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Feedback to the European Commission Inception Impact Assessment on the revision of REACH

June 2021

The 23 organisations forming this Coalition welcome the opportunity to provide comments on the inception impact assessment (IIA) of the Review of the revision of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Our organisations share a view on how the essential use concept (EUC) can be introduced in a way that will tackle actual risks and not slow down the regulatory process or lead to unintended, regrettable substitution. In view of the above, our comments will be limited to the introduction of the essential use concept (EUC) in REACH and the plans to broaden the generic risk approach that – in the IIA – is intrinsically linked to the EUC.

Overall recommendation

We recommend a **pragmatic** and **targeted approach** to the scope of application of the essential use concept in European law in order to avoid a detrimental impact on consumer choices, industry ability to innovate and be competitive, and unintended regulatory impact that would hinder Europe's ability to protect human health and the environment from real threats and jeopardise the achievement of the European Green Deal's climate and circular economy objectives. The EUC should only be applied in a targeted manner, i.e., where uses of a hazardous substance present an unacceptable risk that cannot be addressed by other risk management options.

REACH and the essential use concept

The IIA provides that for restriction procedures, the REACH reform is expected to 'operationalise' the new concept of so-called 'Essential Use' (the potential new legal principle that a substance qualifying as 'most harmful chemical' may be used only if its use is 'essential for society and there are no alternatives'). While we consider that REACH has so far been successful at providing a high level of protection for human health and the environment, the decisions taken up until now have been largely targeted at addressing real risks, also taking into account socio-economic impacts. In this context, Risk / Regulatory Management Option Analyses (RMOAs) have increasingly been contributing to choosing the best regulatory route at an early stage.

The introduction of the EUC, however, poses important challenges regarding its application to REACH. The approach to essential uses as described in the EU Chemical Strategy for Sustainability indeed fundamentally contrasts with the risk-based approach that characterises REACH. It targets a broader category of 'most harmful chemicals' which could be covered by the suggested extension of the generic approach to risk management and those 'further harmful substances' including immunotoxic, neurotoxic and STOT substances.¹ As such, it contrasts with the present system for REACH Restrictions and Authorisations which clearly address risks. Both under Restrictions and Authorisations uses can be continued if they do not present an unacceptable risk or the risks are adequately controlled or outweighed by socioeconomic benefits.

Beyond REACH, the EUC already exists in international law. Its introduction in the Montreal Protocol targets a specific category of substances only to address a specific, pressing risk. Such a scope of application has successfully enabled the minimisation of the use of ozone-depleting gasses due to their impact on the ozone layer and made this intervention proportionate. The Chemical Strategy for Sustainability, to the contrary, proposes a generic approach, banning the use of all most harmful chemicals, regardless of the risk, except when for essential uses. As a result, its application may have undesired consequences on consumers choice, industry competitiveness, innovation and even EU regulatory objectives.

Risks associated with a broad application of the essential use concept

Reducing the use of substances based only on their hazard profile without accounting for the risk and exposure would not benefit society and, to the contrary, would impact consumers and industry, while hindering the ability of the EU to meet its policy objectives (including those of the European Green Deal and circular economy).

- 1) A blanket application of the EUC could, for instance, trigger unfortunate bans which would not deliver benefits to consumers or to society. This would, for instance, be the case for stainless steel which is a safe material for use in kitchen appliances and in construction materials. Similarly, the use of lead to weight the keys of a piano is perfectly safe for human health or the environment and procures benefits to musicians and their audience.
- 2) The suggested broad application of the EUC is also likely to have **an impact on industry competitiveness.** Prohibiting safe uses of hazardous substance could indeed negatively

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¹ Chemical Strategy for Sustainability, p.10

impact the availability of the technological toolkit available to EU manufacturers and will in many cases lead to a gap in performance of EU-manufactured products, reducing their attractiveness and value on markets outside the EU. That would particularly be the case where the article containing a hazardous substance is demonstrated to be safe and performs better or is cheaper and provides the same level of performance. It would also hinder the innovative capacity of EU companies and thus put them at a disadvantage compared to non-EU companies. As an example, in the photovoltaics sector, material science is constantly evolving and pushing the limits of what is possible with today's PV technology. If it is not properly designed or applied too rigidly, the EUC could create obstacles to innovation as materials and substances that are not deemed essential in current technologies could become essential to future innovations, leading to greater efficiencies while using less resources.

