STRUCTURE OF REACH REFIT EVALUATION QUESTIONNAIRE

The questionnaire is structured as follows:

- 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

Part II - General 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
a) Improve protection of consumers				**X**		
b) Improve protection of workers			**X**			
c) Improve protection of the environment				**X**		
d) Free circulation of chemicals on the internal market (Reduce barriers to trade in chemicals across borders within the EU)				**X**		
e) Enhance competitiveness and innovation		**X**				
f) Promote alternative methods to animal testing for hazard assessment of chemicals						**X**

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
a) Generation of data for hazard/risk assessment					**X**	
b) Increase in information on chemicals for risk					**X**	

management						
c) Increase in information exchange in the supply chain				**X**		
d) Improvement in development and implementation of risk management measures			**X**			
e) Shifting the burden of proof from public authorities to industry					**X**	
f) Fostering innovation (e.g. substitution of SVHCs, development of new substances)		**X**				
g) Promoting the development use and acceptability of alternatives to animal testing						**X**
h) Implementation of the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing						**X**
i) Dissemination of information on chemicals for the general public		**X**				

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**	**5) Very much**	**Do not know/not applicable**
a) REACH authorization			**X**			
b) REACH restriction				**X**		
c) Consumer protection legislation concerning chemicals in articles (e.g. cosmetics, toys, food packaging)						**X**
d) Environmental legislation (e.g. Seveso, Industrial Emissions Directive)			**X**			
e) Harmonized Classification & Labelling				**X**		
f) Occupational Exposures Limits (OEL) in the context of worker protection legislation		***X***				

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)					**X**	
b) ECHA has established a strong and trustful relationship with its stakeholders		**X**				
c) ECHA has contributed to reducing the impact of REACH on SMEs	**X**					
d) ECHA's activities and guidance have facilitated an innovation-friendly framework		**X**				
e) ECHA has been successful in facilitating the implementation of the last resort principle concerning animal testing						**X**

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

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
Registration				**X**		
Data-sharing and avoidance of unnecessary testing						**X**
Information in the supply chain			**X**			

Evaluation - dossier						**X**
Evaluation - substance			**X**			
Authorization		**X**				
Restriction				**X**		
Overall implementation of REACH			**X**			

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				**X**		
Data-sharing and avoidance of unnecessary testing						**X**
Information in the supply chain		**X**				
Evaluation - dossier						**X**
Evaluation - substance						**X**
Authorization			**X**			
Restriction				**X**		

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) Strongly agree**	**Do not know/not applicable**
Transparency of procedures				**X**		
Speed with which identified risks are identified				**X**		
Speed with which identified risks are addressed		**X**				
Time to allow duty holders to adapt		**X**				
Predictability of the outcomes		**X**				

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)

Positive Effects:

- Authorization adds additional focus in work place risk management; helps prioritise some research activities increasing industry alignment where cooperation is needed; and increases focus on some substitution activity.

Negative Effects:

- REACH is the major cause of materials obsolescence affecting businesses. Registration costs can lead to manufacturers of chemicals either not registering substances, or not registering certain uses of substances. In addition, SIEFs may disregard niche uses that are critical to users further down the supply chain. In such cases downstream users need some mechanism to restore broken supply chains. However, when the supplier of a specialist product has already decommissioned plant and equipment in anticipation of a registration milestone, this will not help anymore.

- A downstream user can find out too late that an upstream authorization did not cover his use, either as a result of the applicant not covering it, or as a result of committee decisions. The time needed for dossier development and committee decision processes means that such a user will find out far too late to react. This can put such a user out of business, impacting downstream markets. It is therefore important that committee opinions (RAC/SEAC and REACH Committee) do not attempt to change the scope of authorization coverage through review processes.

- REACH impacts SMEs more harshly than larger companies due to a lack of knowledge and resources, which is contrary to the spirit of the Small Business Act.

