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IMPACT ASSESSMENT REPORT

Accompanying the 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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LIST OF ABBREVIATIONS & GLOSSARY

Term or acronym	Definition and/or meaning
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the Classification, Labelling and Packaging of Substances and Mixtures
CMR	Carcinogenic, Mutagenic, Reproductive toxic substances
CSA/CSR	Chemical Safety Assessment: An assessment of the chemical substance according to requirements in Annex I. The CSA is documented in the Chemical Safety Report.
DU	Downstream User: An economic operator in the supply chain who buys a substance from a manufacturer or importer or another downstream user.
ECHA	European Chemicals Agency: The European Chemicals Agency is the EU agency for chemicals, dealing with the implementation of EU legislation related to chemicals, including but not only limited to REACH. The Agency has been established via Title X of REACH and started its operations in 2007.
EDC	Endocrine Disrupting Compound: substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations.
GRA	Generic Risk management Approach: The GRA implies that restrictions in Annex XVII of REACH, are based on the hazardous properties of chemicals and on generic considerations on potential exposures and risks. GRA restrictions currently apply in REACH to CMR substances (cat. 1A and 1B) in consumer uses.
MSC	Member State Committee
MSCA	Member State Competent Authority
PBT/vPvB	Persistent, Bioaccumulative and Toxic and very Persistent and very Bioaccumulative substances: PBT/vPvB substances persist for long periods of time in the environment and have a high potential to accumulate in biota.
PMT/vPvM	Persistent, Mobile and Toxic and very Persistent and very Mobile substances: PMT/vPvM substances are persistent and mobile in the aquatic environment. These intrinsic substance properties allow them to spread to the sources of our drinking water.
PRR	Polymers Requiring Registration: Polymers related to which risks are more likely to occur.
RAC	Risk Assessment Committee: ECHA's scientific committee

Term or acronym	Definition and/or meaning
	that prepares the opinions of ECHA related to the risks of substances to human health and the environment in the following REACH and CLP processes.
REACH	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)
SDS	Safety Data Sheet: Safety data sheets include information about the properties of the substance or mixture, its hazards and instructions for handling, disposal and transport and also first-aid, fire-fighting and exposure control measures.
SEAC	Socio-Economic Analysis Committee: SEAC prepares the opinions of ECHA related to the socio-economic impact of possible legislative actions on chemicals in the following REACH processes.
STOT	Specific Target Organ Toxicity
SVHC	Substance of Very High Concern: are substances that meet the criteria set in Article 57 of REACH, i.e. CMR, PBTs and vPvB substances and substances that have an equivalent level of concern, such as EDC. SVHCs can be subjected to the authorisation requirement, following the procedures in Title VII of REACH.

1 INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Chemicals are everywhere in our daily lives. They are fundamental for our well-being and support key technologies to address the urgent planetary challenges of climate change. However, chemicals with hazardous properties can harm human health and the environment, their presence in products can prevent recyclability of materials, hence hamper the efforts towards a circular economy, and chemical pollution can aggravate biodiversity loss and climate change. The EU is the second largest producer of chemicals in the world with EUR 541 billion turnover in 2018 (7.0% of EU manufacturing by turnover) and 14.4% of global sales in 2020 (CEFIC, 2022)[1]. The chemical industry is one of the most energy-intensive industries and relies on natural gas not only as energy source but also as raw material. The current high energy prices are, therefore, a challenge for the EU chemical industry to maintain its competitiveness on the global market[2]. The EU's chemical sector sells 56% of the chemicals it produces to supply almost all other industrial sectors (e.g. textiles, construction, agriculture, transport, health, hygiene, housing, food).

This impact assessment focuses on the revision of Regulation (EC) No 1907/2006 on the **Registration, Evaluation, Authorisation and Restriction of Chemicals** (REACH) within the wider policy context and the changes envisaged to other relevant legislation. Together with Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP), **REACH is the key EU legislation for the assessment and management of chemicals.** While CLP regulates the classification of substances based on their intrinsic hazard, which determines the packaging and labelling requirements, REACH ensures that companies provide relevant information on the substances they place on the market so to enable the identification of the hazards under CLP. REACH also calls on companies to ensure that the substances are used safely. REACH also provides a horizontal framework for the management of risks to human health and the environment arising from chemicals (see Box 1 for an overview of REACH processes). Sectorial legislation complements the EU framework on risk assessment and management of chemicals. The fitness check on the most relevant chemicals legislation (excluding REACH) identified 40 different pieces of chemical-specific and product-specific EU legislation addressing chemicals (European Commission, 2019). Generally, this body of legislation can be grouped into worker safety legislation (e.g. carcinogens, mutagens and reprotoxic substances at work), environmental protection legislation (e.g. water and industrial emissions) and products control legislation (e.g. detergents, toys, cosmetics etc.).

Since its enactment in 2007, **REACH has been the most advanced regulatory framework producing the largest knowledge base on chemicals globally**. The latest REACH evaluation[3] concluded that REACH is effective but that there are opportunities for further improvement, simplification and burden reduction (European Commission, 2018). Following the evaluation, a number of non-legislative actions were launched (most have been finalised)

[1] Within the EU, two thirds of these sales are generated in four Member States: Germany (32.1%), France (13.5%), Italy (10.7%) and the Netherlands (8.9%) (CEFIC, 2022). See Annex 18 for more information on the chemical sector in the EU.
[2] According to the chemical industry association (August 2022 report), "chemicals production declined by 0.7% in January-June 2022 compared to the first half of 2021. Output in the chemical industry fell markedly in two out of the largest EU economies, Germany (-5.2%), and France (-1.9%), while it remained broadly stable in Italy (+0.4%)". At the same time, NGOs highlighted the latest results of the chemical producer BASF, based on their 2022 second quarterly report: "due to the very positive business development in the first half of 2022, they now expect sales to grow to as much as €89 billion this year (compared to the previous forecast of up to €77 billion)."
[3] Hereinafter referred to as "latest REACH Evaluation".

to improve the implementation of REACH. However, there are problems that remain unaddressed (see section 2).

The Chemicals Strategy for Sustainability (thereon 'the Strategy') (European Commission, 2020) is the first delivery of the zero-pollution ambition set in the European Green Deal (European Commission, 2019). Building on the findings of the latest REACH Evaluation, the Strategy announced the revision of REACH, as well as of CLP and sectorial legislation containing provisions on chemicals. In particular, the Strategy calls for the REACH and CLP Regulations to be reinforced as the EU's cornerstones for regulating chemicals, and to be complemented by coherent approaches to assess and manage chemicals in existing sectorial legislation, especially in relation to consumer products.

The revision of CLP is on-going and includes *inter alia* the introduction of new hazard classes and prioritisation of substances for harmonised classification. In addition to the CLP revision, relevant sectorial legislation currently under revision includes the Cosmetic Products Regulation, the Toys Safety Directive, the Detergents Regulation, the Food Contact Materials Regulation, the Industrial Emissions Directive, the Packaging Waste Directive, the Directive on Restriction of Hazardous Substances in Electrical and Electronic Equipment, and the Batteries Directive. Moreover, as part of the 'One substance, one assessment' approach stemming from the European Green Deal, the Commission is preparing a regulation on the availability, accessibility and interoperability of data on chemicals and is planning to reattribute tasks between EU agencies to ensure consistency in the assessment of chemicals and improve efficiency. This will be accompanied by a standalone Regulation on the European Chemicals Agency (ECHA) to strengthen its governance and its financing model, replacing Title X of REACH[4]. Figure 1 presents the interaction within EU legislation for the assessment of chemical hazard and risk, and for risk management. It also illustrates the complementary nature of the CLP and REACH revisions. For example, the new information requirements under REACH will provide information on the intrinsic properties of substances allowing their classification under the new hazard classes envisaged in the revised CLP. In turn, the harmonised classification of substances for those hazards will be the basis for increased risk management under the revised REACH, but also other pieces of sectorial legislation currently under revision as detailed above.

[4] To be noted that ECHA was established via REACH and its functioning and governance are regulated by Title X of REACH. However, over the years ECHA has taken over additional tasks related to the implementation of other EU legislation and policies related to chemicals, e.g. work on poison centres, PIC Regulation.

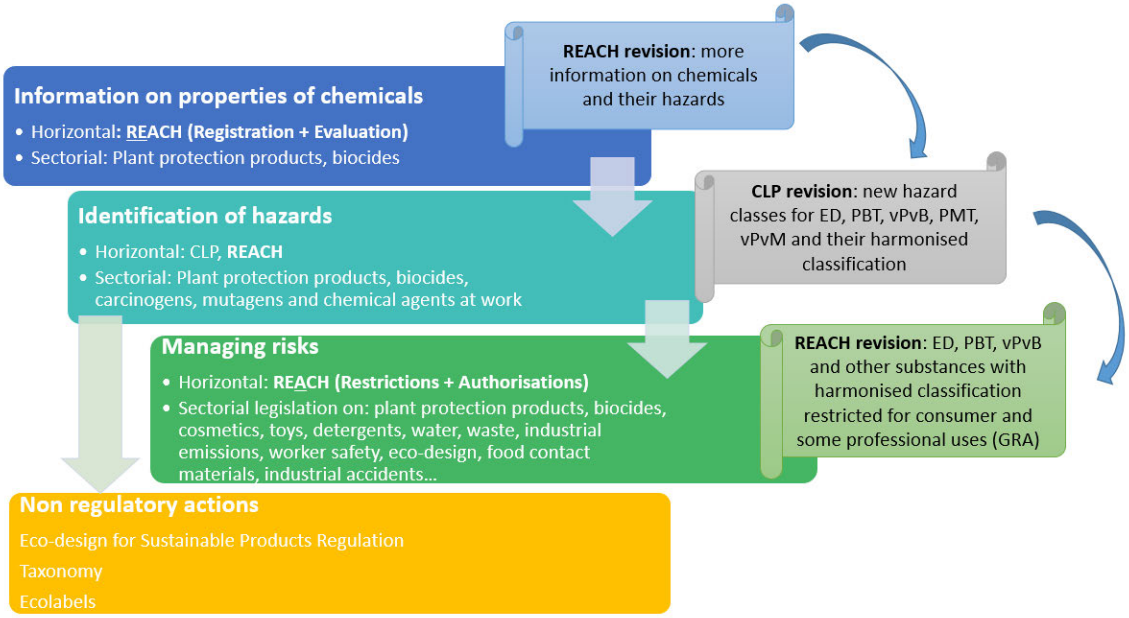

Figure 1: Interaction between REACH and other EU legislation related to chemicals

The Strategy also envisages that chemicals should be produced and used safely and sustainably by 2030. This aims to avoid the negative impacts of chemicals on human health and the environment, while fully exploiting their benefits for the economy and society, safeguarding the competitiveness of EU industry and increasing its innovation capacity. The planned revision of REACH works in conjunction with the establishment of a framework for safe and sustainable by design, the adoption of the Regulation on eco-design for sustainable products and the 'Do No Significant Harm Criteria' for chemicals developed and already applied in the delegated acts under the taxonomy regulation. These initiatives serve the objective of a circular economy and of the recyclability of materials spelled out in the European Green Deal. While REACH and other product legislation can ensure the phase out of the most harmful substances in particular in consumer products, the safe and sustainable by design framework, the rules for taxonomy and for eco-design for sustainable products will ensure that the use of substances of concern is minimised with the objective of having less harmful chemicals, materials and products on the market. The objectives of the Strategy also contribute to the achievement of the United Nations Sustainable Development Goals (see Annex 3 for more details).

The EU's New Industrial Strategy for Europe (European Commission, 2021) supports the objectives set in the Chemicals Strategy through a set of measures for the twin transition to a green and digital economy, with a particular focus on strengthening the resilience of the single market, supporting the EU's strategic autonomy and business cases for the twin transition. In this context, a transition pathway for the chemicals industry[5] is under preparation to ensure a smooth transition towards the objectives of CO_2 emission reduction, safe and sustainable chemicals and digitalisation. From a regulatory perspective, the ongoing work on the transition pathway shows the importance of strengthening predictability of EU legislation on chemicals, including REACH. It also shows the need for an effective and

[5] 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 and as part of the New Industrial Strategy for Europe.

efficient enforcement, to which the REACH revision with its options on imported products contributes as well as to a level playing field. The New Industrial Strategy also entails building capacity and supporting SMEs in their transition to sustainability.

The European Parliament resolution of 10 July 2020 welcomed the Strategy and called for the reduction and prevention of exposure to endocrine disruptors (EDCs), the registration of polymers, the increased protection of vulnerable groups, the extension of the generic risk management approach, and the need for a definition of essential uses. The resolution also called for support to small and medium-sized enterprises (SMEs), to help them comply with EU chemicals legislation and to move towards producing and using safe and sustainable products (European Parliament, 2020). The European Parliament called also for improvement of enforcement and to strengthen cooperation and coordination between enforcement bodies, and to propose EU enforcement instruments, as well as a reinforced cooperation among customs authorities.

The Council conclusions of 15 March 2021 also welcomed the Strategy and called *inter alia* for the extension of the generic approach to risk management in a stepwise process, introducing the concept of essential use, tackling the combination effect of chemicals, action on EDCs and the need to enhance enforcement by strengthening the role of customs authorities and to explore the role of the EU Anti-Fraud Office (OLAF). Moreover, the Council recognised the need to revise REACH and CLP to achieve the objectives of the Strategy (Council of the European Union, 2021).

Box 1: Short overview of the key REACH processes

Objective and scope: REACH aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Manufacturers, importers and downstream users must ensure that chemical substances do not adversely affect human health or the environment. REACH covers all manufactured chemical substances, whether of synthetic or natural origin.

Registration: According to the 'no data, no market' principle, companies must register all substances manufactured or placed on the market in quantities equal to or higher than one tonne per year, per company. The registration is to be submitted to the European Chemicals Agency (ECHA) and must include information on the hazard properties, uses, exposure and volumes of chemicals that are manufactured or imported as well as risk management measures implemented or recommended. The extent of information requirements depends on the volume at which the substance is manufactured or imported.

Evaluation: ECHA and national competent authorities can evaluate the registration dossiers to ensure compliance with the information requirements. MSCAs can evaluate substances that might cause a concern and, if needed for concluding on the concern, request more information.

Authorisation: The Commission can include substances of very high concern (SVHCs) in the 'authorisation list', following a recommendation by ECHA. Once a substance is on the authorisation list, its use is allowed only if it is exempted from the authorisation requirements or if the use is authorised by the Commission. An authorisation can be granted, upon request by companies, if the risk is adequately controlled or if the socio-economic benefits outweigh the risk and there are no suitable alternatives.

Restriction: The Commission, after discussion and agreement with the REACH Committee, can restrict the use of substances if there is an unacceptable risk to human health or the environment (*specific risk management approach*) or, for CMR substances (category 1) in consumer products, if a risk can be assumed based on hazard and generic exposure considerations (*generic risk management approach*).

2 PROBLEM DEFINITION

The REACH Evaluation (European Commission, 2018) concluded that REACH is generally coherent with other EU legislation concerning chemicals and that progress had been made

towards achieving the REACH objectives. Although the latest REACH evaluation did not explicitly recommend a revision, it did identify areas for improvement. For example, the non-compliance of registration dossiers and the complexity of the authorisation process were indicated in the evaluation as requiring the most urgent action. Many of the issues highlighted in the evaluation have also been recognised in the Strategy and the EU Green Deal (see section 1).

The findings of the latest REACH Evaluation have been used as a starting point for the problem definition and the identification of options. The problems have been grouped into three high-level problems for the purpose of this impact assessment.

2.1 Identified problems

2.1.1 Problem A: Significant unaddressed risks for health and the environment from chemicals

Hazardous substances are proven to cause harm to human health and the environment at certain concentrations and exposure levels. While not all hazardous substances raise the same concerns, exposure to certain substances is known to cause cancers or affect the immune, respiratory, endocrine, reproductive or cardiovascular system (Erickson, 2019); (University of Rochester Medical Center, 2019). Furthermore, some hazardous substances are "non-threshold", meaning there is no safe level of exposure. Human biomonitoring studies in the EU point to a high number of different hazardous substances present in human blood and body tissue, including more than 200 synthetic substances identified in umbilical cord blood (Milieu, 2017)[6]. Certain REACH-registered substances (e.g., dibutyl phthalate, cadmium) are among the main drivers of mixture risks to humans (Socianu et al., 2022). Chemical exposure contributes to the cancer burden in the EU (EEA, 2022). The European Environment Agency (EEA) provides evidence on the extent of chemical contamination in water bodies in the EU and highlights a number of failures to achieve good chemical status in EU surface waters (EEA, 2019). As most of the substances on the EU market are poorly characterised for their hazards and exposures, there are substantial uncertainties regarding their risks to humans and the environment, which may well be underestimated (EEA, 2019).

Under problem A, the following four specific problems have been identified:

A1 Information is missing on critical hazard classes

Information on hazards is fundamental for assessing chemical risks and for developing risk management measures. However, one of the problems identified by the Fitness Check for EDCs is that information requirements are not in line with the latest scientific evidence available (European Commission, 2020). In particular, there is a lack of specific information requirements related to endocrine disruption under REACH allowing an assessment whether a substance meets the IPCS/WHO definition[7]. The Fitness Check for EDCs identified stakeholders' concern with the speed of identification of EDCs and concluded that REACH has, compared to the legislation on plant protection products and biocides, the lowest likelihood of identifying EDCs. For carcinogenicity, studies are not normally available for REACH substances (in contrast to other legislation such as the legislation on plant protection

[6] European Commission, Study for the Strategy for the Non-Toxic Environment, p. 123.
[7] International Programme for Chemicals Safety/World Health Organisation

products and biocides) (Ricardo, 2022), limiting the extent to which REACH can help identify carcinogens and prioritise substances for risk management.

The implications of this problem to citizen's health, quality of life, and mortality, are substantial. For example, a growing body of evidence suggests that EDCs contribute to female reproductive disorders (Milieu, 2017); (Hunt et al., 2016))[8]. Regarding carcinogens, an estimated 10% of cancer cases (one of the leading causes of death in the EU (Eurostat, Causes of death statistics, 2022)) are caused by exposure to pollution (which includes industrial chemicals) (EEA, 2022). Information on the overall impacts on humans from substances with these hazard properties is lacking but, given the severity of impacts associated with individual substances and health outcomes as well as the evidence of widespread exposure to some substances, the problem is understood to be severe.

Quantified estimates of the effects of substances with particular environmental hazards are not available, however, they are described qualitatively rather extensively in the scientific literature. For example, EDCs are known to cause fish feminisation, impaired reproduction and abnormal sexual development (Amec Foster Wheeler et al. 2017).

As a result, the information currently required in registration dossiers on critical hazards does not allow a thorough hazard assessment, including for carcinogenicity, neurotoxicity, immunotoxicity, persistency and endocrine disruption, which also hampers a proper hazard classification. See Annex 5 for more details.

A2 Incomplete information on uses and exposure

In addition to hazard information (see problem A1), information on uses and exposure is critical to assess and manage the risks from substances. This information is needed to assess regulatory needs and decide on the most appropriate regulatory tool, e.g. authorisation or restriction under REACH. However, ECHA has identified key information gaps regarding use patterns, tonnages, conditions of use, emissions, and exposures (ECHA, Report on the operation of REACH and CLP, 2021). The information reported in registration dossiers on the use of substances, i.e. in which processes and products, in which quantities they are used, and the resulting exposures, is often either inaccurate or incomplete. See Annex 6 for more details.

A3 Unaddressed risks from polymers[9]

Polymers are currently exempted from the REACH registration requirement, according to Article 2(9). There is only very limited published information on the hazards of polymers, and there is generally a lack of information on the identity of polymers and their uses on the EU market. A recent study indicates that there are approximately 200 000 polymers on the EU market (Wood, 2020).

While some polymers are considered to be of low concern, i.e. to have non-significant human health and environmental impacts, others may pose a risk to human health and the

[8] It is estimated that 56 700 women in the EU are affected by diphenyldichloroethene attributable fibroids and 145 000 women are affected by phthalate-attributable endometriosis.

[9] A polymer is defined as a substance consisting of molecules characterised by the sequence of one or more types of monomer units. For the whole definition, please refer to REACH Article 3(5).

environment.[10] Certain polymers are considered to cause negative human health impacts (e.g., dermatitis, cancer, poisoning events) and environmental impacts (e.g., water body contamination, wastewater treatment), as well as non-quantifiable impacts. See Annex 7 for more details.

A4 Information in the chemical safety assessment provided in the registration dossiers does not allow to adequately address the risks from all substances

The chemical safety assessment (CSA) and chemical safety report (CSR) required currently under REACH present a number of shortcomings that hamper adequate risk management. These relate in particular to combination effects. The current REACH provisions do not take into account that, in reality, humans and the environment are exposed to a plethora of different substances from different sources. For example, a study describes the co-occurrence of 1 791 REACH chemicals in 2 223 European surface water catchments based on modelling (van Gils et al., 2020). Another study 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). Additional case studies based on a large number of individual samples demonstrate risks to the environment and human health from co-exposure to a substantial number of substances covered by REACH; these case studies were based on monitored and modelled data for realistic mixtures of up to approximately 1 300 chemicals in the environment. For human health, no studies including more than approximately 30 substances were identified, therefore risks were almost certainly underestimated (Wood, Unpublished). See Annex 10 for more details.

The consequence of this problem is that the protection of health and the environment from chemical risk is insufficient.

2.1.2 Problem B: REACH regulatory processes and decision-making are not efficient enough

The latest REACH Evaluation 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 (European Commission, 2018)[11]. Despite these contributions, the evaluation also recognised the need to streamline and simplify the authorisation process, with a view to clarifying the requirements and make the process more predictable. Furthermore, the evaluation noted the high costs for individual companies. Since the evaluation, additional issues have also emerged with the increased number of applications for authorisation for low quantities and similar uses, leading to a high workload for public authorities and taking away resources from other regulatory action, like restrictions. The evaluation also found that restrictions had been proposed and introduced at a slower pace than expected. These inefficiencies delay the rate at which regulatory measures are implemented to address risks to human health and the environment.

In particular, the following two specific problems have been identified:

[10] For example, polymers with low average molecular weight (e.g., < 1000 Da), reactive functional groups, high solubility (> 10 mg/L), surface active properties, and/or cationic polymers are more likely to be hazardous or demonstrate potential health concerns (Wood, 2020).
[11] COM (2018) 116 final Annex 5 Page 6.

B1 The pace of new restrictions is too slow to ensure that the most harmful substances are adequately regulated

Based on the *specific risk management approach*[12] (Article 68(1)), a restriction is introduced if there is unacceptable risk for human health or the environment. The preparation of such restriction dossiers is burdensome and costly for authorities, which often lack detailed data and information on the uses and exposure (see specific problem A2) as well as the required expertise to prepare such dossiers[13]. The costs of preparing a restriction dossier have been estimated by ECHA to range from EUR 222 200 to EUR 377 600 (covering FTEs and consulting costs), depending on the complexity of the restriction. The restriction process also includes a six-month consultation period and opinion drafting by the ECHA Committees over 12 months. The time between the preparation of the restriction dossier and the final adoption of a restriction varies depending on the complexity and takes between three and five years[14]. As a consequence, between January 2011 and March 2022, an average of approximately 2.5 restrictions per year were adopted based on the specific risk management approach, falling short of the 11 restrictions per year predicted at the time of adoption of REACH.

The *generic risk management approach*[15] (Article 68(2)) is used for restricting all carcinogenic, mutagenic or reprotoxic (CMR) substances with a harmonised classification when used on their own and in mixtures for consumer uses[16]. This simplified procedure considers the hazards and generic exposure assessments and takes typically one year for substances on their own and in mixtures (drafting of the legal act, Commission internal procedures and comitology procedure). With regard to substances in consumer articles, two restrictions were adopted covering 33 CMRs in textiles[17] and eight polycyclic-aromatic hydrocarbons (PAH) in consumer articles (including toys, activity toys and childcare articles)[18]. However, the simplified procedure (Article 68(2)) cannot currently be used to restrict the consumer uses of other most harmful substances[19], like EDCs to which exposure is shown to lead to neurobehavioral diseases[20] in addition to other possible negative health outcomes. Moreover, professional users are often using the same products as consumers, but much more frequently, during longer periods of time and in some cases without receiving a proper risk management training. See Annex 12 for more details.

B2 The authorisation process is not efficient, decision-making is slow and substitution is not promoted enough

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[12] The *specific risk management approach* is based on a documentation of unacceptable risks from the hazard, the use of the substance and related exposure of humans and the environment.
[13] Workshop with Member States, 9th November (report to be published); see COM (2018) 116 final, Annex 4, page 110.
[14] The preparation of a restriction dossier by MSCAs or ECHA has taken often two years. From the assessment by ECHA Committees until adoption of the restriction, it took around three years but for complex restriction dossiers covering many substances, it might take even longer.
[15] Based on Article 68(1) (specific risk management approach), ECHA or a Member State prepares a restriction dossier, which undergoes a comprehensive procedure, including the assessment by two scientific committees. Article 68(2) (generic risk management approach) allows the European Commission for a simplified restriction to consumer use of CMR substances, on their own, in a mixture or in an article.
[16] Entries 28-30 in Annex XVII of REACH.
[17] Entry 72 in Annex XVII of REACH.
[18] Modification to entry 50 in Annex XVII of REACH.
[19] Defined in the Strategy as CMRs, EDCs, PBT/vPvBs, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs. PMT/vPvMs are not specifically mentioned, but they are a group of substances that raise growing concerns.
[20] Bellanger et al. (2015). Neurobehavioral deficits, diseases, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. https://pubmed ncbi nlm.nih.gov/25742515/.

The REACH Evaluation calls for a simplification of the authorisation process in order to clarify the requirements and make the process and results more predictable. The evaluation also concluded that more efforts are needed to promote substitution of SVHCs, in particular among SMEs (European Commission, 2018). Based on the evaluation findings, some specific actions have been completed, while others are addressed in this impact assessment.

As of April 2022, 59 SVHC entries were added to the 'authorisation list', leading to 248 applications for authorisation submitted to ECHA. Most of these applications concerns three substances[21]. Many applications were submitted for similar uses by different individual companies. ECHA has estimated that the costs for industry are EUR 434 000 per application for single applicants and up to EUR 814 000 per joint application[22]. The costs for authorities (ECHA, European Commission and Member States) to assess each application are estimated to be EUR 78 000 to 143 000 (VVA, Unpublished). The costs for each application for authorisation are an indication that the current authorisation system, where individual applications have been submitted for the same use by different companies, is very costly. Moreover, the authorisation requirements are disproportionate for substances used in low quantities (European Commission, 2018). Unclear criteria for authorisation, in particular concerning the demonstration of lack of suitable alternatives, have led to prolonged discussions and delays in the decision-making.

