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Public consultation on the targeted revision of the REACH Regulation ((EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals)

Fields marked with * are mandatory.

Introduction

REACH (Regulation (EC) No 1907/2006) aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

The REACH Regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in the European Chemicals Agency (ECHA) in Helsinki. The Regulation also calls for the progressive substitution of the most dangerous chemicals (referred to as "substances of very high concern") when suitable alternatives have been identified.

The Chemicals Strategy for Sustainability recognises the need for a targeted revision of REACH to achieve its objectives by addressing a number of problems that have been identified. To address the problems identified, a range of possible measures are being considered:

- Revision of the registration requirements, including increased information requirements to enable effective identification of all carcinogenic substances and substances with critical hazard* properties (including effects on the nervous and the immune systems), registration of certain polymers of concern, and information on the overall environmental footprint of chemicals.
- Introduction of (a) Mixtures Assessment Factor(s) (MAF).
- Simplifying communication in the supply chains.
- Revision of the provisions for dossier and substance evaluation.
- Reforming the authorisation process.
- Reforming the restriction process.
- Revision of provisions for control and enforcement.

The overall objective of the initiative is to ensure that the provisions of the REACH Regulation reflect the

ambitions of the Commission on innovation for safe and sustainable chemicals and a high level of protection of health and the environment, while preserving the internal market, as provided for in the Chemicals Strategy for Sustainability.

Under Article 11 of the Treaty on European Union (TEU), the Commission has a duty to carry out broad consultations with interested parties in order to ensure that EU action is coherent and transparent. This public consultation therefore represents an important means of collecting evidence to support our policymaking. The aims are to take account of stakeholders' views and practical experience and gather data to improve our understanding of the issues at stake, which will lead to better quality and credibility of this policy initiative.

In this questionnaire, general questions are provided to which all respondents are kindly invited to provide feedback. Additional "expert" questions are included to cover more technical points of the REACH Regulation that require prior knowledge and expertise. Based on your answer to question 0, the relevant questions will be presented. Expert questions are presented in red text.

A number of separate 'targeted' stakeholder consultations will run in parallel with this public consultation, to seek more detailed, technical information on the possible changes to REACH.

**Note: a "hazard" is something that has the potential to harm you and "risk" encompasses the likelihood of a hazard causing harm.*

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian

- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* I am giving my contribution as
  - Academic/research institution
  - Business association
  - Company/business organisation
  - Consumer organisation
  - EU citizen
  - Environmental organisation
  - Non-EU citizen
  - Non-governmental organisation (NGO)
  - Public authority
  - Trade union
  - Other

* First name

Nadia

* Surname

Allen

* Email (this won't be published)

nadia.allen@amchameu.eu

* Organisation name

255 character(s) maximum

American Chamber of Commerce to the EU (AmCham EU)

* Organisation size

- ( ) Micro (1 to 9 employees)
- (•) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

Transparency register number

255 character(s) maximum

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

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* Country of origin

Please add your country of origin, or that of your organisation.

- ( ) Afghanistan
- ( ) Åland Islands
- ( ) Albania
- ( ) Algeria
- ( ) American Samoa
- ( ) Andorra
- ( ) Angola
- ( ) Anguilla
- ( ) Antarctica
- ( ) Antigua and Barbuda
- ( ) Argentina
- ( ) Armenia
- ( ) Aruba
- ( ) Australia
- ( ) Austria
- ( ) Azerbaijan
- ( ) Bahamas
- ( ) Djibouti
- ( ) Dominica
- ( ) Dominican Republic
- ( ) Ecuador
- ( ) Egypt
- ( ) El Salvador
- ( ) Equatorial Guinea
- ( ) Eritrea
- ( ) Estonia
- ( ) Eswatini
- ( ) Ethiopia
- ( ) Falkland Islands
- ( ) Faroe Islands
- ( ) Fiji
- ( ) Finland
- ( ) France
- ( ) French Guiana
- ( ) Libya
- ( ) Liechtenstein
- ( ) Lithuania
- ( ) Luxembourg
- ( ) Macau
- ( ) Madagascar
- ( ) Malawi
- ( ) Malaysia
- ( ) Maldives
- ( ) Mali
- ( ) Malta
- ( ) Marshall Islands
- ( ) Martinique
- ( ) Mauritania
- ( ) Mauritius
- ( ) Mayotte
- ( ) Mexico
- ( ) Saint Martin
- ( ) Saint Pierre and Miquelon
- ( ) Saint Vincent and the Grenadines
- ( ) Samoa
- ( ) San Marino
- ( ) São Tomé and Príncipe
- ( ) Saudi Arabia
- ( ) Senegal
- ( ) Serbia
- ( ) Seychelles
- ( ) Sierra Leone
- ( ) Singapore
- ( ) Sint Maarten
- ( ) Slovakia
- ( ) Slovenia
- ( ) Solomon Islands
- ( ) Somalia

- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia

- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **Fo**

r the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published. Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- ○ **Anonymous**
  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.
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☑ I agree with the personal data protection provisions

Questionnaire

Question 0 - What is your level of knowledge of the following?

For this consultation, there are a set of 'general' questions for respondents with no or little knowledge of REACH, and an additional set of 'expert' questions for respondents with good or excellent knowledge of REACH. 'Expert' questions are presented in red text.

- ○ General
- ◉ General + Expert

SECTION I REGISTRATION

Increased information on critical hazards

To better protect human health and the environment, the Chemical Strategy for Sustainability has committed to increase the information requirements under REACH for all chemicals, especially for so-called critical hazards such as carcinogenicity, mutagenicity and reproductive toxicity, endocrine disruption. This may imply the need for companies (registrants of substances, i.e. manufacturers and importers of substances) to test more chemicals for more hazardous properties.

Question 1. To what extent do you agree with the following statements?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Registrants should provide more information on critical hazard properties of substances than is required today under REACH	○	○	○	◉	○	○
I am willing to accept a higher level of uncertainty about the critical hazard properties of a substance, if in return some animal testing could be avoided (through use of non-animal methods)	○	○	○	◉	○	○
In order to facilitate and speed-up their use, non-animal test methods should be adopted in the EU as quickly as possible, even to the detriment of international harmonisation	○	○	○	◉	○	○
In order to facilitate and speed-up their use, non-animal test methods should be adopted in the EU as quickly as possible, even if this might harm the competitiveness of EU producers	○	○	○	○	◉	○
To make Europe's Beating Cancer Plan a success, more information on carcinogenicity for all substances registered under REACH is important	○	○	○	○	◉	○

Information on substances marketed at the lowest tonnage level

The REACH regulation seeks to address information deficits on chemicals by requiring manufacturers and importers to provide toxicological and ecotoxicological information on substances placed on the market in quantities of more than 1 tonne per year. In order to keep the economic and business impacts of the regulation proportional to the likely risks of chemicals, requirements under REACH were tailored according to different tonnages (by means of tonnage bands) at which substances are produced/imported in the EU. To further reduce the burden on (particularly SME) manufacturers and importers of lower volume (1-10 tonnes) substances, the requirements to provide toxicological and ecotoxicological information are quite limited. In addition, all 1-10 tonnes substances were excluded from the requirement to undertake a Chemical Safety Assessment (CSA), provide a Chemical Safety Report (CSR) and supply the extended version of Safety Data Sheets (eSDS) to downstream users. Article 138 of REACH requires the Commission to undertake reviews of the requirements for 1-10 tonnes substances and the Chemicals Strategy for Sustainability notes that information required for substances in the low and medium tonnages under REACH does not fully allow substances with critical hazard properties to be identified and their risks managed.

