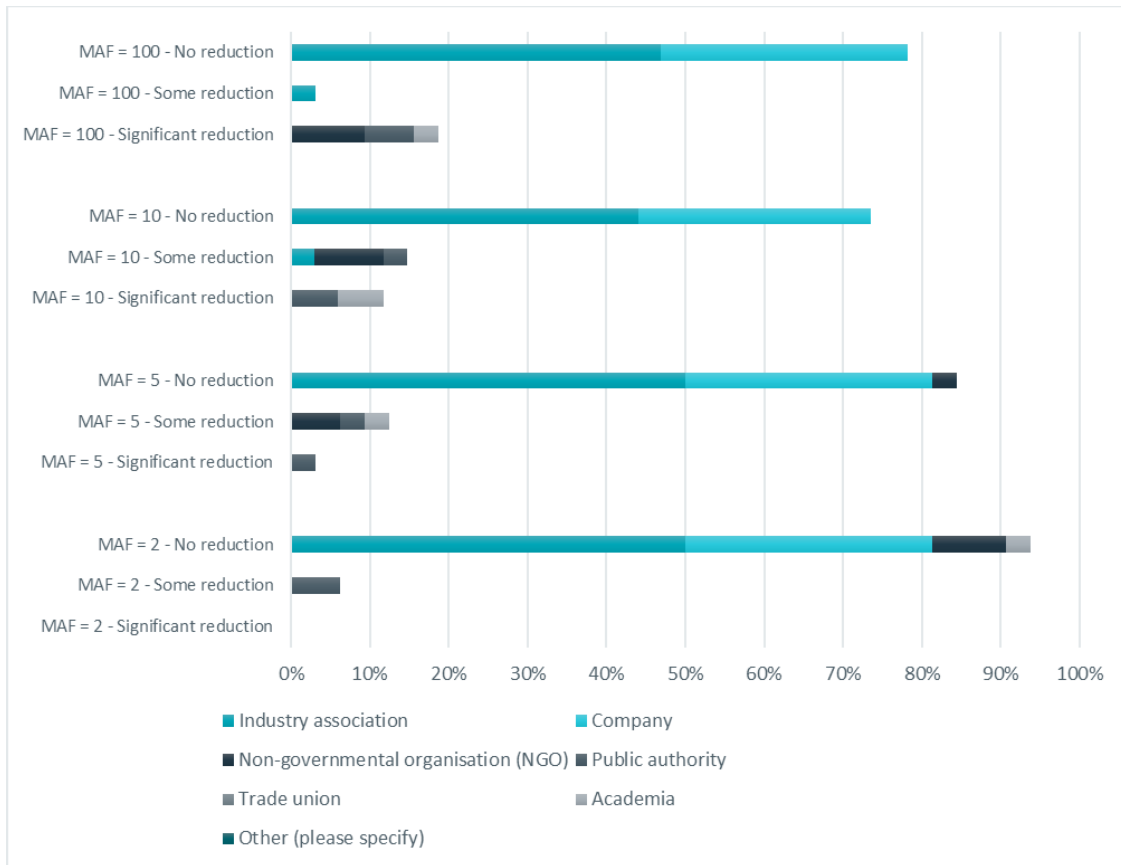
### *Predicted industry response to MAF*

Within your chemical safety assessments (CSAs) (or those of your member companies), if a MAF of 2, 5, 10 or 100 were introduced, approximately what proportion (percentage) of your portfolio (e.g. % of substances or % substance use combinations) would require ... [Additional exposure modelling; Additional exposure monitoring; Refinement of PEC/DNEL; Additional RMMs/OC; Withdrawal of uses]:

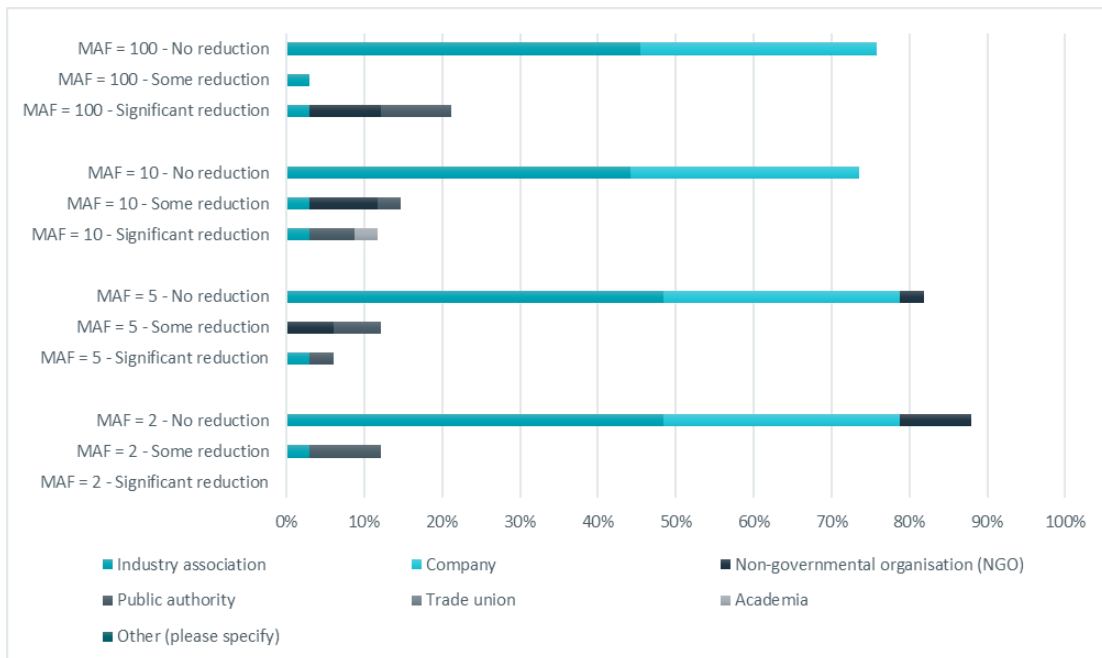


### *Benefits from a MAF*

If a MAF of [2, 5, 10, 100] were introduced, do you think this would lead to a reduction in risks/impacts on health?



If a MAF of [2, 5, 10, 100] were introduced, do you think this would lead to a reduction in risks/impacts on the environment?



*Industry costs required to respond to the MAF*

Overall, relatively few responses were received providing quantitative data on the likely costs associated with implementing a MAF within REACH. These costs will of course depend on the magnitude and approach to application of a MAF or MAFs.

Costs of refining exposure assessments through **higher-tier modelling** and general updating of CSAs were generally in the range of EUR 3 000 to EUR 20 000 per substance, with some lower (e.g. as low as EUR 1 000 and some higher e.g. up to EUR 50 000 or more). Very few estimates were provided for costs of **monitoring**, with the range of costs EUR 10 000 to EUR 100 000 per substance, with key factors determining costs being e.g. extent of monitoring of downstream sites needed.

In terms of **additional testing**, typically large numbers of substances could require additional vertebrate tests, with several respondents indicating this could be up to 90% of substances for the environment (mainly chronic fish studies) but there is generally much less scope for human health (with many substances already having DNELs based on higher tier studies). Costs were typically estimated as in the range EUR 50-100 000 for aquatic toxicity studies, but in some cases, values quoted were higher. Much higher costs (often several EUR 100 000 and up to several million EUR per substance) were quoted for additional testing for human health endpoints.

In terms of costs of implementing additional **risk management measures**, very few respondents were able to provide information on expected RMMs. Those that were able to generally indicated types of RMM applicable to industrial uses (ventilation, personal protective equipment, etc.) with RMM for consumer uses generally much harder to implement (e.g. limited to concentration reduction of the substance). Only two responses on possible cost of RMMs were provided, and these were largely hypothetical.

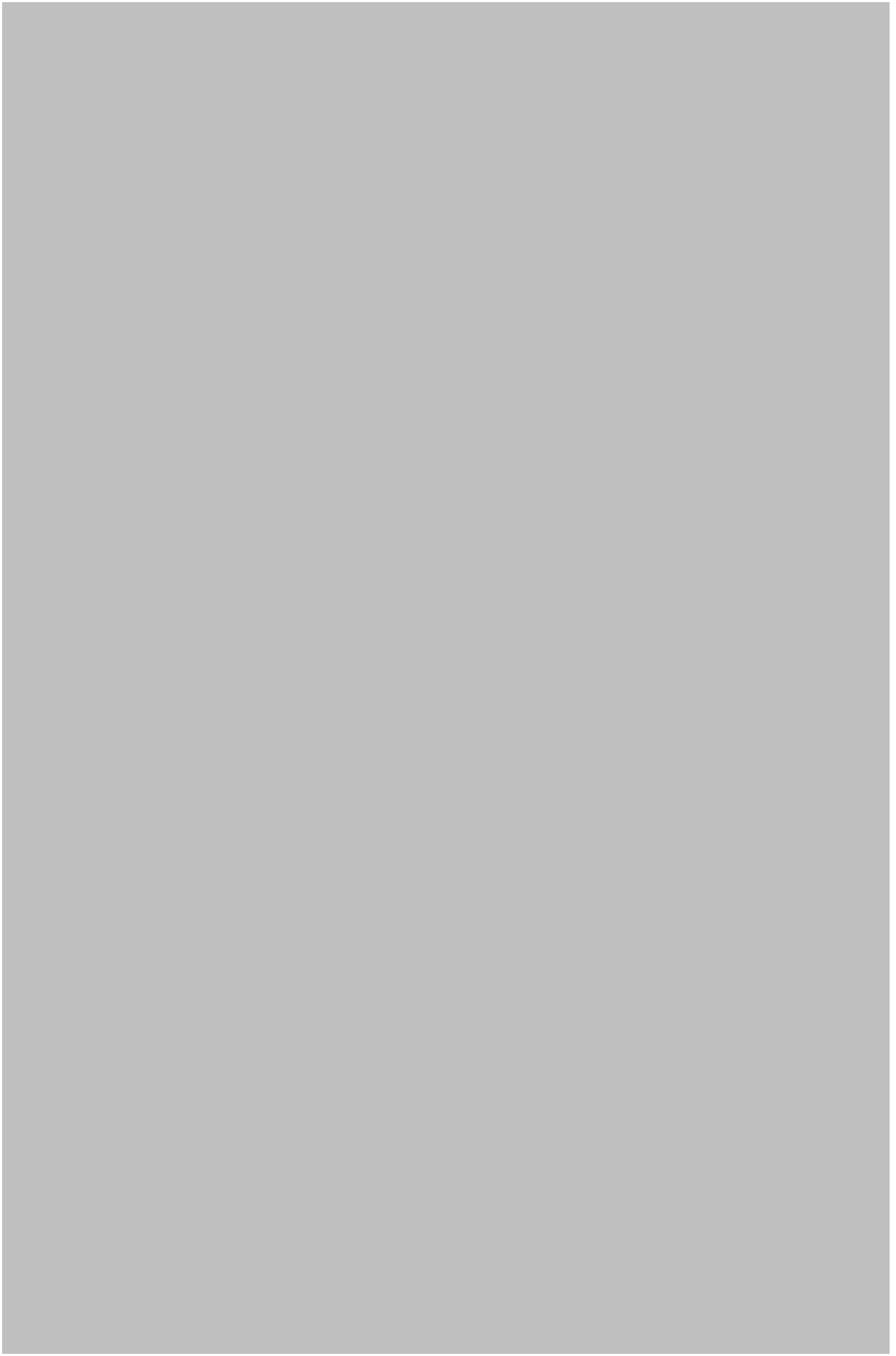
#### *Regulatory costs*

There was no clear consensus regarding the additional resource requirements needed for public authorities in case of introduction of a MAF within REACH. In some cases, additional requirements were expected to be absorbed as part of ongoing regulatory activities, while in other cases, it was specified that it would depend on the number of additional toxicity tests required as those have to be approved by the authorities. Where estimates were not provided, respondents predicted the additional workload to be high in the case of updating registration dossiers for all substances.

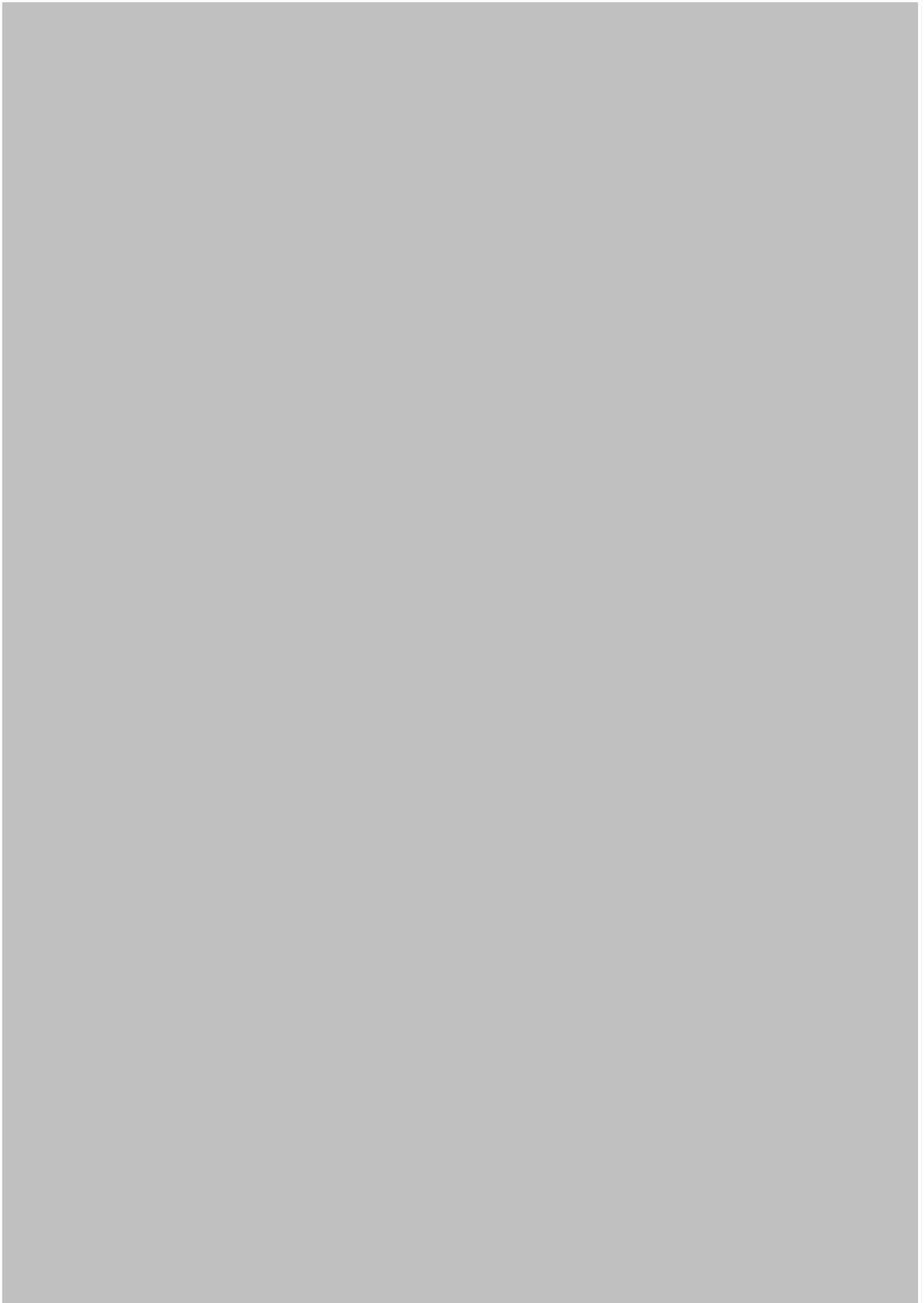






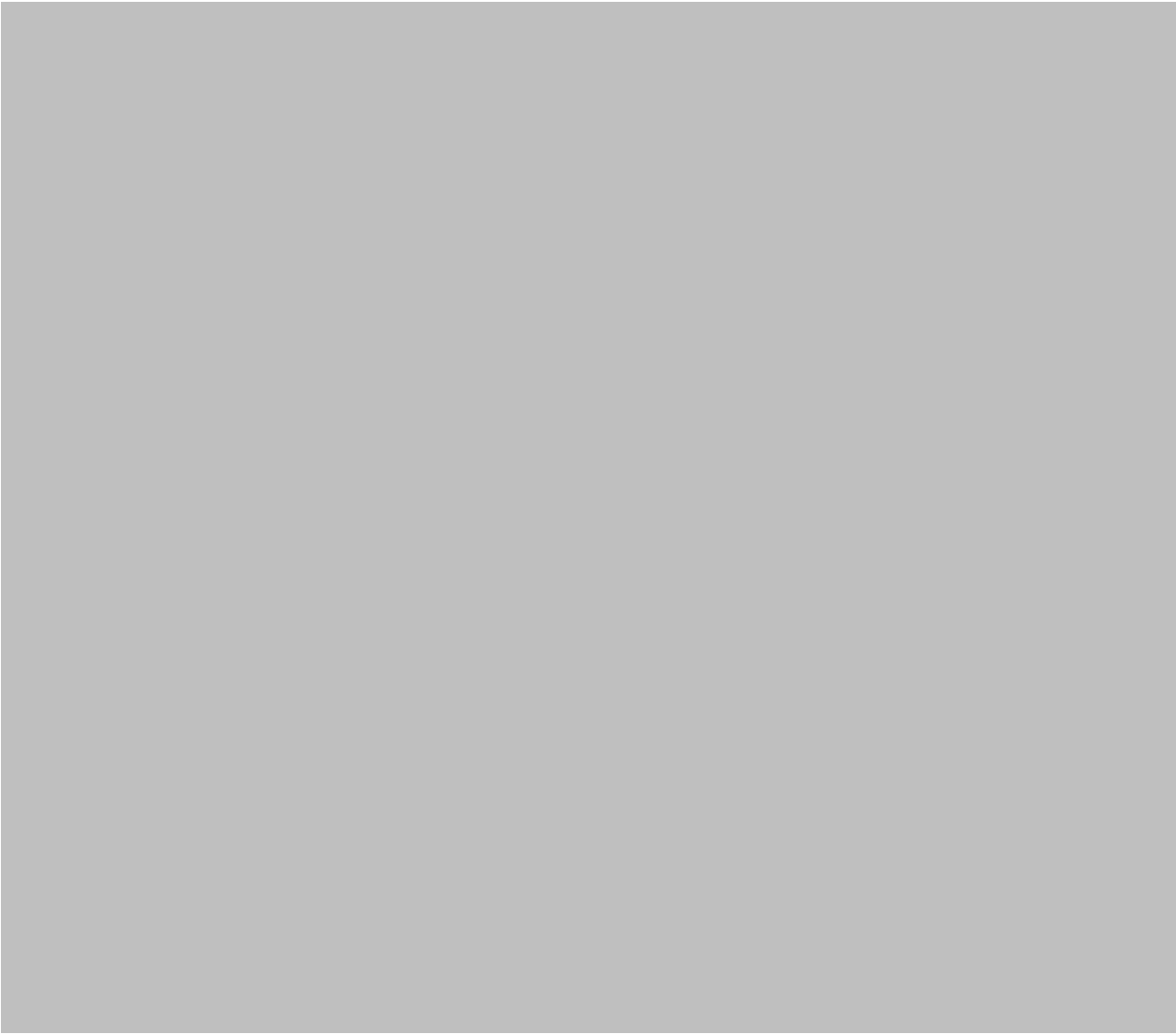








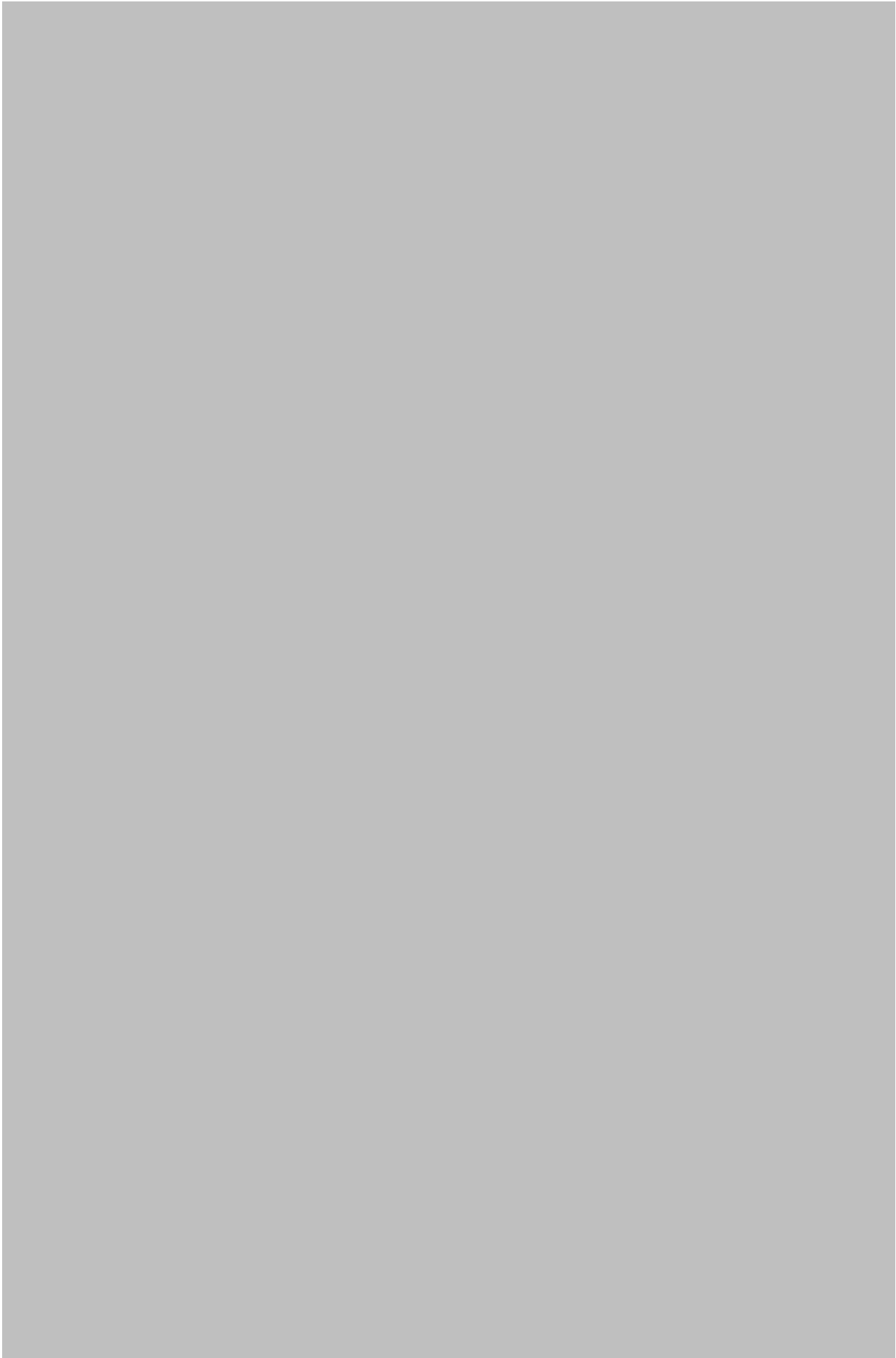






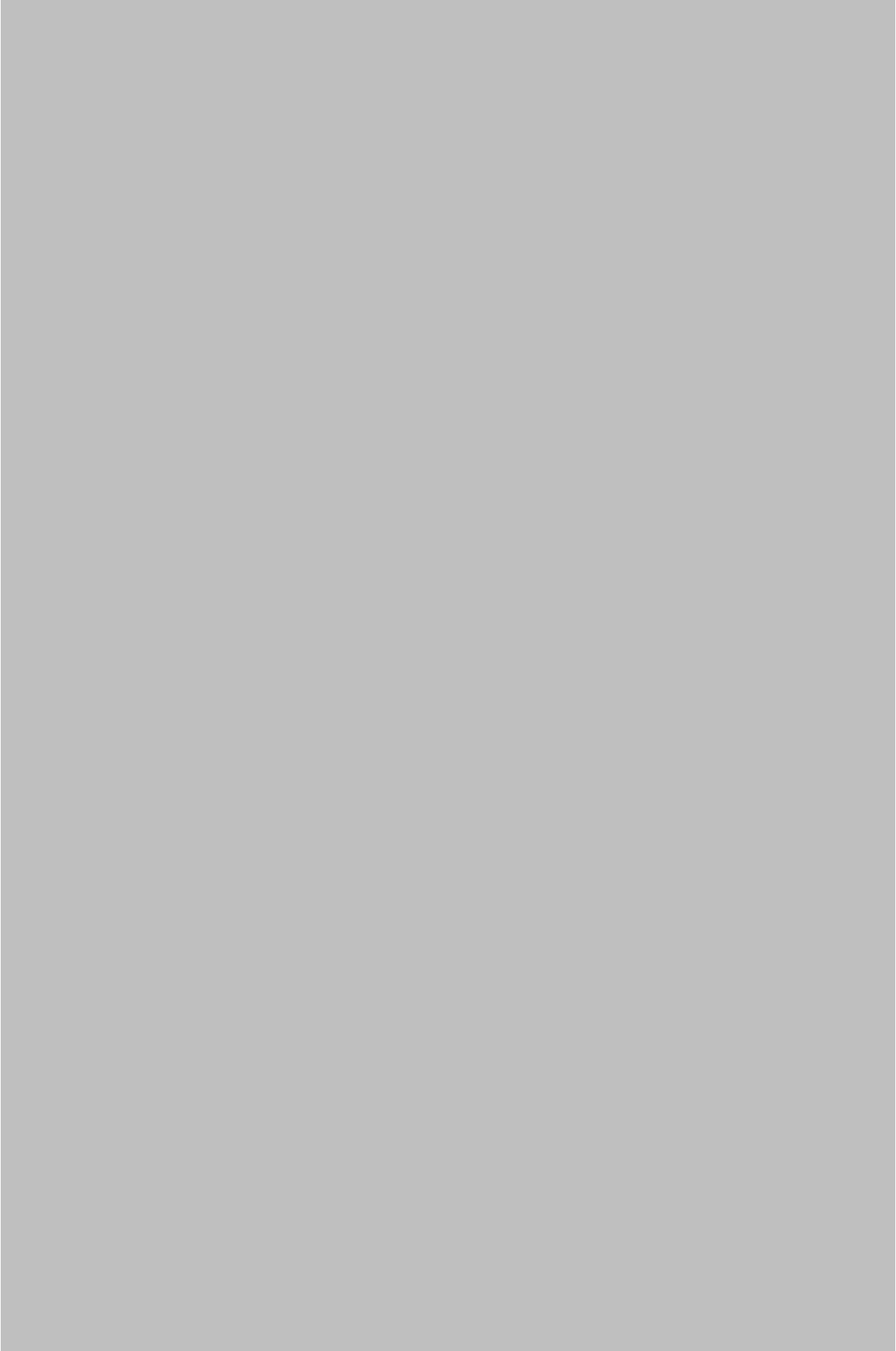
















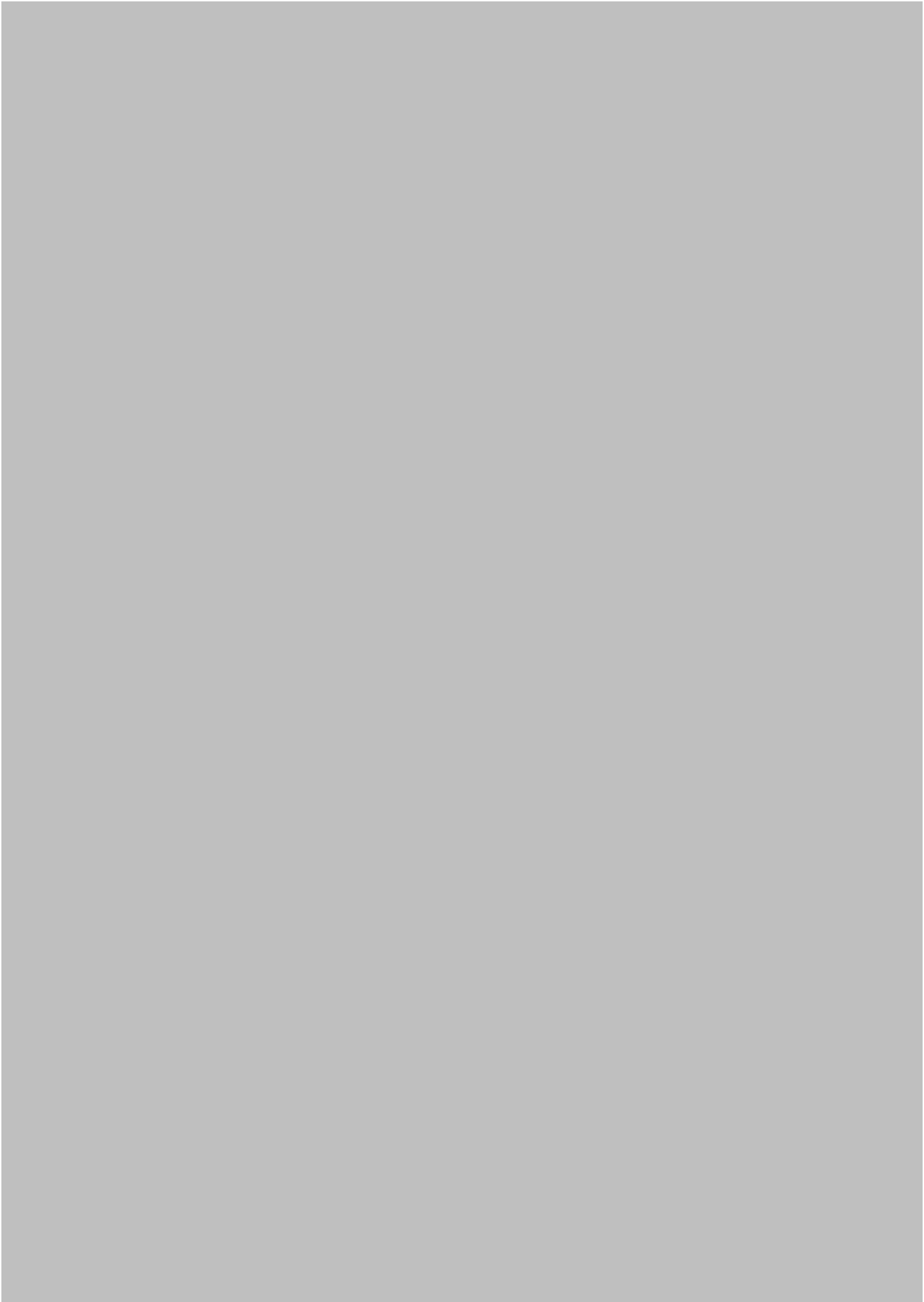
















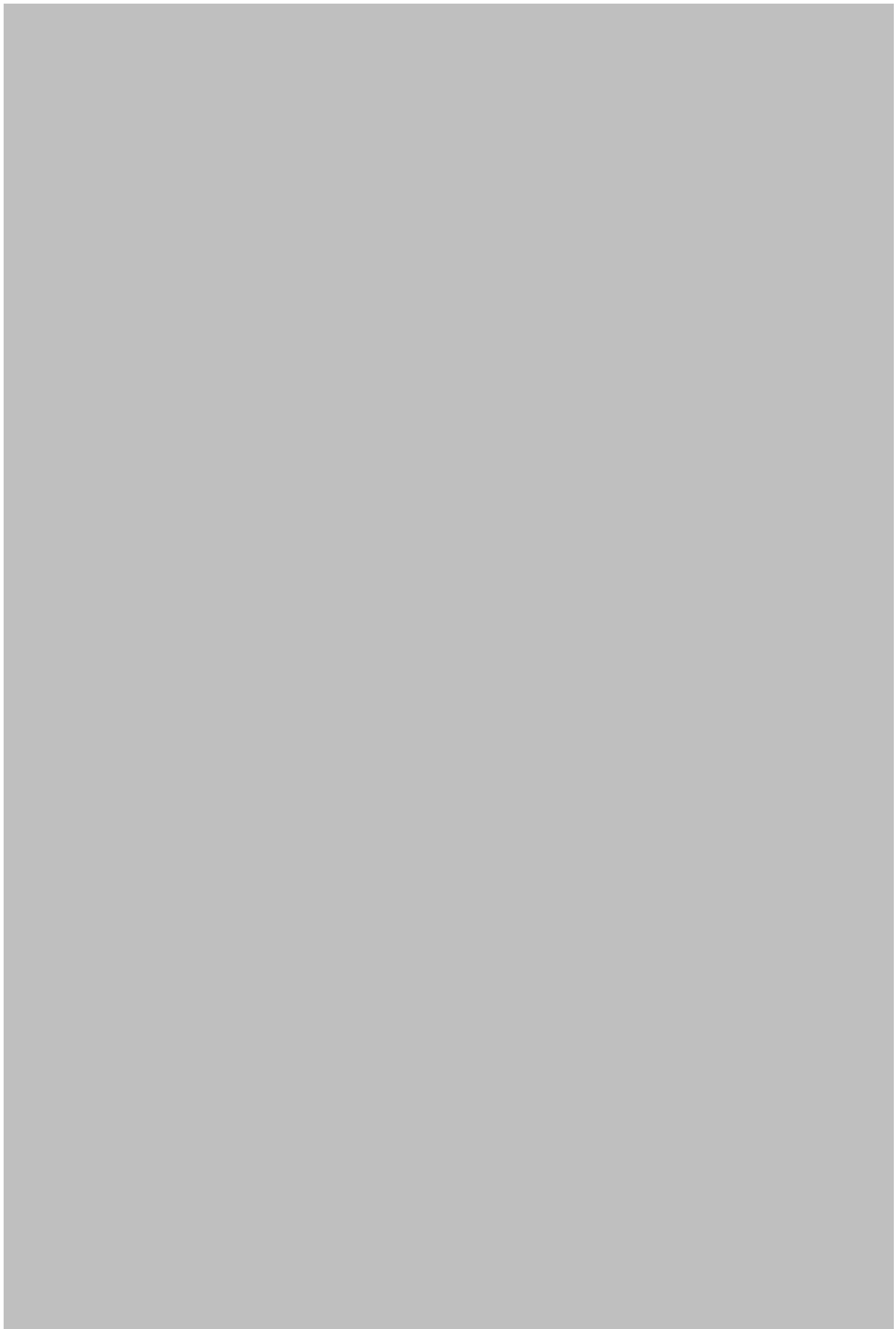
















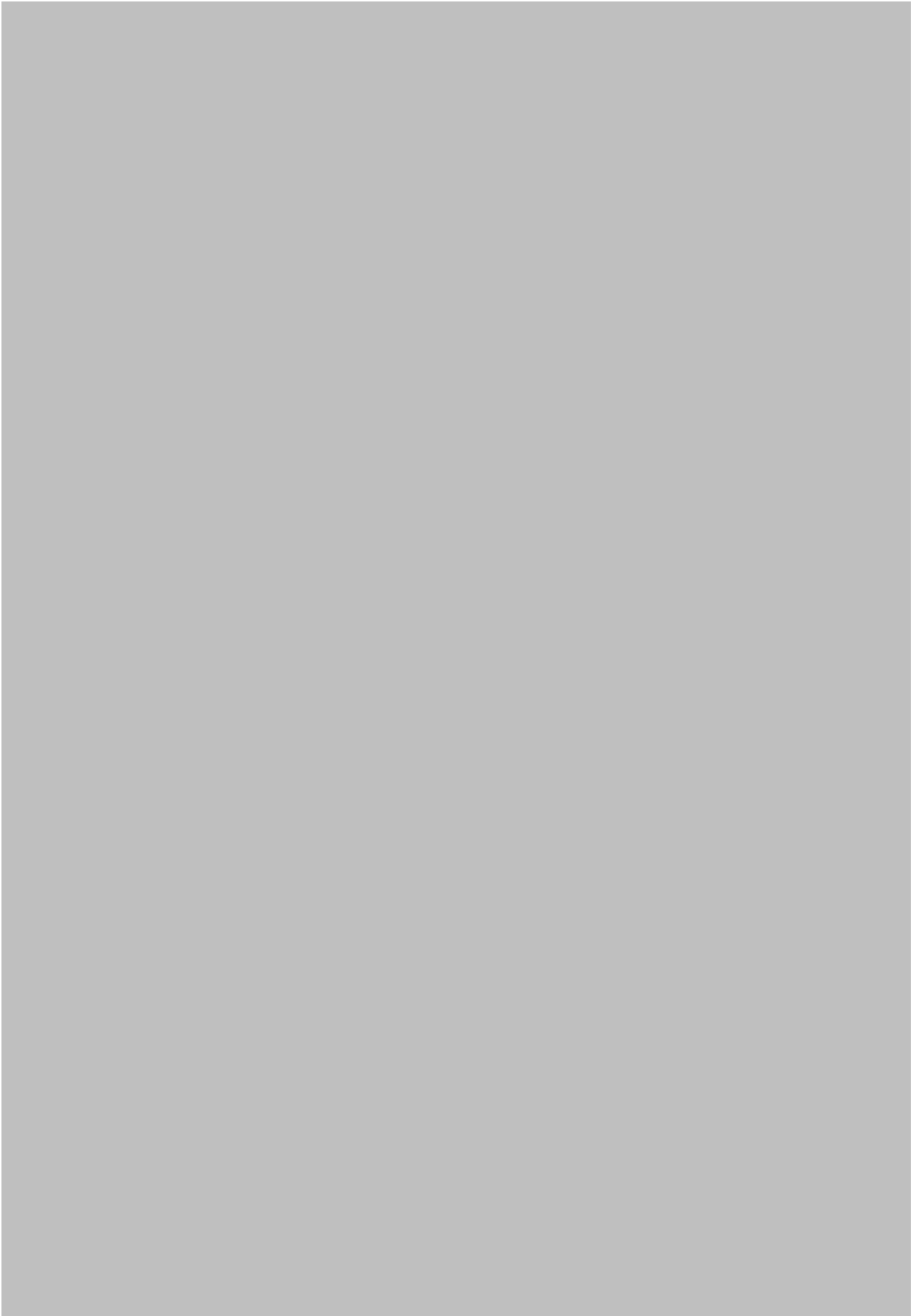




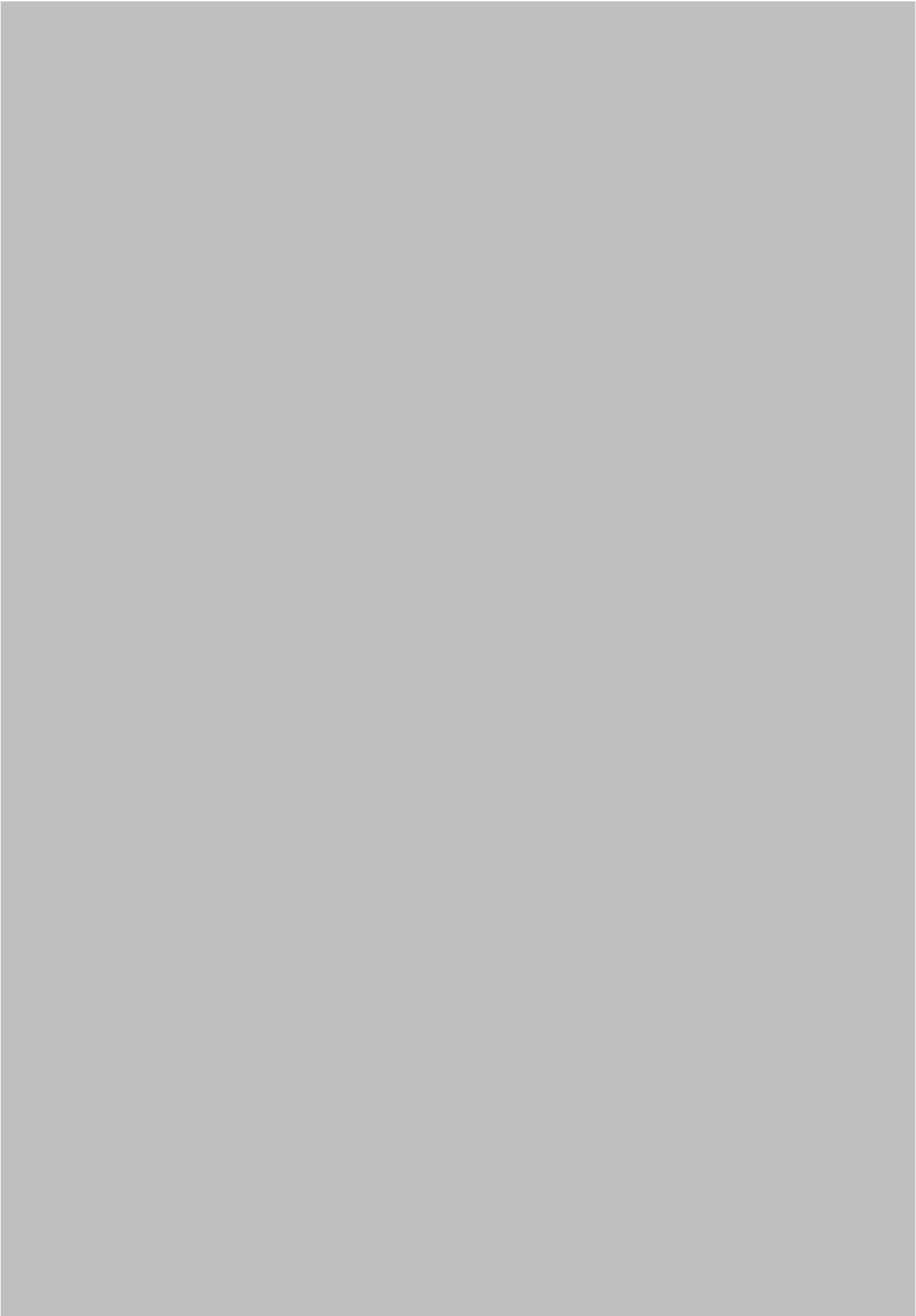




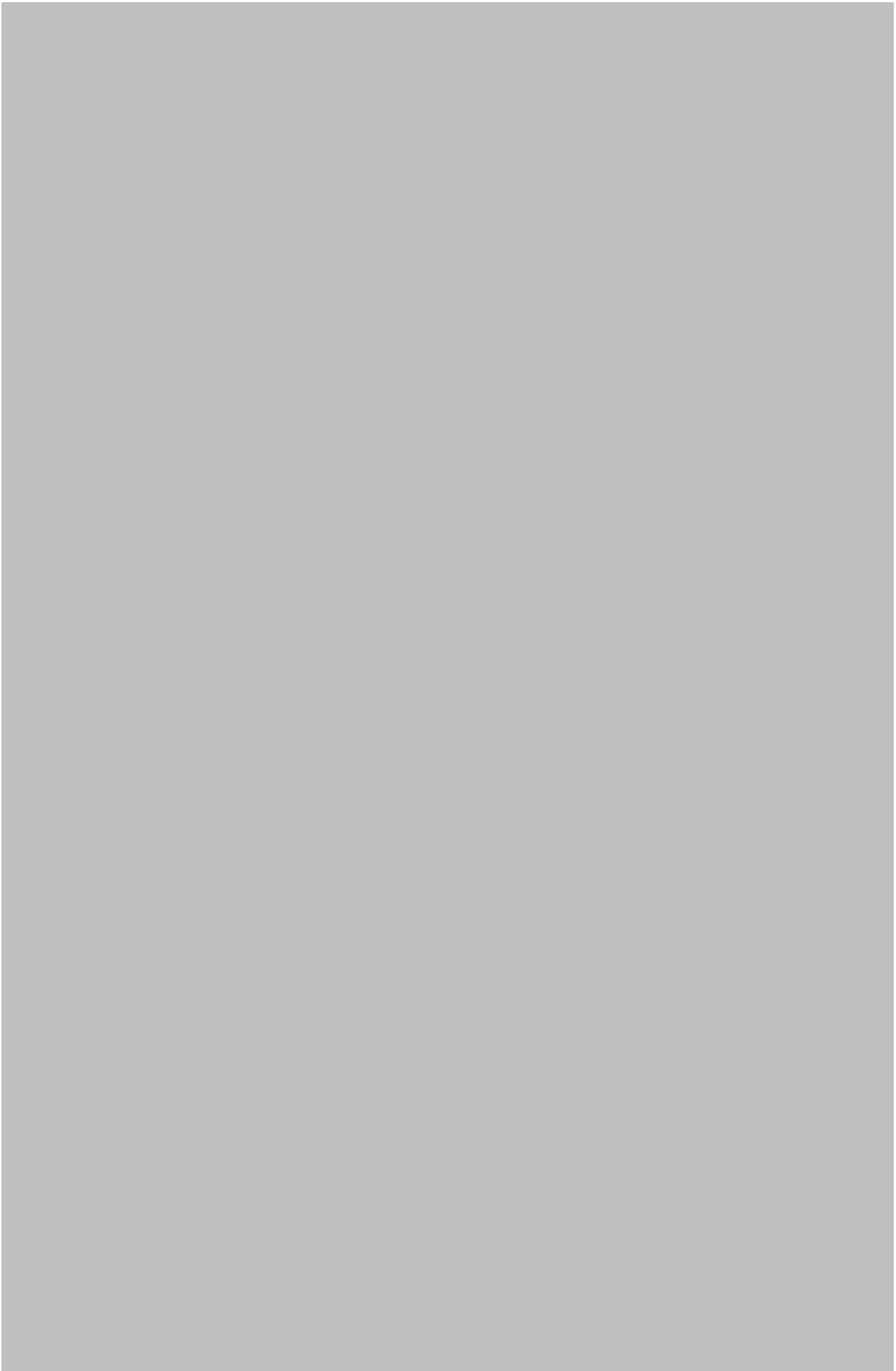






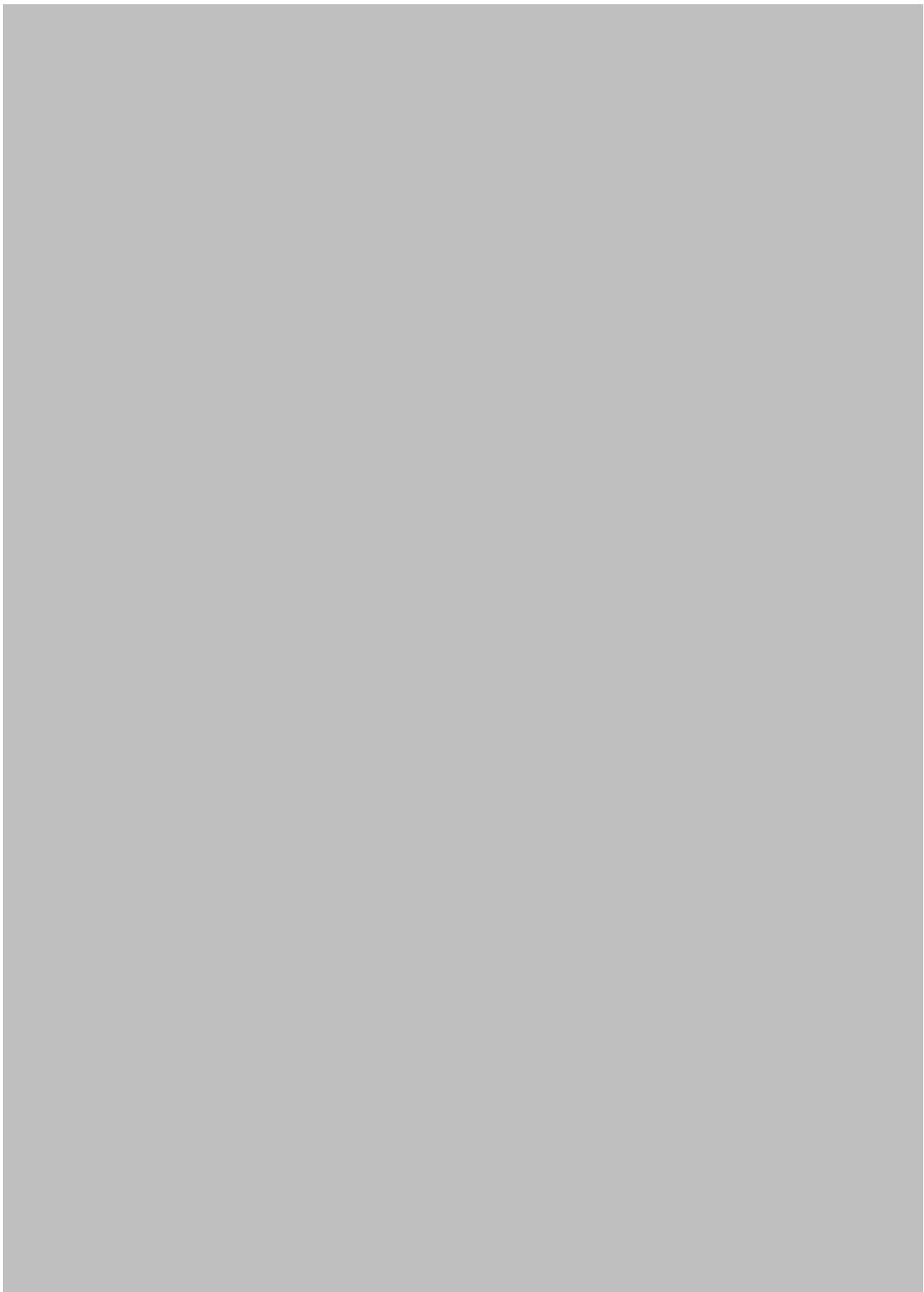




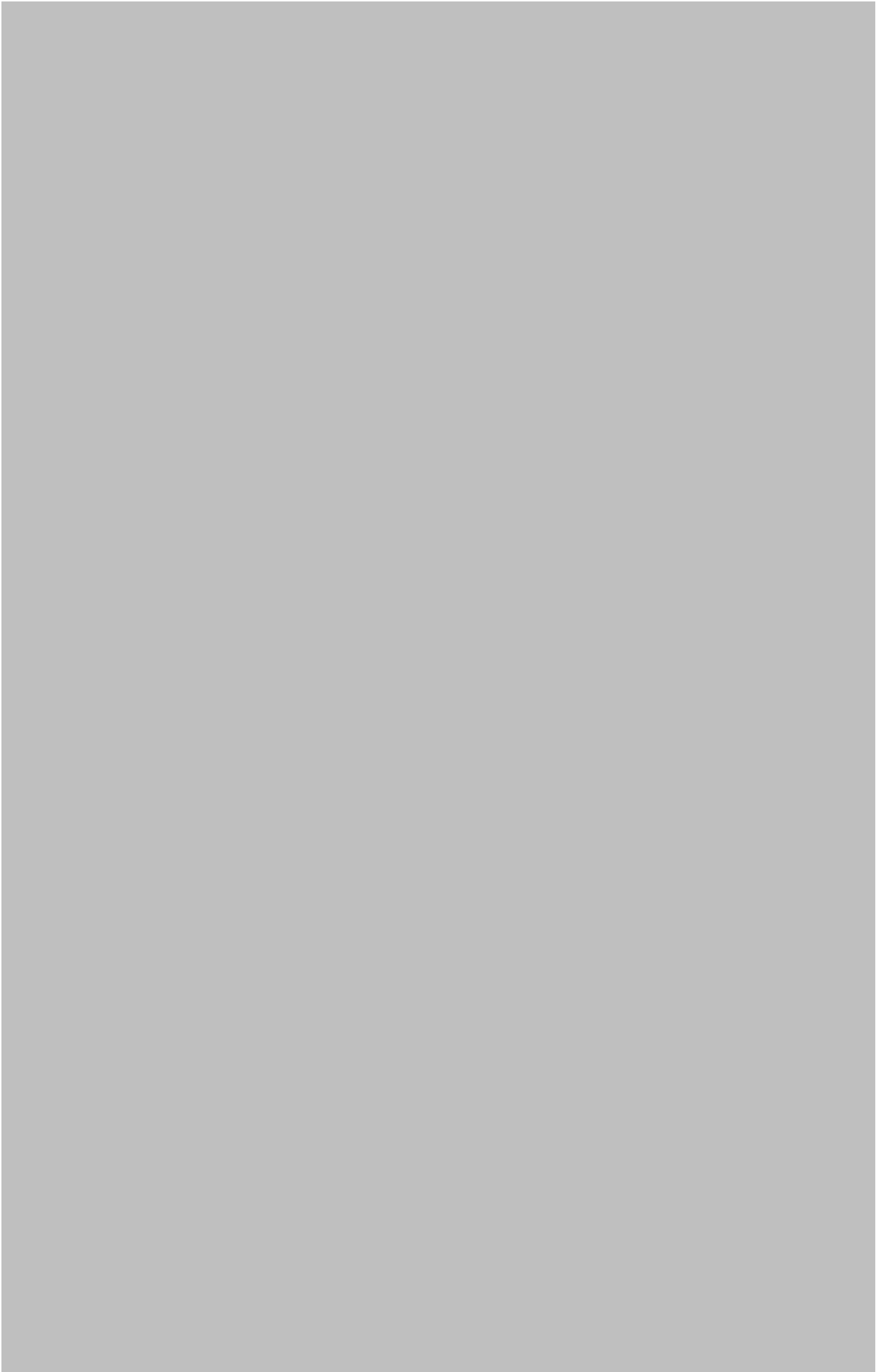


























# **ANNEX 11: USE OF A DERIVED MINIMUM EFFECT LEVEL (DMEL) IN THE CHEMICAL SAFETY ASSESSMENT**

This Annex presents two options to improve the chemical safety assessment via an increased use of Derived Minimal Effect Level (DMEL), i.e. a reference risk level which is considered to be of very low concern. Despite the relevance of this concept, these options are not presented in the main text of the SWD as they are of a more technical nature.

## **1 CONTEXT**

In accordance with the REACH Regulation, manufacturers and importers of a substance in a quantity of more than or equal to 1 t/y per manufacturer or importer are required to submit a registration for that substance to the European Chemicals Agency (ECHA). The registration must contain information on, i.a., the physicochemical, toxicological and ecotoxicological properties of the substance depending on the tonnage, the uses and exposure. For substances registered in a quantity of more than or equal to 10 t/y, the registrant must also conduct a Chemical Safety Assessment (CSA) and include this in a Chemical Safety Report (CSR) in the registration.

As part of the CSA, the registrant shall establish Derived No-Effect Levels (DNELs) for human health, i.e. a level of exposure above which humans should not be exposed. Similarly, the registrant shall establish Predicted No-Effect Concentrations (PNECs) for the environment, i.e. a concentration below which adverse effects to the environment are not expected to occur. These levels shall be used for documenting, through a quantitative comparison of exposure levels and DNELs and PNECs that risks to humans and the environment, respectively, are adequately controlled.

However, it is stated in REACH that “for some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established” (Annex I, 1.4.1). Furthermore, it is stated that “for those human effects [...] for which it was not possible to determine a DNEL [...], a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out” (Annex I, 6.5).

This approach has implications for how registrants should conduct their CSA and document that their substances are manufactured and used safely, as only a qualitative assessment is required for non-threshold substances. Thus, although it is normally anticipated that for some carcinogens and mutagens there are no safe exposure levels, no specific quantification of possible effects is required.

Nevertheless, ECHA has provided guidance on how to set Derived Minimal Effect Levels (DMELs) for a non-threshold carcinogen, cf. the ECHA guidance on information requirements and chemical safety assessment (ECHA, 2012), chapter R.8: Characterisation of dose [concentration]-response for human health, chapter R.8.5. In the guidance, a DMEL is defined as a reference risk level which is considered to be of very low concern, although it is not a level where no potential effects can be foreseen.

In the guidance, it is also mentioned that, contrary to the case for the risk assessment for threshold effects, by definition for non-threshold mutagens and carcinogens a dose without a theoretical cancer risk cannot be derived. Therefore, the establishment of a reference risk level for the DMEL clearly is of societal concern and needs policy guidance. Although there is no EU legislation setting ‘acceptable’ or ‘tolerable’ risk levels for carcinogens in society, such risk levels have been used in different contexts (consumer protection or worker protection, different Member States, countries or institutions). It must be noted that there is a linguistic difference between ‘acceptability’ and ‘tolerability’ that is often neglected and can lead to confusion. Acceptance has a more ‘absolute’ value, whereas tolerance is more conditional. We can accept a value, or a situation, or a behaviour, for what it generally is. If we tolerate it, it is not because we accept it per se, but because we accept it under a specific set of boundary conditions.

An overview of decision points for cancer risk levels that have been used in various countries, organisations and committees is provided in Appendix R.8-14 to the guidance. Without systematically distinguishing ‘acceptable’ and ‘tolerable’ risk levels, the guidance summarises the observations by stating that that cancer risk levels of 1 out of 1 million could be seen as an indicative acceptable risk level for the general population and 1 out of 100 000 could be seen as an indicative acceptable risk level for workers. It is noted that higher risk levels are tolerated in the context of, for example, authorisation decisions under REACH. Higher risk levels (or estimates thereof) are tolerated by the Commission and by Member States competent authorities, because of the important benefits of the substance use, because of appropriate occupational or general health monitoring measures ensuring early detection of adverse effects, and/or because of the conservative nature of the risk estimates reported in the applications for authorisation. In practice, what it means is that tolerated risk values cover the range between acceptable risk values and non-acceptable risk values, both of which could, in theory, be defined, either top-down, in law, or bottom-up, through a systematic analysis of existing regulatory practices. In both cases, defining these levels would require proper consideration of the required confidence level of the risk estimates that would have to be compared to the acceptance or tolerance limits.

In the same context, ECHA’s Risk Assessment Committee (RAC) is developing reference dose-response relationships for non-threshold carcinogens for the evaluation of applications for authorisation and as a guidance for the applicants as well as for evaluation of restriction proposals (ECHA, n.d.). During this analysis, RAC is estimating excess cancer risks, as appropriate, for inhalation, dermal or oral exposure of workers and the general population. These dose-response relationships are mainly used for assessing and monetising the possible effects of granting an authorisation, which is one of the elements for comparison of the risk with the socio-economic benefits linked to a granted authorisation. Similarly, for restriction proposals the dose-response relationships are used for assessing and monetising the risk reduction and the remaining risks.

Following a request from the Commission, a Joint Task Force between the Scientific Committee on Occupational Exposure Limits (SCOEL) and RAC was established in 2015. One of the tasks was to compare and assess the methodologies used by the two committees to assess non-threshold substances (Joint Task Force, 2017). The two committees only addressed carcinogens. They concluded that for genotoxic carcinogens, the default or starting assumption is that there is no toxicological threshold and that there is a linear relationship between exposure and effect. No Occupational Exposure Limit (OEL) or DNEL establishing ‘safe’ exposure levels can be defined and it is outside the

remits of the two committees to do so, as this requires policy advice on which risk levels are acceptable or tolerable for society. Instead, the two committees provide estimates of cancer risk at various exposure levels for use by decision makers.

The Commission is considering expanding the requirement to conduct a CSA to substances manufactured or imported in a quantity from 1 to 10 t/y and to increase the information requirements (cf. Annexes 5 and 9). Such amendments will increase the number of non-threshold substances for which, in the impossibility to derive a DNEL, a dose-response curve and a corresponding DMEL could be derived and, thus, a quantitative risk assessment (instead of only a qualitative one) could be carried out.

Thus, the introduction of DMELs for some non-threshold substances in REACH based on dose-response relationships and politically acceptable and/or tolerable risk levels for human health would allow an increase of the use of quantitative approaches in chemicals risk management.

## 2 DESCRIPTION OF THE PROBLEM

Substances with non-threshold hazards pose a particular challenge, as in essence there is no safe level of exposure. This complicates how risk can be effectively eliminated. Instead, risks need to be determined and managed to an appropriate level. The quantitative risk assessment approaches (DNELs and PNECs) for hazards with a threshold provide a clear approach to determining safe use and outcomes that both have regulatory certainty and ease of communication. For substances with non-threshold hazards, REACH currently allows a qualitative approach with written explanation of how risks and risk controls have been determined and applied. This narrative is then communicated down the supply chain. This approach has three key problematic issues:

- There is no harmonised approach to the qualitative risk assessment, meaning a lack of harmonisation and variation in quality of the assessment.
- The qualitative assessment is textual (rather than numeric), with the exposure scenarios and operational conditions then communicated down the supply chain. Where the exposure scenarios and operational conditions (including risk management measures) are also textual (and potentially subject to language translation) it can impair communication. Particularly, where downstream users are less well placed to judge if the exposure scenario is of good quality.
- Based on the interviews with regulators and the EU risk assessment committee (RAC), the qualitative assessment often focuses primarily on the risk management measures, with often far less details on the specific activity and potential exposure, which undermines confidence in the assessment.