Many companies substitute SVHCs on the candidate list and in Annex XIV before the sunset date to avoid applying for authorisation (ECHA, 2020). Nevertheless, companies that have applied for authorisation have weak incentives to enter into a dialogue with alternative providers, as this would undermine their case to continue using the substance. In reality, innovation is a process that constantly provides technological improvements and new alternatives to substitute SVHCs. See Annex 12 for more details.

This problem results in high administrative costs for single businesses and inefficient use of resources by public authorities, as concluded in the latest REACH evaluation.

2.1.3 Problem C: Insufficient compliance with REACH requirements

For any legislation to be effective, it has to be adequately enforced. REACH provides enforcement mechanisms and entrusts the national authorities to enforce the law. However, the REACH Evaluation indicates that the current level of enforcement is uneven and the level of non-compliance in some areas is high. Thus, enforcement should be enhanced and become more effective and harmonised, including controls on imported goods.

More specifically, the following three specific problems contributing to problem C have been identified:

C1: Registration dossiers are not compliant with REACH requirements

[21] The substances for which most applications for authorisation have been submitted are chromium trioxide (113 applications for 5-10 main categories of uses) and Octyl- and Nonylphenol ethoxylates (67 applications for four main categories of uses). https://echa.europa.eu/received-applications

[22] It is estimated that approximately 83% of applications are from downstream applicants (unit cost of EUR 434 000), and 17% from multiple applicants, i.e. several actors submit a joint application for authorisation (unit cost of up to EUR 814 000).

The REACH Evaluation (European Commission, 2018) highlighted the **non-compliance of registration dossiers** as one of the most urgent issues to tackle. ECHA's findings (ECHA, Unpublished), based on compliance checks through 10 years, indicate high levels of non-compliance. Compliance with registration obligations ranges between 60% and 70% over the period 2007-2019 (European Commission, 2021).[23] This was confirmed also in a study by the German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA) (BfR, 2018) concluding that out of 3 800 dossiers of substances registered at ≥1 000 t/y , only one third met the information requirements, whereas one third likely did not. Similar conclusions were reached for 100-1 000 t/y substances (BfR, 2020), where at least 24% were considered to miss required data in endpoints assessed. To address this, information requirements were clarified, ECHA compliance checks of registration dossiers increased from 5% to 20% and ECHA is on target to check all dossiers with estimated risk management implications by 2027 (ECHA and European Commission, 2018). However, the complexity of the evaluation process results in bottlenecks and delays for the request of information from registrants (the average compliance check process, excluding time to perform any requested study, is 461 days), as well as delays in conclusions being made on possible hazards and risks, resulting in significant costs (European Commission, 2021). Enforcement authorities' intervention to ensure compliance with the evaluation decisions were required in 30-40% of cases in the period 2018-2021 with many requiring follow-up evaluation decisions (ECHA, Unpublished). In addition, it indicates that the current procedures are insufficient to ensure compliance of all registration dossiers. See Annex 13 for more details.

C2 Insufficiently consistent and effective enforcement in all Member States

Almost 30% of the alerts on dangerous products on the market sent by Member States to the Safety Gate[24] involve risks linked to chemicals in products, making it the second most frequent type of risks in the EU (after physical injuries)[25]. Also, data from a recent study indicate that between 2007 and 2019 compliance with REACH ranged between 76% and 87%, but that it has followed a downward trend in the last reporting period (European Commission, 2021). Results of ECHA's Forum for Exchange of Information on Enforcement[26] coordinated enforcement projects in the period 2010-2014 show a relatively high level of non-compliance for registration obligations and Safety Data Sheets (European Commission, 2018)[27]. See Annex 14 for more details.

C3 Non-compliance of imports with REACH, especially of imported products sold online

In recent years, there has been an increase in online consumer purchases, as well as imports from non-EU countries, and insufficient controls of these products. Data from a recent study shows that the level of compliance for imported goods has decreased in the period 2007-2019, bottoming out at 71% in 2018 (Milieu, 2020). A recent study on the level of

[23] REACH and CLP enforcement, EU level enforcement indicators, indicator EU4, p. 17 https://data.europa.eu/doi/10.2873/478225.
[24] The Safety Gate system (formerly RAPEX) enables that information on measures taken against non-food dangerous products is circulated quickly among the national authorities responsible for product safety in the Single Market countries.
[25] Safety Gate 2021, Annual report 2021, https ec.europa.eu safety consumers consumers safety gate statisticsAndAnualReports 2021 RAPEX 2021 report EN.pdf.
[26] Forum for Exchange of Information on Enforcement established under the REACH Regulation.
[27] SWD(2018) 58 final, Part 1/7, p.61.

enforcement for items sold online found that 78% of the items checked for REACH restrictions did not comply with the requirements (ECHA, 2021). This same study notes that, concerning the sales location of 1 690 non-compliances for mixtures containing lead, only one was found in a webshop, the others were on physical marketplaces (99%), of which 60% were established outside the EU. REACH requires a responsible operator for the import to be established in the EU; however, on-line sales circumvent this requirement and this issue is not tackled in the recently adopted Digital Services Act. See Annex 15 for more details.

Enforcement is a task for public authorities, but it concerns all interested parties and it should be supported by consumer associations and other public actors that need to be given the appropriate powers for legal action against non-compliance. In the European Green Deal, the Commission has announced to take action 'to improve their access to justice before national courts in all Member States'. The recently adopted Directive (EU) 2020/1828[28] has made substantial progress in this area, but does not include REACH in its scope. See Annex 16 for more details.

The main consequences from insufficient compliance with and insufficient enforcement of REACH requirements are negative human health and environmental impacts and uneven playing field for companies in the European Economic Area.

2.1.4 Stakeholders affected by the problems

Table 1 below explains how different stakeholders are affected by the high level and specific problems described in section 2.1.1.

Table 1: Overview of stakeholders affected by the problems

Category of stakeholder affected	How stakeholders are affected by the problems
EU companies	• The application for authorisation that companies have to submit if they want to continue the use of a SVHC has caused **administrative costs** for companies producing or using those chemicals. The average cost of one application for authorisation was estimated to be approximately EUR 200 000 per use[29]. If an authorisation is granted, these costs can be offset by the continued profits made by companies producing/using the SVHC. • The large number of applications for authorisation for uses by individual companies, Court cases and unclear criteria have caused delays and back-logs in the Commission's decision making. This has created **uncertainty** on the outcome of authorisation decisions for companies whose business depends on the use of an SVHC. • Authorisation requirements only apply to uses of SVHCs in the EU and not to SVHCs present in imported articles that do not need to comply with the authorisation requirements. This negatively impacts the **competitiveness** of EU-based companies. • Different enforcement of REACH rules across the EU and lack of compliance of imported products has led to a lack of level playing field. • Regulatory and market initiatives have to a large extent been established, but substitution of the most harmful substances has not occurred at the expected pace (Eurostat, 2020) and frontrunners still encounter major economic and technical barriers (Wood and Lowell Institute, 2019).
Non-EU companies	• Since authorisation requirements do not apply to SVHCs in imported articles, non-EU based companies have a competitive advantage.

[28] 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.

[29] ECHA (2021). Socio-economic impacts of REACH authorisations: A meta-analysis of the state of play of applications for authorisation. https://echa.europa.eu/documents/10162/13637/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4.

Category of stakeholder affected	How stakeholders are affected by the problems
SMEs	• Costs linked to registration requirements and applications for authorisation represent a comparatively higher burden for SMEs. Although registration and authorisation fees are lower for SMEs, there are other costs, e.g. testing, consultancy costs, that companies face to prepare a registration dossier or an application for authorisation. • Micro- and small enterprises find it more difficult than large enterprises to fulfil REACH obligations, which leads to a higher rate of non-compliance for SMEs (European Commission, 2018).
General public and consumers	• Humans are exposed directly (e.g. via the use of a product) or indirectly (e.g. via contaminated air, food and water) to a combination of harmful substances and are currently not sufficiently protected. Although it is not always possible to establish a causality link between chemical exposure and certain diseases, it has been shown that exposure to EDCs results in neurobehavioral diseases, with related significant costs[30]. • Online consumer purchases in the EU and imports from outside the EU have been found to be often non-compliant with EU chemicals legislation. A 2020 study on products sold online in the EEA and Switzerland indicates that 78% of products checked did not comply with REACH restrictions (ECHA, 2021).
Workers dealing with chemicals	• With the pace of new restrictions being slower than expected when REACH was adopted and despite the workers safety legislation in place, some categories of workers outside industrial settings[31] (e.g. professional cleaners, hairdressers etc.) do not benefit from the same level of protection as consumers and industrial workers under REACH despite being more exposed.
EU national authorities	• Control and enforcement of REACH is not equally effective, consistent or uniform across Member States. This relates (in part) to the different level of resources available in the different Member States but also to different enforcement cultures. • There are high costs for authorities to prepare restriction dossiers under the specific risk management approach (Article 68(1) of REACH). • The large number of applications for authorisation, often for the same or very similar uses by different companies, has taken up a lot of resources in national authorities.
European authorities (e.g., European Commission, ECHA etc.)	• There are high costs for EU authorities to prepare restrictions under the specific risk management approach (Article 68(1) of REACH). • Regarding the authorisation process, see above.

2.2 What are the problem drivers?

The underlying causes (or "drivers") of the issues and problems described in section 2.1.1 are identified and described in this section. All drivers are considered to be **regulatory failures**.

Table 2 presents the drivers of specific problems A1-A4, resulting in significant unaddressed risks for health and the environment from chemicals.

Table 2: Drivers to specific problems A1-A4

Specific problem	Drivers	Annex
A1 Information is missing on critical hazard classes	• There is a lack of information requirements related to endocrine disruption. • The data requirements for low tonnage substances are limited and do not currently allow to describe safe exposure levels in the chemical safety assessment.	5
A2 Incomplete information on uses and exposure	• Registrants under REACH are manufacturers or importers of substances. However, such actors often lack accurate information on how and in what quantities these substances chemicals are used by other actors down in the supply chain. • The registration software (IUCLID) and the corresponding ECHA guidance is	6

[30] Bellanger et al. (2015). Neurobehavioral deficits, diseases, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. https://pubmed.ncbi.nlm.nih.gov/25742515/.

[31] In the REACH context, the use of chemicals by workers can be differentiated between 'professional uses' and 'industrial uses'.

	not always clear and can lead to different interpretations by different registrants.	
A3 Non-addressed risks from polymers	• Polymers are exempted from the REACH registration requirement (and consequently are not subject to evaluation), according to Article 2(9). Without any requirement to provide information, there is limited knowledge on polymers placed in the EU market and on their hazards.	7
A4 Information in the chemical safety assessment provided in the registration dossiers does not allow to adequately address the risks from all substances	• Combination effects: individual registrants are only responsible for their own substances and have limited knowledge of uses of other substances. The current REACH provisions do not request registrants to take into account that, in reality, humans and the environment are exposed to a plethora of different substances from different sources.	10

Table 3 presents the drivers to specific problems B1-B2, regulatory processes and decision-making are not efficient enough.

Table 3: Drivers to specific problems B1-B2

Specific problem	Drivers	Annex
B1 The pace of new restrictions is too slow to ensure that consumer and professional uses of the most harmful substances are adequately regulated	• For restrictions based on the specific risk management approach, authorities face difficulties to identify and demonstrate that a risk is not adequately controlled for health or the environment due to lack of data on uses of substances and related exposure. • The scope of the generic risk management approach is limited to restriction of CMR substances for consumer uses. This excludes the possibility of fast restriction of these substances for professional uses and restriction of other substances considered as the most harmful.	12
B2 The authorisation process is not efficient, decision-making is slow and substitution is not promoted enough	• Lack of clarity on the information to be submitted in applications for authorisation, especially for actors up in the supply chain. • Unclear definitions of some key requirements for authorisation, in particular concerning documentation of the lack of suitable alternative substances or technologies. • Applications for authorisations covering many different uses and companies have limited knowledge of the specific uses and exposure by the downstream users. • Once an authorisation for the use of SVHCs is granted with a long review period, companies have little incentives to accelerate substitution and to engage in cooperation with alternative providers.	12

Table 4 describes the drivers to problem C, insufficient compliance with REACH requirements, and specific problems C1-C2.

Table 4: Drivers for specific problems C1-C3

Specific problem	Drivers	Annex
C1 High level of non-compliance of registration dossiers with REACH requirements	• Few deterrents for non-compliance with registration requirements. • Evaluation processes in place to verify compliance are working but they are resource-intensive and they are insufficient.	13
C2 Insufficiently effective enforcement in all Member States	• Lack of common criteria for national official control systems; differences in Member State enforcement policies, capacities and resources. • No role for consumer associations and stakeholders.	14 and 16
C3 Non-compliance of imports with REACH, especially for imported products sold online/ Presence on the market of products non-compliant with REACH	• Insufficient regulatory framework to identify REACH infringements at external borders. • In complex cross-border cases, the national authorities do not utilise the possibility to coordinate, at European level, the collection of evidence and other investigative measures in a structured manner.	15

2.3 How likely are the problems to persist?

The European Green Deal, as well as other environmental legislation related to chemicals, like the Water Framework Directive, the Industrial Emissions Directive, the Ambient Air Quality Directive, or the upcoming proposal for a new Soil Health law, will help reduce the pollution coming from various sources. However, none of these initiatives addresses problems in intervention areas A (significant unaddressed chemical risk) and C (insufficient compliance), which are interrelated for REACH and CLP.

The revision of CLP addresses only part of the problem and, despite an increased number of substances with harmonised classifications, phasing out the most harmful chemicals is expected to take place at a slower pace by relying on the existing regulatory tools, like the authorisation requirement and restrictions based on specific risk management.

Even with the revision of CLP but without additional action under REACH, the above identified problems will persist. For example, additional information under REACH is necessary to for identification of substances under the new hazard classes introduced under CLP[32]. The applicable legislation in terms of information gathering and risk management of substances will continue to be REACH. Several practical challenges and concerns that have emerged related to the registration, authorisation, restriction, evaluation processes or their enforcement will persist. In view of the expected increase in trade and import of chemicals and limited resources for national enforcement authorities, the current challenges in enforcing REACH are like to intensify. These limitations can delay decisions and actions to adopt appropriate risk management measures for the most harmful substances and will therefore – together with the insufficient compliance with the REACH provisions – result in their release to the environment as well as exposure of consumers and workers.

3 WHY SHOULD THE EU ACT?

3.1 Legal basis

The EU's right to act, i.e. to revise REACH, follows from Article 114 of the Treaty on the Functioning of the European Union (TFEU), which confers the EU the power to adopt measures for the establishment and functioning of the internal market and has provided the legal basis for the adoption of the original act. The revision of REACH is harmonising provisions on chemicals at EU level to preserve the good functioning of the internal market and the free movement of goods while ensuring a high level of protection for health and the environment. Following Article 4(2) TFEU, the EU has shared competence in the policy areas of internal market, environment, consumer protection and common safety concerns in public health matters. Therefore, the subsidiarity principle applies. The EU's compliance with the subsidiarity principle is explained in sections 3.2 and 3.2.2.

3.2 Subsidiarity

3.2.1 Necessity of EU action

Action at EU level is necessary for the following reasons.

[32] EDC for human health, EDC for the environment, PBT/vPvB, and PMT/vPvM.

The problem of significant unaddressed risks to human health and the environment from chemicals affects all EU Member States, although the extent of the problem may vary between countries and regions. Environmental impacts of harmful substances have no boundaries. A Eurobarometer Survey from 2019 indicates concerns of respondents across the EU in regard to the impact of chemicals present in everyday products on their health and on the environment (Eurostat, 2020).

The problem of slow and burdensome procedures in the current legal framework can only be addressed by improvements of these procedures at EU level. Different rules and procedures on the management of chemicals across Member States would likely lead to wide variations and would conflict with each other. This would undermine the free circulation of goods on the internal market. Companies would not be free to sell their products in other Member States without adapting their products to national rules on chemicals. In turn, this would affect negatively the level playing field between companies based in the different Member States.

The varying level of enforcement across Member States calls for EU action to increase compliance and contribute to strengthening the national official control systems. Amendments of the legislative text to provide clarifications of terms and concepts that Member States have been interpreting differently, to improve the interface with other Union legislation (such as customs) and to adapt the provisions to the reality of online sales would enable more uniform enforcement across the EU. Therefore, the problem presents cross-border aspects that can be better achieved at Union level, compared to individual action by the Member States.

3.2.2 Added value of EU action

The REACH Evaluation concluded that an EU-level intervention is providing more effective and efficient means to achieve the objectives of the legislation than action by individual Member States. Therefore, it is expected that new regulatory measures will also be more effective and efficient if introduced at EU-level. This is due to existing economies of scale in several areas, from registration of chemicals to risk assessment and management. Furthermore, cooperation between Member State authorities, ECHA and the European Commission in risk assessment and management of chemicals provides synergies, pooling of technical expertise and knowledge sharing across the EU. Different rules in the management of chemicals would undermine the free circulation of goods on the internal market and jeopardise the protection of human health and the environment in the EU.

Defining essential elements common to national official control systems and providing for their objective assessment independent from that of the Member States, can contribute to a more effective and uniform enforcement throughout the EU. This would in turn facilitate a level playing field and ensure the same high level of protection of human health and the environment across the EU. To further enhance the level of enforcement of REACH, the Commission (via the EU Anti-Fraud Office) could play a role at the European level by supporting, assisting and complementing Member States, in particular in complex cross-border cases, where there is a severe negative impact on public health and/or the environment.

4 OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1 General objectives

The general objective of this initiative is to achieve a higher level of protection of human health and the environment relating to chemical risks, while ensuring a better functioning, competitive internal market for chemicals.

4.2 Specific objectives

The initiative should achieve the specific objectives detailed below linked to the three problems and their respective drivers.

4.2.1 Objectives concerning problem A: Significant unaddressed risks for health and the environment from chemicals

Increase the information on manufactured and imported substances: The first specific objective is to increase the information on hazards, uses and exposures of manufactured and imported substances, including polymers, available to manufacturers, downstream users and authorities in order to allow hazard classification and assess exposure of workers, consumers and the environment and the associated risks. More specifically, this should result in increased information on particular hazard classes, including EDCs, on uses and exposure and on polymers.

Ensure that companies implement adequate risk management measures: The second specific objective is to ensure that adequate operational conditions and risk management measures are identified, communicated and implemented by manufacturers and downstream users for their risk management, and to enable regulatory action by public authorities when those are not sufficient. More specifically, this should result in an improved risk management by registrants and downstream users and a more efficient communication in the supply chain.

4.2.2 Objectives concerning problem B: REACH regulatory processes and decision-making are not efficient enough

Reduce administrative costs and speed up restriction and authorisation processes: The third specific objective is to reduce unnecessary administrative costs from the authorisation and restriction processes and to speed up these processes by relying more on the generic risk management approach. This should allow for increasing the current pace at which human and environmental exposure to the most harmful substances is reduced to achieve a higher level of protection. This calls for more efficient risk assessment and risk management through a reform of the current authorisation and restriction provisions. Also, the current procedures for industry to apply for and authorities to grant authorisations for uses of SVHC should be streamlined and become less burdensome. This should result in more efficient REACH regulatory processes.

Further incentivise substitution: The fourth specific objective is to further incentivise the substitution of the most harmful substances. Although voluntary initiatives are being established, a stronger push for substitution would help to phase out the most harmful substances from non-essential uses, in particular in consumer products, while creating new business opportunities. This should result in increased substitution of the most harmful substances by safer and more sustainable alternatives.

4.2.3 Objectives concerning problem C: Insufficient compliance with REACH requirements

The fifth specific objective is to *increase compliance with the requirements of REACH*. On the one hand, registrations of substances need to be compliant, which requires more control of registration dossiers and stronger incentives for registrants to comply. On the other hand, the control and enforcement systems of Member States need strengthening to achieve a consistent and effective level across the EU. Likewise, (custom) authorities should be provided with support and a better regulatory framework to combat illicit chemicals placed on the market, notably as regards imports from third countries and online sales. This should result in increased compliance of registration dossiers with REACH requirements and of imports with REACH, including via online sales; and more consistent and effective enforcement in all Member States. Finally, consumer organisations and stakeholders should have better access to justice.

5 WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1 What is the baseline from which options are assessed?

5.1.1 Expected developments under the current REACH requirements

In absence of the REACH revision, the current registration requirements, evaluation, authorisation and restrictions processes would continue to apply, leading to the following main developments. The details of the baseline are explained in Annexes 5-16, while the figures below represent the common baseline for the initiative.

Registration process (relevant for options 1-16)[33]

- **Number of registered substances**: 13 692 substances were fully registered[34] by September 2022 (ECHA) and around 300 new substances are registered under REACH every year. Therefore, it is estimated that **9 000 new substances** would be registered in the next 30 years. The total number of fully registered substances in 30 years is hence projected to be almost 23 000 substances.
- **Costs of registration requirements**: costs of registration for the estimated 9 000 new substances in the next 30 years are estimated to be EUR 1.2 billion[35], based on the average cost per substance of EUR 95 000 (<10 t/y) and EUR 280 000 (10-1000 t/y)[36] (Wood, 2021a).
- **Benefits of registration requirements**: for companies, benefits include competitive advantage and increased transparency of the market. The availability and dissemination of information on hazards and appropriate risk management measures through the supply chain would continue to contribute to adequate risk management of substances. However, the current registration requirements would not allow the identification of substances with the most critical hazard properties, like endocrine disruption.
- **Number of animal tests:** additional animal tests are needed for new substances and for the regularisation of the previously 'notified new substances' (NONS). With the

[33] For more details on the baseline for specific registration processes, see Annexes 5-11.
[34] Excluding substances registered for only intermediate uses.
[35] Present value over 30 years, taking into account a 3% discount rate.
[36] In absence of more precise estimates, the same estimated average cost of EUR 280 000 for 10-100 t/y substances is applied also for substances registered in higher tonnage bands.

current requirements, the number of laboratory animals for testing new substances is estimated to be 400 000 and for bringing NONS in compliance is estimated to be 600 000.

The promotion of alternatives to animal testing is one of the aims of the REACH Regulation and the use of animals should be avoided by using alternative methods to meet the REACH information requirements. To avoid animal testing, REACH contains several provisions:

- duty to share data for joint registrations of substances;
- ensuring that generation of information for registration is tailored to real information needs: registrants must put forward testing proposals which are evaluated by ECHA before tests are performed on animals.
- Annex XI sets provisions on how to adapt the standard testing regime (i.e., avoid animal testing) when testing does not appear scientifically necessary (e.g. exposure-based waiving when the exposure to the substance is absent or not significant enough to induce a risk) or when information can be provided without animal testing (e.g. use of existing data, weight of evidence, alternative methods).

Nevertheless, currently available experimental alternative methods do not allow a proper classification for some hazard classes (e.g., reproductive toxicity, endocrine disrupters, non-genotoxic carcinogens) as the criteria for those classes require the identification of adverse effects that cannot be demonstrated unless a test is performed on an organism (i.e., an animal). For other hazard classes, alternative methods would allow only the classification as category 2 (suspected to be hazardous) and not as category 1 (known or presumed hazardous). Such limitation would not permit the identification of some of the most harmful substances and a proper implementation of regulatory risk management measures. To continue further reducing animal testing, actions are under discussion in the Commission and ECHA to try to ensure that the increase of animals used for testing as a result of the REACH revision will only be a need in the short term, and that the EU is better prepared to replace animal testing in the long term, e.g. through a European roadmap towards full replacement of animal testing. In addition, research projects aiming at developing alternatives suitable for regulatory needs will continue (e.g., PARC[37] or other H2020-funded projects, e.g. ASPIS[38]) that are expected to allow decreasing the reliance on animal testing in the future.

Restriction process (relevant for extension of GRA and options 20-21)[39]

- **Number of restrictions**: it is estimated that ECHA would continue to prepare 3-5 restriction dossiers per year and Member States would prepare 2 restriction dossiers per year based on specific risk assessment.[40] The Commission would continue its current work on restrictions, expected to lead to about one update per year of the restriction for CMR substances and in mixtures based on the generic risk management approach, and two restrictions adopted per year based on the specific risk management approach[41].

[37] European Partnership for the Assessment of Risks for Chemicals

[38] The ASPIS cluster is a joint collaboration of the H2020 funded projects ONTOX, PrecisionTox, RISK-HUNT3R and represents Europe's €60M effort towards the sustainable, animal-free and reliable chemical risk assessment of tomorrow.

[39] For more details on the baseline for restrictions, see section 5.2 (baseline) of Annex 12.

[40] Based on the Article 68(1) procedure of REACH.

[41] Between January 2011 and March 2022, 28 restrictions were adopted, i.e. about two restrictions per year on average, based on the specific risk management approach – Articles 68(1) and 69(2).

- **Costs of restrictions**: for public authorities and companies, the present cost of restrictions based on specific risk assessment is estimated to be EUR 5-6.3 billion[42] and EUR 900 million[43] for restrictions based on the generic risk management approach over 30 years.
- **Benefits of restrictions**: increased protection of humans and the environment against risks from restricted substances. The benefits that can be monetised are estimated to be EUR 3-9 billion over 30 years[44]. Additional non monetised benefits in terms of reduction in emissions and exposure are expected.

Authorisation process (relevant for options 20-21)[45]

- **Number of SVHCs**: every year, it is expected that 18 additional SVHCs would be added to the Candidate List, resulting in five additional entries to the Authorisation list.
- **Number of applications for authorisation**: 31 applications annually covering 47 uses (including review reports)[46].
- **Costs and benefits of inclusion of SVHCs in the authorisation list**: inclusion in Annex XIV is expected to lead to an increased substitution of SVHCs with subsequent human health and environmental benefits. Companies are expected to face increased substitution costs as they are required to substitute SVHCs.
- **Costs of authorisations**: the present costs of authorisations are estimated to be EUR 271-390 million over the next 30 years.[47] The majority (60-80%) of these costs would be borne by companies (applicants), followed by ECHA (10-25%), and the remainder by the European Commission and Member State authorities. In addition, authorised uses are expected to result in some negative impacts to human health and the environment. Health risks that could be monetised were estimated to be about EUR 0.5 billion per year (ECHA, 2021)**.**
- **Benefits of authorisations**: the total socio-economic benefits of authorised uses, i.e. benefits of the continued use of SVHC, in terms of avoided profit and job losses for industry in the EU are estimated to be EUR 22.4-26.6 billion over 30 years.

