Public Consultation in relation to the REACH REFIT evaluation

Fields marked with * are mandatory.

1) Purpose and Context of the Consultation

a) The REACH REFIT evaluation

REACH[1] is the European Regulation for the Registration, Evaluation, Authorisation and Restriction of chemicals (EC) No 1907/2006. It is the main EU law on chemicals, covering substances on their own or in mixtures or in articles for industrial, professional or consumer use[2].

The European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs and DG Environment) is conducting an evaluation of the REACH Regulation as part of the regular reporting obligation to monitor progress in the achievement of the objectives of the Regulation according to Article 117 (4) of REACH. Regular monitoring and reporting provides information to identify needs for adjustment and to propose recommendations to improve the implementation of the Regulation or the need to consider modifications.

This evaluation is part of the Commission's Regulatory Fitness and Performance Programme (REFIT) [3] and will cover the five compulsory evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value, including examining the potential to improve the way in which it delivers on its objectives and the potential for burden reduction and simplification.

The roadmap[4] for the REACH REFIT evaluation outlines the objectives, scope and key evaluation questions to be addressed in the evaluation. Furthermore, the consultation strategy[5] for the REACH REFIT evaluation provides additional details about the consultation objectives, activities and tools planned, including the present open online public consultation.

The objective of the public consultation is to obtain stakeholder views on the general approach to the 2017 REACH REFIT evaluation and to collect stakeholder views on strengths and weaknesses of REACH as well as any potentially missing elements. The responses will be taken into consideration in the preparation of the Commission Staff Working Document, presenting the results of the REACH REFIT evaluation and the Commission general report on the functioning of REACH addressed to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

The current open online public consultation is part of a broader stakeholder consultation strategy which includes also an SME panel circulated through the Europe Enterprise Network. Please note that the results may also be used in the context of other studies in the chemicals field.

** The consultation will last for 12 weeks. Responses to the public consultation must be submitted by 28 January 2017. **

b) Structure of this questionnaire

The questionnaire has four parts and you may choose which parts (or questions) you answer depending on your interest and level of familiarity with the REACH legal text and its implementation:

Part I – General Information about respondents (compulsory)

Part II - General Questions for respondents interested in REACH, but who may not be familiar enough with the legal text and provisions to
answer more detailed questions (compulsory)

Part III – Specific Questions which require more in-depth knowledge and experience in dealing with the REACH Regulation (optional)

Part IV – Additional Comments

You may interrupt your session at any time and continue answering at a later stage. Once you have submitted your answers online, you can download a copy of the completed questionnaire.

To facilitate the preparation of your contribution, a pdf version of the questionnaire is available here.

In view of the limited resources for translation as well as the specialised nature of the topic and technical terminology involved in this consultation, the questionnaire is available in English, German and French. Individual replies may be provided in any EU language.

Privacy Statement: *The information you provide will be used strictly in accordance with the provisions of Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The content of your contribution and identity will be published on the Internet, unless you ask to remain anonymous.*

Disclaimer: *This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties. The suggestions contained in this document do not prejudge the form or content of any future proposal by the European Commission.*

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - OJ L 396, 30.12.2006

[2] http://ec.europa.eu/growth/sectors/chemicals/reach/

http://ec.europa.eu/environment/chemicals/reach/reach_en.htm

[3] http://ec.europa.eu/smart-regulation/index_en.htm

[4] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

[5] http://ec.europa.eu/DocsRoom/documents/17785/attachments/1/translations/

2) Questionnaire

Part I – General Information about Respondents (compulsory)

1. Please indicate your name or the name of your organisation.

* Your name or name of the organisation/company:

Eurometaux

Contact name (for organisations):

Violaine Verougstraete

Transparency Register ID number (for organisations):
(If your organisation is not registered in the transparency register, you have the opportunity to register now. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and as such, will publish it separately.)