While there has been slow uptake of the use of DMELs at EU level, some national authorities have gone beyond the minimum requirements set by REACH and further evolved the approach to use DMELs (including the development of two-tier systems<sup>248</sup>).

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<sup>248</sup> Some Member States have created two-tier systems with a tolerable threshold (i.e., the safe limit which must not be exceeded) and an acceptable threshold (i.e., an aspiration threshold below which the risks are assumed to be very low). It is explained that such two-tier systems provide a minimum setting and a target for continuous improvement. In essence, the two-tier approach results in a tolerance range between an

This may further complicate issues creating less regulatory harmony and exacerbating the concerns and issues highlighted further.

Therefore, the problem identified is three-fold:

- The accuracy of the qualitative risk assessment for non-threshold hazards may be weaker than quantitative approaches, falling below the aims of the REACH Regulation. This has knock-on effects for selection of risk controls, and overall protection of human health and environment.
- Communication of hazards, risks, and risk controls down the supply chain may be weaker when using qualitative risk assessments. This is further undermined where downstream users may be less well placed to judge the quality of exposure scenarios and operating conditions, particularly if the information provided is not comprehensive and lacks transparency. Moreover, downstream users may face additional challenges in cases where they are developing their own CSR in accordance with Article 37(4).
- The operation of different approaches at national level may have consequences for level playing field, and affect the regulatory certainty and clarity of communication. This could potentially create coherence issues between REACH and related legislation such as OSH, and also further undermine the trust in the information provided at downstream user level.

Based on the problems identified above it is also possible to identify who might be affected by the problems. These issues are outlined in the table below.

*Table 166: Overview of who is affected by the problems identified*

<b>Actors</b>	<b>Issue</b>	<b>Description</b>
<b>Businesses</b>	Selection and costs of risk controls.	Potential for the qualitative risk assessment to incorrectly gauge the level of risk. This has two possible consequences: Firstly, if the risk assessment is overly cautious then the selection of risk controls will equally be overly cautious meaning unnecessary costs will be incurred. Secondly, if the risk assessment is not sufficiently cautious it may mean that the safety of working environments and consumer safety are misjudged. This would have direct impacts in terms of lost time injuries/work force unable to work affecting both business continuity and productivity. Additionally, for consumers it would equate to impacts on health and healthcare burden (covered further down this table).
<b>Businesses</b>	Level playing field effects	Evolution of policy at different rates and under different national schemes may have impacts for level playing field. This has direct economic impacts for requirements under different jurisdictions.
<b>Workers</b>	Health effects / safety	If the assessment of risks underestimates the risk and therefore necessary risk controls are not implemented, there are direct potential health effects. This is likely to have impacts on quality of life, indirect impacts on wellbeing of family members/dependents, as well

acceptance limit (below which risks are accepted) and a higher non-acceptance limit (above which risks are not accepted). Exposure and risk values in the tolerance range can be tolerated, or not, depending on the specific context or situation.

<b>Actors</b>	<b>Issue</b>	<b>Description</b>
		as potential to work.
<b>General population</b>	Health effects / safety	If the assessment of risks underestimates the risk and therefore necessary risk controls are not implemented, there are potential direct health effects for consumers and the population in general. This is likely to have impacts on quality of life, indirect impacts on wellbeing of family members/dependents, as well as potential to work.
<b>Society</b>	Healthcare burden	The increased incidence of illness would place burden upon health care services and deplete resources that could be used for other things. This has the potential impact of increased costs of healthcare for the general public or lack of availability for critical resources in cases where the available resource is finite.
<b>Environment</b>	Environmental impacts	If the assessment of risks underestimates the risk and therefore necessary risk controls are not implemented, any releases to environment have the potential to cause negative impacts on the natural environment. This includes potential impacts for ecosystem stability and biodiversity.

RAC has been supportive in helping develop dose-response relationships for a limited number of non-threshold substances for analysis of applications for authorisation. The work required is labour intensive and RAC also has a wide range of other activities which need to be covered. The workers protection legislation (OSH<sup>249</sup> and CMRD<sup>250</sup>) has aimed to develop binding occupational exposure limits (BOELs) for non-threshold substances which could be useful, but again the number of substances whilst limited, with 28 substances, or groups of substances, with BOELs in the annexes of CMRD, has addressed key occupational carcinogens identified as high priorities by the tri-partite Advisory Committee on Safety and Health. As a comparison, 1 286 unique substances have a harmonised classification as carcinogens or mutagens, Category 1A, 1B or 2 under the CLP Regulation, and most of them are non-threshold substances.

The analysis presented here suggests that, without intervention, the further development of quantitative approaches for risk assessment of non-threshold substances could evolve slowly. While the qualitative approach to risk assessment is a reasonable compromise and if suitably managed should provide valuable consideration and management of the risks, further input via quantitative approaches would improve clarity, transparency, and communication across the supply chain.

### **3 OPTIONS AND SUB-OPTIONS**

#### **3.1 Objectives of intervention**

The problem definition identified that there may be concerns with the current approaches for the risk assessment covering non-threshold hazards, on the basis that the qualitative assessment may be more uncertain. This issue is exacerbated where there is no

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<sup>249</sup> The Occupational Safety and Health Framework Directive 89/391/EEC

<sup>250</sup> The Carcinogens, Mutagens and Reprotoxic Substances Directive 2004/37/EC.

harmonised approach to the qualitative assessment and the quality of the assessment may be variable, including the transparency of reporting.

The guidance<sup>251</sup> from ECHA has provided a quantitative approach (DMELs) to the risk assessment for non-threshold hazards which could reduce the uncertainty of the assessment and potentially improve the communication down the supply chain. This is further strengthened on the basis that the outputs of the DMEL approach are likely to have better regulatory scrutiny and certainty, which benefits both REACH registrants, the downstream users of chemical substances, and authorities (incl. regulators).

The intervention should therefore aim to develop an approach which can reduce the uncertainty in the risk assessment for non-threshold hazards and ensure the high level of protection for human health.

The problem definition also identified that the policy landscape is evolving in an irregular fashion, with some Member States spearheading new initiatives. In addition, it is expected that, for non-threshold substances, DMELs could help find a reasoned compromise between the precautionary principle and the proportionality principle.

### 3.1.1 *Policy options*

Two high-level overall options to help reduce the uncertainty in risk assessments for non-threshold hazards have been identified. These two options can be described as follows:

- **Option #15:** Enhanced DMEL use through non-legislative measures within REACH. This option would include modifying, e.g., the REACH guidance to give clearer expectations that a quantitative approach to CSA is expected where possible. It would not include changes to the REACH regulation itself.
- **Option #16:** Amend REACH to further require use of the DMEL concept. This option would include a specific legislative change indicating that a DMEL is required for substances with certain hazard types, as well as which risk levels that are acceptable or tolerable.

These options provide the broad overarching structure for analysis under the impact assessment. However, given the issues identified under the problem definition, further nuance is needed in how these overarching options are applied and assessed.

### 3.1.2 *Sub-options*

A wide range of sub-options have been developed and are broadly grouped under different elements (e.g., which hazard endpoints should be included under Option 1 and 2). The grouped sub-options were assessed and screened in/out based on legal feasibility; technical feasibility; previous policy choices; coherence with other EU policy objectives; effectiveness and efficiency; proportionality; political feasibility; and relevance. Note that these sub-options are grouped under a set of key elements, and that some of these elements/sub-options may only be relevant under a regulatory change (i.e., they only appear under Option #16).

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<sup>251</sup> ECHA, 2012, 'Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose-response for human health', ECHA guidance document v2.1.

Based on the initial screening, options were screened into one of three categories: ‘included’, ‘excluded’, or ‘potentially excluded pending further discussion’. The preliminary outcomes of this screening were then presented at the study workshop with suitable supporting material for a full discussion. Based on that discussion, a second screening step was completed with the sub-options either included or excluded. The table below sets out the finalised version of the sub-options (post feedback from the study workshop) with details of the different sub-options and alternative parameters that need to be considered in order to define how the options would be implemented in practice.

Table 167: Initial screening of sub-options and alternative parameters

Element	Possible sub-options	Comments from screening
<b>A. Which endpoints are covered?</b>	(i). Carcinogens and germ cell mutagens – cat. 1A/1B	Relates to both harmonised and self/notified classification. DMEL concept applied for various substances already. <u>Include</u> .
	(ii) Carcinogens and germ cell mutagens – cat. 2	Typically, insufficient data for cat. 2 to definitively conclude that a substance is carc/muta. <u>Include</u>
	(iii) Respiratory sensitisers	Some DMELs have already been developed under REACH. However, in most cases it is not possible to develop a dose-response relationship for respiratory sensitisers. <u>Exclude on the basis of <b>technical non-feasibility</b></u> .
	(iv) Endocrine disrupters	Note technical challenges based on e.g., non-linear dose response relationships and challenges identifying dose-response relationships. <u>Exclude on the basis of <b>technical non-feasibility</b></u> .
<b>B. Who develops the DMEL?</b>	(i) Registrants only	This mirrors the current process under REACH. <u>Include</u> .
	(ii) Authorities only	Unlikely to be a relevant option given that REACH aims to place burden of proof on industry. Could retain to assess resource implications but likely to be dismissed. <u>Exclude on the basis of <b>coherence with other EU policy objectives; effectiveness and efficiency; and political feasibility</b></u> .
	(iii) For most substances the registrants develop the DMEL; authorities can develop EU harmonised DMEL in certain cases	Allows for a consistent approach to be applied, e.g., similar DMELs for related substances which could otherwise have very different DMELs. Cases where authorities



Element	Possible sub-options	Comments from screening
		develop DMEL could be prioritised based on e.g. the Substance Evaluation process. <u>Exclude on the basis of proportionality and policy objectives.</u>
	(iv) As (iii) with amendment to the Substance Evaluation process to allow authorities to over-ride DMEL used by registrants	Initially considered but excluded based on similarity with (iii). <u>Included in (iii) above.</u>
<b>C. Is the quantitative DMEL approach mandatory?</b>	(i) Mandatory to develop a numerical DMEL value only if suitable dose-response relationship can be derived from the data available for the substance in question	Potentially merge with (ii). <u>Include.</u>
	(ii) Mandatory if registrant can develop new dose-response relationship based on use of read-across or modelling	Potentially merge with (i). <u>Include.</u>
	(iii) Mandatory to develop new dose-response relationship even if this involves new animal testing	Information requirements in Annexes VII-X should be aligned with the need to classify and to do risk assessment (safe level), but the need to be able to derive safe levels should not in itself drive the animal testing. <u>Exclude on the basis of political non-feasibility.</u>
	(iv) Approach is voluntary	Not included as this is essentially the baseline situation. <u>Exclude.</u>
<b>D. Which populations are covered?</b>	(i) Workers (occupational exposure)	Note potential issues with political feasibility based on overlap with worker protection legislation. <u>Include.</u>
	(ii) Humans exposed via the environment	<u>Include.</u>
	(iii) Consumers	Note that all combinations of sub-options (i), (ii) and (iii) should be assessed. <u>Include.</u>
<b>E. Which substance tonnage groups are covered?</b>	(i) Only those that currently require CSA ( $\geq 10$ t/y per registrant)	<u>Include.</u>
	(ii) Those that currently require CSA but also those at 1-10 t/y (if data allows dose-response curve to be developed)	Note, information required may not allow for establishment of Dose-Response curves. <u>Include.</u>

Element	Possible sub-options	Comments from screening
<b>F. How many quantitative risk thresholds are applied?</b>	(i) Single value for tolerable risk level	As is currently the case with the values included in guidance. Consistent with the current CSA approach. <u>Include</u> .
	(ii) One value ('acceptable') below which risk is acceptable and second value below which risk is 'tolerable' if RMM reduce risk as far as practicable (and above which risk is unacceptable)	Potentially not consistent with the existing CSA approach. However, this is the approach applied in some Member States, albeit not directly for CSA under REACH. <u>Include</u> .
<b>G. Is the quantitative risk threshold mandatory?</b>	(i) Non-binding quantitative risk threshold, as included in current REACH guidance.	Note that this is not simply the baseline, as other sub-options would enhance the use of the DMEL concept. Would be less politically challenging. <u>Include</u> .
	(ii) Binding politically-agreed value for acceptable and (maximally) tolerable risk levels.	Would need to take into account values currently applied by EU Member states and elsewhere (e.g. DE, NL, FR, PL). Would enhance consistency of approach. <u>Include</u> .
<b>H. When must the quantitative DMEL approach be applied?</b>	(i) Only when routine update of registration dossiers is done (note link to wider REACH IA and dossier update provisions)	<u>Include</u> .
	(ii) By a specified deadline after entry into force	<u>Include</u> .
<b>I. What is the agreed acceptable or tolerable excess lifetime cancer risk for workers (over 40 years)?</b>	(i) 1 in 1 000 (ii) 1 in 10 000 (iii) 1 in 100 000 (iv) 1 in 1 000 000	Note some Member States have different values e.g. $4 \times 10^{-3}$ prohibitive and $4 \times 10^{-5}$ acceptable in NL and DE. <u>Include all as alternative options/parameters.</u>
<b>J. What is the agreed acceptable or tolerable excess lifetime cancer risk for the public (over 70 years)?</b>	(i) 1 in 1 000 (ii) 1 in 10 000 (iii) 1 in 100 000 (iv) 1 in 1 000 000	<u>Include all as alternative options/parameters.</u>

### 3.1.3 Initial discussion of sub-options

#### ***Sub-option A – Which hazard endpoints are included?***

To date the focus on the use of DMELs was mainly on non-threshold carcinogens and germ cell mutagens, but it is recognised that other non-threshold hazards exist,

particularly respiratory sensitisers, immunotoxicants, neurotoxicants, and endocrine disruptors. Information from the ECHA database on REACH registrations indicated that carcinogens and mutagens were the most common endpoints where registrants had used DMELs (102 substances), with the next biggest hazard type being respiratory sensitisers (23 substances). Based on the analysis, respiratory sensitisers and endocrine disruptors were included as possible sub-options within the amber category (potentially exclude) for further discussion at the study workshop.

Feedback from the delegates at the workshop highlighted that there were still significant technical challenges to address carcinogens and mutagens, and respiratory sensitisers and endocrine disruptors would be even more challenging. Many delegates highlighted that the preference would be to further make use of DMELs for the carcinogen and mutagen endpoints first to help evolve and develop mature approaches, before attempting other endpoints. Respiratory sensitisers and endocrine disruptors were therefore screened out as sub-options for the impact assessment.

A second issue was around whether the DMEL approach should be applied only to Cat 1A/1B substances or also include Cat 2. The original analysis for the state of play cast some doubts over whether sufficient data on substances with Cat 2 classification would be available to support the derivation of a DMEL, but delegates at the workshop felt that Cat 1A/1B and 2 should be included in scope. Additional analysis on the state of play confirms that Cat 2 carcinogens and mutagens should be in scope, with further discussion on the impacts below.

#### ***Sub-option B – Who develops the DMEL?***

Delegates at the workshop highlighted that based on the polluter pays principle which is enshrined in the REACH Regulation by placing responsibility on registrants, REACH registrants should be responsible for developing the DMEL. Members of the RAC also highlighted the labour-intensive nature of developing DMELs and the finite resources of the RAC. It was noted, however, that RAC could act as a review body in specific cases where DMELs needed to be evaluated. The sub-options have been amended accordingly.

#### ***Sub-option C – Is the quantitative DMEL approach mandatory?***

This element sets in place a set of sub-options to help determine rules for how the mandatory option might work. Note that the sub-options that result in a significant increase in animal testing were excluded on the basis that sufficient information from other approaches should take priority, and that animal testing is a last resort.

#### ***Sub-option D – Which populations are covered?***

The sub-options are disaggregated to cover workers, consumers, and exposure of humans via the environment. All three categories are included.

#### ***Sub-option E – Which substance tonnage groups are covered?***

As part of the wider body of work on the revision of the REACH Regulation, an assessment is currently underway to look at the data requirements and obligations on REACH registrants for substances in the 1-10 t/y bracket. Therefore, this element is included in the analysis.

***Sub-option F – How many quantitative risk thresholds are applied?***

The sub-option for a two-tier system approach on an EU-wide basis is included alongside the existing approach.

***Sub-option G – Is the quantitative risk threshold mandatory?***

Under the existing approach, the use of quantitative risk assessments such as DMELs for non-threshold substances is voluntary. This includes allowing the REACH registrants discretion to select their own risk threshold in cases where they decide to derive DMELs. The ECHA guidance does provide some steer on what threshold values for tolerable risk could be used, but the guidance is not specific (e.g., does not distinguish between acceptable and tolerable risk) and registrants are able to deviate from the guidance. This element therefore poses the question over whether one specific threshold excess risk value (e.g.,  $10^{-4}$ ) should form a binding minimum level, similar to binding OELs used under OSH.

The use of maximum risk thresholds has been identified both within related EU legislation (e.g., OSH) and in other OECD geographies, such as the USA and Canada. Therefore, these sub-options are included.

***Sub-option H – When must the quantitative DMEL approach be applied?***

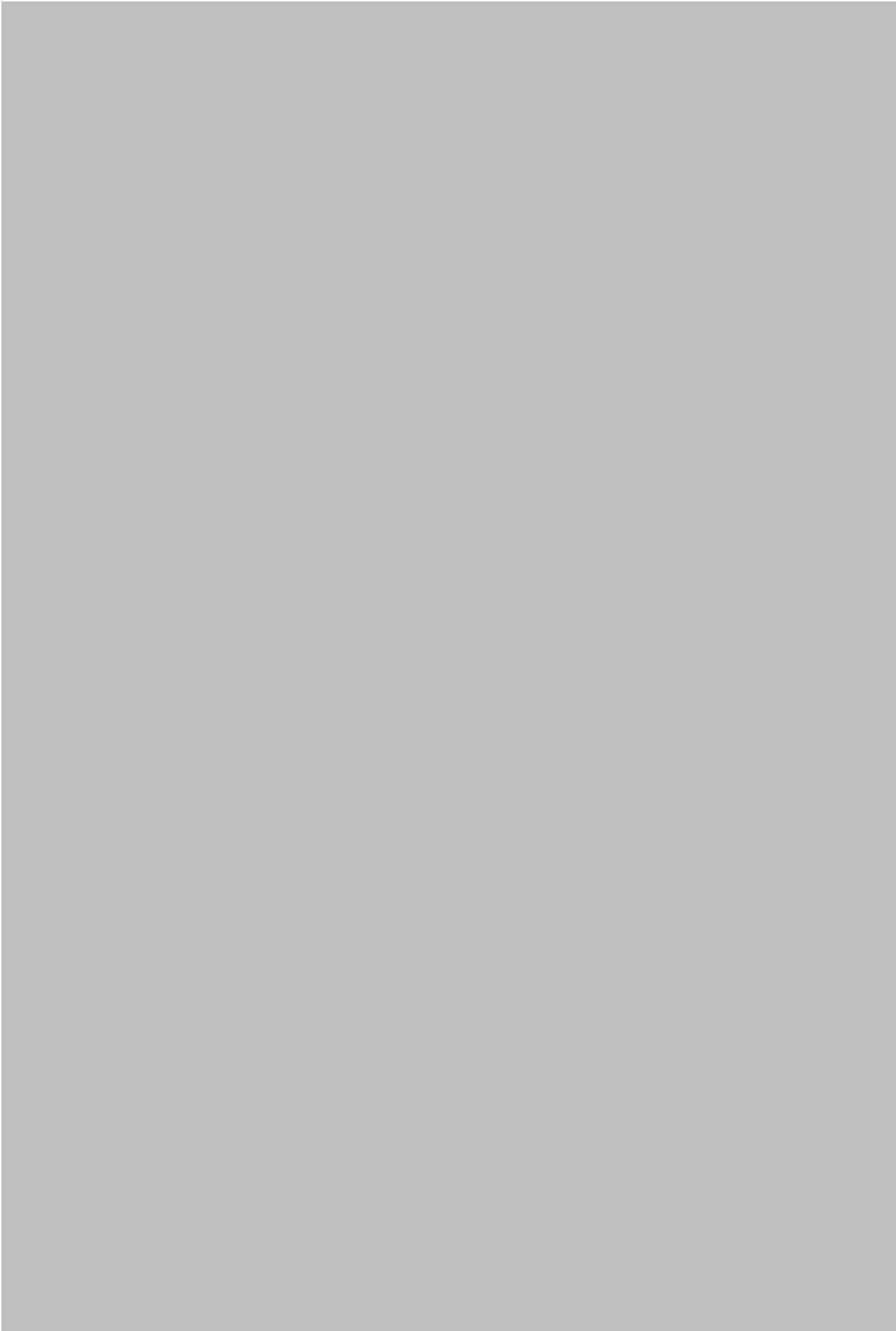
This element provides some additional flexibility to the timing of when data would need to be provided under a mandatory approach.

***Sub-options I & J – What is the agreed excess lifetime cancer risk for workers and for the general public?***

The final two elements pose the question of what the appropriate threshold for DMELs under different settings might be. The thresholds in use for excess lifetime cancers risk typically range from  $10^{-3}$  to  $10^{-6}$ , i.e. from 1 case out of 1,000 exposed to 1 case out of 1 million exposed, depending on the substance and setting. Therefore, the sub-options under both of these elements include the full range of possible thresholds based on increasing orders of magnitude:  $10^{-3}$ ,  $10^{-4}$ ,  $10^{-5}$ , and  $10^{-6}$ .



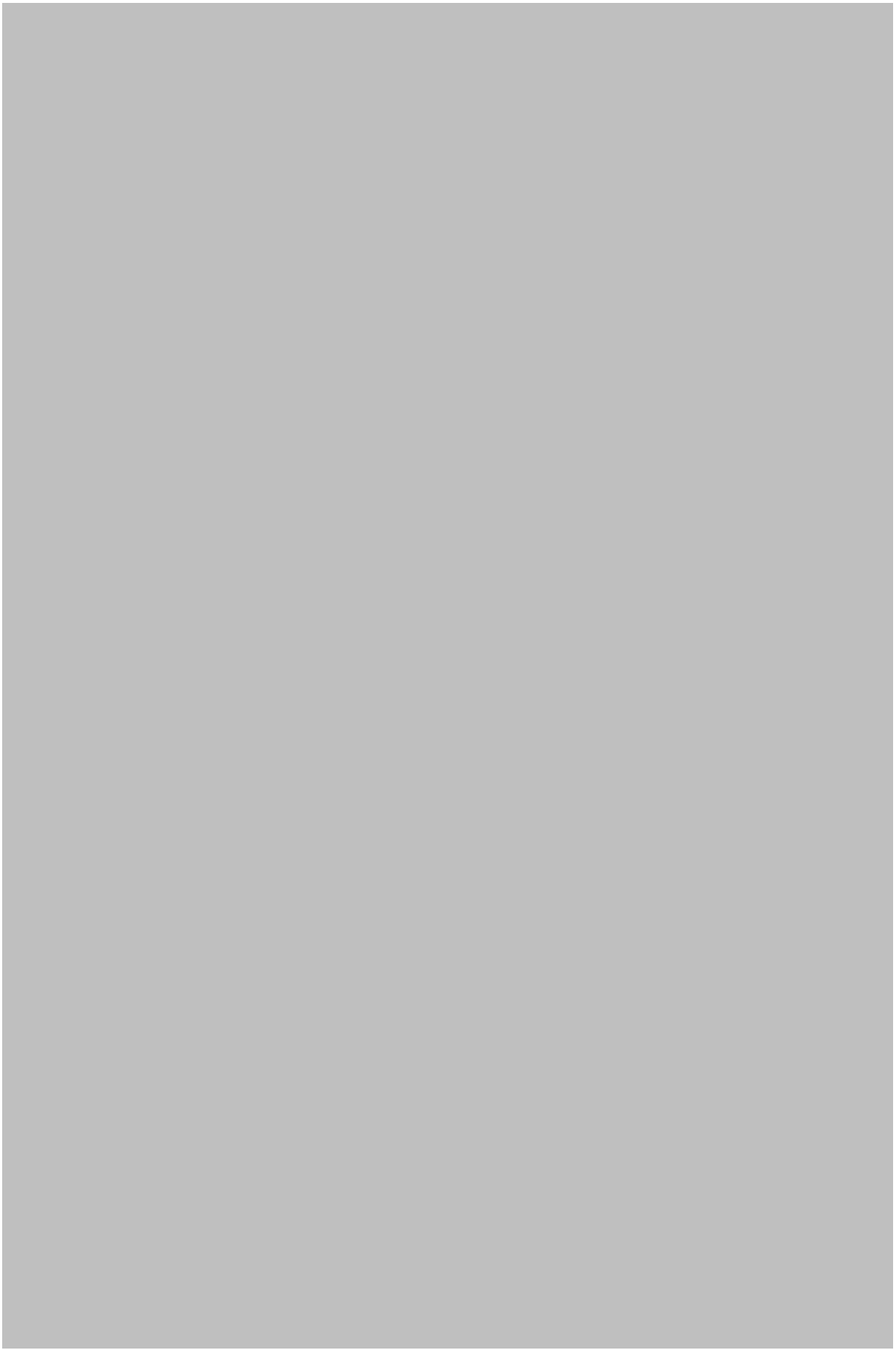






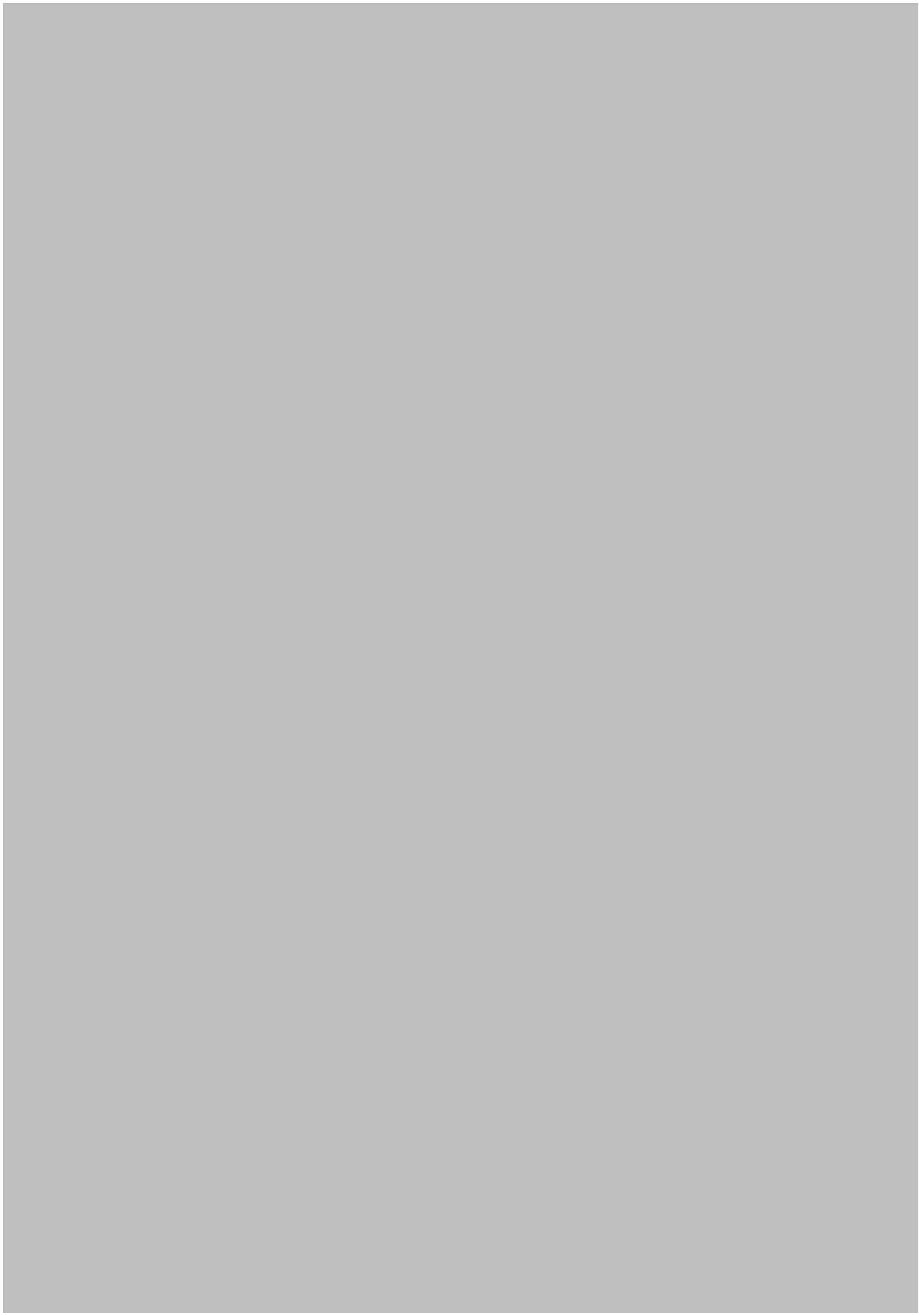


















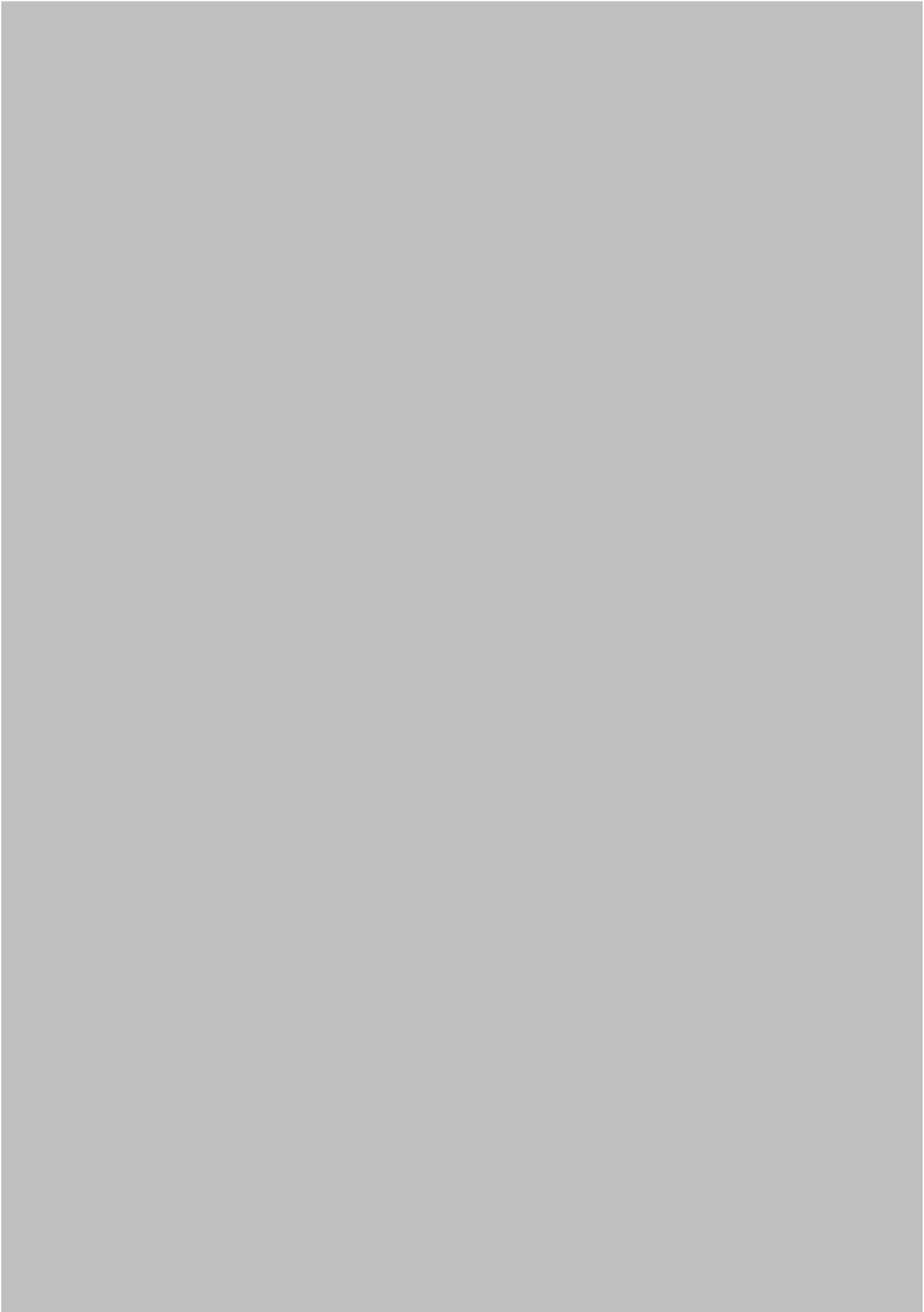






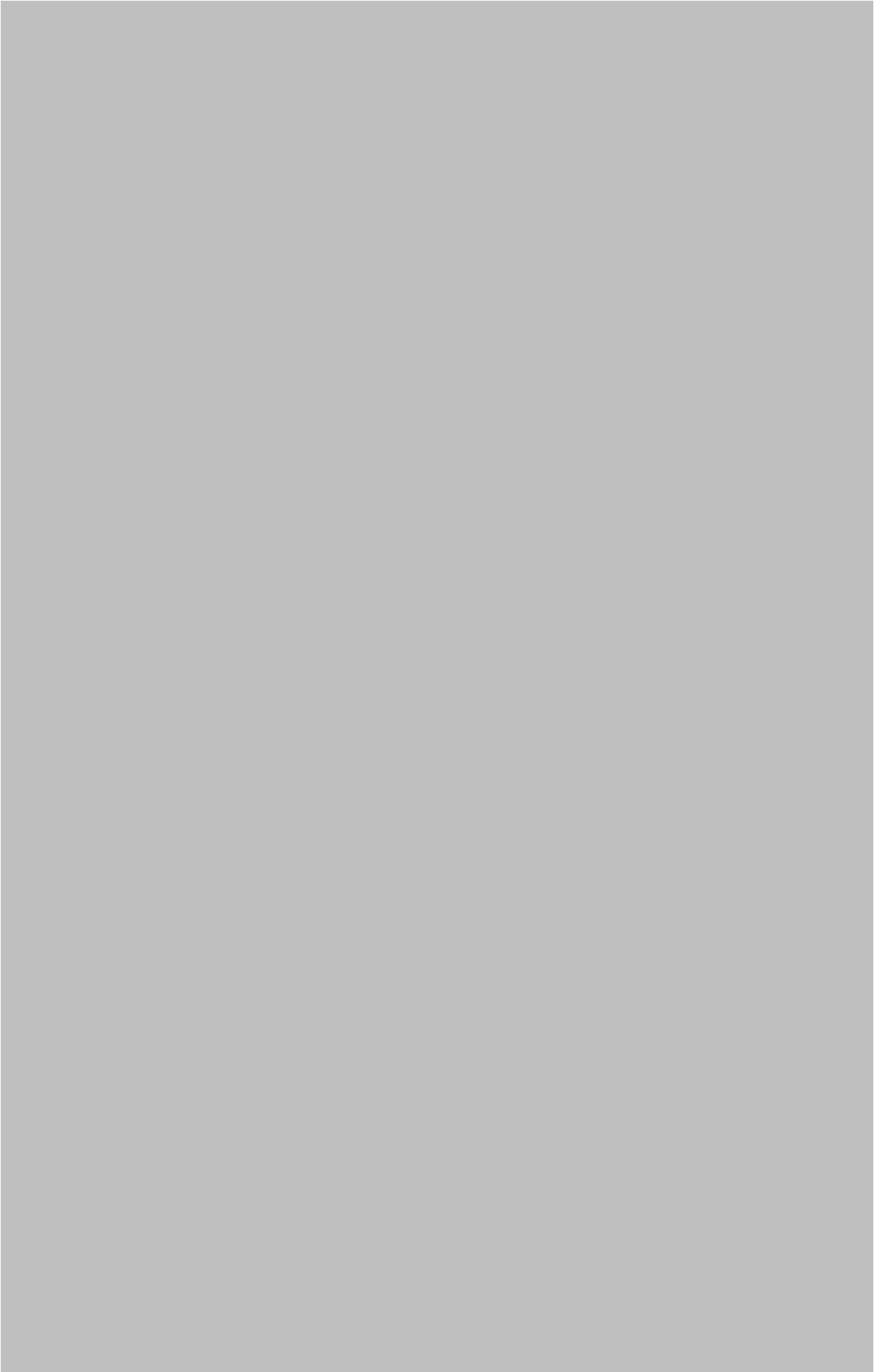
















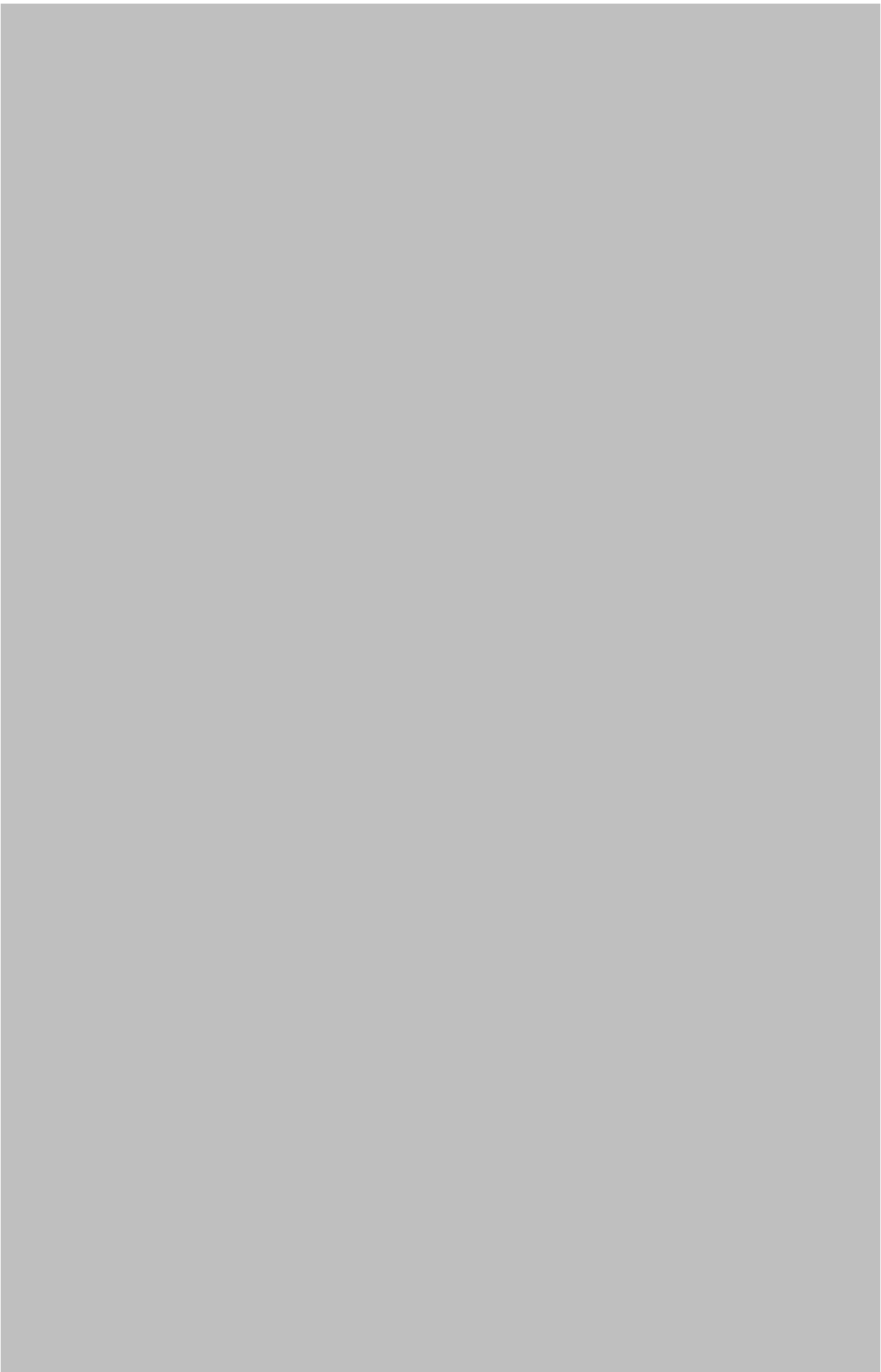








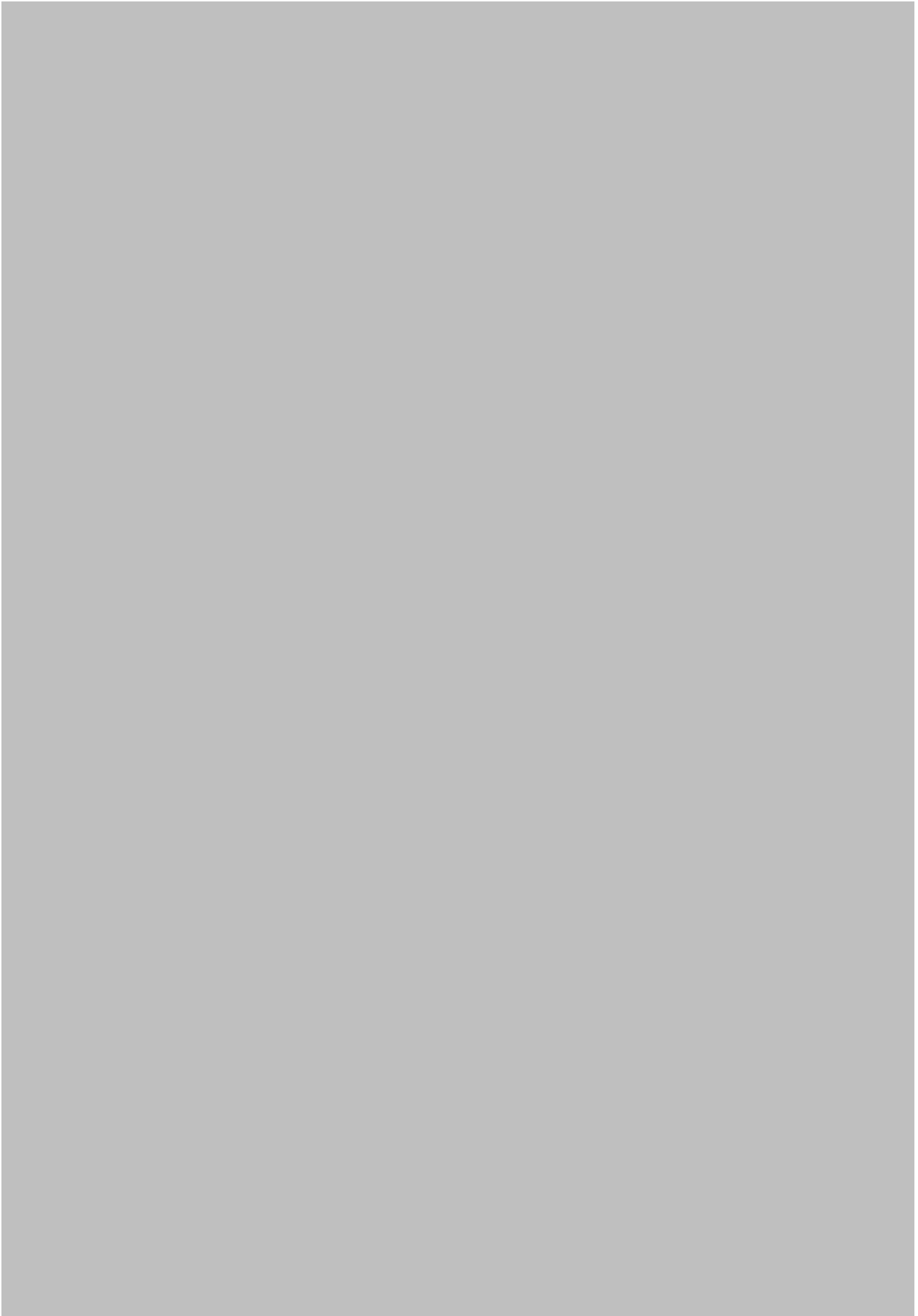


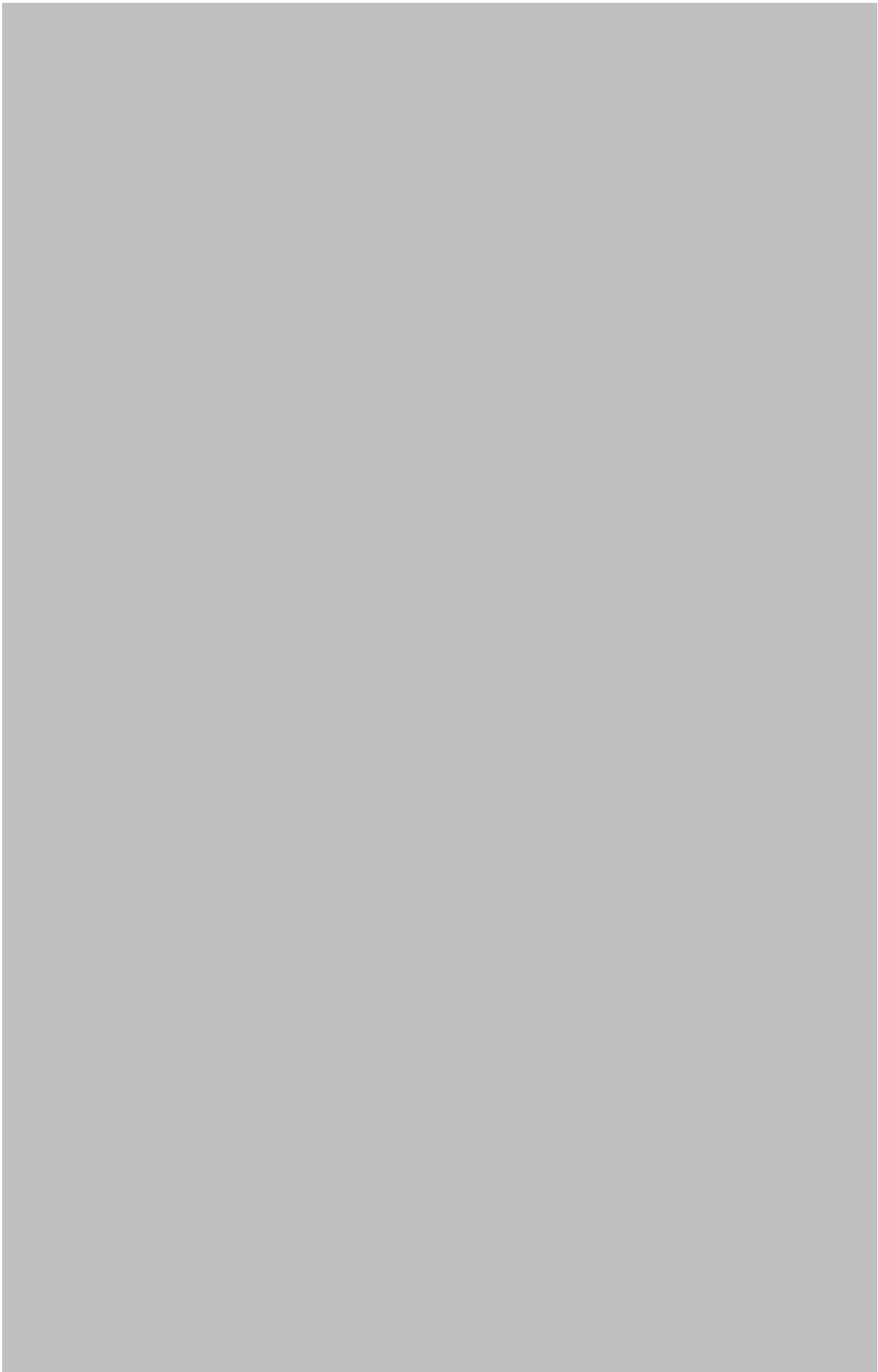


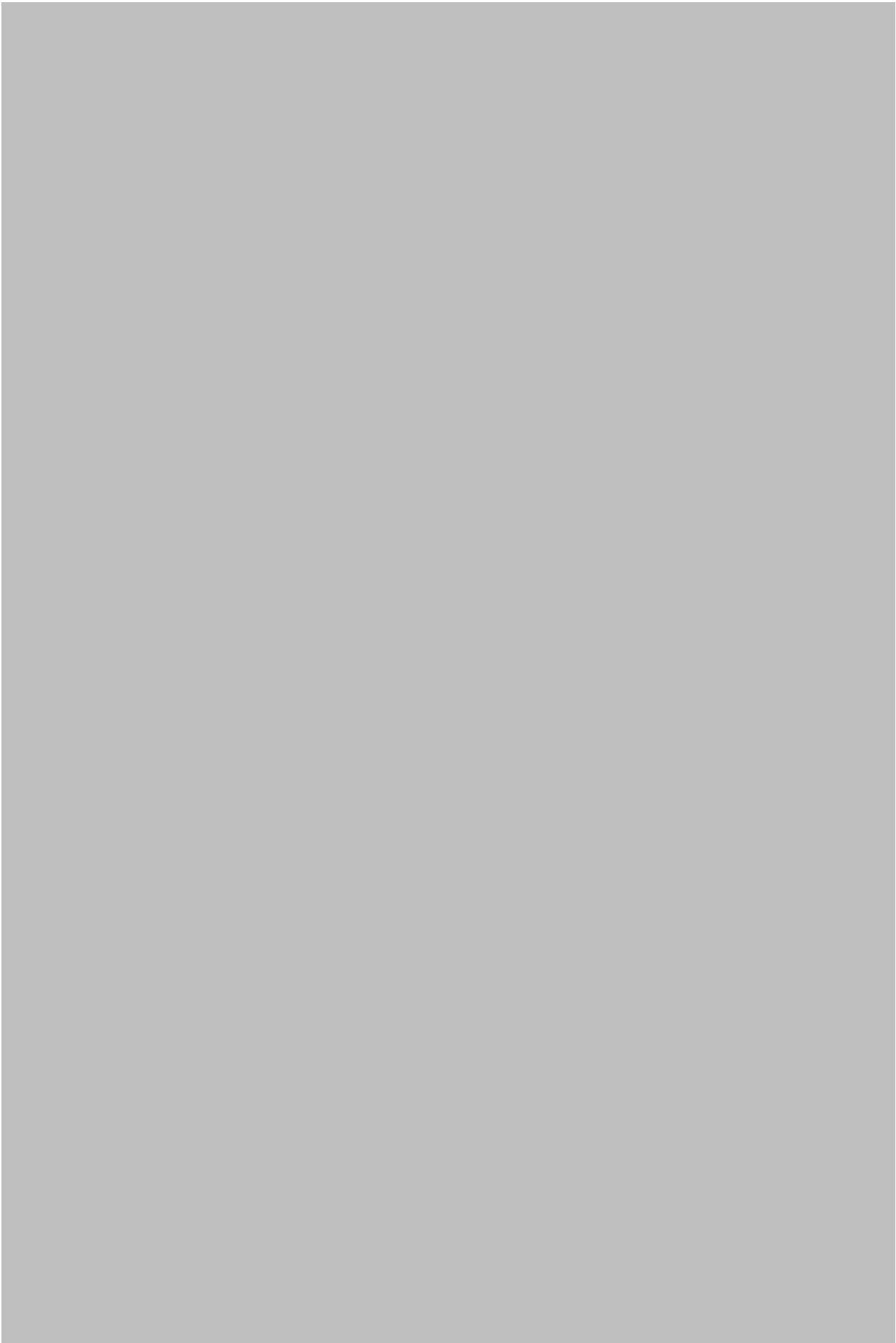




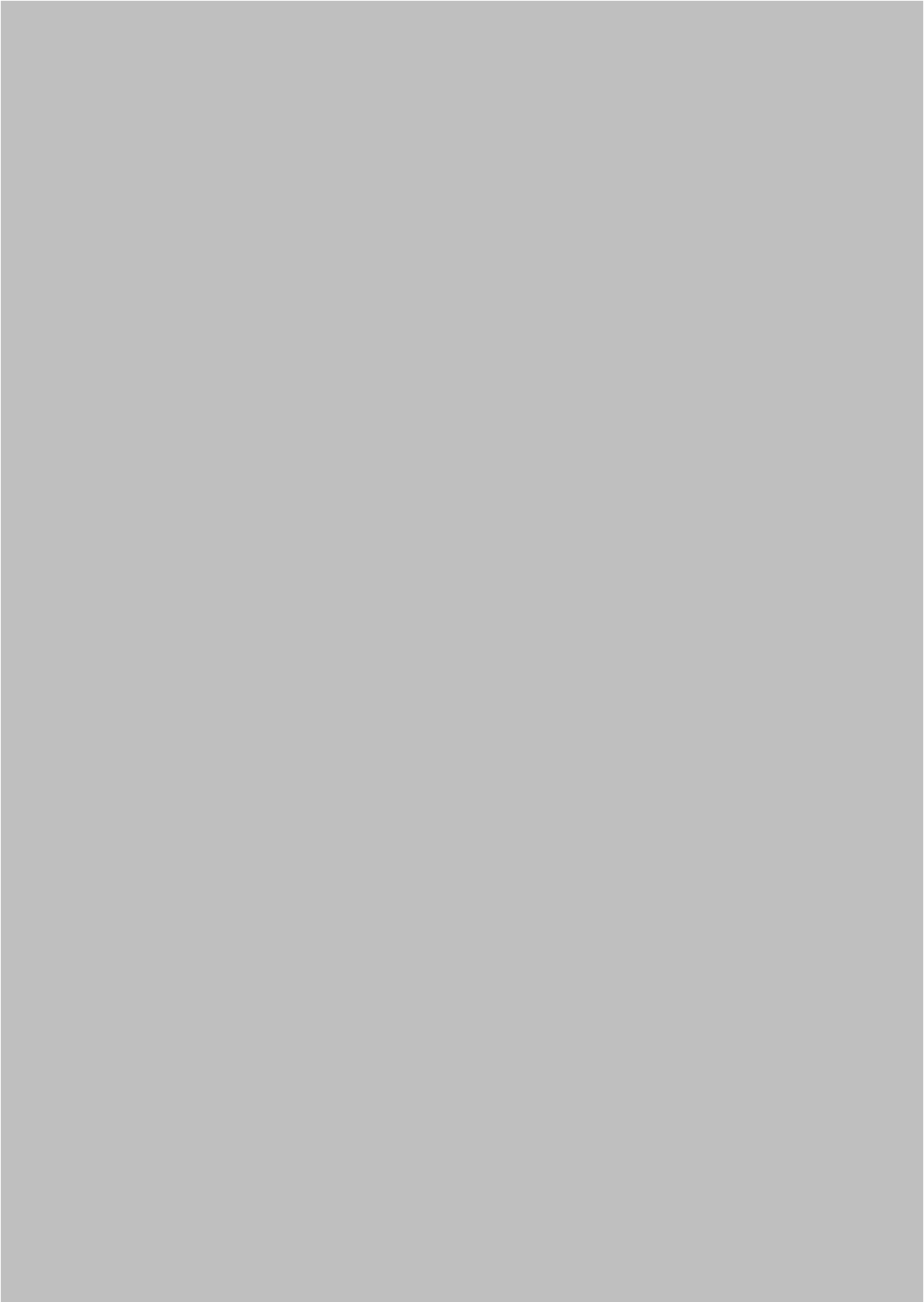










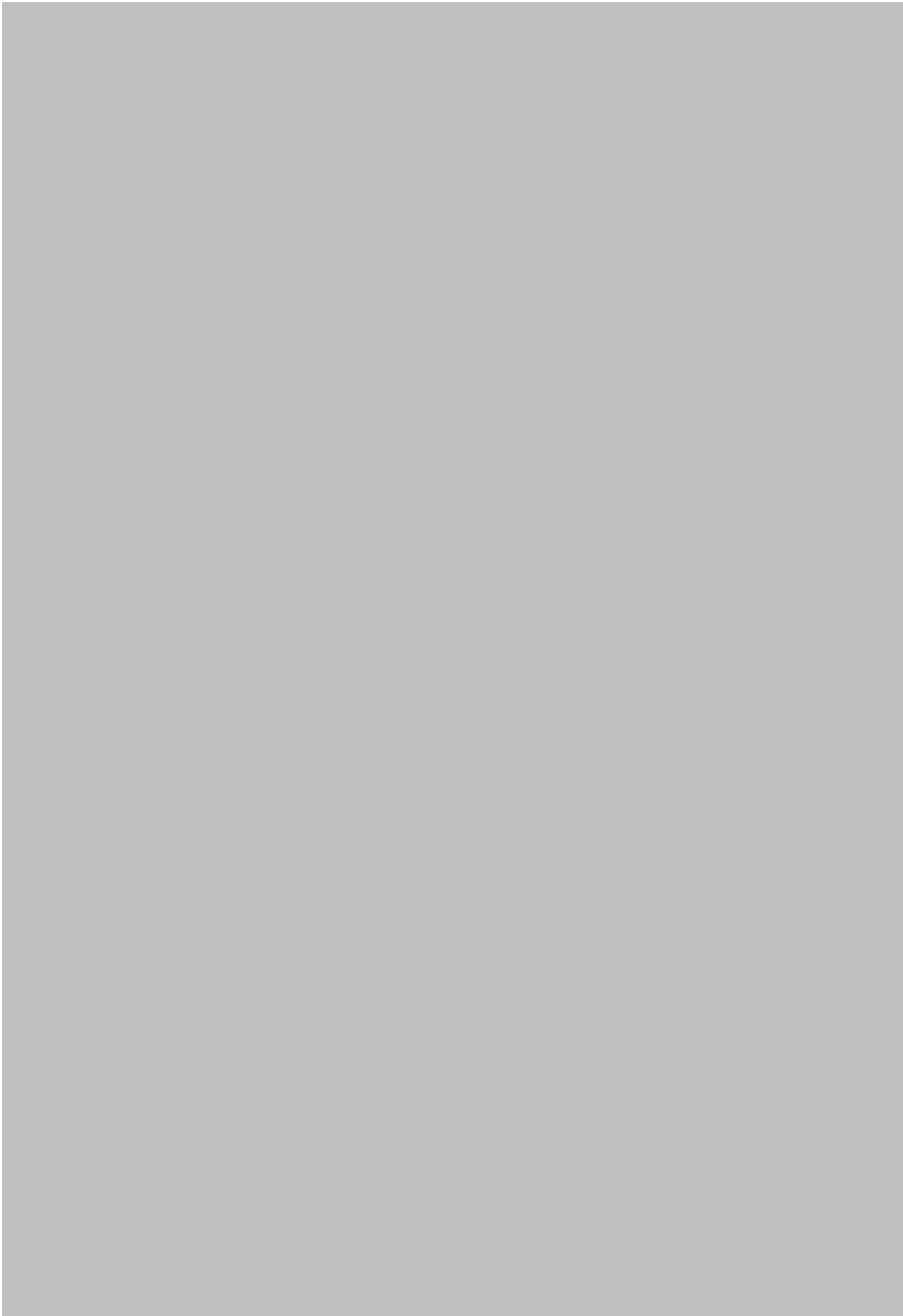




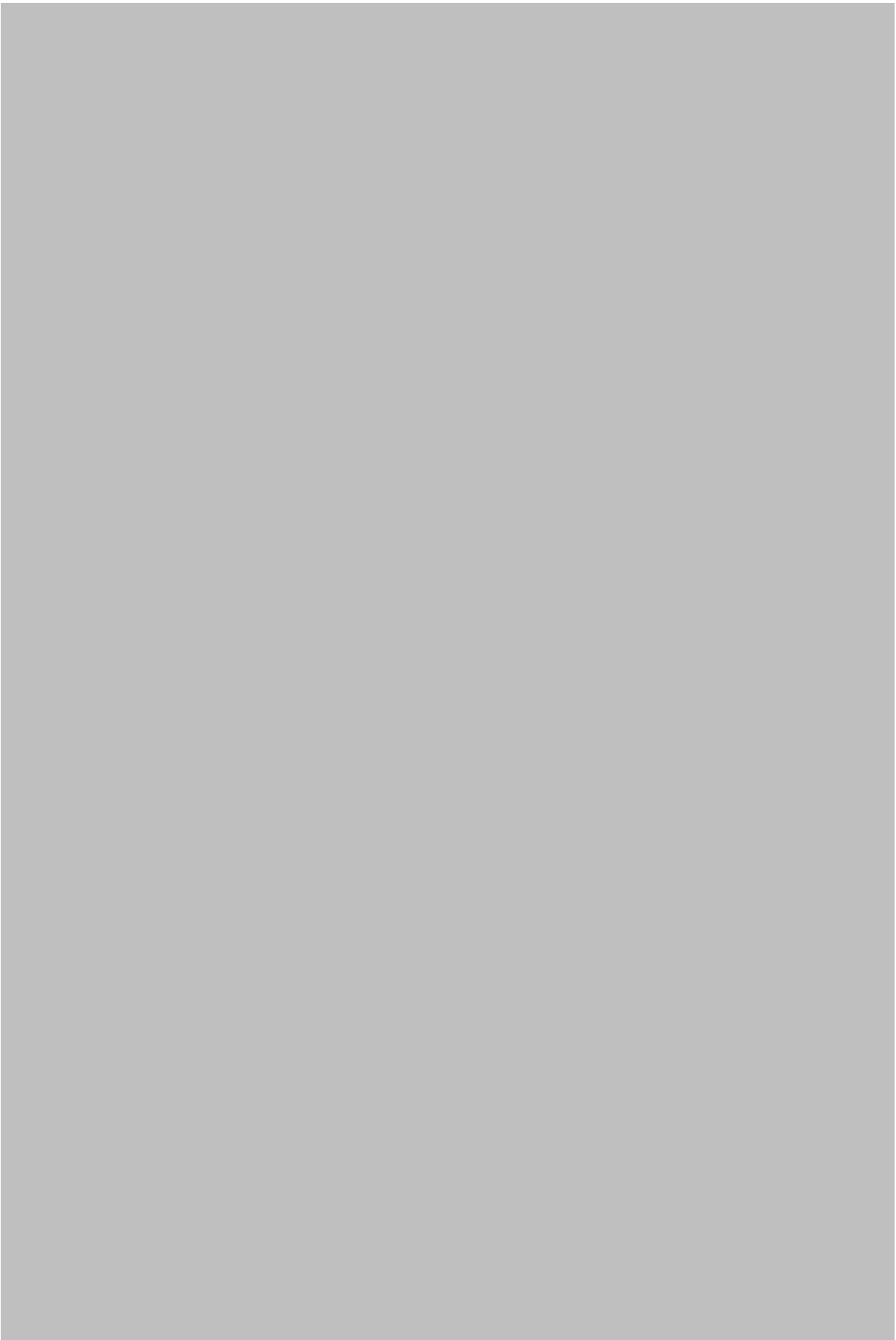






















## ANNEX 12: REFORM OF RESTRICTION AND AUTHORISATION

This annex is based on the work carried out by external consultants in the framework of two supporting studies (see Annex 1):

- Study to support the impact assessment for potential amendments of the REACH Regulation, to extend the use of the generic risk management approach to further hazard classes and uses, and to reform the REACH authorisations and restrictions by the VVA Consortium (referred in the text as VVA unpublished);
- Study supporting the Commission in developing an essential use concept by Wood (referred in the text as Wood unpublished).