Question 2. To what extent do you agree that there is sufficient concern regarding the risks from (certain) low tonnage substances (1-10 tonnes) to introduce additional information requirements into REACH, including a requirement for a chemical safety assessment?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ◉ Strongly disagree
- ○ Don’t know / no opinion

Question 3. To what extent do you agree or disagree that increasing the information requirements for low tonnage substances (1-10 tonnes) under REACH would lead to:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Environmental benefits	○	○	○	◉	○	○
Health benefits	○	○	○	◉	○	○
Socio-economic benefits	○	○	○	○	◉	○
Economic benefits for industry	○	○	○	○	◉	○

Question 4. To what extent do you agree that when updating the information requirements for low tonnage substances (1-10 tonnes), new approach methodologies not relying on animal testing should be the default requirements, even if this means that we might obtain less complete information on critical hazards than for higher tonnage substances?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ◉ Disagree
- ○ Strongly disagree
- ○ Don't know / no opinion

Information requirements to provide information on endocrine disruption

Endocrine Disruptors (EDs) are chemical substances that can alter the functioning of the endocrine (hormonal) system and negatively affect the health of humans or animals (e.g. obesity, infertility). They may either be of synthetic or natural origin. Exposure to endocrine disruptors can occur from different sources, such as residues of pesticides or consumer products used or present in our daily life (COM(2018)734).

Past evaluations of EU legislation [1] have shown that there is a need to update data requirements in the different legislative frameworks, including REACH. Building on this, the Chemicals Strategy for Sustainability seeks to "ensure that sufficient and appropriate information is made available to authorities [on the intrinsic properties of a substance] to allow the identification of endocrine disruptors [which may cause adverse effects on human health and the environment] by reviewing and strengthening the information requirements across legislation". To do this, the European Commission shall "update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH".

As part of the impact assessment on the revision of the REACH Regulation, the Commission is assessing options for introducing standard information requirements at each tonnage level that will allow EDs to be identified.

[1] Out of REACH, PPPR and BPR

Question 5. To what extent do you agree that, in order to allow the identification of endocrine disruptors, registrants should be required to provide to authorities sufficient and appropriate standard information requirements on the intrinsic properties of a substance?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know / no opinion

Question 5a. To what extent do you agree that modifying the standard information requirements annexes under REACH (Annex I, VII-X) is the most suitable approach to obtaining information that will allow the identification of substances with endocrine-disrupting properties?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know / no opinion

Question 5b. Testing for endocrine disruption currently relies mainly on animal testing (mammals, fish, etc.) due to current knowledge and available test methods for endocrine activity. To what extent do you agree with the following statements?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
In the absence of suitable non-animal testing methods,						

EU legislation should prioritise the protection of human health from endocrine disruptors over the protection of laboratory animals.	◉	○	○	○	○	○
In the absence of suitable non-animal testing methods, EU legislation should prioritise the protection of the environment from endocrine disruptors over the protection of laboratory animals.	◉	○	○	○	○	○

Question 5c. How would you expect additional standard information requirements for endocrine disruption testing to affect the following in the EU?

Requirements for endocrine disruptors will have a […] on the elements on the left below.

	Very positive impact	Positive impact	No or limited impact	Negative impact	Very negative impact	Don't know / no opinion
Compliance and administration costs for the chemicals industry (including testing costs, registration costs, etc...)	○	○	○	○	◉	○
Research and Development / innovation for the chemicals industry	○	○	○	○	◉	○
Competitiveness of the EU chemicals sector and wider industry in the global market	○	○	○	○	◉	○
Laboratory capacity and associated costs	○	○	○	○	◉	○
Employment levels	○	○	○	○	◉	○

Public Authorities' resources, including administrative burden and enforcement costs	○	○	○	◉	○	○
Public health and health system	○	○	○	○	○	◉
Environmental protection	○	○	○	○	○	◉
Laboratory animals	○	○	○	○	◉	○

Information requirements for polymers

Polymers, which are the fundamental building blocks of plastics, are exempted from the provisions on registration (under Title II of REACH Article 2(9)). However, Article 138(2) of the REACH regulation indicates that the Commission may present legislative proposals for a practicable and cost-efficient way of selecting polymers for registrations on the basis of sound technical and valid scientific criteria and after a further review of the risks posed by polymers in comparison with other substances.

Comprehensive information on the hazardous properties of polymers is generally not readily available in the public domain. A study carried out in 2020 indicated that, although the overall risk of polymers in general is expected to be lower than that of non-polymer substances, a prioritised sub-set of polymers ("polymers requiring registration", PRR) may present similar hazards as other chemicals, although there are large uncertainties associated with the available data.

Polymer types for which a requirement for registration is likely to have most merit have been identified. Proposals to extend the duty of registration under REACH to certain polymers deal with polymeric substances in a way which is consistent with the non-polymeric substances, but which is proportionate to the relative level of concern for polymers. The proposals aim at better understanding and managing polymers in a cost-effective way that limits the burden on industry, but which provides a higher level of protection for human health and the environment than occurs today.

Question 6. To what extent do you agree that certain polymers should be registered under REACH to provide information and data on their hazards and risks as is already done for other chemicals?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ◉ Disagree
- ○ Strongly disagree
- ○ Don't know / no opinion

Question 7. To what extent do you agree that registering certain polymers under REACH would lead to:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Environmental benefits	○	◉	○	○	○	○
Health benefits	○	◉	○	○	○	○
Socio-economic benefits	○	○	○	◉	○	○
Economic benefits for industry	○	○	○	○	◉	○

Question 7a. To what extent do you agree that future requirements on polymer registration under REACH should be aligned with similar international polymer registration schemes (e.g. US, Canada, Australia) as much as possible?