Furthermore, restricting the uses of certain substances to a limited number of applications could also put at risk certain economic value chains in the European Union. Extracting metals or producing substances only for limited uses may not make economic sense and what is nowadays produced by the European industry might well need to be imported from third countries with possible lower environmental standards, creating a situation of European dependency for essential uses and loss of jobs.

- 3) Finally, a non-targeted application of the EUC could impact EU regulatory objectives such as the EU's greenhouse gas reduction ambitions or the transition to a circular economy. If the EUC were to be applied in a non-targeted fashion to all substances with certain hazard classifications, it would lead to cases of regrettable substitution and to an unmanageable need to review the essentiality of countless uses:
- a. If the EUC, as defined in the Montreal Protocol, were to be automatically applied on the basis of hazard classifications, it would lead to the substitution of products either considered beneficial or even 'essential' for consumers and professionals, for less sustainable and durable materials. The market would be pushed towards using alternatives that taking into account, for example, the CO₂ emissions during their life-cycle or their lack of recyclability may be less sustainable and thus lead to a substitution that would be regrettable from a broader sustainability perspective. This would have a potentially serious impact on the EU's capacity to meet its climate change ambitions.
 - b. The wide application of the EUC to all substances with certain hazardous properties, confirmed by a case-by-case assessment, would inevitably lead to the need for an assessment of the different uses of all these substances. The impact of this on the regulatory process and its length should not be underestimated. There are substances which are used in many different applications, which would therefore require a very granular assessment. Moreover, regardless of the toxicity profile of the substance, there are articles which are safe and which can be safely recycled. If the 'essentiality assessment' were applied to all of these uses, the approval process would be burdensome and much slower. Limited regulatory resources would be deployed to assess essentiality of uses, and could not be dedicated in a more focused manner to address risk.

The way forward

We recommend that the scope of application of the essential use concept only targets cases where no satisfactory risk management option is available, and where it supports, but does not pre-empt regulatory decisions. This could be achieved through a clear, transparent framework and process for decision making that must be subject to appeal by industry stakeholders.

We strongly encourage the Commission and Member States to carefully consider the scope of applicability of the EUC. In this context, we welcome particularly point 9 of the Council conclusions on the CSS.² The assessment should not be limited to a pure chemicals management perspective, but needs to be better integrated with other policy objectives (including others in the frame of the Green Deal) and must consider the risk of negative tradeoffs.

The EUC should not be automatically linked to hazard classifications, but rather be applied in a targeted manner, i.e. where uses of a hazardous substance present an unacceptable risk that cannot be addressed by other risk management options. Those other options could, for example, be targeted restrictions/authorisations covering those uses which lead to an unacceptable risk. Restrictions, for example, could either regulate such uses more strictly (e.g. by setting protective release limits for articles and ensuring the safe disposal / recycling of these articles) or they could, if necessary, ban specific uses, the safety of which cannot be appropriately ensured. These targeted restrictions would spare other safe uses of substances and ensure proportionality of decision making. The burdensome essentiality assessment would only be triggered where justified.

In this context, we encourage authorities to consider very seriously the role of RMOAs in the development of the EUC. RMOAs appear to be the ideal tool to identify the most suitable risk management option, including those cases where the ban except for all essential uses appears to be justified.

Conclusion

A pragmatic and targeted approach to the scope of application of the EUC is needed to avoid a negative impact on consumer choices, industrial competitiveness, and innovation. Moreover, such an approach would prevent unintendedly hindering the EU's ability to protect human health and the environment and thus jeopardising the achievement of the European Green Deal's objectives.

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Sustainable Chemicals Strategy of the Union: Time to Deliver - Council conclusions ² Point 9: "UNDERLINES the importance of the impact assessments that the Commission intends to carry out in order to gather information and assess the possible impact of the actions foreseen in the Strategy, including for SMEs; STRESSES the importance of these impact assessments being performed in a way that supports the timely implementation of the Chemicals Strategy and provides support for evidence-based decision making".

About ACEA - European Automobile Manufacturers' Association

The European Automobile Manufacturers' Association (ACEA) represents the 15 major Europe-based car, van, truck and bus makers: BMW Group, CNH Industrial, DAF Trucks, Daimler, Ferrari, Ford of Europe, Honda Motor Europe, Hyundai Motor Europe, Jaguar Land Rover, Renault Group, Stellantis, Toyota Motor Europe, Volkswagen Group, Volvo Cars, and Volvo Group.