Enforcement of REACH (relevant for options 23-30)

- **Non-compliant registration dossiers**: the current level of compliance checks (20% of registration dossiers) is expected to remain unchanged. The number of non-compliant registration dossiers is expected to remain high (about 30% non-compliant dossiers for substances registered >1 000 tonnes, about 24% non-compliant dossiers for substances registered at 100-1 000 tonnes).
- **Non-compliant products**: without additional efforts, compliance with restriction requirements, especially for imported products and products sold online is expected to remain unchanged (see problem C2). In addition, the level of enforcement across Member States is not expected to become more consistent. For online sales, the

[42] Based on estimated annual costs of EUR 285 million to EUR 359 million (2021 prices), covering administrative costs for public authorities and adjustment costs for industry.
[43] Based on estimated annual costs of EUR 54 million (2021 prices), covering administrative costs for public authorities and adjustment costs for industry.
[44] Based on estimated annual benefits of EUR 396 million to EUR 1.2 billion, resulting from 2 restrictions adopted per year. These estimates cover human health benefits and are extrapolated by using the mean benefit per restriction of EUR 178.5 million and the median benefit per restriction of EUR 66 million reported by (ECHA, 2021).
[45] For more details on the baseline for authorisations, see section 5.2 (baseline) of Annex 12.
[46] Based on the average number of applications for authorisation received in the period 2008-2021 provided by ECHA.
[47] These are administrative costs for industry and for public authorities. These estimates are based on total annual costs of current authorisation procedures of EUR 15.6 million to EUR 22.4 million (2021 prices).

baseline includes the recently adopted Digital Services Act (DSA)[48] as well as the application of the Market Surveillance Regulation[49]. 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 (see Annex 15 for more details).

5.1.2 EU and global policies on chemicals management

In the baseline scenario, other pieces of **EU legislation** that contribute to risk management of chemical substances will continue to remain in force. In addition, there are provisions related to chemical pollution in several pieces of environmental protection legislation, e.g. the Water Framework Directive, the Waste Framework Directive and the Industrial Emission Directive. Some of the sectorial pieces of legislation are also undergoing a revision process, for example the Cosmetic Products Regulation, the Toys Safety Directive, and the Food Contact Materials Regulation. Therefore, in the baseline scenario there would be a discrepancy between REACH and sectorial legislation, which is being adapted to take into account the latest available scientific evidence and growing concerns with critical hazard properties, e.g. endocrine disruption. Moreover, the EU policy to reduce CO_2 emissions and meet its climate objectives would also continue with interlinkages with the manufacture of chemicals, which relies on gas as feedstock. This implies that under the baseline scenario, the manufacturing processes of chemical substances in the EU would anyways need to undergo significant changes with related investments.

At **international level**, several conventions[50] tackle the most serious sources of chemical pollution. In addition, the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is the internationally agreed-upon standard managed by the UN on hazard classification and labelling schemes for global use. These international instruments will remain in place and implemented in existing EU legislation[51]. There is also an ongoing process to set the agenda beyond 2020 for the sound management of chemicals and waste, which is a voluntary, multi-stakeholder instrument.

The expected **socio-economic developments** and trends inside and outside the EU, as well as figures on the EU chemical sector are presented in Annex 18.

5.2 Description of the policy options

Annex 4 explains how the policy options have been designed. The screening process has resulted in the following **list of options retained for the impact assessment**. In the following section, the retained options to address each specific problem are described. Additional measures that are envisaged but that are considered either non-controversial or having limited impacts are explained and addressed in the Annexes but not presented in the

[48] Reference to DSA once published.
[49] 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.
[50] Including the Stockholm Convention on eliminating or restricting the persistent and organic pollutants (POPs), the Minamata Convention tackling anthropogenic emissions of mercury, the Rotterdam Convention on shared responsibilities on imports of hazardous chemicals, and the Basel Convention on reducing the movements of hazardous waste between nations.
[51] The UN Conventions are implemented in the EU by several regulations (POPs Regulation, PIC Regulation, Transboundary shipments of hazardous waste) and the UN GHS is implemented via the CLP Regulation.

SWD (see Annex 8 on safety data sheets, Annex 9 on CSA for 1-10 tonnes substances, Annex 11 on Derived Minimal Effect Level).

5.2.1 Options to address problem A: significant unaddressed risks for health and the environment from chemicals

Specific problem A1: Information missing on critical hazards

To gather more information on critical hazards, companies could be required to provide **new hazard information** in the registration dossiers.

In particular, to enable the ***identification of EDCs,*** two options have been assessed that differ in terms of information requirements and how the need to perform certain tests would be decided or avoided[52]. In general terms, option 1 is more lenient regarding the triggering of new tests, whereas option 2 is stricter in terms of the required tests.

- *Option #1:* More information required, allowing full identification of EDCs for substances registered in quantities 10-100 t/y and higher;
- *Option #2:* More information required, allowing full identification of EDCs for substances registered in quantities of 1-10 t/y and higher.

To enable the identification of other critical hazards, an ***extension of the general information requirements*** is also considered. Two combinations of options (see Annex 5 for the details) are presented here as two alternative options:

- *Option #3A* (corresponding to the combination of sub-options 2A/3B in Annex 5) would require more information at the lowest tonnage level on health and environmental hazards from both alternative non-animal methods and conventional testing (i.e. with animals). In particular, this includes a set of non-animal new approach methods for substances registered in quantities of 1–10 t/y or higher, as well as additional in vivo tests[53] for health hazards and tests not involving animals for environmental hazards. In order to balance the additional testing at this tonnage level, some requirements are deleted for substances in the higher tonnage bands (which mainly impacts new substances that would be registered in the future).
- *Option #3B* (corresponding to the combination of sub-options 2B/3B in Annex 5) would require more information at the lowest tonnage level on health and environmental hazards from alternative non-animal methods, and more in vivo testing for environment hazards but less for health hazards. The same set of non-animal new approach methods would be required for substances in quantities of 1-10 t/y or higher (same as in option #3A) but more information for human health from in vivo tests only starting at quantities above 10 t/y. This would be compensated by the same reduction of in vivo testing for the higher tonnage levels as in #3A.

Specific problem A2: incomplete information on uses and exposure

[52] Triggering system means leading to additional tests, whereas waiving means foregoing certain tests based on a sound reasoning.
[53] In vivo tests refers to tests, experiments or procedures that researchers perform in or on a whole living organism, such as a laboratory animal.

To fill the existing data gaps, which hamper the assessment and management of risk by authorities, companies would be required to provide **more detailed and/or additional information on the use of substances and on exposure.** Four complementary options were considered:

- *Option #4:* Authorities would improve guidance, registration tools and definitions of existing requirements (technical optimisation);
- *Option #5:* Companies would be required to provide more detailed information on quantities per use and to update this information more regularly (increase information requirements);
- *Option #6:* Downstream users would be required to report directly on composition of hazardous mixtures and their use of SVHCs in articles;
- *Option #7:* Companies would be obliged to provide information on uses, tonnage per use and exposure upon inclusion in the candidate list.

Specific problem A3: Non-addressed risks from polymers

To address the risks from polymers, it is important to first gather more information on polymers. Companies could be required to first notify all polymers and then register a sub-set of polymers requiring registration, while authorities would need to develop a methodological framework to allow registration in groups according to (still-to-be-defined) grouping criteria. The notification step would provide an overview of the total number and types of polymers on the EU market, while the registration step would allow to gather information on polymers requiring registration, their hazard properties, use conditions, exposure and on risk management measures.

Three alternative options are considered on how authorities would identify polymers requiring registration (PRR):

- *Option #8a:* entails the identification of PRR based on strict criteria that would include a wider number of substances.
- *Option #8b:* entails the identification of PRR following less strict criteria and capturing less substances.
- *Option #8c:* entails the identification of PRR following medium strict criteria and capturing a medium number of substances.

In parallel, two other alternative options are considered on how to organise the registration process:

- *Option #9a:* **two-step registration process**, with an initial notification after three years from entry into force and a full registration after eight or 10 years, depending on the molecular weight of polymers[54]. During the **notification step**, companies would be requested to provide to ECHA basic information on the polymers. After the notification, ECHA would develop objective criteria for grouping polymers for the **registration step**, where polymers requiring registration would be registered in groups.
- *Option #9b* envisages a **three–step registration process**, with an initial notification after one year from entry into force, a pre-registration after five years and the full registration after eight or 10 years, depending on molecular weight. In this case, the

[54] Polymers with low molecular weight are expected to be more hazardous than polymers with high molecular weight. Therefore, their registration could be prioritised.

notification by companies to ECHA would be simplified. During the **pre-registration step**, companies would provide more information to ECHA only on polymers requiring registration to support the preparation for the registration step. During the **registration step**, companies would register polymers requiring registration in groups in a case-by-case approach.

Specific problem A4: Information in the chemical safety assessment provided in the registration dossiers does not allow to adequately address the risks from all substances

To address the issue of combination effects of substances in unintentional mixtures, companies would be requested to apply a mixture assessment factor (MAF) in the chemical safety assessment. The MAF is a risk management tool to manage the 'known unknowns', i.e. that humans and the environment are co-exposed to an unknown number of substances, which is currently not taken into account in safety assessments of individual substances. Two alternative options to introduce the MAF were considered:

- *Option #13:* MAF(s) would be applied in all chemical safety assessments, with no possibility for deviation;
- *Option #14:* MAF(s) would be applied in all chemical safety assessments, but with the possibility to deviate i.e. to reduce or eliminate the MAF value according to the extent to which a substance is likely to contribute to risks from unintentional mixtures in practice.

5.2.2 Options to address problem B: REACH regulatory processes and decision-making are not efficient enough

Specific problem B1: The pace of restrictions is not sufficient to ensure that the use of the most harmful substances by consumers and professionals are adequately regulated

To speed up the pace of restrictions, improving the information basis on hazardous substances could facilitate restrictions based on the specific risk management approach (see option #7). However, this would not be sufficient. Only a **stronger reliance on the generic risk management approach (GRA)** for substances with critical hazards and for uses for which risk control is unlikely to be effective can address, in a more preventive approach, those risks with the speed necessary to protect vulnerable citizens and the environment. Currently, GRA restrictions can be introduced only for CMR in products[55] used by consumers. However, as more scientific evidence is emerging on other hazards, this extension would need to cover all the most harmful substances (i.e. endocrine disruptors, PBT/vPvB substances, substances with specific target organ toxicity, immunotoxic and neurotoxic substances and respiratory sensitisers) to better protect the most exposed people (consumers and some categories of professional users) and the environment. Some professional uses[56] have common characteristics with consumer uses (e.g. uses by construction workers) while others are closer to uses in industrial settings (e.g. use of chemical in laboratories). GRA restrictions are intended to address the first type of professional uses, where exposure and emissions are expected to be higher. The possibility to extend the empowerment also to persistent mobile and toxic (PMT) or very persistent very

[55] Substances on their own, in mixtures and in articles.
[56] Professional use is defined in ECHA guidance as "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". In the revised REACH Regulation, it is envisaged to introduce a clear definition of professional use.

mobile (vPvM) substances is also considered in this impact assessment. Based on the extended Commission empowerment, additional GRA restrictions would be introduced according to a **work plan,** which would not be part of the legislative proposal but would be developed in parallel. Such work plan aims to increase transparency and predictability of the EU chemicals legislation for all stakeholders, and, in turn, can feed into the transition pathway for the chemical industry. **Derogations** from the GRA restrictions would be possible **for uses proven essential for society** (see below). Depending on the choice between options #20 and #21, such derogations would be proposed by authorities only or could also be requested by companies.

As the work plan is not yet ready at this stage, **three different implementation scenarios** have been considered for the purpose of the impact assessment. They give an approximate estimate of the impacts of such empowerment and inform the discussions on the future work plan:

- *Implementation scenario #1:* Restrictions based on GRA for all of the most harmful substances at the same time, in consumer uses and in a large share of professional uses, and a large share of articles;
- *Implementation scenario #2:* Restrictions based on GRA for all of the most harmful substances in a stepwise manner, in consumer uses and in a medium share of professional uses and of articles;
- *Implementation scenario #3:* Restrictions based on GRA for all of the most harmful substances in a stepwise manner, in consumer uses and in a low share of professional uses and of articles.

Specific problem B2: the authorisation process is not efficient, is burdensome and does not provide enough incentives for substitution

To simplify the authorisation system and to avoid a large number of authorisation requests for very similar uses, two main alternative options are assessed[57].

Option #20 is the closest option to the baseline. However, a number of measures to improve the authorisation system would be introduced. In addition to those described in Annex 12, the main measures are:

- Applications for authorisation: specify use description, technical function, level of details required (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.

Option #21 consists of merging the authorisation and restriction processes: substances of very high concern (SVHC) prioritised from the candidate list would be included in the restriction list (Annex XVII), while the current authorisation list (Annex XIV) would disappear. The possibilities for authorisations or derogations would be aligned into one common system of restrictions, with three different possibilities:

[57]

- **Authority-driven derogations**, already included in the restriction decision (same as in the baseline);
- **Industry-driven derogations of general applicability** (new element), i.e. the derogation is applicable to all uses, not only the specific applicants, when the restriction decision allows for their submission.
- **Industry-driven authorisations of individual applicability**, i.e. applicable only to the specific applicants, when the restriction decision allows applications. This would, however, remain exceptional and be discouraged by strict requirements compared to industry-driven derogations of general applicability.

In addition, the option to introduce an **essential use concept** to grant authorisations or derogations from restrictions has been assessed as a horizontal measure, applicable to options #20 and #21 (four possibilities considered, see Annex 12). In other words, the use of SVHCs or other harmful substances subject to restriction would be authorised or derogated if the following two criteria set out in the Strategy would be met:

- The use is necessary for health or safety or is critical for the functioning of society and
- There are no alternatives that are acceptable from the standpoint of environment and health.

To facilitate the implementation of the essential use concept by companies when preparing their applications and to ensure a coherent assessment by authorities, the definitions and specifications of this concept are being developed in parallel to this impact assessment. These would be included in a horizontal document applicable across different pieces of legislation that would implement the essential use concept.

5.2.3 Options to address problem C: insufficient compliance with REACH requirements

Specific problem C1: Registration dossiers are not compliant with REACH requirements

To increase the compliance of registration dossiers, public authorities would intensify control and enforcement of registration requirements. One option has been identified (*#23)* that would strengthen processes addressing dossier compliance and which includes the following main measures:

- Revocation of registration numbers in case of non-compliance;
- Expiry of registration dossiers if no updates are made for a long period of time, e.g. 10 years;
- Clarifications of existing provisions on dossier updates;
- Empowering ECHA to perform substance evaluation, alongside Member State authorities.

Specific problem C2: insufficiently effective enforcement in all Member States

To strengthen the Member States' official control systems for chemicals across the EU (covering REACH and CLP), three alternative options have been considered see Annex 14 for the introduction of a European Control Capacity system. The following options differ in intensity of controls:

- *Option #25* would introduce a European Control Capacity with ad hoc Commission controls and voluntary Member States peer review;
- *Option #25* would introduce a European Audit Capacity empowering the Commission to carry out targeted audits;
- *Option #26* would introduce a comprehensive, proactive European Audit Capacity system with a mandate for general and specific audits and other activities.

In addition, to reinforce the enforcement of REACH in Member States as well as to take due consideration of the contribution of the revision of REACH to environmental fairness, and its dimensions of tackling environmental inequality, of 'leaving no one behind', and of ensuring fair distribution of environmental policy costs in line with the polluter pays principle, the possibility to strengthen the role of consumers and civil society organisations has been considered, resulting in three additional options that are complementary to each other:

- *Option #27:* Facilitate access to justice;
- *Option #28:* Provide for the possibility for collective redress;
- *Option #29:* Provide for the possibility to claim compensation for damages related to non-compliance.

Specific problem C3: non-compliance of imports with REACH, especially for imported products sold online

To increase the compliance of imports with the REACH requirements, specific powers could be given to customs authorities and to the European Anti-Fraud Office (OLAF). In particular, four complementary options have been considered:

Option #30 consists of strengthening **customs controls** with automated controls of authorisations and restrictions (for substances only), which implies:

- Obliging importers to indicate the authorisation number and the Economic Operator Registration and Identification (EORI) number[58] of the authorisation holder in their customs declaration; the authorisation should also indicate their EORI number.
- Integrate the REACH IT system into the EU Single Window Environment for Customs[59].
- Empower the Commission to adopt implementing provisions laying down arrangements for the establishment of automated customs controls on authorisations;
- Enhance customs control on REACH restrictions on imported substances.

Option #31 consists of strengthening **customs control** with automated controls of registrations, which implies to:

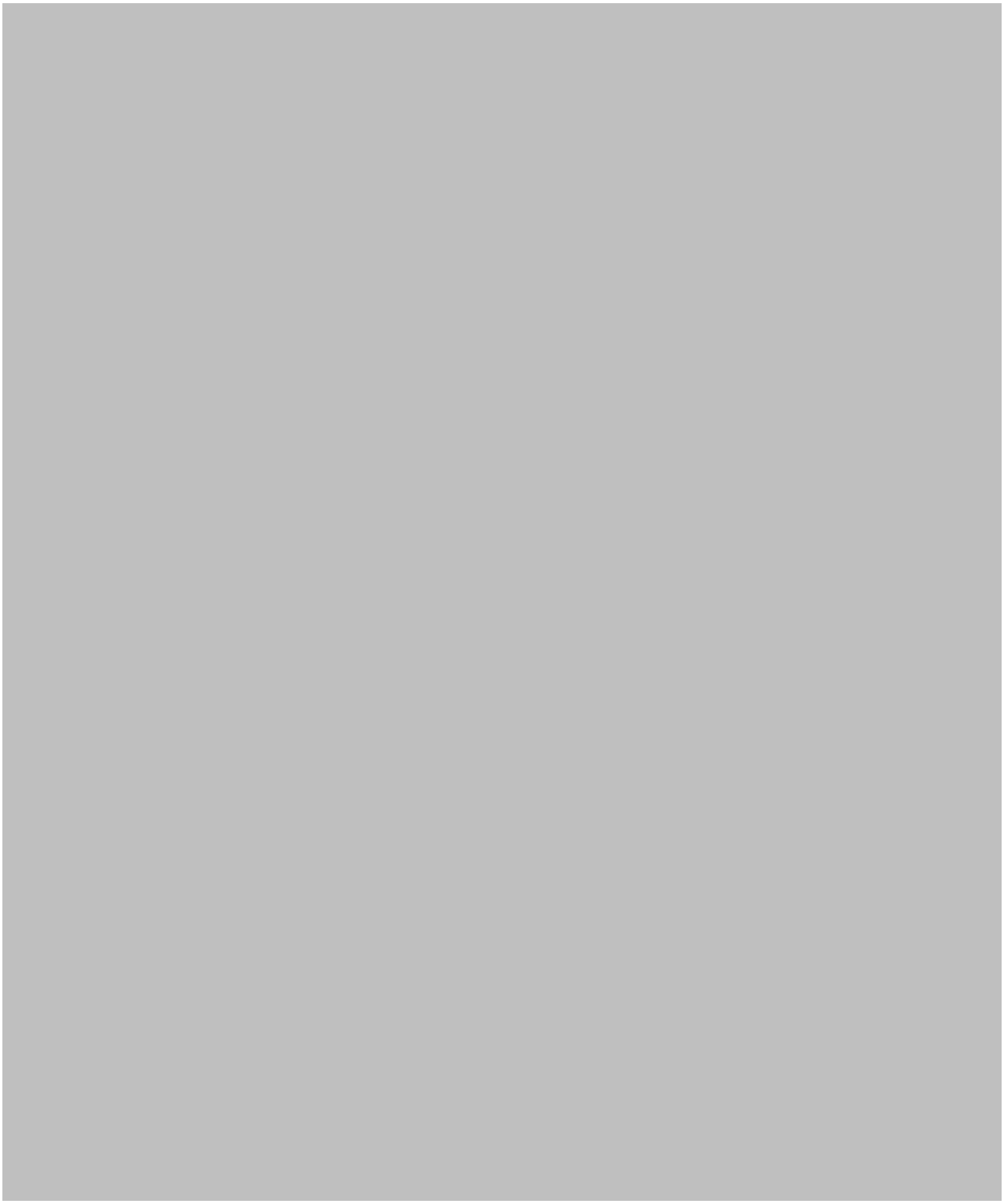
- Legally oblige that REACH registration numbers are indicated in the customs declaration.
- Amend Annex VI to REACH and require registrants to provide the EORI number of the registrants who have the role of importer or only representative, and the CUS

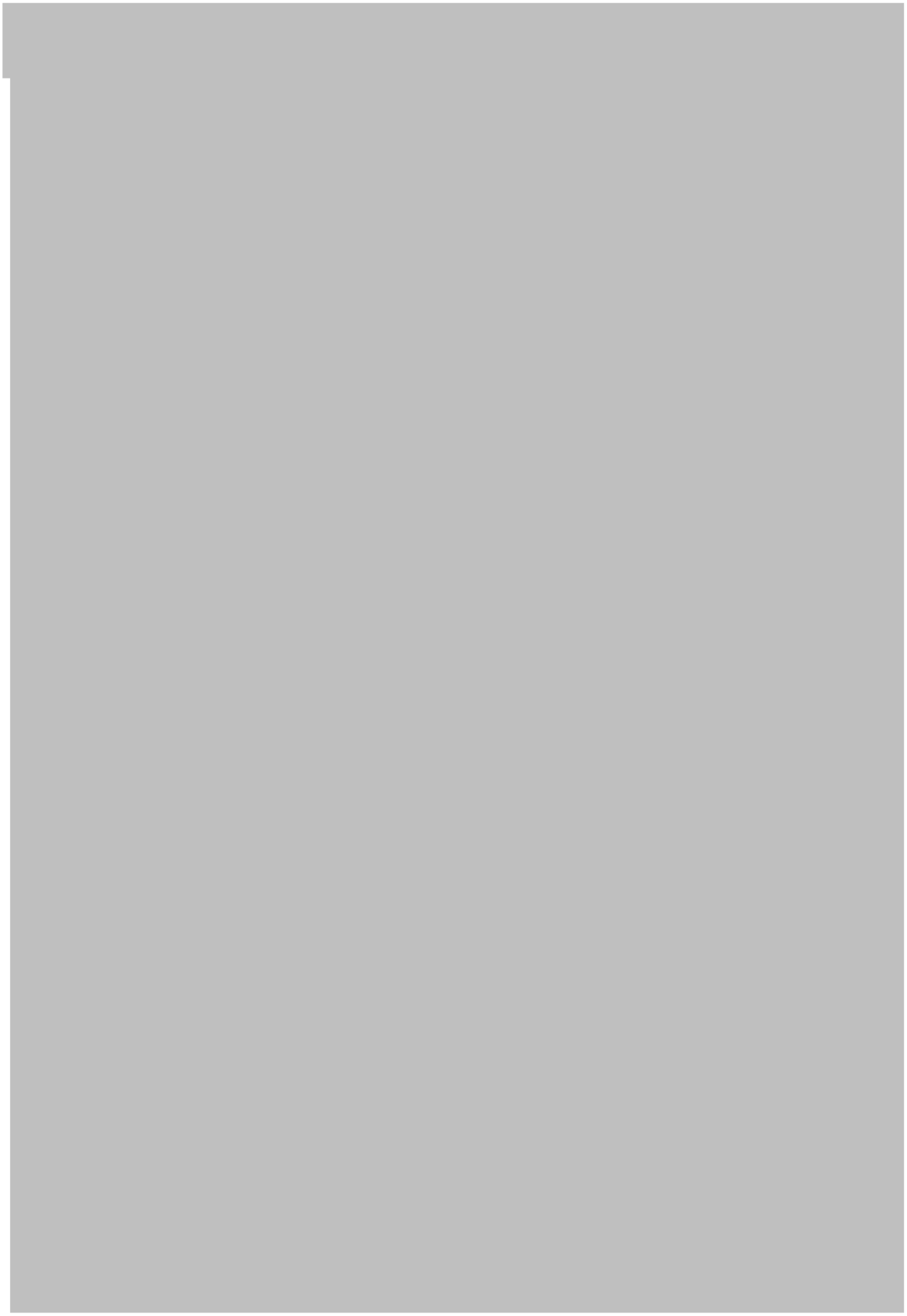
[58] In order to carry out customs operations, businesses must have an EORI number. The EORI number, which is granted by an EU Member State, is recognised by all the customs authorities of the EU.
[59] The EU Single Window Environment for Customs is the EU customs IT tool and is designed to provide quicker and more efficient sharing of electronic data between national customs administrations and EU regulatory authorities across policy domains.

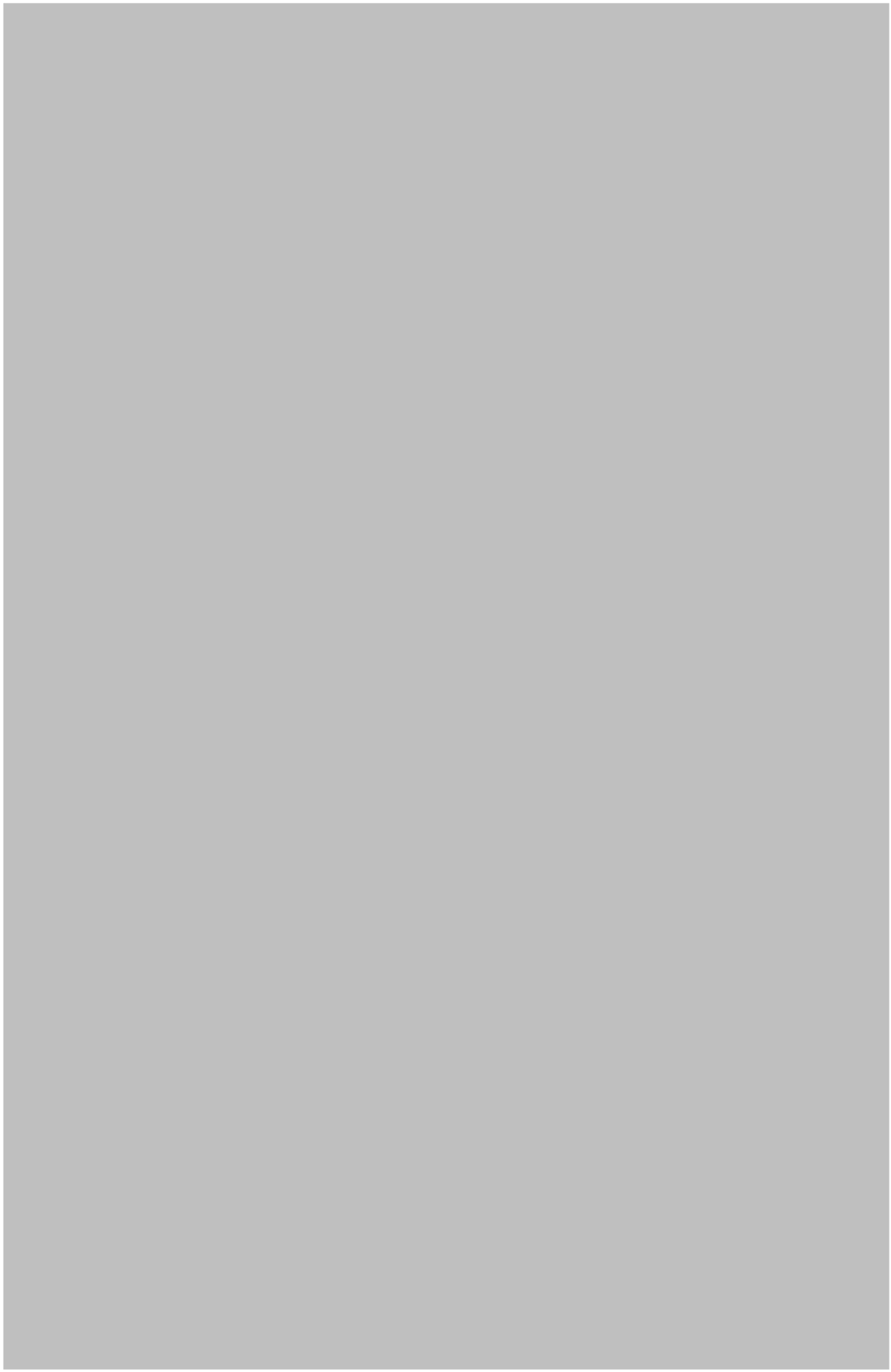
number[60] for the chemical substance and the corresponding commodity code. Importers should be required to provide a Safety Data Sheet on request of customs.