- ◉ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don't know / no opinion

Question 7b. If registration requirements were introduced into REACH for certain polymers, do you think these should apply to

(Multiple answers possible)

- ☑ Cationic polymers or polymers that can be reasonably expected to become cationic in a natural environment?
- ☑ Polymers with low molecular weight (≤1000 Da) which are expected to behave similar to non-polymeric substances?
- ☐ Polymers with higher molecular weight (>1000 Da) even if they might behave differently than non-polymeric substances?
- ☑ Polymers classified for certain severe hazards (like e.g. mutagenicity, carcinogenicity, acute toxicity for humans and the environment, reprotoxicity)?
- ☑ Polymers having reactive functional groups of concern?
- ☐ Polymers suspected to form hazardous components during degradation?
- ☐ Fluoropolymers and perfluorinated polymers?
- ☐

Don’t know / no opinion

Information on environmental footprint

The Chemicals Strategy for Sustainability concludes that the EU is still lacking a comprehensive information base on all substances placed on the market and on their overall environmental footprint, including their impact on climate, and that this hinders the proper management of chemicals and products and does not allow for a full sustainability assessment. Therefore, to improve the availability of chemical data, the Chemicals Strategy for Sustainability asks for an assessment of how to best introduce information requirements under REACH on the overall environmental footprint of chemicals, including on emissions of greenhouse gases.

Question 8. To what extent do you agree that registrants should provide information on the environmental footprint of their substances (e.g. impact on climate, natural resources, biodiversity, land use)?

- Strongly agree
- Agree
- Neither agree nor disagree
- (•) Disagree
- Strongly disagree
- Don’t know / no opinion

Question 8a. To what extent do you agree that the information on environmental footprint should only relate to the substance as produced (e.g. per kg of the substance placed on the market)?

- Strongly agree
- Agree
- Neither agree nor disagree
- (•) Disagree
- Strongly disagree
- Don’t know / no opinion

Question 8b. To what extent do you agree that the information on environmental footprint should cover the whole lifecycle of the substance (e. g. including how the substances are being used by downstream users or even in typical end (consumer) products, and including the recycling/recovery /waste stage)?

- Strongly agree

- ○ Agree
- ○ Neither agree nor disagree
- ◉ Disagree
- ○ Strongly disagree
- ○ Don’t know / no opinion

Information requirements on use and exposure

Information on uses and exposures is one of the key building blocks of REACH, allowing registrants to implement and/or recommend operational conditions and risk management measures to downstream users (end users) that ensure the safe use of chemicals. Sufficient and reliable use and exposure data provided through registration are also a key source of information for subsequent activities by authorities under REACH, including evaluation, prioritisation, restriction and authorisation, as well as for the assessment of the overall effectiveness of REACH and EU chemicals legislation more generally.

However, shortcomings in the currently available use and exposure data have been identified which impact regulatory management of chemical risk including the above-mentioned processes under REACH. The European Commission is therefore considering a potential revision of the registration requirements and downstream user obligations as regards the provision of information on uses and exposures.

Note: Under REACH, downstream user means any natural or legal person established within the EU, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.

Question 9. Who should be responsible for informing ECHA about the uses of chemicals (and providing exposure data)?

(Multiple answers possible)

- ☑ Registrants (manufacturers and importers of substances)
- ☑ Downstream users (end users) of substances
- ☑ Companies placing products (including articles) on the market (including importers of products)
- ☐ Authorities (based on information from surveys)
- ☐ Don’t know / no opinion

Question 9a. Given that REACH requires companies to record the quantities of the substances they manufacture or import annually, how often should registrants update the information in the registration dossiers?

- ○ Every year
- ○ Every three years
- ○

Every five years

- ◉ Whenever new information becomes available
- ○ When ECHA requests an update on its own initiative
- ○ Never

Question 9b. To what extent do you agree that the following processes have not been as effective as they could have been because of insufficient or incomplete information on uses and/or exposure?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
The registrant's demonstration of safe use in the Chemical Safety Report (CSR)	○	○	○	◉	○	○
Substance evaluation	○	○	○	○	◉	○
The authorities' prioritisation of substances that require regulatory management	○	○	○	◉	○	○
Drafting restriction proposals	○	○	○	◉	○	○
Prioritisation of SVHCs for Annex XIV inclusion	○	○	○	◉	○	○
Granting of authorisations	○	○	○	◉	○	○

Question 9c. To what extent do you agree that the following issues are hindering the correct implementation of the REACH registration process?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Data gaps with regard to tonnage allocation to uses	○	○	○	◉	○	○
Insufficient or incomplete data on						

dispersive consumer and professional uses	○	○	○	◉	○	○
Lack of information on the specific product category or article category that the substance is used in	○	○	○	◉	○	○
Inconsistent use information from different registrants	○	○	○	◉	○	○
Insufficient/vague information on the technical function of the substance	○	○	○	◉	○	○
Outdated registration tonnage data in registration dossiers	○	○	○	◉	○	○
Outdated use tonnage data in registration dossiers	○	○	○	◉	○	○
Unclear conditions of use and exposure levels in Chemical Safety Reports	○	○	○	◉	○	○

Question 9d. To what extent do you agree that the following issues are leading to deficiencies in use and exposure data in REACH registration dossiers?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Data provided in the Chemical Safety Reports are not conducive to automated processing	○	○	○	○	○	◉
Lack of updating of registration dossiers	○	○	◉	○	○	○
Use descriptors are not sufficiently specific	○	○	◉	○	○	○

Complex supply chains hinder upstream communication	○	○	◉	○	○	○
Confidentiality issues hinder upstream communication	○	○	◉	○	○	○

Question 9e. To what extent should information on use patterns, volumes and exposures from structurally similar substances that are expected to have the same or similar technical function be used to inform regulatory risk management measures for the whole group or other substances belonging to the group?

- ○ Always
- ○ Yes, but with caution
- ○ No, unless fully justified on a case-by-case basis
- ◉ Never
- ○ Don't know / no opinion

Derived Minimal Effect Level for non-threshold substances

As part of the REACH chemical safety assessment, registrants derive quantitative Derived No-Effect Levels (DNELs) for human health and Predicted No-Effect Concentrations (PNECs) for the environment. These are used to demonstrate that risks are adequately controlled, by comparing these values to exposure levels.

However, for certain hazard classes (especially germ cell mutagenicity and carcinogenicity), it may not be possible to define a toxicological threshold. In such cases, the registrant must provide either a qualitative assessment of the likelihood that effects are avoided or develop and use a Derived Minimal Effect Level (DMEL) in combination with qualitative demonstration that control measures will minimise exposure and emissions. Exposure below the DMEL is considered to be tolerable, although there is no EU legislation setting 'tolerable' risk levels for these substances.

The introduction of DMELs for more non-threshold substances, based on dose-response relationships, coupled with the application of politically acceptable risk levels, would mean that registrants would be required to quantitatively demonstrate that risks are adequately controlled instead of the current qualitative demonstration of minimised exposure and emissions.