The most significant results from the above-mentioned studies in the context of this impact assessment are presented in this annex. Where the European Commission disagrees with the outcome of these studies, different views, assumptions and estimates might be presented and explained in this Annex.

### 1 CONTEXT: OVERVIEW OF AUTHORISATIONS AND RESTRICTION PROCESSES

Where registration requirements and the general obligation to companies to ensure that substances throughout the life cycle do not adversely affect human health and the environment is insufficient to ensure the necessary protection, there are currently two main procedures in REACH to control or limit the risks from harmful chemicals: authorisations (Title VII of REACH) and restrictions (Title VIII of REACH). This is the case where substances are particularly hazardous and where risks due to exposure to the substance need to be further regulated as they are considered unacceptable (despite actions already taken by companies to control and limit them). This is done through **restrictions based on specific risk assessment** (REACH Articles 68(1) and 69(2)), i.e. where a non-adequately controlled risk is identified, the manufacture, placing on the market or use of the substances is banned or subject to certain conditions.

As the identification of risks is burdensome for authorities, and risks are either obvious due to the hazard properties, expected exposure and the nature of the use, or require specific information that authorities do not necessarily have, REACH also uses the **generic risk management approach**. This approach is applied where exposure from particularly hazardous substances cannot be controlled. Therefore, the hazardous properties of the substance together with generic considerations of exposure patterns are the basis for restrictions of such substances on their own, in mixtures or in articles. The generic risk management approach is currently applied in REACH in two ways:

- Restrictions based on Article 68(2) for carcinogenic, mutagenic and reprotoxic (CMR) substances on their own, in mixtures or in articles that could be used by consumers;
- Authorisation requirement, i.e. inclusion in Annex XIV, for uses of substances of very high concern (SVHC). Once SVHCs are included in Annex XIV, they may only be used if authorised or exempted from authorisation.

In the context of this impact assessment, it is important to note that the authorisation requirement is equivalent to a generic ban to use a substance, i.e. the use of a substance is

banned unless authorised or exempted from the authorisation obligation. In the case of authorisation, the authorisation decisions are addressed to the applicant(s), in the case of Article 68(2) restrictions certain uses can be derogated as part of the restriction in Annex XVII.

Sections 1.1 and 1.2 describe the details of the current authorisation and restriction processes, respectively.

### 1.1 The current REACH authorisation requirement

The REACH authorisation process is defined in Title VII of REACH. After a specific date ('sunset date') set in Annex XIV, the use of a substance included in Annex XIV ('authorisation list') is allowed only if authorised or exempted. The authorisation requirement is intended to ensure that substances of very high concern (SVHC) are progressively substituted, while allowing their continued use under certain conditions defined by the legal terms of REACH and complemented by further conditions in authorisation decisions addressed to the applicants. The different steps of the authorisation process are explained in the following.

#### Step 1: identification of Substances of Very High Concern (SVHCs)

Based on the screening of information available on chemical substances and gathered through the registration, EU Member States or ECHA, at the request of the European Commission, can propose an SVHC identification for substances by submitting a dossier in line with the requirements in Annex XV to REACH (SVHC identification). The dossiers are submitted to ECHA, which checks that the dossiers meet the Annex XV (SVHC) requirements. Compliant dossiers are published on ECHA's website for a 45-days consultation of interested parties. Considering the comments received if the Member State Committee (MSC) adopts its opinion on the proposal by unanimity, the substance is identified as SVHC and is added to the **Candidate List**. If the MSC does not reach a unanimous agreement, the matter is referred to the European Commission for final decision making.

#### Step 2: prioritisation of substances on the Candidate List, recommendation and inclusion of substances in Annex XIV (the authorisation list)

Step 2 typically takes between a year and a year and a half<sup>265</sup>. ECHA assesses substances in the Candidate List to prioritise them for inclusion on the Authorisation List. Prioritisation is based on information submitted in registration dossiers on uses and volumes and on information received during the SVHC consultation. In accordance with Article 58(3) of REACH, priority is given to substances with PBT or vPvB properties, wide dispersive use, or that are used in high volumes. The outcome of the prioritisation exercise is made available to the MSC (for commenting), before ECHA makes its draft recommendation. Based on the prioritisation, ECHA prepares a draft recommendation proposing the following for each substance:

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<sup>265</sup> ECHA Authorisation process: Phase II: Recommendation for inclusion in the Authorisation List. <https://echa.europa.eu/phase-2-recommendation-for-inclusion-in-the-authorisation-list>

- The **sunset date** from which the placing on the market and use of a substance is prohibited, unless an authorisation is granted or the use is exempt from authorisation;
- The **latest application date** by which applications must be received if the applicant wants to continue placing the substance on the market for a use or using it after the sunset date;
- Review periods for certain uses, if any; and
- Uses exempted from the authorisation requirement, if any.

ECHA's draft recommendation is then made available online for consultation over a three month period<sup>266</sup>. The MSC provides an opinion on the draft recommendation to ECHA, which then finalises the recommendation based on the MSC's input and comments from the consultation. The finalised recommendation and the MSC opinion on that recommendation is submitted to the European Commission and published on ECHA's website. Subsequently, the **European Commission decides on substances to be included in the Authorisation List, i.e. added to Annex XIV of REACH, via the comitology procedure**. Details on the final entry of Annex XIV, including the sunset date, latest application date, review period and exemptions, are determined at this point.

### Step 3: application for authorisation

Certain uses are exempted from authorisation requirements and do not require an authorisation. Examples of exempted uses include uses as intermediates (Article 2 (8)(b)) and uses in scientific research and development (SR&D)<sup>267</sup> (Article 56(3)). In addition, uses or categories of uses can be exempted if the risk is properly controlled on the basis of other existing specific EU legislation imposing minimum requirements for the protection of human health or the environment from the use of the substance (Article 58(2)). For all other uses, **companies** wishing to continue using a substance included on the Authorisation List after the sunset date **are required to prepare an application for authorisation to be submitted to ECHA before the latest application date**. As this authorisation requirement bans the use of a substance unless the use is authorised, it is *de facto* a (generic) ban, with a possibility for continued use via a granted authorisation. It is also possible to submit an application for authorisation after the latest application date. In such case, however, the application does not have a suspension effect and, if there is no decision on the application by the sunset date, the use must stop at the sunset date and can only start when and if it is authorised.

The Commission is responsible for taking decisions on the applications for authorisation. There are two main routes under which it is possible for the Commission to grant an authorisation:

- **Adequate control route** (based on Article 60(2)): an authorisation is granted if the applicant(s) demonstrate(s) that risk to human health or the environment is

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<sup>266</sup> Comments can be submitted on the uses in the scope of authorisation and their respective volumes, latest application and sunset dates, and uses that should be exempted.

<sup>267</sup> ECHA (2015). Generic exemptions from the authorisation requirement. [https://echa.europa.eu/documents/10162/13640/generic\\_exemptions\\_authorisation\\_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc](https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc)

adequately controlled. So far, very few authorisations were granted based on the adequate control route.

- **Socio-economic route** (based on Article 60(4)): an authorisation may only be granted if the applicant(s) demonstrate(s) that:
  - The **socio-economic benefits** from the continued use of the substance **outweigh the risk to human health or the environment**, and
  - There are **no suitable alternative** substances or technologies.

Applications can be submitted for one or several uses of one or a group of substances. Applicants may apply for authorisation for their own use(-s) of a substance, or for use(-s) for which they intend to place the substance on the market. The applications may be made by the manufacturer(s), importer(s) or downstream user(s), who may apply individually or jointly. It has also been an agreed practice to accept applications also made by the ‘Only Representative’ based in the EU representing a non-EU manufacturer. Applicants are advised to notify their intention to apply for an authorisation to ECHA and can request an information session with ECHA during which they can pose case-specific questions and clarify requirements and their obligations within the authorisation application process. Thereafter, the applicant finalises the application, which should include information specified in Article 62, amongst other:

- specification of uses for which the application is sought, covering the use of the substance in mixtures and/or incorporation of the substance in articles, as relevant;
- A Chemical Safety Report (CSR), covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;
- An Analysis of Alternatives (AoA) considering their risks, the technical and economic feasibility of substitution, and information about any relevant R&D activities by the applicant;
- Where the analysis of alternatives shows that suitable alternatives are available, a substitution plan is required setting out a timetable for proposed actions by the applicant to substitute the Annex XIV substance;

The application may also include a socio-economic analysis (SEA) prepared in line with Annex XVI of REACH. In practice, a SEA is always included, especially in the applications in which the applicants do not try to demonstrate that the risk from the use is adequately controlled.

Applicants have to pay a fee to ECHA. Base fees vary depending on the companies’ size, with reduced fees for SMEs (see Table 188 for the overview of fees as set by the latest amendment of the Fees Regulation of 15 July 2018)<sup>268</sup>.

*Table 188: Fees and charges payable to ECHA for applications for authorisation*

Company size	Base fee	Additional fee per substance (% of base	Additional fee per use
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<sup>268</sup> Note, while this is the current status, in the past the Fee Regulation had different provisions and an additional fee has been collected for additional applicants also.

		fee)	(% of base fee)
<b>Non-SME</b>	€54 100	€10 820 (20%)	€48 690 (90%)
<b>Medium</b>	€40 575	€8 115 (20%)	€36 518 (90%)
<b>Small</b>	€24 345	€4 869 (20%)	€21 911 (90%)
<b>Micro</b>	€5 410	€1 082 (20%)	€4 869 (90%)

Source: [Commission implementing regulation \(EU\) 2018/895 of 22 June 2018 amending Regulation \(EC\) No 340/2008 on the fees and charges payable to the European Chemicals Agency.](#)

Applicants submit applications for authorisation to ECHA, which conducts an administrative check and later a check of the application's completeness and conformity with requirements. Once accepted as complete, applicants are invoiced as per the fee scheme above. Applications are considered 'received' once fees are paid by the specified deadline. ECHA Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) have ten months to draft their opinion from the date of receipt of the application, according to REACH Art. 64(1). ECHA then publishes the broad information on uses on its web-site and opens the application for consultation on alternatives over an eight-week period with interested parties, including providers of alternative substances or technologies, citizens, NGOs and authorities.

During the opinion making process, RAC and SEAC rapporteurs may request additional information from the applicants (in line with Art. 64(3)). Based on the results of the consultation on alternatives, RAC and SEAC rapporteurs may call on third parties who have provided information on possible alternatives in the consultation to join a discussion with the applicant(s) in a dialogue. Thereafter, the RAC and SEAC rapporteurs prepare their draft opinions, which are discussed and adopted by RAC and SEAC during plenary meetings. Applicants have two months to provide comments on the adopted draft opinions, which are followed by final opinions of RAC and SEAC taking account applicants' comments on the draft opinions, where relevant. Non-confidential versions of the opinions are published on ECHA's website. The RAC and SEAC final opinions are submitted to the European Commission, which takes them into account to prepare a draft decision on the application for authorisation. According to REACH, Article 64(8), the European Commission has three months from receipt of the opinions to prepare a draft authorisation decision. The draft decisions are discussed at the REACH Committee meetings and afterwards the opinion of the REACH Committee members is sought by a vote following the Comitology rules. Eventually, the European Commission adopts the decision.

If an authorisation is granted, downstream users using the substance must comply with the conditions set in the authorisation decision, even if it has been granted to an actor higher in the supply chain who is supplying the substance for the authorised use. These actors must, without delay, also include the authorisation number on any labelling before placing the substance on the market for the authorised use. Member State authorities are responsible for enforcing the authorisations. The European Commission can review an authorisation at any time in cases where (i) the circumstances of the original authorisation have changed so that they affect the risk to human health and/or the environment change, or the socio-economic impacts, or (ii) new information on possible substitutes becomes available.

Authorisation decisions are adopted with a time-limited review period during which authorisation holders must continue looking for suitable alternatives to the authorised substance. If it is not possible to substitute and holders need to continue the use, they must submit a review report at least 18 months before the end of the review period. This should include an update of the documents submitted during the original application for authorisation. Review report documents are submitted and reviewed following the same procedure as for the initial application for authorisation.

## 1.2 The current REACH restrictions

The REACH restriction process is defined in Title VIII of REACH. Substances that are subject to a restriction are included in Annex XVII of REACH and may only be manufactured, placed on the market and/or used if the conditions specified in the restriction in Annex XVII are complied with.

REACH restrictions can be categorised broadly into restrictions based on specific risk management approach and those based on generic risk management approach.

### Restrictions based on specific risk management approach

In **specific risk management**, the exposure and risk assessment is performed for each substance (or group of substances). The specific risk assessment is based on the hazard and specific exposure of humans and the environment, i.e. the specific exposure scenarios related to the manufacture, use or placing on the market of substances. The specific risk management approach is the basis of restrictions under Article 68(1) and 69(2).

Based on **Article 68(1)**, a restriction can be adopted where there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of a substance, which is not adequately controlled and needs to be addressed on a Union wide basis. Member States or ECHA, at the request of the European Commission, prepare a restriction dossier.

Under **Article 69(2)**, after the “sunset date” for a substance listed in Annex XIV, ECHA assesses whether the use of an Annex XIV substance in articles poses a risk to human health or the environment that is not adequately controlled. If ECHA considers that the risk is not adequately controlled, it prepares a restriction dossier in accordance with Annex XV. The restriction dossier then follows the same procedure as the dossiers based on Article 68(1).

In addition, **Article 129** of REACH introduces a safeguard clause, allowing Member States to take provisional measures where urgent action is required to protect human health and the environment. Where these provisional measures involve restriction of a substance in its own, in a mixture or in an article, and the European Commission authorises them, the Member State in question is required to initiate an EU-wide procedure by submitting a restriction dossier within three months<sup>269</sup>.

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<sup>269</sup> Note that this possibility was used twice as of September 2022.

In the following, the main steps to prepare and adopt a restriction based on Article 68(1) are explained.

### **Step 1: preparation and submission of a restriction dossier**

Authorities proposing a restriction must notify ECHA of their intention to prepare a restriction dossier 12 months prior to the dossier submission. ECHA maintains a public online registry of restriction intentions until outcome<sup>270</sup>.

Annex XV of REACH sets out content requirements for restriction dossiers. This includes, amongst other:

- Identification of the substance, the restriction(s) proposed and a summary of the justification for the restriction;
- Information on hazard and risks to be addressed by the restriction, and evidence should be provided to demonstrate that existing risk management measures are insufficient;
- Detailed information on alternative substances and technologies need to be provided, including their risks to human health and the environment, their availability (including the time scale) and the technical and economic feasibility.
- Justification for restrictions at EU level, including an assessment of effectiveness, practicality and monitorability;
- Socio-economic assessment of the impacts of the proposed restriction may be analysed in line with requirements set out in Annex XVI of REACH<sup>271</sup>; and
- Information on any consultation of stakeholders, and how their views have been taken into account in the dossier.

As part of the restriction dossier, authorities assess whether a derogation or a longer transitional period is justified for some specific uses. Currently, there are **no specific criteria for derogations from restrictions in REACH**, but Article 68(1) indicates that the **socio-economic impacts** of a restriction and the **availability of alternatives** should be taken into account. In practice, currently, derogations from restrictions based on Article 68(1) are based either on pure risk considerations, or on the availability of alternatives and socio-economic considerations.

Restriction dossiers are submitted to ECHA, and RAC and SEAC check that the submitted dossiers are in conformity with REACH requirements.

### **Step 2a: consultation on the restriction dossier**

Restriction dossiers conforming to the requirements are published on ECHA's website for a six-month consultation of interested parties. During the consultation, often companies and trade associations submit documents, information and data relating to the restriction dossier, including suggestions for derogations from the restriction for specific

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<sup>270</sup> ECHA (2022). Registry of restriction intentions until outcome. <https://echa.europa.eu/registry-of-restriction-intentions>

<sup>271</sup> While the socio-economic assessment is not a compulsory section of the restriction dossier, it is usually included.

uses. All the information submitted during the consultation is assessed by the dossier submitter, RAC and SEAC.

### **Step 2b: Forum advice and RAC and SEAC opinions**

The Forum for Exchange of Information on Enforcement (‘the Forum’) is a network of authorities which undertake enforcement of European chemicals legislation in the EU, Norway, Iceland and Liechtenstein<sup>272</sup>. The Forum seeks to co-ordinate, improve and harmonise enforcement of the legislation. Following consultation on the restriction dossier, the Forum examines the restriction dossiers and provides an advice on enforceability of the proposed restrictions, based on Article 77(4)h.

The RAC examines whether the suggested restrictions are appropriate in reducing risks to human health and/or the environment. RAC is required to formulate an opinion within 9 months of the publication of a restriction dossier on ECHA’s website. In parallel, SEAC prepares a draft opinion on the socio-economic impacts of the suggested restrictions, including considerations on the availability of alternatives. The SEAC draft opinion is published for comments and feedback from interested parties, and based on this input SEAC adopts its final opinion within 12 months of the publication of the restriction dossier on ECHA’s website. Where the RAC opinion “*diverges significantly*” (Article 71(3)) from the original restriction proposal, ECHA may postpone the adoption of the SEAC opinion by up to 90 days. After the final opinions are adopted, they are submitted by ECHA to the European Commission along with relevant supporting documentation, which are also made publicly available on ECHA’s website.

### **Step 3: decision, compliance and enforcement**

Upon receiving the final RAC and SEAC opinions and if the conditions laid down in Article 68 are fulfilled, the European Commission has three months to prepare a draft amendment to the list of restrictions in Annex XVII of REACH. The draft is submitted for discussion and an opinion to the REACH Committee, composed of representatives from Member States. The draft proposal is notified in parallel to the World Trade Organisation (WTO) to give other WTO member countries the opportunity to assess impacts on their exports, identify any breaches of the TBT Agreement, and provide comments<sup>273</sup>. Afterwards, and if the REACH Committee has given a positive opinion, the proposal is sent to the Council and the European Parliament for scrutiny. Where the European Parliament and the Council do not oppose the draft restriction within three months, it is adopted by the Commission and published in the Official Journal of the European Union. Following adoption, those concerned must comply with the conditions of the restriction and EU Member States are responsible for its enforcement.

#### Restrictions based on generic risk management approach

The **Generic Risk management Approach (GRA)** implies that regulatory risk management measures, in this context restrictions in Annex XVII of REACH, are taken based on the hazardous properties of chemicals and on generic considerations on

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<sup>272</sup> ECHA (2022). Enforceability of Restrictions. <https://echa.europa.eu/about-us/who-we-are/enforcement-forum/enforceability-of-restrictions>

<sup>273</sup> See: [https://ec.europa.eu/growth/single-market/barriers-trade/tbt-notification-procedure\\_en](https://ec.europa.eu/growth/single-market/barriers-trade/tbt-notification-procedure_en)



potential exposures and risks. This approach is applied for chemicals used where the exposure is considered to be more difficult to control and monitor, e.g. uses by consumers, or for uses resulting in exposure of vulnerable groups, e.g. children.

In REACH, the GRA is enshrined in **Article 68(2)**, which empowers the Commission to introduce restrictions for substances on their own, in mixtures or in articles that meet the criteria for classification as CMRs (Category 1A and 1B) and could be used by consumers as such, in mixtures or in articles. Under this process, the Commission develops a restriction proposal, which is submitted for discussion and an opinion to the REACH Committee, composed of representatives from Member States, following the Comitology rules. As part of the restriction proposal, the Commission can consider whether there is a need and justification to derogate specific uses from the restriction. However, there are **no specific criteria in REACH to assess when derogations would be justified and should be proposed**. In Article 68(2), no reference is made to consideration of alternatives or socio-economic impacts and a restriction dossier is not required. However, for restrictions of CMR substances in articles, the Commission developed a document that sets the procedure and criteria for the implementation of restrictions based on Article 68(2), including considerations of when it is recommended to apply the Article 68(2) procedure as the best regulatory option. This document indicates that limitation to the scope of the restriction or derogations should be considered for e.g. critical materials or critical uses.<sup>274</sup>

The draft restriction proposal is notified to the World Trade Organisation (WTO) to give other WTO member countries the opportunity to assess impacts on their exports, identify any breaches of the TBT Agreement, and provide comments<sup>275</sup>. Afterwards, and if the REACH Committee has given a positive opinion, the proposal is scrutinised by the European Parliament and the Council. If they do not oppose the restriction proposal during three months, it is adopted by the Commission and published in the Official Journal of the European Union. This process is considered to be simpler and faster than for Article 68(1) restrictions since it does not follow the procedure set out in Articles 69 to 73 (see above). This process has routinely been used to semi-automatically restrict CMRs as such or in mixtures for consumer use (entries 28-30 of Annex XVII) for over 20 years, also under Directive 76/769/EEC. As regards CMRs in articles, the procedure has been used so far to restrict polycyclic aromatic hydrocarbons (PAHs) in rubber and plastic articles (amendment to entry 50 of Annex XVII) and to restrict CMRs in clothing, textiles and footwear (entry 72 of Annex XVII).

## **2 DESCRIPTION OF THE SPECIFIC PROBLEMS**

### **2.1 B1: The pace of introducing new restrictions is too slow to ensure that the most harmful substances are adequately regulated**

REACH restrictions regulate risks to human health and the environment from the use of chemical substances, where the general obligation to companies to ensure that substances throughout the life cycle do not adversely affect human health and the environment is insufficient to ensure the necessary protection. By default, a restriction requires that an

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<sup>274</sup> European Commission, CA/102/2014 – Brussels, 7 November 2014

<sup>275</sup> See: [https://ec.europa.eu/growth/single-market/barriers-trade/tbt-notification-procedure\\_en](https://ec.europa.eu/growth/single-market/barriers-trade/tbt-notification-procedure_en)

authority (Member State or ECHA) identify a risk that is not adequately controlled and needs to be addressed at the EU level. Demonstrating such a risk for specific substances and for a wide range of uses may not be always straightforward, and therefore there is a trade-off between the detail of proof of the risk and the need to take action to address that risk in order to protect human health and the environment against the risks from wide range of substances and uses.

The latest REACH review concluded that the restriction process for substances and groups had contributed towards lowering human and environmental exposure to harmful substances<sup>276</sup>. However, new restrictions under Article 68(1) or 69(2) have been proposed and introduced at a slower pace than expected. Between January 2011 and March 2022, a total of 28 restrictions (an average of approximately 2.5 per year) were adopted under article 68(1) and 69(2). This fell well short of the 11 restrictions expected per year at the time of the adoption of REACH. Restrictions adopted under Article 69(2) included those for four phthalates (DEHP, DBP, BBP and DIBP) in certain articles, submitted in 2016 and adopted in 2018.

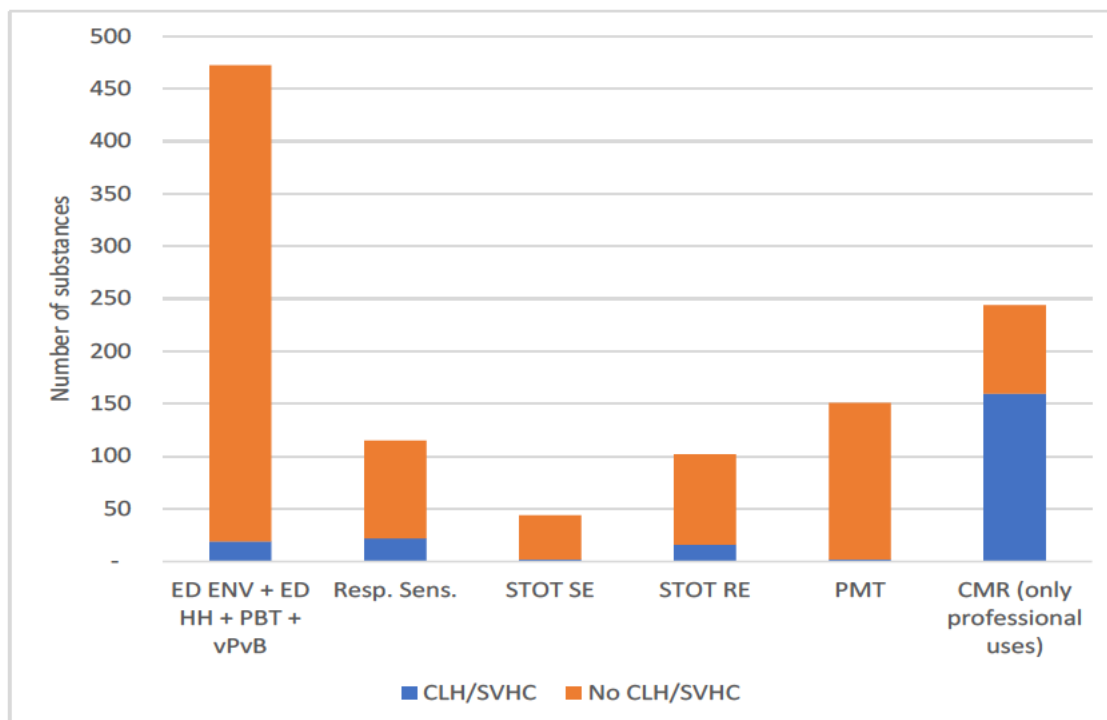
Therefore, there are concerns that the slow progress with restrictions undermines protection of human health and the environment and that the system is able to prevent harm to humans and the environment and respond quickly enough to pressing and emerging chemical risks. Consumers, vulnerable groups, as well as professional users and the natural environment should be more consistently protected from the most harmful chemicals, which, due to the hazards involved and due to the exposure patterns, are very likely to create substantial damage. This concerns, in particular, the chemicals in the following hazard classes in consumer and professional uses: endocrine disruption with effects on human health), endocrine disruption with effects on the environment), PBT/vPvB, respiratory sensitisation, specific target organ toxicity - repeated exposure (STOT-RE) and single exposure (STOT-SE), immunotoxicity and neurotoxicity. Concerns are also growing concerning PMT/vPvM substances, although these hazards are not yet regulated. Therefore, for the purpose of the impact assessment, also PMT/vPvM substances are included in the analysis.

Based on REACH registration data, it is estimated that there are several hundreds of substances, out of the currently 13 692 substances fully registered under REACH, used in products for consumers and professionals that could be considered to fall under the above-mentioned hazard classes. Figure 2 shows the number of substances that have confirmed hazard properties (in blue) or that are likely to have certain hazard properties (in orange).

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<sup>276</sup> See COM (2018) 116 final Annex 5 Page 6

Figure 28: Number of substances registered under REACH for consumer and professional uses, by hazard properties



Source: VVA (unpublished), based on REACH registration data provided by ECHA

For each of these hazard classes, the main negative human health and/or environmental effects – as documented by the available scientific evidence to date – are summarised below. While this information does not provide an assessment of the risk linked to each of the substances identified, it nevertheless gives an indication of the problem at stake.

#### Endocrine disruption with effects on human health

Endocrine disrupting chemicals (EDCs) interfere with hormone action. EDCs are known to have a range of effects including impacts on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology.<sup>277</sup> EDCs and potential EDCs can be found in a wide variety of products which result in human and environmental exposure, via diet, air, skin and water<sup>278</sup>. Products range from plastic bottles, metal food cans, detergents, flame retardants, food, toys to cosmetics and pesticides<sup>279</sup>.

#### Endocrine disruption with effects on the environment

<sup>277</sup> Diamanti-Kandarakis, E., Bourguignon, J. P., Giudice, L. C., Hauser, R., Prins, G. S., Soto, A. M., Zoeller, R. T., & Gore, A. C. (2009). Endocrine-disrupting chemicals: an Endocrine Society scientific statement. *Endocrine reviews*, 30(4), 293–342. <https://doi.org/10.1210/er.2009-0002>

<sup>278</sup> National Institute of Environmental Health Sciences. Endocrine Disruptors. <https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm>

<sup>279</sup> Yang, O., Kim, H. L., Weon, J. I., & Seo, Y. R. (2015). Endocrine-disrupting Chemicals: Review of Toxicological Mechanisms Using Molecular Pathway Analysis. *Journal of cancer prevention*, 20(1), 12–24. <https://doi.org/10.15430/JCP.2015.20.1.12>

EDCs are associated with various adverse effects on wildlife, including disrupted reproductive function and development in birds, fish, amphibians and molluscs. Species can be impacted through mechanisms including male and female reproductive dysgenesis and thyroid hormone disruption.

#### PBT and vPvB substances

PBT/vPvB substances cover a range of chemicals with varying effects that can be damaging to human health and the environment. PBTs and vPvBs persist in the environment for long periods of time, accumulate in living organisms, and are transported over long distances and to remote areas. Exposure is very difficult to reverse because reducing emissions may only result in reductions in environmental concentrations many years later. As such, a particular concern with vPvB substances is that effects may occur even when not demonstrated in laboratory testing<sup>280</sup>.

#### Substances with specific target organ toxicity, single exposure (STOT SE) and repeated exposure (STOT RE)

STOT SE refers to specific, non-lethal effects on organs or organ systems in the body following single exposure to a chemical substance or mixture. All significant health effects that can impair function occurring after exposure (immediate or delayed), are included in the hazard class, whether reversible or irreversible. Significant effects to a target organ after repeated exposure are classified as STOT RE<sup>281</sup>. Quantitative information on population level effects are limited, but indicative values for specific effects are available and can be used for illustrative purposes.

#### Immunotoxic and neurotoxic substances

Immunotoxic substances can impact the functionality of the immune system directly, resulting in reduced resistance to infections and tumours from immunosuppression. Direct action can also result in dysregulation of homeostasis, causing allergic or autoimmune phenomena from exaggerated immune responses. Chemicals can also be recognized as foreign by the immune system, resulting in allergy or autoimmunity<sup>282</sup>.

Over 200 chemicals are known to be neurotoxic in humans and over 1 000 are known to be neurotoxic in animals. **Error! Bookmark not defined.** The neurodevelopmental effects with the most extensive evidence associated with chemicals exposure are loss of intelligence quotient (IQ) points and associated increased incidence of mild mental retardation (MMR), and attention deficit hyperactive disorder (ADHD). Numerous substances, including lead and mercury, are linked with declines in intellectual ability which can be expressed as a loss of IQ points. While IQ loss in itself is not classed as a disease, it can result in a classification of MMR where IQ scores fall below 70. This is

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<sup>280</sup> ECHA. (n.d.) PBT assessment. Available at: <https://echa.europa.eu/understanding-pbt-assessment>

<sup>281</sup> Certain toxic health effects excluded from this classification, for example respiratory or skin sensitisation, carcinogenicity or reproductive toxicity Regulation (EC) No 1272/2008 of the European Parliament and of the Council

<sup>282</sup> World Health Organisation. (2012). Guidance for Immunotoxicity Risk Assessment for Chemicals. Harmonization Project Document No. 10. Available at: <https://inchem.org/documents/harmproj/harmproj/harmproj10.pdf>

associated with higher risk of developing mental health, behavioural and academic difficulties and of experiencing socio-economic disadvantages<sup>283</sup>. In childhood, MMR may not be easily identifiable, but may manifest in delayed speech<sup>284</sup>. ADHD is a behavioural disorder manifesting in inattentive, hyperactive and impulsive behaviours.<sup>285</sup>

### Respiratory sensitisers

Respiratory diseases are a significant problem in the EU, and represented approximately 7.5% of deaths in 2016<sup>286</sup>. Whilst there is an extensive scientific literature on associations between air pollution and respiratory diseases<sup>287</sup>, the evidence on *specific* chemical exposures and their effects is less detailed. Respiratory diseases identified as being potentially caused or exacerbated by chemical substances include asthma, asbestosis, chronic obstructive pulmonary disease and allergic rhinitis, among others.<sup>288</sup> Various occupations are associated with an increased risk of asthma, such as domestic and equipment cleaners,<sup>289</sup> animal health, cosmetology, farming and food production, healthcare, industrial, manufacturing or construction, laboratory and some office and educational work<sup>290</sup>. Occupations known to have an increased risk of chronic obstructive pulmonary disease include mining, construction, foundry, welding, steel, textiles (especially cotton) and farming<sup>291</sup>.

It should be noted that substances with ED, PBT, vPvB, PMT, vPvM properties will be added as new hazard classes in the revised CLP and prioritised for harmonised classification. Although this is expected to facilitate the adoption of regulatory risk management measures under REACH, it is not considered sufficient to address the described problem. While harmonised classification triggers already some actions under other legislation, it will not be sufficient to ensure that consumers and professional users are not exposed to those substances.

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<sup>283</sup> Nouwens et al. (2017). Identifying classes of persons with mild intellectual disability or borderline intellectual functioning: a latent class analysis, *BMC Psychiatry*, Volume 17, 257. <https://doi.org/10.1186/s12888-017-1426-8>

<sup>284</sup> Daily et al. (2000). Identification and evaluation of mental retardation, *American Family Physician*, Volume 61(4), 1059-1067. <https://www.aafp.org/afp/2000/0215/p1059.html>

<sup>285</sup> Swanson et al. (1998). Attention-deficit hyperactivity disorder and hyperkinetic disorder, *The Lancet*, Volume 351(9100), 429-433. [https://doi.org/10.1016/S0140-6736\(97\)11450-7](https://doi.org/10.1016/S0140-6736(97)11450-7)

<sup>286</sup> Eurostat. (2021). Respiratory diseases statistics. [https://ec.europa.eu/eurostat/statistics-explained/index.php?oldid=497079#Deaths\\_from\\_diseases\\_of\\_the\\_respiratory\\_system](https://ec.europa.eu/eurostat/statistics-explained/index.php?oldid=497079#Deaths_from_diseases_of_the_respiratory_system)

<sup>287</sup> Arbex, M. A., Santos, U., Martins, L. C., Saldiva, P. H., Pereira, L. A., & Braga, A. L. (2012). Air pollution and the respiratory system. *Jornal brasileiro de pneumologia : publicacao oficial da Sociedade Brasileira de Pneumologia e Tisiologia*, 38(5), 643–655. <https://doi.org/10.1590/s1806-37132012000500015>

<sup>288</sup> European Commission, Amec Foster Wheeler Environment & Infrastructure UK (2017). Study on the cumulative health and environmental benefits of chemical legislation. <https://op.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en>

<sup>289</sup> Arif AA, Delclos GL, Whitehead LW, Tortolero SR, Lee ES. Occupational exposures associated with work-related asthma and work-related wheezing among U.S. workers. *Am J Ind Med*. 2003 Oct;44(4):368-76. doi: 10.1002/ajim.10291. PMID: 14502764.

<sup>290</sup> Centers for Disease Control and Prevention. (n.d.) Occupational Exposures: Asthma. <https://www.cdc.gov/niosh/topics/asthma/exposures.html>

<sup>291</sup> Kraïm-Leleu M, Lesage FX, Drame M, Lebargy F, Deschamps F. Occupational Risk Factors for COPD: A Case-Control Study. *PLoS One*. 2016 Aug 3;11(8):e0158719. doi: 10.1371/journal.pone.0158719. PMID: 27487078; PMCID: PMC4972406.

## *Drivers*

The underlying reason for the slower pace of introducing Article 68(1) restrictions is that, by definition, those restrictions based on the specific risk management approach require a detailed assessment of risk, based on specific information on the uses and exposure. If the restrictions are too narrow and limited only to substances and uses with relatively good data availability, it would unlikely be possible to promptly tackle pressing and emerging risks where the data are usually scarce. There is also a risk of a burdensome piecemeal approach possibly leading to “regrettable substitution”, i.e. replacement of one substance by another often similar substance with similarly serious effects, with less available information. For this reason, restrictions have lately taken a wider scope (“grouping approach”). However, this has further increased the challenges to gather appropriate data for authorities<sup>292</sup>, who are bearing the burden of proof to prepare restriction dossiers. This in turn reflects a general lack of data on the substances’ intrinsic properties, lack of specific information on uses and exposure in registration dossiers.

Restrictions based on Article 69(2), require an analysis and assessment by ECHA before substances listed in Annex XIV can be restricted in articles. Only a limited number of restrictions were adopted on this basis and with delays after the sunset dates for the corresponding substances in the EU. This puts doubts on the efficiency of this mechanism, and whether it should not be replaced by other, more direct ways to ensure a level playing field between articles containing Annex XIV substances, produced in the EU and imported articles.

Member States in the November 2021 workshop<sup>293</sup> also agreed that the demonstration that a risk is not adequately controlled in the restriction dossiers was highly complex and time consuming. Whilst improvements have been made via the Restrictions Task Force<sup>294</sup>, development of an Article 68(1) Annex XV (restriction) dossier is still considered by some Member States to be technically challenging. It requires large amounts of data, and typically receives challenging reviews/critique and requests for further analysis from ECHA Committees during opinion making stages. Several Member States and NGOs noted that conformity checks were overly strict and the level of evidence required in a restriction proposal was too high<sup>295</sup>.

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<sup>292</sup> Background paper Workshop on the reform of the REACH Authorisation and Restriction System. Ares (2021)6676028 – 29/11/2021 Note that based on the contribution from the workshop participants, it was concluded that this background paper was an accurate description of the problems encountered. See: European Commission “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021.

<sup>293</sup> European Commission “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021.

<sup>294</sup> The Restriction Task Force is composed of experts in the REACH restriction process from Member States, ECHA and the Commission, where solutions to practical issues with the restriction process are discussed and proposed. This task force was set up to implement some actions stemming from the latest REACH review.

<sup>295</sup> See COM (2018) 116 final, Annex 4, page 110

## 2.2 B2: The authorisation process is not efficient, decision-making is slow and substitution is not promoted enough

One of the main advantages of authorisation is that it places the burden of proof on industry, which has generated a lot of new information about uses of SVHCs and corresponding risk management measures. The latest REACH review concluded that the authorisation process had contributed to the progressive replacement and phase out of SVHCs and to ensuring that the risks from SVHCs are better identified and properly controlled when these substances are used in authorised uses (European Commission, 2018)<sup>296</sup>. This conclusion was confirmed by the findings of ECHA that inclusion of a substance in the Candidate List and in Annex XIV are, besides REACH restrictions, the most significant triggers for companies to start their substitution activities (ECHA, 2020). Many companies have substituted SVHCs after their inclusion in the candidate list or Annex XIV and have reduced the risks stemming from the remaining uses due to improvements made in risk management measures when preparing for applications for authorisation. No applications were received for over half of the substances in Annex XIV<sup>297</sup>, implying that those SVHCs are no longer used or have been substituted (ECHA, 2021) (European Commission, 2018).

Despite these contributions of the authorisation process to substitution and better control of SVHCs, the latest REACH review recognised the need to streamline and simplify the authorisation process with a view to clarifying the requirements and make the process more predictable (European Commission, 2018). Workshops<sup>298</sup> and targeted interviews<sup>299</sup> with NGOs, Public Authorities and industry representatives conducted in the context of this impact assessment also confirmed that **the authorisation procedure is resource intensive, complex and slow, both for authorities and companies**. They also agreed on the need to simplify the authorisation system, increase efficiency and speed of the process and relieve bottlenecks in the decision making.

### 2.2.1 Burden and inefficiencies of applications for authorisation

Applications by actors up in the supply chain (referred to as “upstream applications”), some made by the ‘Only Representatives’<sup>300</sup> on behalf of non-EU manufacturers of Annex XIV substances, and covering up to several hundreds of downstream users have turned out to be problematic to assess and decide upon, creating delays (see section 2.1.2). Where downstream users applied individually, this resulted in a multitude of often repetitive individual applications for similar uses or for sometimes small quantities of SVHCs (e.g. uses of 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (‘OPE’) and 4-Nonylphenol, branched and linear, ethoxylated (NPE) in production of pharmaceuticals and in diagnostic applications).

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<sup>296</sup> COM (2018) 116 final Annex 5 Page 6

<sup>297</sup> <https://echa.europa.eu/received-applications>

<sup>298</sup> VVA (not published yet) “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction”, Member States and stakeholders workshop reports, 9 and 12 November 2021.

<sup>299</sup> VVA study, Targeted stakeholder interviews with National Competent Authorities, NGOs and Industry, May 2022

<sup>300</sup> According to Article 8 of REACH, non-EU companies can appoint a natural or legal person established in the EU to fulfil, as only representative, the registration obligations on importers.

As of April 2022, 59 SVHCs entries were added to the ‘authorisation list’, for which in total 248 applications for authorisation were submitted to ECHA. The majority of these 248 applications concerns the uses of two groups of substances<sup>301</sup>: Chromium(VI) compounds (11 different entries in Annex XIV) and Octyl- (OPE) and Nonylphenol ethoxylates (NPE) (two different entries in Annex XIV).

For **Chromium(VI) compounds**, 113 applications<sup>302</sup> for authorisations (out of 248, i.e. 46%) were received until March 2022 (ECHA). Other 79 additional applications for authorisation for uses of Cr(VI) compounds (out of 85 expected in total, i.e. 93%) are expected for the rest of 2022 and additional 86 applications (out of 132 expected in total, i.e. 65%) in 2023<sup>303</sup>. This increasing workload is illustrated in Figure 29. The red dashed line in the figure indicates that RAC and SEAC currently have the capacity to provide 15 opinions on applications for authorisation in any quarter (corresponding to maximum 60 opinions per year).



Figure 29: Projection of applications of authorisations and review reports in 2022-23 (258 uses) (source: ECHA)

The majority of these applications for authorisation concern uses of Cr(VI) substances in functional chrome-plating<sup>304</sup> and can be grouped into 5-10 main categories of very similar uses of the 11 concerned Cr(VI) substances.

For **OPE and NPE**, 67 applications for authorisation were received, covering 109 uses that can be grouped into four main categories:

<sup>301</sup> ECHA, Statistics on received applications for authorisation and review reports (accessed on 14 September 2022), available at: <https://echa.europa.eu/received-applications>

<sup>302</sup> Chromium trioxide (66), Sodium dichromate (22), Chromium trioxide, Sodium dichromate and Potassium dichromate (1), Sodium chromate (3), Sodium chromate, Potassium chromate (1), Potassium dichromate (4), Ammonium dichromate (3), Dichromium tris(chromate) (3), Chromium trioxide and Dichromium tris(chromate) (1), Strontium chromate (2), Potassium hydroxyoctaoxidizincatedichromate (1), Chromic acid (2), Chromium trioxide, Sodium dichromate (2)

<sup>303</sup> Estimates provided by ECHA via direct communication on 31 August 2022 and based on companies' intention to submit an application for authorisation.

<sup>304</sup> Both hard chrome-plating and plating with decorative character.



- Industrial uses of OPE/NPE in the production of in vitro diagnostic product (IVD) kits;
- Professional uses of OPE/NPE in IVD kits by hospitals/analytical and diagnostic laboratories;
- Uses of OPE/NPE in the manufacture of active pharmaceutically active ingredients and production of vaccines;
- Uses of OPE/NPE in the manufacture of siliconized containers and various products (safety glass, resins etc.) and hardeners in the aerospace sector.

For some of these applications, the quantity of the Annex XIV substances used was very small but still a full assessment of the application was required. This makes the process disproportionate, considering the low quantities of substances subject to authorisation. Moreover, some companies reported having submitted an application for authorisation as they were not sure whether their use would meet the exemption from the authorisation requirement for uses of SVHCs in scientific research and development (Article 56(3)).

The inefficiency of the current authorisation system can be shown by comparing the numbers of individual applications for similar uses or for small quantities of SVHCs with the unit costs of preparing, assessing and deciding on applications for authorisation (see table below).

Table 189: Costs related to applications for authorisation for the different actors involved

Step	Actors	Time and costs
<b>Preparation and submission of AfA</b>	Applicants, ECHA	<b>Applicant AfA costs per use:</b> ECHA estimates indicate an average cost of applying of approximately €200,000 per use (ECHA, 2021). More recent and detailed data from ECHA from 2022 indicate that total costs amounted to €434,000 per application (€349,000 per use) for DU applicants, and €814,000 per application (€261,000 per use) for multiple applicants <sup>305</sup> .
<b>Opinion-making</b>	RAC, SEAC, applicants, ECHA	<ul style="list-style-type: none"> <li>• <b>RAC non-plenary activities (per MS CA per AfA case):</b> 7 (4-15) hours; total costs €361-€389 (€160-€849).</li> <li>• <b>SEAC non-plenary activities (per MS CA per AfA case):</b> 12 (5-21) hours; total costs €623-€854 (€197-€1,129).</li> <li>• <b>RAC and SEAC plenary activities:</b> total 18 days opinion-making per use, at a cost of €7,200.</li> <li>• <b>ECHA (secretariat and rapporteurs) (2014-2016):</b> 49 days opinion-making per use, at a cost of €29,750. (EFTEC, 2018)</li> <li>• <b>Costs to ECHA (including RAC and SEAC):</b> other data provided by ECHA indicate that opinion-making for AfAs in the period 2013-2021 typically took up 0.6 FTE of ECHA's resources (including RAC and SEAC time) per application.<sup>306</sup></li> </ul>
<b>Decision-making</b>	Commission,	• <b>REACH Committee preparation and attendance</b>

<sup>305</sup> ECHA (2022). Direct communication

<sup>306</sup> ECHA (2022). Direct communication.

REACH Committee	<p><b>of one meeting:</b> 34 (17-61) hours per MS CA; total costs €1,471-€1,844 (€52-€3,306) per MS CA.</p> <ul style="list-style-type: none"> <li>• <b>Commission:</b> DG ENV and DG GROW had 2.2 and 6 FTEs available respectively in 2016 for authorisation activities (costing €303,600 and €28,000 respectively). Both DG ENV and DG GROW used 50% of their resources for authorisation decisions . (EFTEC, 2018)</li> </ul>
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Source: VVA (unpublished)

The current projection of expected applications for Cr(VI) substances (see Figure 1), as well as the periodic backlogs in authorisation decisions show that the number of applications, even for one single substance, may exceed the capacity of ECHA and the Commission to process those applications within the imposed legislative deadlines. At least for substances with very diverse uses concerning a broad range of different manufacturing industries, leading to highly complex applications for authorisations, the current authorisation system therefore seems not to be functioning well. On the other hand, if the authorisation system were to be limited to substances with only few uses, its relevance for the overall management of chemical risks would decline, while still binding a significant amount of resources. The problem described above was also recognised by Member States competent authorities during a workshop on the reform of authorisations and restrictions in November 2021<sup>307</sup>. A national competent authority also noted that currently there is an inefficient use of the time of specialists in ECHA, RAC and SEAC and the process is expensive and time consuming for applicants<sup>308</sup>.

Finally, requirements for authorisation applications apply independently of the company size of the applicant and are particular burdensome for small and medium-sized companies, who have limited resources and expertise for complex analyses.

### *Drivers*

The large number of applications for similar uses by downstream users (see the issue with Cr(VI) substances) are linked to the issues encountered with **applications for authorisations submitted by upstream operators in the supply chain** (“upstream applications”) in which **the uses have been defined too broadly**. Initially, many downstream users of Cr(VI) substances were covered by “upstream applications”, which were considered by many as broad, insufficiently specific and detailed and failing to exclude the uses for which alternatives might be, at least to a certain extent, available. Upstream operators who usually do not use substances themselves but are only supplying them down the supply chain often lack knowledge of the specific uses, related exposure, operational conditions, risk management measures and possibilities for substitution at downstream level or in some cases fail to gather such information from downstream users. An additional reason for the complexity is that some applications were submitted

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<sup>307</sup> European Commission “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021.

<sup>308</sup> Targeted Stakeholder interview, National Competent Authority, May 2022

by the ‘Only Representatives’ on behalf of non-EU manufacturers of Annex XIV substances.

Two particular weaknesses of such “upstream applications” were identified:

- Lack of representativeness of the exposure scenarios and data supporting the exposure assessment for all the companies covered by the applications. This made assessing risks to human health particularly challenging.
- Too broad description of uses in the applications, including a number of sub-uses or utilisations with different substitution profiles and possibilities, where the use covered several different sectors and different articles. This made the analysis of alternatives overly complex and challenging to prepare and assess<sup>309</sup>.

These weaknesses have led to long discussions, resulting in increased time to make decisions, concerns raised by Member States, NGOs and the European Parliament and to the first case law on authorisation. Further guidance was published on the description of uses, the representative exposure scenarios, and on the socio-economic analysis to mitigate the shortcomings seen with “upstream applications”. Nevertheless, given the sub-optimal outcome of these “upstream applications” so far, many companies prefer applying for authorisation for their own use – even if similar to other companies – as this gives them more certainty and a more predictable outcome.

In addition to the drivers identified above, the number of applications for authorisation has depended on how wide was the range of uses and in how many different industrial sectors the substances included in Annex XIV were used.

### **2.2.2 Unclear requirements and legal challenges, resulting in slow decision-making in authorisation**

The authorisation title of REACH, lacking detailed definitions of certain key requirements, has led to different interpretations, lengthy discussions, for example, at the Member States Committee and legal challenges of Commission authorisation decisions. This has compounded the complexity, delays in decision making and uncertainty for industry.

The Court cases on authorisation decisions include:

- Case T-837/16 Sweden v. European Commission ('lead chromate case'), where Sweden challenged the Commission decision granting an authorisation for uses of lead sulfochromate yellow and of lead chromate molybdate red. That decision was annulled by the General Court due to shortcomings in the assessment and conclusion on lack of suitable alternatives. With the subsequent Case C-

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<sup>309</sup> See COM (2018) 116 final Annex 4, page 87. Further guidance was published to aid development of the description of uses, of the representative exposure scenarios, and on the socio-economic analysis to try and mitigate this.

389/19P<sup>310</sup>, the Commission appealed certain parts of that judgment, but the Court dismissed the appeal;

- Case T-108/17 Client Earth v. European Commission, where the NGO Client Earth challenged the Commission decision rejecting the request of internal review of the decision granting an authorisation for uses of DEHP in Poly vinyl chloride (PVC). The Court dismissed the request and this outcome was confirmed in the appeal case brought by Client Earth (C-458/19 P).<sup>311</sup> The Court clarified several procedural and substantial aspects of the authorisation process.
- Case T-436/17 Client Earth against the Commission on lead chromate pigment authorisation challenging the response to an internal review request<sup>312</sup>. Following the judgement in case C-389/19P the Court concluded that there was no need to adjudicate in this action.
- Case C-144/21 European Parliament v. European Commission ('Chemservice case'), where the European Parliament challenged the Commission decision to partially grant an authorisation for certain uses of chromium trioxide ('CT\_Chemservice', one the broadest authorisation granted so far to upstream actors representing non-EU manufacturers)<sup>313</sup> claiming that the authorisation was granted in breach of the requirements laid down in articles 60(4) and 60(7) The case is ongoing and the judgment, is expected to clarify certain important aspects concerning applications for authorisations by actors upstream in the supply chain.

The judgment in the first case provided elements to better consider whether the applicant has discharged the necessary burden of proof, in particular that the Commission needs to refuse authorisations where the uncertainties on the conclusions of the assessment of alternatives are non-negligible. Moreover, the judgment clarified that where there are suitable alternatives available 'in general' but are not feasible for the applicant, an authorisation may still be granted if socioeconomic benefits outweigh the risk arising from the use of the substance and the applicant submits a substitution plan.

The judgments in the second and third cases relate to the whether NGOs can request before the Court the annulment of Commission decisions that had been the object of a request for internal review and also clarified, among others, aspects related to the interpretation of the term 'use' as well as to the scope of the risk assessment within the socio-economic analysis.

### *Drivers*

The Court cases and subsequent delays in the decision-making find their root cause in **unclear definitions of certain key requirements** in authorisation **and lack of clarity** on the information to be submitted in applications for authorisation, in particular concerning

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<https://curia.europa.eu/juris/document/document.jsf?text=&docid=238162&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=3091412>

<sup>311</sup> See COM (2018) 116 final, Annex 4, page 101. See also: <https://curia.europa.eu/juris/document/document.jsf?text=ECHA&docid=212665&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=468623#ctx1>

<sup>312</sup> <https://curia.europa.eu/juris/liste.jsf?language=en&num=T-436/17>

<sup>313</sup> <https://curia.europa.eu/juris/document/document.jsf?text=&docid=240681&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=299634>

the concept of ‘suitable alternatives’. Although those judgments provided important new elements in the interpretation of the legal provisions in authorisation, they also highlighted the complexity of assessing the suitability of alternatives. Ultimately, this complexity cannot sufficiently be addressed with the existing criteria and processes.

In particular, long discussions in the REACH Committee and subsequent delays are also due to the fact that the current criterion that socio-economic benefits must outweigh the risk does not sufficiently take into account societal aspects and needs. Although REACH does not require the inclusion of a socio-economic analysis in the application for authorisation,<sup>314</sup> most of the applicants have chosen to prove this legal criterion through a socio-economic analysis, following existing guidance from ECHA<sup>315</sup>. Furthermore, it is usually not possible to quantify and monetise all the socio-economic benefits of continued use of an SVHC. The benefits of continued use that are usually quantified and monetised typically include profit and job losses that would result from the discontinued use of the SVHC<sup>316</sup>. Other societal benefits, if included, are in some cases described qualitatively (e.g. continued availability of medicines) but not assessed in detail. The applicants consider the socio-economic benefits mostly from their own perspective but usually do not consider wider societal aspects and needs. The costs of the authorisation, i.e. the risks, are quantified and monetised by the applicants and assessed by SEAC based on economic valuation techniques like willingness to pay to accept certain health outcomes (see in this respect ECHA reference willingness to pay values<sup>317</sup>). However, currently it is not always sufficiently considered that the risks are usually born by different actors than those perceiving benefits of continued use.

The issue can be illustrated by the example of applications for authorisation for the use of chromium trioxide (a carcinogen and mutagen) in industrial settings to produce chrome-plated and shiny lipstick cases. While the socio-economic benefits of such an authorisation might outweigh the risks, the question remains whether from a societal point of view, authorities should accept that workers are exposed to a carcinogenic substance, for which no safe level can be established, to ensure a functionality like the shiny effect for a lipstick case. In this sense, the question is whether a less shiny effect can be accepted in this use, making a less performing alternative to chromium trioxide acceptable from a societal perspective. Similar examples include the chrome-plating of shiny decorative plastic parts of cars, like the rear-view mirror, with the use of chromium trioxide or dyeing of fabrics for suits with the aid of sodium dichromate to obtain a particularly dark shade for the fabric.

Moreover, the current legal requirements insufficiently take into account that the availability of alternatives is not static but evolves over time. Equally, in order to promote substitution, not enough emphasis is given to the fact that identification of

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<sup>314</sup> See Article 62(5)(a) of REACH which specifies that “The application **may** include: (a) a socio-economic analysis conducted in accordance with Annex XVI”.

<sup>315</sup> <https://echa.europa.eu/applying-for-authorisation/start-preparing-your-application>

<sup>316</sup> SEAC has developed a methodology to take into account changes in producer surplus with the aim of taking into account redistribution of resources within the economy, see [https://echa.europa.eu/documents/10162/0/afa\\_seac\\_surplus-loss\\_seac-52\\_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138](https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138)

<sup>317</sup> [https://echa.europa.eu/documents/10162/17229/seac\\_reference\\_wtp\\_values\\_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9](https://echa.europa.eu/documents/10162/17229/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9)

alternatives is not a ‘one to one’ exercise, and hence alternatives like non-chemical solutions or even just not using the substance should be integrated in the assessment.

### 3 POLICY OPTIONS

#### 3.1 Extending the Commission empowerment to introduce restrictions based on the generic approach to risk management

To address the specific problem and drivers described in section 2.2, it is proposed to speed up the phasing out of the most harmful substances by **relying more on the generic approach to risk management (GRA)**, which is considered more preventive and faster than the specific risk management approach. In particular, this means that the Commission can make proposals to ban the most harmful substances on their own, in mixtures and in articles that could be used by consumers and professional users. Derogations from these bans would be possible for uses proven essential for society (see section 3.2.4). This would be done through an **extension of the existing Commission empowerment to introduce GRA restrictions**, based on Article 68(2). The extension would cover the following hazard classes, in addition to carcinogenicity, mutagenicity and toxicity for reproduction: endocrine disruption, PBT/vPvB, specific target organ toxicity, immunotoxicity and neurotoxicity, and respiratory sensitisation. Whether PMT/vPvM substances should be in the scope of GRA restrictions is considered in this impact assessment. Moreover, the whole extended empowerment would also apply to professional uses, in addition to consumer uses (see table below).

Table 190: Extension of the scope of GRA restrictions based on Article 68(2)

	Baseline: scope of GRA without REACH revision	Scope of GRA in REACH revision
<b>Uses covered</b>	Consumer uses: <ul style="list-style-type: none"> <li>• Substances</li> <li>• Substances in mixtures</li> <li>• Substances in articles</li> </ul>	Consumer uses: <ul style="list-style-type: none"> <li>• Substances</li> <li>• Substances in mixtures</li> <li>• Substances in articles (with high exposure/emissions)</li> </ul> Professional uses: <ul style="list-style-type: none"> <li>• Substances</li> <li>• Substances in mixtures</li> <li>• Substances in articles (with high exposure/emissions)</li> </ul>
<b>Hazards covered</b>	<ul style="list-style-type: none"> <li>• CMR cat. 1</li> </ul>	<ul style="list-style-type: none"> <li>• CMR cat. 1</li> <li>• ED (for human health and the environment) cat. 1</li> <li>• PBT/vPvB</li> <li>• STOT (SE and/or RE<sup>318</sup>) cat. 1</li> <li>• Respiratory sensitisers cat. 1</li> <li>• Substances affecting the immune or neurological systems</li> <li>• PMT/vPvM (subject to the</li> </ul>

<sup>318</sup> It is not explicitly stated in the CSS that both SE and RE will be part of the future system. However, in the context of the impact assessment, both categories are examined in order to be able to consider the impacts of including both hazard classes.

The table below provides an overview of how the option considered address the specific problems and drivers identified.

Table 191: Overview of how the proposed options tackle the problem drivers

Specific problem(s)	Drivers (level 1)	Drivers (level 2)	Policy options
Pace of introducing new restrictions is too slow to ensure that the most harmful substances are adequately regulated	Specific risk management requires detailed assessment of uses and related exposure patterns to determine the risk.	Detailed information on uses and exposure often lacking in REACH registration dossiers.	Extension of Commission empowerment to introduce restrictions under Article 68(2) for all the most harmful substances (covering additional hazard classes than only CMR) and for professional uses (in addition to the already covered consumer uses).  Increased information requirements on use and exposure for the most harmful substances (see Annex 6 – policy options 4 to 7).