- 14.6 million Europeans work in the auto industry (directly and indirectly), accounting for 6.7% of all EU jobs.
- 11.5% of EU manufacturing jobs some 3.7 million are in the automotive sector.
- Motor vehicles account for €440.4 billion in taxes in major European markets.
- The automobile industry generates a trade surplus of €74 billion for the EU.
- The turnover generated by the auto industry represents over 7% of EU GDP.
- Investing €60.9 billion in R&D annually, the automotive sector is Europe's largest private contributor to innovation, accounting for 29% of total EU spending.

http://www.acea.be/

About AmCham EU

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and U.S. positions on business matters. Aggregate U.S. investment in Europe totalled more than €3 trillion in 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

About APEAL

APEAL – the Association of European Producers of steel for packaging – unites the six producers of steel for packaging in Europe. APEAL's membership accounts for the totality of European production of ETP and ECCS steel for packaging. The six companies that comprise the APEAL member companies employ 200,000 people in Europe, with an estimated 15,000 workers directly in steel for packaging activities. APEAL is committed to working with all relevant stakeholders to ensure understanding and support for steel as a sustainable and resource efficient packaging solution through documentation of, support for and communication on the environmental, social and economic benefits of steel for packaging. We support our mission by contributing positively to the development of EU policy related to steel for packaging, particularly in the areas of packaging, waste, recycling and recovery.

About BeST

The Beryllium Science and Technology Association (BeST) represents the suppliers of beryllium to the EU market and industries who rely on the unique properties of beryllium to design for miniaturisation, energy conservation, greater reliability and longer product life.

About Cerame-Unie – The European Ceramic Industry Association

Cerame-Unie is the voice of the European ceramic industry. This industry covers a wide range of products including abrasives, bricks & roof tiles, clay pipes, wall & floor tiles, refractories, sanitaryware, table- & ornamentalware, technical ceramics and porcelain enamel. The industry generates over 200,000 direct jobs and a production value of €27 billion within the EU.

About CETS – European Committee for Surface Treatment

CETS is an international federation of national associations engaged in the supply of technology, chemicals, and paint products to the surface treatment industry. Its purpose is to provide a scientific and engineering voice at the European Union on proposals for environmental, health and safety legislation.

About ECGA – European Carbon and Graphite Association

ECGA is the Carbon and Graphite Industry's representative voice on all carbon and graphite industry's related issues.

About ETRMA

ETRMA is the voice of tyre and rubber goods producers in the European Union and its activities focus on the following key interdependent areas: representation, co-ordination, communication, promotion and technical liaison. The primary objective of ETRMA is to represent the regulatory and related interests of the European tyre and rubber manufacturers at both European and international levels. ETRMA is the sole interlocutor, specifically designated by the European tyre and rubber producers to carry out this critical task. www.etrma.org

About Eurobat

EUROBAT is the association for the European manufacturers automotive, industrial and energy storage batteries. EUROBAT has more than 50 members from across the continent comprising more than 90% of the automotive and industrial battery industry in Europe. The members and staff work with all stakeholders, such as battery users, governmental organisations and media, to develop new battery solutions in areas of hybrid and electro-mobility as well as grid flexibility and renewable energy storage.

About Eurogypsum

Eurogypsum is a European federation of national associations of producers of gypsum products, including plaster and plasterboard. It is one of the few fully integrated industries (from cradle to cradle) within the construction products field. The companies which mine gypsum also process it and manufacture the value-added products and systems used extensively in construction and other industries.

With a turnover of EUR 7 billion, the European gypsum and anhydrite industry operates some 160 factories and 154 quarries and generates employment directly to 28,000 persons and indirectly for 300,000 persons. The gypsum industry provides jobs to 1,100,000 plasterers and plasterboard installers. It trains around 25,000 persons per year across Europe.

www.eurogypsum.org | info@eurogypsum.org | @Eurogypsum

About the European Steel Association (EUROFER)

EUROFER AISBL is located in Brussels and was founded in 1976. It represents the entirety of steel production in the European Union. EUROFER members are steel companies and national steel federations throughout the EU. The major steel companies and national steel federations in Switzerland and Turkey are associate members.

About EXCA

The European Expanded Clay Association (EXCA) represents the interests of all major expanded clay producers throughout Europe. Expanded clay is a natural, light and durable material, widely used in construction and as a growing media all over Europe. EXCA represents 90% of the European expanded clay industry.

About FEC

The Federation of European manufacturers of Cookware and cutlery (FEC) represents European companies dealing with cookware, cutlery and other products* used for preparing and serving of food as well as for dining, with one voice, wherever common interests are met.