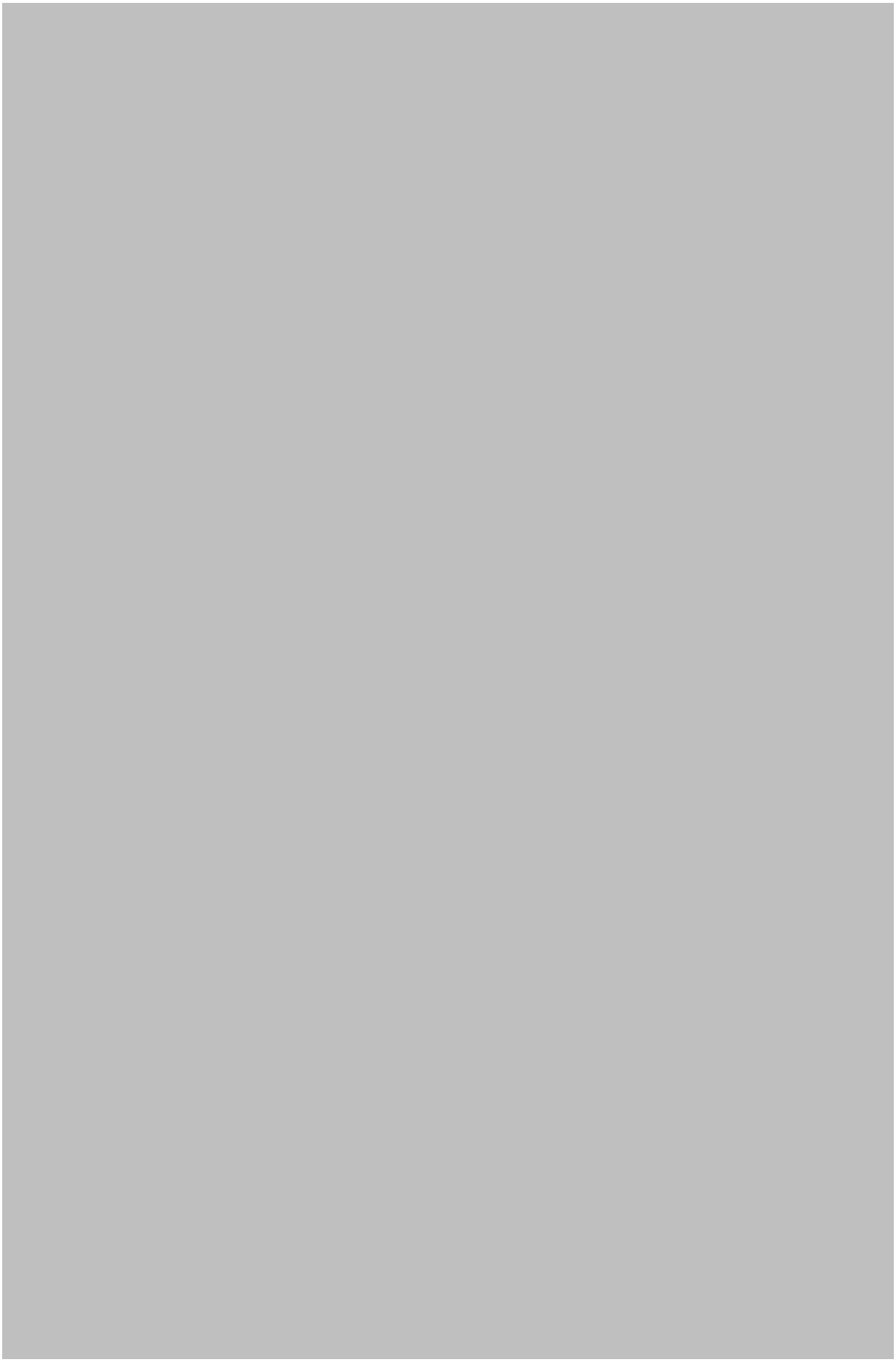
Option #32 would empower the Commission (via **OLAF) to assist, support and complement Member States' enforcement of REACH** in case of serious breaches related to imports, with an enabling clause to cover intra-EU movements at a later stage.

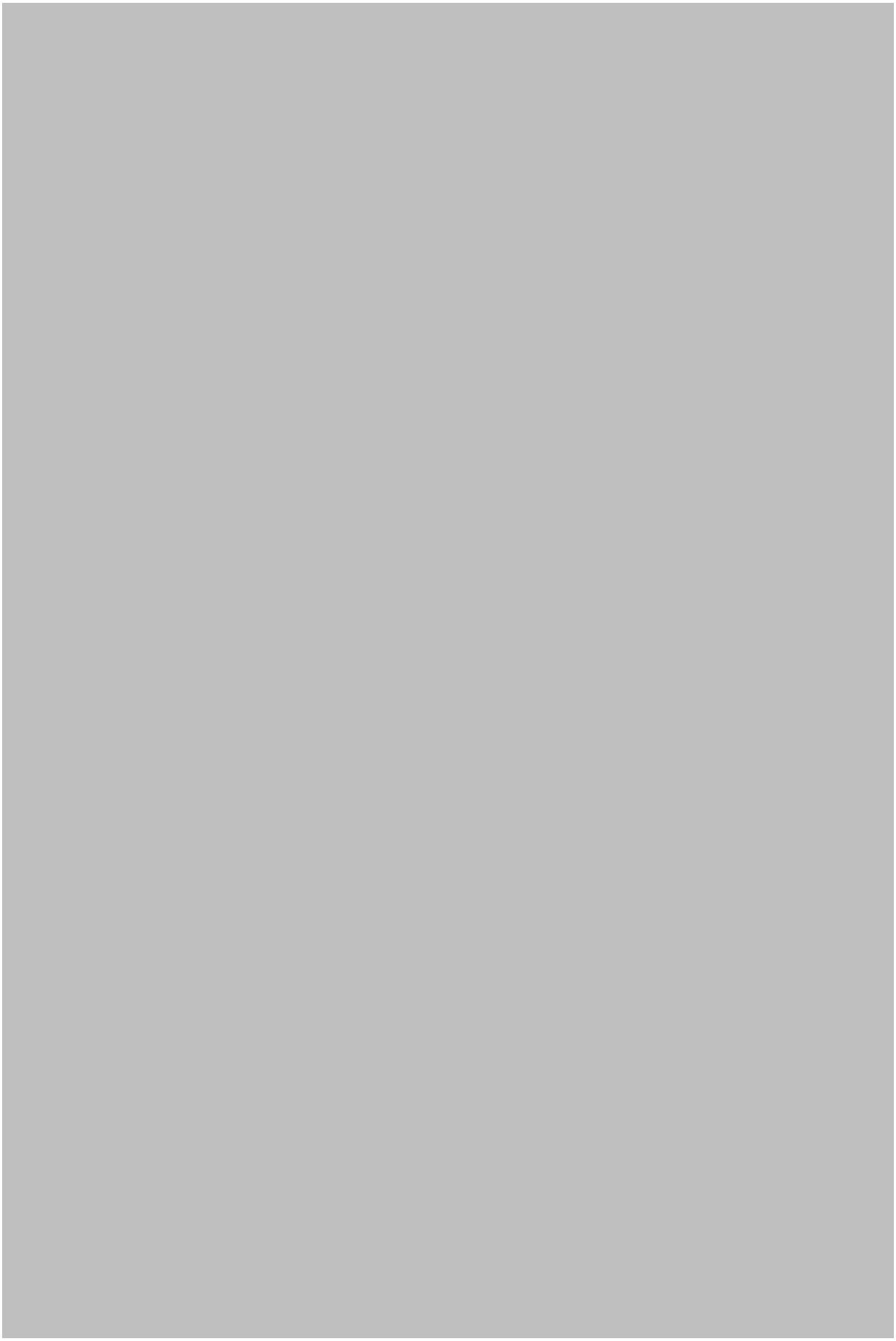
Option #33 would introduce the obligation to have a responsible economic actor in the EU for **online sales** directly shipped to consumers from a third country. Such actor should carry out a commercial activity and could be a natural or legal person.