### 3.1.1 Implementation scenarios

Based on the extended Commission's empowerment in Article 68(2), additional GRA restrictions in Annex XVII would be introduced after the revised legislation enters into force and according to a **work plan**. Such work plan aims to increase transparency and predictability for all stakeholders, and can feed into the transition pathway for the chemical industry<sup>319</sup>. The work plan is not intended to be part of the Commission's legislative proposal but it will be developed separately as a Commission Staff Working Document and discussed with Member States and relevant stakeholders, following the example of the 2022 Restrictions Roadmap<sup>320</sup>. Therefore, the impacts of extending the empowerment will materialise only when the new GRA restrictions will be introduced. In absence of a detailed work plan that has not been established yet, **three different implementation scenarios** have been considered for the purpose of the impact assessment to give an approximate estimate of the impacts of such empowerment and inform the Commission's decision on the future work plan. The implementation scenarios assessed in this impact assessment differ in terms of:

- Timing and pace of new restrictions;
- Prioritisation of the hazard classes in scope;
- Share of articles restricted, based on prioritisation;

<sup>319</sup> The transition pathway is a roadmap leading towards the achievement of both the green and digital transition (twin transition) and towards the resilience of the chemical industry. The roadmap is the result of a co-creation process with stakeholders, under the European Green Deal framework. It is also part of the implementation of Communication COM(2020) 102 final on A New Industrial Strategy for Europe <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0102>

<sup>320</sup> SWD(2022) 128 final, [DocsRoom - European Commission \(europa.eu\)](https://ec.europa.eu/docsroom/documents/128)

- Share of professional uses restricted, based on prioritisation.

Across scenarios, the Commission’s priority remains to first restrict substances on their own and in mixtures due to the expected high human exposure and emissions to the environment. Examples of mixtures include paints and detergents, which are often directly released into the environment. Restrictions of substances in articles will, at least initially, be limited to selected types of articles with highest potential exposure to consumers and professionals<sup>321</sup>, and will be proposed either in parallel or at a later stage. Similarly, restrictions for professional uses will, at least initially, be limited to selected categories of professionals with similar exposure patterns as consumers, and where other risk control measures are difficult to implement. An assumption is that the restrictions will be limited to substances with confirmed hazard properties, for example via harmonised classification and labelling under the CLP Regulation or via inclusion in the candidate list under the REACH Regulation. The list of concerned substances will be periodically updated.

The difference between the implementation scenarios lies mostly in the pace at which different hazard classes will be addressed, whether restrictions for consumers and professional uses will start at the same time or consecutively, and whether the GRA restriction would target specific uses by professionals and specific article types. A summary of the three implementation scenarios is presented in the table below.

Table 192: Assumptions for implementation scenarios for the extension of GRA

	Implementation scenario 1	Implementation scenario 2	Implementation scenario 3
<i>Consumer uses</i>	All	All	All
<i>Professional uses</i>	Large share of professional uses (75%) restricted <u>at the same time</u> as uses by consumers	Medium share of professional uses (50%) restricted <u>after</u> uses by consumers	Low share of professional uses (25%) restricted <u>after</u> uses by consumers
<i>Hazard classes</i>	All at the same time	Stepwise implementation, with priority to CMR, ED and PBT/vPvB	Stepwise implementation, with priority to CMR, ED and PBT/vPvB
<i>Product type</i>	First, restriction of substances on their own and in mixtures  Then, restriction of selected article types  Share of uses in articles covered: 50%	First, restriction of substances on their own and in mixtures  Then, restriction of selected article types  Share of uses in articles covered: 10%	First, restriction of substances on their own and in mixtures  Then, restriction of selected article types  Share of uses in articles covered: 1%

<sup>321</sup> This follows the same approach as current Article 68(2) restrictions, e.g. for CMR substances in textiles, REACH Annex XVII, entry 72; see more details in the sections below.



Two aspects of the implementation scenarios are worth describing more in details: the prioritisation and selection of article types and of professional uses.

#### Prioritisation and selection of article types

During the preparation of proposals for GRA restrictions, the Commission envisages to prioritise restrictions for **article types with the highest exposure/emissions potential** for the user and/or the environment and throughout the lifecycle of the article. Similar considerations, but targeting only the exposure potential at the consumer-use stage, were used in the past for selecting a group of textile articles used by consumers to enact a restriction of CMR substances, i.e. restriction of 33 CMR substances in textiles in entry 72 of Annex XVII. The choice of article types will be based on generic exposure/emission considerations, based on specific criteria for prioritisation to be developed. Factors to be considered when estimating the exposure potential for articles include, for example:

- distribution patterns of the type of article in society (e.g. used by many, in high numbers, wide geographical spread);
- use pattern (e.g. direct human exposure such as skin contact, specifically intended for sensitive groups);
- potential for material recycling and circular economy, including life cycle length or length of use phase;
- potential for release of hazardous substances from the article (leaching from the material or abrasion of particles);
- potential for hazardous substances to disperse to the environment during production, use, waste management or recycling of the article.

#### Prioritisation and selection of professional uses

Currently there is no definition in the REACH Regulation of consumer, professional and industrial uses and such definitions will be introduced during the revision. However, based on ECHA guidance, a professional use “is any use of a substance on its own, in a mixture or in an article by a professional that takes place as part of a work-related activity outside an industrial site”<sup>322</sup>.

The rationale for extending GRA restrictions to professional users is that they are exposed for longer periods to certain hazardous substances compared to consumers and deserve the same level of protection as consumers. Although many professional users would normally receive adequate information and training on handling hazardous substances and might use some types of personal protective equipment or apply other risk management measures, there are also professional users that do not receive instructions and training. Therefore, a differentiation between different uses by professionals seems warranted. GRA restrictions should apply to professional uses where risk control is

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<sup>322</sup> ECHA, Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.12: Use description, July 2015.  
[https://echa.europa.eu/documents/10162/2324909/r12\\_guidance\\_draft\\_for\\_committees\\_201507\\_en.pdf/a28688f2-d804-4526-a8d9-578f4383a031](https://echa.europa.eu/documents/10162/2324909/r12_guidance_draft_for_committees_201507_en.pdf/a28688f2-d804-4526-a8d9-578f4383a031)

difficult and where the exposure/emissions pattern are similar to those of consumer uses. Possible preliminary criteria to determine the professional uses to be restricted are the following:

- no equipment for automation or engineering controls to limit the exposure to humans and release to the environment is in place;
- there is no work supervision by a health and environmental manager;
- there is limited or no training specifically related to safe use of chemicals;
- many of the professional users involved are self-employed, where EU OSH legislation does not apply;
- substances are used in an environment where co-exposure of consumers may occur;
- there is frequent use of certain products during large fractions of work shifts, possibly associated with co-exposure to the same or similar substances contained in different mixtures.

It should be noted that these criteria would need to be discussed with interested parties, including OSH authorities.

### **3.1.2 Derogations from GRA restrictions**

Currently, derogations from GRA restrictions in Annex XVII can be included by the Commission when the restriction proposal is prepared and adopted. In addition, in some cases derogation requests from industry could be allowed in the future, depending on the preferred option for the reform of the authorisation and restriction processes (see section 3.2). The assessment of derogations will be based on the essential use criteria (see section 3.2.4) to achieve the overall objective of this revision, in line with the CSS. However, industry stakeholders have been arguing that uses that are proven to be safe should also be derogated.

## **3.2 Reform authorisation and restriction processes, and introduce the essential use criteria to grant authorisations and/or derogations from restrictions**

To address the specific problem and drivers described in section 2.1, three options (in addition to the baseline) have been identified to improve the authorisation system:

- Baseline: no changes to the authorisation and restriction titles of REACH;
- Option 20: streamline and keep separate the authorisation and restriction provisions;
- Option 21: merge authorisation and restriction provisions into one system;
- Option 22: abandon the authorisation provisions, but keep the candidate list<sup>323</sup>.

**The main difference between options 20, 21 and 22 lies in the way authorisations or derogations from bans or restrictions are designed.** Each of these options are described in more details in sections 3.2.1, 3.2.2, and 3.2.3.

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<sup>323</sup> To be noted that in the VVA and Wood supporting studies, option 20 corresponds to option 1, option 21 corresponds to option 2 and option 22 corresponds to option 3.

In addition, the following horizontal sub-options, i.e. applicable across options 20, 21 and 22, have been considered:

- **Role of Forum** and enforceability of authorisations and restrictions:
  - Sub-option F1: Forum becomes a Committee and provides an opinion on enforceability, in addition to RAC and SEAC opinions
  - Sub-option F2: Forum gives a formalised advice on authorisations and restrictions.
- **Additional information on use and exposure for substances in the Candidate list (see Annex 6).**
- Introducing the **essential use concept** for authorisations and/or derogations from Article 68(1) and/or Article 68(2) restrictions (see section 3.2.4).

### **3.2.1 Option 20: streamline and keep separate the authorisation and restriction provisions**

Option 20 is the closest to the baseline since it envisages that the authorisation requirement (ban in Annex XIV, unless the use is authorised) and restrictions (ban or conditions for use in Annex XVII) would be kept separate and the current authorisation requirements would broadly apply as in the baseline. However, a number of actions to improve the authorisation system would be introduced. The main elements of option 20 are the following:

- Substances of very high concern (SVHC) prioritised from the candidate list will continue to be included in Annex XIV to make their uses subject to authorisation. This corresponds to a generic ban, i.e. uses are only allowed if an authorisation is granted.
- The authorisation requirement would be extended to also cover placing on the market of substances in articles, including imported articles, which would make the provisions of Article 69(2) redundant (measure 20a).
- The Member State Committee would not provide an opinion anymore on ECHA's draft recommendation to include substances in Annex XIV (measure 20b).
- Authorisations for the use of SVHCs listed in Annex XIV would remain applicable only to the applicants, being those either upstream or downstream actors. In other words, companies would be authorised to use SVHCs if there is a Commission decision granting an authorisation to their company or to an actor upstream in their supply chain if the company's use is in line with the conditions of the granted authorisation.
- Clarifications would be introduced on several elements that led to controversies in the past (measure 20c), amongst other:
  - Applications for authorisation: specify use description, technical function, level of details required (information should be detailed enough to allow for assessment) and representativeness of downstream user's information when an application is made by actors up in the supply chain;
  - Clarify which actors in the supply chain can apply for authorisation: downstream users, their immediate upstream actors, manufacturers/importers (Art. 62(2)).

- Introduction of a new legal provision not allowing to authorise the uses to produce products (articles/mixtures) that are banned from placing on the market in the EU (measure 20d).
- Introduction of a new legal obligation for the authorisation holder to notify to the relevant authorities (ECHA and/or Member State Competent Authorities) of any relevant changes on tonnages, RMMs and operational conditions and legal entity (measure 20e).

The table below presents an overview of how authorisations and derogations from restrictions would be designed under option 20 for the three main different regulatory tools, i.e. authorisation requirement in Annex XIV, restrictions based on Article 68(1) in Annex XVII and GRA restrictions based on Article 68(2) in Annex XVII.

Table 193: Authorisation/derogation possibilities under option 20

<b>Regulatory tool</b>  <b>Type of derogation</b>	<b>Generic ban in Annex XIV (SVHC, mainly industrial and professional uses)</b>	<b>Specific restrictions in Annex XVII (Article 68(1), all uses)</b>	<b>GRA restrictions in Annex XVII (Article 68(2), most harmful substances, consumer and certain professional uses)</b>
<b>Derogations based on authorities' assessment at the time of ban/restriction</b>			
Authority-driven derogations, applicable to all users	Included in Annex XIV, subject to conditions in Article 58(2)	Included in restriction	Included in restriction
<b>Derogations or authorisations based on requests by industry</b>			
Industry-driven derogations, i.e. applicable to all users	Not possible	Not possible	Not possible
Applicant-specific authorisations, i.e. applicable only to applicant(s)	Same as baseline, but with clarification of requirements	Not possible	Not possible

Green: possible; Orange: possible in certain cases (see text); Red: not possible

### 3.2.2 Option 21: merge authorisation and restriction provisions into one system

In option 21, substances of very high concern (SVHC) prioritised from the candidate list would be included in a specific section of Annex XVII, while Annex XIV would disappear and be integrated in Annex XVII. All procedures and principles to identify and include substances in this section would remain the same as in the current Annex XIV listing (see section 1.1) and the relevant provisions would be transferred from Title VII to

Title VIII. Some of the clarifications envisaged under option 20 might be applicable also in option 21. The presence of substances in articles would be covered in the new section of Annex XVII for listed<sup>324</sup> SVHCs, which would make Article 69(2) redundant.

Under option 21, the possibilities for authorisations/ derogations would be aligned into one common system of restrictions in Annex XVII (including for listed SVHCs, after integration of ex-Annex XIV into Annex XVII), with three different possibilities:

- **Authority-driven derogations.** This would follow the same principles as those currently applied under restrictions, i.e. the derogation is part of the restriction proposal and must be justified by the authority submitting the dossier, e.g. as part of the Annex XV dossier for Article 68(1) restrictions or in a Commission proposal for Article 68(2) restrictions.
- **Industry-driven derogations of general applicability (*new element*),** in cases where the restriction allows for their submission. Companies would need to make a formal application for derogation and the application would be subject to a formal assessment process after the restriction has been adopted. The derogation would be applicable to all users rather than being specific to the applicants. This partly shifts the burden of proof from authorities to justify derogations as part of restriction dossiers to industry that needs to justify why their use needs a derogation. This formal process would allow transferring the major benefit from the authorisation system, i.e. burden of proof on industry, into the restriction system, by improving the amount and structure of information to justify a derogation.
- **Industry-driven authorisations,** in cases where the restriction allows for their submission. Industry could apply for individual authorisations for uses of restricted substances applicable only to the applicant(s), like in the current authorisation system. This would however remain exceptional and be discouraged by strict requirements compared to industry-driven derogations of general applicability. For example, to encourage companies to cooperate and submit a request for a derogation of general applicability, instead of single authorisation requests, the same fee could apply for derogations of general applicability and authorisations. This would make the fee for authorisations much higher in comparison to the fee for derogations of general applicability that could be shared among companies.

Industry-driven derogations and authorisations should be limited to where this is explicitly allowed in the restriction. This means that these applications cannot be submitted retroactively for existing restrictions. The exact criteria for when such industry-driven applications could be allowed are to be determined in the legislative proposal.

Compared to the baseline, option 21 presents the following main differences:

- Difference with the current authorisation system: the range of tools to allow the use of listed SVHCs would be enlarged from authorisations applicable to the

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<sup>324</sup> Where “listed” SVHCs is mentioned this means restricted SVHCs on Annex XIV (option 1) or on a specific new section of Annex XVII, into which Annex XIV will be transferred.

applicants to derogations of general applicability, i.e. applicable to all users (new). The conditions in Article 58(2) to exempt uses (authority-driven exemptions) would be expanded.

- Difference with the current restriction system: authorities can set in the restriction the possibility for industry to formally submit applications for derogations of general applicability and/or for authorisation, shifting the burden of proof to justify derogations to industry.

The table below presents an overview of how authorisations and derogations from restrictions would be designed under option 21 for the three main different regulatory tools, i.e. authorisation requirement in Annex XIV, specific restrictions based on Article 68(1) in Annex XVII and GRA restrictions based on Article 68(2) in Annex XVII.

Table 194: Authorisation/derogation possibilities under option 21

Regulatory tool Type of derogation	Restrictions of SVHC in Annex XVII; mainly industrial/professional uses	Specific restrictions in Annex XVII (Article 68(1), all uses)	GRA restrictions in Annex XVII (Article 68(2), most harmful substances, consumer and certain professional uses)
<b>Derogations based on authorities' assessment at the time of ban/restriction</b>			
Authority-driven derogations, applicable to all users	Included in restriction		
<b>Derogations or authorisations based on requests by industry</b>			
Industry-driven derogations, i.e. applicable to all users	Main route for derogations	If allowed in restriction	Main route for derogations
Applicant-specific authorisations, i.e. applicable only to applicant(s)	Only in specific circumstances	If allowed in restriction	Only in specific circumstances

Green: possible; Orange: possible in certain cases

### 3.2.3 Option 22: abandon the authorisation provisions, but keep the candidate list

In option 22, there would be no more prioritisation of SVHCs from the Candidate list for their inclusion in Annex XIV. However, the identification of SVHCs and the candidate list would be retained as a tool for prioritisation of substances requiring regulatory action. Annex XIV would be phased out and eventually repealed, after a transitional period.

Authorisation decisions would remain valid until the end of the review period, but companies will not be able to submit review reports at the end of the review period.

Restrictions in Annex XVII, either based on the generic risk management approach following Article 68(2) or based on specific risk management approach following Article 68(1), would be the main regulatory tool in REACH. Article 69(2) restrictions to cover the use of Annex XIV substances in articles would become redundant. Given that authorisations concern mainly industrial and professional uses, abandoning the authorisation system would require more reliance on other existing EU legislation that regulates the use of harmful substances in industrial and professional settings. This includes the EU Occupational Safety and Health legislation and the EU Industrial Emissions Directive. Member State Competent Authorities would remain responsible for controlling industrial uses of substances under national legislation.

Under option 22, the use of a substance covered by a restriction in Annex XVII (based on Article 68(1) or 68(2)) would only be possible if authorities include a derogation in the restriction (see table below). The burden of proof to justify such derogations would be on the authorities preparing the restriction proposal.

Table 195: Authorisation/derogation possibilities under option 22

<b>Regulatory tool</b>  <b>Type of derogation</b>	<b>Generic ban in Annex XIV (removed)</b>	<b>Specific restrictions in Annex XVII (Article 68(1), all uses)</b>	<b>Generic restrictions in Annex XVII (Article 68(2), most harmful substances, consumer and certain professional uses)</b>
<b>Derogations based on authorities' assessment at the time of ban/restriction</b>			
Authority-driven derogations	Not applicable	Included in restriction	Included in restriction
<b>Derogations or authorisations based on requests by industry</b>			
Industry-driven derogations	Not applicable	Not possible	Not possible
Applicant-specific authorisations	Not applicable	Not possible	Not possible

Green: possible; Red: not possible

### 3.2.4 Role of Forum

*Sub-option F1: Forum becomes a Committee and gives an opinion in addition to RAC and SEAC*

The Forum would become an ECHA Committee developing a third official 'opinion' on enforcement and enforceability, with the equivalent status to RAC and SEAC, as defined

in Article 70 and 71 of REACH. The Forum would give such opinions on enforceability for the following:

- Applications for authorisation (under option 20)/ individual requests for authorisations (under option 21)
- Requests for derogations of general applicability (under option 21)
- Restriction proposals under Article 68(1).

*Sub-option F2: Forum gives formalised advice for authorisations and restrictions*

The Forum would continue to give advice on enforceability of restrictions in parallel to RAC and SEAC opinion making. In addition, it would also provide advice on the enforceability of recommended conditions for authorisation, including RMMs/operational conditions proposed by RAC or other conditions proposed by SEAC at draft opinion stage. This would be done for groups of substances or uses, rather than for every application for authorisation.

### 3.2.5 Introducing the essential use concept in REACH

According to the Chemicals Strategy for Sustainability, the **use of a chemical is considered essential** if:

- it is necessary for health, safety or is critical for the functioning of society, and
- there are no alternatives that are acceptable from the standpoint of environment and health.

In order to facilitate the implementation of the two above criteria by companies when preparing their applications and to ensure a coherent assessment by authorities both in REACH and in other different pieces of legislation that implement the essential use concept, the definitions and specifications of this concept are being developed in parallel to this impact assessment and will be included in a horizontal document.

The implementation of these two cumulative criteria in REACH should serve to determine whether a use is essential for society. These criteria would then be used as a ground for decisions on authorisations and derogations from restrictions (under Article 68(1) and/or 68(2)), depending on whether the future system will be based on option 20, 21 or 22 (e.g. whether the authorisation title would be maintained or not). Therefore, for each of the options 20 to 22, the possibility to modify the criteria for granting authorisations and for derogations from restrictions and implement the essential use concept has been considered (see overview in the table below).

*Table 196: Applicability of the essential use concept to options 20, 21 and 22*

Type of regulatory tool	Type of derogation (application for authorisation or derogation from restriction)	ESU in baseline	ESU in option 20	ESU in option 21	ESU in option 22
Authorisation requirement in Annex XIV	Application for authorisation (authorisation valid only for applicant-s)	◆	◆		
Restriction in Annex XVII based on article 68(1)	Authority-driven derogation	◆	◆	◆	◆
	Industry-driven derogation (of general applicability to all users)			◆	
	Applicant-specific derogation (authorisation valid only for applicant-s)			◆	



Restriction in	Authority-driven derogation	◆	◆	◆	◆
Annex XVII based	Industry-driven derogation(of general			◆	
on article 68(2), i.e.	applicability to all users)			◆	
GRA	Applicant-specific derogation			◆	
	(authorisation valid only for applicant-s)				

In particular, **different possibilities to introduce the essential use concept** in REACH have been assessed, in addition to the baseline (i.e. no changes to the current criteria):

**A. *Non-binding guidance for the introduction of the essential use concept in authorisation and restriction***

The essential use concept would be introduced within the current legal framework of REACH as an interpretative principle in guidance. This implies that it would be possible to submit an application for authorisation or justify a derogation from restriction by arguing that a use is essential following the guidance, but the existing legal criteria for authorisation (Article 60) still need to be met. This means that the essential use concept would be complementary to the existing legal criteria within the socio-economic and adequate control routes, for authorisation. The legal feasibility of introducing the essential use concept via a guidance is uncertain.

**B. *Binding implementing legislation and guidance for the introduction of the essential use concept in authorisation and restriction***

The essential use concept would be introduced without amending the current legal framework of REACH, as an interpretative principle in implementing legislation and, if needed, in a guidance document. This implies that it would be possible to submit an application for authorisation or request a derogation from restriction based on the current legal provisions under REACH and, at the same time, by arguing (within the current legal provisions) that a use is essential following the implementing legislation. In this case, the essential use criteria would be legally binding and its interpretation supported by a guidance document.

**C. *Introduction of legal changes in REACH for essential use under authorisation and/or restriction, with the essential use concept being a complementary approach to the socio-economic route and [modified] adequate control route to decide on authorisations and derogations from restriction***

The essential use concept would be introduced via legal changes to the enacting terms of REACH under the authorisation and/or restriction titles (depending on option 20, 21 or 22). The essential use concept would complement the socio-economic analysis (SEA) for deciding on derogations from restrictions in accordance with Article 68(1) (note that SEA is not required for restrictions under Article 68(2)). SEA would remain part of the restriction dossiers under Article 68(1) and the essential use concept would only apply to derogations from restrictions. The adequate control route in authorisation would remain applicable (under option 20).

**D. *Introduction of legal changes in REACH for essential use under authorisation and/or restriction, with the essential use concept replacing the socio-economic route as an approach to decide on authorisations and replacing the socio-***

***economic analysis and lack of alternatives criterion to decide on derogations from restriction; the adequate control route for authorisation is removed, so that granting of all authorisations would be based on the essential use concept***

The essential use concept would be introduced via legal changes to the enacting terms of REACH under the authorisation and/or restriction titles (depending on option 20, 21 or 22). The essential use concept would replace the risk-benefit comparison (demonstrated usually through SEA) and the lack of alternatives criterion for deciding on authorisations or *derogations* from restrictions in accordance with Article 68(1) (note that no SEA is required for restrictions under Article 68(2)). SEA would remain part of the restriction dossiers under Article 68(1); the replacement of SEA by the essential use concept would only apply to derogations from Article 68(1) restrictions. The adequate control route in authorisation would be removed and fully replaced by the essential use concept (under option 20). All uses of SVHCs or the most harmful substances would be authorised or derogated from Article 68(2) restrictions only if considered essential.

*The essential use criteria, and assessment of alternatives*

The **first criterion** of the essential use concept, i.e. criticality for the functioning of society and necessity for health and safety, goes beyond merely a technical assessment. Therefore, the assessment of this criterion will need to be done by an appropriate legitimated body. The interaction between the scientific/technical and the more policy/political levels would need to reflect this specificity.

The **second criterion** concerns the lack of alternatives, which is a similar criterion in current processes and in the essential use concept. To better take into account the weaknesses in the current decision making system on the suitability of alternatives (see section 2.1), the dynamic nature of innovation and substitution and possible non-chemical solutions, it is necessary to clarify and partly modify the way the availability of suitable alternatives is assessed and to better incentivise substitution of harmful substances.

Only in some cases drop-in alternatives are available, so the focus should be on setting the timing and actions needed to substitute the substance as quickly as possible. To do this, the role of substitution plans should be strengthened and co-operation between the users of the substance and alternative providers promoted. This should go beyond setting an appropriate review period and assessing the credibility of the substitution plan submitted by the applicant. The process should be accompanied, supported e.g. by analysis of obstacles to substitution and agreeing steps to be taken to overcome those, which may, if appropriate be added to the substitution plans and be added to the derogation/authorisation conditions. Alternative providers should be involved from an early stage, in order to actively promote innovation, to better plan and speed up substitution.

A better use of substitution plans should overcome practical obstacles in the substitution process. Those tools should minimise substitution times, while avoiding disruptions in the supply of essential functions that currently can only be provided by these controlled substances. This, in turn, aims to further booster research and innovation into sustainable

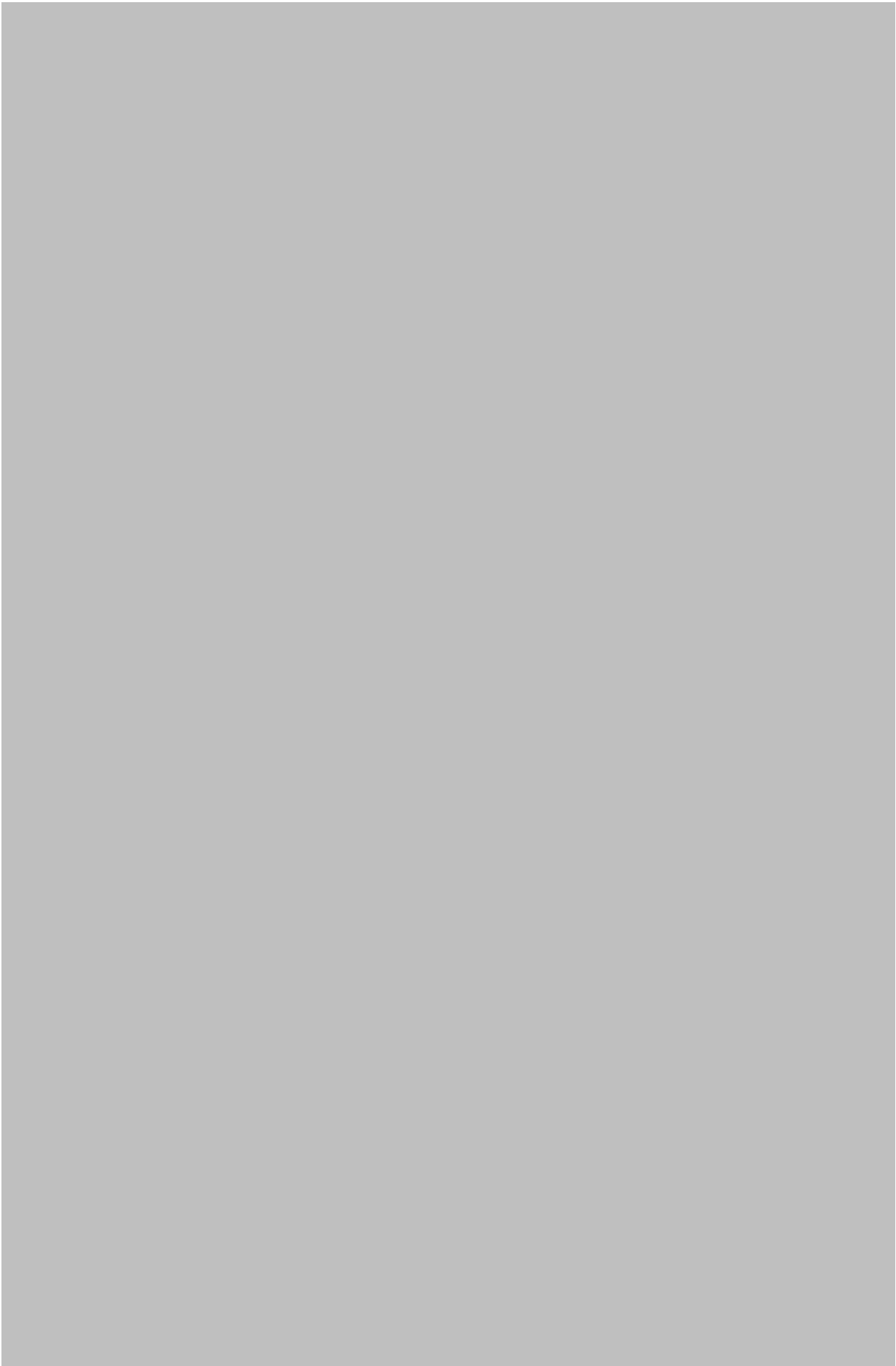
alternatives in uses considered essential and enable to speed up the phase out of the most harmful substances.

The following table explains how the options considered address the specific problems and drivers identified in section 2.1.

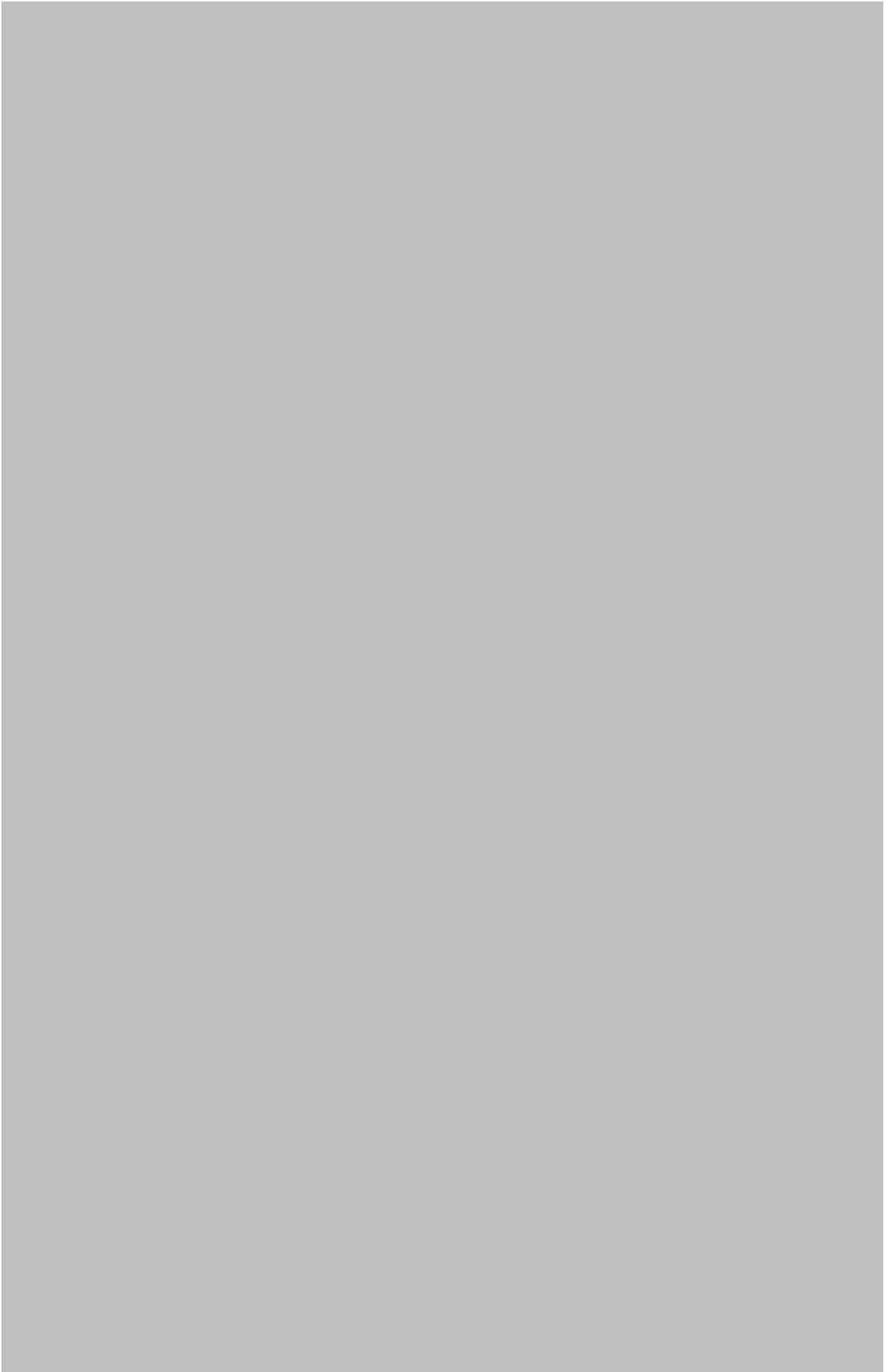
Table 197: Overview of how the options 20, 21 and 22 tackle the problem drivers

Specific problem(s)	Drivers (level 1)	Drivers (level 2)	Option 20	Option 21	Option 22
Burden and inefficiencies of applications for authorisation	Multitude of often repetitive individual applications for similar uses of sometimes very small quantities of SVHCs due to difficulties in processing of upstream applications (Cr(VI) cases) or confidentiality issues (OPE/NPE cases)	Unclear information requirements for applications for authorisation	Clarify requirements for applications for authorisation and criteria for granting authorisations in REACH	Derogations from restrictions of general applicability, i.e. applying to all users, become the main route for derogations  Individual applications for authorisations allowed only in exceptional circumstances	Authorisation title deleted and no more applications for authorisation, restrictions become main risk management tool under REACH
Lack of international level playing field vis-à-vis non-EU companies	Authorisation requirements do not apply to the imported articles containing SVHCs listed in Annex XIV		Extend authorisation requirements to placing on the market of articles containing SVHCs listed in Annex XIV, including from imports	Authorisation list is incorporated into Annex XVII, which applies also to imports	Authorisation requirement is discontinued, restrictions in Annex XVII apply to imports

Specific problem(s)	Drivers (level 1)	Drivers (level 2)	Option 20	Option 21	Option 22
Slow decision-making	Controversies linked to the assessment of alternatives, delays in decision making and Court cases	Unclear criteria for authorisation: lack of definition and different interpretations of what constitutes a suitable alternative	Increased role of substitution plans as part of the assessment of alternatives in the essential use concept		
Lengthy discussions on cases where there is no clear societal need, but economic benefits are demonstrated to outweigh the risk	Under the socio-economic route, the SEA criterion does not take into account sufficiently societal aspects, under the adequate control route, no societal aspects and needs are considered at all.		<p><b>Introducing the essential use concept in REACH</b> considering these possibilities:</p> <ul style="list-style-type: none"> <li>A. <b>non-binding guidance</b> for the introduction of the essential use concept in authorisation and restriction.</li> <li>B. <b>binding implementing regulation and supporting guidance</b> for the introduction of the essential use concept in authorisation and restriction through implementing legislation and guidance.</li> <li>C. Introduction of <b>legal changes</b> in REACH for essential use under authorisation and/or restriction, with the essential use concept being a <b>complementary approach to the socio-economic route and [modified] adequate control route</b> to decide on authorisations and derogations from restriction</li> <li>D. Introduction of <b>legal changes</b> in REACH for essential use under authorisation and/or restriction, with the essential use concept <b>replacing the adequate control and the socio-economic routes</b> for granting authorisations and replacing socio-economic analysis and lack of alternatives criterion to decide on derogations from restriction</li> </ul>		