61650796093-48

* Country:

Belgium

* E-mail address

verougstraete@eurometaux.be

*** 2. Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution:**

(Please note that regardless the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In this case the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules)

- (●) My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
- ( ) My contribution may be published but should be kept anonymous; I declare that none of it is subject to copyright restrictions that prevent publication
- ( ) I do not agree that my contribution will be published at all

*** 3. We might need to contact you to clarify some of your answers. Please state your preference below:**

- (●) I am available to be contacted
- ( ) I do not want to be contacted

*** 4. Please indicate whether you are replying to this questionnaire as:**

- ( ) A citizen
- ( ) A business
- ( ) A non-governmental organisation (NGO)
- ( ) A consumer association
- (●) An industry association
- ( ) A trade union
- ( ) A government or public authority
- ( ) An intergovernmental organisation
- ( ) Academia or a research or educational institute
- ( ) Third country private organisation
- ( ) Third country public authority
- ( ) Other (please specify)

*** 4.2. Business or industry association - fields of interest or activity(ies) - multiple choises possible** (the letters in brackets correspond to NACE codes)

- [ ] Agriculture, forestry and fishing (A)
- [x] Mining and quarrying (B)
- [ ] Manufacture of food products (C10)
- [ ] Manufacture of beverages (C11)
- [ ] Manufacture of tobacco products (C12)
- [ ] Manufacture of textiles (C13)
- [ ] Manufacture of wearing apparel (C14)
- [ ] Manufacture of leather and related products (C15)
- [ ] Manufacture of wood and of products of wood and cork except furniture (C16)
- [ ] Manufacture of paper and paper products (C17)
- [ ] Printing and reproduction of recorded media (C18)
- [ ] Manufacture of coke and refined petroleum products (C19)
- [ ] Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)
- [ ] Manufacture of pesticides and other agrochemical products (C20.2)
- [ ] Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3)
- [ ] Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4)
- [ ] Manufacture of other chemical products (C20.5)
- [ ] Manufacture of man-made fibres (C20.6)
- [ ] Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)
- [ ] Manufacture of rubber and plastic products (C22)
- [x] Manufacture of other non-metallic mineral products (C23)
- [x] Manufacture of basic metals (C24)
- [x] Manufacture of fabricated metal products, except machinery and equipment (C25)
- [ ] Manufacture of computer, electronic and optical products (C26)
- [ ] Manufacture of electrical equipment (C27)
- [ ] Manufacture of machinery and equipment (C28)
- [ ] Manufacture of motor vehicles, trailers and semi-trailers (C29)
- [ ] Manufacture of other transport equipment (C30)
- [ ] Manufacture of furniture (C31)
- [ ] Manufacture of games and toys (C32.4)
- [ ] Manufacture of medical and dental instruments and supplies (C32.5)
- [ ] Other manufacturing (excluding manufacturing of toys or medical and dental instruments) (C32)
- [ ] Electricity, gas, steam and air conditioning supply (D)
- [ ] Water supply; sewerage; waste management and remediation activities (E)
- [ ] Construction (F)
- [ ] Wholesale and retail trade (G)
- [ ] Transporting and storage (H)
- [ ] Professional, scientific and technical activities (M)
- [ ] Other (please specify)

5. Please indicate the level at which your organisation is active:

- ○ Local
- ○ National
- ○ Accross several countries (e.g. Scandinavia)
- ◉ EU
- ○ Global

Part II – General questions (compulsory)

This part is intended for all respondents interested in REACH, including those who may not be familiar enough with the legal text to answer more detailed questions.

6. To what extent do you think REACH is achieving the following objectives?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
*a) Improve protection of consumers	○	○	◉	○	○	○
*b) Improve protection of workers	○	○	◉	○	○	○
*c) Improve protection of the environment	○	◉	○	○	○	○
*d) Free circulation of chemicals on the internal market (Reduce barriers to trade in chemicals across borders within the EU)	○	◉	○	○	○	○
*e) Enhance competitiveness and innovation	○	◉	○	○	○	○
*f) Promote alternative methods to animal testing for hazard assessment of chemicals	○	○	◉	○	○	○

7. To what extent do you think REACH is delivering the following results?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
*a) Generation of data for hazard /risk assessment	○	○	○	○	◉	○
*b) Increase in information on chemicals for risk management	○	○	○	◉	○	○
*c) Increase in information exchange in the supply chain	○	○	○	◉	○	○
*d) Improvement in development and implementation of risk management measures	○	○	○	◉	○	○
*e) Shifting the burden of proof from public authorities to industry	○	○	○	○	◉	○

*f) Fostering innovation (e.g. substitution of SVHCs, development of new substances)	○	◉	○	○	○	○
*g) Promoting the development, use and acceptability of alternatives to animal testing	○	○	○	○	◉	○
*h) Implementation of the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing	○	◉	○	○	○	○
*i) Dissemination of information on chemicals for the general public	○	○	○	○	◉	○

8. **The various processes of REACH (e.g. registration, evaluation) are expected to generate data that can be used by public authorities to adopt adequate risk management measures under REACH or in other EU legislation. To what extent do you think that the data generated are adequate for adopting the following measures?**