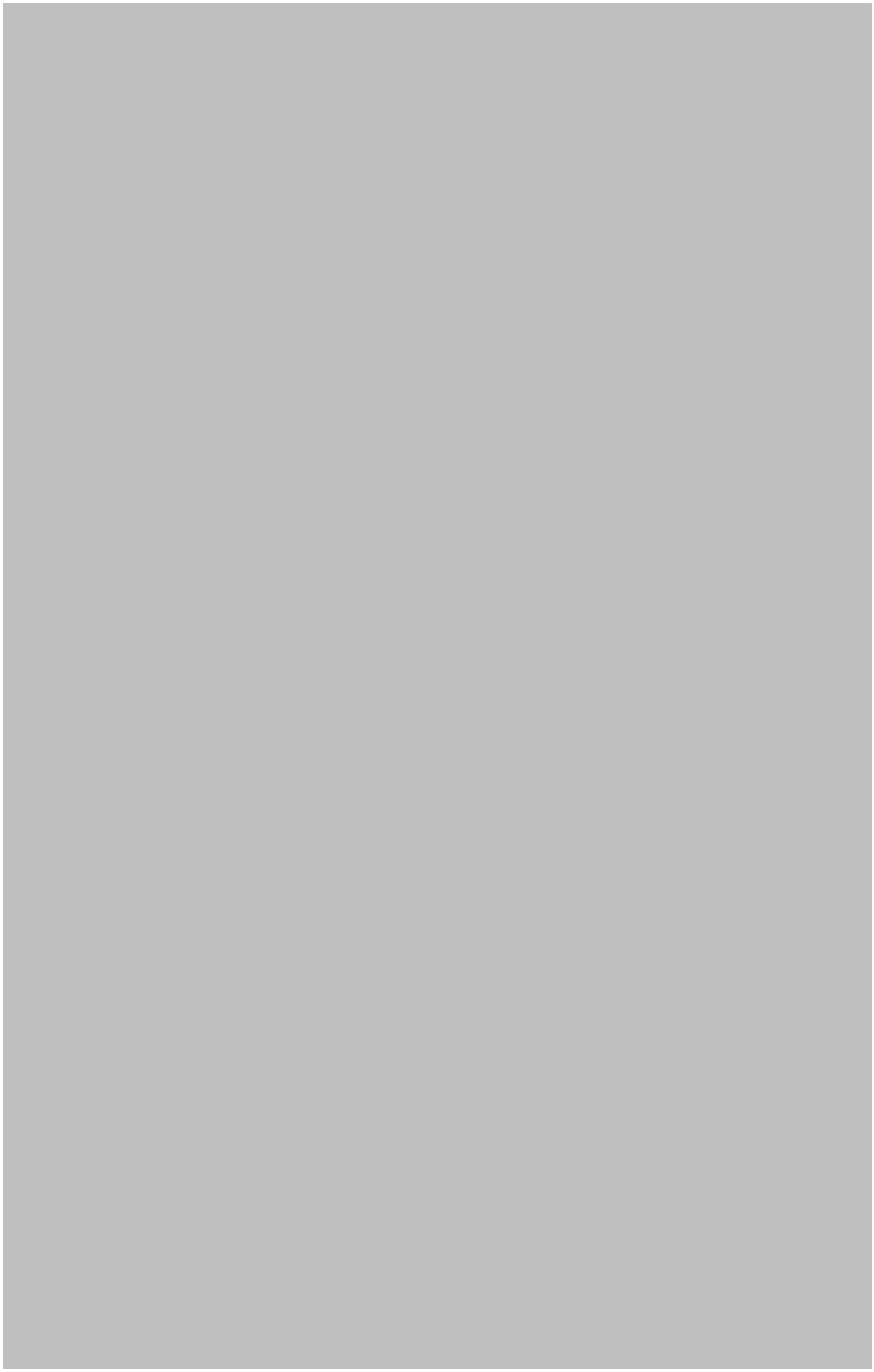


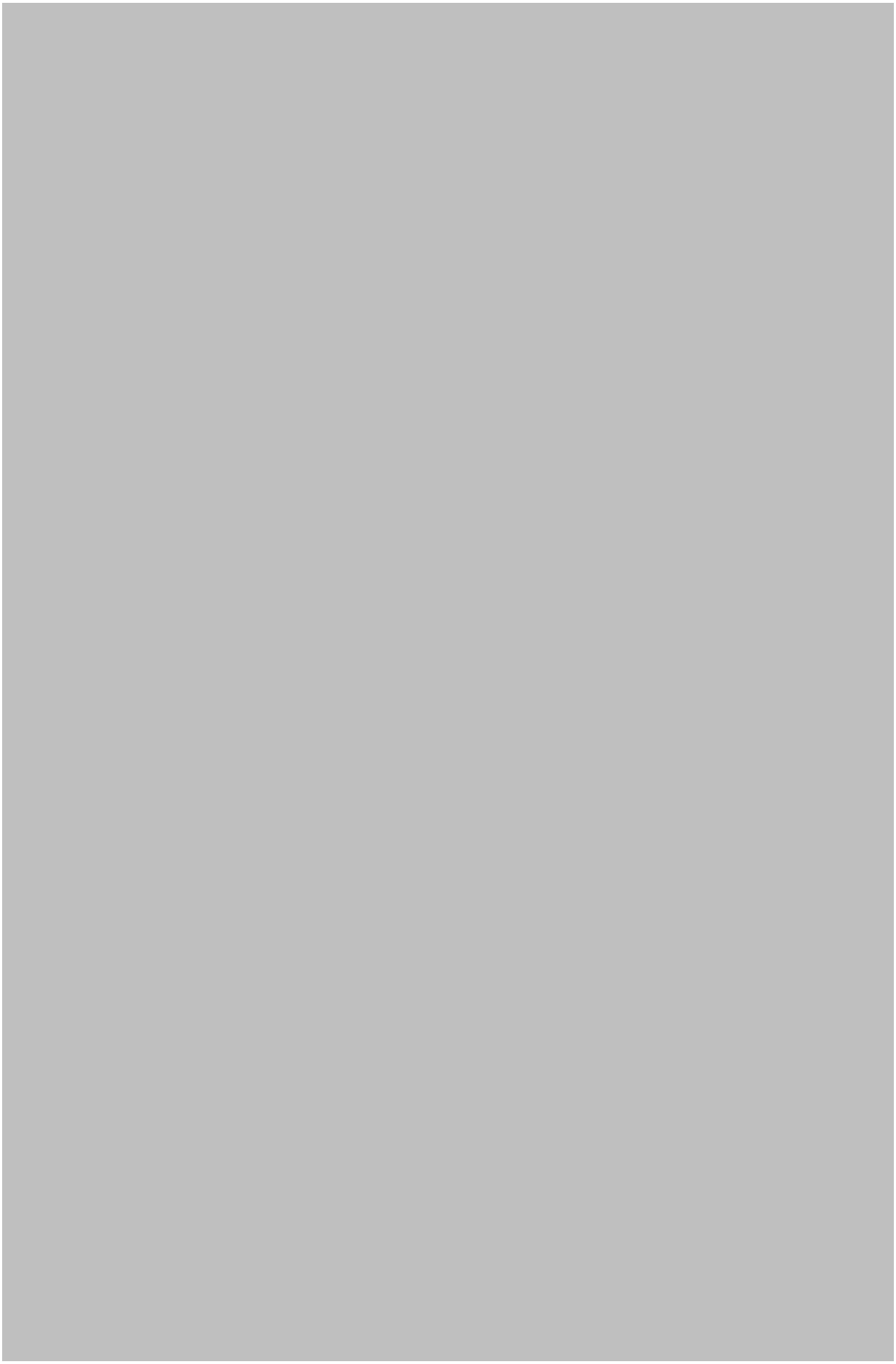


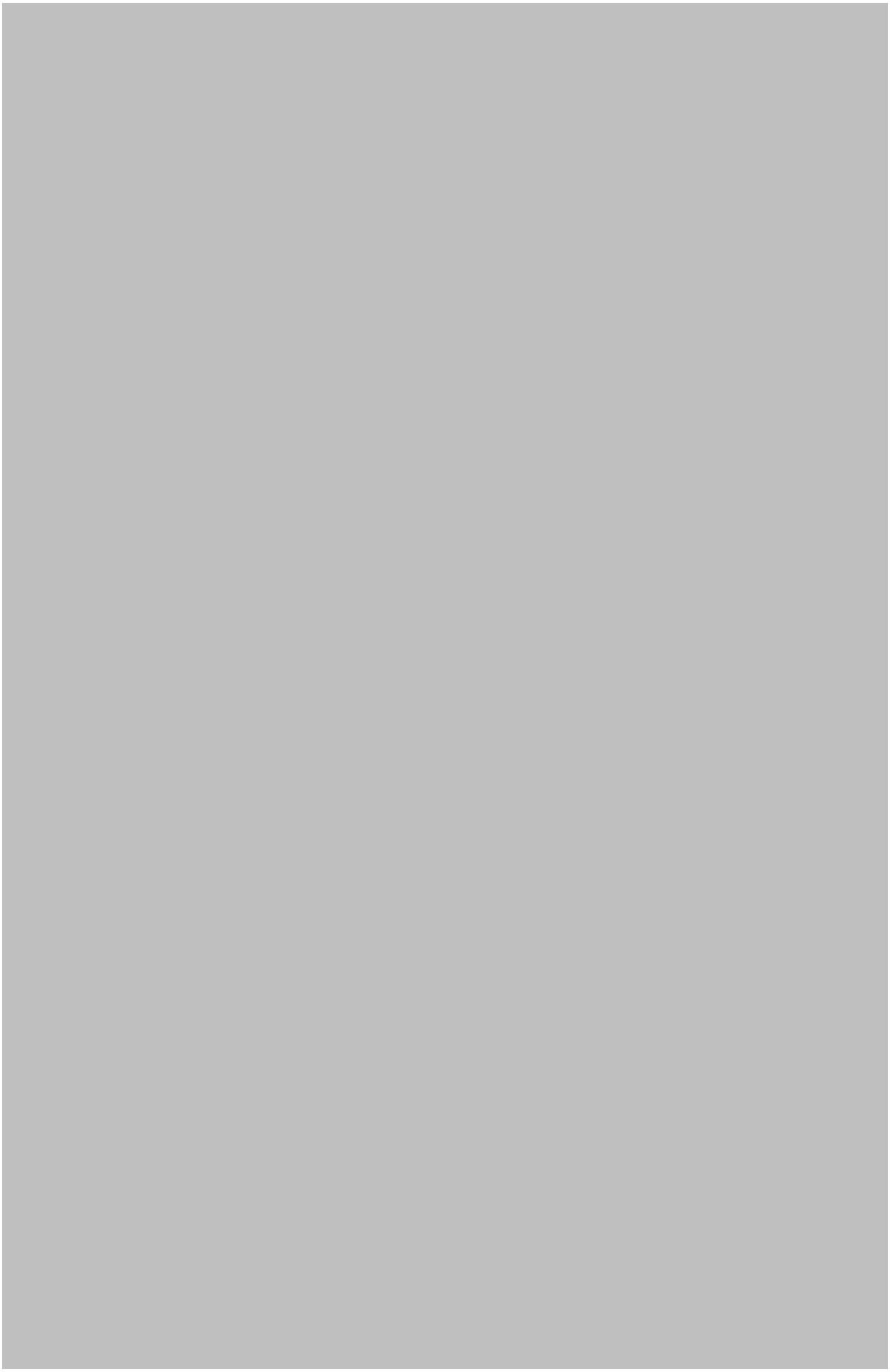


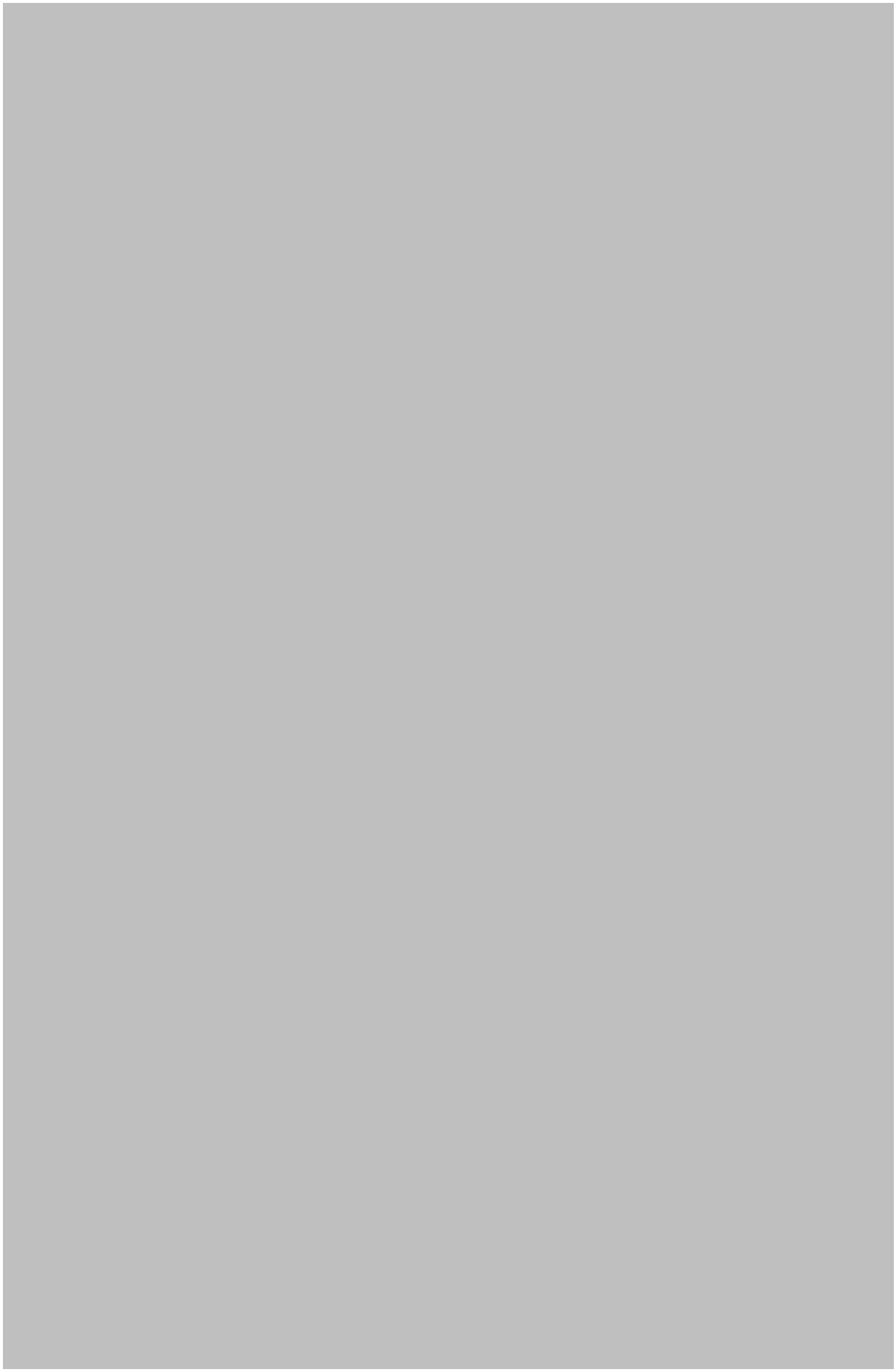


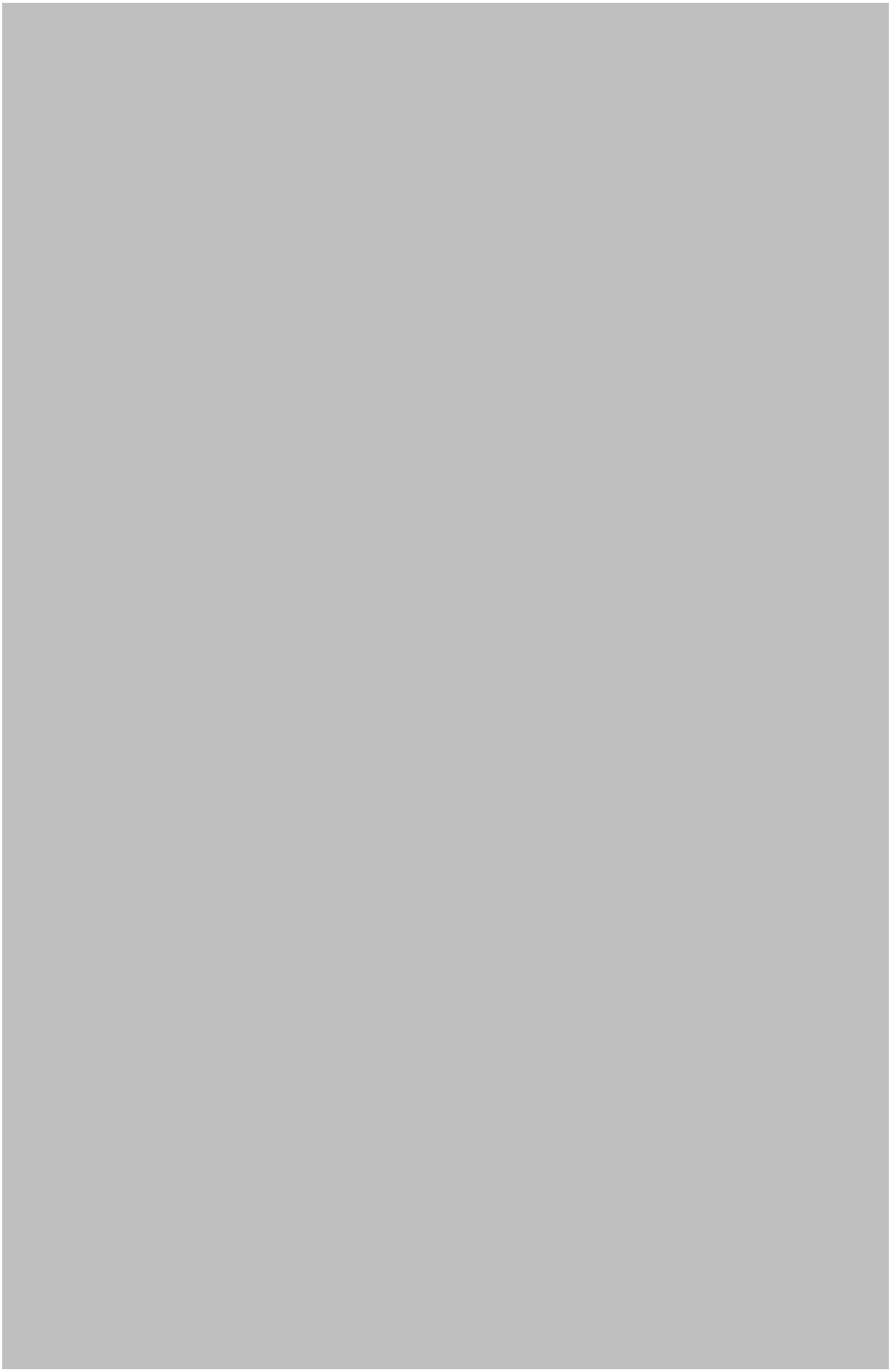


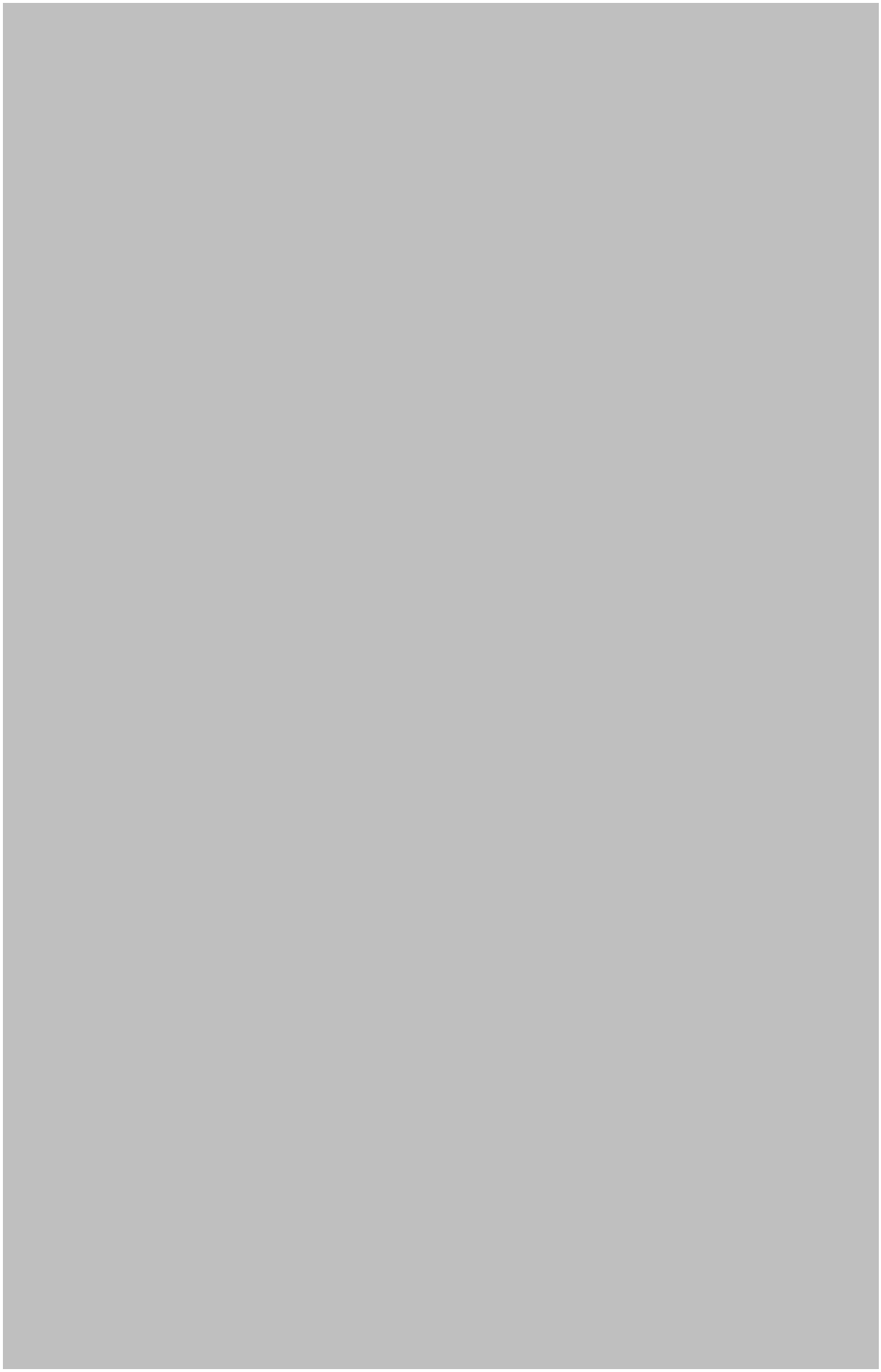


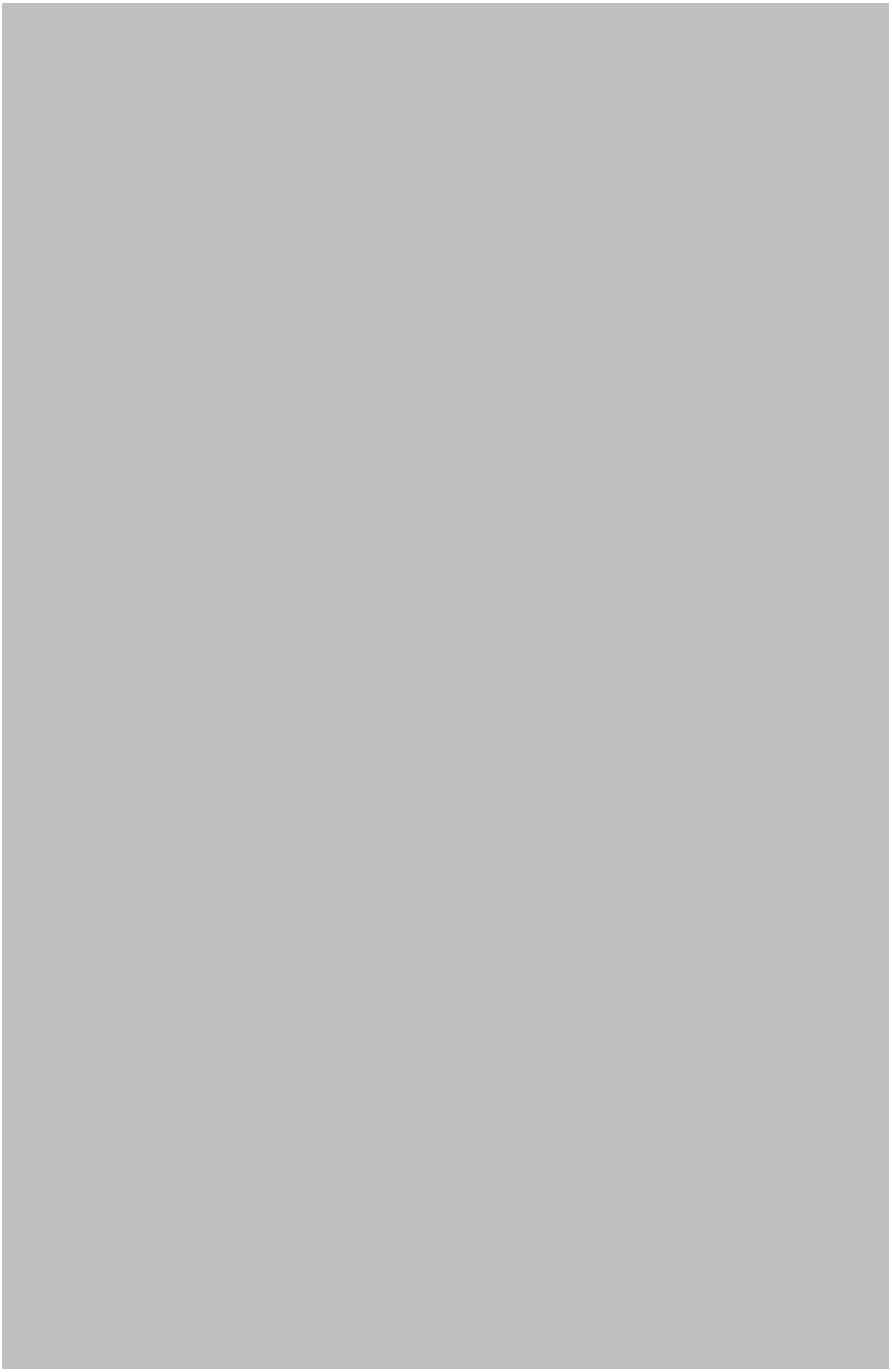


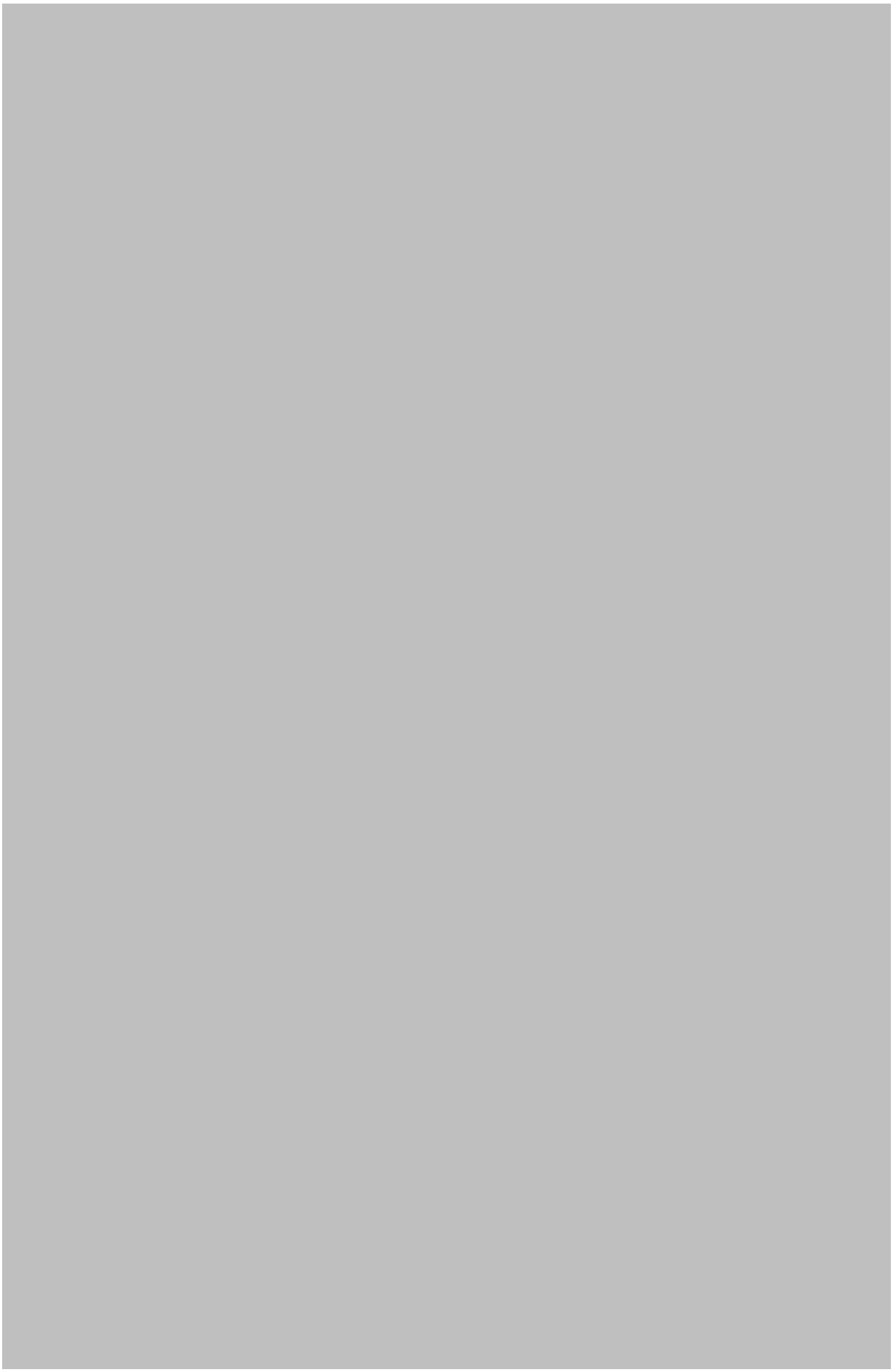


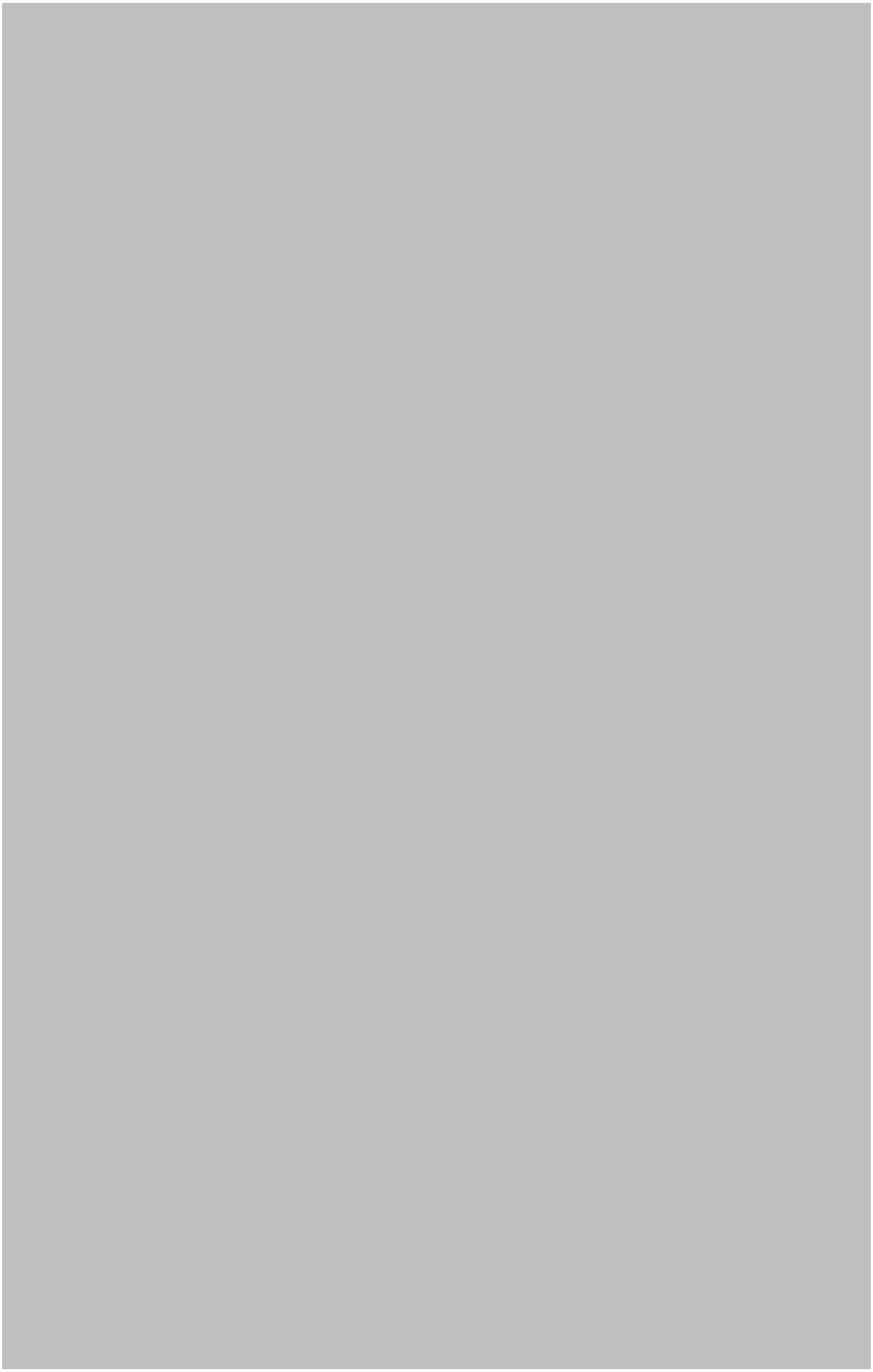