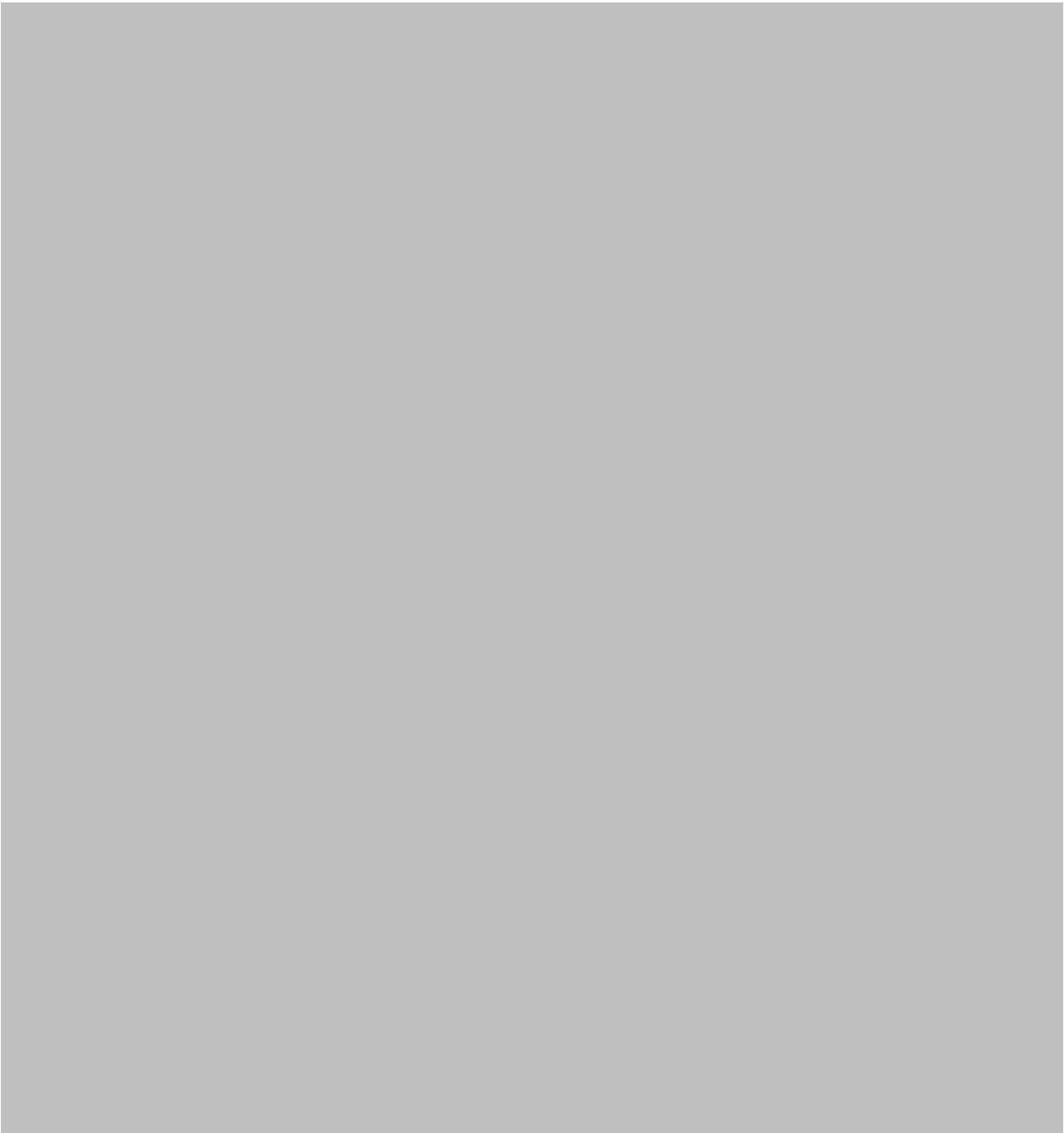


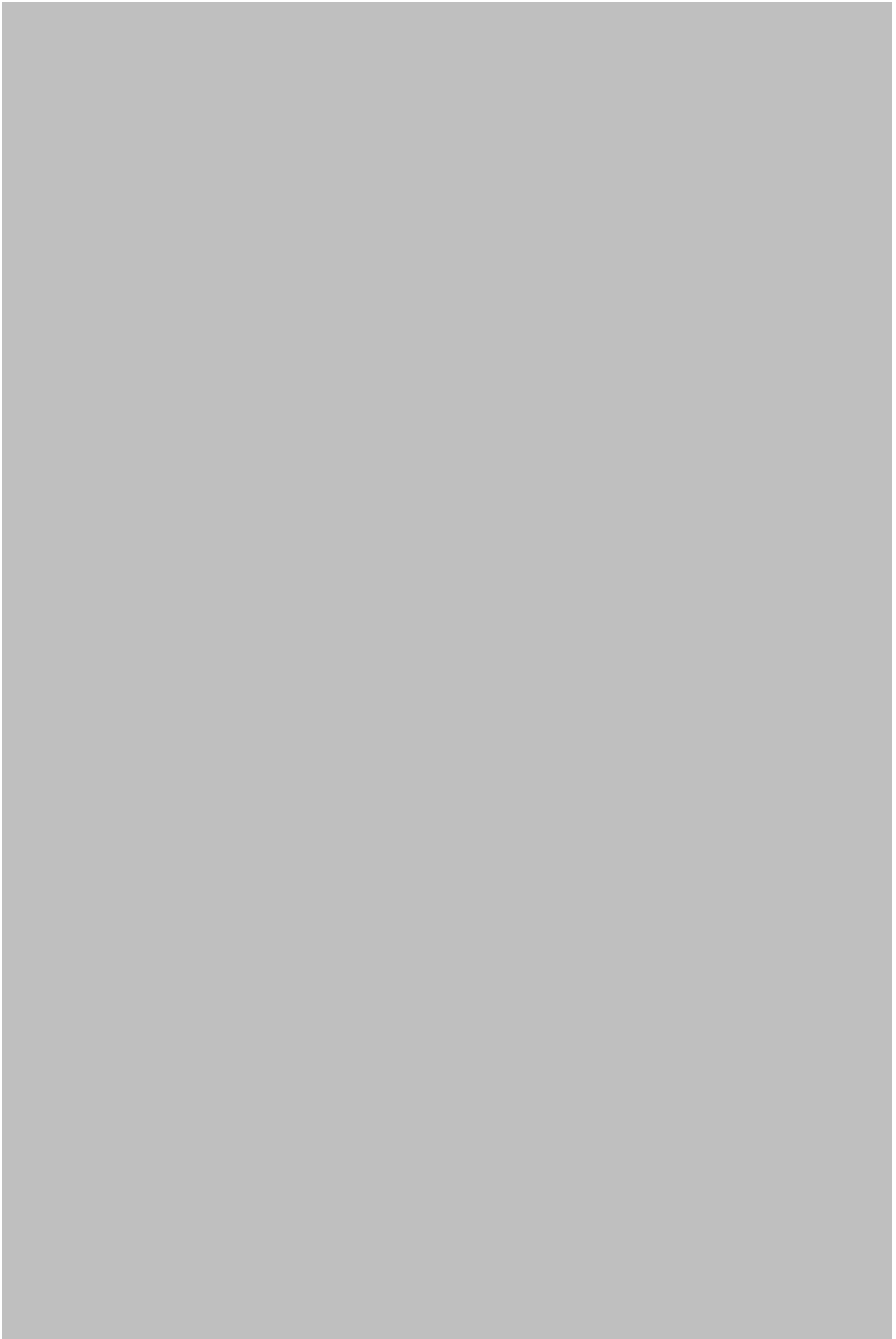


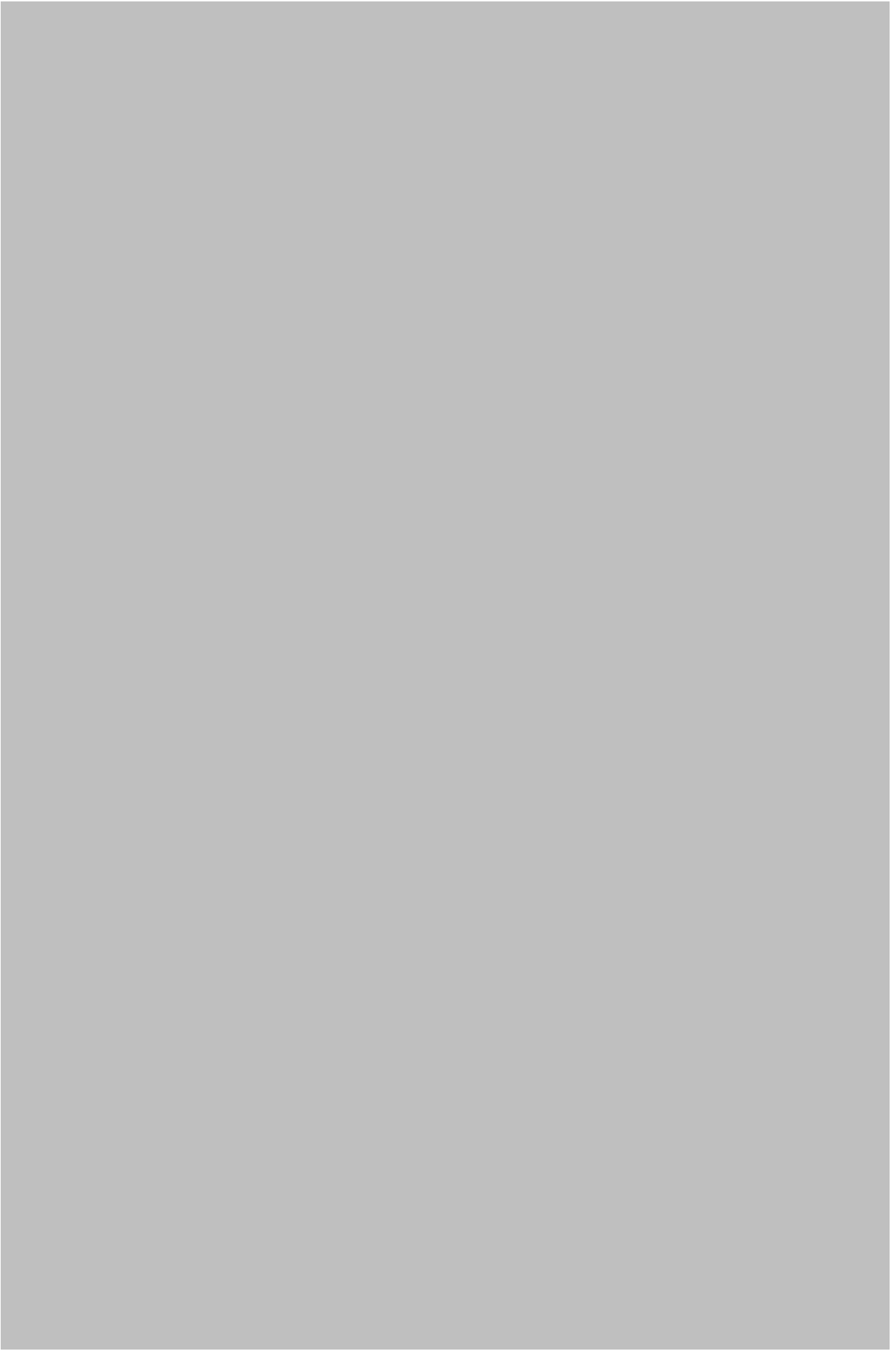




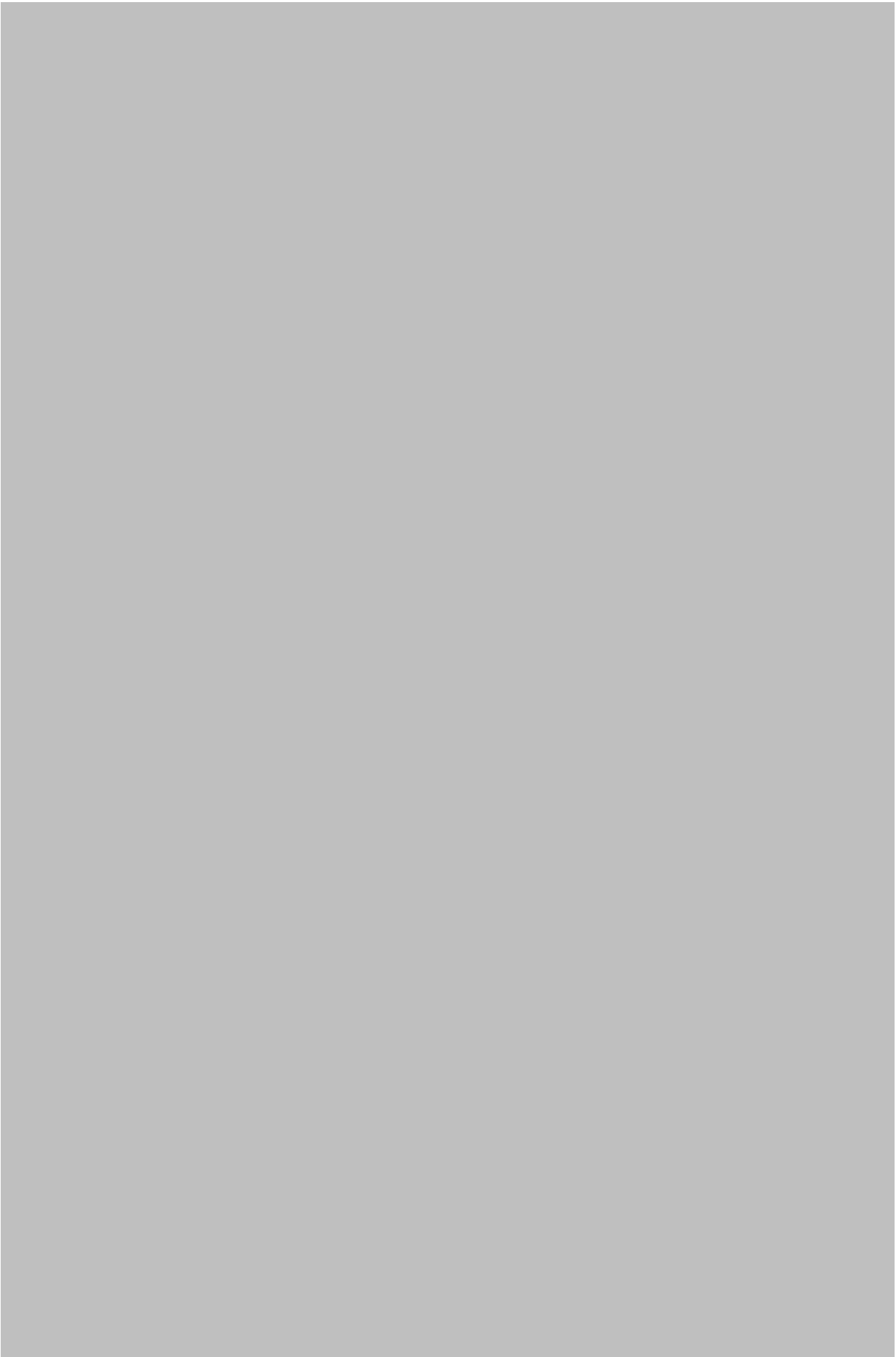


















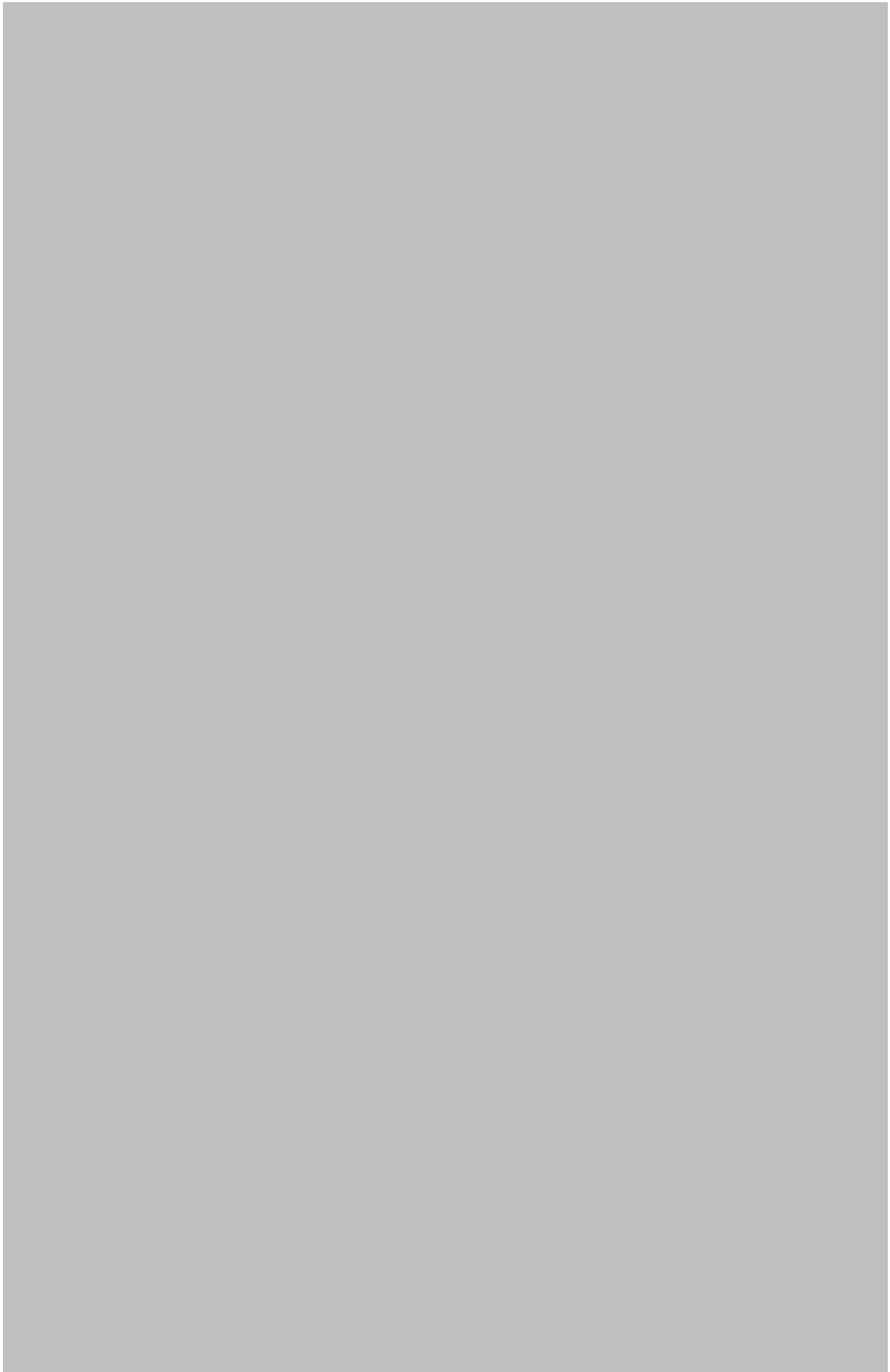




















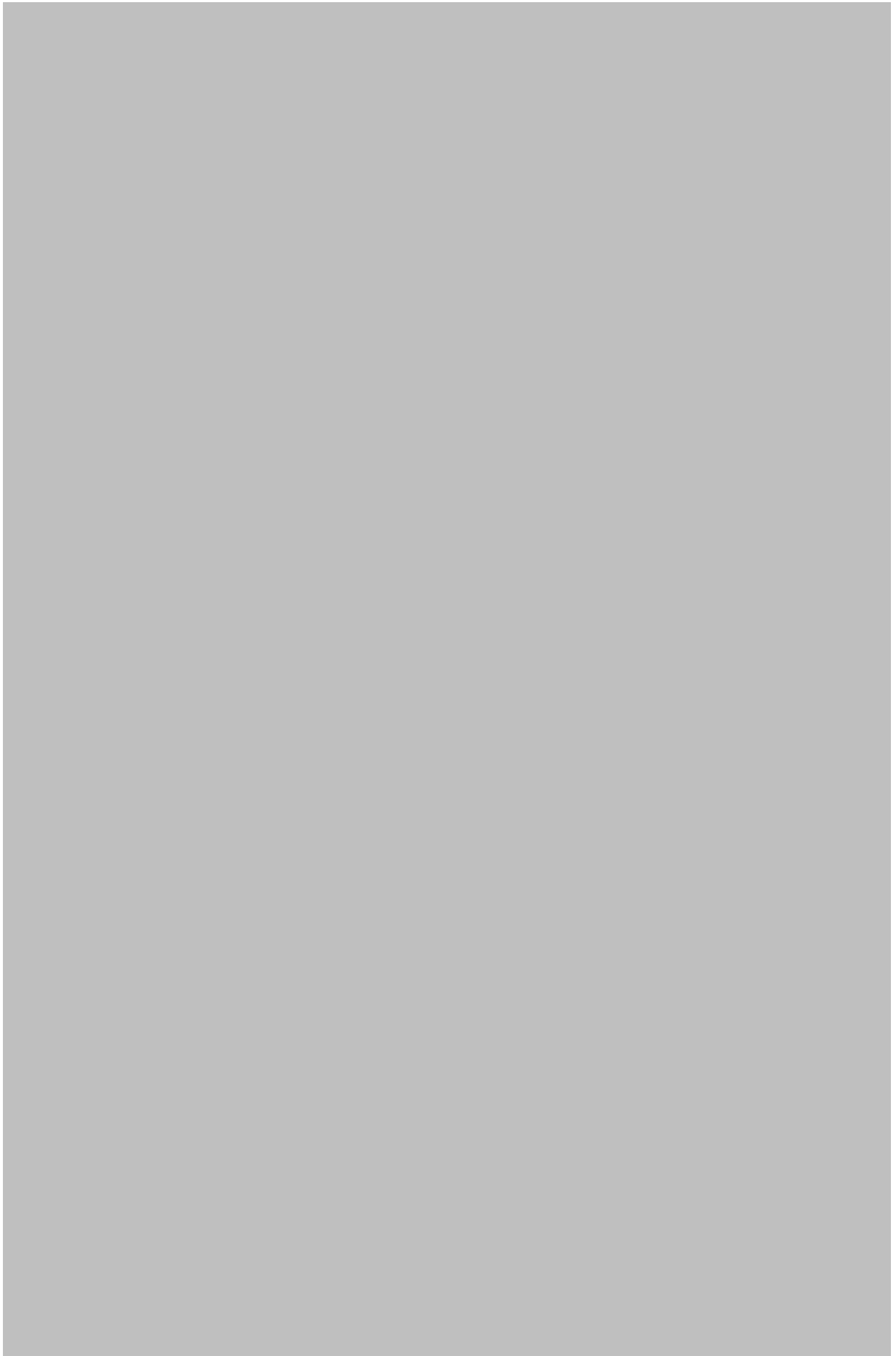












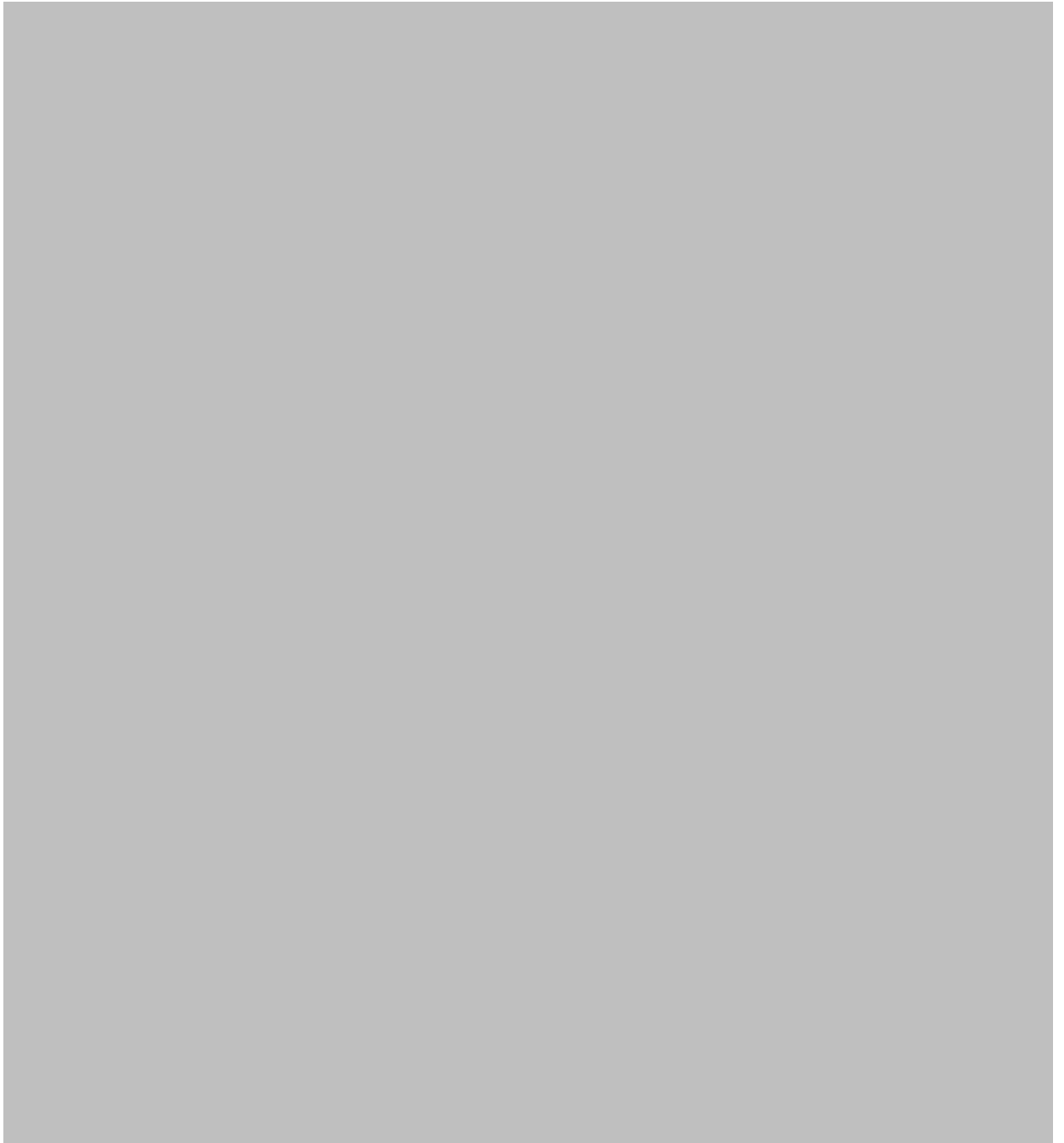


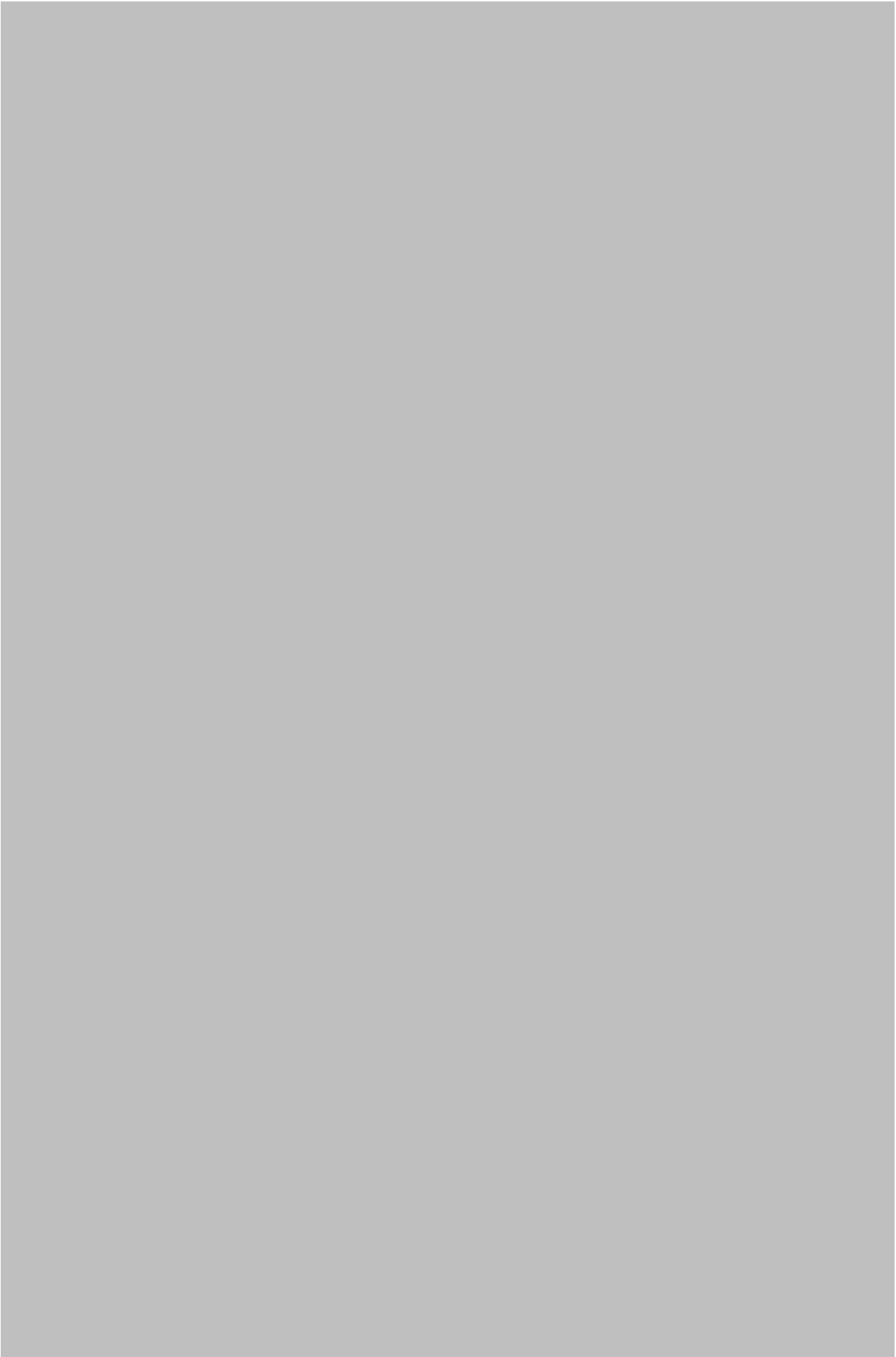










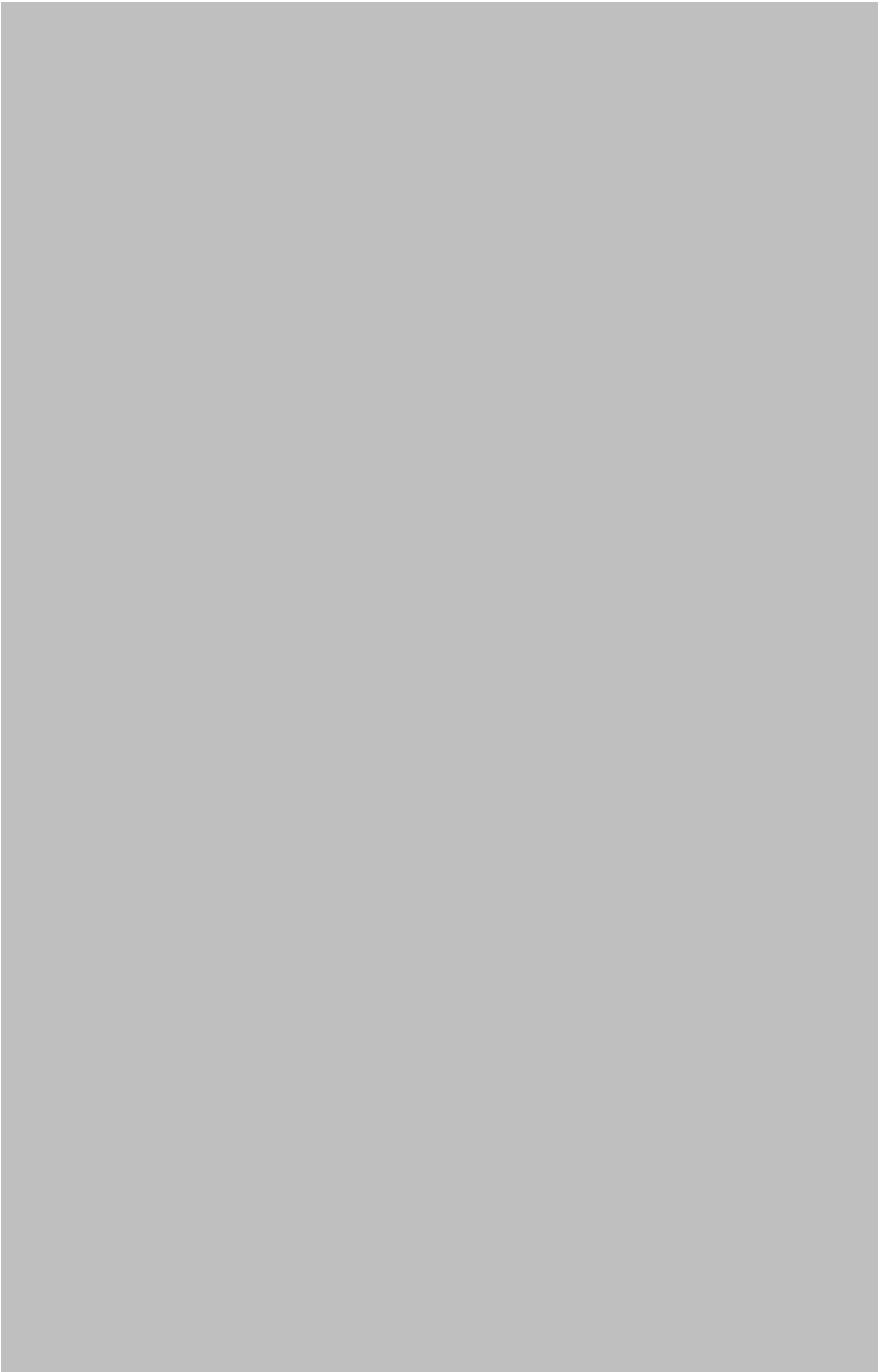


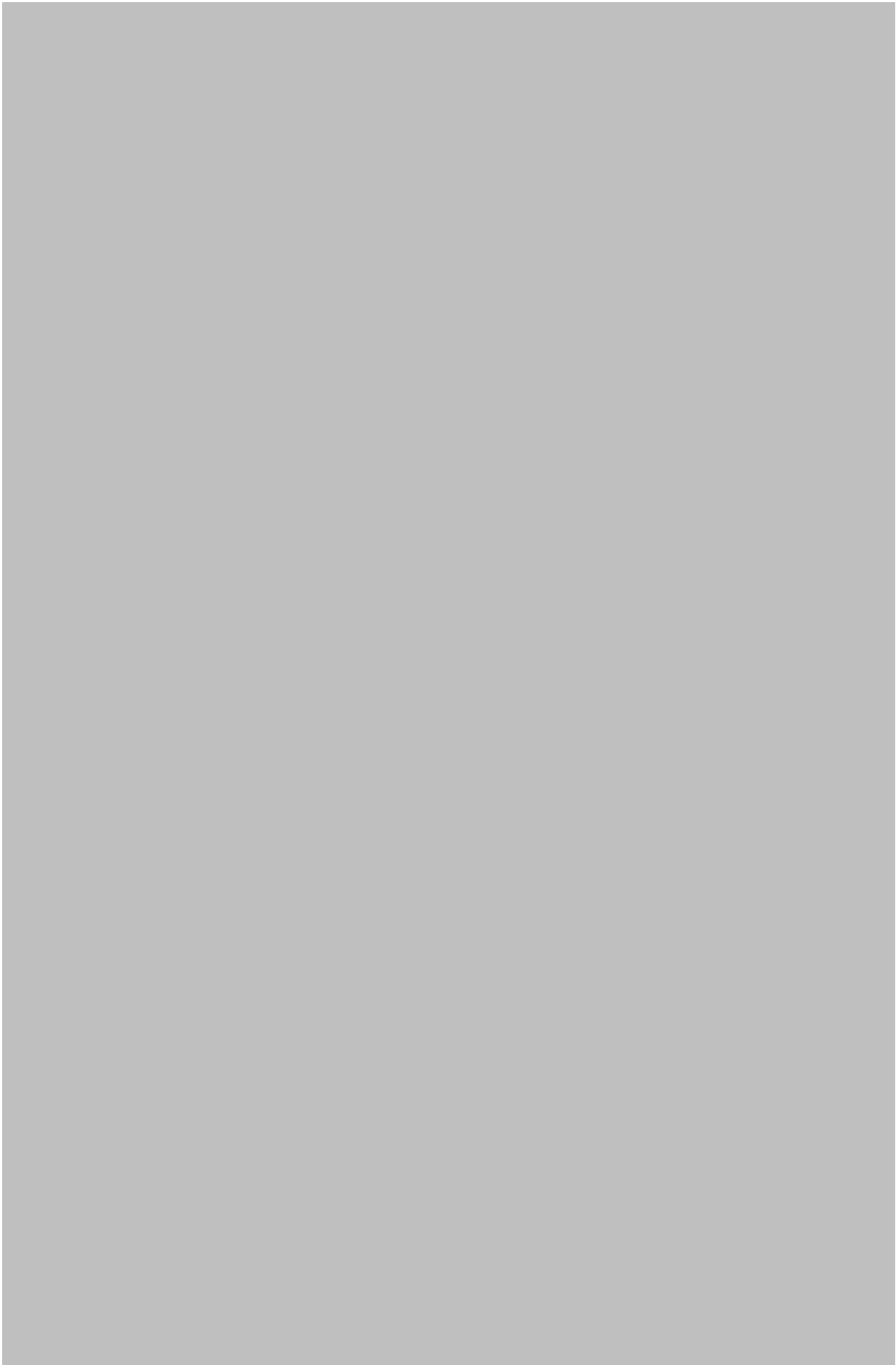








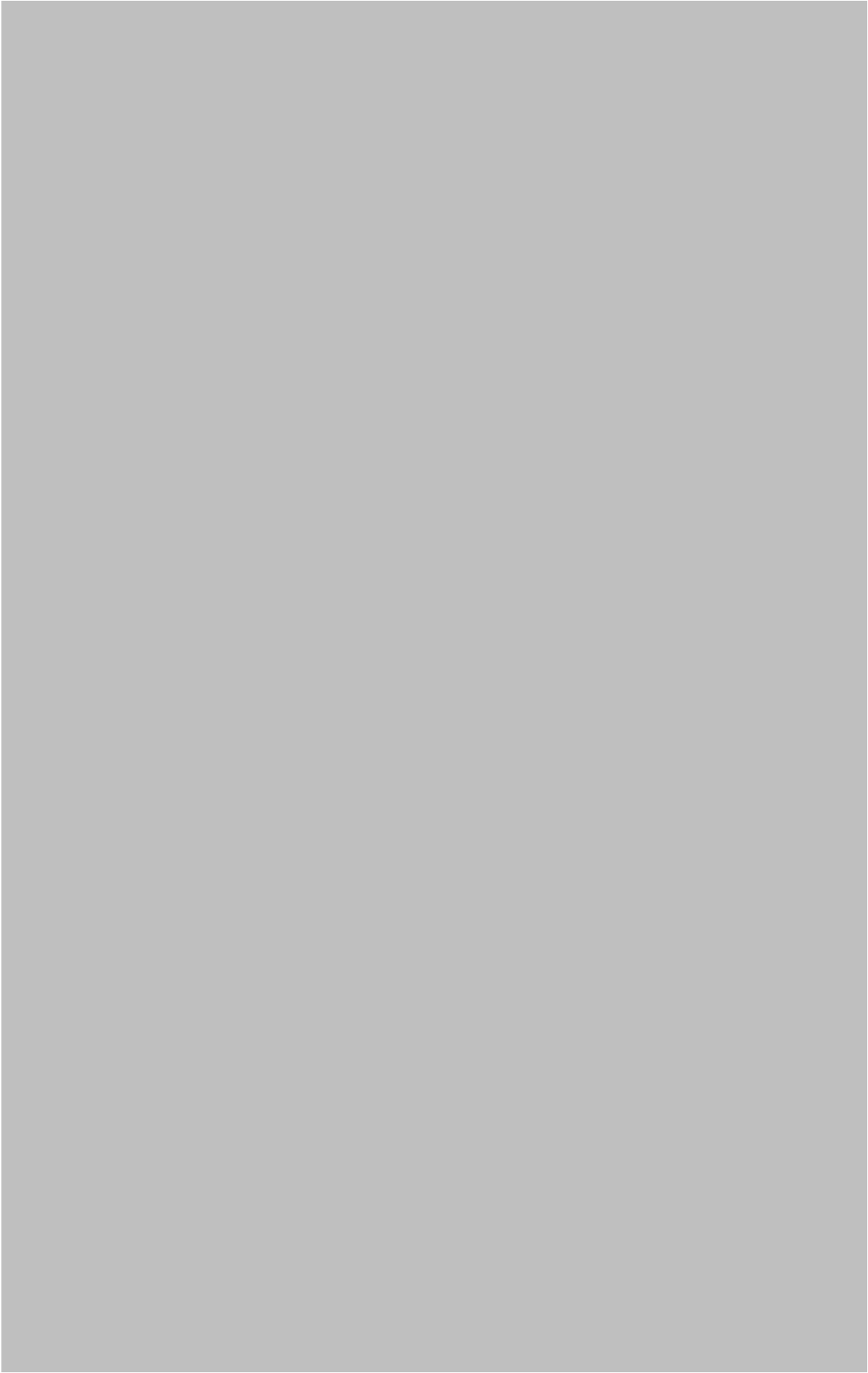


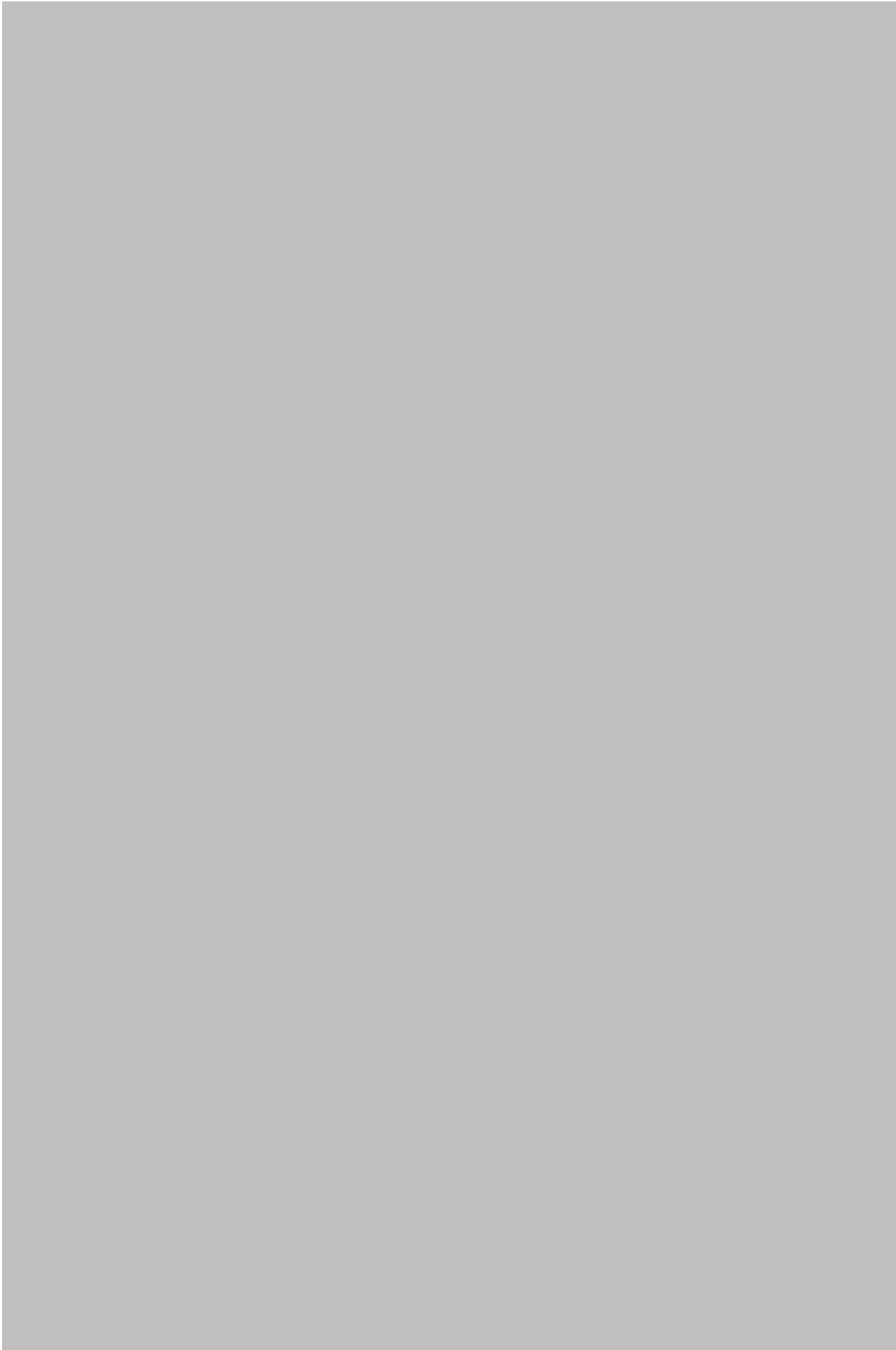










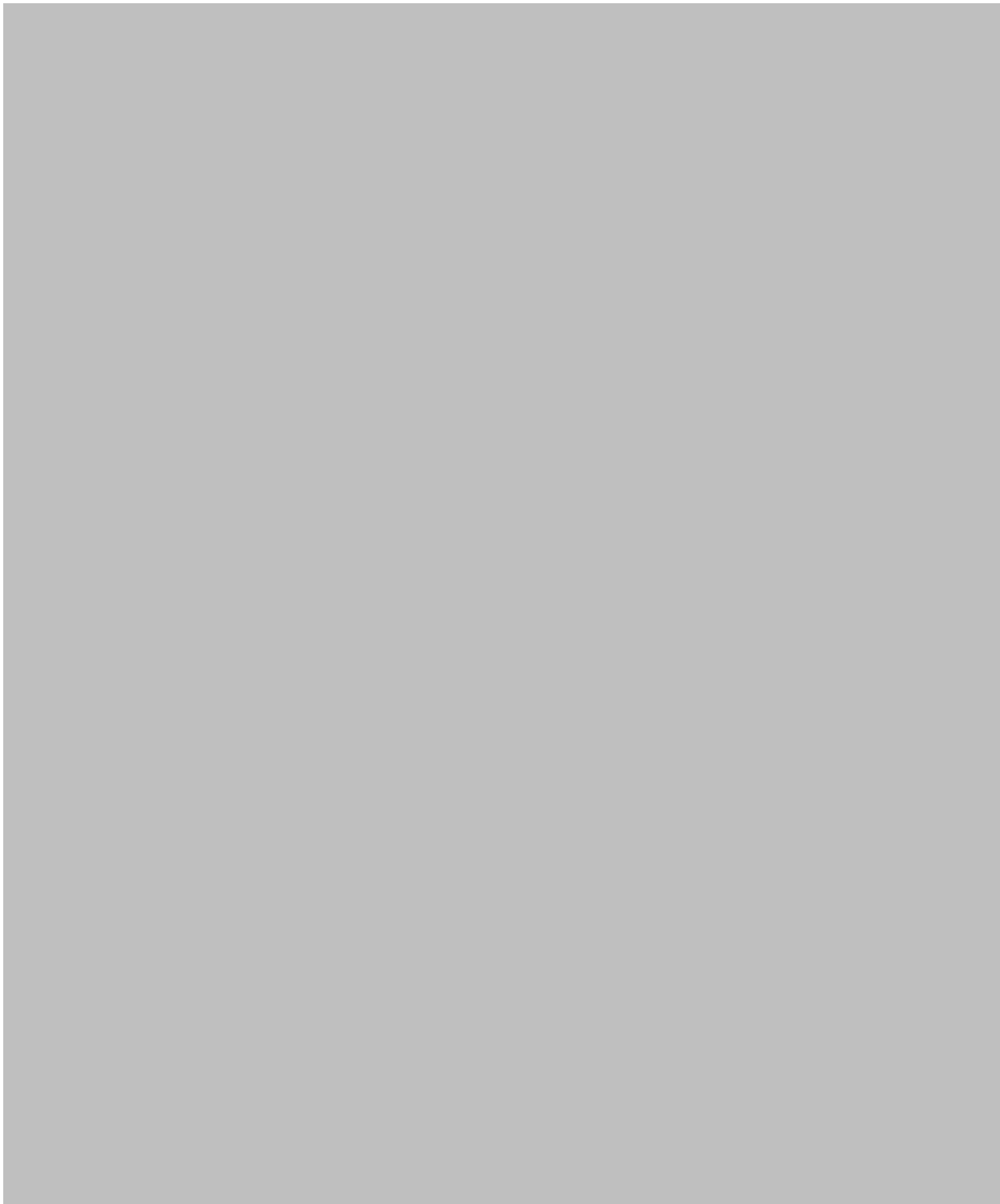


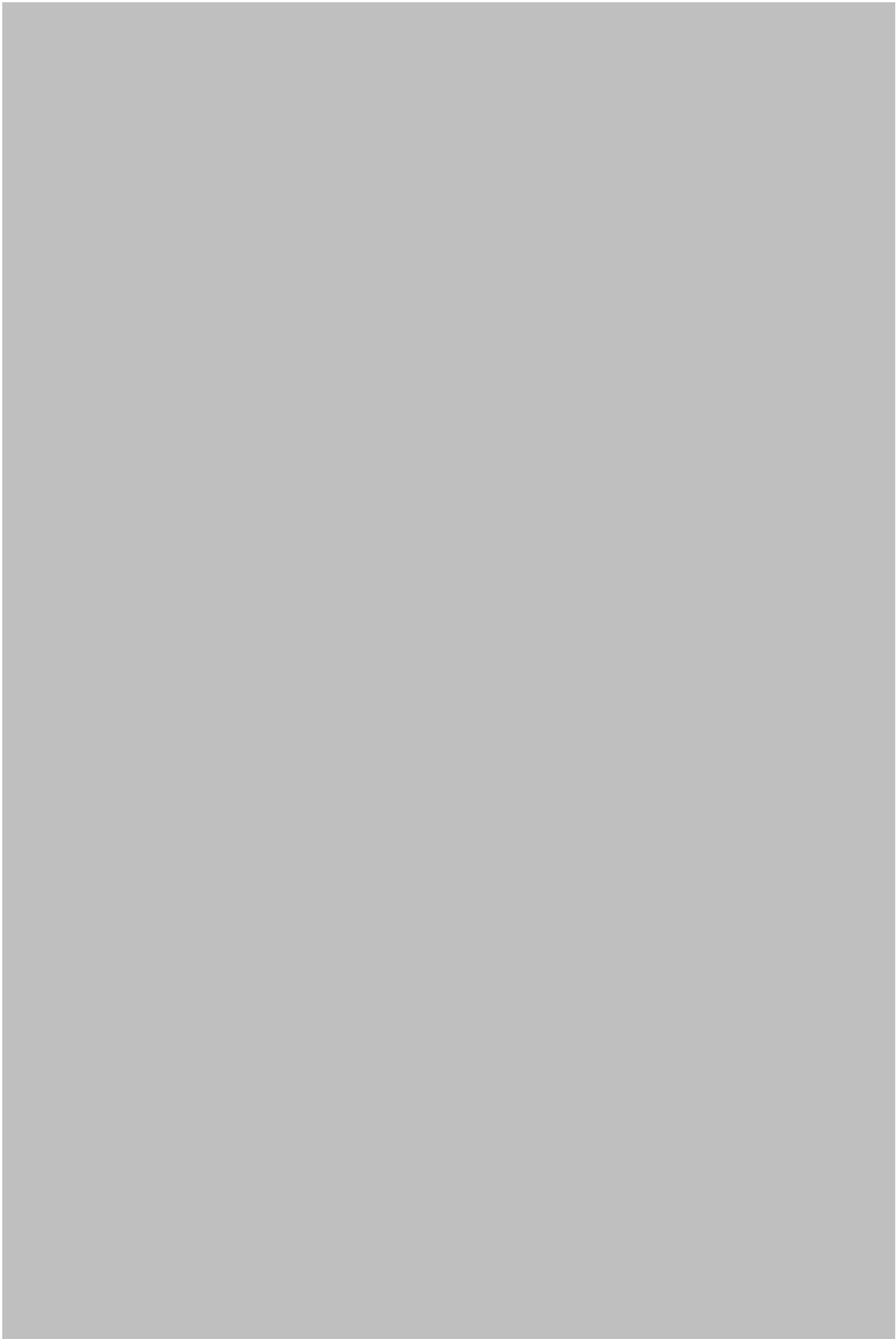










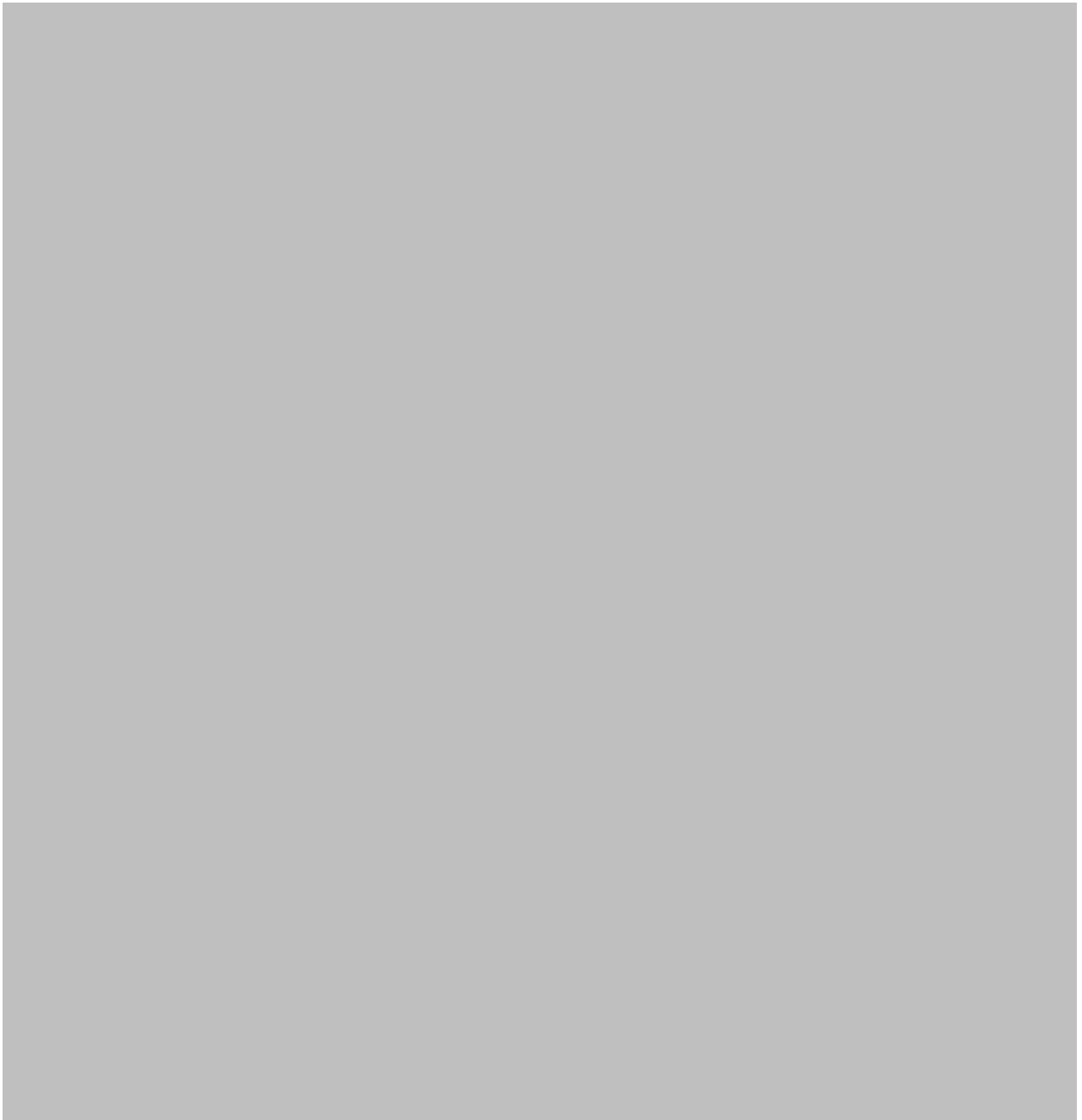












# **ANNEX 13: INTENSIFY CONTROL AND ENFORCEMENT OF REGISTRATION REQUIREMENTS**

## **1 CONTEXT**

The registration dossier is the principal REACH instrument that compiles information on intrinsic properties, uses of a substance and chemical safety assessment, informing the safe management of a substance. In the same spirit, sharing information on the substance between companies and its re-use across substances maximizes utility of information, reduces costs to generate it and avoids unnecessary testing on animals. The registration dossier also provides a documentary evidence of compliance of registrants with REACH registration obligations, enabling enforcement and providing level playing field for companies. Importance of adequacy and comprehensiveness of this information in line with the REACH standard information requirements cannot be overstated: gaps or even erroneous information may in worst case mislead risk management, leading to adverse effects to health and environment; in less critical scenarios it still imposes mayor inefficiencies, resource implications and delays in prioritisation and development of regulatory actions under REACH.

The standard information that registrants are obliged to provide is determined by the REACH Annexes VI to X. Preparation of the Chemical Safety Report (documenting chemical safety assessment, Annex I of REACH) may also be required. The information needs to be generated by the registrants, when not already available, and submitted in a registration dossier to ECHA. REACH applies a tonnage triggered approach to information requirements, which has proven to be proportionate (European Commission, 2018).

The technical completeness check (TCC), which ECHA is performing after submission of a dossier by registrants, is verifying that information for all required entries of a dossiers has been submitted. With the TCC, ECHA allows only complete dossier into the REACH database. Full adequacy of information and compliance are however not checked at the time as REACH does not have a pre-market authorisation system. Information in the dossier is presumed to be in compliance with information requirements.

Registrants that need to generate information listed in Annex IX or X are required to submit testing proposals (TP) to ECHA before launching a study. This ensures that information generation is tailored to real information needs (Recital 63 of REACH), in particular for more complex endpoints (e.g. for the assessment of persistent, bioaccumulation and toxic substances). Furthermore, testing proposals are a tool to support the REACH principle of vertebrate animal testing as last resort by providing a possibility for ECHA, Member States and stakeholders to review and provide input on the generation of information using higher tier tests involving vertebrate animals. The TP procedure currently applies for standard information requirements in Annex IX or X only despite the fact that vertebrate tests are also part of lower annexes.

Registrants are expected to keep dossier compliant and updated with pertinent information on volumes, supported uses and any new information on the substance influencing safe use.

Compliance check (CCH) by ECHA is applied to certain percentage of dossiers in the database, addressing any identified incompliances by dossier evaluation decisions, requesting a dossier update with submission of missing within a specific timeframe. These dossiers are chosen strategically for maximum impact.

Some substances may also be subject to substances evaluation (SEV), aimed at clarifying specific concerns that could not be confirmed or cleared based on the information available in the dossier. Assessments under SEV are currently within the remit of Member States. When considered necessary, registrants may be asked via substance evaluation to generate further information going beyond standard requirements.

This REACH construction has been in the last review assessed as functioning but in need of refinement to address different issues affecting effectiveness and efficiency of the processes. Most important changes were taken in the last four years by extending technical completeness check, embedding dossier and substance selection for the evaluation processes into an integrated regulatory system to work on those that matter most. Harmonized set of 15 actions of the 2018 REACH evaluation Joint Action Plan (ECHA and European Commission, 2018) intensified compliance check while at the same time clarified information requirements and worked bilaterally with industrial federations and the Member States on maximizing efficiency of compliance check. The plan sets the compliance check ambition until 2027.

## **2 DESCRIPTION OF THE PROBLEM**

While in general the REACH processes are working, compliance with the information requirements by registrants is considered insufficient. According to the review of REACH (European Commission, 2018), this is mainly related to two issues: (i) registrants might replace tests that are costly or involve the use of animals with adaptations (waivers, read-across, alternative methods), even if not justified; and (ii) difference in the assessment of hazard between registrants and authorities. Furthermore, it outlined that the complexity of the processes supporting generation of further information, when required, leads to addressing issues too slowly, and ECHA's decision-making procedures, should be further improved.

During the design of REACH and initial implementation requirements, checking 5% of dossiers for compliance was considered an adequate deterrent and corrective to allow proper functioning of REACH. Even when these percentages were already well exceeded, continued compliance check was still showing an unacceptable level of incompliance of the dossiers checked for compliance. Addressing remaining data gaps requires significant investment in resources by the authorities. A follow-up involvement of enforcement authorities was required in an average of 30 to 40% of the cases in the period 2018-2021 (ECHA, n.d.). Significant time elapses under CCH before the required and adequate information is available for risk management purposes by the company or the authorities. On average, 461 days are needed by authorities to finalise a CHH decision, plus the time required by the registrant to perform the study and update the dossier (European Commission, 2018).

For substance evaluation, processes, clarifying concern on selected substances, are on average taking even longer (25 months, on top of 13 months to get substance on the CORAP, plus the time to perform the study by the registrant (European Commission, 2018). Conclusions with regard to these substances is further prolonged when their

dossiers are also non-compliant and require CCH complement. The generation of required information are complex, time and resource intensive.

While the absolute number of new substance evaluations launched annually is not an appropriate metric to either determine adequacy or effectiveness of the mechanism (there is no absolute list of substances benefiting from substance evaluation data generation mechanism as such determination is substantial part of evaluation itself), it is telling that the original REACH planning announced that around 100 substance evaluations would be performed each year, following a learning phase with ca. 50 substances in the first years (European Commission, 2018). Substance evaluation trend indicates (ECHA, n.d.) that such high numbers were never achieved and were further reduced in the recent past to only 27 new substances in total planned for the three consecutive years 2022-24 (ECHA, Budget 2022, 2022a).

Several drivers are behind both the current status as well as the anticipation of further evolution of the problem:

(a) Registrants are obliged under REACH to update their dossier on their own initiative if new information on the registered substance is becoming available or in case of other changes relevant for their registration (Article 22 of REACH). REACH registration can be understood as a license for access to the market, associated with continuous duty of care including keeping the dossier compliant and updated. However, some dossiers were updated in the past only with delay, or an update never occurred. REACH does not offer incentives for updating dossiers. Many registrants would review information in the dossiers only when moving manufacturing or import to higher tonnage levels, motivated by gaining access to the market at a higher tonnage band and might not otherwise revise the dossiers if not specifically prompted by the evaluation decision (compliance check or substance evaluation). There is no penalty, and sufficient time is provided to generate data and update the dossier as requested.

(b) It is assumed, based on the high number (40% in 2021 (ECHA n.d.)) of cases requiring follow-up intervention to eventually comply, that enforcement is not sufficiently effective as a deterrent. While many reasons (e.g. delaying test due to unforeseen lab shortage) may be legitimate, many are not, with need to step up enforcement, taking perhaps additional evaluation decision and further years before the information requirement in the evaluation decision is, at least in 98% of the cases<sup>358</sup>, eventually addressed. Enforcement interventions addressing persistent non-compliances in registration dossiers across Member States in evaluation follow-up are not consistent, with impact limited to the operation in their territory and not across the internal market<sup>359</sup>. This driver is expected to be most efficiently addressed by measure that acts as

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<sup>358</sup> Information provided as part of communication with ECHA on evaluation activities in March 2022. Number is approximate as it is dynamic, dependent on timeframe used and confounded by parallel/complementary action on the same dossier. But in other words; only several of follow-up activities are not in some way resolved within 5 years.

<sup>359</sup> Member state enforcement activities diverge in speed and penalty imposed. Even the harshest penalty (which has been threatened a few times in two MS but never put into effect as the issue was resolved, or substance was pulled from the market voluntarily) has only national scope and does not restrict or even deter from gaining access in another Member State, listing the same registration number and thus, prompting another enforcement authority to intervene.

a strong deterrent, is applied in transparent and systemic way to all follow-up, and has an impact across the internal market (see in particular revocation measure 1a below).

(c) As indicated, the extent of non-compliance in dossiers is higher than probably anticipated during drafting of REACH. Clarity of legal provisions, has already been identified as an important driver and addressed through successive modifications of REACH technical Annexes (European Commission, 2021) (European Commission, 2022) and is an important consideration in all further considered changes (see registration Annex 5). A less obvious driver related to clarity are however documentation requirements. They determine the efficiency of a technical completeness check of the dossier in preventing unsupported information entering REACH database. This is evident through the case of inadequate adaptations (Annex VII-X column 2 adaptations and Annex XI of REACH), which is by far the most important identified non-compliance in the dossiers in REACH database. Stopping incomplete dossiers has not been efficient in separating inadequate adaptations from appropriate ones. At the same time, adaptations are an important element to bring to life the obligation of reducing animal testing under REACH, where possible (see also driver e) below), and should be supported also by the registration mechanisms. This is an aspect of importance for considerations on improving the compliance of dossiers under REACH.

(d) Effectiveness of mechanisms in place (compliance check, substance evaluation) is in direct proportion to their complexity and resources required per intervention, as that limits the number of cases to which they can be applied.

(e) With science progressing, society puts an increasing emphasis on reducing vertebrate animal testing for generating hazard and risk information on chemicals as far as possible (European Parliament, 2021). REACH is already based on the principle of animal testing as the last resort, and obliges registrants and authorities to replace vertebrate testing if possible. But how effectively the principle is followed in practice is dependent also on the (clarity of) requirements, processes, available tools and data sharing. The two principal instruments, identified also in the REACH review (European Commission, 2018) for their potential in addressing this driver, are the use of adaptations to fulfil information requirements, and the application of Testing Proposal (TP) mechanism.

(f) Evolution in dossier submissions: REACH Evaluation action plan (ECHA and European Commission, 2018) provides a narrative under which, by checking by 2027 in excess of 20% of dossiers in each tonnage band, prioritized through integrated regulatory strategy substances pre-screening processes, information gaps for all substances 'that matter' will be addressed, thus successfully addressing the issue of compliance of the registration information. The plan with its 2027 target however does not explicitly take into account continuous registrations of new substances, changes to information requirements and potential extensions of scope of registrations (see Annex 5), all leading to significant number of further dossier updates or submissions. If other drivers influencing compliance of information in these dossier submissions (see e.g. a-c above) are not addressed, overall problem with non-compliance of the REACH database will not be resolved with time.

(g) Evolution in standard information requirements: the current principal driver for selection of substance for substance evaluation are identification and characterization of possible properties like endocrine disruption. Endocrine disruption is not the only

property being addressed through changes to standard information requirements, expecting in the mid to long term to reduce the need for substance evaluation's ability to request data beyond standard requirements in order to clarify concern.

The Chemical Strategy (European Commission, 2020) summarizes well some of the anticipated action combating drivers a)-d) requiring "...strengthening the principles of 'no data, no market' and the 'polluter-pays'".

### 3 POTENTIAL POLICY OPTIONS

The Commission is considering several types of measures, prepared on the basis of extensive discussion with ECHA and stakeholder input within CARACAL, provided in writing and during a dedicated ad hoc CARACAL meeting<sup>360</sup>.

Between them, the measures are complementary and independent (may be selected individually). They do not compete and do not interfere with other REACH processes and associated measures considered in this impact assessment. With the exception of the revocation measure (see measure 1 below) represent adjustment of existing mechanisms rather than new solutions. A single option is bringing forward all related measures, optimized for their effectiveness, and assesses their impact. As elaborated also below, at least some measures include parameters (like expiry timeframe under measure 2) that clearly influence the impact of the measure and could be expanded in different options, but are considered to be of such granularity that would obfuscate the principal objective of the exercise. If the (optimized) measure itself cannot demonstrate its positive contribution, it should not be included.

The considered measures can be grouped:

#### 1. No data, no market

Set of measures that through intensified control during dossier submission and a strong deterrence to consider avoiding timely address of any identified gaps once the dossier is already supporting registration, increases compliance in the REACH database.

#### a. Revocation of registration number

Following the submission of complete dossier and payment of registration fee, ECHA awards registration number to an economic operator, a numerical identifier for allowed access to the EU market. New EU-level measure would empower ECHA to revoke this registration number in case of persistent non-compliance with the information requirements as (repeatedly) identified in the registration dossier. At present, failure to comply with requests to address non-compliances listed in the evaluation decisions had been addressed only by action by national enforcement authorities.

The mechanism would principally rely on the established compliance check process and would be triggered in the follow-up phase in case the non-compliance persists (e.g. no timely or inadequate update). ECHA would be in position to consider justification for delay or other reasons as provided by the operator to the national enforcement authority.

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<sup>360</sup> Ad hoc CARACAL Meeting on Evaluation measures, Webex, 16 March 2022

If assessed to be justified, ECHA would issue evaluation decision supplement (appealable in front of Board of Appeal) awarding new deadline. Anytime before final revocation, adequate effort by registrant can stop the final act.

b. Expiry of registration dossier

Registrants with registration dossiers that had not been updated in the last X (X=10) years should reconfirm their continued interest in access to the EU market by dossier resubmission. Without the (re)submission, ECHA would consider the technical dossier to be expired, and consequently revoke the associated registration number.

This measure is without prejudice to any consideration with regard to future financing of REACH (i.e. with the measure itself no specific fee is proposed). While the measure is providing some additional incentive to registrants to keep their dossiers up to date in accordance with their obligation under Article 22 of REACH, this effect is seen as limited and not the main driver for the planned change. A mandatory periodic update that would aim to address such an objective across the full pool of registrants would have to be much more frequent and has been dismissed as an effective measure due to the excess burden imposed both on all registrants (also those keeping up with their obligations) and ECHA. The expiry measure should in formal way help to 'clean' REACH database of obsolete entries and on the other hand encourage those with continued interest but very likely outdated dossier (note changes to information requirements, IUCLID format etc. during the long time since the last submission) to update their dossier. The revocation is a final backstop. As a flanking measure it is proposed that ECHA launches specific ECHA awareness campaigns to all 'coming of age' registration dossier well prior to the expiry date.

c. Towards more effective completeness check during dossier submission based on clarification of information requirements

Providing further precision to specific information requirements, in particular to include list of mandatory elements when using adaptations, can help establish completeness criteria and minimise inadequate application.

2. Evaluation processes and conditions

Changes in the legal provisions (Articles 40, 41 and 51) are required to in part clarify existing provisions with regard to consideration of dossier updates (change of volume, including cessation of activity) during and after the decision making phase, and in addition provide clear instruction on the limited nature of commenting during compliance check, all with the common objective of a transparent and more efficient compliance check evaluation decision making and follow-up. Significant resources can be saved by avoidance of re-assessments during a single process due to changed circumstances (outdated information on volume, uses) or mostly unsuccessful attempts to update dossier with additional information during the tight commenting deadlines. The right to be heard must be maintained and even particular fresh external circumstances should be considered (e.g. identification of new relevant studies) but should be specifically listed.

An obvious candidate for measures within this family would be potential revision of the current 20% thresholds in compliance check (Article 41.5) and the scope of compliance assessment (Article 41.1). While the written scope of compliance is considered adequate,

setting an ambition level after the year 2027 is considered necessary but should not be determined now as the Evaluation Action Plan (ECHA and European Commission, 2018) is still delivering its impact. In addition, such a threshold hardwired in a legal text is hardly needed and should rather be replaced by an optimised operational planning.

Last but not least, providing reasonable deadlines to perform the studies and update the registration dossier is already currently a very important element of effective dossier evaluation. The Commission will consider measures to optimise deadlines with the aim to limit the time during which dossiers maintain data gaps (e.g. individual deadlines for performing a study or when applying an adaptation).

### 3. Testing proposals (TP)

TP is an important tool for gathering information on whether a specific information required under REACH can be provided with a method not requiring the use of vertebrate animals. TP also provides certainty for registrants whether their testing strategy will be accepted by authorities and the modifications required. The current system in REACH requires TP for all testing performed for requirements listed in the annexes IX and X, irrespective of whether they lead to vertebrate animal testing or not. At the same time, no TPs have to be submitted for requirements listed in annexes VII and VIII, also in reflection to the balance with regard to the expected benefit (less study modalities, alternative methods and number of animals used in lower tier tests). This balance may be shifting with the evolving science and changes to the registration requirements (see Annex 5 – endocrine disruption, polymer registration). It seems to be unnecessary to ask registrants for the submission of TP in case vertebrate animal testing is not part of the testing method, but the added certainty for the registrants with regard to complex and long testing schemes e.g. on degradation in the context of the PBT-assessment cannot be disregarded.

The Commission will consider optimisation of the TP regime to maximise efficiency of its role both in ensuring adequate information is generated and that animals are used as a last resort only.

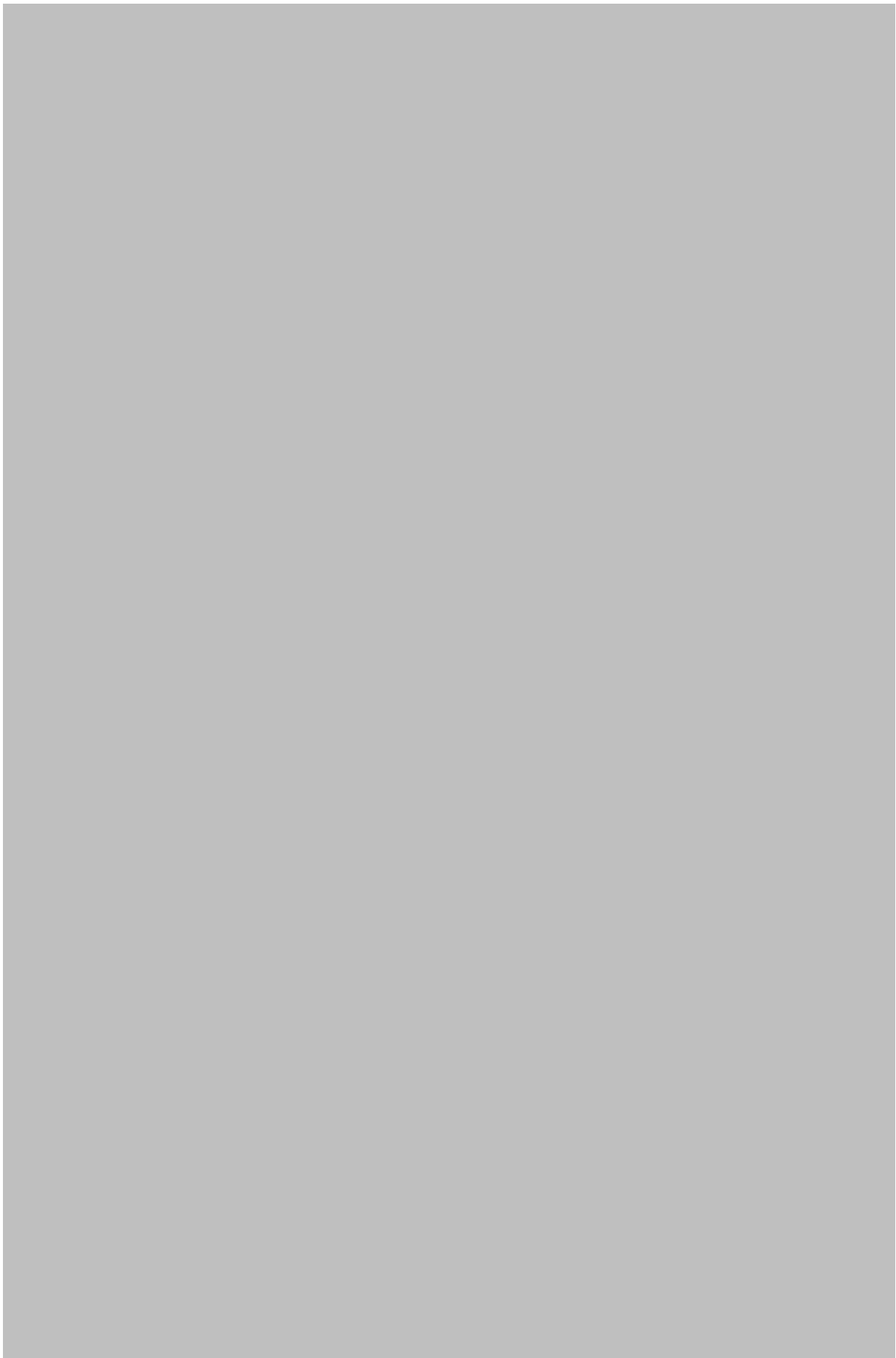
### 4. Substance evaluation

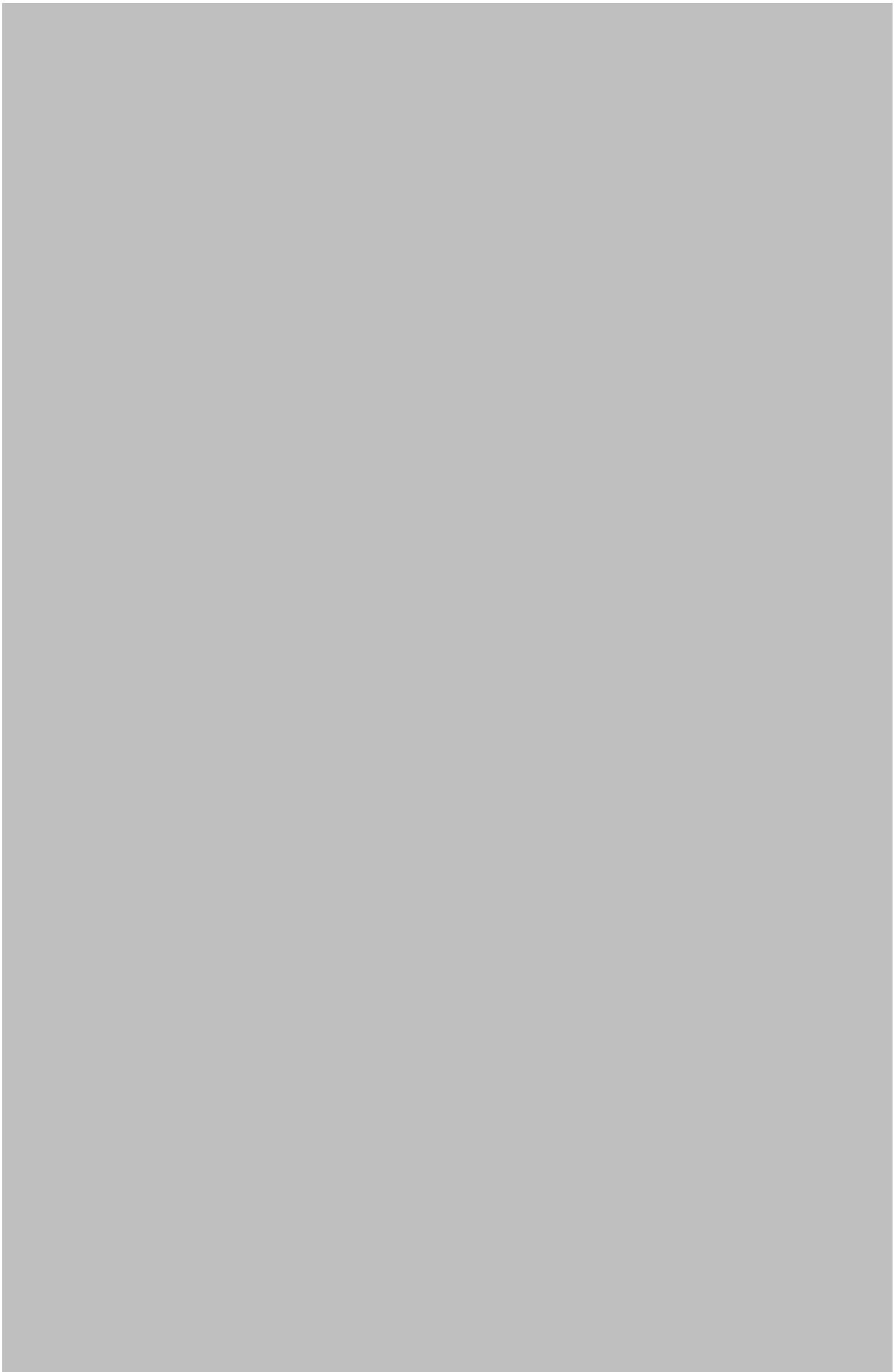
The relatively heavy process of updating the Community Rolling Action Plan (CORAP) with new substances with potential concern can be replaced by a lightweight registry that would continue to provide transparency and advance warning to the registrants. Empowering ECHA to perform substance evaluation alongside MSCA would align ECHA's role to one in other process (e.g. preparation of Annex XV dossier) and builds on its expertise, contributing to the common effort to clarify potential concern and close the gaps in knowledge on registered substances that might hamper their safe management. Precision of the legal text with regard to prioritisation of substances for substance evaluation and further information that can be requested, should improve present complex implementation and enhance its output, returning the mechanism as valuable contributor addressing the problem described above. Specifically, explicit precision that clarifying potential hazard-based (as opposed to already listed risk-based) concern, covering groups of substances where relevant, are legitimate objectives under substance evaluation.















# ANNEX 14: STRENGTHENING MEMBER STATES' OFFICIAL CONTROL SYSTEMS FOR CHEMICALS (COVERING REACH AND CLP)

## 1 CONTEXT

The European Green Deal<sup>368</sup> defines an ambitious goal of zero pollution and a toxic-free environment. The Chemicals Strategy for Sustainability (European Commission, 2020) outlines more practical actions for achieving this, including improving enforcement of chemicals legislation and adopting a zerotolerance approach to non-compliance. As one of the cornerstones of EU chemicals legislation, compliance with the REACH and CLP Regulations is critical in meeting these ambitious goals.

The latest REACH Evaluation (European Commission, 2018) concluded that the Regulation is effective overall. However, there are areas for improving its implementation, especially with relation to increasing compliance and improving enforcement: *'Member States should ensure a more effective and harmonised enforcement of REACH'*<sup>369</sup>. The Fitness check of chemicals legislation which included CLP, also pointed at the challenges of CLP enforcement noting the different enforcement levels among Member States<sup>370</sup>. Various other studies and data point to a need to increase compliance and to strengthen enforcement and ensure its effectiveness and consistency across the EU. For instance, the Chemicals Strategy for Sustainability notes that the objective of ensuring that *'all chemicals, materials and products produced in the EU or placed on the European market fully comply with EU information, safety and environmental requirements'* has yet to be achieved (European Commission, 2020, p. 17).

Taking into account these considerations, the Chemicals Strategy for Sustainability highlights the need to increase both enforcement of REACH and market surveillance and asks for the establishment of a European Audit Capacity, entrusting the Commission with the duty to carry out audits in Member States, where relevant, to ensure compliance and enforcement of chemicals legislation, in particular REACH, and use infringement procedures as necessary.

## 2 DESCRIPTION OF THE PROBLEM

Non-compliance with chemicals legislation is evidenced by alerts related to non-compliant products in Safety Gate<sup>371</sup> and the non-compliance rates detected through Member States' enforcement activities. Almost 30% of the alerts in Safety Gate on dangerous products on the market involve risks linked to chemicals. General compliance rates reported by Member States have tended to decrease in previous years. Data from the five-year Member States' reporting indicate that REACH compliance between 2007 and

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<sup>368</sup> [European Green Deal – COM\(2019\) 640 final](#)

<sup>369</sup> [COM\(2018\) 116 final, p.4.](#)

<sup>370</sup> SWD(2019)199 final, p.18-19, 71.

<sup>371</sup> [Safety Gate for dangerous non-food products \(europa.eu\)](#)

2019 ranged between 76% and 87%<sup>372</sup>, with a tendency to slowly decrease in the period 2015-2019 compared to the previous reporting period<sup>373</sup>.

Areas with lower levels of compliance include imports of products, registration, and supply chain obligations. Almost 90% of products concerned by Safety Gate alerts relating to chemicals risks come from outside the EU (European Commission, 2020, p. 17). Data reported by Member States also show that the level of compliance with REACH and CLP in imported goods has decreased over the years (in the period 2007<sup>374</sup>-2019), bottoming out at 71% in 2018<sup>375</sup>. A pilot project by Forum carried out in 2019 examining imports of products into the EU found that 23% of inspected products were non-compliant with REACH restrictions or with CLP labelling provisions. In particular, non-compliance with restriction obligations was around 17% and the non-compliance rate with CLP amounted to 64% (ECHA, 2020). For more specific information on non-compliances of imported goods see Annex 15 to this impact Assessment.

Among other areas checked by Member States, supply chain obligations are where the highest rates of non-compliance are reported by Member States' authorities (they are also the most frequently checked REACH requirement)<sup>376</sup>. Results of the Forum's<sup>377</sup> coordinated enforcement projects in the period 2010-2014 showed that a relatively high level of non-compliance could be found regarding registration obligations and Safety Data Sheets (European Commission, 2018, p. 61). This was a finding also in a more recent study of the hazard classification of mixtures in the context of CLP<sup>378</sup>. The results of this project also point at different interpretations among Member States of requirements in the legislation as a challenge for the harmonisation of enforcement. Regarding registration obligations, the level of compliance established by ECHA<sup>379</sup> ranges between 60 % and 70 % over the period 2007-2019<sup>380</sup>. A recent study on the level of compliance for items sold online found that 78% of the items checked for REACH restrictions did not comply and 5% did not comply with the obligations for providing

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<sup>372</sup> Median compliance rates across EU Member States; range between lowest median compliance rate in 2018 and highest median compliance rate in 2007.