	1 Not useful at all	2 Slightly useful	3 Somehow useful	4 Substantially useful	5 Very useful	Do not know / not applicable
*a) REACH authorisation	○	○	◉	○	○	○
*b) REACH restriction	○	○	◉	○	○	○
*c) Consumer protection legislation concerning chemicals in articles (e.g. cosmetics, toys, food packaging)	○	○	◉	○	○	○
*d) Environmental legislation (e.g. Seveso, Industrial Emissions Directive)	○	○	○	◉	○	○

*e) Harmonised Classification & Labelling	○	○	○	○	◉	○
*f) Occupational Exposure Limits (OEL) in the context of worker protection legislation	○	○	○	○	◉	○

9. To what extent do you agree with the following statements in relation to the European Chemicals Agency (ECHA)?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
*a) ECHA has handled the registrations of chemical substances effectively (i.e. support for registrant, access to IT tools)	○	○	○	○	◉	○
*b) ECHA has established a strong and trustful relationship with its stakeholders	○	○	○	○	◉	○

*c) ECHA has contributed to reducing the impact of REACH on SMEs	○	○	◉	○	○	○
*d) ECHA's activities and guidance have facilitated an innovation-friendly framework	○	◉	○	○	○	○
*e) ECHA has been successful in facilitating the implementation of the last resort principle concerning animal testing.	○	◉	○	○	○	○

Part III – Specific questions that require more experience with REACH

This part contains more detailed questions related to the five evaluation criteria and to REACH procedures.

You may further explain your answers at the end of the consultation.

Part III. A

Effectiveness

The following questions explore the extent to which the objectives of the REACH Regulation have been met, and any significant factors which may have contributed to or inhibited progress towards meeting those objectives.

10. In your view, to what extent have the REACH Regulation and its various chapters been implemented successfully?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable

Registration	○	○	○	○	◉	○
Data-sharing and avoidance of unnecessary testing	○	○	◉	○	○	○
Information in the supply chain	○	◉	○	○	○	○
Evaluation – dossier	○	○	○	◉	○	○
Evaluation – substance	○	○	○	◉	○	○
Authorisation	○	○	○	◉	○	○
Restriction	○	○	◉	○	○	○
Overall implementation of REACH	○	○	○	◉	○	○

11. Do you agree that the REACH legal text presents requirements regarding the following chapters in a clear and predictable manner?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
Registration	○	○	◉	○	○	○
Data-sharing and avoidance of unnecessary testing	○	○	◉	○	○	○
Information in the supply chain	○	○	○	◉	○	○
Evaluation – dossier	○	◉	○	○	○	○
Evaluation – substance	○	○	◉	○	○	○
Authorisation	○	○	◉	○	○	○
Restriction	○	○	○	◉	○	○

12. In your view, to what extent are the following elements of REACH working well?

	1 Not well at all	2 Rather not well	3 Neutral	4 Rather well	5 Very well	Do not know / not applicable
Transparency of procedures	○	○	◉	○	○	○
Speed with which hazards/risks are identified	○	○	◉	○	○	○
Speed with which identified risks are addressed	○	○	○	◉	○	○
Time to allow duty holders to adapt	○	○	○	○	○	◉
Predictability of the outcomes	◉	○	○	○	○	○

13. Please identify unintended effects of REACH, indicating whether you consider those to be positive or negative. Please provide evidence to quantify such effects or a qualitative description.

(max. 5.000 characters)

• AVAILABILITY, QUALITY OF INFORMATION IMPACTING CREDIBILITY – Whilst REACH, thanks to the registration information requirements, allows to build a unique database covering key aspects of chemicals management (hazard-, exposure-, risk -assessment and management); there is still a variability in quality and completeness of the dossiers for metals. This variability affects the level playing field and the overall credibility of the Registration process.

• LEADERSHIP in CHEMICALS DATA – REACH has created unique databases on chemicals and their uses. Industry proposes to build further on this concept

and stimulates the REACH registration data being used for other regulatory purposes in the EU or in other areas/countries to prevent doubling activities. Such a recognition will further encourage industry to keep the dossiers up to date.