(*Electrical household appliances are not part of the product range.)

About FEPA

FEPA, the Federation of European Producers of Abrasives, is an association representing over 80% of the European manufacturers of abrasive products, including SMEs and international companies, as well as the abrasives National Associations and their members. FEPA members cover 90% of abrasives European production, exporting 35% of it in the world.

FEPA's main mission is to represent the European abrasive industry by promoting abrasives manufactured in Europe, informing members on the evolution of the regulatory framework worldwide, supporting producers with a range of technical, legal and scientific services, and anticipating future challenges in the abrasives sector. Abrasives are essential components weaved into numerous industries such as construction, automobile, aeronautics, environment, optical activities, glass, electronics, and the DIY market.

About ILA

With its member companies at the forefront of the mining, smelting, refining and recycling, the International Lead Association (ILA) represents the producers of ~3 million tonnes of lead worldwide. As the trusted trade association for the lead industry, ILA is working towards a vision of a sustainable global lead industry that is recognised for the positive contribution it makes to society.

About IMA-Europe

IMA-Europe represents industrial minerals such as Calcium Carbonates (GCC/PCC), Dolomite, Andalusite, Bentonite, Borates, Diatomite, Feldspar, Kaolin, Lime, Mica, Plastic Clays, Sepiolite, Silica, Talc. This industry consists of about 300 large, medium and small companies or groups operating about 810 mines and quarries and 830 plants across Europe, Norway, Switzerland and Turkey. Industrial minerals are essential raw materials for various products such as glass, ceramics, industrial fluids, agriculture, construction materials, metallurgy, coatings, pet litter, plastics, paper, paints, electronics, detergents and other.

About the Nickel Institute

The Nickel Institute represents primary nickel producers at European and international level. Through our science division, NiPERA, we also undertake leading edge scientific research relevant to human health and the environment. The Nickel Institute is the centre of excellence for information on nickel and nickel-containing materials.

About PVthin

PVthin is an international, not-for-profit coalition representing global leaders in the Thin-Film Solar Industry and broader value chain based on chalcogenide, perovskite, tandem and heterojunction PV technologies. Its objective is to strengthen global energy security and help create sustainable energy infrastructures by promoting the social, economic and environmental benefits of thin-film solar photovoltaic technologies.

About RECHARGE

Representing the battery industry of the future, RECHARGE is the industry association of the advanced rechargeable and lithium batteries value chain in Europe. Advanced rechargeable batteries are a strategic key technology that contribute to a more empowered, sustainable and circular economy by enabling decarbonized electricity and mobility. Founded in 1998, RECHARGE's unique membership covers all aspects of the battery value chain: From suppliers of primary and secondary raw materials, to battery and original equipment manufacturers (OEMs), to logistic partners and battery recyclers. For more information, visit www.rechargebatteries.org or follow us at @RechargeEurope.

About SME United

SMEunited is the employers' organisation representing the interests of European crafts, trades and SMEs at EU level. SmeUnited is a recognised European Social Partner. It is a non-profit seeking and non-partisan organisation. As the European SME umbrella organisation, SMEunited incorporates around 80 member organisations from 34 countries consisting of national cross-sectorial SME federations, European branch federations and other associate members, which support the SME family. SMEunited represents more than 12 million enterprises, which employ around 55 million people across Europe.

About UNIFE

Operating in Brussels since 1992, UNIFE represents European train builders and rail equipment suppliers. The association advocates on behalf of more than 100 of Europe's leading rail supply companies – from SMEs to major industrial champions - active in the design, manufacture, maintenance and refurbishment of rail transport systems, subsystems and related equipment. UNIFE also brings together national rail industry associations from 11 European countries. Our members account for 84% of the European, and 46% of the global, market for rail equipment and services. We communicate members' interests at the European and international levels while actively promoting rail equipment and standards worldwide.

About WSM – German Steel and Metal Processing Industry Association

WSM represents the economic policy interests of the steel and metal processing industry and is one of the largest business associations in Germany. The German steel and metal processing industry are approximately 5,000 mainly medium-sized industrial companies with a turnover of about 80 billion euros a year and an average number of employees of around 500,000.

About WVMetalle

WirtschaftsVereinigung Metalle (WVMetalle), the German Non-Ferrous Metals Association, represents the German Non-Ferrous (NF) metals industry towards politics and economy in order to maintain and establish measures at a very high level. Today, WVMetalle has about 670 member companies, including producers and processors of most base and special metals and compounds.