Question 9f. To what extent do you agree that the existing approach for the assessment of non-threshold risks (i.e. use of Derived Minimal Effect Levels (DMELs) in certain situations or a qualitative approach) is appropriate and effective?

- ○

Strongly agree

- ○ Agree
- ◉ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don't know / no opinion

Question 9g. To what extent do you agree that more extensive use of a quantitative approach to Chemical Safety Assessments for non-threshold substances should be introduced, including more extensive use of quantitative dose-response relationships coupled with politically agreed levels for tolerable or acceptable risks?

- ○ Strongly agree
- ○ Agree
- ◉ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don't know / no opinion

Question 9h. If such an approach were to be formalised in REACH, what do you think would be an appropriate benchmark for "politically acceptable risk"? Values in the table are expressed as excess lifetime risks of contracting cancer, for workers and the general public (based on an exposure period of 40 years for workers and 70 years for the general public):

	1 in 1 000	1 in 10 000	1 in 100 000	1 in 1 000 000	Other / don't know
Workers	○	○	○	○	◉
General public	○	○	○	○	◉

Introduction of a Mixture Assessment Factor

Various studies have shown that 'unintentional' co-exposure to substances can lead to adverse effects on people and the environment. Exposures at concentrations that are regarded as safe for individual substances (i.e., where no effects are expected) can still result in adverse (eco)toxicological effects when humans or other organisms are exposed to several substances together or subsequently, i.e. when they are exposed to an 'unintentional' mixture. The Commission's Progress Report on Chemical Mixtures

highlights real-world examples of such exposures and effects.

Under REACH, registrants are required to document the safety of their substances, but they are not required to take into account the possibility of co-exposure to other substances. Indeed, they are seldom in a position to do so, as they usually do not have information on how other substances are used.

Assessment factors are already widely used in REACH to account for uncertainties in data, such as when extrapolating information on effects of chemicals between species and among humans. A mixture assessment factor (MAF) is a pragmatic approach to manage the unknown unintentional co-exposures, i.e., that a registrant does not know about the other substances which would also affect the humans and the environment that are exposed to his substance. Different MAF values could apply to different exposed populations (e.g. the general public, the environment, occupational settings) or different types of chemicals.

When applying a MAF, exposure levels that are considered sufficiently safe for single chemicals are reduced by a certain factor (i.e., by MAF) to safeguard against risk from combined exposure to multiple chemicals. The maximum risk quotient (PEC/PNEC or exposure/DNEL ratio [1]) demonstrating “safe use” for the substance is then equal to 1/MAF to account for unintentional co-exposures of substances.

[1] PEC = predicted environmental concentration, PNEC = predicted no-effect concentration; DNEL = derived no-effect level. See the European Chemicals Agency’s guidance for more information.

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

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ◉ Strongly disagree
- ○ Don’t know or no opinion

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

- ○ A single MAF addressing both human health and the environment
- ○ One MAF for human health and another MAF for the environment
- ○ One MAF for the environment, another MAF for exposure of the general public and a different MAF for human occupational exposure
- ○ Different MAFs applied to substances with different types of effects/hazards
- ○ Different MAFs applied to substances with different types of uses
- ◉ Another option (please provide details in your response below)

- ○ Don’t know / no opinion

Another option:

Combined exposure is a complex matter and cannot be addressed via a ‘simple’ solution. The CSS proposes to introduce a Mixture Assessment Factor (MAF) in REACH Annex 1. While a MAF applied to all substances has the allure of simplicity, it would not be proportionate to use the same value to thresholds for human health and the environment. In addition, the proposal would lack specificity considering for the vast range of chemistries on the EU market that to a great extent do not co-occur. An appropriate and pragmatic approach is required which would be both proportionate and flexible. It is important to gather sufficient evidence to identify real-life cases to target in a legislative approach. In this context, we would also draw attention to the conclusions of Herzler et al (2021): “Introducing measures such as […] a generic MAF—in their proposed generality—will clearly result in a significant quality loss of chemical risk assessment in the EU. It is foreseeable that in the end this will lead to ill-prepared regulatory proposals, the scientific inadequacies of which will eventually have to be dealt with at the “green table” in the REACH committee or in court and might even result in an overall failure of the proposed regulation"

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

	Yes	No	Don’t know / no opinion
Environmental benefits	○	◉	○
Health benefits	○	○	○
Socio-economic benefits	○	◉	○
Economic benefits for industry	○	◉	○

Question 10c. If a MAF were introduced into the REACH chemical safety assessment (under the REACH registration process), do you think this should apply:

- ○ To cover all currently registered substances
- ○ To registered substances that require an update of their registration
- ○ Only to new registrations
- ◉ Don’t know / no opinion

Simplifying communication in the supply chain (options for improving SDS, including harmonised electronic formats)

The exchange of information on chemical substances and mixtures within supply chains, e.g. between suppliers and manufacturers, is inefficient. (Extended) safety data sheets provide – in theory – an effective mechanism for transmitting safety information on hazardous substances and mixtures. However, in

practice, communication up and down the supply chain on uses and necessary risk management measures lacks accuracy and clarity. This can have a significant negative impact on the control of risks. The simplification of supply chain communication and the improvement of (extended) safety data sheets could be achieved via improved tools for communication, including, in particular, harmonised electronic formats. The introduction of harmonised electronic formats for (extended) safety data sheets could also reduce the administrative burden for companies.

Question 10d. To what extent do you agree that the introduction of harmonised electronic tools for the preparation and exchange of (extended) safety data sheets would improve the supply chain communication on chemical substances?

- ○ Strongly agree
- ○ Agree
- ◉ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don't know / no opinion

SECTION II EVALUATION

Changes to the provisions on the evaluation process

Companies must ensure that the information contained in their registration dossiers is correct at the time of registration and that any changes to this information are reported without delay. The REACH evaluation provisions give ECHA the responsibility to check whether registrations are in compliance. ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. However, update of registration dossiers by companies is still a weak point: most dossier owners do not routinely review their REACH data and most dossier updates only take place after prompting by the authorities.

The REACH review from 2018 identified specific weaknesses and opportunities to further increase the effectiveness of some of the evaluation provisions. Moreover, in relation to the announced zero tolerance approach to non-compliance, EU-wide measures are being considered to address persisting non-compliance established during an evaluation process.

Question 11. To what extent do you agree that dossiers should be fully compliant with all REACH provisions at the time of submission and that they should be kept updated?

- ◉ Strongly agree

- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don’t know or no opinion

Question 12. To what extent do you agree that, when a registrant fails to bring a registration dossier into compliance, the substance should no longer be manufactured or placed on the market?