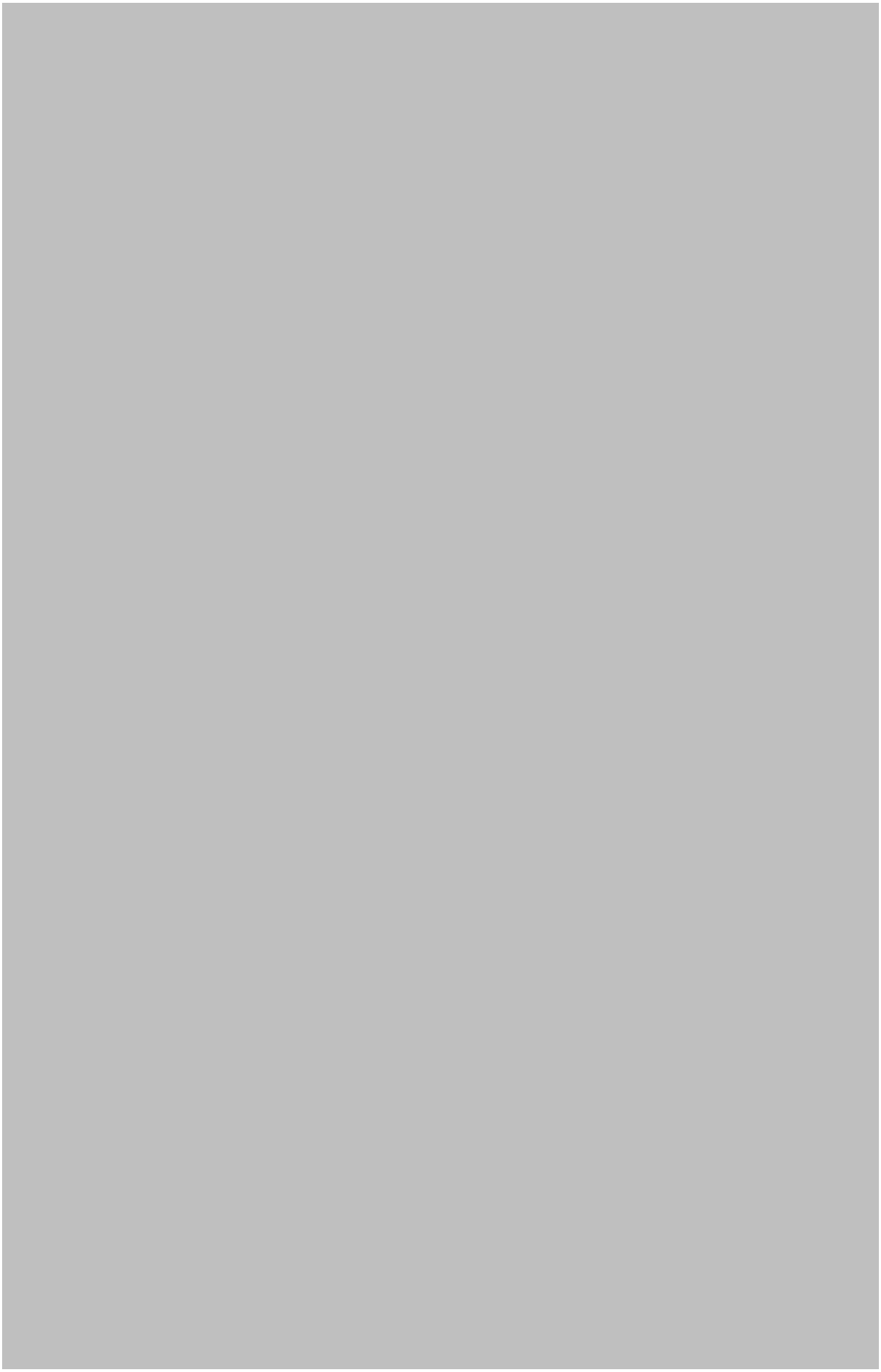


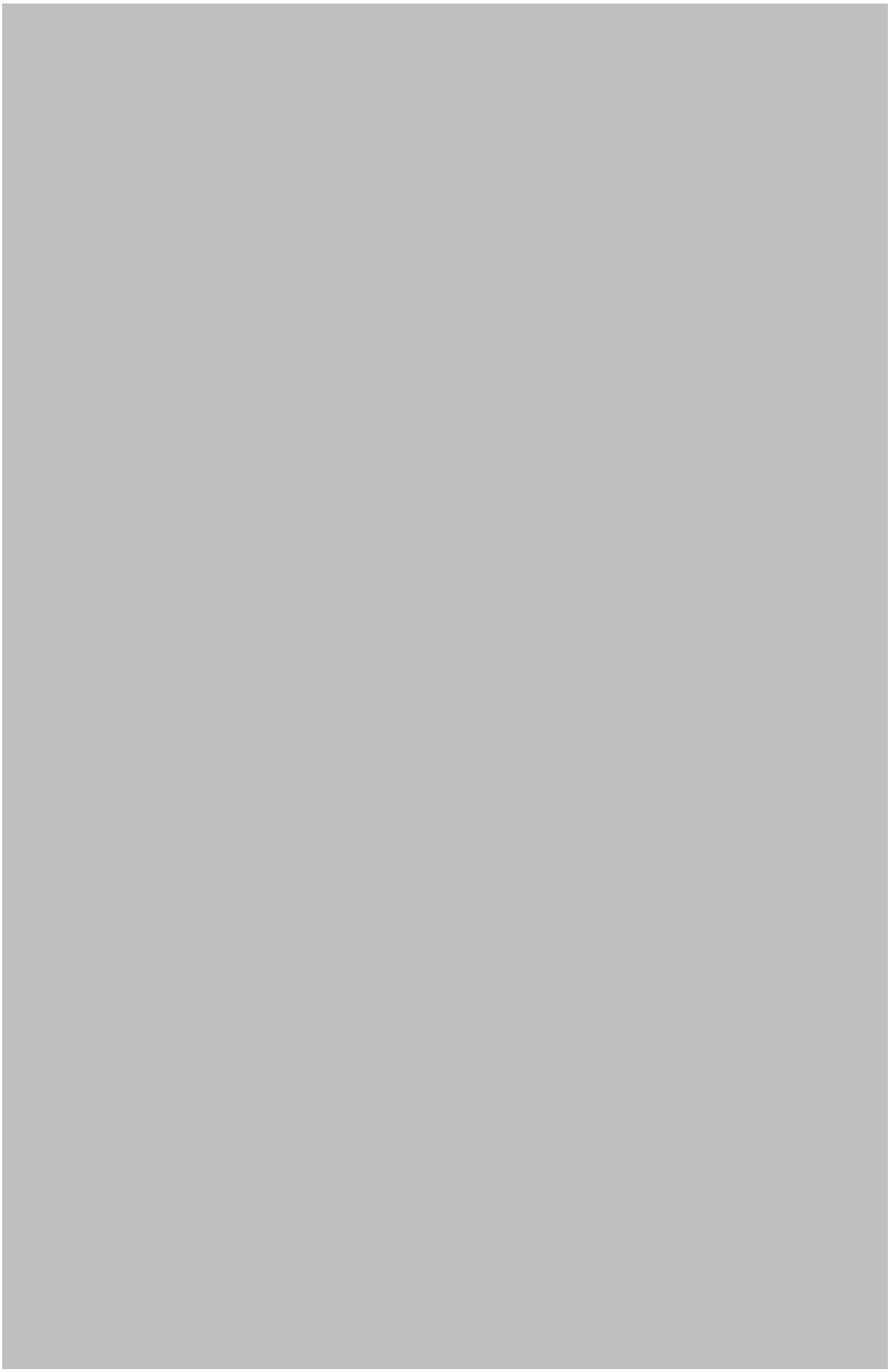


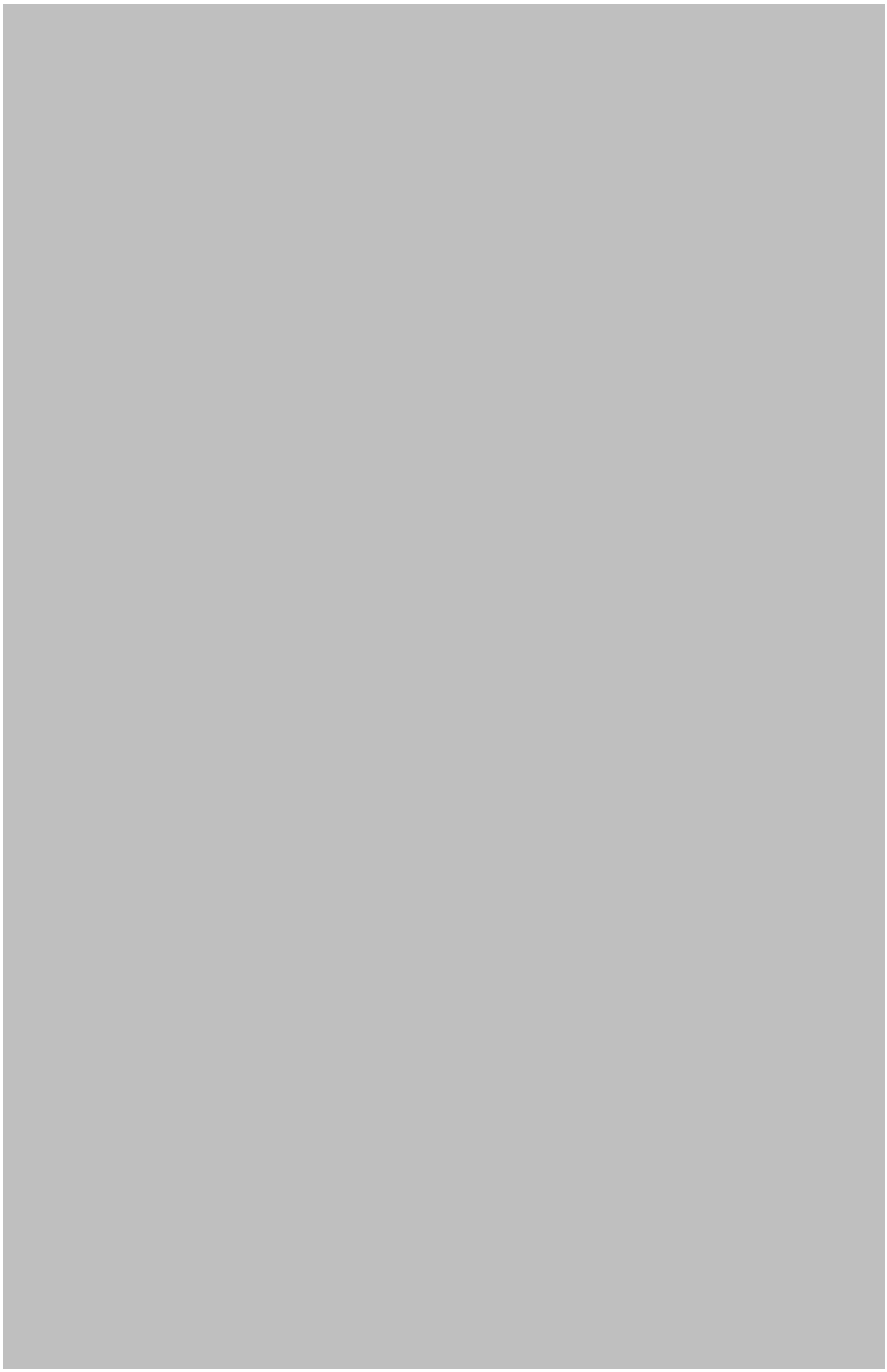


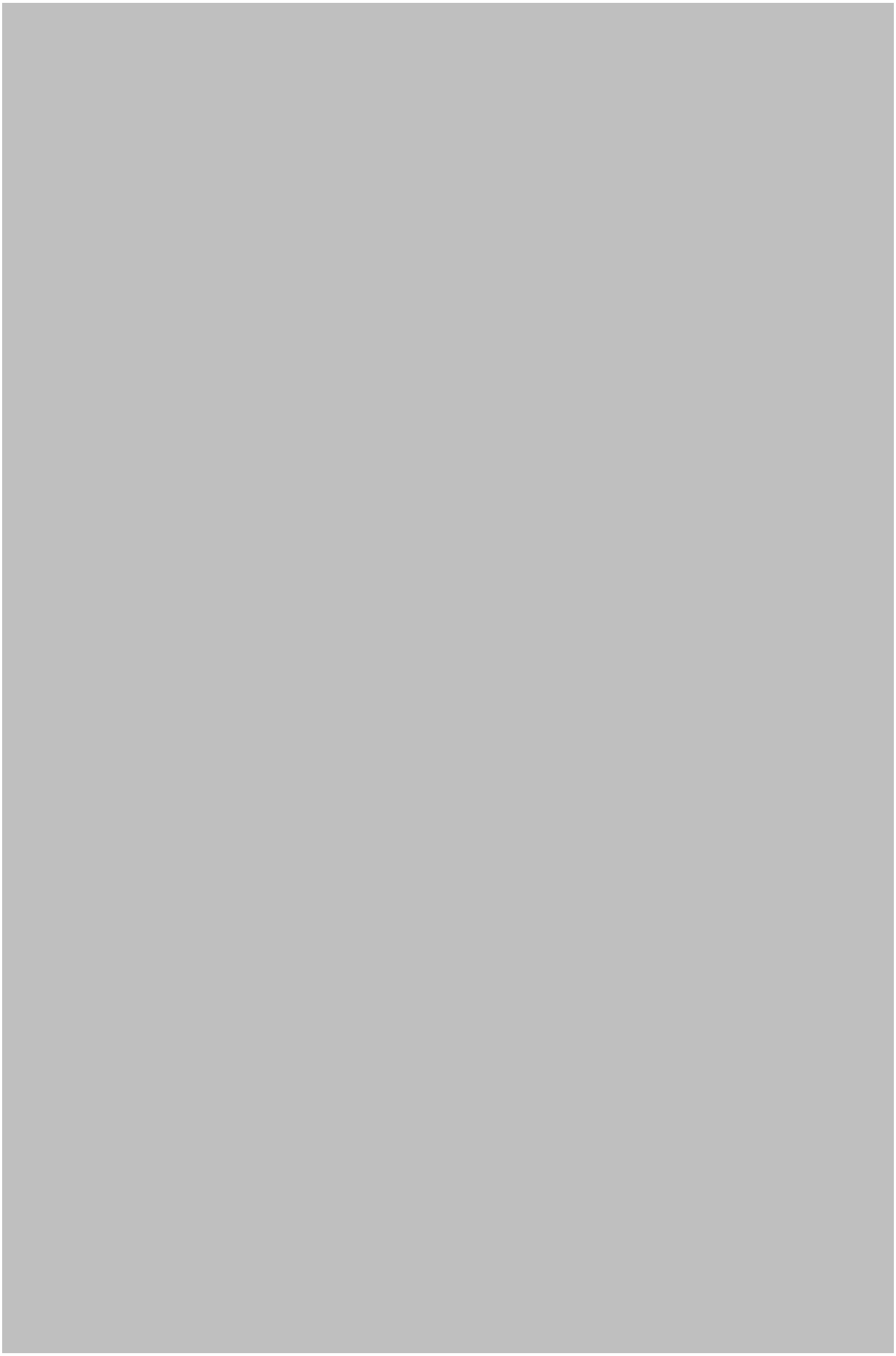


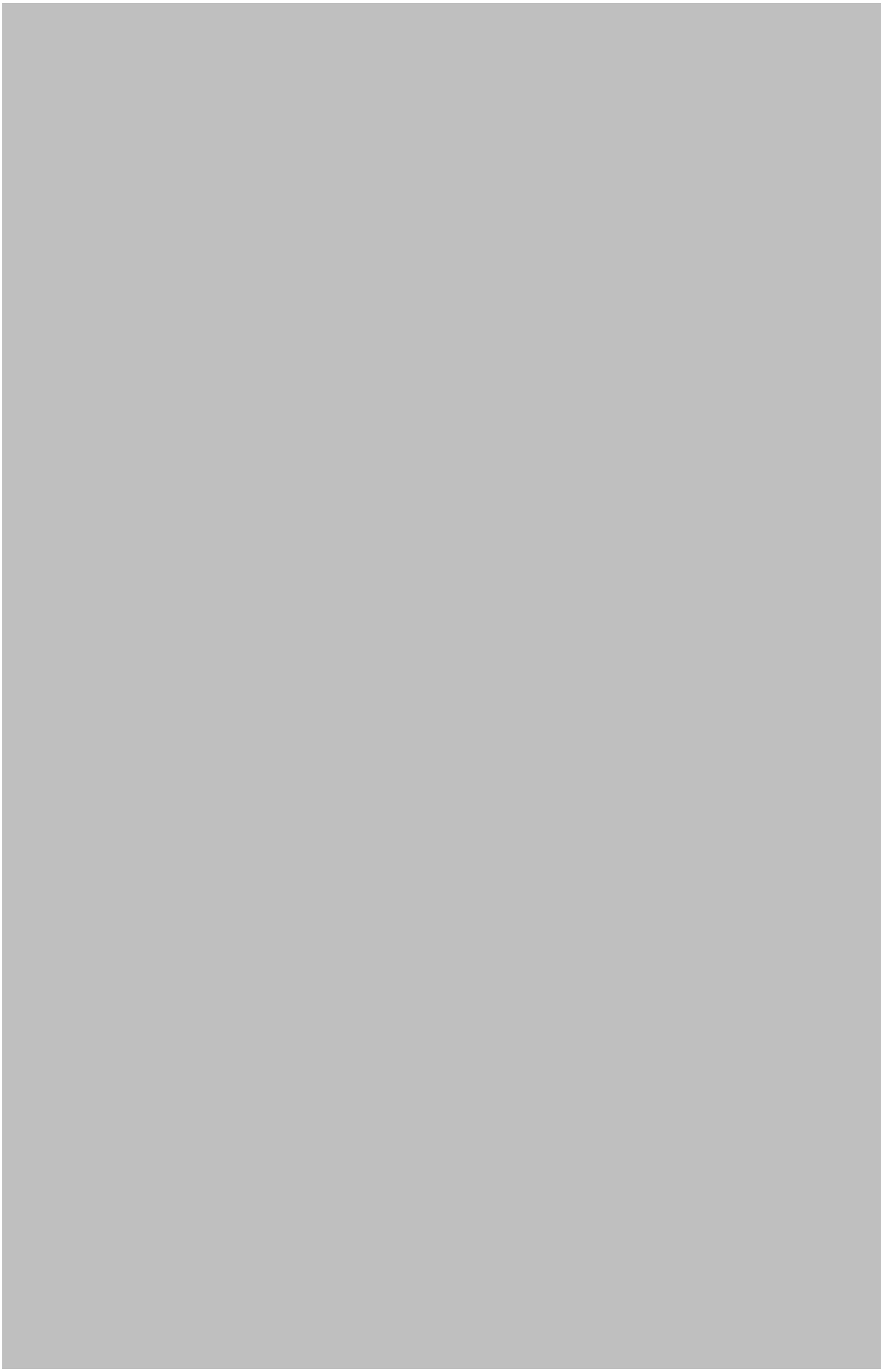


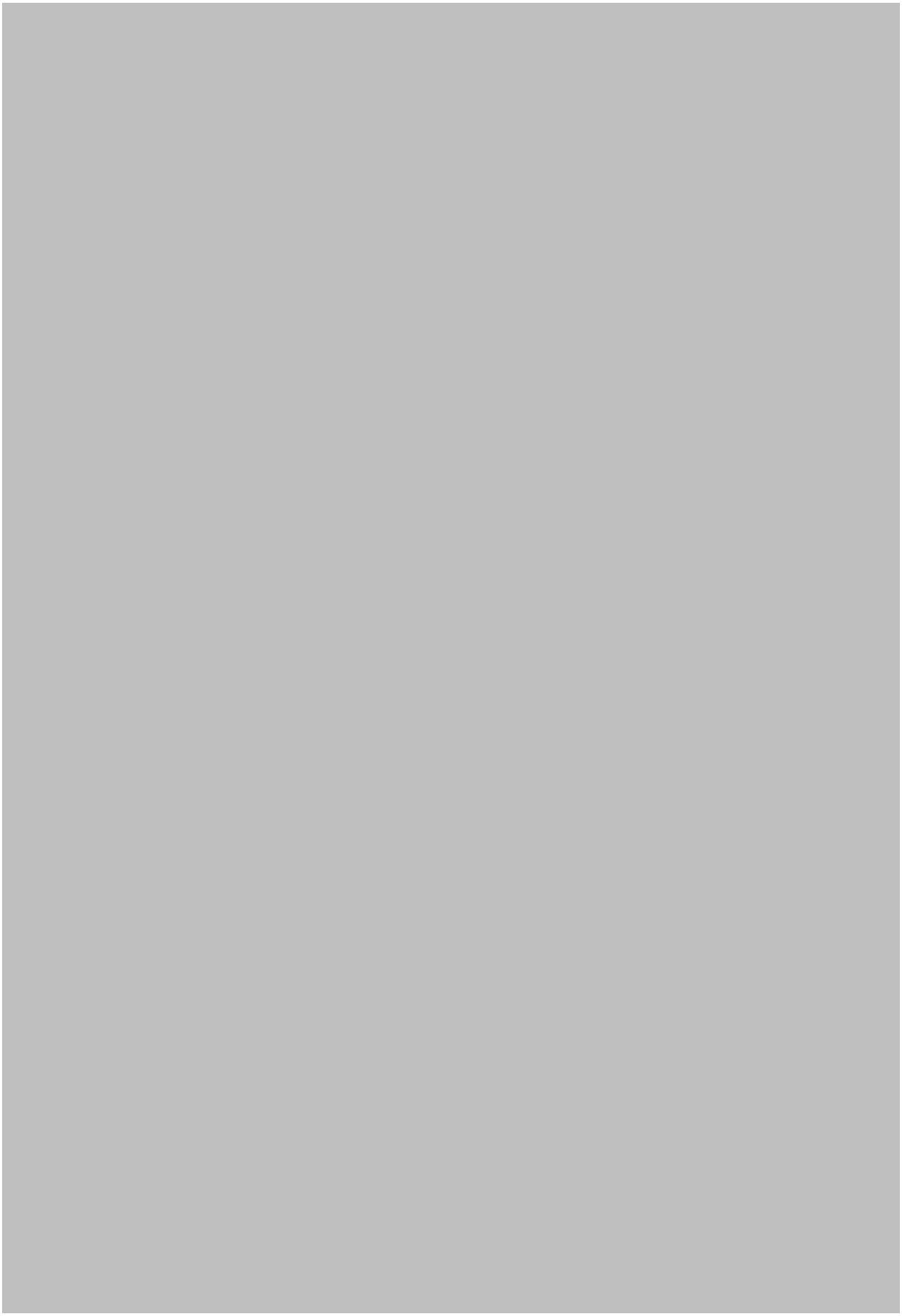


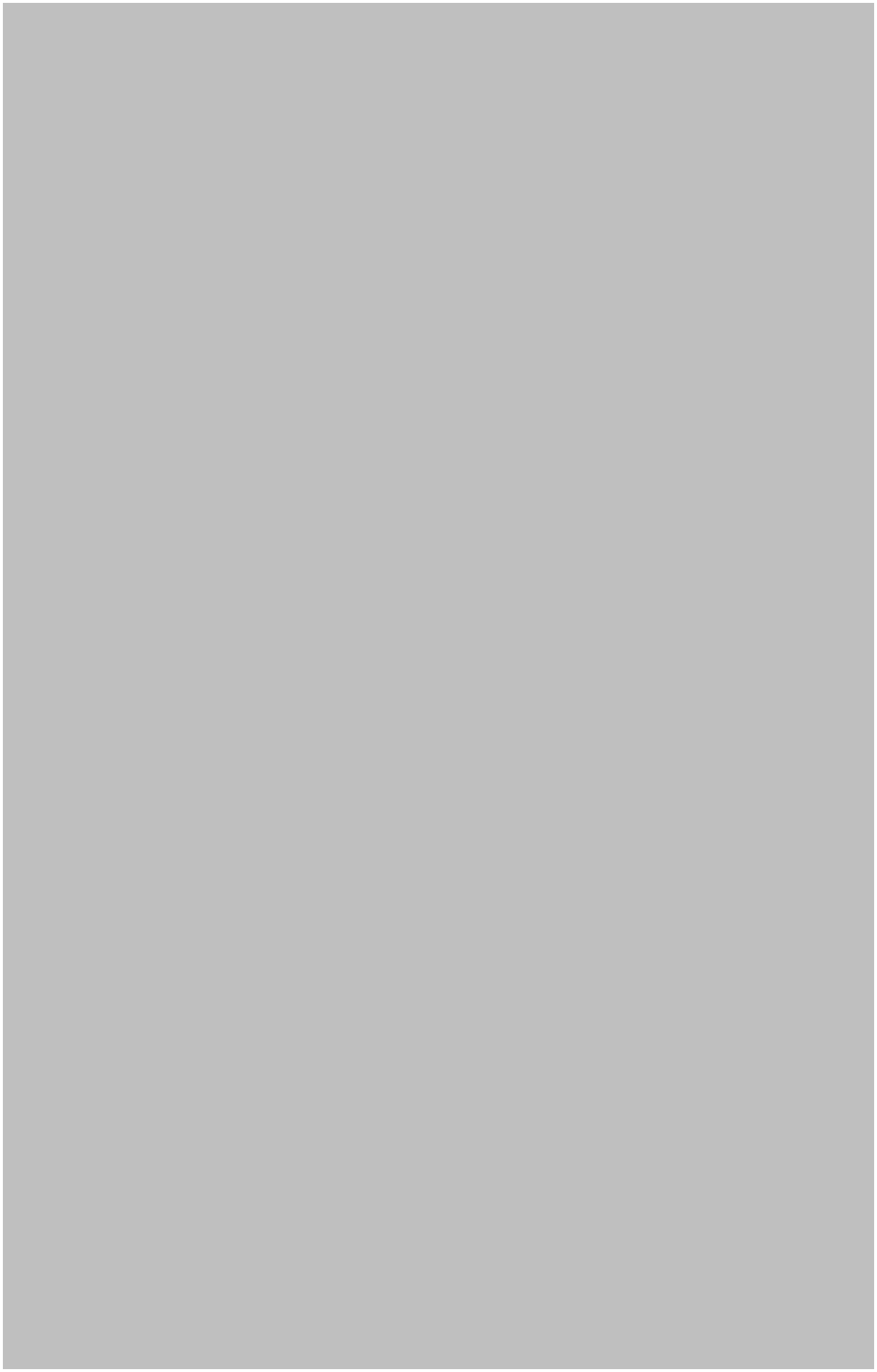


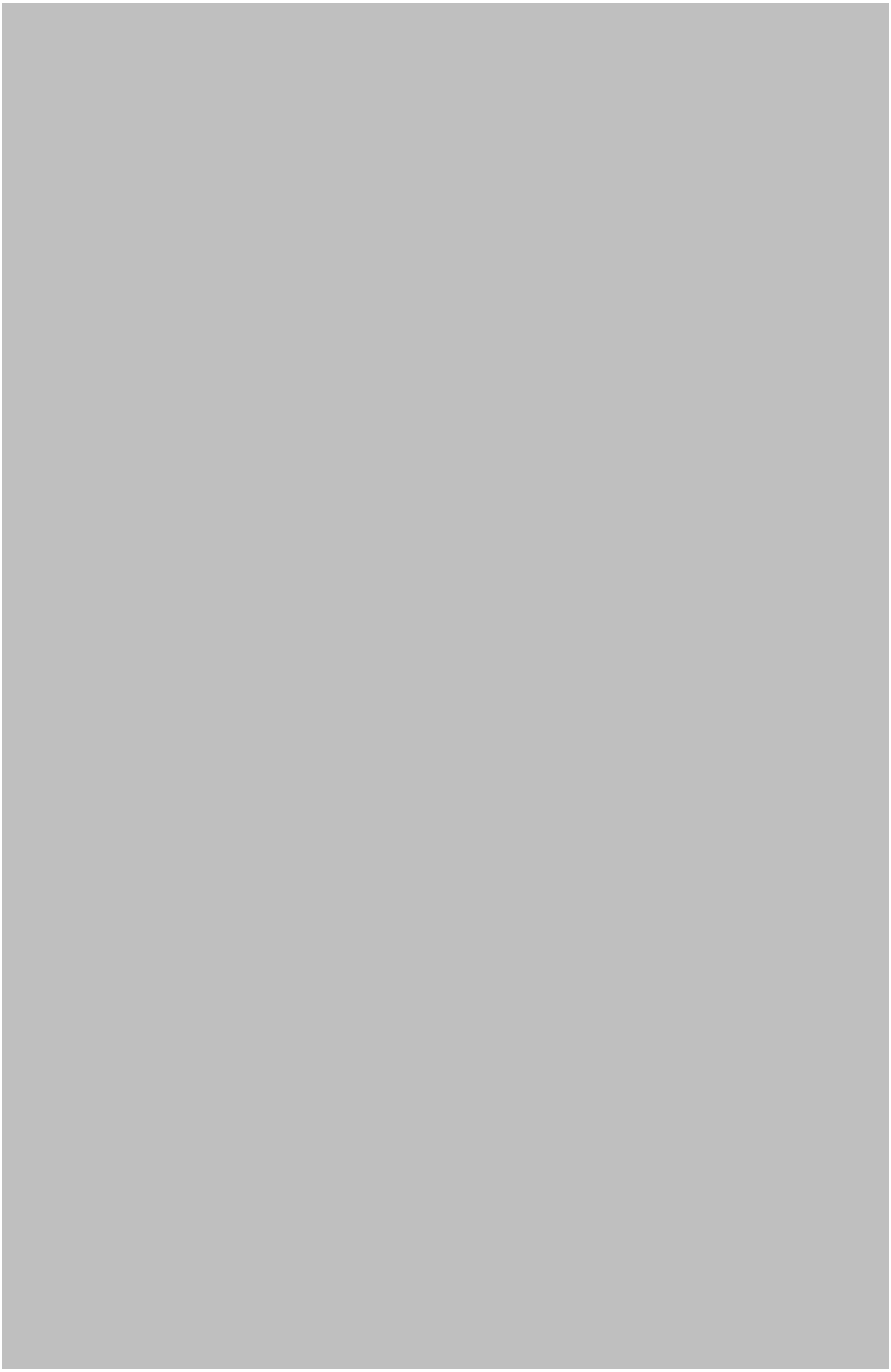