European Commission, Directorate-General for Environment, Study on the establishment of a European audit capacity to ensure compliance and effective national control and enforcement of the REACH regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC regulations, Publications Office, 2022, <https://data.europa.eu/doi/10.2779/951>

<sup>373</sup> European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (2021) REACH and CLP enforcement. EU level enforcement indicators. Publications Office, <https://data.europa.eu/doi/10.2873/478225>, indicator EU1 p. 14.

<sup>374</sup> According to that study, as CLP entered into force some years after REACH, no data is available for 2007 and very little for 2008.

<sup>375</sup> REACH and CLP enforcement, EU level enforcement indicators, indicator EU3, p. 16 <https://data.europa.eu/doi/10.2873/478225>.

<sup>376</sup> [Member States Reports on the operation of REACH \(Article 117\)](#), 2015 and 2020.

<sup>377</sup> Forum for Exchange of Information on Enforcement established under the REACH Regulation.

<sup>378</sup> ECHA (2019) [Forum REF-6 PROJECT REPORT Classification and labelling of mixtures](#).

<sup>379</sup> Data relate to two combined aspects of compliance: 1) compliance of registration dossiers (CCh) and dossier evaluation cases (DEV); 2) registration dossiers' compliance with some information requirements (substance identity, SME status, hazardous information).

[Study on the establishment of a European audit capacity to ensure compliance and effective national control and enforcement of the REACH regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC regulations - Publications Office of the EU, 2022 \(europa.eu\)](#)

<sup>380</sup> REACH and CLP enforcement, EU level enforcement indicators, indicator EU4, p. 17 <https://data.europa.eu/doi/10.2873/478225>.



Safety Data Sheets<sup>381</sup>. For more specific information on non-compliant items sold online, see Annex 15 to this Impact Assessment.

While Member States control should be able to detect non-compliances where they occur and in certain cases, detection of infringements reflects a proper operation of controls, an effective and strong control system should also act as a deterrent to non-compliance. Lack of enough enforcement or control and enforcement systems that are insufficiently effective preclude the deterrent effect of such systems against non-compliance. The high levels of non-compliance show that the deterrent effect of such systems is not developed to its full potential.

Furthermore, enforcement of chemicals legislation is not equally effective among Member States (European Commission, 2020, p. 18). This leads to a different protection of human health and the environment across the EU and to a lack of level playing field among operators. Lack of uniform enforcement and of a level playing field across the EU was one of the main problems highlighted by industry and NGOs during the REACH evaluation (European Commission, 2018, pp. 125-126). Different levels of enforcement and of its uniform application were also signalled for CLP in the Fitness check of the most relevant chemicals legislation (excluding REACH)<sup>382</sup>.

In the last reporting period (2015-2019) only 21 countries out of 31 (including EU27, the UK, and European Economic Areas countries) fully implemented an overall strategy for the enforcement of REACH. Regarding the remaining countries, six only partially implemented it, two claimed to have intentions to devise a plan, and two others had no plans to develop one<sup>383</sup>.

In addition, differences among Member States have been noticed in the way REACH has been implemented, resulting in an inconsistent application of the EU law. To date, four countries (out of 31 countries<sup>384</sup> where REACH applies) do not have a devised strategy to enforce REACH. The remaining 27 countries have implemented or partially implemented an enforcement strategy. All but two Member States reported having developed their strategy according to the 2017 criteria for enforcement of chemicals established in 2017 by the Forum<sup>385</sup>.

On another note, 26 countries reported that several authorities are responsible for enforcing different parts of REACH, adding complexity to the enforcement mechanism across Member States.

During the last reporting period (2015-2019), controls from national Competent Authorities focused on distributors, downstream users, and SMEs rather than larger companies. These controls generally had a routine and proactive character and mostly covered information on the supply chain and restrictions. Other areas of coverage were

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<sup>381</sup> ECHA (2021) [Forum REF-8 project report on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online](#).

<sup>382</sup> [SWD\(2019\)199 final](#), p.18-19

<sup>383</sup> Enforcement of REACH through European Audit Capacity, custom authorities and OLAF. Wood E&IS GmbH. (Not published)

<sup>384</sup> EU27 plus UK for the latest reporting exercise, in addition to Iceland, Liechtenstein, and Norway

<sup>385</sup> Enforcement of REACH through European Audit Capacity, custom authorities and OLAF. Wood E&IS GmbH. (Not published)

registration, dossier evaluation, data sharing duties, requirements related to substances in articles, and authorisations. For 19 countries, information in the supply chain entailed the most significant share of controls, whereas, for eight countries controls on restrictions was the main focus. As might be expected, most cases of non-compliance were found in the most controlled REACH requirements (information in the supply chain), as well as dossier evaluation (although very few controls were performed). Non-compliance is also widely present in registration dossiers. Manufacturers and importers have completed their registration dossiers, but many have not updated them, and work is still needed to rectify data gaps and inappropriate adaptations to testing. As a matter of fact, only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA<sup>386</sup>.

Finally, during the last reporting period 2015-2019, about 25% to 30% of REACH controls resulted in no areas of infringement. The majority of controls for which infringements were found, were resolved by means of written advice – thus without penalties – followed by administrative measures (mainly fines), and verbal advice.

A stronger regulatory framework, supported by non-regulatory elements, is thus needed in order to enhance competitiveness of the European chemical industry, while ensuring protection from the most harmful chemicals. Effective compliance with the EU chemicals acquis requires a stronger effort with regards to implementation and enforcement.

**Drivers** for the problems concerning non-compliance with REACH/CLP and a lack of equally effective enforcement throughout the EU are linked to insufficient and varying enforcement levels in Member States, differences in capacities and resources, different strategies, priorities and enforcement culture<sup>387</sup> and a lack of harmonised criteria for the organisation, implementation and evaluation of the official national control systems for the whole scope of REACH.

The Fitness check of the most relevant chemicals legislation, which included CLP (but not REACH)<sup>388</sup> signalled that some of the differences in the level of enforcement of chemicals legislation are due to differences in the resources allocated and made available by Member States. Other factors, leading to non-uniform application of the EU law included the national control set ups (planning and frequency of controls, number of inspectors, training and other professional qualifications, etc.), differences in the interpretation of the EU law, differences in or lack of standards, lack of harmonised requirements and guidelines, etc. In particular, as regards CLP, it pointed at notable differences in administrative organisation in Member States, resulting in different frequency of controls. It also referred to a different interpretation by Member States of the legislation, as well as to lack of guidance documents and/or harmonised analytical methods for testing, impacting the implementation of the legislation.

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<sup>386</sup> Enforcement of REACH through European Audit Capacity, custom authorities and OLAF. Wood E&IS GmbH. (Not published)

<sup>387</sup> [Chemicals Strategy for Sustainability – COM\(2020\) 667 final](#), p. 18; [SWD\(2018\)58 final, Annex 4](#), p. 121

<sup>388</sup> [SWD\(2019\)199 final](#), p.18-19

### 3.1 Baseline

#### 3.1.1 Legal framework of Member States' official control systems:

##### - REACH and CLP

REACH lays down in Article 125 an obligation for Member States to maintain a system of official controls and other activities as appropriate to the circumstances. A similar obligation exists for the CLP Regulation (Art. 46 and recital (59)). However, neither of those two regulations lays down rules on how such a system should be organised or implemented nor they lay down criteria to ensure that the official control systems are effective so that their obligations are effectively enforced in all Member States consistently.

##### - Regulation (EU) 2019/1020 on market surveillance (Market Surveillance Regulation)<sup>389</sup>:

This Regulation lays down some of the criteria relevant for Member States' control systems (in particular in Articles 10, 11 and 13 to 18) that apply to CLP and to part of the scope of REACH. However, there are also other aspects relevant to a control system that are not covered by the Market Surveillance Regulation, such as requirements to ensure that all operators are considered within official controls, to have documented procedures for the performance of controls, and to ensure that Member States revise the operation of their own systems, including through internal control verification procedures or internal audits. Those criteria are however foreseen in other areas of the legislation such as [Regulation \(EU\) 2017/625](#)<sup>390</sup>. See the Appendix to this Annex 14 for a wider list of criteria relevant for national control systems which includes, besides those in the Market Surveillance Regulation, other relevant criteria identified in the Study for the establishment of a European Audit Capacity (hereinafter referred to in this Annex as the 'European Audit Capacity study'<sup>391</sup>.

Furthermore, the scope of the Market Surveillance Regulation is limited to the control of requirements applicable to products available on the market, while REACH lays down obligations beyond that (e.g. control of risks during manufacturing and use of

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<sup>389</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

<sup>390</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

<sup>391</sup> [Study on the establishment of a European audit capacity to ensure compliance and effective national control and enforcement of the REACH regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC regulations - Publications Office of the EU, 2022 \(europa.eu\)](#)

substances). Therefore, criteria for Member States' control systems in the Market Surveillance Regulation do not apply to the whole scope of obligations laid down in REACH. This leads to measures being required to ensure effectiveness of national control partially, depending on the obligations to be enforced. This limitation seems less relevant for CLP, as it is considered that, overall, the Market Surveillance Regulation applies to the enforcement of most of the scope of CLP obligations<sup>392</sup>.

- **Guidance on criteria for official control systems**

Criteria for Member States control systems are laid down in guidance by OECD<sup>393</sup>. The recommendations providing for minimum criteria for environmental inspections in Member States issued by the European Parliament and Council<sup>394</sup> also contain criteria relevant in this context. Furthermore, criteria for official control systems are also laid down in guidance produced in the context of Forum<sup>395</sup>.

However, such guidance has not ensured that all relevant criteria are implemented, nor that they are implemented by all Member States or that the official control systems are strong enough throughout the EU to avoid the problems described in previous sections.

### **3.1.2 Existing tools and initiatives aiming at improving/coordinating Member States' enforcement**

- **Forum:**

Forum has a role in spreading good enforcement practice. Several harmonised enforcement projects have been promoted as reflected above and guidance on criteria for official control systems has been developed within this context<sup>396</sup>. However, better effectiveness of control systems in all Member States and higher compliance is still to be achieved, as evidenced by the high number of non-compliances detected.

The report on the operation of REACH and CLP 2021 indicates that there are varying levels of Member State support and time allocated to Forum activities, and a scarcity of Member State resources at Forum level (ECHA, s.d.)<sup>397</sup>. This report also reflects that the lack of data on national enforcement activities on an annual basis is hampering the creation of a full continuous picture of what enforcement is taking place in the EU and thus is not providing the best information base for Forum to focus its harmonisation efforts where they could add most value. The report points out that a European Audit

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<sup>392</sup> According to Article 4(2) of CLP, manufacturers, producers of articles and importers must classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006

<sup>393</sup> OECD Best Practice Principles for Regulatory Policy – Regulatory Enforcement and Inspections. (2014)

[Regulatory Enforcement and Inspections \(oecd-ilibrary.org\)](https://www.oecd-ilibrary.org/regulatory-policy/best-practice-principles-for-regulatory-policy-regulatory-enforcement-and-inspections_9d9d9d9d)

[Regulatory Enforcement and Inspection Toolkit \(oecd-ilibrary.org\)](https://www.oecd-ilibrary.org/regulatory-policy/regulatory-enforcement-and-inspection-toolkit_9d9d9d9d) (2018)

<sup>394</sup> Recommendation of 4 April 2001 providing for minimum criteria for environmental inspections in the Member States, OJ L 118, 27.4.2001, p. 41–46

<sup>395</sup> [Strategies and minimum criteria for enforcement of Chemical regulations \(2017\)](https://www.oecd-ilibrary.org/regulatory-policy/strategies-and-minimum-criteria-for-enforcement-of-chemical-regulations_9d9d9d9d)

<sup>396</sup> [Strategies and minimum criteria for enforcement of Chemical regulations \(2017\)](https://www.oecd-ilibrary.org/regulatory-policy/strategies-and-minimum-criteria-for-enforcement-of-chemical-regulations_9d9d9d9d)

<sup>397</sup> ECHA (2021) [Report on the Operation of REACH and CLP 2021](https://www.echa.europa.eu/en/operations/reports/reports-on-operations), p. 60.

Capacity as mentioned in the Commission's Chemicals Strategy for Sustainability could help to address that need.

- **Peer reviews under Regulation (EU) 2019/1020 on market surveillance (Market Surveillance Regulation):**

Article 12 of the Market Surveillance Regulation provides for a system of peer reviews with the aim to strengthen consistency in market surveillance activities in relation to the application of that Regulation. Member States participation is voluntary.

This system has not been implemented yet, and – even more importantly – the Market Surveillance Regulation does not cover the whole scope of REACH so nor would peer reviews under this Regulation. Furthermore, as the Market Surveillance Regulation covers a wide range of product legislations, resources will have to be distributed among all of them.

As regards CLP, as explained above, it is considered that, overall, the Market Surveillance Regulation applies to the enforcement of most of the scope of CLP obligations and therefore peer reviews under the Market Surveillance Regulation could also cover the overall scope of enforcement of CLP.

### **3 POTENTIAL POLICY OPTIONS**

The intervention area presented here focuses on **strengthening the effectiveness of Member States official control systems across the EU** by two complementary measures:

- establishment of an European Audit Capacity **for the verification and control** of such systems by means of audits and/or other types of controls of the organisation and functioning of those national systems;
- laying down **criteria** for the design, organisation, implementation and review of Member States official control and enforcement systems. This should ensure a comprehensive and consistently effective approach to official controls among Member States and their uniform evaluation by an EU verification system.

Although these two measures are independent, they are complementary to each other. On the one hand, criteria for national control systems are those aiming at ensuring their effectiveness and they should be taken into account by Member States when designing, implementing and reviewing their respective systems. The criteria consist of essential elements necessary for the effectiveness of official control and therefore, in principle, Member States should already have incorporated them in order to ensure the fulfilment of their existing obligation to have effective official control systems. However, their implementation is not the same in all Member States. Where criteria are laid down as binding in the legislation at EU level, it will provide for legal clarity and a common framework for Member States' organisation and functioning of official controls systems, improving their effectiveness and consistency across the EU as well as contributing to harmonisation of enforcement.

On the other hand, a system at EU level would verify the application of EU rules by Member States and the effectiveness of their control systems. This would identify potential weaknesses and their causes so that corrective action can be taken. Criteria for

national control systems thus constitute standards against which the Member States' system should be evaluated, allowing their uniform assessment and comparability. Both aspects complement each other in ensuring (i) the long term sustainability of Member States' systems, (ii) that non-compliance is detected and (iii) effective corrective action is taken. In turn, this would lead to an increased deterrent effect to non-compliance, and contribute to the improvement of the consistency, efficiency and effectiveness of enforcement throughout the EU.

As Member States' enforcement authorities for CLP are often the same as those for REACH this intervention area targets the strengthening of national control systems for both regulations.

The effectiveness of an EU audit system is in particular evidenced by the results of the feedback mechanism for the audit system implemented by DG SANTE, as regards food law, animal health and welfare, among other legislations on the basis of Regulation (EC) No 882/2004<sup>398</sup> (repealed and replaced by Regulation (EU) 2017/625<sup>399</sup>). A 2017 internal Commission report on that feedback<sup>400</sup> shows the practical unanimity of audited competent authorities in considering the audits a useful experience which would improve the performance of official controls. It should also be noted that binding criteria are laid down in the above referred Regulations and applied to the Member States official control systems covered by those audits.

In the following sections, possible options for the two above mentioned measures ((i) establishment of a European Audit Capacity and (ii) laying down criteria for national systems) are described.

### **3.1 European Audit Capacity**

The following options are considered for this measure:

#### **Option 24: European Control Capacity system**

As regards REACH, this option consists of the combination of two measures:

- i) A system of *ad hoc*, reactive, Commission controls of Member State(s)' control and enforcement system when there is a specific concern only (e.g., by alert, whistle-

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<sup>398</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p. 1–141

<sup>399</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) OJ L 95, 7.4.2017, p. 1–142

<sup>400</sup> Competent Authority Feedback Received in 2017 on DG Health And Food Safety Audits And General Follow-Up Audits

blower, important or recurring problems with the application or enforcement of the rules).

Being a reactive control, it would not necessarily imply the setting up of a 'permanent' Commission's capacity. It would not necessarily cover all Member States either as that would depend on the concern or problem identified triggering the need for a Commission control. The scope of the Member State control and enforcement system targeted can also vary for each Member State controlled.

ii) A **voluntary peer review** system arranged between Member States beyond that within the Market Surveillance Regulation.

Article 12 of the Market Surveillance Regulation foresees the voluntary participation of market surveillance authorities in peer reviews with the aim to strengthen consistency in market surveillance activities. However, the scope of this Regulation is limited to the surveillance of compliance of products made available on the market and therefore, narrower than the scope of requirements to be enforced under the REACH Regulation, which lays down also other obligations, such as those related to risk management measures to control risk during manufacture and use of substances. Therefore, peer reviews within the context of the Market Surveillance Regulation cannot provide for the assessment of national enforcement as regards the entire scope of REACH obligations.

As regards CLP, measure (ii) 'voluntary peer review' is less relevant, as the Market Surveillance Regulation already covers the overall scope of CLP. Therefore, within option 24, only measure (i) 'ad hoc, reactive, Commission controls', applies to CLP.

### **Option 25: European Audit Capacity system**

In addition to the ad hoc Commission controls in option 24, a 'proactive' system providing for Commission's specific programmed audits (e.g., on certain aspects of enforcement and of the legislation, including on important or recurring problems with the application or enforcement of the rules) covering a representative number of Member States per specific audit series and to be carried out with some regularity.

### **Option 26: Comprehensive European Audit Capacity system**

In addition to Commission activities under options 24 and 25, a 'proactive' system providing also for programmed general audits (i.e. covering all aspects of enforcement and of REACH legislation) to be carried out in all Member States. Additional complementary control activities such as fact-finding missions are also included. The audits under this sub-option will also be based on certain regularity.

Out of the three options, options 25 and 26 consist of the establishment of a 'capacity' for 'audits'. Option 24 does not necessarily constitute the establishment of a 'capacity' or require that the controls carried out take necessarily the form of 'audits'. Nevertheless,

for simplification purposes, where this Annex 14 refers to ‘European Audit Capacity’, the three options are jointly referred to. Where this Annex 14 refers to the audit capacity system in options 25 or 26, it would explicitly mention those options.

### **3.2 Criteria for Member States official control systems**

This second measure of the intervention area C2 consists of setting criteria relevant for ensuring effective Member States control systems at all stages of their design, implementation and review. The added value of criteria for national control systems are recognised by the international community. Many criteria have been further included in different EU pieces of legislation as binding criteria<sup>401</sup> or are reflected in guidance (See section 2.1.1).

This includes aspects related to:

- the enforcement authority (e.g. requirements to ensure lack of conflict of interest, that the enforcement authority has adequate powers to carry out control activities and to take corrective action and requirements for internal audits),
- the organisation of controls (e.g. requirements to ensure that Member States establish control strategies that takes into consideration all sectors, operators, steps in the supply chain and a risk based planning),
- the implementation of controls (such as the establishment of documented procedures to ensure consistency), and
- Member State review of its own controls and system (such as control verification procedures). (See the Appendix to this Annex).

The following alternatives are considered within this measure:

#### **Alternative ‘a’. Laying down in guidance criteria that are not currently binding for REACH or CLP**

Criteria already existing in the Market Surveillance Regulation are binding for the entire scope of CLP and, as regards REACH, they are binding on Member States only in relation to the enforcement of requirements for products made available on the market (i.e. they are binding to part of the scope of REACH). Most criteria can also be found in a guidance produced in the context of Forum (ECHA, 2017).

This situation could be complemented by laying down in a further guidance document, drafted by the Commission in consultation with the Forum, a comprehensive set of criteria applicable to the whole scope of REACH and to CLP. As developing guidance does not require an amendment of the legislation, this alternative ‘a’ is considered to be, in fact, very close to the baseline. Nevertheless, to facilitate the reading of this impact assessment it is named as alternative ‘a’.

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<sup>401</sup> In addition to MSR mentioned in the baseline, other pieces of EU legislation impose the fulfilment of certain criteria for national control systems, such as Regulation (EC) 1224/2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy or Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.



**Alternative ‘b’. Only criteria that are already included in the Market Surveillance Regulation will be laid down, *mutatis mutandis*, as binding criteria for the whole scope of REACH.** Other relevant criteria are laid down in guidance for REACH and CLP

Relevant criteria that are already established in the Market Surveillance Regulation (in particular in its Articles 10, 11 and 13 to 18) and that therefore already apply to CLP and to part of the scope of REACH, will be laid down as binding for the whole scope of REACH.

Remaining relevant aspects such as provisions for establishing documented procedures to ensure consistency of controls in the Member State or procedures to ensure internal verification and review procedures of controls and audit of control authorities will be laid down in guidance for both, REACH and CLP (see also the Appendix of this Annex).

Shortcomings identified by the European Audit Capacity that relate to a specific criteria only listed in guidance, may not be able to support a requirement for Member States to implement those criteria in particular.

**Alternative ‘c’. Comprehensive set of binding criteria are laid down for the whole scope of REACH and CLP**

Relevant criteria that are already established in the Market Surveillance Regulation (in particular in its articles 10, 11 and 13 to 18) and that therefore already apply to part of the scope of REACH, will be laid down for the whole scope of REACH. As regards CLP, the Market Surveillance Regulation applies to the enforcement of the overall scope of CLP obligations on operators so there is no need to further extend them to CLP (see section 2.1.1 of this Annex).

In addition, further criteria relevant for Member States’ control systems that are not covered by the Market Surveillance Regulation will also be included for the purpose of REACH and CLP (e.g. a requirement for ensuring that all operators are considered within the scope of official controls, for documented procedures for the performance of controls and internal control verification procedures or internal audits) (See the Appendix to this Annex 14). The effective implementation will be verified by the European Audit Capacity and, where shortcomings in relation to those criteria are identified, Member States are required to take corrective actions, which will be closely followed by the Commission, as their non-fulfilment constitutes a non-compliance with a specific provision of the legislation.

### 3.3 Options for intervention area C2

The combination of the three options for a European Audit Capacity with each of the alternatives for laying down criteria for national official control systems leads to the following matrix with options within intervention area C2:

*Table 220: Matrix of potential options for a European Audit Capacity and alternatives for laying down criteria for control systems*

European Audit Capacity	Option 24	Option 25	Option 26:
	European Control Capacity system:	European Audit Capacity system:	Comprehensive European Audit

<b>Criteria</b>	<ul style="list-style-type: none"> <li>- Ad hoc Commission controls (reactive)</li> <li>- MS peer review system (voluntary)</li> </ul>	<ul style="list-style-type: none"> <li>- Commission specific audits (proactive)</li> <li>- Ad hoc Commission controls (reactive)</li> </ul>	<b>Capacity system:</b> <ul style="list-style-type: none"> <li>- Commission general and specific audits (proactive)</li> <li>- Ad hoc Commission controls (reactive)</li> <li>- Other control activities (e.g. fact-finding missions)</li> </ul>
<b>Alternative 'a'</b>	<b>Guidance:</b> criteria that are not currently binding for part or for the whole scope of REACH or CLP are laid down in guidance.	<b>Guidance:</b> criteria that are not currently binding for part or for the whole scope of REACH or CLP are laid down in guidance.	<b>Guidance:</b> criteria that are not currently binding for part or for the whole scope of REACH or CLP are laid down in guidance..
<b>Alternative 'b'</b>	<b>Binding criteria + guidance:</b> only criteria that are already included in the Market Surveillance Regulation are laid down, <i>mutatis mutandis</i> , as binding criteria for the whole scope of REACH. Other relevant criteria are laid down in guidance	<b>Binding criteria + guidance:</b> only criteria that are already included in the Market Surveillance Regulation are laid down, <i>mutatis mutandis</i> , as binding criteria for the whole scope of REACH. Other relevant criteria are laid down in guidance	<b>Binding criteria + guidance:</b> only criteria that are already included in the Market Surveillance Regulation are laid down, <i>mutatis mutandis</i> , as binding criteria for the whole scope of REACH. Other relevant criteria are laid down in guidance
<b>Alternative 'c'</b>	<b>Binding criteria:</b> comprehensive set of binding criteria are laid down for the whole scope of REACH and CLP	<b>Binding criteria:</b> comprehensive set of binding criteria are laid down for the whole scope of REACH and CLP	<b>Binding criteria:</b> comprehensive set of binding criteria are laid down for the whole scope of REACH and CLP

For the purpose of this impact assessment, taking into account the high number of possible options, the ones assessed are **24.a**, **25.c** and **26.c** to cover both ends on the spectrum of stringency, as well as an option in the middle of the spectrum, i.e. one concerning very low measures, another including very high measures and one considered as an option in the middle<sup>402</sup>.

Table 221: Options assessed in this Impact Assessment

	<b>European Audit Capacity</b>	<b>Criteria</b>
<b>Option 24.a</b>	<b>European Control Capacity system:</b> <ul style="list-style-type: none"> <li>- Ad hoc Commission controls (reactive)</li> <li>- MS peer review system (voluntary)</li> </ul>	<b>Guidance:</b> criteria that are not currently binding for part or for the whole scope of REACH or CLP are laid down in guidance
<b>Option 25.c</b>	<b>European Audit Capacity system:</b> <ul style="list-style-type: none"> <li>- Commission specific audits (proactive)</li> <li>- Ad hoc Commission controls (reactive)</li> </ul>	<b>Binding criteria:</b> comprehensive set of binding criteria are laid down for the whole scope of REACH and CLP
<b>Option 26.c</b>	<b>Comprehensive European Audit Capacity system:</b> <ul style="list-style-type: none"> <li>- Commission general and</li> </ul>	<b>Binding criteria:</b> comprehensive set of binding criteria are laid down for the whole scope of REACH and CLP

<sup>402</sup> We did not look in detail to the combination of the European Audit Capacity with alternative 'b' separately, as that is contained in alternative 'c'.

	<ul style="list-style-type: none"> <li><b>specific audits</b> (proactive)</li> <li>- <b>Ad hoc Commission controls</b> (reactive)</li> <li>- <b>Other control activities</b> (e.g. fact-finding missions)</li> </ul>	
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The table below provides an overview of different aspects in each option for the European Audit Capacity. For some of those aspects, in particular working methods, transparency or type of auditors, a specific possibility has been assigned to each option for the purpose of this Impact Assessment (e.g. under option 26.c it is foreseen that national experts can take part in the audits lead by the Commission while this possibility is not included in options 24.a or 25.c. However, those aspects can, in practice, be combined and exchanged among those options.

Table 222: Options. Modular system and some elements from different options can be combined

Aspects Options	Trigger of the audit	Scope of the audit	Working methods used	Additional activities	Criteria audited	Follow-up actions	Transparency	Actors	Type of auditors	Evaluation of the European Audit Capacity control system
<b>Option 24.a: A control capacity system</b>	Combination of:  i) <b>Ad hoc control capacity only when there is a specific concern</b>  ii) <b>Voluntary action: Peer review system (beyond Market Surveillance Regulation, covering all aspects of REACH, arranged voluntarily between MS)</b>	i) <b>Ad hoc targeted controls</b> focusing only on the specific concern that triggered the control (e.g., alert, whistleblower, important, or recurring problems with the application or enforcement of the rules)  Frequency: occasional, e.g. around 0-2 MS controlled in total per year  ii) based on voluntary participation from other MS. Scope based on voluntary acceptance  Irregular frequency. For CA in MS to decide	i) Only combination of remote and on the spot verification  The control activity itself could also take the form of a fact-finding mission  ii) to be agreed based on voluntary acceptance	None	Alternative 'a': Current existing binding criteria in REACH (and in the Market Surveillance Regulation where applicable) Further criteria are laid down in guidance	i) Control reports do not include recommendations/instructions, but only identify specific shortcomings to be addressed by the MS  Lack of recommendations/instructions is without prejudice to the obligation of MS to take action to ensure compliance with legislation  Follow-up mechanism to check action taken by MS  i) and ii) Discussion at the Forum	i) A <b>summary report</b> to be published and available to the public and a <b>more detailed version</b> sent to the Member State visited only and discussed at the FORUM where needed  ii) Discussion at the Forum	i) European Commission  ii) Member States' authorities based on own initiative (FORUM could have a coordination role)	a) Auditors from the European Commission,  b) MS representatives	a) Internal evaluation by the European Commission (i.e. under IAS)
<b>Option 25.c: An audit capacity system</b>	Combination of: - Specific audit programme - Ad hoc targeted	Specific programmed audits only covering a representative number of MS (e.g., on	Remote only or a combination of remote and on the spot verification,	None	Alternative 'c': Relevant criteria for national control systems other than those already in	Detailed recommendations/instructions are provided in the report to the MS identifying the	A <b>summary report</b> to be published and available to the public and a	The European Commission.  Input	Mix of auditors from the European Commission and where appropriate, ECHA	Internal evaluation by the European Commission (i.e. under IAS)

	<b>control based on specific concern</b>	<p>certain aspects of enforcement and of the legislation, including on important or recurring problems with the application or enforcement of the rules). On frequency e.g. at least one audit per MS every five years.</p> <p><b>Ad hoc targeted controls</b> based on specific concern can be triggered e.g., by alert, whistleblower, important or recurring problems with the application or enforcement of the rules). Frequency: occasional, e.g. around 0-2 MS controlled in total per year</p>	where appropriate (on the spot part not to be carried out systematically).		REACH (and in the Market Surveillance Regulation where applicable) are laid down in the legislation as binding criteria	<p>weaknesses to be addressed as regards specific aspects of the control system or its implementation</p> <p>MS are required to take measures to address the shortcomings identified</p> <p>Discussion at the Forum</p> <p>Follow-up mechanism to check action taken by MS</p>	<b>more detailed version</b> sent to the Member States audited only and discussed at the FORUM where needed	(consultation) with Forum in preparing the regular audit programme could be considered within this option		
<b>Option 26.c: Comprehensive audit capacity system</b>	<p>Hybrid system:</p> <ul style="list-style-type: none"> <li>- General audit programme</li> <li>- Specific audit programme</li> <li>- Ad hoc targeted control,</li> </ul>	<p>A combination of regular general and specific audits and ad hoc targeted controls</p> <p>Regular programmed audits can be of a general nature, i.e. covering all aspects of</p>	<p>The combination of remote and on the spot verification, for each audit</p> <p>(‘remote verification’ means desk based and by online meetings)</p>	Additional complementary activities to the audit may include fact-finding missions	Alternative ‘c’: Relevant criteria for national control systems other than those already in REACH (and in the Market Surveillance Regulation where applicable) are laid down in the legislation as binding	Detailed recommendations/instructions are provided in the report to the MS identifying the weaknesses to be addressed as regards general and specific aspects of the control system or its implementation	Publication of all reports (with removal of any confidential data if necessary)	The European Commission  Input (consultation) with Forum in preparing the regular audit programme could be considered within this option	Mix of auditors from the European Commission and where appropriate, ECHA, national experts from other Member States enforcement authorities and where needed, external experts	<p>External evaluation by independent assessors</p> <p>In addition to European Commission (i.e. under IAS)</p>

	<p><b>based on specific concern</b></p>	<p>enforcement and of REACH legislation, and all MS, (e.g. every five years) or of a <b>specific nature</b>, i.e. covering certain aspects of enforcement and of the REACH legislation, including recurring problems, and a representative number of MS, as relevant (e.g. a MS audited every five years).</p> <p><b>Ad hoc targeted controls</b> based on specific concerns can be triggered e.g., by an alert, whistleblower, important or recurring problems with the application or enforcement of the rules)</p> <p>Frequency: occasional, e.g. around 0-2 MS controlled in total per year</p>			<p>criteria</p>	<p>MS are required to take measures to address the shortcomings identified</p> <p>Discussion at the Forum</p> <p>Follow-up mechanism to check action taken by MS</p> <p>Use of information from the audits (e.g. overviews of MS control systems, identification of weaknesses at EU level, input for policy action, scoreboard) e.g. to inform EU policy makers</p> <p>Sharing good practices for other Member States</p>			<p>via public procurement tenders</p>	
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### 3.4 Consultations

The different aspects relevant for a European Audit Capacity included in Table 223 as well as the possibility to lay down criteria for Member States' official control systems either as binding criteria or in guidance were the object of consultations among different stakeholders, either within the European Audit Capacity study<sup>403</sup> or, by the Commission services. Consultations included experts from Commission's or EU Agencies, Member States' experts from Forum, CARACAL, POPs<sup>404</sup> and PIC<sup>405</sup> competent authorities and other stakeholders in CARACAL. The European Audit Capacity was also part of the public consultation to the revision of REACH.

Consultations within the Commission or EU agencies included experts from DG SANTE, DG MARE, DG REGIO, DG ENV, DG MOVE and EMSA involved in EU control systems in other areas of the EU legislation, such as those foreseen or implemented within the scope of Regulation (EU) 2017/625, Regulation (EC) 1224/2009, Regulation (EU) 2021/1060, Directive (EU) 2010/63 and Regulation 1406/2002. Only the system in Directive (EU) 2010/63 that foresees Commission controls in cases of due concern only has never in practice been implemented. The European Audit Capacity study reflects that those experts generally considered as benefits of the implemented EU control systems the improvements over time in the performance of individual Member States' control systems. Those benefits are observed through the monitoring of the uptake of recommendations and follow-up audits and were reported by interviewees from all implemented EU control systems<sup>406</sup>.

Some experts from Member States, strongly questioned the added value of a European Audit Capacity. Their views reflect that the need for a European Audit Capacity and its difference from existing control mechanisms (e.g. reporting under Art. 117 of REACH, peer review under the Market Surveillance Regulation) may not be clearly understood at this point in time so that differences would need to be clearly communicated when a specific option is proposed. Some other Member States' experts supported its establishment and several considered it could help to improve official controls and consistency among Member States.

In a survey carried out within the European Audit Capacity study among Member States' experts, on a question about what benefits would audits bring to Member States, around 63% of the replies (representing experts from 22 EEA states) provided views on benefits brought by the audit capacity system while around 30% responses (from experts from four EEA states) clearly opposed. The rest of the replies either considered the benefits low (from experts from two EEA States) or that benefits could not be predicted at this point in time. As regards a question on costs, replies were rather general referring to administrative burdens.

In general, most views expressed by experts from Member States point to a clear concern on resources needed for participating in audits and, in the opinion of some experts, such

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<sup>403</sup> [European Audit Capacity study \(europa.eu\)](https://europea.eu)

<sup>404</sup> Regulation (EU) No 2019/1021 on persistent organic pollutants (POPs Regulation)

<sup>405</sup> Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (PIC Regulation)

<sup>406</sup> [European Audit Capacity study \(europa.eu\)](https://europea.eu), page 59.

resources would be detracted from regular enforcement activities, risking, in their views, for weakening the overall enforcement. Thus, should a European Audit Capacity be established, they would favour streamline approaches that would not increase their administrative burden. At the same time, other experts indicated the importance of having a level playing field where all Member States would be subject to audits and a situation where certain Member States would be audited more frequently than others should be avoided. These Member States' experts favour an option with clearly defined audit programmes that cover all Member States.

In the survey carried within the European Audit Capacity study among Member States experts in relation to laying down criteria for control systems, around half of the respondents did not agree with the option of having binding criteria laid down in legislation. According to the study their answers may have been impacted by their overall opinion of the establishment of a European Audit Capacity (respondents who disagreed with the establishment of a European Audit Capacity often disagreed with the introduction of binding criteria and with the relevance of the criteria themselves). Those that commented on the option to lay down criteria in a guidance document, underlined that a guidance would be more flexible to adapt to different enforcement systems and structures at national level, and easier to revise if necessary. These comments reflect that that the criteria are of general nature and be implemented, which is to be decided by the Member State. About a fourth of respondents supported the inclusion of the criteria as binding elements in the legislation. In addition to the fact that binding criteria contribute to harmonisation of enforcement, some of these respondents underlined that binding criteria may increase legal certainty for Member States and may support competent authorities in leveraging more funding for enforcement to ensure compliance with the criteria<sup>407</sup>.

The Open Public Consultation to the revision of REACH highlighted that the majority of business associations and companies would welcome a European Audit Capacity, as uniform enforcement within the EU, extended monitoring of online trade, and optimized cooperation with the customs authorities are the only way to prevent distortion of competition and improve environmental protection.

### **3.5 Assessment of the effectiveness of the options**

The effectiveness of the options concerns the extent to which each of them contributes to achieving the specific objectives of (i) improving and ensuring effectiveness of REACH (and CLP) enforcement and, (ii) such effectiveness is ensured in all Member States, so that enforcement is consistent and effective across the EU, allowing for a level playing field and reducing non-compliance with the legislation and delivering the wider impacts of the options, in particular the benefits. Among the elements which have an impact on effectiveness there are, the representativeness of Member States covered by the option, the option's potential to help Member States to build strong control systems, and the extent to which the option provides for ensuring that corrective action is taken by the Member States to address the shortcomings in their control systems.

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<sup>407</sup> Page 127 of the [European Audit Capacity study \(europa.eu\)](http://europa.eu)



### 3.5.1 Options for a European Audit Capacity

All options propose some form of a European audit capacity/control system for REACH and CLP, which would strengthen the opportunities for problem identification and learning while promoting that appropriate corrective action is taken by the Member States and followed up at the EU level. This in turn would make national practices consistent with the objective of an effective enforcement of REACH and CLP across Member States. However, the trigger of the audit/control activity in each option (proactive/reactive/voluntary Member States peer review), scope, frequency, representativeness of Member States targeted and other elements vary among the options. This would thus affect the extent to which each of the options contributes to building strong national control systems preventing and correcting non-compliance in all Member States. The effectiveness of the options is also affected by whether all relevant criteria are binding for national control systems for CLP and for the whole scope of REACH or laid down in guidance as that would influence the extent to which there is a clear obligation for Member States to take corrective measures.

- i. Commission control/audit system (options 24 (ad hoc COM control aspect), 25 and 26) vs voluntary Member State peer review system (option 24 (the peer reviews aspect))

A Commission centralised system ensures an assessment of Member States that is independent from them and that is common to all Member States audited/controlled. It also allows for an oversight of Member States systems throughout the EU. In its role as guardian of the Treaties, the Commission can carry out a follow-up and request that corrective action be taken by the Member State. The representativeness of Member States will depend on the option chosen (all Member States in **options 25 and 26**, only those Member States where a concern arises in **option 24 (ad hoc COM control aspect)**).

In contrast to these options, a Member State peer review system cannot ensure a common independent assessment as good and as effective as a Commission system:

Firstly, it can be expected that the Member State carrying out the peer review will also be itself peer reviewed by another Member State, which may compromise both Member States' independence. Secondly, different Member States may have different approaches to official controls or different ways to implement them and therefore, even if guidance is provided to carry out the peer reviews, a common implementation of the peer reviews cannot be ensured. Furthermore, a Member State peer review system cannot ensure a follow up of corrective action taken by Member States as the Commission is able to do in its role of guardian of the treaties. Finally, as they are voluntary, it cannot be ensured that all Member States will take part in peer reviews.

It should also be noted that a peer review system is already foreseen under the Market Surveillance Regulation (although not implemented yet). Yet, this covers only part of the scope of REACH. A peer review system under the REACH Regulation could cover the whole scope of REACH although in its implementation Member States would have to coordinate with actions within the MSR to avoid inefficiencies or duplications.

ii. Proactive approach to audit (options 25 and 26) vs reactive approach to controls (option 24 (ad hoc COM controls aspect))

Overall, it could be expected that a proactive approach of programmed regular audits would better help Member States to build strong official control systems that may prevent potential difficulties before serious problems with enforcement or non-compliance occur. In contrast, a reactive approach is limited to empower the Commission to verify what did not work correctly in a given Member State after the problem materialises, while the objective of programmed regular audits is rather to ensure that Member States systems are strong enough to detect those problems themselves in time and to take corrective measures; this includes a Member State system that verifies its own functioning and takes necessary remedial action.

Within a 'proactive approach' it is also possible to cover a wider range of Member States than with a 'reactive' one, which would be limited, by definition, to the country(ies) where the problem arises. Although lessons learnt can be applied to the future and to other Member States, the contribution of a reactive approach to strengthening national control systems throughout the EU so that consistency of enforcement and of its effectiveness is achieved is consequently more limited.

As regards a voluntary system for Member States peer reviews (option 24 (peer review aspect)), it being voluntary, it is not possible to predict the approach (proactive or reactive) that would be implemented.

iii. Scope of the audits/controls

General audits (**option 26**) can cover the functioning of the overall national control systems for the enforcement of all obligations in REACH and CLP. While they are relevant to verify how the different aspects of the system interact in practice with each other and how efficiently the system works as a whole, such a wide scope may leave less room for a detailed and in-depth analysis of certain issues.

Specific audits (**options 25 and 26**) or controls based on a specific concern (**options 24, 25 and 26**) can target certain elements of the control system or the control system concerning specific obligations, but may achieve a more limited view of the effectiveness of the national system for REACH/CLP as a whole. Nevertheless, several specific audits on different aspects may still provide a picture of most aspects of the control system for REACH/CLP.

Generally speaking, it can be assumed that the broader the coverage of the audit/control system and the wider the representativeness of Member States audited/controlled, the more effective it will be in terms of improving enforcement throughout the EU. Therefore, audits with a broader scope in combination with audits with specific scope, consistent coverage of all Member States in the audits (i.e., through programmed regular audits) and a higher number of audits overall, would help to identify and address more potential shortcomings, contributing to a greater extent to improving REACH enforcement across the EU (**option 26**).

iv. Follow-up of audits/controls, publication of reports

The provision of recommendations for improvements through the audit reports (**options 25 and 26**) together with the establishment of a mechanism for following up on the actions taken by Member States to address the shortcomings identified (all options) would further enhance effectiveness compared with an option where no such recommendations are provided (**option 24**) or followed-up. In addition, the publication of the audit reports might produce additional pressure on Member States to take corrective action (**option 26**). The discussion of findings at the Forum can facilitate the exchange of good practices and lessons learned between competent authorities, further strengthening enforcement under all three options.

v. Experience under other EU control systems

As evidenced by existing EU control systems carrying out proactive programmed audits covering all Member States such as those implemented by DG SANTE directorate F, DG MARE or EMSA<sup>408</sup>, audits or similar forms of control are positive for strengthening and ensuring effective enforcement of EU legislation across all Member States. Those existing EU control systems carry out a critical assessment of the operation of national control systems which is independent from that of the national competent authorities of their own system, thus contributing to an objective identification of possible weaknesses and their potential causes and to the taking of appropriate corrective action. Furthermore, they provide an overview at EU level of different strengths and weaknesses of national systems and their potential reasons. The identification of specific issues, provision of recommendations as well as exchanges between EU auditors and Member States authorities are considered helpful for national authorities to develop their capacities and improve the functioning of their control systems, in turn improving the enforcement of EU legislation. The outcome of the activity contributes to strengthening enforcement systems in the EU as whole, and not only in the Member States individually considered.

The effectiveness of a comprehensive proactive system is in particular evidenced by the results of the feedback mechanism for the Commission audit system based on Regulations (EC) No 882/2004<sup>409</sup> (repealed and replaced by Regulation (EU) 2017/625)<sup>410</sup> implemented by DG SANTE. In that system, after each audit, the audited

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<sup>408</sup> For instance audit systems implemented by DG SANTE. Dir F based on Regulation (EU) 2017/625 as regards food and feed law, animal health and welfare, plant health and plant protection products among other areas or by DG MARE based on Regulation (EC) 1224/2009 in relation to the Common Fisheries Policy or by EMSA-DG MOVE based on Regulation 1406/2002 in relation to maritime safety. MARE/EMSA controls concern all 'relevant' Member States (e.g. countries with a sea port subject to certain EMSA controls).

<sup>409</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p. 1–141

<sup>410</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC,

country was asked whether they had found the audit to be a useful experience which would improve the performance of official controls. A 2017 internal Commission report<sup>411</sup> reflects that in the feedback received in 2017, which mainly concerned audits conducted in 2015, 2016 and, to a lesser extent, in 2017, 100% of respondents had found the ‘audit’ and ‘general audit’ process to be a useful experience which would improve the performance of official controls for all the reported years, except as regards the feedback for the ‘audit’ process for year 2016 where the positive feedback was 96%. This shows the practical unanimity in considering the effectiveness of Commission regular audits of Member States to improve their official control system. It should also be noted that binding criteria laid down in the above referred Regulation (EC) No 882/2004 applied to the Member States official control systems covered by those audits.

### **3.5.2 Alternatives for laying down criteria for Member States official control systems**

Binding criteria provide for legal clarity and a common framework for Member States organisation and functioning of official controls systems. Requiring their implementation contributes to strengthening Member States’ control systems.

The effectiveness of the audit/control activity is linked to whether Member States are obliged to take corrective action to address weaknesses identified. In case of non-compliance with binding criteria, corrective action needs to be taken. In contrast, non-compliance with non-binding criteria does not automatically trigger an obligation for corrective action.

- i. All relevant criteria are laid down as binding for the whole scope of REACH and CLP (alternative ‘c’).

In alternative ‘c’, applying the criteria laid down in the Market Surveillance Regulation to the whole scope of REACH enforcement would avoid the complex situation where horizontal essential elements for an official control system would apply to the enforcement of some obligations under REACH, and not of others. (See the Appendix to this Annex). These criteria will be complemented by other relevant criteria not included in the Market Surveillance Regulation and also made binding (e.g. provisions to ensure documented procedures to guarantee consistency of controls in the Member State or procedures to ensure internal verification and review procedures of controls and audit of control authorities). This way, all main relevant aspects related to the organisation, functioning and review of Member States control systems will be required to be implemented in all Member States.

Laying down binding criteria in the legislation at EU level as regards all relevant aspects of national control systems will provide for legal clarity and a common framework for Member States organisation and functioning of official controls systems, improving their

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90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). OJ L 95, 7.4.2017, p. 1–142

<sup>411</sup> Competent Authority Feedback Received in 2017 on DG Health And Food Safety Audits And General Follow-Up Audits

effectiveness and consistency across the EU as well as contributing to harmonisation of enforcement. The effective implementation of the criteria will be verified by the European Audit Capacity and, where shortcomings are identified, Member States are required to take corrective actions, which will be closely followed by the Commission, thereby contributing to achieving effective national control systems. Thus, this alternative is likely to achieve a high level of consistent effective approach among Member States to enforcement policies and practices and strengthens the effectiveness of the EAC. It strengthens both the effectiveness and efficiency of the European Audit Capacity.

- ii. Only criteria that are already included in the Market Surveillance Regulation will be laid down, *mutatis mutandis*, as binding criteria for the whole scope of REACH. Other criteria are laid down in guidance (**alternative ‘b’**)

Alternative ‘b’ has the benefit of avoiding the situation where horizontal essential elements for an official control system (e.g. risk based planning of controls, independency and impartiality of the authority responsible for controls or their powers to ask operators to take corrective action) will be dependent of the object of the obligation controlled. Nevertheless, the lack of obligation to implement the other relevant criteria for control systems (e.g. provisions to ensure documented procedures to ensure consistency of controls in the Member State or procedures to ensure internal verification and review procedures of controls and audit of control authorities) has the drawbacks explained below under alternative ‘a’, which is close to the baseline.

Laying down the remaining relevant criteria in a guidance by the Commission can clarify relevant elements needed for an effective control system beyond what is already contained in the existing guidance by Forum, OECD or European Parliament and the Council (See section 2.1.1). Having the status of a Commission guidance may have a higher influence in Member States following them.

It could be argued that Member States would be less proactive in implementing the criteria laid down in yet, another guidance document. Furthermore, this alternative could be seen as reflecting an approach that considers certain hierarchy among criteria, while all are necessary to ensure that an official control system is effective (e.g. requiring that the planning of official controls takes into account all operators would not be binding, see the Appendix to this Annex). Thus, this could lead to lack of clarity or interpretation discussions as regards criteria necessary for the implementation of Articles 125 REACH and 46 CLP as it could have the negative effect of criteria in guidance be interpreted as ‘less relevant’ or not necessary to fulfil the obligation of having effective official control systems laid down in Articles 25 REACH and 46 CLP compared to those that are binding.

However, as the effectiveness of criteria and of the European Audit Capacity increases when they are both considered, other aspects of the options for a European Audit Capacity may help to their implementation by Member States even if they are not binding. In particular, the fact that their implementation would, in the future, be audited and it may be that the results are published in national reports should create a strong incentive for Member States to follow them.

- iii. Criteria that are not currently binding for part or for the whole scope of REACH or CLP are laid down in guidance (**alternative ‘a’**)

In alternative ‘a’ (i.e. very close to the baseline), criteria other than those already laid down in REACH (or CLP) or in the Market Surveillance Regulation would not be legally binding, and those in the latter are only obligatory for part of the REACH scope. Therefore, the obligation for Member States to implement them for CLP or for the part of the scope of REACH not covered by the Market Surveillance Regulation could appear less straightforward or weakened as well as their obligation to take corrective actions to remedy related shortcomings identified by the European Audit Capacity.

The European Audit Capacity could however still issue recommendations to the Member State’s competent authority to address the identified shortcomings related to those criteria. However, the implementation of the recommendations would depend on Member States’ willingness. A Commission follow up with Member States on potential corrective actions could also be undermined.

This alternative is therefore likely to result in less Member States implementing the criteria and taking corrective actions compared to the alternative of laying down binding criteria as regards all relevant elements and for the whole scope of REACH, which would be more successful in ensuring the effectiveness of official control systems throughout the EU and complete effectiveness of the European Audit Capacity activity. Thus, this alternative is likely to achieve a lower level of consistent approach among Member States to enforcement policies and practices than binding criteria.

Nevertheless, laying down the remaining relevant criteria in a guidance by the Commission can clarify relevant elements needed for an effective control system beyond what is already contained in the existing guidance by Forum or others. Having the status of a Commission guidance may have a higher influence in Member States following them. Furthermore, this instrument could facilitate changes in the control system that could be important to address at the very early stages of a European Audit Capacity. On another hand, taking into account that guidance exists in the baseline and that it did not prevent the problem that this action intends to address, it is not clear that issuing yet, another non-binding document, would achieve better results.

As it is the case for current Forum guidance, such non-binding guidance by the Commission would have to ‘co-habit’ with binding enforcement criteria that market surveillance authorities in charge of monitoring REACH ‘placing on the market’ provisions will have to comply with. It could thus lead to paradoxical situations where in case the European Audit Capacity identified shortcomings in REACH control systems related to a criterion in the Market Surveillance Regulation, Member States would only be obliged to correct them as regards the enforcement of requirements for products available on the market but not, e.g. as regards the enforcement of conditions of use of a substance in production sites.

As in alternative ‘b’, the fact that some criteria are binding and other are laid down in guidance may lead to lack of clarity or interpretation discussions as regards criteria necessary for the implementation of Articles 125 REACH and 46 CLP and could have the negative effect of criteria in guidance be interpreted as ‘less relevant’ or not necessary to fulfil the obligation of having effective official control systems laid down in Articles 25 REACH and 46 CLP compared to those that are binding. However, it could add the necessary flexibility to introduce changes and support national authorities based on experience that will be gained once the European Audit Capacity is established.

### 3.5.3 Comparison of effectiveness of options

#### *Establishment of the European Audit Capacity:*

Taking into account all the above, while all three options are expected to contribute to some degree to improving the effectiveness of Member States' control systems, it can be assumed that, as regards alternatives for a European Audit Capacity, **option 26** which envisages:

- a 'proactive' system including Commission regular general and specific audits covering all Member States as well as additional control activities in addition to ad hoc controls in case of concern,
- provision of recommendations for corrective action on all main relevant aspects of official control systems and
- publication of the audit reports,

would be the most effective in contributing to building strong national control systems across all Member States and reducing non-compliance with REACH.

**Option 25** is expected to be less effective than **option 26** because:

- the scope of the audits would be specific only, targeting therefore certain issues,
- no additional activities other than potential ad hoc controls in case of concern are expected, and
- only (at least) a summary audit report would be published.

However, **option 25** would be more effective than **option 24** because the latter would only entail, as regards Commission controls, a reactive approach of EU controls to respond to specific concerns that have materialized rather than a proactive approach aiming to prevent them, and would not necessarily cover all Member States. Its potentially lower number of controls per year compared to the programmed audits may also lead to a less frequent identification of weaknesses/good practices in national control systems which could also be useful to non-controlled Member States.

As regards Member States peer reviews in **option 24**, as they are based on a voluntary approach, it is difficult to predict their trigger (reactive-proactive), scope and frequency and therefore also their effectiveness compared to the other options.

#### *Laying down criteria:*

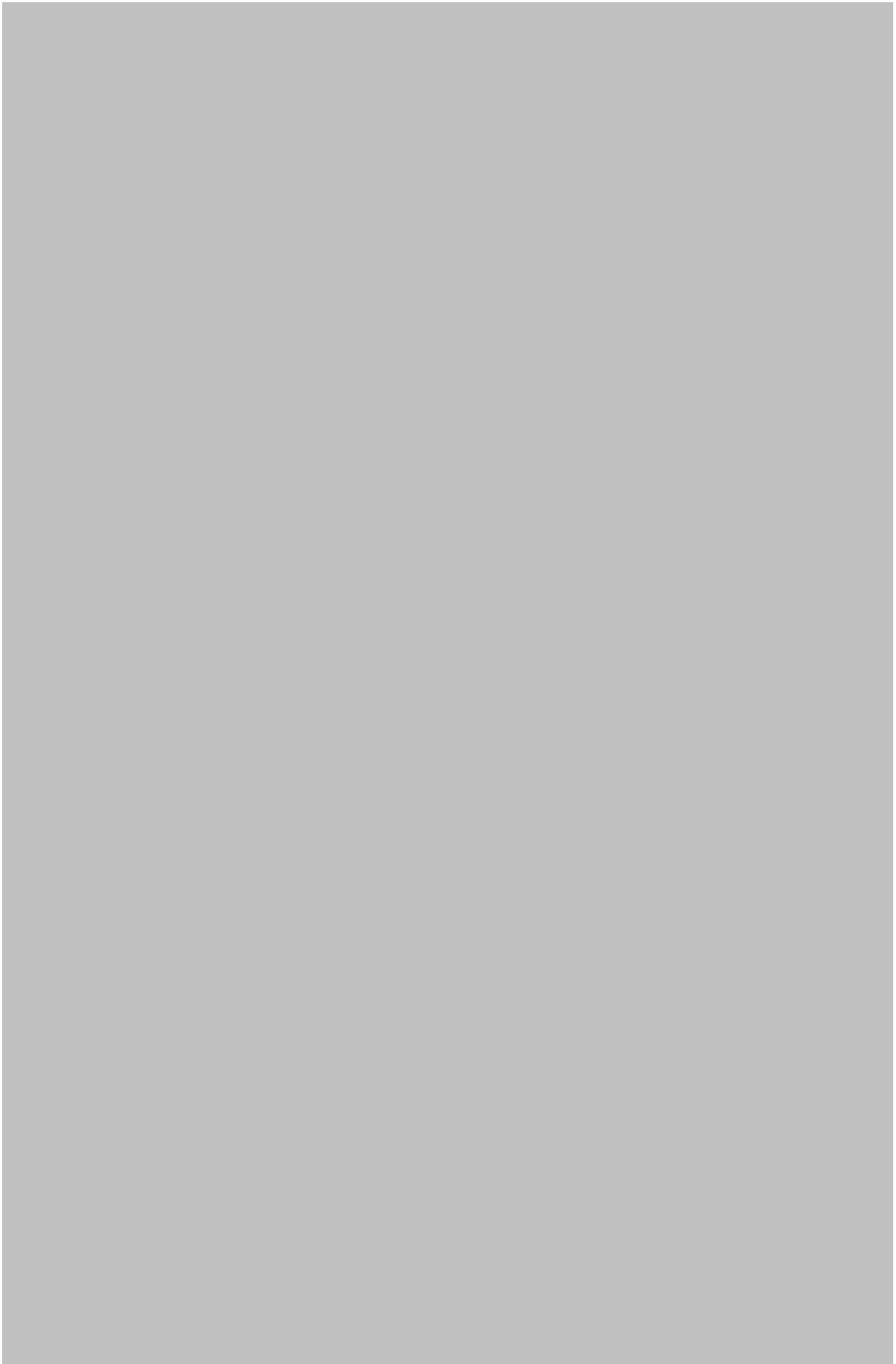
As regards alternatives for laying down criteria for national official control systems, **alternative 'c'** would be the most effective. This alternative is the one that ensures to a wider extent a functioning of Member States' control systems that is strong and consistent in the EU. Furthermore, it allows the effectiveness and efficiency of the European Audit Capacity to achieve its full potential, since Member States would be clearly obliged to take corrective action to address recommendations based on binding legal requirements which may refer to all main relevant aspects of national control systems. **Alternative 'b'** would be less effective as the criteria specified as binding

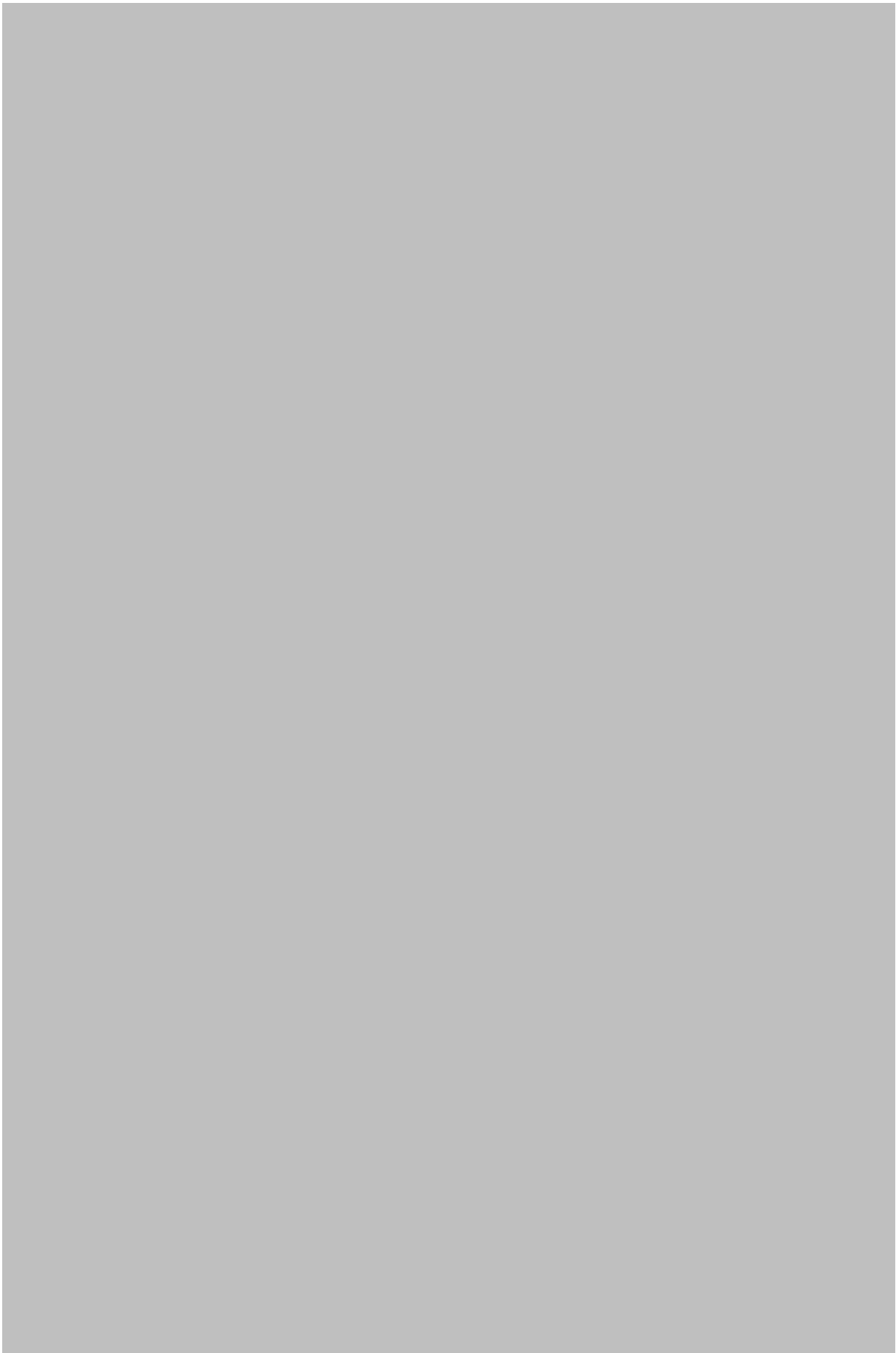
would be more limited and **alternative ‘a’** would have even less binding criteria and the problems explained in section 2.1.1.