- ○ Strongly agree
- ◉ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don’t know or no opinion

Question 12a. How would you rate the following options for improving the effectiveness of the evaluation process?

	Very effective	Effective	Neither effective nor ineffective	Ineffective	Very ineffective	Don't know / no opinion
Changing the waiving regime for information requirements (e.g. by limiting waivers to those that have been established by public authorities)	○	○	○	◉	○	○
Empowering ECHA to assess compliance (not just completeness) during dossier submission	○	○	○	◉	○	○
Explicitly limiting the number of decision-making cycles addressing specific information requirements	○	○	○	◉	○	○
Clarifying requirements for the registrants in case manufacturing is ceased or the registered volume changed during the evaluation procedure or in any follow-up re-registration	○	◉	○	○	○	○
Limiting commenting on the draft evaluation decision by the addressee registrant during the decision-making process to the information contained in the existing dossier and to the ECHA arguments regarding non-compliance. The addressee registrant should be barred from introducing new information including new or improved adaptations	○	○	○	○	◉	○
Modifying some procedural requirements in the decision making process to decrease the administrative overhead and facilitate more efficient decision-making, e.g. replacing CORAP procedure with a lighter registry of intentions, limit MSC role within ECHA decision making under compliance check	○	○	○	○	◉	○

Question 12b. Standard information requirements for higher-volume registrations require typically higher-tier testing. Where that is indeed the case, to what extent do you agree that registrants should perform the higher-tier testing by default, rather than only after submitting a testing proposal to ECHA?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Studies that **do not** use animal tests	○	◉	○	○	○	○
Studies that **require** animal tests	○	○	○	○	◉	○

SECTION III AUTHORISATION AND RESTRICTION

Including the concept of essential use in authorisations and restrictions

The Commission's Chemicals Strategy for Sustainability outlines a number of commitments to tackle chemical pollution and exposure to better protect humans and the environment, and to step up innovation of safe and sustainable chemicals and products for the green transition. One of the commitments is to "define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health".

At present, there is no common definition of 'essential use of a chemical substance '; therefore, defining criteria will be the first step in achieving this ambition. This will allow the adoption of criteria to be used in policy, ultimately to prevent the non-essential use of the most harmful chemicals, in turn improving the protection of human health and the environment. While current requirements under REACH have successfully resulted in the restriction of many of the most harmful substances, the introduction of an 'essential use' concept aims to make the process of phasing out these chemicals simpler, more effective, more predictable, and faster, for example by improving the restriction and authorisation processes under REACH.

Question 13. To what extent do you agree that applying an essential use concept specifically under REACH could increase the protection against the most harmful chemicals and lead to benefits for the environment and human health and reduced costs for society and for industry?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Environmental benefits	○	○	○	◉	○	○
Health benefits	○	○	○	◉	○	○
Socio-economic benefits	○	○	○	○	◉	○
Economic benefits for industry	○	○	○	○	◉	○

Question 13a. To what extent do you agree that the application of a defined 'essential use' concept in REACH, in terms of the restriction of non-essential uses could make the process of phasing out the most harmful chemicals:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Simpler	○	○	○	○	◉	○
More effective	○	○	○	○	◉	○
More predictable	○	○	○	○	◉	○
Faster	○	○	○	○	◉	○

Question 13b. To what extent do you agree that the application of a defined 'essential use' concept in REACH, in terms of the granting of authorisations / derogations for essential uses could make the process of phasing out the most harmful chemicals:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Simpler	○	○	○	○	◉	○
More effective	○	○	○	○	◉	○
More predictable	○	○	○	○	◉	○
Faster	○	○	○	○	◉	○

Reform of authorisations and restrictions

Under the REACH Regulation, there are two main procedures in place to control or limit the use of harmful chemicals: authorisations and restrictions. The use of certain harmful chemicals can be authorised in the EU if the risk from using the substance is adequately controlled or if the socio-economic benefits of the use outweigh the risk and there are no suitable alternatives (authorisation process). The EU can also impose restrictions (e.g. ban, specific risk control measures or concentration values) on the manufacturing, placing on the market and use of chemicals if there is an unacceptable risk to human health or the environment (restriction process) that need to be addressed at EU level. Although overall, authorisations and restrictions have been effective, some problems with these procedures have been identified.

The authorisation procedure is considered too heavy and inflexible and the current restriction process is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances. Further details are provided in the inception impact assessment.

The objective of the reform of the authorisation and restriction processes is to reduce the burden on public authorities and industry and to increase the level of protection for human health and the environment. Simplifications of the authorisation and restriction processes should free-up resources in national authorities, ECHA and the Commission to better address emerging risks by putting in place broader restrictions, while allowing derogations for essential uses.

Based on the initially identified problems, three main options for the revision of authorisation and restriction processes under REACH have been identified:

- **Option 1: Keeping the authorisation process, with clarification and simplifications**
  - This involves modifying elements to address weaknesses identified during its current implementation, but without more fundamental change. This option may include the following elements: strengthening the conformity process for applications for authorisation, clarifying procedures for introducing changes to granted authorisations; transitional provisions for refused authorisations; fixed time limits; clarifying Article 66 notifications for ECHA by downstream users; introduction of “stop the clock” procedures during opinion making and simplified procedures for substances used in small quantities; integration of the concept of “essential uses”; and/or other process changes which aim to improve efficiency of Committee decision making and clarity of definitions and data requirements.

- **Option 2: Merging the authorisation and the restriction processes**
  - Instead of requiring authorisations for the use of certain substances (Annex XIV listing), the concerned substances would be restricted by default. There would be three possible ways to derogate from the default restriction: Derogations would already be included as part of the restriction as proposed and adopted by authorities (as in the existing restriction system); Joint derogations requested by companies (a new element, with the burden of proof on industry); Individual derogations/authorisations requested by companies (similar to existing REACH authorisation system).

- **Option 3: Removing the authorisation title from REACH**
  - This assumes the weaknesses of the REACH authorisation system outweigh its achievements, and that restrictions following the current models of Article 68(1) and 68(2) (if

and as appropriate, with certain modifications) alone can better address the risks of the use of substances of very high concern.

Under all the three options, the candidate list would be maintained, but used for prioritisation for regulatory action in general and, for this purpose, may be linked with additional obligations for companies (e.g. obligation to provide information on uses, alternatives, emissions or exposure).