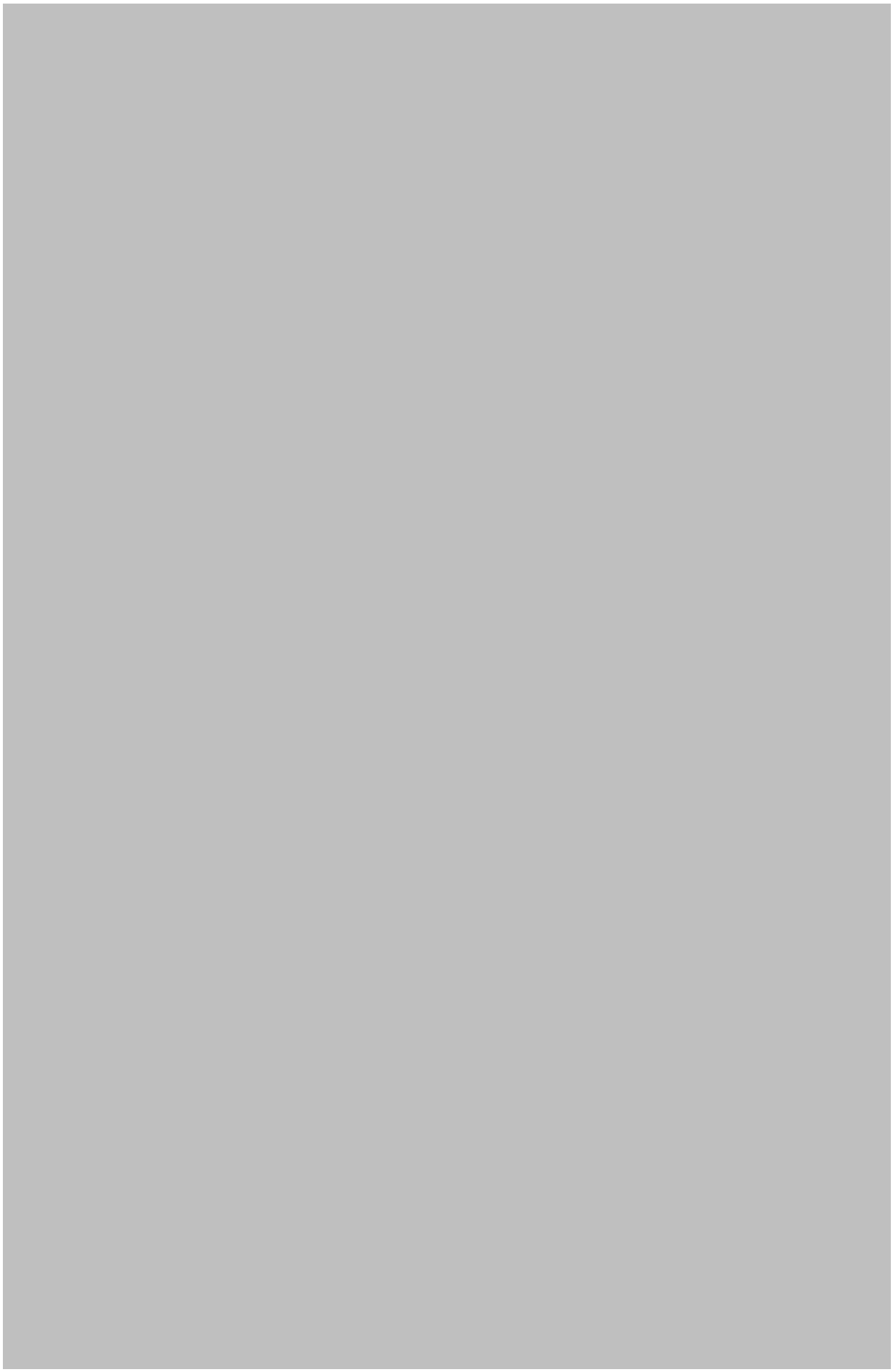


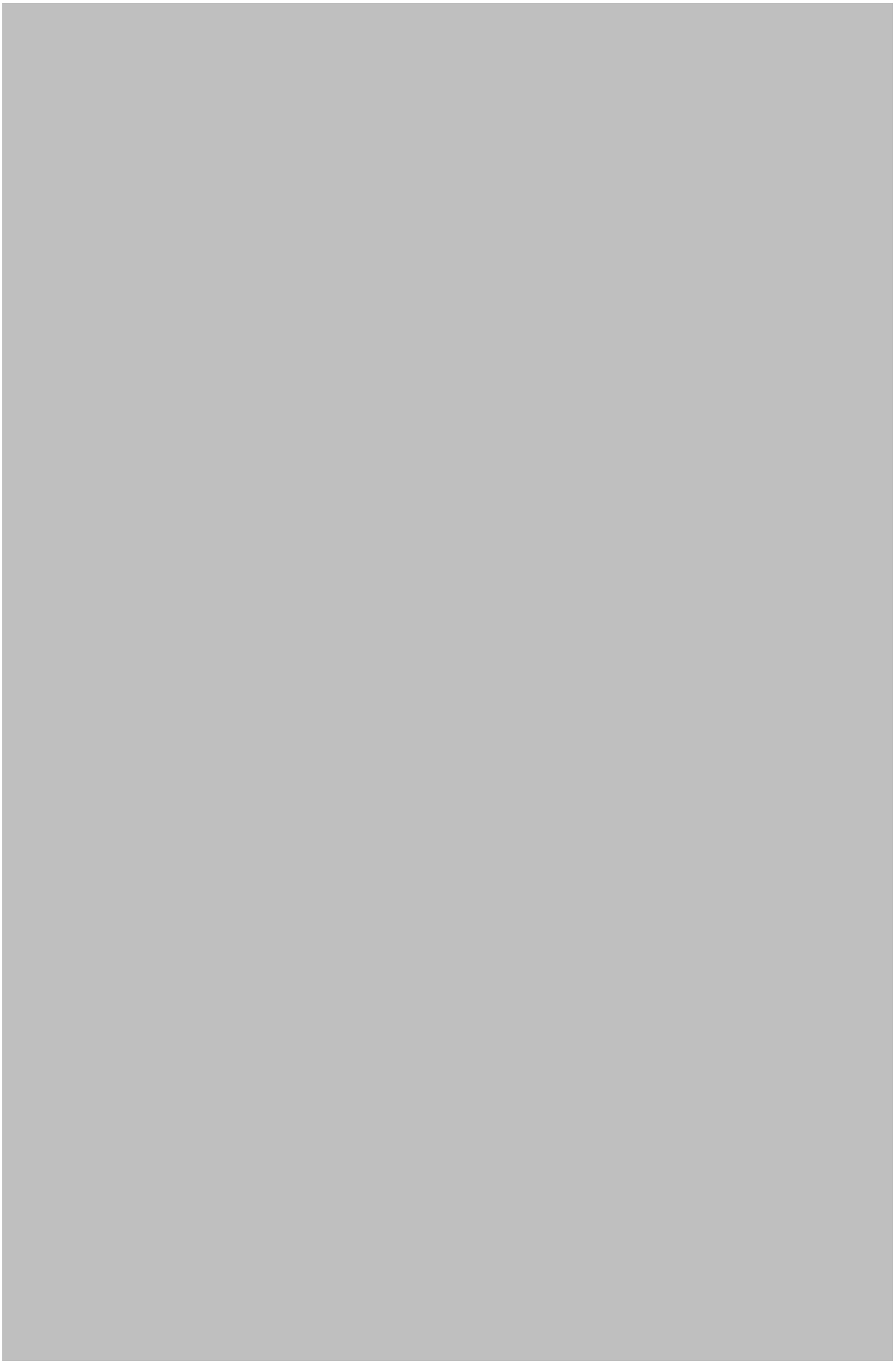


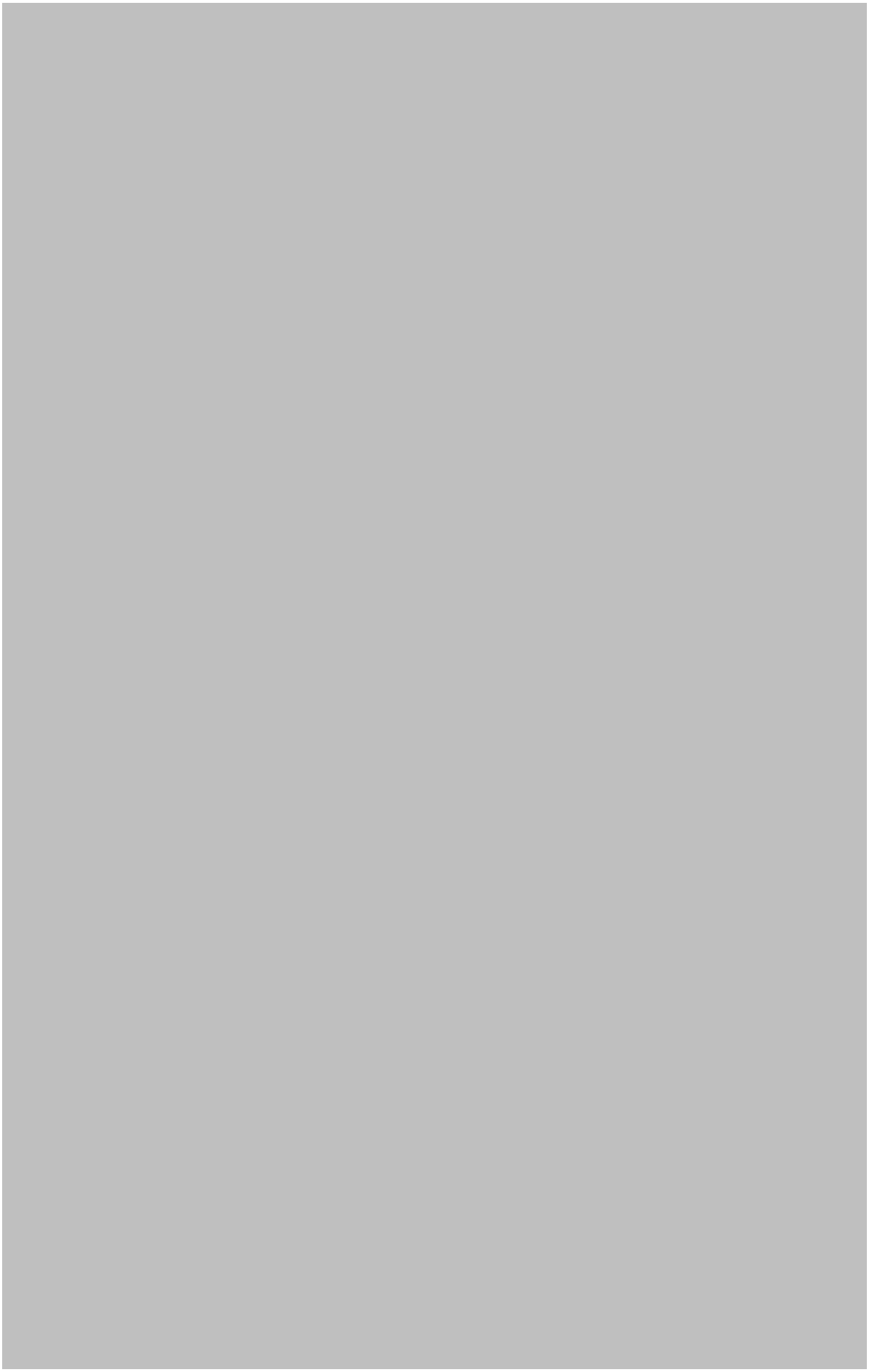


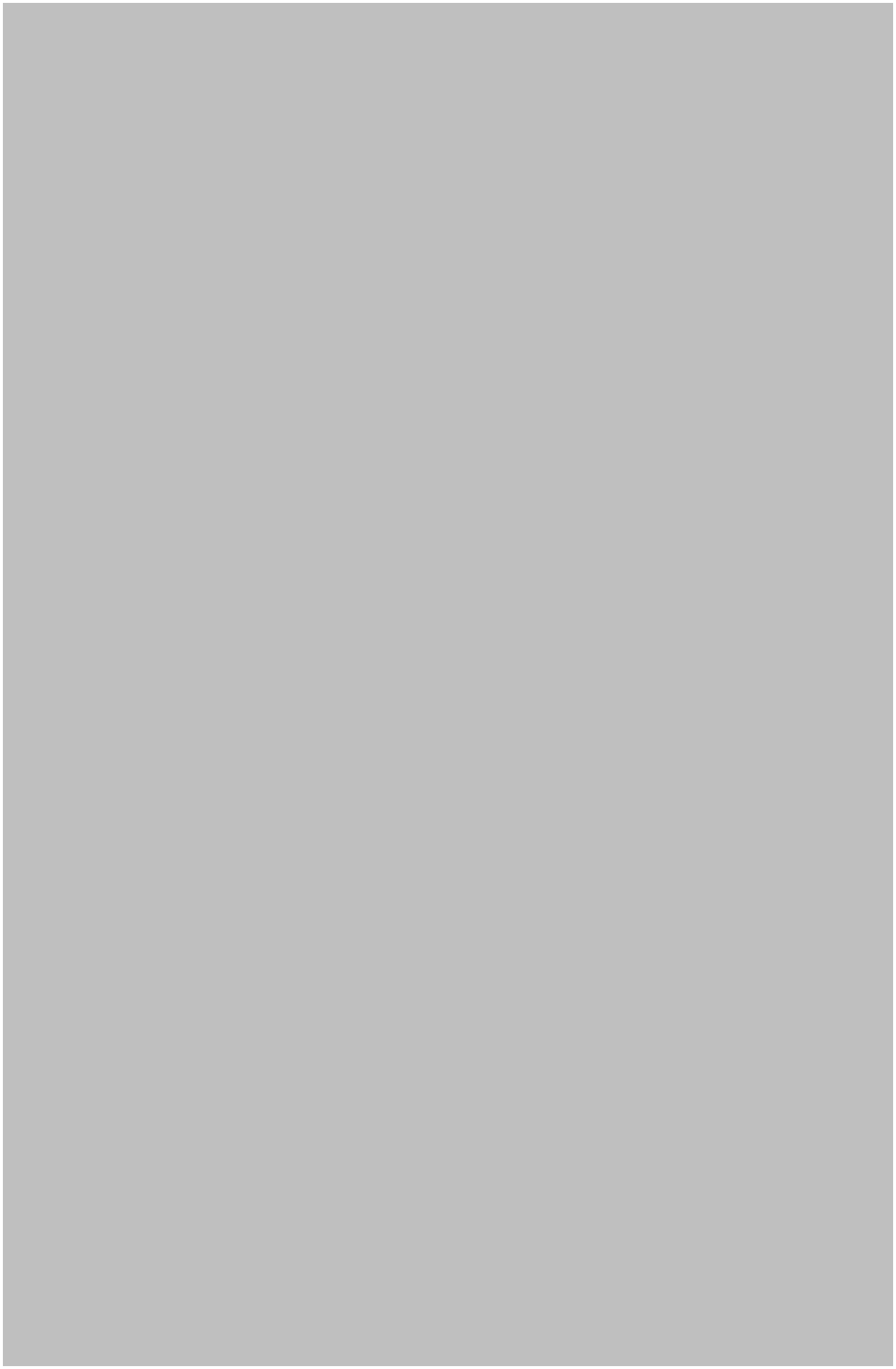


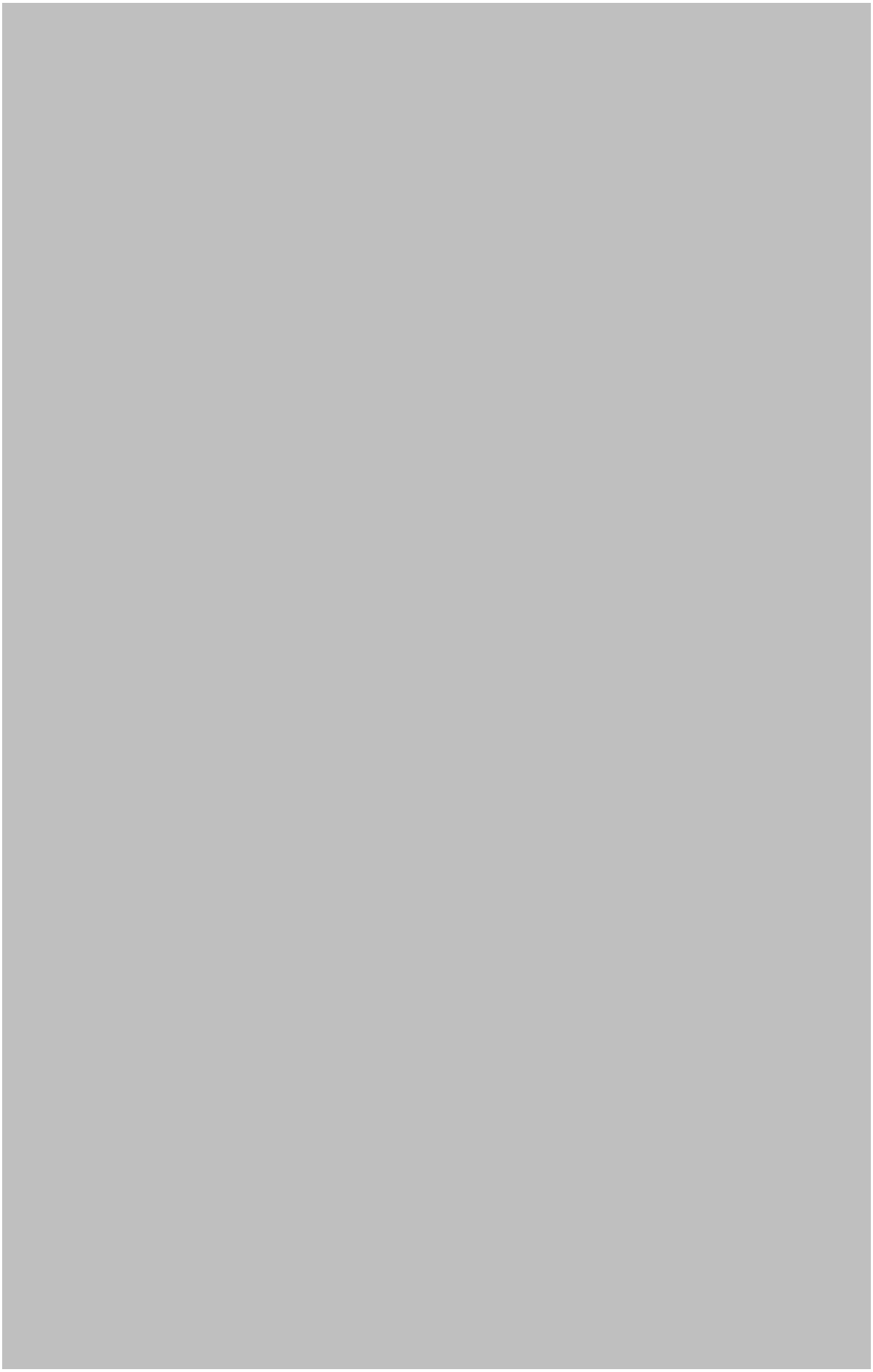


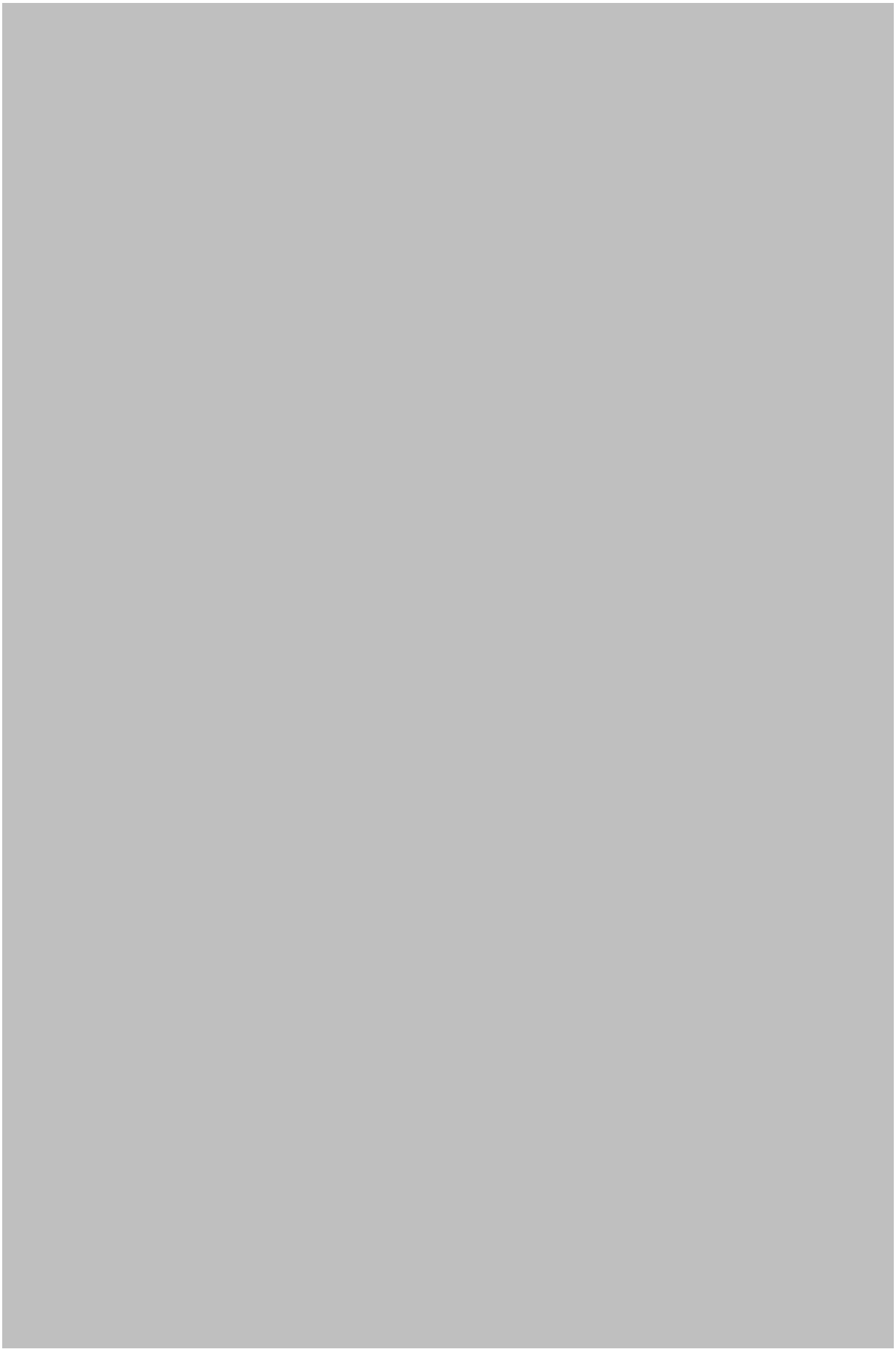


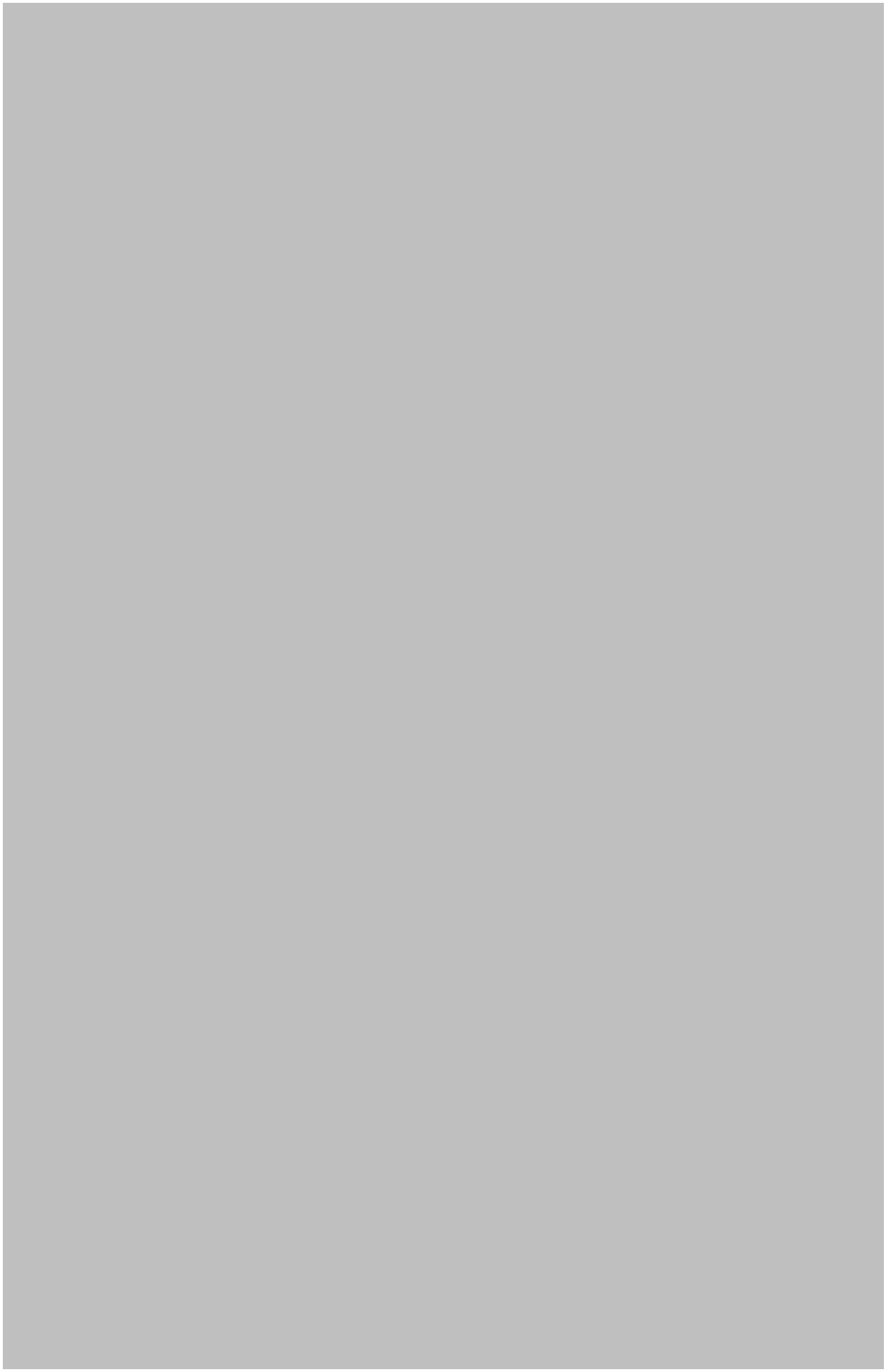


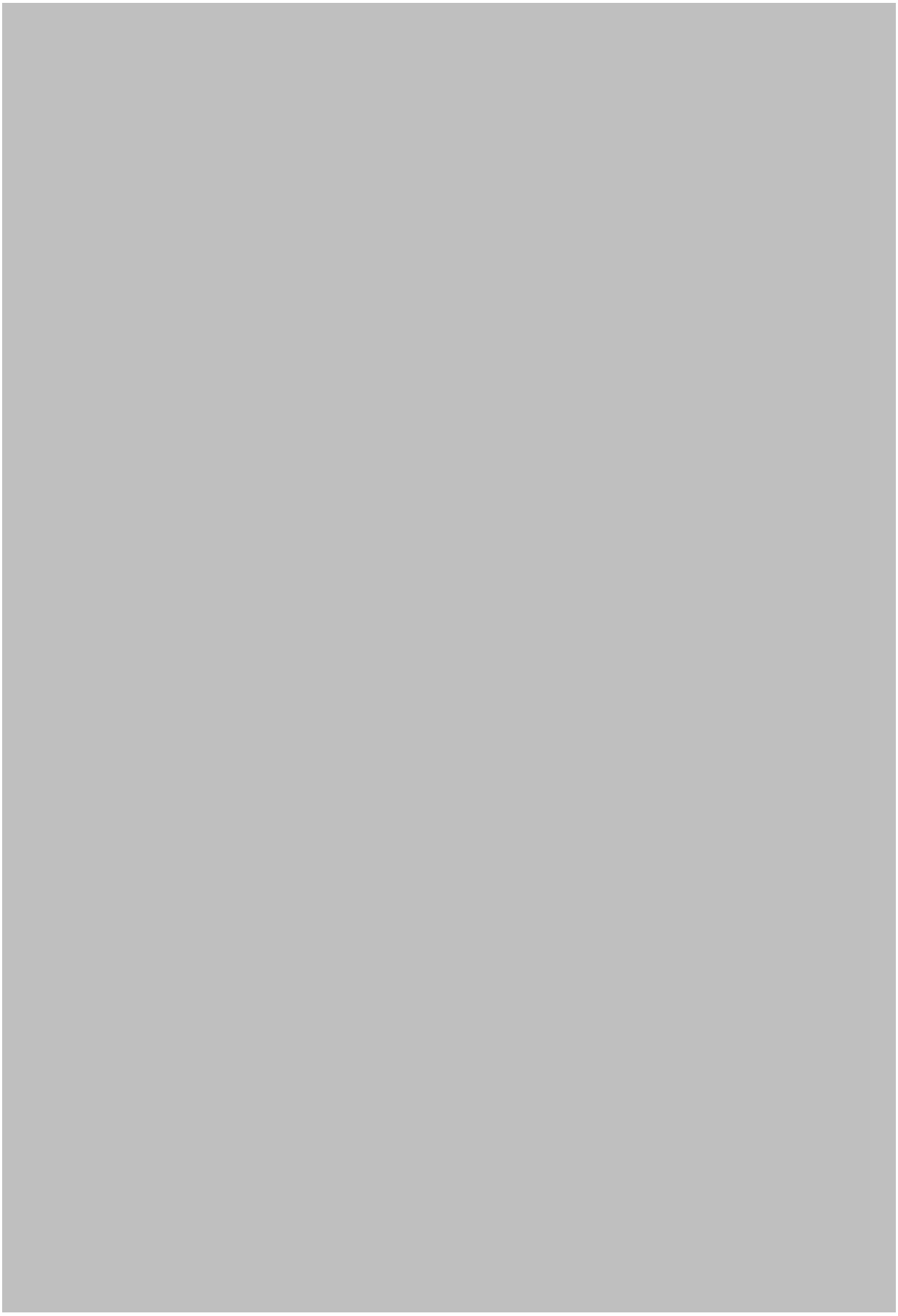


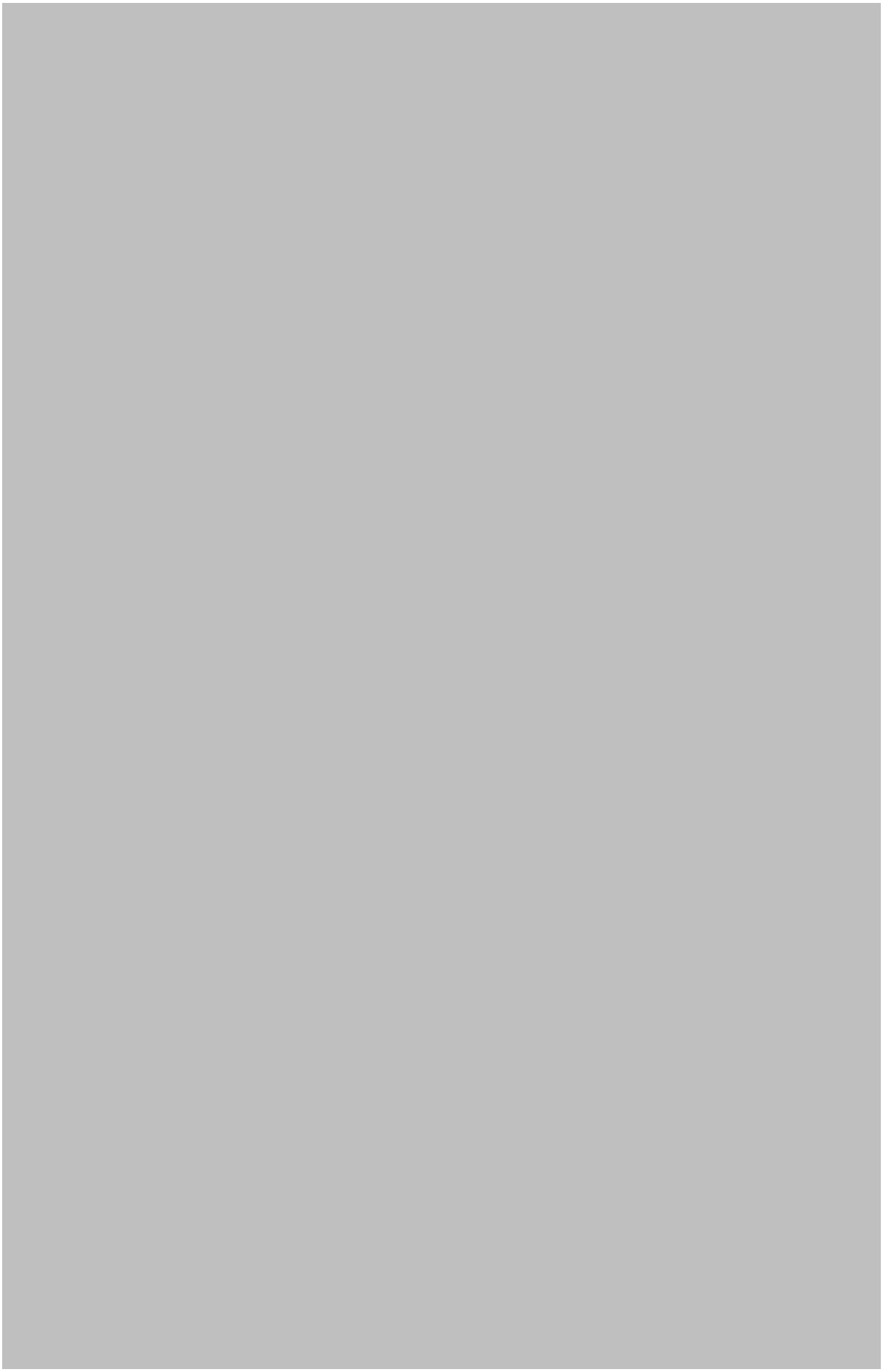