- NO MINIMISED NEED FOR ANIMAL TESTING – A point of concern is the drive for extensive higher tier testing based on culminating negative evidence in lower tiers. A negative RDT 90 d or a first PNDT almost automatically trigger higher or second species requirements. This generic philosophy leads to extensive testing packages to provide a second PNDT and an EOGRTS, whilst a weight of evidence may demonstrate that the probability for any repro or development effects is (very) low. The costs are on average 1 to 1.2 million Euros/substance and this impacts a number of substances. It can be questioned if this cannot be replaced by a smarter "intelligence gathering system" focusing on toxicokinetics or a more pragmatic implementation of the read- across concepts to ensure more balance between costs, societal return and animal welfare.
- INDIRECT IMPACTS OF ANNEX XIV – The reduced use due to the listing on the Candidate or the Annex XIV lists has in some specific cases led to unwanted effects, which from a more holistic sustainability perspective do not make much sense. The decreased uses of inorganics such as As2O3 in safe applications like glassware resulted in increased volumes to be disposed off on hazardous waste dumpsites.
- FOCUS on LOW-HANGING FRUIT SUBSTANCES: Prioritisation for Risk Management (Annex XIV) has focussed the first 5 years almost exclusively on CMRs substances that are already reasonably well controlled with existing EU-wide legislation. The efficiency of the prioritisation process can therefore be questioned.
- EU NEEDS vs NATIONAL POLICIES – There is still an obvious lack of alignment/consistency between altruistic EU needs and individual national policies affecting the overall efficiency and effectiveness of REACH (e.g. by generating high workload for all actors for restrictions of limited or no relevance when it comes to exposure/risk, like it was the case for cadmium compounds in artist paints or lack of coherence between classification and testing proposals (e.g. cobalt compounds). More rigidity in the selection of appropriate cases would be recommended.
- APPROPRIATE RISK MANAGEMENT MEASURES – The selection of efficient and effective risk management measures is still a weakness of the system. Too many restrictions fail proportionally but have nevertheless taken a lot of effort and time from the ECHA Committees, countries and stakeholders during the review processes. A more in-depth or formal RMOa process including proportionality considerations could most probably have prevented this, while confirming the relevance for larger cases
- IMPORT OF SECONDARY RAW MATERIALS – EU industry may lose the flexibility to import frequently changing complex secondary raw materials that are essential for recycling/refining business if substance identification in the REACH dossiers would need to be more specific/narrowed down compared to the status in the current dossiers. In the worst case this could lead to a relocation of the recycling/refining to non-EU regions.
- DIFFICULTIES IN MAINTENANCE OF REACH REGISTRATIONS – After Registration, Registrants are expected to update their dossiers spontaneously when new available and relevant scientific (studies/publications) and

technical information (volumes, technologies…) becomes available. This is, especially for data rich substances, a resource intensive and cumbersome issue. Updates are also expected along evolving interpretation of the legal text and updated guidance documents. The trigger of the registration number has forced registrants to organise themselves and to work in a cooperative, shared mode. There is however no mechanism or trigger to force all co-registrants to continue to participate in the maintenance and updates of dossiers once the registration number has been acquired, generating updates "free-riding".

14. In your view, to what extent are the following elements of REACH enforcement satisfactory?

	1 Not at all satisfactory	2 Rather unsatisfactory	3 Neutral	4 Rather satisfactory	5 Very satisfactory	Do not know / not applicab
Overall REACH enforcement in the EU	○	◉	○	○	○	○
REACH enforcement at Member States level	○	◉	○	○	○	○
REACH is enforced uniformly across the EU	○	◉	○	○	○	○
Prioritisation of enforcement activities at EU level (by Forum)	○	○	○	◉	○	○
Communication on enforcement activities from Member States and Forum	○	○	◉	○	○	○

14.1. If you answered 3 or less for any of the above, please explain how the relevant aspect of REACH enforcement could be improved.

(max. 5.000 characters)