Question 13c. Please assess how each option is expected to affect the following, on a scale from 1 (strongly negative, i.e. detrimental) to 5 (strongly positive, i.e. beneficial):

Option 1: Keeping the authorisation process, with clarifications and simplifications

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know / no opinion
Administrative burden on companies, e.g., compliance costs	○	○	◉	○	○	○
Resources of public authorities at EU (Commission, ECHA) and national level	○	○	◉	○	○	○
Human health (e.g., impacts on workers and consumers)	○	○	◉	○	○	○
Environment	○	○	◉	○	○	○
Competitiveness of EU companies and level playing field vis-à-vis non-EU companies	○	○	◉	○	○	○
Innovation and research	○	○	◉	○	○	○
Legal certainty for companies	○	○	◉	○	○	○
Other (please specify)	○	○	◉	○	○	○

Other:

In AmCham EU's view, the future REACH should still include a simplified Authorisation Chapter. One important remark is that Authorisation should not be automatically be considered to be the most appropriate risk management option for all SVHCs. We support a more formal use of screenings for SVHCs, based on which the most appropriate RMO can be selected (Authorisation, Restriction, OSH, etc).

Option 2: Merge the authorisation and restriction processes by allowing authorised uses of restricted substances

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know / no opinion
Administrative burden on companies, e.g., compliance costs	○	◉	○	○	○	○
Resources of public authorities at EU (Commission, ECHA) and national level	○	◉	○	○	○	○
Human health (e.g., impacts on workers and consumers)	○	◉	○	○	○	○
Environment (e.g. impacts on biodiversity, water quality, waste)	○	◉	○	○	○	○
Competitiveness of EU companies and level playing field vis-à-vis non-EU companies	○	◉	○	○	○	○
Innovation and research	○	◉	○	○	○	○
Legal certainty for companies	○	◉	○	○	○	○
Other (please specify)	○	○	○	○	○	○

Other:

Option 3: Remove the authorisation title from REACH

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know / no opinion
Administrative burden on companies, e.g., compliance costs	◉	○	○	○	○	○

Resources of public authorities at EU (Commission, ECHA) and national level	◉	○	○	○	○	○
Human health (e.g., impacts on workers and consumers)	◉	○	○	○	○	○
Environment (e.g. impacts on biodiversity, water quality, waste)	◉	○	○	○	○	○
Competitiveness of EU companies and level playing field vis-à-vis non-EU companies	◉	○	○	○	○	○
Innovation and research	◉	○	○	○	○	○
Legal certainty for companies	◉	○	○	○	○	○
Other (please specify)	◉	○	○	○	○	○

Other:

Not having the ability to request authorisation could have a strong negative impact on industries who need continued use(s) which are not included in a derogation

Question 13d. Can you elaborate on the reasons for your above assessments of potential reviews of the authorisation and restriction process under REACH? What are the main costs expected, for example in terms of additional costs (compliance costs, data collection, Committees' resources etc.) as well as the benefits (allowing more and faster regulation of risks, health and environmental benefits, more legal certainty) for each of the options?

In line with the findings of the 2018 REACH review, we encourage the Commission to pursue improvements that are targeted and incremental, avoiding the severe uncertainty that would stem from an unjustified overhaul of EU chemicals legislation. Options 2 and 3 above would result in major changes to the way REACH works today, which in our view are not justified. Generally speaking, the reform of authorisation and restriction cannot be adequately discussed without taking into account parallel work on generic risk management (GRM) and essential use criteria (EUC), as both elements carry the potential to radically impact the framework for risk management under REACH. The rationale to reform authorisation and restriction is partially driven by a willingness to alleviate unjustified burdens on authorities and stakeholders. While some proposals (such as a merger of restriction and authorisation based on GRM and EUC) may appear simple in principle, we are seriously concerned that in practice these could result in extremely burdensome regulatory procedures. As an example, industry would need to prepare (and authorities would need to assess) significant numbers of EUC derogation requests for professional and consumer uses that

may not pose an actual risk but may nevertheless be restricted automatically based on hazard classification under GRM. We agree that the Candidate List should be removed from the Authorisation Chapter of REACH. Inclusion in Annex XIV is not necessarily the most appropriate risk management option for all SVHCs, particularly in cases where uses are primarily industrial (including intermediate uses). Once new substances are included in the Candidate List, ECHA could be tasked to conduct a screening to determine the most appropriate regulatory pathway to address potential risks (where this has not already been done earlier in the process eg through the Public Activities Coordination Tool, PACT). This would also allow for a more comprehensive assessment of the interface between risk management measures under REACH and other legislation, such as OSH. As regards options 2 and 3 (merging authorisation with restriction or removing authorisation altogether), we would note that authorisation currently exempts certain uses and applications, including intermediate uses which are safely managed and contained on manufacturing sites. These exemptions are fully justified and should be maintained.

Generic risk management approach

The Chemicals Strategy for Sustainability announced extending the generic risk management approach to further hazard classes and uses. This generic approach means that the existing mandate to the Commission to prohibit substances that may cause cancer (carcinogenic), gene mutations (mutagenic) or affect the reproductive system (reprotoxic), based on their hazard and on generic exposure considerations (e.g. used by consumers, used by children), will be extended to additional very harmful chemical substances and to professional uses (e.g. use by construction, equipment maintenance or cleaning workers), while allowing limited exemptions for essential uses. This differs from a specific approach to risk management requiring proof of an unacceptable risk for each use before introducing a restriction.

This will be done for substances on their own and in mixtures, and for certain articles, very much following the experience with CMR substances.

The extension of the generic approach to risk management under REACH concerns the following further hazard classes (in addition to the already covered carcinogenic, mutagenic or toxic for reproduction substances):

- Endocrine disruptors (ED) with effects for human health;
- ED with effects on the environment;
- Persistent, bioaccumulative and toxic substances (PBT);
- Very persistent and very bioaccumulative substances (vPvB);
- Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ;
- Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target organ;
- Immunotoxic substances;
- Neurotoxic substances;
- Respiratory sensitisers.

Question 14. To what extent do you agree that, to ensure that citizens and the natural environment are more consistently protected, the most harmful

chemical substances should be prohibited in the following products (even if this may cause the remaining safer products to have lower performance and /or higher price)?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Products used by consumers, without exception	○	○	○	○	◉	○
Products used by consumers, except if they are designed to ensure safety during production, consumption, disposal and recycling	○	◉	○	○	○	○
Products used by consumers, except for uses that are essential for society	○	○	○	◉	○	○
Products used by professionals (e.g. hairdressers, cleaning staff), without exception	○	○	○	○	◉	○
Products used by professionals (e.g. hairdressers, cleaning staff), except if they are designed to ensure the safety during production, consumption, disposal and recycling	○	◉	○	○	○	○
Products used by professionals (e.g. hairdressers, cleaning staff), except for uses that are essential for society	○	○	○	◉	○	○

Question 14a. Please assess the expected effects of extending the generic risk management approach to additional critical hazard classes on the following, on a scale from 1 (strongly negative i.e. detrimental) to 5 (strongly positive, i.e. beneficial):

	1 (strongly negative)	2	3	4	5 (strongly positive)	Don't know / no opinion
Administrative burden on companies, e.g., compliance costs	◉	○	○	○	○	○
Resources of public authorities at EU (Commission, ECHA) and national level	◉	○	○	○	○	○
Human health protection (e. g., impacts on professional workers and consumers)	◉	○	○	○	○	○
Environmental protection	◉	○	○	○	○	○
Competitiveness of EU companies	◉	○	○	○	○	○
Innovation and research	◉	○	○	○	○	○
Other (please specify)	○	○	○	○	○	○

Other:

Question 14b. Can you elaborate on the reasons for your assessment above of an extension of the Generic risk management approach? What are the main positive (e.g., human health and environmental protection, faster regulation of risks) and negative (e.g., additional compliance or administrative costs) impacts expected? For which substances do you expect the most notable impacts (positive or negative) of such an approach?