*Options 24.a, 25.c and 26.c:*

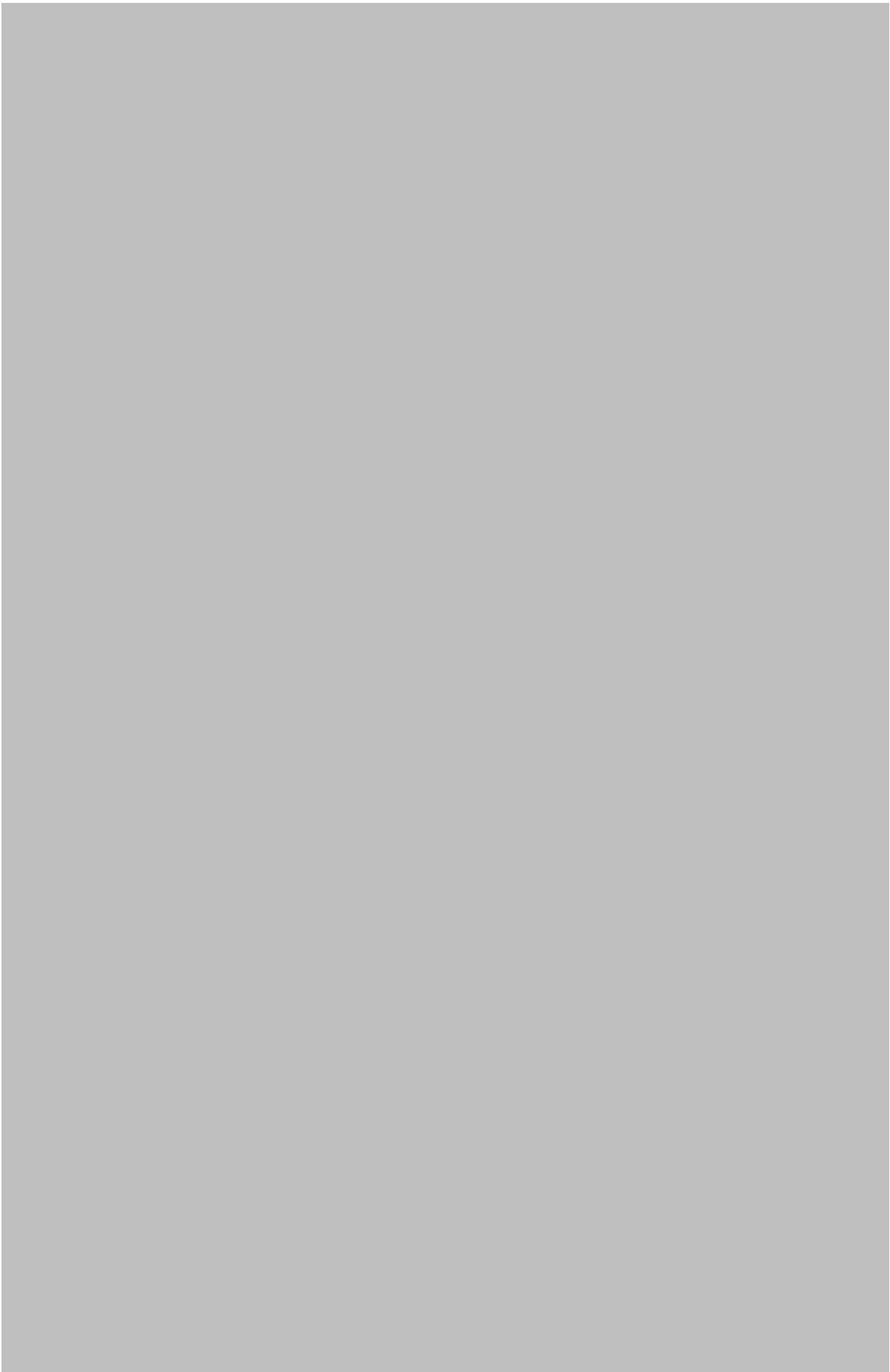
While all three options are expected to contribute to some degree to improving the effectiveness of Member States’ control systems (**option 26.c** is expected to contribute the most based on the reasons above and **option 24.a** the least). Only **options 25.c and 26.c** are expected to clearly result in strengthening the effectiveness of national control systems in all Member States thanks to, the proactive controls by a European Audit Capacity in all Member States and the obligation for Member States to take corrective measures where shortcomings are identified as they would be based on binding legal requirements in all cases. Within **option 24.a**, with only reactive controls, it is not ensured that problems are prevented, that all Member States are covered by the controls or that, due to lack of obligation for them to fulfil certain criteria, related weaknesses are corrected in all Member States where they may exist. Lessons learned from controlled Member States can nevertheless also be exchanged and applied in other Member States.



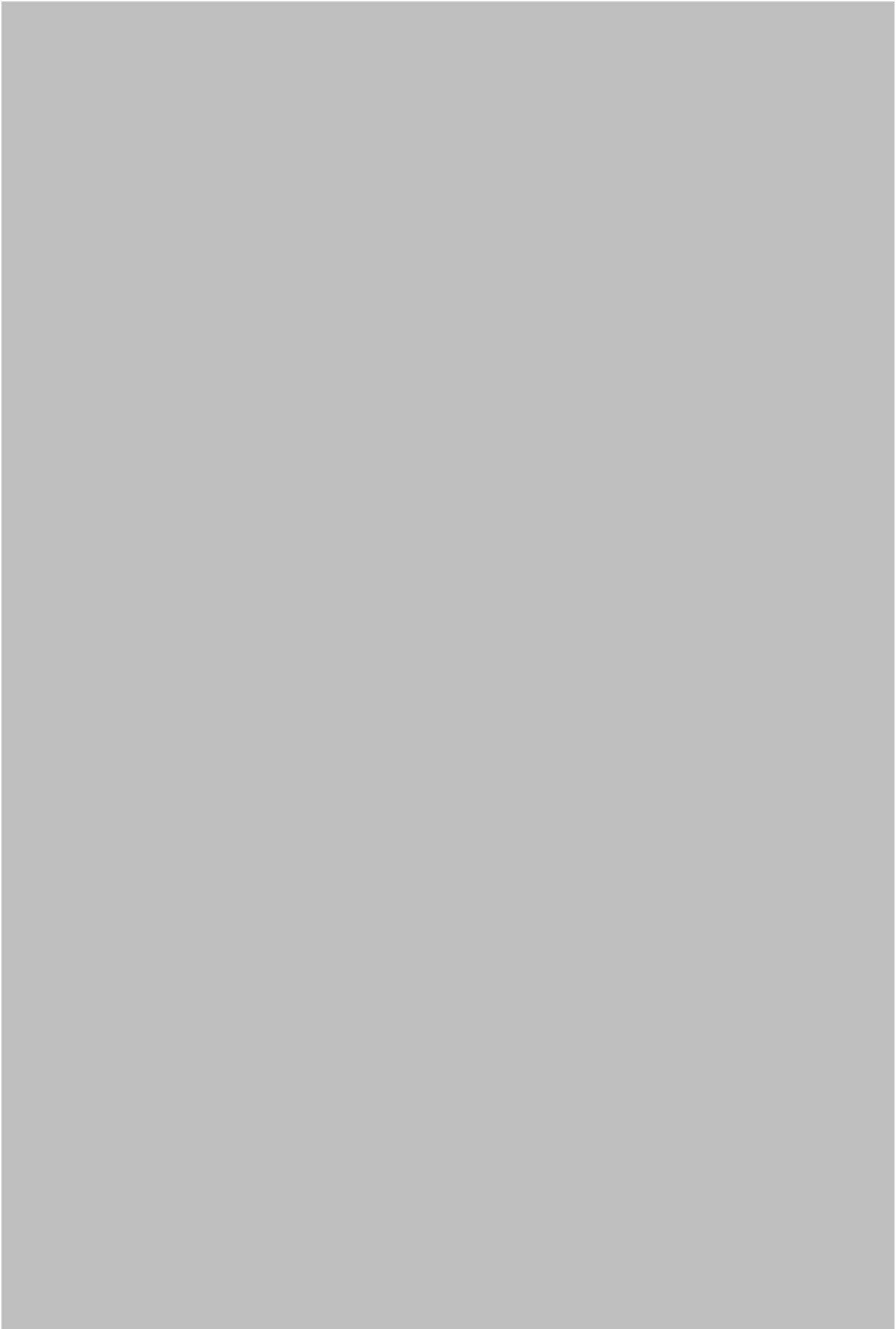












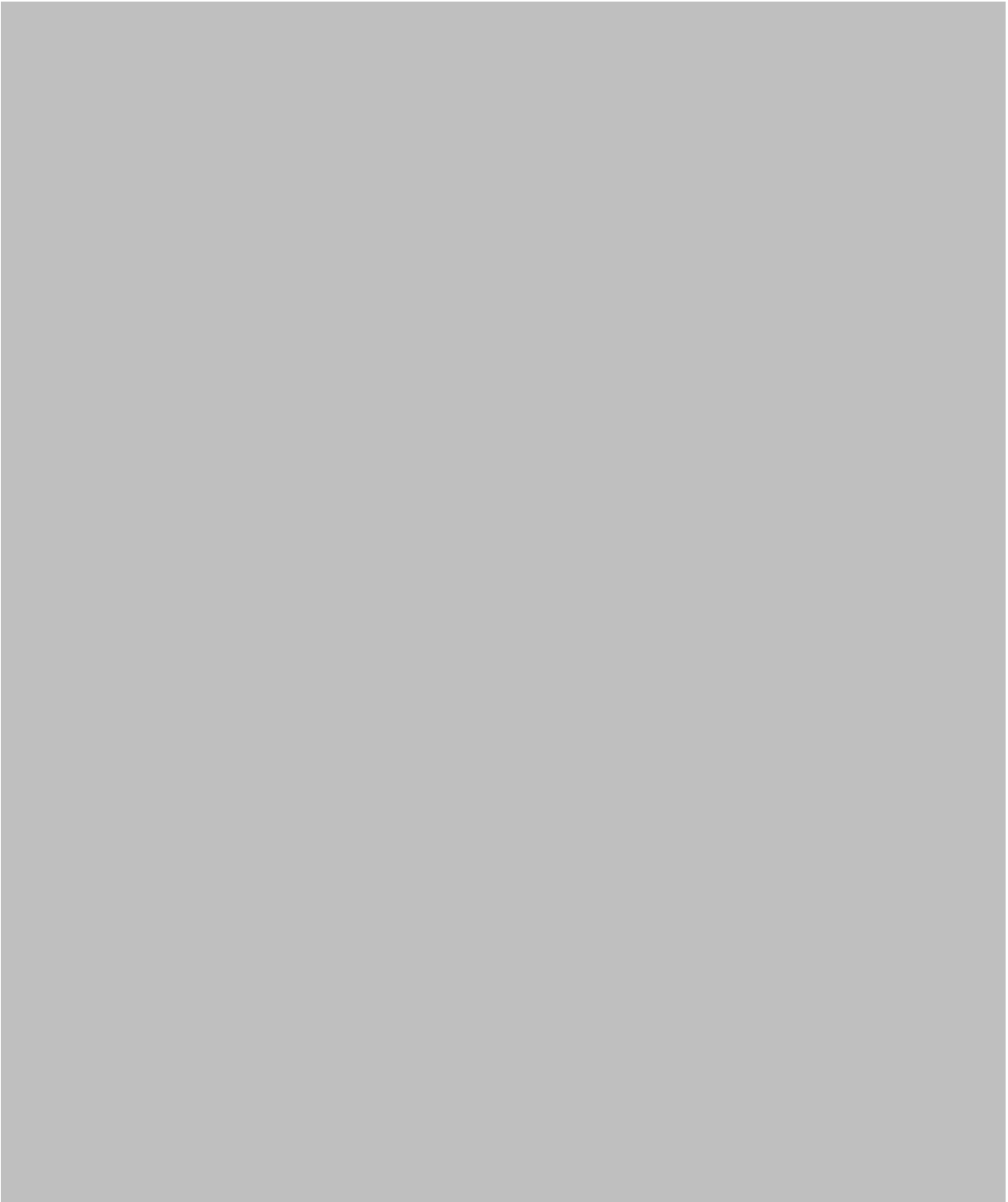














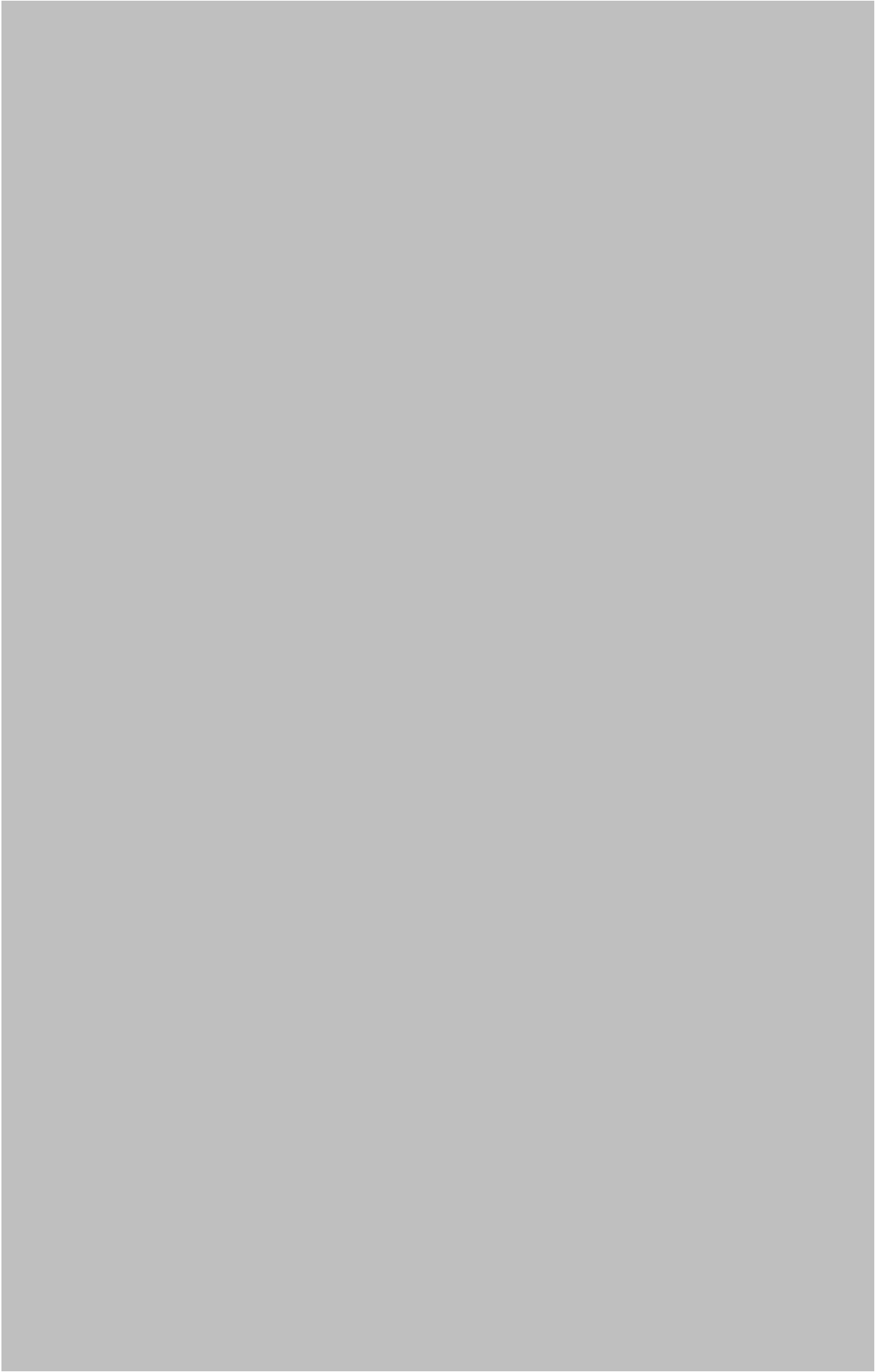








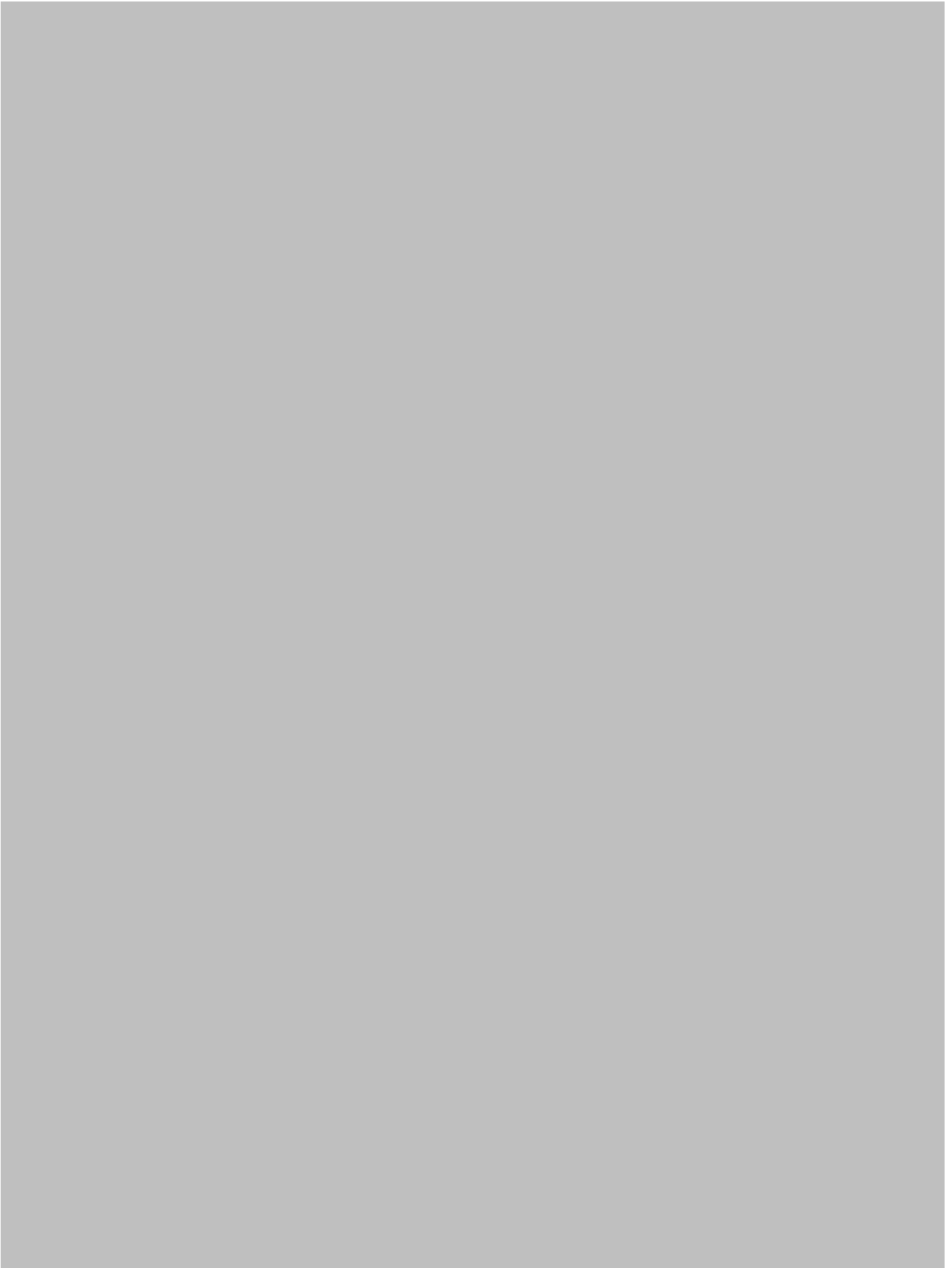


































## APPENDIX

Table 237: Relevant criteria for national official control systems

Criteria for national official control systems	Article in Reg. 2019/1020 (MSR)	Article in REACH	Article in CLP	Number of criteria in the study <sup>434</sup>	Comments
<b>Criteria covered (or partially covered) in Regulation 2019/1020 on market surveillance (MSR)</b>					
<b>Designation of enforcement authorities</b>	Art 10(2) MSR	Art. 121 REACH	Art. 43 CLP	Criterion 1	
<b>Appointment of single liaison office</b>	Art. 10(3) MSR				
<b>Resources</b> Member State shall ensure that authorities responsible for controls have the necessary resources, including sufficient budgetary and other resources, such as a sufficient number of competent personnel, expertise, procedures and other arrangements for the proper performance of their duties.	Art. 10(5) MSR	Art. 121 REACH (partially)		Criterion 6	Art. 121 REACH requires adequate resources for competent authorities in general, without requiring specific types of resources.
<b>Communication, coordination and collaboration</b>	Art. 10(6) MSR	Art. 122 REACH (partially covered)	Art. 43 CLP (partially covered)	Criterion 5	REACH and CLP require cooperation between competent authorities but not coordination and communication
<b>Obligation to ensure effectiveness</b> Authorities responsible for controls have procedures and arrangements to ensure effectiveness of the controls; they conduct their activities in order to ensure effectiveness of controls	Art. 10(5) and Art. 11(1)(a) MSR			Criterion 3	
<b>Exercise of the powers by enforcement authorities with impartiality, independency and no bias</b>	Art. 11(2) MSR				
<b>Control methods</b> Authorities responsible for controls perform appropriate checks on the characteristics of products on an adequate scale, by means of	Art. 11(3) MSR			Criterion 14	

<sup>434</sup> [Study on the establishment of a European audit capacity to ensure compliance and effective national control and enforcement of the REACH regulation and on the extension of that capacity and of those standards to CLP, POPs and PIC regulations - Publications Office of the EU, 2022 \(europa.eu\)](#)



Criteria for national official control systems	Article in Reg. 2019/1020 (MSR)	Article in REACH	Article in CLP	Number of criteria in the study <sup>434</sup>	Comments
documentary checks and, where appropriate, physical and laboratory checks based on adequate samples, prioritising their resources and actions					
<b>Risk based planning of controls</b> Priorities of controls are defined on a risk-based approach taking into account, among others: (a) possible hazards and non-compliance (b) activities and operations under the control of the operator; (c) the operator's past record of non-compliance; (e) consumer complaints and other information received from other authorities, economic operators, media and other sources that might indicate non-compliance.	Art. 11(3) MSR			Criterion 12	
<b>Authorities responsible for controls have procedures for follow up on complaints, issues relating to risks or non-compliance and procedures to verify corrective action taken by operators</b>	Art. 11(7) MSR			Criterion 16 and 17 (partially covered)	
<b>The Member State has a pluriannual national enforcement strategy</b>	Art. 13 MSR			Criterion 10	
<b>Scope of controls</b> When drawing the strategy all sectors and all stages of the product supply chain, including imports and digital supply chains shall be considered	Art. 13(1) MSR Art. 11(1)(a) MSR			Criterion 11	
<b>Powers of enforcement authorities</b> Authorities responsible for controls are given the powers of control, investigation and enforcement necessary for the application of the Regulation. This includes, among others, power to required documents and information from operators, power to carry out unannounced on-site inspections, to enter premises, power to require operators to take appropriate action to bring a non-compliance to an end or to eliminate the risk , power to take appropriate measures where an operator fails to take appropriate corrective action, power to impose penalties	Art. 14 MSR			Criterion 4	
<b>Recovery of costs by market surveillance authorities</b>	Art. 15 MSR				

Criteria for national official control systems	Article in Reg. 2019/1020 (MSR)	Article in REACH	Article in CLP	Number of criteria in the study <sup>434</sup>	Comments
Member States may authorise their market surveillance authorities to reclaim from the relevant economic operator the totality of the costs of their activities with respect to instances of non-compliance.					
<b>Follow-up on controls</b> When non compliances are identified, authorities responsible for controls shall require the relevant economic operator to take appropriate and proportionate corrective action to bring the non-compliance to an end or to eliminate the risk	Art. 16(1)(2)(3)(4) MSR			Criterion 16	
<b>Enforcement measures</b> If the operator fails to take corrective action or where the non-compliance or the risk persists, authorities shall take measures to bring the non-compliance to an end.	Art.16(1) and 16(5) MSR			Criterion 17	
<b>Use of information, professional and commercial secrecy</b> Authorities responsible for controls perform their activities with a high level of transparency	Art. 17 MSR				
<b>Procedural rights of economic operators</b> Any measure taken by authorities responsible for controls shall state the grounds on which it is based. Operators are informed of the remedies available to it under the law of MS	Art. 18 MSR				
<b>Reporting on controls</b> Authorities responsible for controls must report on all controls performed and their outcomes. This includes reporting in writing to the controlled operator	Art. 34(4) MSR (partially covered)	Art. 117 REACH (partially covered)	Art. 46 CLP (partially)	Criterion 15	Art. 117 REACH, Art. 46 CLP or Art. 34(4) MSR do not require to provide written reports to controlled operators on the outcome of the controls
<b>Horizontal analysis</b> Results from controls are analysed horizontally, in the form of, for instance, an annual enforcement report, to provide an overall picture of the level of compliance at national level, which may inform the planning of future controls	Art. 34(4) to 34(6) MSR, (partially covered)	Art. 127 REACH (partially covered)		Criterion 20	Art. 127 REACH, Art. 46 and Art. 25(6) of CLP and 34(4) to 34(6) of MSR do not include a requirement to analyse data or to inform future planning.
<b>Penalties</b>	Art. 41 MSR	Art. 126 REACH	Art. 47 CLP	Criterion 17	
<b>Other criteria identified in the study not included in MSR</b>					

Criteria for national official control systems	Article in Reg. 2019/1020 (MSR)	Article in REACH	Article in CLP	Number of criteria in the study <sup>434</sup>	Comments
<b>Preventing conflict of interest</b> Member States must ensure that staff performing official controls are free from any conflict of interest				Criterion 2	
<b>Training</b> Controllers must receive appropriate training enabling them undertaking their duties competently and performing official controls in a consistent manner				Criterion 7	
<b>Coordinated enforcement</b> Authorities responsible for official controls actively contribute to the exchange of information and coordination of enforcement at the EU level via the Forum for Exchange of Information for Enforcement in ECHA				Criterion 8	
<b>Internal and external audits</b> Authorities responsible for controls should carry out internal audits or have audits carried out on themselves and take appropriate measures to take account of the results of those audits				Criterion 9	
<b>Scope of controls</b> The planning of controls must cover operators at any stages of the manufacturing, use and placing on the market, all products, ways of placing on the market, and all legal obligations in the legislation				Criterion 11	MSR in Art. 11(1)(a) or Art. 13 does not specify that the scope of controls must cover all operators and all legal obligations. Due to MSR scope it does not require either that the scope of controls covers manufacturing or use stages.
<b>Documented processes and procedures</b> Authorities responsible for controls perform control activities according to documented processes and procedures, which ensure impartiality, quality and consistency of controls				Criterion 13	
<b>Right of appeal and formal complaints</b> Provisions for making formal complaints and for appealing decisions taken by authorities as a result of controls must be provided for in national law				Criterion 18	
<b>Control verification procedures</b>				Criterion 21	

Criteria for national official control systems	Article in Reg. 2019/1020 (MSR)	Article in REACH	Article in CLP	Number of criteria in the study <sup>434</sup>	Comments
Authorities responsible for controls must have quality control and control verification procedures in place					
<b>Internal evaluation</b> Authorities responsible for controls regularly evaluate the effectiveness of the control system				Criterion 22	

## **ANNEX 15: INCREASE CONTROLS TO COMBAT REACH INFRINGEMENTS AT EXTERNAL BORDERS, INCLUDING ILLICIT ON-LINE SALES**

This annex (addressing specific problem C3) focuses on customs controls and enforcement under REACH to tackle illicit chemicals import from third countries, including illicit online sales and the lack of tools to cooperate in cross-border situations. The annex covers insufficient cooperation in intra-EU situations to the extent that the Commission, via OLAF, should be given relevant powers in accordance with a possible enabling clause as envisaged in section 3.5 below.

### **1 CONTEXT – OVERVIEW OF REACH ENFORCEMENT AT EXTERNAL BORDERS**

Enforcement is primarily a national responsibility as each Member State must ensure that there is an effective system of controls including at the external borders. Nevertheless, in order to achieve efficient enforcement throughout the European Union, it is necessary to ensure coherence of national approaches and to exploit synergies, co-operation and co-ordination of national activities<sup>435</sup>. This includes EU-support to complement Member States enforcement efforts in complex cross-border cases.

#### **1.1 Customs**

Customs authorities play a crucial role in the control of imports. Amongst others, the task of customs is the risk-based control of goods entering or leaving the customs territory of the European Union and their compliance with non-fiscal measures. “Goods” entering or leaving the customs territory include substances, mixtures and articles as defined in the REACH Regulation. Legally, there is no difference in the customs treatment of these different categories of goods.

Currently, customs authorities are already obliged to monitor compliance of imported products with REACH and CLP obligations. In practice, customs controls are carried out based on risk analysis and evidence demonstrates that imports are often not in conformity with EU chemical legislation. Non-compliance of imports ranges from 17% (for REACH restrictions) to 64% (for CLP), being the overall (REACH and CLP) non-compliance rate 23% as detected by the Forum<sup>436</sup>, which means that almost one in every four imported products is not in conformity with the applicable rules. Moreover, the REACH and CLP enforcement indicators showed a variation between 0 and 30% non-compliance for imports in the period 2008-2019<sup>437</sup>. Non-compliance is a concern in particular to the restrictions of substances in articles rather than to substances on their own or in mixtures,

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<sup>435</sup> See Context section Annex 14.

<sup>436</sup> Forum pilot project on cooperation with customs:

[https://echa.europa.eu/documents/10162/17086/customs2\\_project\\_report\\_en.pdf/](https://echa.europa.eu/documents/10162/17086/customs2_project_report_en.pdf/)

<sup>437</sup> REACH and CLP enforcement indicators. Compliance with imports. <https://op.europa.eu/en/publication-detail/-/publication/199c348e-00e9-11ec-8f47-01aa75ed71a1>

and covers products such as jewellery, plastic articles, food contact materials, textiles or leather<sup>438</sup>.

The Union Customs Code (UCC)<sup>439</sup> legal package intends to modernise EU customs. It provides a comprehensive framework for customs rules and procedures in the EU customs territory adapted to modern trade realities and modern communication tools. The UCC aims at a paperless and fully automated customs union.

The EU Single Window Environment for Customs<sup>440</sup> (EU SWE-C) is the newest legislation proposed by the Commission in the customs domain. It creates a digital interoperability framework between customs and non-customs authorities, by enabling the exchange of information and documents between national customs systems and Union non-customs systems.

In order to better understand how the integration of REACH aspects into customs legislation, procedures and processes can improve existing practices, the Commission carried out a study in 2020-2021 (hereafter: “Commission customs study”)<sup>441</sup>. The main purpose of that study was to elaborate a set of options and tools to support and improve the enforcement of REACH<sup>442</sup> when substances, mixtures and articles are imported in the EU. The study identified seven areas of concern and provided short, medium or long-term recommendations to improve customs controls of compliance with REACH requirements.

## 1.2 EU assistance to national law enforcement authorities

Next to customs authorities, other national enforcement entities such as market surveillance authorities, chemical inspectors, and environmental agencies hold key roles in enforcing REACH<sup>443</sup>. The ECHA Forum for Exchange of Information on Enforcement (ECHA Forum) plays a major role in coordinating the national enforcement efforts. It is a network of Member State authorities that aims to harmonise enforcement through coordinated enforcement projects, developing best practices as well as tools and guides for inspectors. Its actions have strengthened enforcement by boosting cross-border cooperation between the enforcement authorities, including exchange of inspectors, and building capacity through trainings and thousands of controls at EU level. In complex cross-border cases, when carrying out their enforcement mission, Member States do normally not benefit from the possibility to coordinate, at European level, the collection of evidence and other investigative measures in several Member States in a structured manner.

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<sup>438</sup> Evidence to be added, reference to Forum REF-8 project, SE study. REF-8 project report: [https://echa.europa.eu/documents/10162/17088/project\\_report\\_ref-8\\_en.pdf](https://echa.europa.eu/documents/10162/17088/project_report_ref-8_en.pdf)

<sup>439</sup> [UCC - Legislation \(europa.eu\)](https://echa.europa.eu)

<sup>440</sup> Adoption by the European Parliament and European Council expected in October 2022

<sup>441</sup> Published in Jan 2022 - [Study to support the integration of REACH aspects into customs legislation and procedures - Publications Office of the EU \(europa.eu\)](#)

<sup>442</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

<sup>443</sup> Reference to Market Surveillance Regulation? PM

### 1.3 Online sales

The relevance of online sales including with third country origin, has been steadily growing both for individuals and businesses. According to Eurostat, in 2020, 73% of Internet users in the EU shopped online, while online purchases increased by 20% in comparison to 2010. Thirty-one per cent (31%) of online shoppers bought goods from sellers in other EU countries.<sup>444</sup> According to the EU consumer survey, in 2018, 18.4% of Europeans purchased services or goods online outside of the EU<sup>445</sup>. One in five EU enterprises made online sales in 2020, amounting to 18% of total turnover of companies that employ 10 or more people<sup>446</sup>. The trend of increased online sales, in particular to consumers, is also noted in UN's Global Chemicals Outlook<sup>447</sup>. Although there is no specific data for chemicals, the increasing trend is equally applicable to articles containing chemicals.

## 2 DESCRIPTION OF THE SPECIFIC PROBLEMS

Appropriate enforcement is key in order to achieve the objectives of REACH. Unfortunately, enforcement has been identified as a weakness requiring improvement. The Commission's last review of REACH in 2018<sup>448</sup> identified the strengthening of the enforcement of the obligations on all actors, including registrants, downstream users and in particular importers, as a necessary element to guarantee a level playing field, meet the objectives of REACH and ensure consistency.

In addition, the Chemicals Strategy for Sustainability (CSS)<sup>449</sup> mentions that *“currently almost 30% of the alerts on dangerous products on the market involve risks due to chemicals, with almost 90% of those products coming from outside the EU and imported articles and online sales representing a particular challenge.”*

### 2.1 Customs

Customs must deal with a great variety of different goods falling under REACH. Two important drivers to the insufficient enforcement at the external borders are: (i) the complexity and the broad scope of REACH, i.e. more than 26 000 chemical substances that can be found in almost all products imported in the EU; and (ii) the lack of information on REACH requirements and on the composition of products (presence of hazardous substances) available to customs. Multiple other factors such as lack of relevant risk information on non-compliant products and fraudulent operators, insufficient cooperation between authorities amplify this problem. The identification as well as the handling of goods often requires specific knowledge. Customs administrations of the Member States make efforts to train their staff (e.g. through the Customs Laboratory European Network), but keeping a high level of expertise in the different areas (e.g. fuels, drugs, food, tobacco, polymers, chemicals) is a challenge.

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<sup>444</sup> Eurostat (2022) [E-commerce statistics for individuals](#)

<sup>445</sup> GfK Belgium (2019) Survey on consumers attitudes towards cross-border and consumer-related issues 2018 – Final Report

<sup>446</sup> Eurostat (2021) [Online sales continue to grow among EU enterprises](#)

<sup>447</sup> UNEP (2019) [Global Chemicals Outlook II: From Legacies to Innovative Solutions](#)

<sup>448</sup> [https://ec.europa.eu/growth/sectors/chemicals/reach/review\\_en](https://ec.europa.eu/growth/sectors/chemicals/reach/review_en)

<sup>449</sup> [COM\(2020\) 667 final](#)

The Commission customs study highlighted a series of issues, for instance that the standard data elements of a customs declaration do not currently allow the identification of goods which are subject to REACH requirements. Additionally, there is no requirement in REACH for importers to indicate their registration or authorisation numbers in their customs declaration. Therefore customs authorities do not receive enough data to be able to check REACH compliance. The only exceptions are Code C073, that has to be indicated in data groups 1203 and 1204 (former Box 44) of the customs declaration if goods are subject to REACH authorisation, as well as Codes Y105, Y109 or Y115 in case an exemption applies, but currently there is no possibility to check automatically whether the importer itself has been granted an authorisation. The Commission customs study concluded that more generic and mandatory methods should be developed to indicate whether the imported products are subject to REACH.

The customs classification of commodities (Combined Nomenclature, based on the international Harmonised System) was designed to facilitate trade but not to e.g. control REACH or other chemical legislations. The main issue is that the customs classification system does not allow to uniquely identify the great number of individual chemical substances (tens of thousands) and their mixtures that are subject to REACH. Currently, TARIC (the integrated Tariff database) contains some indicators for REACH requirements (in particular for authorisations). REACH restrictions are in the process of being integrated into the TARIC database. However, it is challenging to link specific TARIC codes to REACH requirements for chemicals. For instance, a mixture may be classified under one TARIC code but consist of multiple substances. Another example is an article that has one TARIC code but may contain restricted substances or substances of very high concern (SVHC) that are regulated under REACH without being reported in the customs declaration.

Concerning REACH restrictions, many restrictions on substances in articles depend on the usage of the article. For instance, entry 52(1) of Annex XVII refers to toys and childcare articles which can be placed in the mouth by children. Other entries refer to the concentration of the substance in a mixture or article. This poses a challenge for customs authorities as composition of a good or its end use is unknown at the time of import. It prevents them from being able to make a proper risk evaluation and compliance assessment in case of control.

Concerning registration, for a given registered chemical substance, there are often multiple registration numbers, one unique for each company which is part of the joint registration. Currently, there is no requirement for importers to indicate the registration number in their customs declaration. Therefore, customs authorities are not aware whether REACH applies. For customs systems to control a requirement automatically, it has to be identifiable based on the (mandatory) data elements of the customs declaration. One of the most important data elements in a customs declaration is the commodity code (Combined Nomenclature code) which identifies the type of goods that is being declared. However, REACH identifies chemical substances by their name and by their CAS number<sup>450</sup>, and EC number, as available.

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<sup>450</sup> Chemical Abstract Service registry number.



Concerning the CLP Regulation, considering that customs declarations are processes without necessarily seeing the actual consignment, for checking for compliance with CLP, it is necessary to inspect the good itself. Such checks are only possible when a consignment is selected for physical control by comparing e.g. the information contained in the Safety Data Sheet with the information on the label.

REACH-related parameters are currently not sufficiently included in the customs risk assessment, for example there is no standard risk scoring for REACH for the selection of checks at EU level and even at national level. The main element to be addressed here is improving the prioritisation of REACH enforcement without creating undue burden together with good communication lines between National Enforcement Authorities (NEAs) and customs authorities.

EU customs agents at the control of imports are not sufficiently familiar with the details of REACH. They lack tools to facilitate the understanding of which are the specific aspects to be checked at the borders, how to recognise potential violations or how to easily translate REACH<sup>451</sup> requirements into standard customs language and procedures. Even where goods are selected for customs controls together with the NEA, relevant documentation to allow the control of REACH requirements may not be available at the point of customs control e.g. NEAs may check composition of the mixture in Safety Data Sheet and check whether the substances have been registered under REACH.

It appears that REACH does not provide customs authorities with the appropriate legal tools to control for the enforcement of chemicals legislation. Currently, information collected under REACH is not available electronically so as to allow fully automated (i.e. 100%) controls by customs.

## **2.2 EU assistance to national law enforcement authorities**

There are areas where illicit imports of chemicals escape the best efforts of the authorities concerned, e.g. when a complex cross-border import fraud case involves several Member States. A fraud might not have the same impact in each and every Member State involved. Consequently, it might not be given the same level of priority, for very legitimate and understandable reasons. Not all Member States have the capacity to finance operational meetings or missions to other Member States or third countries; this could hamper effective investigative activities in the other Member States and at EU level.

OLAF is the Union's main investigative body. It has developed specific expertise to carry out advanced analysis to detect and investigate various types of illicit trade with third countries. OLAF has a dedicated team of analysts using both commercial and restricted (government only) databases as well as analytical and forensic tools. In its work, OLAF draws on a variety of sources when gathering information, including law enforcement and customs agencies, environmental authorities, partner entities in third countries, companies and sometimes NGOs and individual complainants.

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<sup>451</sup> In this note, at occasions "REACH" should be read as "REACH/CLP".

OLAF does have certain means to coordinate the actions of national customs authorities as regards cross-border movements from third countries (i.e. related to imports and exports): The most important legal basis for such coordination cases is contained in Regulation 515/977 applying to customs and agricultural matters. Under Regulation 515/97, OLAF can assist Member States in the conduct of their investigations. OLAF does this by e.g. collecting documents and information in any format that can be used as evidence; arranging operational meetings as well as requesting the execution of concrete activities from partner authorities in the Union and beyond. In these cases, the role of the Commission, through OLAF, is to support Member States and to ensure operational synergies among all competent authorities.

The coordination tools provided for by Regulation 515/97 can be used to any breach of EU sectorial legislation when it comes to imported goods: importing a good from a third country, non-compliant with the EU standards, constitutes a custom fraud and can be tackled by OLAF under the provisions of Regulation 515/97. In that respect, OLAF has already demonstrated in its operational work that it is well-equipped to coordinate the work of customs authorities in large and complex import cases, in the fight against illicit import of refrigerant gases or import of dangerous products putting at risk health's consumers, including in the chemicals area.

A case from 2020 illustrates what OLAF can provide in such instances: in that international operation, OLAF, via alerts and intelligence systems, supported law enforcement authorities in 19 Member States and eight third countries to seize i.a. 140.000 litres of illicit hygiene sanitizers (COVID) with a dangerous high level of methanol and 8 tonnes of raw materials.

However, these cases notwithstanding, the current legal framework overall only presents limited possibilities for OLAF to intervene in support of REACH. In particular, OLAF's independent administrative tools (like inspections of premises, interview of suspicious economic operators...) based on Regulation 883/2013 serve only to protect the Union's financial interests against fraud, corruption and other illegal activities as well as certain cases of professional misconduct. Conversely, OLAF's independent investigative mandate does not stretch to enforce regulatory compliance as such.

Overall, the limitations of the current legal framework result in a situation where the potential of OLAF's investigative capacities to support and complement Member States in enforcing REACH, and thus protecting the environment, health and the Internal Market, are not fully exploited.

### **2.3 Online sales**

Several enforcement surveys on online chemicals sales indicate that restricted chemicals and related products are increasingly being offered for sale via the Internet. Chemicals legislation is also applicable to online trade. However, access to websites and relevant information on transactions, vendors or service providers<sup>452</sup> represents a particular challenge for market surveillance authorities for ensuring consumer protection and fair

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<sup>452</sup> Fitness check of the most relevant chemicals legislation (excluding REACH). Commission's Staff Working Document, SWD(2019) 199 final/2, p. 19.

competition. When consumers buy directly online from suppliers established abroad, enforcement authorities cannot act beyond their territory.

Based on the results of ECHA Forum's enforcement project report on substances, mixtures and articles sold online<sup>453</sup>, out of 2 629 products checked for compliance with REACH restrictions, 2 042 (78%) did not comply<sup>454</sup>. Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) and that are restricted under entries 28-30 of REACH Annex XVII had a very high level of non-compliance (99%). These substances are only allowed to be sold to professional users, but they were found to have been offered to the general public. Concerning the sales location of 1 690 non-compliances for mixtures containing lead, only one was found in a web-shop, the others were on marketplaces (99%) of which 60% were established outside the EU.

Many products that are sold online in the EU but manufactured outside the EU do not meet the EU product safety and chemical legislation requirements<sup>455</sup>. Consumers can be exposed to hazardous chemicals when buying online substances, mixtures or articles non-compliant with REACH provisions. This is particularly relevant when consumers buy from non-EU actors that ship chemicals directly into the EU. In these situations there is no intermediary in the EU who qualifies as importer under REACH to ensure compliance with the provisions of the legislation. As a result the consumer becomes, de facto, the importer, but he is not a legal actor that can be held accountable by the national enforcement authorities in case of importing an non-compliant product<sup>456</sup>.

Data on REACH non-compliances of online chemicals' sales in and outside the EU and data on imports is not available<sup>457</sup>. However, modelling data<sup>458</sup> suggests that in just one year (2021) 251 million consumers in the EU purchased more than 1.6 billion items from seller within the EU, of which 71 million were expected not to be compliant with REACH requirements. Looking beyond EU's borders, 70 million consumers in the EU who purchased 470 million items online from sellers outside the EU of which 31 million were expected not compliant with REACH requirements.

REACH does not specifically address online sales, nor provides for the need of having a responsible duty holder established in the EU (i.e. importer, manufacturer or only representative) when consumers buy online from traders outside the EU. Therefore, non-

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<sup>453</sup> ECHA (2021) Forum REF-8 project report on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online

<sup>454</sup> The non-compliance for restrictions on substances/mixtures was 95% and 25% for restrictions in articles. These figures should take into account that non-compliance of substances/mixtures is more easily identified, since they are based on the information readily available on the web page. While, for products containing substances/mixtures, additional chemical analysis may be needed to confirm non-compliance, for example, lead in leaded solders. See also the so-called REF-8 report: Please add reference/link to REF-8 report: [https://echa.europa.eu/documents/10162/17088/project\\_report\\_ref-8\\_en.pdf/](https://echa.europa.eu/documents/10162/17088/project_report_ref-8_en.pdf/)

<sup>455</sup> RAPEX; Kemi (2021) [Rapport 6/21: Increased e-commerce – increased chemicals risks?](#)

<sup>456</sup> Among the issues are difficulties in identifying responsible persons for compliance of the substance/mixture sold online with the legislation, applying enforcement measures to companies located outside the EU, identifying non-compliance cases in vast streams of online content, as these issues were reported by public authorities (cf. (KEMI, 2021); (Klar, Rumar, & Ramström, 2020); Kemi, 2018; feedback by CARACAL members (CA/77/2020)).

<sup>457</sup> Use data from FORUM projects.

<sup>458</sup> See detailed description of the methodology used in the Appendix to the impact assessment of the CLP revision – not yet published

EU based operators could sell online via a service provider or their own web-shop and ship directly to EU consumers without the need of having a responsible duty holder in the EU carrying out a commercial activity, which could be followed-up in case of non-compliance. This results in incompliances not being enforced.

Furthermore, such situation leads to a competitive advantage for non-compliant actors operating online from abroad and a disadvantage for EU actors such as (commercial) importers, downstream users, distributors and manufacturers who have to comply with REACH, as well as to insufficient protection of consumers, human health, and the environment. The volume of online sales is expected to grow, hence increasing the problem.

## **2.4 How likely are the problems to persist?**

Without further action, it is expected that the enforcement problems at external borders will persist. The REACH review has highlighted the need for reinforcing national enforcement activities and controls on imported goods.<sup>459</sup> Even if efforts in ECHA's Forum to date have been substantial, with annual enforcement projects targeting different areas of enforcement under REACH, additional actions both at national and EU level are necessary in order to achieve the zero tolerance targets for non-compliance targets set by the CSS<sup>460</sup>.

In the future, online sales are expected to be positively affected by horizontal draft EU legislation and already applicable legislation related to market surveillance, product safety, digital services and customs legislation as well as by non-regulatory initiatives. Although this legislation will have a positive impact on ensuring that consumers are better able to make informed choices upon purchase and use of chemicals sold online, they will not entirely eliminate the problem, in particular as the number of online sales is increasing

## **3 POLICY OPTIONS**

### **3.1 Baseline Scenario**

The baseline is defined as the 'no policy change' scenario. This translates into a situation in which no new policies or provisions relating to control and enforcement of REACH are adopted, but the present chemicals policy framework – including the current limited powers of OLAF - continues to be applied as currently expected.

In the baseline scenario, there would be no new mechanisms to tackle the problems identified with REACH compliance. In particular, the high level of non-compliance of imported chemicals and articles will remain because the capacity of customs to control REACH at the point of entry into the EU will remain very limited due to challenges

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<sup>459</sup> European Commission. (2018). 2018 REACH Review: Conclusions and Actions (Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions). Retrieved from <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN>

<sup>460</sup> European Commission. (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. Chemicals strategy for sustainability. Towards a toxic free environment. Retrieved from <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

described above. There will be multiple adverse impacts of this. Firstly, imported non-compliant substances, mixtures and articles will continue to cause risk to EU citizens and environment. Secondly it will give an advantage to importers compared to EU manufacturers who are often controlled at the stage of production, thus preventing level playing field. Thirdly, it will result in inefficient use of national enforcement capacities, because imported substances, mixtures and articles will need to be controlled after entering and spreading into the internal market. It is assumed that under a no policy change scenario, compliance would keep decreasing, following the trends observed during the 2007-2019 period.

However, the existing ECHA Forum on Enforcement will remain, providing support to Enforcement Authorities and solutions to the main enforcement issues identified. In addition, actions that are already ongoing to enhance enforcement, such as in the context of the implementation of Regulation (EU) 1020/2019 on market surveillance and product compliance to enhance cooperation between market surveillance authorities and customs, are expected to improve the situation. This is expected to improve sharing of information to enrich respective risk analysis, e.g. by having an electronic interface to communicate in real time on individual suspicious cases, etc.

For online sales, the baseline should take into account the recent adoption of the Digital Services Act (DSA)<sup>461</sup> as well as the application of the Market Surveillance Regulation<sup>462</sup>. The Market Surveillance Regulation introduced the obligation to have an economic operator responsible for cooperation with market surveillance authorities in the EU for listed pieces of legislation but does not include REACH in that list. A change to that list would be complicated since the definitions of actors (importer, distributor, etc.) and of placing on the market in both legislations do not match exactly. The DSA confirms that online platforms can only be held liable for the illegal content on their websites if they do not remove it after being made aware. The DSA will also develop new tools to enhance the engagement of online platforms in the fight against illegal content. Both pieces of legislation should contribute to a better REACH compliance by online platforms and other (digital) intermediaries. However, the specific problem of consumers importing directly from third countries via online platforms would not be tackled.

### **3.2 Option #27: Strengthen customs controls with automated controls of authorisations and restrictions (for substances only)**

- **Require importers to indicate the authorisation number and the EORI number of the authorisation holder in their customs declaration. The authorisation decision should also indicate their EORI number.**
- **Integrate REACH IT into the EU Single Window Environment for Customs**

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<sup>461</sup> Reference to DSA once published.

<sup>462</sup> [Regulation \(EU\) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations \(EC\) No 765/2008 and \(EU\) No 305/2011, OJ L 169, p. 1.](#)

- **Empower the Commission to adopt implementing provisions laying down detailed arrangements for the establishment of automated customs controls on authorisations.**

Substances of very high concern ('SVHC') listed in Annex XIV to REACH can no longer be placed on the market for a use or used after the designated "sunset date", unless an authorisation has been granted for the use applied. Although substances listed in Annex XIV to REACH are earmarked accordingly in TARIC, customs systems cannot automatically check the accuracy of authorisation codes in a customs declaration. It can only be done manually, by inspectors familiar with REACH requirements, and only if the consignment is selected for control.

For a consignment identified as subject to authorisation (Annex XIV) by the unique commodity code, the importer needs to declare an authorisation number, and the Economic Operator Registration and Identification (EORI) number of the authorisation holder, if the importer in accordance with REACH is not identical with the declarant in accordance with the Union Customs Code. In addition, the authorisation decision should also indicate the economic operator's EORI number. If the chemical should benefit from an exemption from the authorisation requirements, the relevant TARIC certificate code needs to be provided ("escape code"). The TARIC certificate codes should allow to identify the reason for the exemption from the REACH authorisation (e.g., intermediate, before sunset date, application for authorisation ongoing). Cases where the declarants use an "escape code" will be forwarded to the national REACH enforcement authority for post-import verification. The intelligence obtained from post-import verifications should inform customs in their risk analysis.

When an authorisation number and the EORI number of the authorisation holder is provided, customs IT systems can perform a relevant query on data from ECHA databases via the Single Window Environment for Customs, thus performing an automated check. This entails customs systems accessing data from ECHA databases through the EU Single Window Environment for Customs to automatically check the existence of a valid authorisation for that chemical and the declared authorisation holder.

This option requires a transitional period of 4 years allowing the Commission to develop the required IT solution and for Member States to implement it.

Under this option, the relationship between the ECHA databases, the EU Single Window Environment and the EU Digital Product Passport should also be defined.

- **Enhance customs control on REACH restrictions on imported substances that are restricted on their own from being placed on the market.**

Automated customs controls of the (future and often unknown) use of the imported chemical would only be feasible in the case of REACH restrictions where the import of a chemical (substance) is banned through the restriction (e.g. asbestos). In this case, a similar customs procedure as described for authorisation is applied as consignments will be identified by TARIC codes. No EORI or reference numbers would be required in customs declarations, but the declarant will have the opportunity to provide an "escape code" to cover exemptions from REACH. Where the declarant does not provide an escape code, the consignment would be stopped.

A more targeted approach should be envisaged for restrictions where the chemical is not explicitly banned as it may refer to a future use or certain concentration. A more targeted approach would mean, in particular, focusing customs controls on specific consignments, based on customs risk management.

Since information on composition of mixtures and articles is not readily available, findings of market surveillance authorities in the Member States should be used for targeting customs controls. Market surveillance authorities are best placed to identify risks related to specific chemicals, non-compliant products or operators. Identified risks should be communicated to customs authorities in order for the latter to focus better their risk management systems (e.g. results and findings from national market surveillance activities; Article 25.5 of the Market Surveillance Regulation).

OLAF can further support customs fraud detection by analysing non-compliant cases detected by market surveillance authorities, as described in policy option 4.

### **3.3 Option #28: Strengthen customs controls with automated control of registrations**

- **Require that REACH registration numbers are indicated in data element 1203 (former box 44) of the customs declaration.**
- **Amend Annex VI to REACH and require registrants to provide the EORI number of the registrants who have the role of importer or only representative. In addition, it may also be necessary to provide the CUS number for the chemical substance and the corresponding commodity code.**
- **Importers should be required to provide Safety Data Sheet on request of customs, when goods are selected for customs control**

For imports of chemical substances of more than one tonne per year that are subject to REACH registration, the importer needs to include in the customs declaration the relevant registration number, and the EORI number of the registrant of the substance in cases where the importer in accordance with REACH is different from the declarant in accordance with the Union Customs Code. If the importer does not provide this information, they must provide an “escape code”, based on existing TARIC measures to indicate that they are exempted from registration. In this process, the various exemptions from registration listed in the REACH Regulation should be taken into consideration via the option to include “escape codes” in the customs declaration. The TARIC “escape codes” should allow to identify the reason for exemption from REACH registration. Potentially the CUS number and the corresponding commodity code needs to be added by the registrants as well.

When goods are selected for customs control importers need to provide a Safety Data Sheet upon request by customs authorities. The SDS can in practice be provided by the non-EU supplier or registrant of the substance or non-EU supplier or importer of the mixture. The information in the SDS will be used by the NEA control REACH requirements during customs control e.g. control of registration of substances in a mixture.

### **3.4 Option #29: Enhancing risk management by risk analysis and automating the sharing of risk information with customs**

- **ECHA to identify and prioritise articles that could potentially contain one of the most hazardous prohibited substances (list of the most 100-200 dangerous substances prohibited) and share this information with customs**
- **ECHA to identify categories of high-risk articles, that could potentially contain substances subject to restrictions based on ICSMS (Information and Communication System for Market Surveillance) data**
- **ECHA to identify and prioritise importers of substances not in compliance with REACH**
- **ECHA to share risk information directly usable by customs and transferred automatically from ICSMS to CRMS2 (new Customs Risk Management System)**

Automated customs controls are only feasible in the case where the restriction concerns the placing on the market (here: import) of a chemical substance on its own. A more targeted approach is needed for other types of restrictions, focusing customs controls not only on specific shipments but also on specific economic operators, based on risk management.

The more information customs authorities have, the more effective risk analysis will be. Therefore, the (automatic) exchange of risk-related information between customs and market surveillance authorities would improve both the customs and NEAs risk management. As market surveillance authorities are best placed to identify risks related to specific products of economic operators, that information should be communicated to customs authorities for the latter to focus better their risk management systems. A collaboration between NEAs and ECHA could inform the latter on high-risk non-compliant products that are placed on the market. There may also be a role for the Forum to enhance risk management, in particular if coupled with additional duties for Member States to share risks. Additional resources for ECHA and, if appropriate, the Forum should be foreseen for this.

### **3.5 Option #30: Empower OLAF to carry out investigations under REACH**

- **Empower OLAF to carry out investigative and coordination actions in case of serious breaches of REACH in particular related to imports**
- **OLAF to support and coordinate Member State actions**

Under this option, Member States would remain the primary responsible for enforcing REACH. The option aims to build upon the long established experience the European Anti-Fraud Office (OLAF) has in cooperating closely with Member State Authorities and third countries in complex cross-border cases in the field of protecting the EU financial interests and in the protection of e.g. the environment.

The option responds to the respective calls from the European Parliament and the Council to step up REACH enforcement including at the European level, as well as to the commitment taken by the Commission in the CSS to “extend the scope of action of OLAF for coordination and investigation, to tackle the circulation of illicit chemical products in the EU”.



The role envisaged for the OLAF would replicate its existing powers elsewhere, and would not contain any ‘novel’ powers as such. At issue is only clarifying and extending those existing powers to a specific economic sector in order to strengthen compliance with and enforcement of the sectoral regulatory framework.

In this context, the scale and the rhythm by which it would be opportune to bring in EU-level support to REACH enforcement could differ. Three scenarios can be distinguished:

- First of all, the Commission, via OLAF<sup>463</sup>, could assist, support and complement Member States’ enforcement action in relation to illegal imports of chemicals.

Such work would naturally build on the Commission’s existing work, via OLAF, in protecting the internal market against illicit imports, including smuggling. To this effect, the Commission / OLAF could leverage the well-established working relationship with customs authorities in Member States and in third countries, and link these to national environmental and other competent authorities. Many of the tools to detect and investigate illicit cross-border movements are already in place (such as for example the monitoring of global container movements) and when hooked up with the existing and future REACH data bases, powerful tools to stop especially the illicit import of the most hazardous substances would be readily available.

Beyond coordination activities, the Commission, via OLAF, could be entitled to mobilize similar investigative tools (i.e., on site inspections, interviews of suspicious economic operators, forensic acquisition, etc.), as currently available to OLAF to protect the Union’s financial interests, to complement enforcement action.

- Second, the option to support and complement Member States could be extended to both imports and intra-EU movements, by extending the same powers to the Commission, via OLAF, to support REACH enforcement also as regards intra-EU movements.

This would be a major qualitative step. In such a scenario, there would be no legal obstacle for the Commission, via OLAF, to assist, support and complement Member States enforcement action relating to virtually all types of cross-border cases – even if in practice, such EU-level support would always only focus on the most important (i.e. the most harmful) cases.

- Finally, it could be considered to support and complement Member States via OLAF as regards imports, with the option to extend this in the future to certain intra-EU movements based on an Enabling Clause. Such a step could be achieved by means of a secondary act. In terms of scope, such a step might plausibly cover, for example, intra-EU movements of the most hazardous substances.