- QUANTITATIVE ENFORCEMEMENT TARGETS – There should be more consistent quantitative targets for enforcement for all and across individual Member States, which focus more on Risk Management Measures implementation (ultimate objective of REACH is safe use) than on more administrative aspects. There is also currently too much focus on companies who actually met their Registration obligations, while the search or enforcement for 'free-riders' is generally lacking.
- OSOR PRINCIPLE – REACH Registration required clear "cooperation agreements" been set up between different industry sectors/actors, namely on data-sharing. Most of the metals industry has invested a huge amount of financial and human resources on data gathering, testing and legal interpretation. Respecting the OSOR principle has been the key driver within the metal sector for setting agreements and modes of cooperation. This has however not prevented free-riders to deliberately open parallel joint submissions for their full REACH dossiers. This issue has been raised at several levels (ECHA, Commission and Member States) as being against the spirit of REACH, leading to unfair competition in the SIEF and demotivating for the registrants. The solution is actually in the hands of the Member States, who up to now have not appeared keen on using their enforcement rights.
- RESTRICTIONS – Restrictions shall be more consistently implemented and controlled, including at the EU borders, so as to restore a level-playing field between EU production and imports, and support the coherence of the Restriction system.
- (NON-)EU COMPETITION – Enforcement on the correct application of the Authorisation regime is critical to prevent that markets previously provided by EU producers are supplied by non-EU sources (due to a lack of inspections on users). Besides undermining the Authorisation system, it creates an unfair competition with non-EU manufacturers. Ensuring the enforcement of the AfAs for EU uses is critical as well to avoid competition between applicants and non-applicants.
- COOPERATION WITH STAKEHOLDERS – The ECHA REACH Enforcement Forum includes an open session where stakeholders can present once a year some issues they see as relevant for the Enforcement authorities. However, impact /follow-up seems to be limited. Is there any way to facilitate further the cooperation between all REACH actors on enforcement (e.g. CSR/ES Roadmap focusing on eSDS, possibility to organise trainings on some specific approaches etc.)?
- FREE-RIDERS ON DOSSIER UPDATES – It shall be noted that free-riding has become an issue especially in the context of dossier updates and maintenance: it appears that many co-registrants become inaccessible, and subsequently "free-riders", once the first version of the joint registration is submitted and the registration number granted after payment. The remaining co-registrants are faced with the huge burden of having to assume considerable update costs while no mechanism exists, except Court, to ensure that all co-registrants pay their right share of the dossier updates. A mechanism shall be set in place to distinguish contributors from non-contributors at enforcement level, otherwise there is a risk that updates will not be actioned and quality of the reference dataset over time will not be ensured.

15. Have you, in the past 5 years, experienced a REACH inspection/control or have your products been controlled for REACH compliance? - To be answered only by companies (REACH dutyholders).

- ○ Yes
- ○ No
- ○ I don't know

Efficiency

The following questions explore the costs and benefits of implementing the REACH Regulation. The legislation was designed to deliver benefits in terms of protection of human health and the environment, better functioning of the EU internal market (e.g. facilitating trade between EU Member States) and fostering competitiveness and innovation of EU industry (e.g. better and safer chemicals). Costs can relate to costs for businesses, public authorities and society as a whole.

16. In your view, how significant are the following benefits generated for society by the REACH Regulation?

	1 Not significant at all	2 Rather not significant	3 Neutral	4 Rather significant	5 Very significant	Do not know / not applicable
Reducing the exposure of citizens in general to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	○	○	◉	○	○	○

Reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	○	○	○	◉	○	○
Reducing damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up contaminated land, etc.	◉	○	○	○	○	○

Encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry by encouraging /supporting a shift towards green, sustainable chemistry and a circular economy	○	○	◉	○	○	○
Stimulating competition and trade within the EU single market	○	○	◉	○	○	○
Stimulating international trade between the EU and other countries	○	◉	○	○	○	○

For businesses: Increasing the confidence of your clients /customers in your products	○	○	○	○	○	○

17. In your view, to what extent are the costs linked to the following REACH chapters (for society, companies, public authorities, etc.) proportionate to the benefits (for society, companies, public authorities, etc.) achieved?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
Registration	○	○	◉	○	○	○
Information in the supply chain (e.g. eSDS - extended Safety Data Sheets)	○	○	◉	○	○	○
Evaluation - dossier	○	◉	○	○	○	○
Evaluation - substance	○	○	◉	○	○	○
Authorisation	○	◉	○	○	○	○
Restriction	○	○	◉	○	○	○
Requirements for substances in articles	○	○	◉	○	○	○

18. Is the level of the fees and charges paid to ECHA as provided by the Fee Regulation (Commission Regulation (EC) No 340/2008), still adequate?

	Yes	No, it is too high	No, it is too low	I don't know
Fee for registration	◉	○	○	○
Fee for authorisation	○	◉	○	○
Fee for appeal	○	○	○	◉

19. Do you believe that there are areas where the REACH Regulation could be simplified or made less burdensome?

- ○ Yes to a large extent
- ◉ Yes but only to a minor extent
- ○ No
- ○ I don't know

If yes, you may provide ideas, preferably substantiated with quantitative evidence or qualitative information, at the end of the questionnaire.

Relevance

The following questions explore the extent to which REACH is consistent with current needs.