- With regard to consumer products, changing product design (encouraged by REACH) can be done relatively quickly. They have relatively short life cycles before product redesign is undertaken. Product safety, whilst important, is often not determined by, or a critical factor of, the materials used to make the product. However, when REACH drives the substitution of materials and chemicals in products where safety is critical - mainly determined by the materials used -, alternatives are not always compatible with existing products – especially for products having long life cycles that may be in production and use for many decades (typical for the aerospace/defence sector – life cycles up to 50 years and more). This can create significant configuration management and compatibility issues on complex platforms. Substitution in these products normally requires extensive qualification testing, and substitution of alternatives can be extremely expensive. It should be understood that newly established replacement technologies do not have the confidence and trust in safety issues acquired throughout decades of service experience.

- The current practice of sunset dates 3 years after Annex XIV inclusion and latest application dates 1,5 years before the sunset date do not consider use-specific product lifecycles (e.g. the duration of specific programmes), nor the time needed to achieve substitution in particular

sectors. The short Annex XIV timelines tend to affect sectors with particularly long programme duration, such as the aerospace and defence sectors disproportionately.

- Whilst it was intended that Authorization would encourage increased innovation and R&D, in practice this means that innovation focus is taken away from the areas of most value to the user or customer. For example, in civil aviation the major drivers for innovation are fuel burn (carbon dioxide emissions), nitrous oxide emissions, and noise. Increased focus on chemical substitution reprioritises efforts away from more important areas.

- REACH Article 33 compliance (in light of CJEU ruling in case C-106/14) for very complex articles poses significant challenges.

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 applicable
Overall REACH enforcement in the EU			X			
REACH enforcement at Member States level			X			
REACH is enforced uniformly across the EU		X				
Prioritization of enforcement activities at EU level (by Forum)					X	
Communication on enforcement activities from Member States and Forum		X				

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)

Uniformity of approach

We are aware of differing styles of approach between member states, with some favouring a hazard-based approach (precautionary principle) and others take more of a risk based approach.

This has translated into differences of interpretation with regards to Article 33 interpretation which has created uncertainty of many years. This uncertainty still exists since the updated guidance document has not yet been published.

Communication on enforcement activities

Member state authorities need to better communicate enforcement priorities and objectives.

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).

Not applicable to ASD

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.						**X**
Reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.			**X**			
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.			**X**			
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		**X**				
Stimulating competition and trade within the EU single market	**X**					
Simulating international trade between the EU and other countries	**X**					
For businesses: Increasing the confidence of your	**X**					

clients/costumers 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				X		
Information in the supply chain (e.g. eSDS – extended Safety Data Sheets)		X				
Evaluation - dossier						X
Evaluation - substance			X			
Authorization			X			
Restriction					X	
Requirements for substances in articles		X				

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		X		
Fee for authorization		X		
Fee for appeal				X

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

Yes to a large extent	X
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	X
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		**X**		
Endocrine Disruptors	**X**			
Substances in articles		**X**		
Combination effects of chemicals	**X**			
Extremely persistent substances	**X**			

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 chapter (e.g. registration, authorization, restriction) in REACH are applied in a coherent manner (e.g. there are no contradictions, inconsistencies…)				**X**		
The different chapters in REACH (e.g. registration, authorization, 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)		**X**				

The implementation of the SVHC Roadmap, including the Risk Management Option Analysis /RMOA) contributes to coherent implementation of authorization and restriction under REACH		**X**				
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…)		**X**				

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)

- Where risks from chemical uses primarily relate to **worker exposure**, the **Chemical Agents Directive** and **the Carcinogens and Mutagens Directive** should be prime routes for risk control. However, we are seeing signs that some member states are advocating applying these directives and REACH Authorisation in parallel.

  There are a number of problems here with coherence and effectiveness:
  - The ECHA Risk Assessment Committee (RAC) and the Scientific Committee on Occupational Exposure Limits (SCOEL) take very different approaches to limit setting which results in confusion.
  - Binding OEL values can be set too low to be practical in some applications, irrespective of the socio-economic justification for continued use, effectively becoming a ban, even if it is intended to be just a risk reduction measure.