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<sup>463</sup> In this document references to OLAF should be read as the Commission, via OLAF

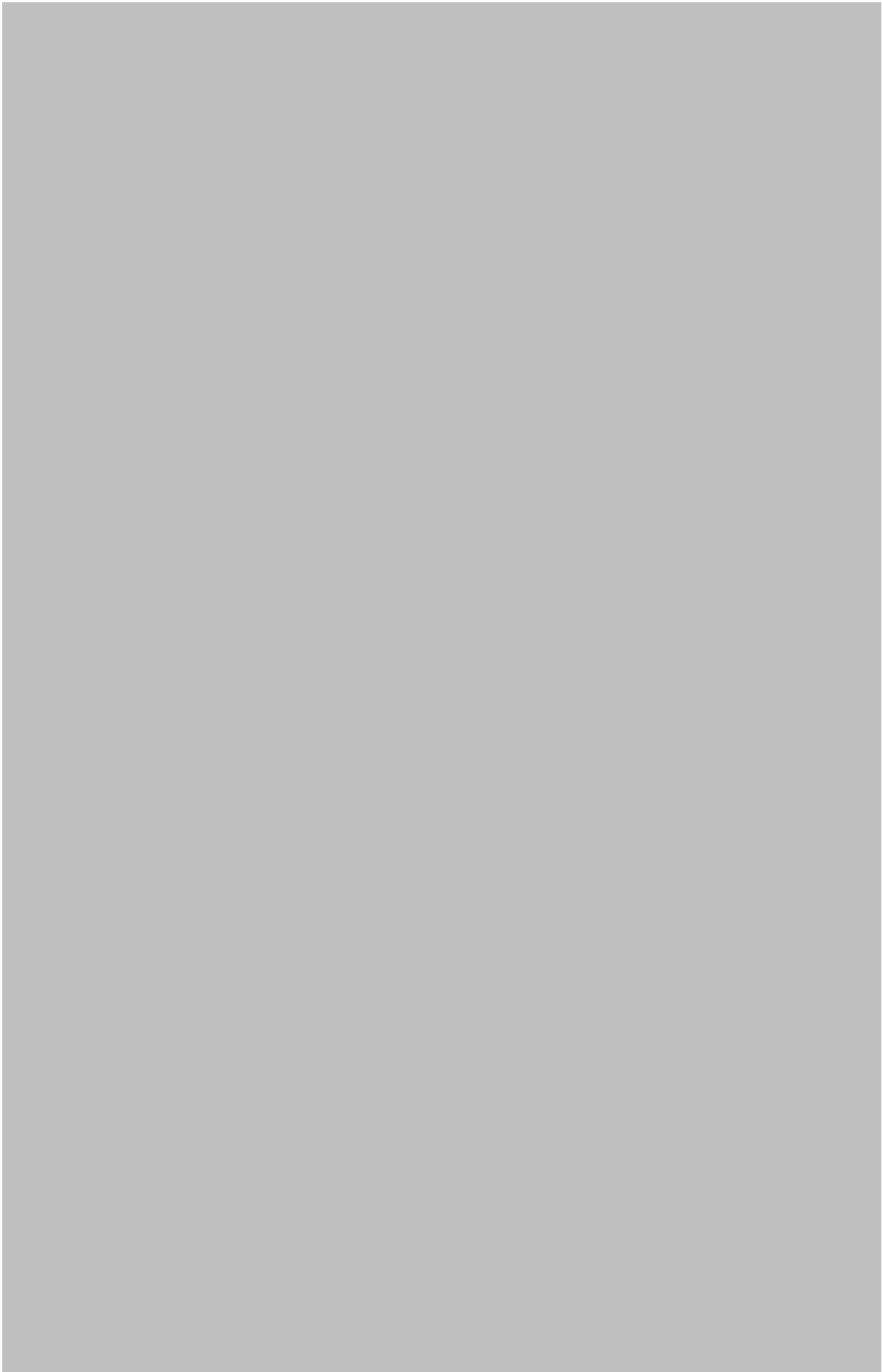
### **3.6 Option #31: Always have a responsible economic actor for REACH compliance**

- **Introduce the obligation to have a responsible economic actor in the EU for online sales directly shipped to consumers from a third country**

Such actor should carry out a commercial activity (and therefore excluding the consumer), and could be a natural or legal person. This measure targets the case where the consumer buys directly through an online platform from a seller outside the EU and there is no economic actor in the EU involved in commercial activity. REACH already foresees other actors, either the importer or the only representative, to ensure that chemicals manufactured abroad and placed on the EU market during a commercial activity are REACH compliant.

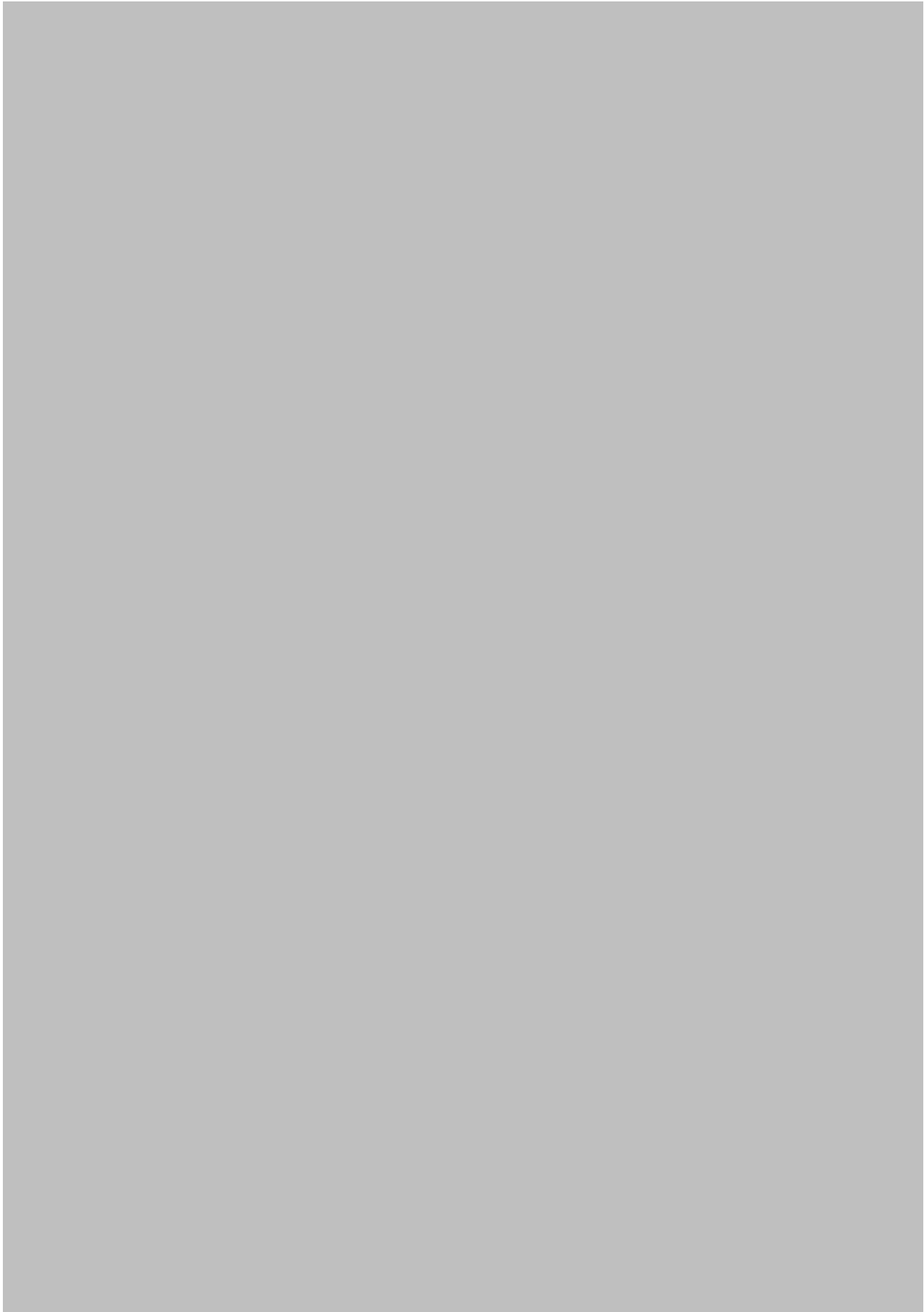




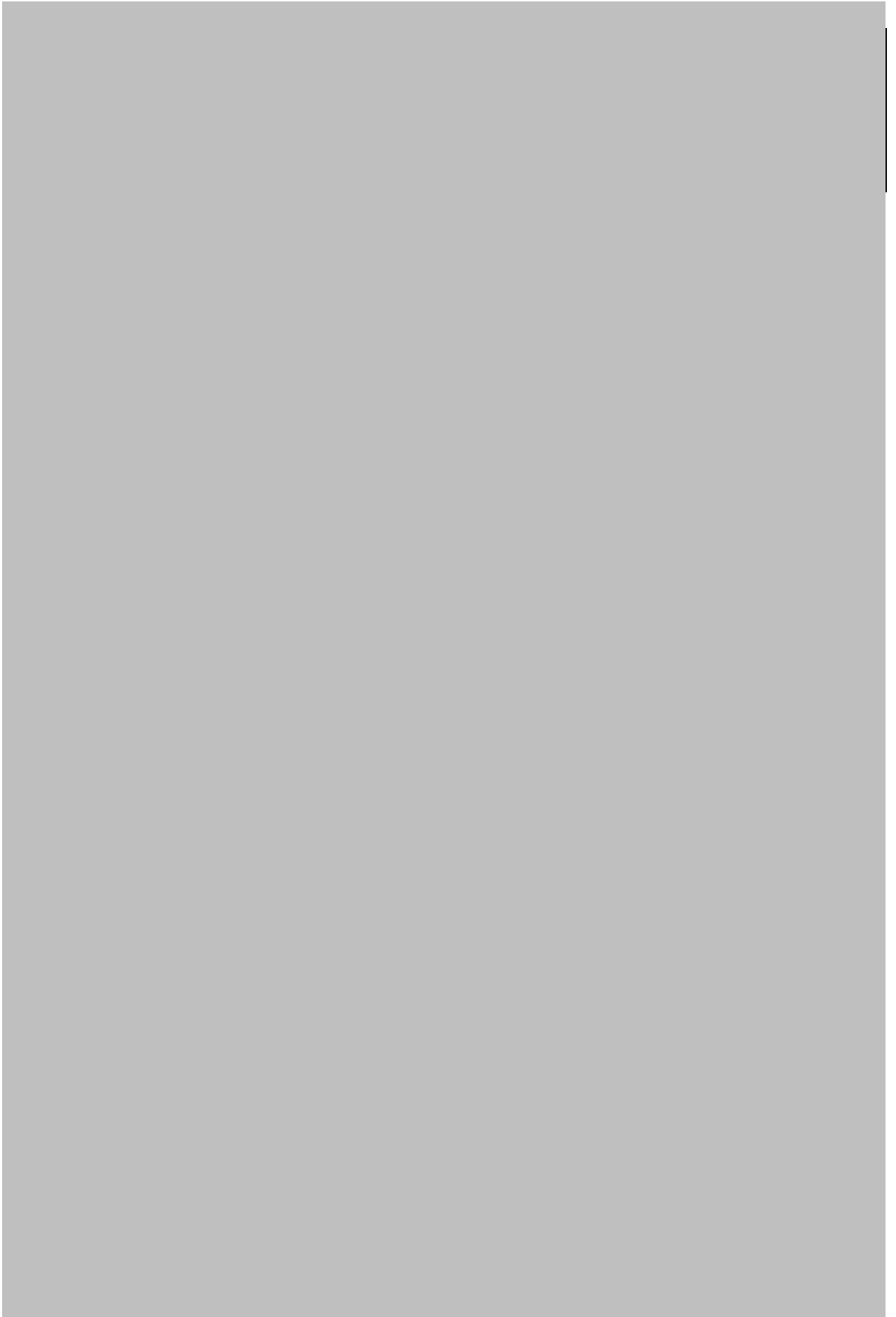












## ANNEX 16: PROVIDE FOR THE POSSIBILITY FOR COLLECTIVE ACTION AND COMPENSATIONS

This Annex is added to the enforcement part of the Impact Assessment, as the options it proposes will help to improve compliance and enforcement. However, the described policy options aim – besides improving compliance and enforcement - to adjust REACH to general legal developments regarding access to justice, collective redress and compensations to better protect the consumers/citizens from any damages caused due to non-compliance with REACH. As impacts of these policy options are not considered to be significant, they were only qualitatively assessed.

### 1 CONTEXT

The United Nations Economic Commission for Europe (UNECE) [Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters](#) (Aarhus Convention)<sup>465</sup>, which was adopted in 1998 and entered into force on 30 October 2001, is the primary international legal instrument for the support of public awareness and participation in the implementation of environmental legislation. The Convention establishes a number of rights of the public (individuals and their associations) with regard to the environment and more specifically it provides for:

- the right of everyone to receive environmental information that is held by public authorities ('access to environmental information').
- the right to participate in environmental decision-making ('public participation in environmental decision-making').
- the right to review procedures to challenge public decisions that have been made without respecting the two aforementioned rights or environmental law in general ('access to justice').

The EU is a Party to the Convention since May 2005<sup>466</sup> and its provisions have been implemented by the EU in a number of Union acts, primarily Directives (Directive 2003/4/EC<sup>467</sup> and Directive 2003/35/EC<sup>468</sup>) concerning public access to environmental information and public participation in programmes relating to the environment, as well as the "Aarhus Regulation",<sup>469</sup> which lays down related requirements for EU institutions and bodies.

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<sup>465</sup> [Convention on access to information, public participation in decision-making and access to justice in environmental matters](#), Aarhus, 25 June 1998

<sup>466</sup> [Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters](#), OJ L 124, 17.5.2005, p. 1.

<sup>467</sup> [Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC](#), OJ L 41, 14.2.2003, p. 17.

<sup>468</sup> [Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC](#), OJ L 156, 25.6.2003, p. 17.

<sup>469</sup> [Regulation \(EC\) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation](#)

More recently, in the European Green Deal<sup>470</sup>, the Commission has also made clear again the importance it attaches to enforcement and compliance with EU legislation and the role of both the Commission and the Member States to “ensure that policies and legislation are enforced and deliver effectively”. Besides the consideration to revise the Aarhus Regulation to improve access to administrative and judicial review at EU level for citizens and NGOs<sup>471</sup>, the Commission has also announced to take action ‘to improve their access to justice before national courts in all Member States’.

In addition, in October 2020 the Commission published its Communication on Improving Access to Justice in Environmental Matters in the EU and its Member States<sup>472</sup>. In this Communication the Commission acknowledges that “the public is and should remain a driving force of the green transition and should have the means to get more actively involved in developing and implementing new policies”, and that “access to justice in environmental matters, both via the Court of the Justice of the EU (CJEU) and the national courts as Union courts, is an important support measure to help deliver the European Green Deal transition and a way to strengthen the role which civil society can play as watchdog in the democratic space.” In that Communication the Commission also recognised that “individuals and NGOs play a crucial role in identifying potential breaches of EU law” by means of both administrative and judicial review, and thus contribute to improve the enforcement of EU legislation. Furthermore, the Commission invited the co-legislators to include provisions on access to justice in EU legislative proposals made by the Commission for new or revised EU law concerning environmental matters and announced that it seeks active support by the European Parliament and the Council when the Commission comes forward with such proposals.

In this context, with the adoption of Directive (EU) 2020/1828<sup>473</sup> - (adopted after the Chemicals Strategy for Sustainability) – the EU has made substantial progress in this area. This Directive provides for certain “qualified entities” that represent the collective interests of consumers and are designated by the Member States for this purpose, to bring “representative actions” for both injunctive and redress measures against traders that infringe provisions of Union law, in order to protect the interests of consumers. Injunctive measures are sought in order to cease or prohibit an infringing practice, while redress measures require from a trader to provide consumers concerned with remedies such as compensation, repair, replacement, price reduction, contract termination or reimbursement of the price paid. While numerous Directives and Regulations are within

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[in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, OJ L 264, 25.9.2006, p.13.](#)

<sup>470</sup> [Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of Regions, The European Green Deal, COM/2019/640 final.](#)

<sup>471</sup> Which was implemented by [Regulation \(EU\) 2021/1767 of the European Parliament and of the Council of 6 October 2021 amending Regulation \(EC\) No 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, OJ L 356, 8.10.2021, p.1.](#)

<sup>472</sup> [Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of Regions, Improving access to justice in environmental matters in the EU and its Member States, COM\(2020\) 643 final.](#)

<sup>473</sup> [Directive \(EU\) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC \(Text with EEA relevance\), OJ L 409, 4.12.2020, p.1.](#)

its scope, as provided in its Annex I, including the CLP Regulation<sup>474</sup>, the Representative Actions Directive does not apply to REACH.

However, and in any event, representative actions provided for under this Directive could be brought primarily by consumer organisations, and only against traders and for the purpose of protecting the interests of natural persons that qualify as consumers. It would not be applicable for the protection for other natural or legal persons, even if concerned by the same infringement, nor for any infringements damaging the environment as such and in which there are no consumers directly harmed by an unlawful practice. Therefore, in case REACH was brought under the scope of this Directive, it is possible that many infringements of REACH provisions would still be excluded from the scope of protection by means of representative actions, simply because the type of damage and the persons concerned would not be within the scope of the Directive.

In addition to the fact that the protection provided under the Representative Actions Directive is ensured via a more limited consumer protection angle, this Directive provides for a procedural mechanism, but does not ensure the right to (full) compensation for the damage inflicted by the infringement. The type of the remedy that could be sought within the specific representative action (e.g. repair, reduction of price, compensation etc.) will still depend on whether such a remedy is available under national or Union law. In the specific case of the REACH Regulation, if no specific or satisfactory remedy is established under national legislation implementing REACH provisions, the protection provided under this Directive would still not be effectively implemented.

A piece of EU legislation that could be relevant for the specific issue of compensations for breaches of REACH is Directive 2004/35/CE on environmental liability<sup>475</sup>. This Directive establishes a framework of environmental liability based on the ‘polluter-pays’ principle<sup>476</sup>, in order to prevent and remedy environmental damage. More specifically, it aims at ensuring that the financial consequences of certain types of harm caused to the environment will be borne by the economic operator who caused this harm. For this purpose, it provides for two liability regimes: under the first regime of strict liability, operators of certain activities deemed to be of actual or potential concern, listed in Annex III, can be held liable for damage to protected species and natural habitats, water damage and land damage, without the need for establishment of fault or negligence. The second liability regime applies to damage to protected species and natural habitats caused by any occupational activities other than those listed in Annex III, and to any imminent threat of such damage, whenever the operator has been at fault or negligent.

Despite its role in establishing an effective liability regime in general terms, it can be deduced that the scope of the Environmental Liability Directive is, however, limited to damage to protected species and natural habitats, water damage and land damage.

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<sup>474</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1

<sup>475</sup> [Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, OJ L 143, 30.4.2004, p.56.](#)

<sup>476</sup> The principle that the polluter should pay is established in Article 191(2) of the Treaty on the Functioning of the European Union.

Therefore, there would possibly be aspects of REACH infringements that would fall out of its scope. In addition, liability under this Directive has few in common with standard civil liability rules. For instance, it does not give private parties a right of compensation as a consequence of environmental damage or of an imminent threat of such damage occurring.

Recent revisions of environmental legislation have also started to introduce specific provisions for collective redress and compensation, with compensation being added in almost all of these revisions (e.g. proposal for the revision of the Industrial Emissions Directive<sup>477</sup>, proposal for a regulation on deforestation-free products<sup>478</sup> and the proposal for a Nature Restoration Law<sup>479</sup>). (add proposal for revision of the Ambient Air Quality Directive once available).

## 2 DESCRIPTION OF THE PROBLEM

At this stage, REACH has no explicit provision in place to allow for access to justice, collective actions - both by individuals or non-governmental organisations (NGOs) - or for actions to claim any compensation for damage done to human health and the environment as a result of the infringements of its provisions.

In a Recommendation from 2013<sup>480</sup>, the Commission called upon all Member States “to have collective redress mechanisms at national level for both injunctive and compensatory relief, which respect the basic principles set out in this Recommendation. These principles should be common across the Union, while respecting the different legal traditions of the Member States. Member States should ensure that the collective redress procedures are fair, equitable, timely and not prohibitively expensive”. However, compensatory collective redress has been reported<sup>481</sup> to be available only in 19 Member States, but in over half of them it is limited to specific sectors, mainly to consumer claims. Also the differences in scope between the Member States which apply a sectoral approach are substantial, and only 6 Member States have taken a horizontal approach in their legislation, allowing for collective compensation proceedings across all areas. More details on how collective redress is addressed differently in the Member States can be found in a report from BEUC<sup>482</sup>.

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<sup>477</sup> Revision of the Industrial Emissions Directive, <https://ec.europa.eu/environment/industry/stationary/ied/evaluation.htm>

<sup>478</sup> Proposal for a regulation on deforestation-free products, [https://environment.ec.europa.eu/publications/proposal-regulation-deforestation-free-products\\_en](https://environment.ec.europa.eu/publications/proposal-regulation-deforestation-free-products_en)

<sup>479</sup> Nature restoration law, [https://environment.ec.europa.eu/topics/nature-and-biodiversity/nature-restoration-law\\_en](https://environment.ec.europa.eu/topics/nature-and-biodiversity/nature-restoration-law_en)

<sup>480</sup> Commission Recommendation of 11 June 2013 on common principles for injunctive and compensatory collective redress mechanisms in the Member States concerning violations of rights granted under Union Law, OJ L 201, 26.7.2013, p. 60–65

<sup>481</sup> Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation of the Commission Recommendation of 11 June 2013 on common principles for injunctive and compensatory collective redress mechanisms in the Member States concerning violations of rights granted under Union law (2013/396/EU). COM(2018) 40 final

<sup>482</sup> Report: Where does collective redress for individual damages exist. BEUC, 2017. [beuc-x-2017-117 collective redress country survey.pdf](https://www.beuc.eu/files/2017/11/117_collective_redress_country_survey.pdf)

Another report from BEUC<sup>483</sup> also stresses that “national collective redress mechanisms are being developed differently across the EU and, as a result, consumers are being treated differently according to their place of residence” and that “the EU Recommendation on the common principles for collective redress of 2013 did not have a satisfactory impact for this problem”. The report also provides the Volkswagen case as typical example, of divergences in redress mechanism, as the company refuses to compensate European car owners despite having done so for the American consumers.

This situation that collective redress is addressed so differently in the Member States allows that millions of European consumers suffer damages from a trader and leads to unequal conditions in the Single Market, both for consumers and for businesses.

Under Title XIV of REACH, and more specifically Articles 125 and 126 thereof, Member States have the obligation to maintain a system of official controls and other activities as well as lay down provisions for penalties, while provisions that would oblige Member States to establish an adequate regime of access to justice/collective redress/compensations are left at their discretion.

Since the adoption of REACH, a number of policy initiatives –some of which have also been mentioned in the previous section– have set a frame to address such aspects when drafting new or revising existing legislation.

#### *Access to justice*

In the present state of the law, national legal systems do not always provide for efficient means allowing citizens bring a case to court or to an independent body for dispute settlement in case of potential non-compliance of the REACH provisions. The rules vary across the Union and offer different levels of protection for citizens.

#### *Compensation*

REACH risk management measures (e.g. authorisations, restrictions, Annex XIV listing) aim to protect human health and the environment from harmful effects of chemicals. Non-compliance with many of these measures remains an issue (see problem descriptions in previous chapters). This normally leaves affected people with only general mechanisms for compensation under national tort law being available to them, which may largely diverge in their effectiveness across Member States<sup>484</sup>. The Charter of Fundamental Rights of the European Union, in its Article 47, however, provides that everyone “whose rights and freedoms guaranteed by the law of the Union are violated has the right to an effective remedy before a tribunal”. This is also reflected in Article 19(1) TEU which requires Member States to provide remedies sufficient to ensure effective legal protection in the fields covered by Union law, and the case law of the Court of Justice of the European Union on access to justice in environmental matters.

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<sup>483</sup> Report: European collective Redress – what is the EU waiting for. BEUC, 2017. [beuc-x-2017-086\\_ama\\_european\\_collective\\_redress.pdf](https://beuc.europa.eu/086_ama_european_collective_redress.pdf)

<sup>484</sup> Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States , Milieu, 2010. [https://ec.europa.eu/environment/chemicals/reach/pdf/report\\_reach\\_penalties.pdf](https://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf)

There exist differences in liability regimes (strict liability in comparison with fault-based liability) between national legal systems, due to the lack of harmonisation of tort law provisions, that may create difficulties for the fulfilment of this right in some Member States. In any case, the causal link between a pollution event and the respective impact on human health and the environment is a challenge to prove in court. However, where damage to human health and the environment occurs as a result of a violation of REACH risk management measures, among other measures provided for under REACH, the individuals affected should have the right to effectively claim compensation from the polluter. Such damage claims, moreover, serve as an additional enforcement mechanism because companies will have to factor in possible compensation claims if they breach, for instance, the operational conditions and risk management measures established in an authorisation decision or the conditions for the placing on the market of a substance, for which a restriction under REACH has been adopted.

### *Collective redress*

The Chemicals Strategy for Sustainability<sup>485</sup> stresses the importance of actions to empower consumers and consumer organisations “as their behaviour is a powerful driver to industrial change and to ensuring compliance with legislation” and made the commitment to pursue this “by implementing consumer protection rules”. The measure envisaged for this purpose was the representative actions mechanism to collectively enforce breaches of EU law instruments, already foreseen in the proposal for the Representative Actions Directive<sup>486</sup>. Currently, general procedural mechanisms for representative actions, both for injunctive measures and for redress measures, vary across the Union and offer different levels of protection for consumers. In addition, some Member States do not at present have any procedural mechanisms for collective actions for redress measures in place<sup>487</sup>.

The Annex of the Representative Actions Directive, which was finally adopted following the adoption of the Chemicals Strategy, includes several pieces of EU chemicals legislation, but not REACH. Thus, taking into account the choice of the legislator not to consider REACH as a relevant piece of legislation, and in light of the more limited scope of this Directive compared to the scope of REACH, a measure providing collective redress that would be specific for the REACH framework should be envisaged.

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<sup>485</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, [COM\(2020\) 667 final](#), see above.

<sup>486</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of Regions on representative actions for the protection of the collective interests of consumers, and repealing Directive 2009/22/EC, [COM\(2018\) 184 final](#).

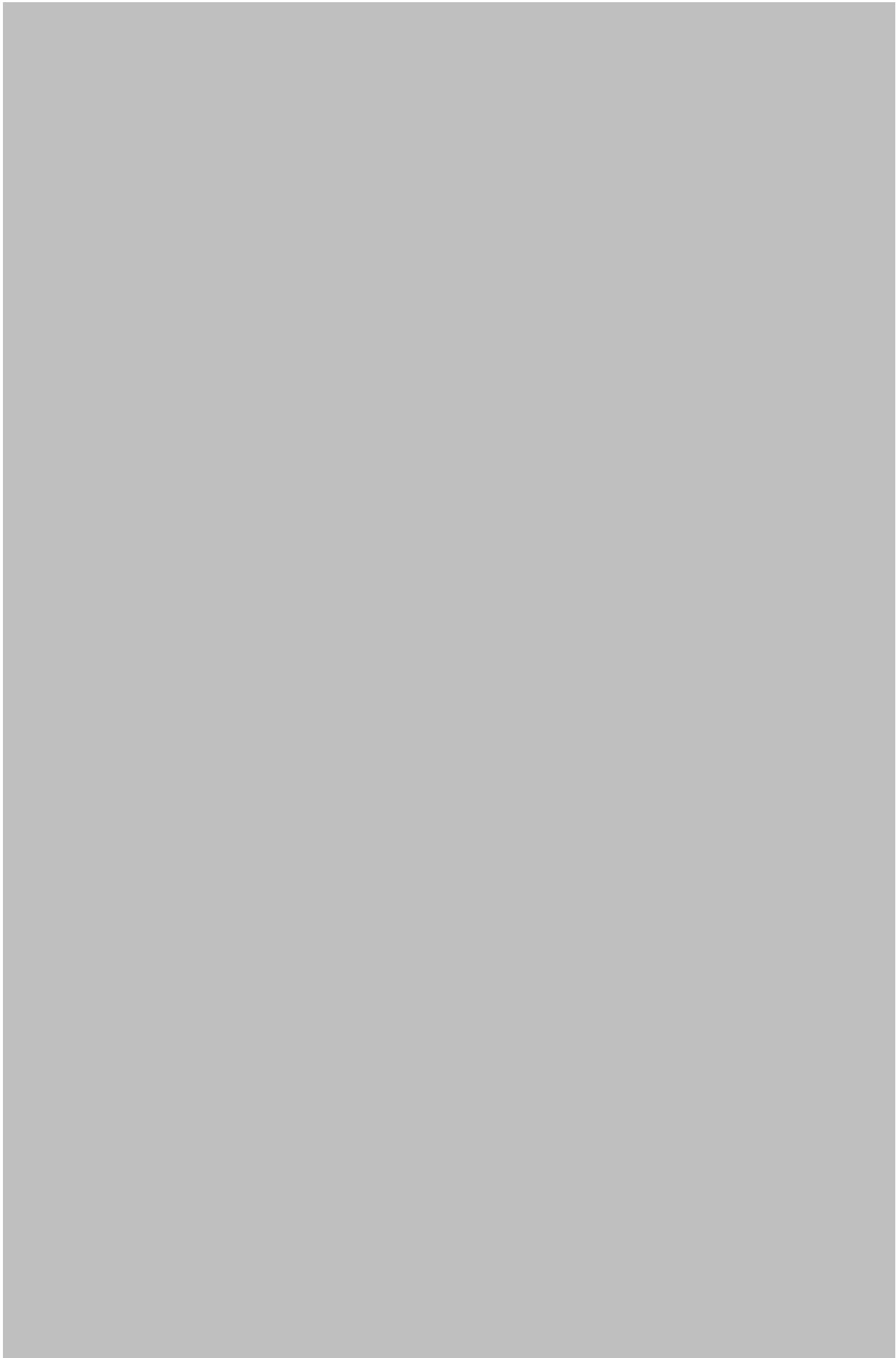
<sup>487</sup> [Directive \(EU\) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC, OJ L 409, 4.12.2020, p.1, recital 6.](#)

### 3 POTENTIAL POLICY OPTIONS

The three policy options considered herein aim to introduce respective provisions into REACH, to address the deficiencies described above. This would be done by three separate but linked provisions to be read together (constituting one option), notably with the following objectives:

- to ensure that, in accordance with the relevant national legal system, members of the public concerned have access to justice in order to bring a case to a court or an independent and impartial body established by law, seeking adequate and effective remedies, including injunctive relief and redress measures as appropriate, [and to challenge omissions of the Member States who have failed to secure compliance with the obligations under REACH];
- to ensure that the public concerned in case of damage to health or the environment, fully or partially as a result of an infringement of measures adopted under this Regulation, are able to claim and obtain compensation for that damage from the relevant natural or legal persons responsible for the infringement, both ;
- to ensure that, as part of the public concerned, non-governmental organisations promoting the protection of human health or the environment and meeting any requirements under national law are allowed to represent the individuals affected and bring collective actions for remedies, including injunctive relief and compensation.









## ANNEX 17: COHERENCE OF THE REACH REVISION WITH OTHER EU OBJECTIVES

As stated in detail in section 4 of the Staff Working Document, the need for the revision of REACH is recognised by the CSS, which is part of the EU's zero-pollution ambition under the European Green Deal. The revision of REACH can be considered coherent with the following further EU objectives and strategies:

- [Zero pollution action plan](#): An action in the European Green Deal on zero pollution, to better prevent, remedy, monitor and report on pollution. Six key 2030 targets in the zero pollution action plan intend to speed up the reduction of pollution at source.
- **European industrial strategy**: The [2020 strategy](#) leads the transition to a green and digital economy in the EU. Three drivers for transformation are outlined in the strategy: a globally competitive and world-leading industry; an industry that paves the way to climate-neutrality; and an industry shaping Europe's digital future. In 2021, the [2020 New Industrial Strategy](#) was updated, taking into consideration the COVID-19 pandemic.
- [Europe's beating cancer plan](#): A political commitment to take action against cancer in the EU, and to address the entire disease pathway along the four key action areas of prevention, early detection, diagnosis and treatment, and quality of life of cancer patients and survivors. Ten flagship initiatives and many supporting actions support the plan.
- [Hydrogen strategy](#): A strategic road map for hydrogen to contribute to reducing greenhouse gas emissions, assist in the recovery of the EU, and build towards a climate-neutral and zero pollution EU economy.
- [Pharmaceuticals strategy](#): A policy instrument which aims to create a 'future proof' regulatory framework, where industry is supporting in promoting research and technologies which patients then receive, while also addressing market failures.
- [Circular Economy Action Plan](#): A key component of the European Green Deal, the plan introduces measures and 35 actions, with initiatives introduced along the entire life cycle of products.
- [European Digital Strategy](#): The strategy aims to make the digital transformation taking place work for people, businesses and the planet, with 3 streams of action covering technology that works for people; a fair and competitive digital economy; and an open, democratic and sustainable society.
- [EU SME Strategy](#) for a sustainable and digital Europe: this strategy is based on three pillars, capacity-building and support for the transition to sustainability and digitalisation; reducing regulatory burden and improving market access; and improving access to financing.

In addition to general EU strategies and action plans, the EU chemicals acquis includes approximately 40 pieces of legislation (see section 1 of the SWD). The coherence of the revision of REACH with these other pieces of legislation should therefore be considered.

The majority of chemicals legislation shares (to some degree) with REACH the common objective to ensure protection of human health and/or the environment. For example, the Industrial Emissions Directive (Directive 2010/75/EU) and Water Framework Directive

(Directive 2000/60/EC) include provisions aiming to reduce emissions of harmful chemicals across the EU. In addition, the Chemical Agents Directive (Directive 98/24/EC) and the Carcinogens, Mutagens and Reprotoxic Substances Directive (Directive 2004/37/EC) include general provisions to protect workers health and safety together with limit values for a number of chemicals. Some substances regulated by each of these pieces of legislation are also regulated by REACH. Therefore, if improvements to REACH help ensure the safe production and use of these substances, their emissions to the environment can be prevented, contributing also to the aims of these pieces of legislation.

# ANNEX 18: GENERAL ECONOMIC OUTLOOK AND THE ECONOMICS OF THE EU CHEMICALS SECTOR

## 1 GENERAL ECONOMIC OUTLOOK

To put the REACH revision in a larger economic perspective, this annex presents a very brief overview of the current economic outlook from a global and European viewpoint. This is followed by figures on the EU chemicals industry in terms of sales, trade and innovation, as well as a future forecast.

### 1.1 IMF World Economic Outlook July 2022

A tentative recovery in 2021 has been followed by increasingly gloomy developments in 2022. The baseline forecast is for global growth to slow from 6.1% in 2021 to 3.2% in 2022. Reduced household purchasing power, and tighter monetary policy drove a downward revision in the United States. In China, further lockdowns and the deepening real estate crisis have led growth to be revised down with major global spillovers. In Europe, significant downgrades reflect spillovers from the war in Ukraine and tighter monetary policy. The risks to the outlook are overwhelmingly tilted to the downside. The war in Ukraine could lead to a sudden stop of European gas imports from Russia; inflation could be harder to bring down than anticipated; tighter global financial conditions could induce debt distress in emerging market and developing economies; renewed COVID-19 outbreaks and lockdowns as well as a further escalation of the property sector crisis might further suppress Chinese growth; and geopolitical fragmentation could impede global trade and cooperation.

### 1.2 EU Summer 2022 Economic Forecast

- **Real GDP** is forecast to grow by 2.7% in 2022 and 1.5% in 2023 in the EU. In the Euro area, 2.6% growth is expected in 2022 and 1.4% in 2023.
- **Inflation** in the EU is forecast to increase to 8.3% in 2022 (7.6% in the Euro area); and to 4.6% in 2023 (4.3% in the Euro area).

The assessment of the economic consequences of the war in Ukraine for the global economy is turning grimmer. The shocks unleashed by the war are hitting the EU economy both directly and indirectly, setting it on a path of lower growth and higher inflation. The rapid increase in energy and food commodity prices is feeding global inflationary pressures, eroding the purchasing power of households and triggering a faster monetary policy response than previously assumed. Real GDP is forecast to grow by 2.7% in 2022 and 1.5% in 2023 in the EU. The projected annual growth rate for is propped up by the momentum gathered with the recovery of last year and a strong first quarter. In 2023, economic growth is expected to gather some momentum, on the back of a resilient labour market, moderating inflation, support from the Recovery and Resilience Facility and a still large amount of excess savings.

## 2 THE EU CHEMICALS SECTOR AT A GLANCE

The chemical sector has developed a strategic role in the European economy, with currently most manufactured goods relying on chemicals to provide a wide range of various functions. Chemicals are at the basis of Europe's major value chains, including pharmaceuticals, electronics, batteries for electric vehicles, construction materials, etc.

The chemical industry is typically made of i) chemicals producers, ii) mixture manufacturers and iii) producers of articles.

The EU-27 is the second largest chemicals producer in the world with EUR 499 billion in sales in 2020. The EU's share of the global chemicals market has reduced from 24.9% in 2000 to 14.4% in 2020. The forecast is that the EU will move from second to third position (10.5% share) by 2030, being overtaken by the US (NAFTA) while China is number one and on the rise with current sales volume of EUR 1 547 billion. By volume, the average annual production growth in the EU from 2010 to 2020 has been relatively flat with an average annual growth of 0.1% over that period.



Figure 40: EU27 share of global chemicals market (2022)

The chemical industry is the fourth largest European producer overall, representing around 7% of manufacturing by turnover<sup>493</sup>. It accounts for more than 20% of EU exports in goods and generates a trade surplus of EUR 36.4 billion. On the labour market, it provides 1.2 million direct highly skilled jobs and 3.6 million indirect jobs in addition to supporting around 19 million jobs across all value supply chains. SMEs are present at every level of the chemical supply chain: as manufacturers of raw materials, formulators, distributors and users of chemicals.

Investments in research and innovation (R&I) and patents filed are two indicators of levels of innovation. In 2020, spending on R&I in the chemicals industry reached EUR 9.4 billion<sup>494</sup>. Whilst the EU has seen an increase in R&I spending of 34% since 2010, globally the increase was almost the double (about 65%). China has seen an increase of 225% over the same period, spending EUR 14 billion in 2020. This is consistent with the number of patents being filed in the region, with data from the World Intellectual

<sup>493</sup> CEFIC, 2022. The European chemical industry: a vital part of Europe's future. Facts & Figures 2022.

<sup>494</sup> OECD and Cefic Chemdata International

Property Organization (WIPO)<sup>495</sup> showing a large increase in chemicals-related patents in Asia, compared to other regions, between 2003 and 2016<sup>496</sup>.

Manufacturing and transport of chemicals is energy intensive as fuel is not only a source of energy but also a raw material input. In fact, it is the largest contributor in terms of carbon dioxide emissions (920Mt CO<sub>2</sub> in 2020<sup>497</sup>), behind cement and iron steel. However, the industry is permanently innovating in order to become more energy efficient and to use low-carbon technologies. With its innovation capacity, the EU chemical industry plays a key role in developing safe and sustainable substances and mixtures, as well as process technologies that can help other sectors of the economy in their own climate transition. The chemical industry will also play a central role in achieving a circular economy in numerous value chains, creating sustainable carbon cycles by recycling waste streams into new chemicals and materials, by offering defossilisation options and by further developing bio-based materials and solutions.

Given its size and strategic relevance, the chemical industry is at the centre of the European Green Deal and a major contributor to achieving its targets and objectives. In addition. The chemicals industry is fundamental for the digitalisation transformation, serving as an enabler for many other industries. Such contributions remains dependent on the industry's ability to stay competitive and to attract global investments.

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<sup>495</sup> World Intellectual Property Organization (2018). Patentscope.  
<https://patentscope.wipo.int/search/en/search.jsf>

<sup>496</sup> United Nations Environment Programme. (2019). 1. The evolving chemicals economy: status and trends relevant for sustainability. Available at: <https://www.unep.org/resources/report/global-chemicals-outlook-ii-legacies-innovative-solutions>

<sup>497</sup> IEA Tracking Report, November 2021: Chemicals – Analysis - IEA



## ANNEX 19: REFERENCES

- Amec Foster Wheeler, Eftec, & University, B. (2017). *Study on the cumulative health and environmental benefits of chemicals legislation*. Brussel: European Commission.
- Annamalai, J., & Namasivayam, V. (2015). Endocrine disrupting chemicals in the atmosphere: Their effects on humans and wildlife. *Environment International*, 76, 78-97.
- Arts, J. (2020). How to assess respiratory sensitization of low molecular weight chemicals? *International Journal of Hygiene and Environmental Health*. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/32058937/>
- Baakhuis. (2019). Testing developmental toxicity in a second species: are the differences due to species or replication error? *Regul Toxicol Pharmacol*, Regulatory Toxicology and Pharmacology 107 (2019) 104410.
- Baynes, A., Jobling, S., Lange, A., & Tyler, C. R. (2020). *Oestrogenic effects in wild fish: comparing contemporary and historical impacts*. Bristol: Environment Agency.
- Benucci, & al., e. (2016). Costs associated with rheumatoid arthritis in Italy: past, present, and future. *Clinico Economics and Outcomes Research*, 8, 33–41.
- Bieleninik, L., & Gold, C. (2021). Estimating Components and Costs of Standard Care for Children with Autism Spectrum Disorder in Europe from a Large International Sample. *Brain Science*, 11(340). doi:<https://doi.org/10.3390/brainsci11030340>
- Cambridge University Press. (2022). *Cambridge Dictionary: Capacity*. Retrieved February 20, 2022, from <https://dictionary.cambridge.org/dictionary/english/capacity>
- Cohen, S. (2017). The relevance of experimental carcinogenicity studies to human safety. *Current Opinion in Toxicology*, 6–11. Retrieved from <https://doi.org/10.1016/j.cotox.2017.04.002>
- Commission, E. (2020). *Executive summary of the Fitness Check on Endocrine Disruptors*.
- Congress, U. S. (1996, August 3). Food Quality Protection Act of 1996. *Public Law No. 104–170, 110 Stat. 1489 (104th Congress)*.
- CSES, R. O. (2015). *Monitoring Impacts of REACH on Innovation, Competitiveness and SMEs*. Retrieved from <http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native>
- CSES, RPA, & Oekopol. (2015). *Monitoring the impacts of REACH on innovation, competitiveness and SMEs*.
- Daley, D., Jacobsen, R., Lange, A.-M., Sørensen, A., & Walldorf, J. (2019). The economic burden of adult attention deficit hyperactivity disorder: A sibling comparison cost analysis. *European Psychiatry*, 61, 41-48. doi:<https://doi.org/10.1016/j.eurpsy.2019.06.011>
- de Brouwere, K. C. (2014). Application of the maximum cumulative ratio (MCR) as a screening tool for the evaluation of mixtures in residential indoor air. *Science of the Total Environment*, 479, 267-276.
- Doe, J. e. (2019). Chemical carcinogenicity revisited 2: Current knowledge of carcinogenesis shows that categorization as a carcinogen or non-carcinogen is not scientifically credible. *Regulatory Toxicology and Pharmacology*, 124-129. Retrieved from doi: 10.1016/j.yrtph.2019.01.024.
- ECHA. (n.d.). Retrieved from <https://echa.europa.eu/applying-for-authorisation/evaluating-applications>
- ECHA. (2012). *Guidance on information requirements and chemical safety assessment; Chapter R.8: Characterisation of dose[concentration]-response for human health*. Helsinki: ECHA.
- ECHA. (2015). *Monitoring the Impacts of REACH on Innovation, competitiveness and SMEs - Final Report*. Luxembourg: Publications Office of the European Union.

- ECHA. (2016). *Valuing selected health impacts of chemicals: Summary of the results and a critical review of the ECHA study*.
- ECHA. (2017). Strategies and minimum criteria for enforcement of Chemical regulations.
- ECHA. (2017a). *Willingness-to-pay values for various health endpoints associated with chemicals exposure*. 32nd MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS.
- ECHA. (2020). *FORUM REF-7 project report on registration duties*. Helsinki, Finland: European Chemicals Agency.
- ECHA. (2020). *Impacts of REACH restriction and authorisation on substitution in the EU*. doi:10.2823/39789
- ECHA. (2021). *Costs and Benefits of REACH restrictions proposed between 2016-2020*.
- ECHA. (2021). *Socio-economic impacts of REACH authorisations - A meta-analysis of the state of play of applications for authorisation*. doi:10.2823/893300
- ECHA. (2021a). *Costs and benefits of REACH restrictions proposed between 2016-2020*. doi:10.2823/122943
- ECHA. (2022a). *Budget 2022*. Retrieved from <https://echa.europa.eu/de/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2022>
- ECHA and European Commission. (2018). *REACH Evaluation joint Action Plan*. Retrieved from [https://echa.europa.eu/documents/10162/21877836/final\\_echa\\_com\\_reach\\_evaluation\\_action\\_plan\\_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17](https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17)
- ECHA. (n.d.). *Progress in Evaluation*. Retrieved September 06, 2022, from ECHA: <https://echa.europa.eu/overall-progress-in-evaluation>
- ECHA. (n.d.). Statistics on received applications for authorisation and review reports. Retrieved September 14, 2022, from <https://echa.europa.eu/sv/received-applications>
- EEA. (2020). *The European Environment - state and outlook 2020*. European Environment Agency.
- EFTEC. (2018). *Impacts of REACH authorisation : final report*.
- Emiel Rorije, P. N. (2022). Characterization of ecotoxicological risks from unintentional mixture exposures calculated from European freshwater monitoring data: Forwarding prospective chemical risk management. *Science of the Total Environment* 822 (2022) 153385.
- Environment Agency (UK). (2020). *Oestrogenic effects in wild fish: comparing contemporary and historical impacts*.
- European Parkinson's Disease Association. (n.d.). *The European Parkinson's disease standards of care consensus statement*. Retrieved from <https://www.parkinsonseurope.org/media/1181/epda-consensus-statement-en.pdf>
- European Commission . (2021). Commission Regulation (EU) 2021/979, OJ L 216, 18.6.2021, p. 121–132. OJ.
- European Commission. (1999). *Communication from the Commission to the Council and the European Parliament: Community Strategy for Endocrine Disruptors (COM (99)706)*. Retrieved from <https://ec.europa.eu/environment/archives/docum/99706sm.htm>
- European Commission. (2018). *Commission General Report on the operation of REACH and review of certain*. Brussels: SWD(2018) 58 final.
- European Commission. (2018). *Commission Staff Working Document (SWD(2019) 58 Final Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions: Annex 5 (COM(2018) 116 final)*.
- European Commission. (2018). *General Report on the operation of REACH, SWD(2018) 58 final. Action 3 Improving the quality & workability of the extended SDS, and Action 12 REACH-OSH interface*.

- European Commission. (2018d). *Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC, methodological note.*
- European Commission. (2018e). *Towards a comprehensive European Union framework on endocrine disruptors COM/2018/734 final.*
- European Commission. (2020). *Review of certain provisions of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), as laid down in Article 138.* Retrieved from [https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD\\_article\\_138.pdf](https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_article_138.pdf)
- European Commission. (2020e). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment COM/2020/667 final.*
- European Commission. (2022). Commission Regulation (EU) 2022/477, OJ L 98, 25.3.2022, p. 38–53.
- European Environment Agency. (2012). *The impacts of endocrine disruptors on wildlife, people and their environments.* Copenhagen: European Environment Agency.
- European Environment Agency. (2012). *The impacts of endocrine disruptors on wildlife, people and their environments.*
- European Environment Agency. (2012). *The impacts of endocrine disruptors on wildlife, people and their environments.* Copenhagen: European Environment Agency.
- European Parliament. (2021). *P9\_TA(2021)0387 Plans and actions to accelerate a transition to innovation without the use of animals in research, regulatory testing and education.* Resolution.
- Eurostat. (2020). *Eurobarometer Survey: Attitudes of Europeans towards the Environment - March 2020.*
- Falk, K., Møller, S., Rigét, F. F., Sørensen, P. B., & Vorkamp, K. (2018). A long-term increase in eggshell thickness of Greenlandic Peregrine Falcons *Falco peregrinus tundrius*. *Ornis Hungarica* 2018, 26(2), 171-176.
- Felter, S. e. (2018). Human relevance of rodent liver tumors: Key insights from a Toxicology Forum workshop on nongenotoxic modes of action. *Regulatory Toxicology and Pharmacology*, 1 - 7. Retrieved from <https://doi.org/10.1016/j.yrtph.2017.11.003>
- Gibson, J., & al., e. (2013). *Lung Health in Europe. Facts and Figures.* Sheffield: European Respiratory Society - European Lung Foundation.
- Golden, J. H.–S. (2021). *Green Chemistry: A Strong Driver of Innovation, Growth, and Business Opportunity.* Lowell, MA: Sustainable Chemistry Catalyst, Lowell Center for Sustainable Production, University of Massachusetts Lowell. Retrieved from <https://greenchemistryandcommerce.org/documents/GC3GreenChemReport-ES-Nov2021.pdf>
- Goodman, J. (2018). Goodbye to the bioassay. *Toxicology Research*, 558-564. Retrieved from <https://doi.org/10.1039/c8tx00004b>
- Gray, J. R. (2017). State of the evidence 2017: an update on the connection between breast cancer and the environment. *Environmental Health* 16, 94 (2017). doi:<https://doi.org/10.1186/s12940-017-0287-4>
- Hamilton, D., Dee, A., & Perry, J. (2018, April). The lifetime costs of overweight and obesity in childhood and adolescence: a systematic review. *Obesity Reviews*, 19(4), 452-463. doi:doi: 10.1111/obr.12649
- HM Treasury. (2020). *The Green Book.* Retrieved from <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government/the-green-book-2020>
- Hood, E. (2006). Endocrine Disruption and Flame-Retardant Chemicals. *Environmental Health Perspectives*, 114, 112-113.

- Ing-Marie Olsson et al. (2014). *The Cost of Inaction: A Socioeconomic analysis of costs linked to effects*. Nordic Council of Ministers.
- International Diabetes Federation. (2021). *Diabetes in Europe – 2021*. Retrieved from [https://www.mepinterestgroupdiabetes.eu/wp-content/uploads/2021/11/IDF-Atlas-Factsheet-2021\\_EUR.pdf](https://www.mepinterestgroupdiabetes.eu/wp-content/uploads/2021/11/IDF-Atlas-Factsheet-2021_EUR.pdf)
- Jacobs, M. (2016). International regulatory needs for development of an IATA for non-genotoxic carcinogenic chemical substances. *Altex*. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/27120445/>
- Jing-Jing Fan, S. W.-P.-L.-X.-L.-X. (2019). Bioaccumulation of endocrine disrupting compounds in fish with different feeding habits along the largest subtropical river, China. *Environmental Pollution*, 247, 999-1008.
- Johnsson. (2022). The personal economic burden of dementia in Europe. *Lancet Reg Health Eur*. doi:10.1016/j.lanpe.2022.100472
- Joint Task Force. (2017). *ECHA Committee on Risk Assessment (RAC) and Scientific Committee on Occupational Exposure Limits (SCOEL) on Scientific aspects and methodologies related to the exposure of chemicals at the workplace*. Helsinki: ECHA.
- KEMI. (2021). *Kemikalieinspektionen*. Retrieved June 24, 2022, from <https://www.kemi.se/publikationer/rapporter/2021/rapport-6-21-increased-e-commerce-increased-chemicals-risks>
- Klar, M., Rumar, K., & Ramström, F. (2020). Nordic project on enforcement of internet trade. Retrieved from <http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1424143&dsid=-5968>
- Kortenkamp, A. S. (2022). Combined exposures to bisphenols, polychlorinated dioxins, paracetamol, and phthalates as drivers of deteriorating semen quality. *Environment International*, p.107322. .
- Lintelmann, J., Katayama, A., Kurihara, N., Shore, L., & Wenzel, A. (2003). *ENDOCRINE DISRUPTORS IN THE ENVIRONMENT*. Pure Appl. Chem.
- Lv, Y.-Z., Yao, L., Wang, L., Liu, W.-R., Zhao, J.-L., Liang-YingHe, & Guang-GuoYing. (2019). Bioaccumulation, metabolism, and risk assessment of phenolic endocrine disrupting chemicals in specific tissues of wild fish. *Chemosphere*, 226, 607-615.
- M. Salapasidou, C. S. (2011). Endocrine disrupting compounds in the atmosphere of the urban area of Thessaloniki, Greece. *Atmospheric Environment*, 3720-3729.
- Madia, F., Worth, A., & Corvi, R. (2019). Carcinogenicity Assessment: Addressing the challenges of cancer and chemicals in the environment. *Environ Int*, 417-429. Retrieved from doi: 10.1016/j.envint.2019.04.067.
- Manon Sorais, M. J.-F. (2020). Landfills represent significant atmospheric sources of exposure to halogenated flame retardants for urban-adapted gulls. *Environment International*, 135.
- Markert, N. R. (2020). Mixture toxicity in the Erft River: assessment of ecological risks and toxicity drivers. . *Environmental Sciences Europe*, 32, 1-13.
- N. Salgueiro-González, M. L.-L.-R. (2014). *Analysis and occurrence of endocrine-disrupting chemicals in*. Trends in Analytical Chemistry.
- Novo, M., Verdu, I., Trigo, D., & Martinez-Guitarte, J. L. (2018). Endocrine disruptor in soil: effects of bisphenol A on gene expression of the earthworm *Eisenia fetida*. *Ecotoxicology and Environmental Safety*.
- Odsjö, T., & Sondell, J. (2014). Eggshell thinning of osprey (*Pandion haliaetus*) breeding in Sweden and its significance for egg breakage and breeding outcome. *Science of The Total Environment*, 470-471, 1023-1029.

- Olsson, I. e. (2014). *The Cost of Inaction - A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health*. Norden. Retrieved from <https://www.norden.org/en/publication/cost-inaction>
- Oltmanns, J., Licht, O., Bohlen, M.-L., Schwarz, M., Escher, S. E., Silano, V., . . . Merten, C. (2020). Potential emerging chemical risks in the food chain associated with substances registered under REACH. *Environmental Science: Processes & Impacts*(1).
- Oosterhuis, F., & Brouwer, R. (2015, September 21). *Benchmark development for the proportionality*. IVM Institute for Environmental Studies. Retrieved from [https://echa.europa.eu/documents/10162/17241/R15\\_11\\_pbt\\_benchmark\\_report\\_en.pdf/a695a7fd-e2bd-4dc5-b69a-bc02f9f98fef?t=1449837319194](https://echa.europa.eu/documents/10162/17241/R15_11_pbt_benchmark_report_en.pdf/a695a7fd-e2bd-4dc5-b69a-bc02f9f98fef?t=1449837319194)
- Paz-Zulueta. (2020, August). A literature review of cost-of-illness studies on the economic burden of multiple sclerosis. *Multiple Sclerosis and Related Disorders*, 43. doi:<https://doi.org/10.1016/j.msard.2020.102162>
- PFA, W. a. (2020). *Scientific and technical support for the development of criteria to identify and group polymers for Registration/ Evaluation under REACH and their impact assessment*.
- Posthuma, L. v. (2019). Species sensitivity distributions for use in environmental protection, assessment, and management of aquatic ecosystems for 12 386 chemicals. . *Environmental toxicology and chemistry*, 38(4), pp.905-917.
- R Thomas Zoeller, Å. B. (2014). A path forward in the debate over health impacts of endocrine disrupting chemicals. *Environmental Health*, 13, 118.
- Rabea Gräpel, A. R. (2014). *ASSESSMENT OF THE ADDED VALUE OF INFORMATION FROM A SECOND SPECIES IN THE EVALUATION OF PRENATAL DEVELOPMENTAL TOXICITY*. Special briefing under the terms of Service Level Agreement SLA/ECHA-JRC/2012-2, European Commission Joint Research Centre.
- Ricardo. (2021). *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability*. Final Report for European Chemicals Industry Council. Retrieved from <https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf>
- Ricardo. (2021). *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability*. Phase 1 report. Retrieved from <https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf>
- Ricardo. (2022). *Gather Further Information to be Used in Support of an Impact Assessment of Potential Options, for the Update of REACH Annexes for Inclusion of Data Requirements on Endocrine Disruption*.
- Rijk, I., van Duursen, M., & ven den Berg, M. (2016). *Health costs that may be associated with Endocrine Disrupting Chemicals*. Universiteit Utrecht, Institute for Risk Assessment Sciences. Retrieved from [https://www.uu.nl/sites/default/files/rijk\\_et\\_al\\_2016\\_-\\_report\\_iras\\_-\\_health\\_cost\\_associated\\_with\\_edcs\\_3.pdf](https://www.uu.nl/sites/default/files/rijk_et_al_2016_-_report_iras_-_health_cost_associated_with_edcs_3.pdf)
- RPA. (2017). *Study to gather further information to be used in support of an Impact Assessment of .....*
- RPA. (2017). *Study to gather further information to be used in support of an Impact Assessment of potential options, in particular possible Amendments of REACH Annexes*. Retrieved from <https://op.europa.eu/en/publication-detail/-/publication/9380c012-055f-11e7-8a35-01aa75ed71a1>
- RPA. (2020). *Gather further information to be used in support of an Impact Assessment of potential options, in particular possible amendments of REACH Annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement*.
- RPA. (2020). *Study to gather further information to be used in support of an impact assessment of potential options, in particular possible amendments of REACH Annexes, to modify requirements for registration of low tonage substances (1-10t/year) & the CSA/CSR requi*. Report prepared for DG Environment.

- RPA; Fobig. (2017). *The Cost of Occupational Cancer in teh EU-28*. Retrieved from [https://www.etui.org/sites/default/files/ez\\_import/RPA+FOBIG+-+The+Cost+of+Occupational+Cancer++in+the+EU-28++November+2017.pdf](https://www.etui.org/sites/default/files/ez_import/RPA+FOBIG+-+The+Cost+of+Occupational+Cancer++in+the+EU-28++November+2017.pdf)
- Ruthann A. Rudel, L. J. (2008). Endocrine disrupting chemicals in indoor and outdoor air. *Atmospheric Environment*, 170-181.
- Sachana, M. (2021). The potential of mechanistic information organised within the AOP framework to increase regulatory uptake of the developmental neurotoxicity (DNT) in vitro battery of assays. *Reproductive Toxicology*. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/34147625/>
- Sauve-Cienciewicki, A. (2019). A simple problem formulation framework to create the right solution to the right problem. *Regulatory Toxicology and Pharmacology*. Retrieved from <https://www.sciencedirect.com/science/article/pii/S0273230018303076>
- Scalone, & al., e. (2015). The societal burden of chronic liver diseases: results from the COME study. *BMJ Open Gastro*, 2. doi:doi:10.1136/ bmjgast-2014-000025
- Sebastian Socianu, S. K. (2022). Chemical Mixtures in the EU Population: Composition and Potential Risks. *International Journal of Environmental Research and Public Health*, 19, 6121.
- Selroos, & al., e. (2015). National and regional asthma programmes in Europe. *European Respiratory Review*, 24, 474-483. doi:DOI: 10.1183/16000617.00008114
- Simoens, & al., e. (2012). The burden of endometriosis: costs and quality of life of women with endometriosis and treated in referral centres. *Human Reproduction*, 27(5), 1292-1299.
- Soliman, A. M., Yang, H., Du, E. X., K. S., & Winkel, C. (2015). The direct and indirect costs of uterine fibroid tumors: a systematic review of the literature between 2000 and 2013. *American journal of obstetrics and gynecology*, 213(2), 141-160.
- Spurgeon, D. B. (2021). *Worst-case ranking of organic substances detected in groundwater and surface waters in England*. Report ENV6003531R to the UK Environment Agency.
- Sullivan, K. M. (2017). An Adverse Outcome Pathway for Sensitization of the Respiratory Tract by Low-Molecular-Weight Chemicals: Building Evidence to Support the Utility of In Vitro and In Silico Methods in a Regulatory Context. *Applied In Vitro Toxicology*. Retrieved from <https://www.liebertpub.com/doi/10.1089/aivt.2017.0010>
- van Gils, J., Posthuma, L., Cousins, I. T., Brack, W., Altenburger, R., Baveco, H., . . . W, v. (2020). Computational Material Flow Analysis for Thousands of Chemicals of Emerging Concern in European Waters. *Journal of Hazardous Materials* 2020, 397, 122655. .
- Verbruggen, V. V. (2007). *Guidance for the derivation of environmental risk limits within the framework of ‘International and national environmental quality standards for substances in the Netherlands’*. Bilthoven, The Netherlands: RIVM report 601782001/2007.
- Vos, J. G., Dybing, E., Greim, H. A., Ladefoged, O., Lambre, C., Tarazona, J. V., . . . Vethaak, A. D. (2000). Health effects of endocrine-disrupting chemicals on wildlife, with special reference to the European situation. *Critical Reviews in Toxicology*, 30(1).
- Wegner, P., Kleinstäuber, G., Baum, F., & Schilling, F. (2005). Long-term investigation of the degree of exposure of German peregrine falcons (*Falco peregrinus*) to damaging chemicals from the environment. *Journal of Ornithology*, 146, 34-54.
- WHO. (2017). *Guidelines for drinking-water quality, 4th edition*. World Health Organization.
- Wilkins, E., & al., e. (2017). *European cardiovascular disease statistics 2017*.
- Wood. (2021). *Study on the impacts of the 2018 REACH registration deadline : final report*. European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. doi:<https://data.europa.eu/doi/10.2873/934585>
- Wood. (2022). *Assessment of the impacts of policy options for increased REACH information requirements*.

- Wood. (2022). *Technical note: Assessment of the impacts of policy options for increased information requirements*. Document submitted under contract No 09029901/2021/853548/SFRA/ENV.B.3 on technical and scientific support to the Commission's impact assessment for the revision of REACH.
- Wood, & PFA-Brussels. (2020). *Scientific and technical support for the development of criteria to identify and group polymers for registration/ evaluation and their impact assessment*.
- Wood, E. G. (2022). *Technical note: Registration of polymers under REACH*.
- Wood, PFA and Milieu. (2021). *Study on the impacts of the 2018 REACH registration deadline, final report for the European Commission, May 2021*. Retrieved from <https://op.europa.eu/en/publication-detail/-/publication/bbf2a250-c996-11eb-84ce-01aa75ed71a1/language-en>