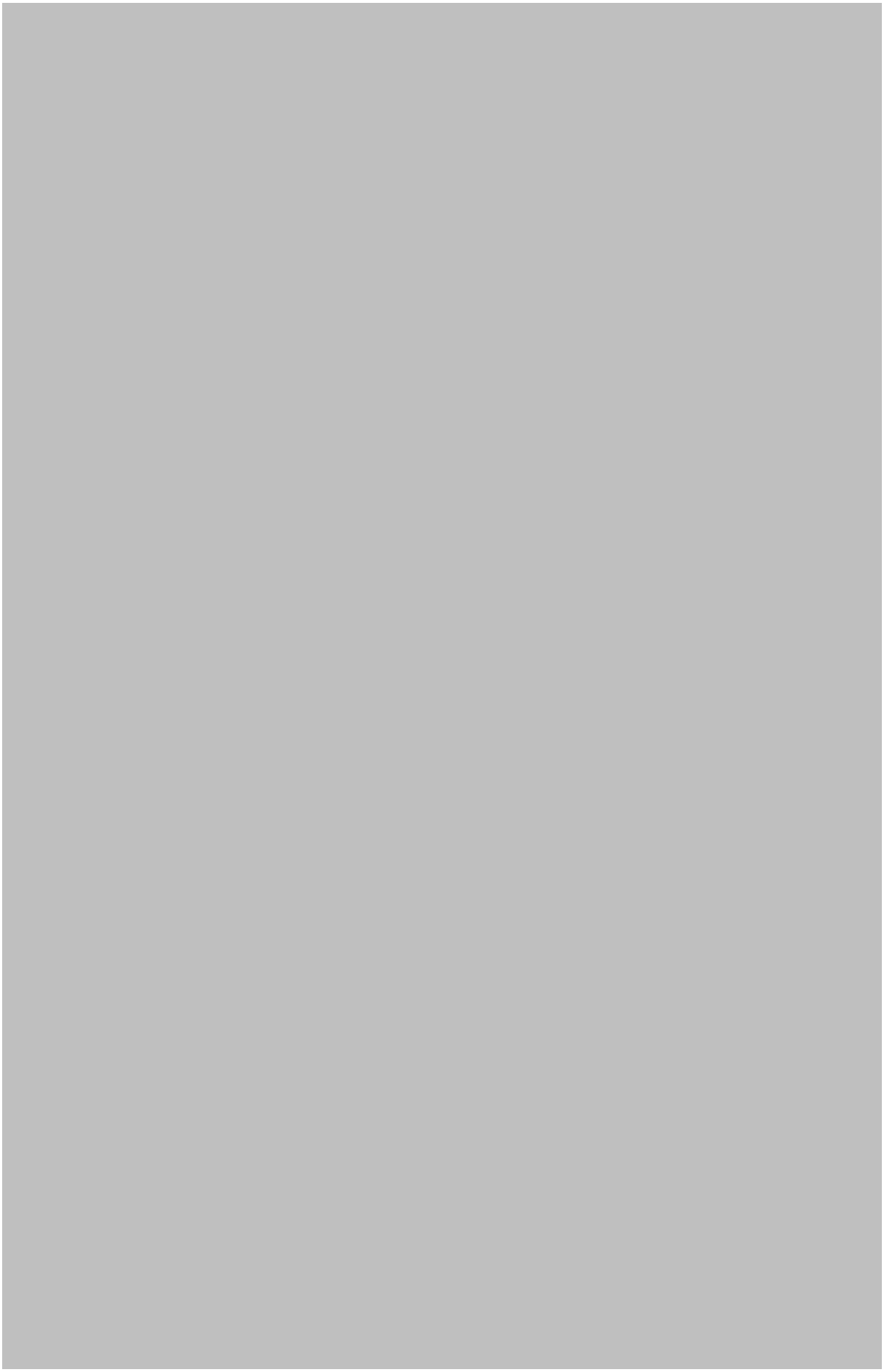


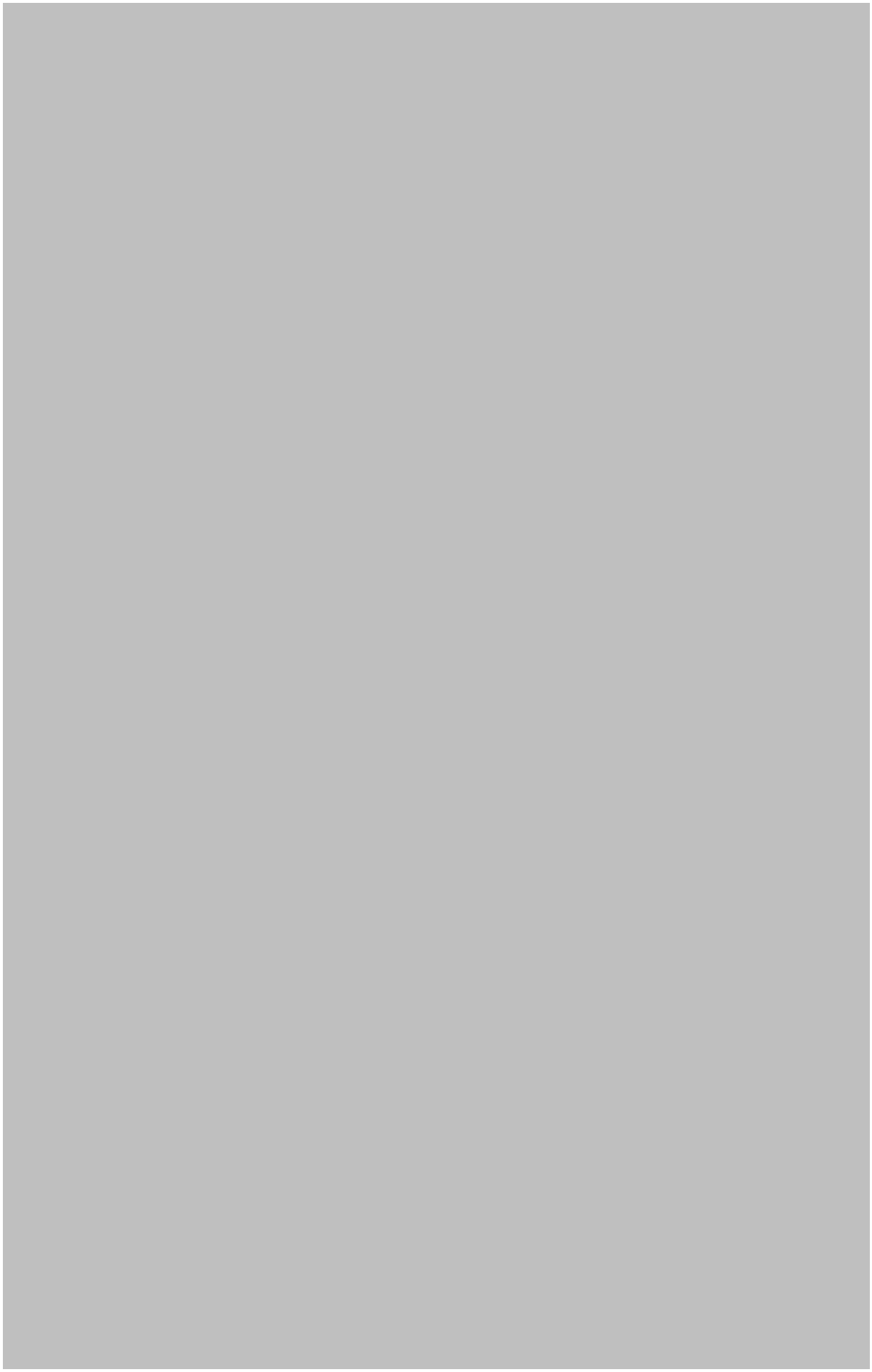


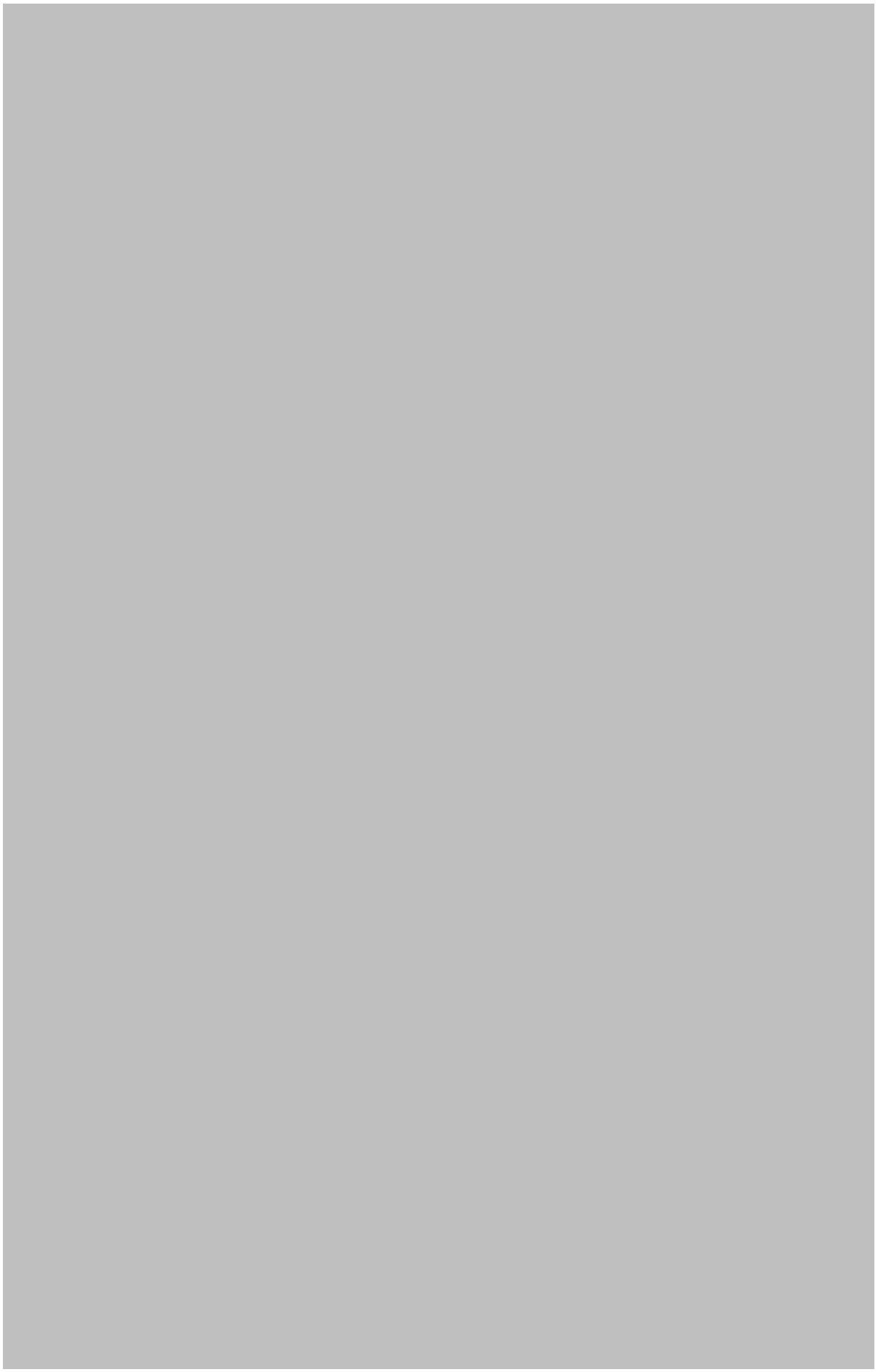


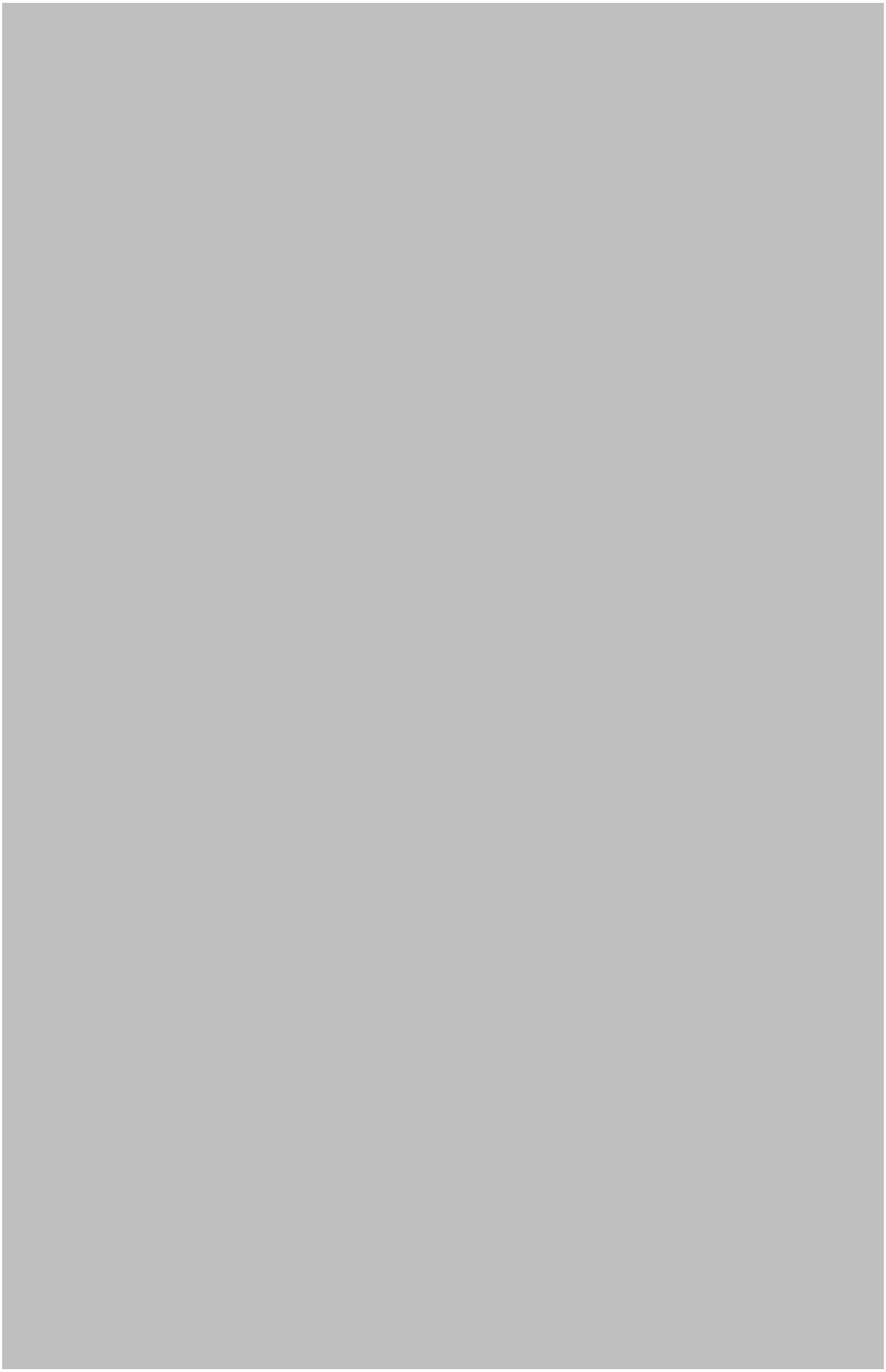


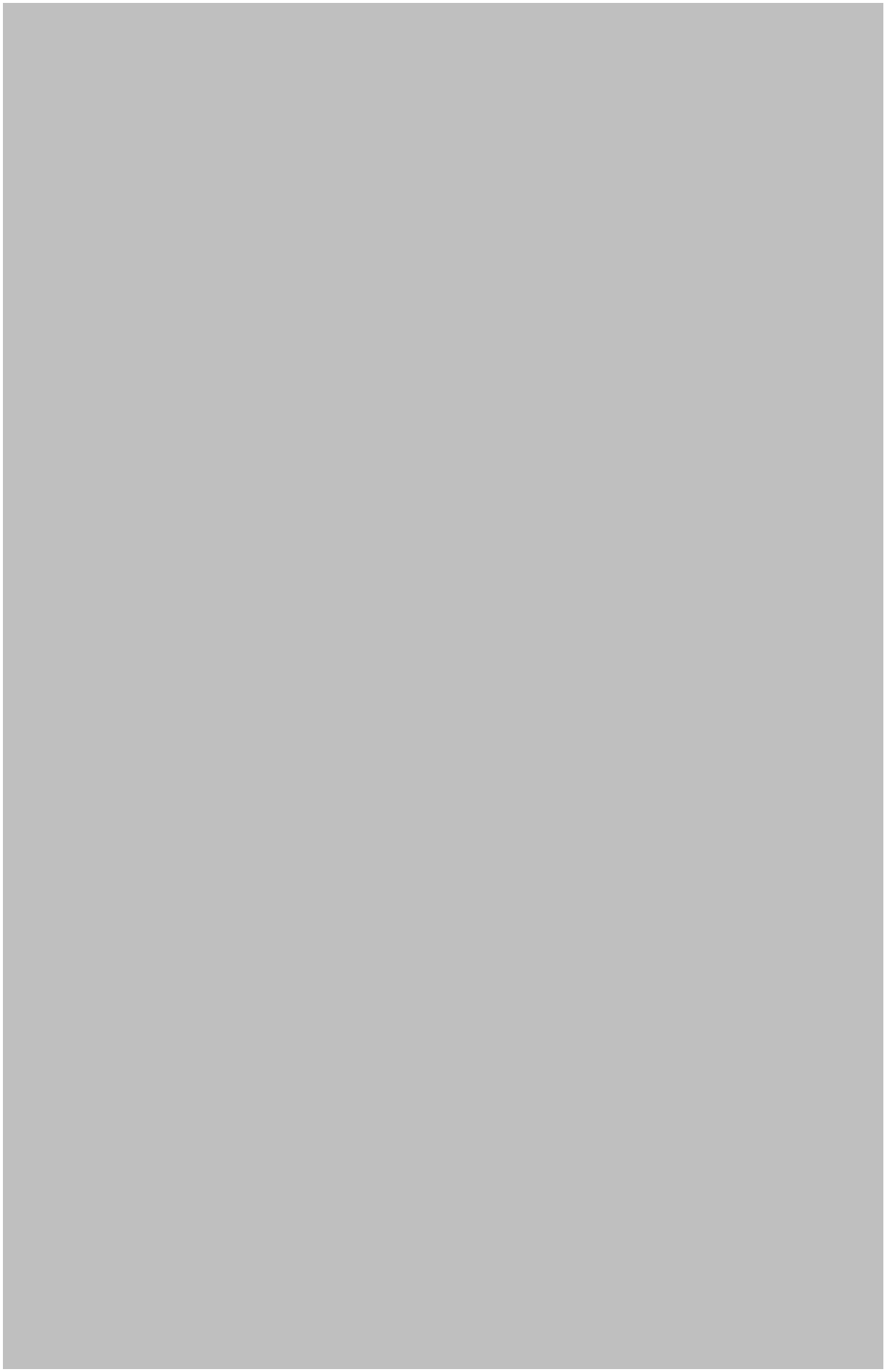


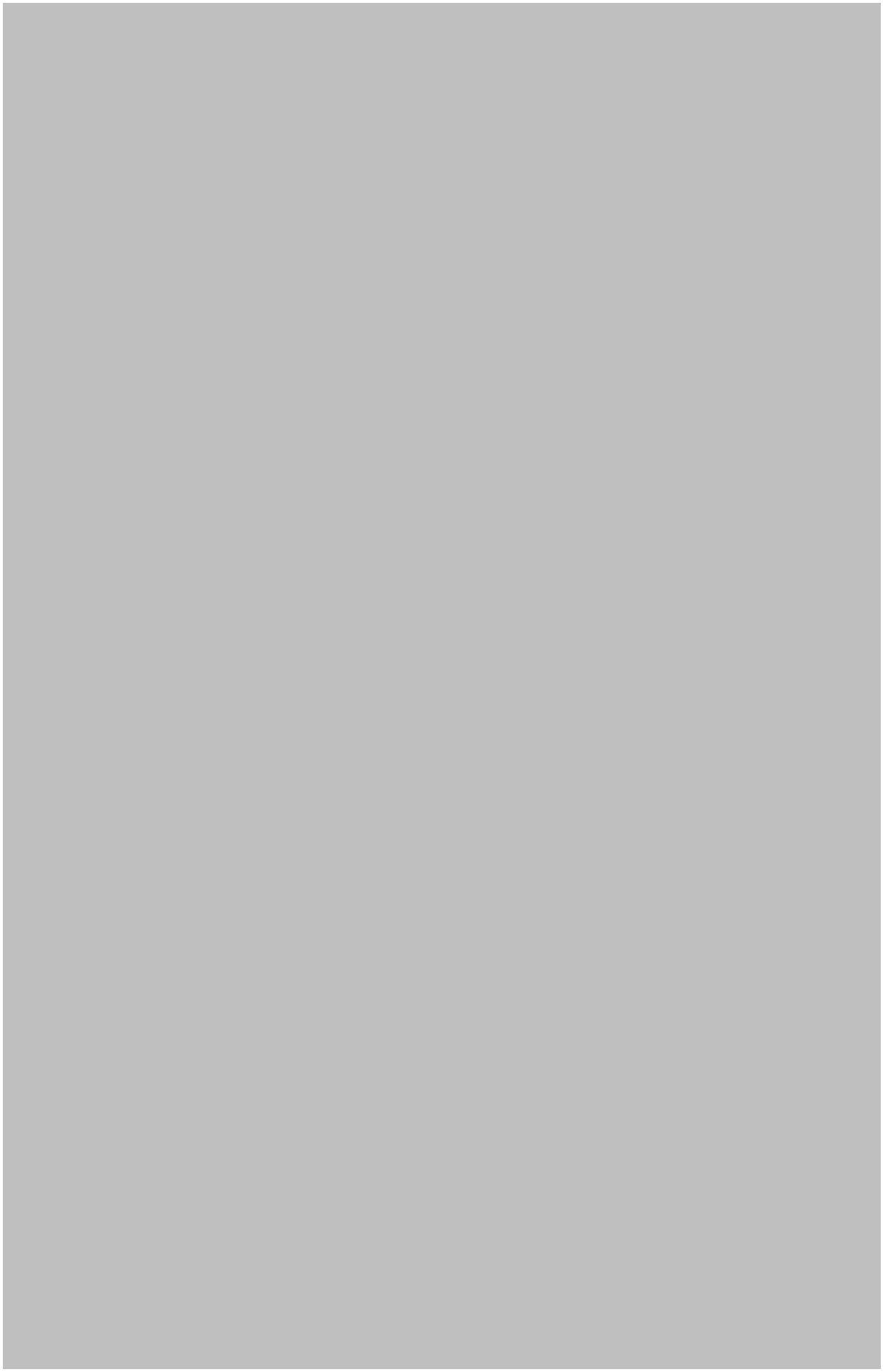


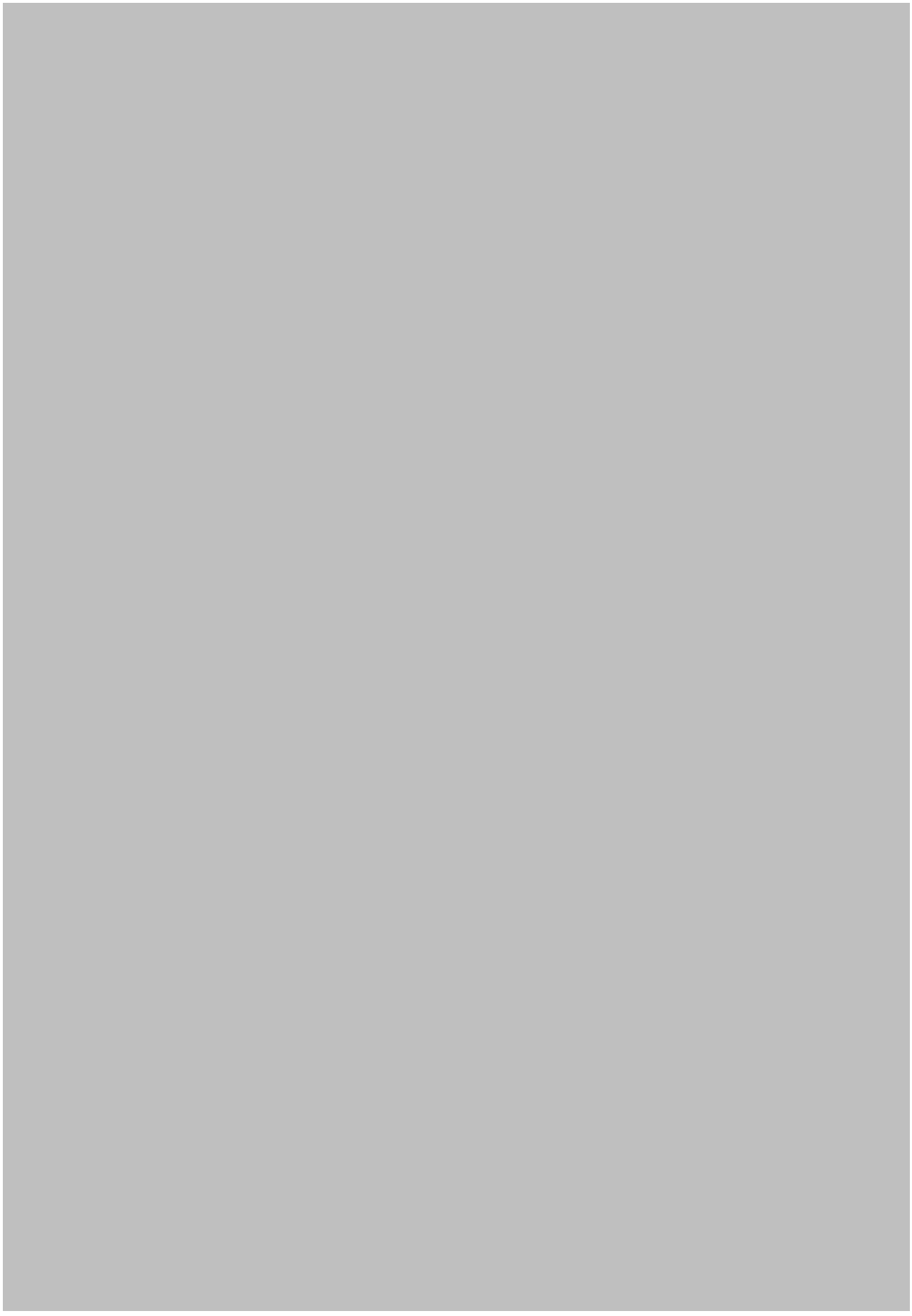












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