  There would be less scope for potentially confusing and contradictory OELs if clear guidance was made available to indicate one route OR the other - and not both -, based on a case-by-case review of the nature of uses, the nature of risks and the availability of alternatives.

- The purpose of the **Candidate List** needs to be clarified and agreed with all member states. In essence, some member states (who undertake risk management options analysis) have the view that ALL candidate list substances will eventually be included in Annex XIV. This is at odds with the Commission **SVHC Roadmap** communicated at the end of 2013, which recognized that there is benefit in leaving "difficult" substances on the candidate list only, since this increases social and supply chain pressure in many industries to substitute, even without inclusion in Annex XIV. Since some broad use substances (e.g. chromates) have become difficult to handle in the authorization system, a combination of candidate listing and a practical Binding OEL value may be a more effective risk control route than Authorization listing.

- In spite of the SVHC Roadmap, there is considerable unpredictability whether, when and in which process a given substance will be further regulated under REACH. The unrestricted possibility of further RMOAs by other Member States for the same substance after conclusion of the initial RMOA (e.g. to address another concern of the substance) creates additional uncertainties. The launching of R&D activities for substitution, followed by re-qualification and industrialization (if a suitable alternative is found), has huge resource implications, and therefore requires a clear signal by the regulators that the substance will be banned in the foreseeable future. Today

however, it is not always clear whether an SVHC will be included in the candidate list, and whether a candidate list substance will be included in the authorization list. It may also be that a restriction is deemed as sufficient to manage the risk to human health or the environment, and industrial use may continue within the defined conditions / derogations. It might therefore be equally important to have a clear signal in case a substance will further be allowed for industrial uses.

- Member states have different practices with regard to the application of RMOA and the implementation of the achieved results. While the RMOA is a very helpful tool in some member states, other member states do not use the RMOA or do not give opportunity for participation to all stakeholders. This is especially true for smaller member states where it is difficult for companies not situated in this country to get information about the taking place of a RMOA / participating if one does not speak the respective language.

- With regard to the exchange of information within the supply chain for upstream applications for Authorisation, uncertainties remain with regard to the strained interplay between REACH requirements and e.g. **competition law** and **data protection** legislation (e.g. concerning biomonitoring data).

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					**X**	
Data-sharing and avoidance of unnecessary testing						**X**
Information in the supply chain			**X**			
Evaluation - dossier					**X**	
Evaluation - substance					**X**	
Authorization					**X**	
Restriction					**X**	

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 applicable

Awareness raising for duty holders on key obligations and deadlines	X					
Support for preparation of registration dossiers				X		
Participation in substance Information Exchange For a (SIEFs) – data sharing						X
Dossier submission – IT tools					X	
Communication of information along the supply chain		X				
eSDS – extended Safety Data Sheets	X					
Notification of SVHCs in articles			X			
Information concerning presence of SVHCs in articles		X				
Assessment of testing proposals						X
Dossier compliance check						X
Enforcement/follow-up of compliance check decisions						X
Substance evaluation activities by Member States			X			
Identification of relevant SVHC's for the candidate list		X				
RMOA (Risk Management Option analysis) process				X		
Prioritization of SVHCs for authorization			X			
Amendments to the list of substances subject to authorization			X			
Substitution of SVHCs			X			
Support for applicants for authorization		X				
Assessment of applications for authorization by ECHA		X				
ECHA public consultations (e.g. in restriction or authorization)				X		
Consideration of the availability and feasibility of alternatives			X			
Decision making by Commission on applications for authorization			X			
Preparation of Annex XV dossiers to propose new restrictions				X		
Assessment of proposals for new restriction				X		
Decision making by				X		

Commission on new restrictions						
Exemptions for R&D activities				X		
Reduction of fees for SMEs				X		
Guidance by ECHA			X			
Guidance by national authorities			X			
Guidance by industry associations				X		
Support provided by Helpdesks				X		
Operation of the Board of Appeal						X
Inspections by enforcement authorities				X		

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

See our supporting position paper

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

YES	X
NO	

As signed by Jan Pie, ASD Secretary General, 24th January 2017