20. Do you believe that the REACH Regulation addresses the key issues in relation to the management of chemicals?

- ○ Yes to a large extent
- ◉ Yes but only to a minor extent
- ○ No
- ○ I don't know

If you answered no, you may provide detailed comments at the end of the questionnaire.

21. How suitable do you consider REACH to be to deal with the following emerging issues?

	REACH is the most suitable EU legal instrument to address the issue	REACH should only play a secondary role and the issues should be addressed by specific legislation	REACH is not a suitable instrument and should not address the issue at all	Do not know / Not applicable
Nanomaterials	◉	○	○	○
Endocrine disruptors	○	○	○	◉
Substances in articles	◉	○	○	○
Combination effects of chemicals	○	◉	○	○
Extremely persistent substances	◉	○	○	○

Coherence

22. Please tell us to what extent you agree or disagree with the following statements:

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
The different chapters (e.g. registration, authorisation, restriction,…) in REACH are applied in a coherent manner (e.g. there are no contradictions, inconsistencies…)	◉	○	○	○	○	○

The different chapters in REACH (e.g. registration, authorisation, restriction,…) are applied in a coherent manner (e.g. there are no contradictions, inconsistencies, they are complementary…) in relation to other EU legislation (e.g. worker protection legislation, consumer protection legislation, environmental legislation)	◉	○	○	○	○	○

The implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), contributes to coherent implementation of authorisation and restriction under REACH	○	○	○	◉	○	○
The implementation of the SVHC Roadmap, including the RMOA, contributes to coherent implementation of REACH in relation to other EU legislation (e.g. there are no contradictions, inconsistencies, they are complementary…)	○	○	○	◉	○	○

22.1. If you disagree with one or more of the statements above, where do you consider coherence should be enhanced?

(max. 5.000 characters)

• REACH CORE SHALL REMAIN FOCUSED ON DATA QUALITY AND COMPLETENESS: REACH provided for the first time a structural frame and way to develop a minimal data set for all chemicals with an emphasis on data quality allowing to demonstrate safe manufacturing and use with sufficient certainty. It aligned hereby the responsibilities of the registrants as the information developers and the authorities as guidance developer and reviewer of the quality, completeness and relevance of the safe use demonstration. This feature and related responsibilities should remain the core focus of REACH also in the future

• NO MIXING UP OF COMPETENCIES – The strengths of the respective EU legislations shall be used in a constructive and cooperative way: e.g. REACH vs. OSH or EQS Water/Waste Framework Directives. As an example, OSH and EU-wide OELs have in the past not been consistently considered as a Risk Management Option that could effectively address concerns. While it is clear that there will remain differences in targets and approaches, further coherence can be supported by communication and reflection on common objectives by the different actors, in full transparency.

• ENSURE EU POLICIES ALIGNMENT- Avoid lack of alignment between EU policies directly or not directly linked to chemicals (e.g. Circular Economy, Climate, Industrial Emissions, CMD/CAD and REACH). Examples are the use of borates for energy use reductions in smelter operations

• RISK CONTROL BASED APPROACH- Currently SVHC identification is exclusively focused on hazard whilst a risk-control based approach can be far more effective and efficient as focusing on where exposure matters

• MORE FORMALISED RMOA- The RMOA tool can provide significant added value. It potentially increases the efficiency and efficacy of the Risk Management process, provides a more holistic perspective and enables early cooperation between stakeholders to address ‘concerns’. It allows industry to

predict the regulatory fate of a substance, update the registration dossier with relevant information and to contribute. To make the best use of the tool, it should however be further harmonised and formalised

- SELECT AUTHORISATION WHEN SUBSTITUTION SEEMS POSSIBLE BUT NOT FUNCTIONING: The possibility of substitution and alternatives should be assessed during the RMOA, keeping in mind the feasibility (technical and economical) aspects to avoid regrettable or non-implemented substitution.
- EFFECTIVE RMOA ADDRESSING USES – Listing on Annex XIV means the Authorisation regime being applicable unless exempted for all uses. Defining the most effective Risk Management Measure by main use during the RMOA phase would not only increase the effectiveness of Risk Management and reduce the collateral damage, it would also speed up the system.
- RMOA TO AVOID OVERLAPPING RMMs – Avoid multiple overlapping risk reduction initiatives for same uses like e.g. on substances in articles legislation (Restrictions or Authorisation vs. RoHS, ELV, Battery Directive)
- INDUSTRY's INPUT IN RMOA AND ANNEX XV – Restrictions require quite some work, data-gathering and assessment for authorities, making it an instrument that is not often used even when proven it can be more effective than other tools (e.g. Annex XIV). Industry can at this stage neither submit Annex XV proposals for Risk Management (e.g. restrictions) nor structurally participate in the RMOA process. Both measures could however stimulate more appropriate Risk Management settings while speeding up the system.
- USE-DRIVEN RESTRICTIONS – Restrictions are still lacking a solid impact efficiency before they are started. This could be promoted by a transparent RMOA at the start of the process. Restrictions are still too often substance-driven rather than use-based. This leads to multiple assessments for the same use, which is not effective and may lead to regrettable substitution. Examples are the use of Cd and Pb in jewellery on which independent restriction assessments were made. A risk based assessment of CMR materials in jewellery could have been a more effective way.
- MAKING the AUTHORISATION SCHEME USE specific – All uses fall under the authorisation requirement while this tool may not be helpful for specific uses (e.g. essential elements, critical safety uses). It is suggested to make the authorisation scheme more flexible allowing use specific authorisation