As regards the reform of restriction and the extension of GRM to professional and consumer uses, AmCham EU continues to support the requirement under REACH Art. 68(1) that restrictions should be initiated where there are unacceptable risks that need to be addressed on a Community-wide basis. These unacceptable risks should be well documented in Annex XV dossiers and thoroughly reviewed by ECHA's committees. We are concerned that the extension of GRM proposed in the CSS will weaken this principle by simply assuming that a risk is present based on hazard classification and shortcutting scientific and socio-economic assessments by RAC and SEAC. In the absence of safeguards for uses that are proven to be safe, we

strongly believe this would be to the detriment of EU competitiveness and innovation. AmCham EU supports the introduction of a “concept of safe use” as a safeguard, should the Commission proceed with the extension of GRM to professional and consumer uses as announced in the CSS. Another key issue is the future role of ECHA committees. While AmCham EU agrees that there are areas where improvements can be made (e.g. more resources to ensure committees are equipped to thoroughly review the scientific and technical details of specific proposals), we also believe the answer is to strengthen the role of ECHA committees, rather than remove them from regulatory processes. The latter option can only result in weaker, less thorough decision-making. In a recent CARACAL paper, for example, the Commission indicates that RAC and SEAC may not be included in the restriction process under the planned GRM extension. We find these proposals to be extremely concerning, particularly when it comes to the EU’s ability to assess derogations based on essentiality or safe use under GRM. The paper indicates that, in such cases, the burden of proof for justifying and assessing derogations and review periods (including potentially complex joint derogation requests by industry) would be with the Commission. We would strongly advise that the Commission includes a role for RAC and SEAC in delivering expert opinions as part of this critical process. We also believe derogations should be assessed by ECHA committees during the restriction adoption process (as opposed to after adoption). This would help avoid unintended consequences and allow for regulatory decisions that are based on a comprehensive understanding of how potential restrictions are likely to impact EU industry, technology and overall competitiveness. We particularly disagree that GRM should be applied indiscriminately to the wide range of current and future hazard classes presented above (e.g. sensitisers, neurotoxic/immunotoxic substances, STOT).

SECTION IV ENFORCEMENT

Establishing a European Audit Capacity

Enforcement is essential to accomplishing the objectives of the legislation. To ensure the highest protection of EU citizens and the environment, it is vital that EU chemicals legislation is applied by all operators (manufacturers, importers, downstream users, etc.) in all Member States and that it is effectively enforced across all Member States.

Member States are responsible for the enforcement of EU chemical legislation, but – as pointed out in the Chemical Strategy for Sustainability – enforcement is not equally effective throughout the EU, due to the different capacities and resources at national level. This affects a level playing field for operators and consumers. Therefore, stepping up compliance with the legislation and its enforcement is needed.

Among the set of actions for this purpose, the Chemicals Strategy for Sustainability has announced that the Commission will propose a European Audit Capacity for REACH, with the duty to carry out audits in Member States, where relevant, to ensure compliance and enforcement of chemical legislation.

The European Audit Capacity will therefore carry out audits [1] of Member States’ control and enforcement systems and their implementation to verify their effectiveness. This will help to identify potential weaknesses in the national systems or in their operation, including potential systemic weaknesses, as well as to the identification of their cause(s) so that corrective action can be taken.

[1] Audit is a control methodology. Article 3(30) of Regulation (EU) 2017/625 defines ‘audit’ as a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements

are applied effectively and are suitable to achieve the objectives. Audits can include, among others, verifications on the basis of documents and also physical observation of how activities are carried out.

Question 14c. To what extent could the creation of a new European Audit Capacity for REACH contribute to more effective enforcement of the REACH Regulation by Member States?

- ○ High contribution
- ◉ Medium contribution
- ○ Low contribution
- ○ Don’t know / no opinion

Question 14d. To what extent do you agree that a European Audit Capacity should audit Member States’ control systems and their implementation against common EU standards (the alternative being to audit against individual Member State standards)?

- ◉ Strongly agree
- ○ Agree
- ○ Neither agree not disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don’t know / no opinion

Question 14e. To what extent do you agree that a European Audit Capacity should also carry out audits on EU chemicals legislation other than REACH, such as the Regulation on Persistent Organic Pollutants (POPs), the Regulation concerning the Export and Import of Hazardous Chemicals (PIC), or the Regulation on Classification, Packaging and Labelling (CLP)?

- ○ Strongly agree
- ○ Agree
- ◉ Neither agree not disagree
- ○ Disagree
- ○ Strongly disagree
- ○ Don’t know / no opinion

Enhance the Enforcement of national controls, including stricter border controls

The control and enforcement of REACH is not equally effective in all Member States. Considerable differences exist between Member States depending on available resources and different policies leading to inconsistent effectiveness of controls. The increasing import of products from countries outside the EU, including by consumers' direct purchases through online portals, allows for import of goods that are not subject to the necessary controls to ensure compliance with EU law. These differences represent a risk for consumers and the environment, and they negatively affect the competitiveness of compliant European industry.

Seven issues were identified as the main ones causing sub-optimal REACH enforcement upon import. The following questions suggest solutions to each of these issues to improve the enforcement of REACH at the border.

