

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

Michela

* Surname

VUERICH

* Email (this won't be published)

mvu@anec.eu

* Organisation name

255 character(s) maximum

ANEC, the European consumer voice in standardisation

* 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.

507800799-30

* Country of origin

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

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

Public

Organisation details and respondent 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. Your name will also be published.

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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
To make Europe's Beating Cancer Plan a success, more information on carcinogenicity for all substances registered under REACH is important	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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:

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	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / no opinion
Environmental benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Socio-economic benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Economic benefits for industry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

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
-

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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Socio-economic benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Economic benefits for industry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

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
-

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
-
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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 $1/\text{MAF}$ 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
-
-

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

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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Health benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Socio-economic benefits	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Economic benefits for industry	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Products used by consumers, except if they are designed to ensure safety during production, consumption, disposal and recycling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Products used by consumers, except for uses that are essential for society	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Products used by professionals (e.g. hairdressers, cleaning staff), without exception	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Products used by professionals (e.g. hairdressers, cleaning staff), except if they are designed to ensure the safety during	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

production, consumption, disposal and recycling						
Products used by professionals (e.g. hairdressers, cleaning staff), except for uses that are essential for society	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other:

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)

ANEC has repeatedly pointed to the weaknesses of the regulatory frameworks in protecting consumers from the exposure to hazardous chemicals in products. We have especially challenged the usefulness and effectiveness of the REACH regulation in this respect.

While in the replies to this questionnaire we highlight the opportunities and challenges at hand in the context of the envisaged REACH revision, we repeat we believe it important to take into account the shortcomings of the tool for consumer protection as we described in ANEC position paper in response to the respective IIA Roadmap (<https://tinyurl.com/2rz7rkuy>, also attached).

We provide here our perspective to the current consultation, given the REACH targeted revision seems the main route chosen by the European Commission for now. Still, we continue also calling on a consistent approach to address chemicals in all consumer relevant products rather than limiting to an improved REACH restriction procedure. In that way gaps and benefits of current regulatory frameworks vis-à-vis REACH can be assessed comprehensively.

Specific comments in support of answers to the questionnaire above:

- Q8: ENVIRONMENTAL FOOTPRINT

We highlight the limitations of LCA methods to assess chemicals as Usetox methods to assess chemicals in products like USEtox. (See Chapter 1.4 of ANEC paper 'Environmental assessment goes astray', <https://tinyurl.com/593zya6b>, also attached). We believe this and similar models have little to do with traditional toxicological risk assessment models and are thus potentially misleading.

The idea of collecting such information through REACH is rather strange and unexpected. It is unclear how it would work as there is a big difference between information on inherent hazard properties of chemicals and generic environmental footprint information, possibly representing an average of different producers /production facilities, feedstocks and energy sources.

- Q9: INFORMATION REQUIREMENTS ON USE AND EXPOSURE

It should not be decided here what risk is acceptable. This needs to be addressed on a case by case basis by the legislator.

- Q10: MIXTURE ASSESSMENT FACTOR (MAF)

We strongly agree that the MAF is the most feasible and practically workable option to systematically address mixtures/combination effects in the short and medium term.

- Q13: INCLUSION OF ESSENTIAL USE CONCEPT IN AUTHORISATIONS AND RESTRICTIONS

we strongly agree in principle with the application of the essential use concept to increase the protection against the most harmful chemicals. It is important to note that for this concept to be useful it is essential that clear and scientific criteria are developed to define the only instances when the use of certain harmful chemicals can be allowed to avoid problems with the implementation.

Moreover, there is a need for regular review of the innovation progress for the substances and uses that will be identified (i.e. when safe substitution becomes possible).

- Q14: GENERIC RISK MANAGEMENT APPROACH

A major improvement of consumer safety can only be brought about if a broad and systematic implementation of the Generic Risk Assessment is achieved and not only in an ad hoc and slow manner on consumer articles, as in the few cases where article 68(2) of REACH has been applied (CMRs in textiles and PAHs in rubber granulates).

Also, the use of the Sustainable by design concept should not be used as a regulatory tool to grant exceptions/provide a fast track in the regulatory assessment of chemicals, this may create possible loopholes.

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

[916d9e4a-04ba-4680-9b93-0972cd882d31/ANEC-ENV-2012-G-008final.pdf](#)

[7b8d33b3-75cf-46f7-af15-d44ce081634a/ANEC-PT-2021-CEG-013.pdf](#)

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