requirements.
• INTERMEDIATES NOT IN THE SVHC ROADMAP SPIRIT – Substances of potential Equivalent Concern (EC) are put on the Candidate List even if they are exclusively used as an intermediate so cannot be prioritised for Authorisation. The preparation by the submitting country that prepares the Annex XV and subsequent MSC debate and review requires very extensive resources. While this is not in line with the spirit of the SVHC Roadmap it will not improve the workplace situation at EU scale given requiring rather an EU-OEL or other workplace measures

EU Added Value

23. To what extent do you consider that taking action through the different chapters of REACH has added value above what could have been achieved through action by Member States alone at national level? (1= no value, 5= a very high value)

	1	2	3	4	5	Do not know / not applicable
Registration	○	○	○	○	◉	○
Data-sharing and avoidance of unnecessary testing	○	○	○	○	◉	○
Information in the supply chain	○	○	○	○	◉	○
Evaluation – dossier	○	○	○	○	◉	○
Evaluation – substance	○	○	○	○	◉	○
Authorisation	○	○	○	○	◉	○
Restriction	○	○	○	○	◉	○

Part III. B

24. In your view, how satisfactory are the following mechanisms and procedures of the REACH Regulation?

	1 Not at all satisfactory	2 Rather unsatisfactory	3 Neutral	4 Rather satisfactory	5 Very satisfactory	Do not know / not applicab
Awareness raising for duty holders on key obligations and deadlines	○	○	○	◉	○	○
Support for preparation of registration dossiers	○	○	◉	○	○	○
Participation in Substance Information Exchange Fora (SIEFs) – data sharing	◉	○	○	○	○	○
Dossier submission - IT tools	○	○	○	◉	○	○
Communication of information along the supply chain	○	◉	○	○	○	○
eSDS - extended Safety Data Sheets	○	○	○	◉	○	○

Notification of SVHCs in articles	○	◉	○	○	○	○
Information concerning presence of SVHCs in articles	○	◉	○	○	○	○
Assessment of testing proposals	○	○	◉	○	○	○
Dossier compliance check	○	◉	○	○	○	○
Enforcement /follow-up of compliance check decisions	○	○	○	○	○	◉
Substance evaluation activities by Member States	○	○	◉	○	○	○
Identification of relevant SVHCs for the candidate list	◉	○	○	○	○	○
RMOA (Risk Management Option Analysis) process	○	○	◉	○	○	○
Prioritisation of SVHCs for authorisation	◉	○	○	○	○	○
Amendments to the list of substances subject to authorisation	○	○	◉	○	○	○

Substitution of SVHCs	○	○	◉	○	○	○
Support for applicants for authorisation	○	○	○	○	◉	○
Assessment of applications for authorisation by ECHA	○	○	○	◉	○	○
ECHA public consultations (e. g. in restriction or authorisation)	○	○	○	◉	○	○
Consideration of the availability and feasibility of alternatives	○	◉	○	○	○	○

Decision making by Commission on applications for authorisation	○	◉	○	○	○	○
Preparation of Annex XV dossiers to propose new restrictions	○	◉	○	○	○	○
Assessment of proposals for new restriction	◉	○	○	○	○	○
Decision making by Commission on new restrictions	○	○	○	◉	○	○
Exemptions for R&D activities	○	○	○	○	○	◉
Reduction of fees for SMEs	○	○	○	○	○	◉

Guidance by ECHA	○	○	○	◉	○	○
Guidance by national authorities	○	○	○	○	○	◉
Guidance by industry associations	○	○	◉	○	○	○
Support provided by Helpdesks	○	○	◉	○	○	○
Operation of the Board of Appeal	○	○	○	○	◉	○
Inspections by enforcement authorities	○	○	○	○	○	◉

Part IV – Additional comments

25. If you have any additional comments relevant to this public consultation, please insert them here. You may also upload position papers.