Question 14f. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following issue:

The importer or its representative (e.g., transporters, customs agents, etc.) should have better knowledge regarding REACH requirements. Limited knowledge could disconnect customs requirements at the moment of importation from REACH requirements that should be imposed when goods are imported

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Better share the existing information on REACH online	◉	○	○	○	○	○
Launch REACH newsletters at European level	◉	○	○	○	○	○
Organise REACH training sessions for the importer or its representative	○	◉	○	○	○	○
Inspect chemical analysis certificates as part of the documentary check	○	○	◉	○	○	○
Make the inclusion of the SDS in the data file mandatory upon importation	○	○	◉	○	○	○

Question 14g. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following

issue:

The importer or its representative (e.g., .transporters, customs agents, etc.) should have sufficient information about the goods, e.g.,. REACH- relevant chemicals. Lack of that information on the import declaration may negatively impact the ability of customs to perform controls as efficiently as possible

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Embedding REACH in the Authorised Economic Operator solution	○	○	○	○	○	◉
Create standard information to be voluntarily filled in by the manufacturer in order for the importer to demonstrate compliance upon importation	○	○	◉	○	○	○
Create an inter-institutional platform at national level where all relevant administrations have regular meetings	○	○	○	○	○	◉
Create mandatory standard information to be filled in by the manufacturer in order for the importer to demonstrate compliance upon import	○	○	◉	○	○	○

Question 14h. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following issue:

No specific data elements on customs declaration indicating products being subject to REACH requirements. For example, there is no requirement to include REACH Registration / Authorisation numbers in the customs declaration. The only exceptions are Code C073, that has to be indicated in Box 44 of the customs declaration if goods are subject to REACH authorisation, as well as Codes Y105, Y109 or Y115 in case an exemption applies

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Further develop the European Customs Inventory of Chemical						

Substances (ECICS) database to show link between CUS number and REACH requirements	○	○	○	○	○	◉
Additional national codes to be implemented in Box 44 of the Single Administrative Document (SAD) (and on the future data submission format for import declarations)	○	○	○	○	○	◉
Mandatory inclusion of the Customs Union and Statistics (CUS) number(s) on the SAD	○	○	○	○	○	◉
Commission to implement additional codes for Box 44 of the SAD (and on the future data submission format for import declarations)	○	○	○	○	○	◉

Question 14i. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following issue:

Currently, the integrated Tariff of the European Union (TARIC) shows some indicators for REACH requirements (Annex XIV). This integration only concerns pure substances and not articles and mixtures. The restrictions under Annex XVII are in the process of being integrated into the TARIC database. However, it is challenging to link specific TARIC codes to REACH requirements for substances, mixtures and articles, e.g., a mixture has one TARIC code but consists of multiple substances; articles have one TARIC code where the (unreported) substances of very high concern (SVHC) content is relevant for REACH

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Additional national codes for box 33 of the SAD for articles posing a high risk of containing restricted substances (see above suggested solution)	○	○	○	○	○	◉
Linking CUS numbers to registration requirements	○	○	○	○	○	◉

EU-wide TARIC list of high-risk products	○	○	○	○	○	◉

Question 14j. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following issue:

REACH-related parameters are currently not included in the customs risk assessment to such an extent that they could be considered as sufficient, e.g., no standard risk scoring for REACH for the selection at EU level and even at national level

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Giving customs authorities access to REACH-IT data through a specific interface	○	○	○	○	○	◉
NEAs to decide on and implement in the short term a minimum of three REACH-related risk profiles	○	○	○	○	○	◉
Creation of an interface between the Information and Communication System for Market Surveillance (ICSMS) and national customs systems to provide access to additional data to customs on high-risk goods (e.g. substances of very high concern (SVHC) and articles containing SVHC) encountered in free circulation, allowing for further targeted controls	○	○	○	○	○	◉
Customs authorities to do more first-line checks with manual scanning equipment; NEAs to train customs authorities	○	○	○	○	○	◉

Question 14k. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following

issue:

No uniform risk assessment approach throughout the Member States. Risk elements to be considered not harmonised at EU level

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Setting up a specific project group for REACH issues, in which there will be best practice sharing, training, and risk profile development	○	○	○	○	○	◉
Creation of harmonised REACH-related risk profiles	○	○	○	○	○	◉
Creation of harmonised operations on certain articles	○	○	○	○	○	◉

Question 14l. Please rate the effectiveness of each of the suggested solutions (from 1 as least effective to 5 as most effective) to the following issue:

Problems with checking online purchases (internet trade) and small parcels. These goods often benefit from simplification and reduced data requirements (low value shipments)

	1 (Least effective)	2	3	4	5 (Most effective)	Don't know / no opinion
Promoting the use of portable measuring devices by NEAs and customs authorities	○	○	○	○	○	◉
Using Import Control System 2 (ICS2) platform and leverage Entry Summary Declaration (ENS) or H7 data to increase REACH compliance for small parcels	○	○	○	○	○	◉
Establish a list of relevant portable measuring devices that can be used to detect REACH relevant chemicals	○	○	○	○	○	◉
Create a REACH ‘certified’ label for e-commerce vendors	○	○	○	○	○	◉

Launch information campaigns targeted for consumers	○	○	○	○	○	◉

FINAL (ADDITIONAL) FEEDBACK

In case you would like to share anything else in addition to the previous questions related to the targeted revision of the REACH regulation, please provide details here (optional)

In addition to our responses to the questions above and to the attached documentation, AmCham EU would like to add the following clarifications.
Question 1: We selected “strongly disagree” for the statement that further REACH data can support Europe’s Beating Cancer Plan as the current REACH regulation already mandates significant data generation on carcinogenicity endpoints.
Question 2: We would note that substance evaluation is an appropriate tool to investigate potential hazards from low tonnage substances. Putting additional requirements on all low tonnage substances to generate data on some hazardous substances would be disproportionate and go against the principles of REACH registration. In some cases, this could jeopardize innovation and marketing of new substances.
Question 5a: Substance evaluation should be used here. AmCham EU would support a tiered approach, not standard testing.
Question 5b: Dossier and substance evaluation under REACH are established procedures that should be used for this purpose. This course of action should be given priority over wide-ranging additional standard information requirements in the REACH annexes.
Question 9: The answer here depends on the stage in the REACH process. During registration, information must be provided by the registrants. During public consultations and calls for evidence, downstream users can also supply information on uses. We would also stress the need to ensure confidentiality as appropriate and that exposure data should be limited to relevant classified substances.
Question 11:Without indicating a cadence for which dossiers need to be updated, this might be overwhelming for registrants to keep up with.
Question 12: The question’s wording is very black and white. Ideally there should be a stepwise process to bring the dossier into compliance. Revoking registration should be a last resort in cases where non-compliance is significant and repeatedly left unaddressed.
Question 13b: We note that it is difficult to properly reply to this question without knowing how the essential use concept will be defined. We do not support that derogations should be granted solely on the basis of the essential use concept and support integrating the safe use concept.

Extra space for additional comments (if met the 5,000 character limit of the above field):

In case you would like to share a document in view of the targeted revision of the REACH regulation, please upload it below (optional)

Please note the maximum file size is 1 MB, however, multiple files may be uploaded.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

b920f727-6217-42bb-8d35-95f2e44d6dc7/amcham_eu_comments_reach_restriction_authorisation_final.pdf

Contact

Mateo.GALLEGO@ec.europa.eu