(max. 5.000 characters)

Q19: simplifications
RMOA- This tool defines the best risk management measure and can be used to trigger industry to prepare relevant risk management information that's not part of the registration. A more open and transparent RMOa process could stimulate this
CLARIFY SCOPE OF AUTHORISATION with stakeholders. Many registrants/consortia lose time due to the unclear scope of the Authorisation requirements. An interaction with industry upfront the Annex XIV listing (e.g. during the prioritisation) should facilitate this and result in an enhanced consistency of the submitted AfA, as well as more legal certainty
EVALUATION - The decision making process for DE/SE is cumbersome and long for involved companies: can it be shortened or made more efficient? Also industry gets only limited time to react on a draft decision for a SE (30 days) while authorities take a year or more to draft or review. Registration dossiers cannot be updated as soon as a registrant receives a draft decision on a DE. Overall, more balance is needed to avoid unnecessary decision forming and frustration
DATA SHARING and MAINTENANCE OF DOSSIERS - A number of difficulties remain - despite the Guidance- when it comes to ensure fair, transparent and sustainable data-sharing mechanisms, both for Registration and maintenance of the dossiers. These difficulties relate e.g. to the absence of a definition of "potential registrant" able to challenge existing data-sharing agreements (i.e. anyone in the SIEF can submit a challenge, even if it does not finally register) and/or the lack of practical recommendations on how to achieve

“unanimous consent” or “making every effort”. These aspects add to the work already created by the Regulation and may result in unnecessary disputes: they give too much weight to elusive potential registrants, and eliminate the flexibility necessary to accommodate the multitude of data-sharing scenarios encountered in the real world. It is also obvious that the data sharing provisions are not always consistent with the Joint Submission requirements in general. The current Regulation does not provide enough indications on the duties for joint submission participants to continue to contribute to the maintenance of the dossiers, even after a registration number has been obtained. Non contributors to article 22 will retain their registration number and as such, their access to the market. This goes against the principles of fair, transparent and non-discriminatory cost-sharing embedded in the REACH regulation. This will become a barrier to proactively and regularly update the existing registration dossiers. A better alignment between the data-sharing process, the joint submission obligations and the overall aims of REACH would be welcome.

Q22 : coherence
-USE OF REACH DATASETS – The main part of industry has made significant investments in developing REACH quality datasets. Having those used /considered for other EU legislations will stimulate their further completeness and maintenance

-RECONSIDER RESPONSIBILITY FOR NON-CORE ITEMS The Committees launched some new activities like the D(N)MEL development as an example that does not fit with the division of responsibilities. Also, the Classification and Labelling activity is in essence not in line either with this principle. Like in other jurisdictions in the world, it is suggested that from both a conceptual, efficiency and efficacy viewpoint both tasks should be dedicated to the registrants and the role of the ECHA Committees restricted to checking quality and completeness

Additional comments:
-SYSTEMATIC, QUANTITATIVE WEIGHT OF EVIDENCE is essential for data-rich

substances. Whilst the REACH text refers to weight-of-evidence, its application remains incoherent and inconsistent. It is however crucial for assessing the relevance of intrinsic hazards to human health and the environment and from there, effective chemicals management
-NEED FOR A PROCESS TO CHANGE classification and take substances off the Candidate list. There is no process to take it off the Candidate List even if new data questioning the SVHC status become available. Similarly the process foreseen for a reclassification when new data (e.g. mechanistic data) are calling for a refinement of an Annex VI classification is dependent on the willingness/capacity of a Member State to submit Annex XV, making consideration of science dependent on workload and resources
-ECHA SHOULD FACILITATE interaction between industry and Member States during SE and ensure proportionality of additional information requests, securing equal treatment of all registrants
-TRANSLATION OF ES: It is questioned whether translating ES attached to the SDS in the different EU languages (Article 31.5) actually improves communication on safe use. This represents significant costs (translating a full ES into all EU languages can reach 200k EUR for a single data-rich substance) without enhancing the use/accessibility of this complex communication tool

Please upload your additional document(s) (one by one, any format)

26. Are you interested in being contacted in the context of the ongoing study on the impact of authorisation?

- (●) Yes
- ( ) No

Contact

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