AmCham EU's response to the consultation in relation to the REACH REFIT evaluation

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2015, directly supports more than 4.3 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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CONSULTATION RESPONSE

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27 January 2017

PART II: GENERAL QUESTIONS

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?

	Not at all	Slightly	Somewhat	Substantially	Very much	Do not know / not applicable
*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?

	Not at all	Slightly	Somewhat	Substantially	Very much	Do not know / not applicable
*a) Generation of data for hazard/risk assessment				X		

*b) Increase in information on chemicals for risk management				X		
*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?

	Not useful at all	Slightly useful	Somehow useful	Substantially useful	Very useful	Do not know / not applicable
*a) REACH authorisation			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) Harmonised Classification & Labelling				X		
*f) Occupational Exposure 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)?

	Strongly disagree	Disagree	Neutral	Agree	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			X			

resort principle concerning animal testing.						

Part III – SPEFIFIC 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.

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?

	Not at all	Slightly	Somewhat	Substantially	Very much	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				
Authorisation		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?

	Strongly disagree	Disagree	Neutral	Agree	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			
Authorisation				X		
Restriction				X		

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

	Not well at all	Rather not well	Neutral	Rather well	Very well	Do not know / not applicable
Transparency of procedures			X			
Speed with which hazards/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)*

Please see enclosed AmCham EU's position paper on unintended consequences of REACH and its impact on competitiveness.

R&D resources shifted to compliance (negative)

REACH requires significant compliance resources to meet registration, evaluation, restriction and authorisation obligations. It has led to shifts of resources that could be damaging in the medium and long term in Europe. REACH compliance requires in-house specialist knowledge and expert competence. One of the negative indirect impacts of REACH on innovation is that company expert staff (R&D, process improvement, product testing experts) is mobilised for compliance efforts associated with REACH rather than for the R&D priorities they were hired for.

Innovation (positive and negative)

REACH has incentivised companies to systematically identify and prioritise substances they are not interested in producing or using in the future. Many of the substances on the market today are the best substances available based on performance (often related to safety, health, environment and sustainability). Unfortunately, substitution required by REACH seems to have overtaken the entire innovation debate. Meanwhile, innovation is market and performance driven. A disproportiate focus on regulatory-led substitution can thus be a barrier to the development of innovative applications needed for societal improvements (energy and resource efficiency, modern health care and transport, the digitalisation of the economy). Some breakthrough technologies are not being investigated to their full extent in Europe because of uncertainties surrounding the regulatory regime that will affect them.

Implementation issues and unpredictability (negative)

A very high level of uncertainty can sometimes derive from REACH, and is damaging for industry and society at large. Given the number of different REACH processes and the plurality of actors involved in their implementation, it is sometimes difficult to understand which substances are targeted under which process and why. It is particularly difficult to understand why the same substance would be targeted by different processes led by different national competent authorities. Efforts have been made to address this (CoRAP, SVHC roadmap) and communication has improved with European authorities. The situation with national authorities however varies a lot from one Member State to the other. Thus we would encourage the Commission and ECHA to clarify everyone's obligations and rights (see for instance our paper on substance evaluation attached). Furthermore, REACH is becoming increasingly politicised with some countries using the regulation to achieve national political objectives such as a non-toxic environment, at the expense of scientific standards (quality and robustness of data, weight of evidence).

A specific area where we observed implementation deficiencies is in the application of exposure-based waiving to optimise testing requirements. In practice, the interpretation and implementation of this approach, (eg. recommendations on guidance or on how testing proposals are assessed and on how dossier compliance is checked), imposes scientifically unjustified, excessive conditions that render exposure-based waiving provisions impossible to use in practice, in particular in the human health area.

Impact on SMEs (negative)

Regulation is an even greater challenge for SMEs than for large organisations. AmCham EU is aware of efforts made by the European Commission and ECHA to address challenges SMEs face with REACH. We would like to emphasise the need to do more because SMEs are critical to industrial competitiveness in Europe. Innovation relies on the industrial networks which SMEs are intrisincally part of.

Communication in the supply chain (negative)

The REACH requirements related to communication of chemicals in articles are a considerable administrative and practical burden. The Court ruling of September 2015 will result in significant challenges and costs for industry, especially for the producers of complex articles. Investments

undertaken towards the compliance with REACH SVHC requirements have generally produced mixed results due to the complexity of products and the difficulties experienced in retrieving information in complex and international supply chains.

Consideration of comments by regulators
We welcome the efforts towards transparency and the increasing use of public consultation mechanism. However, we do not see clearly the extent to which comments received by decision-makers in the various consultations are considered when final decisions are made. The strengthening of existing consultation mechanisms will allow a dialogue to take place on the impact of measures on industry and end-products.

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

	Not at all satisfactory	Rather unsatisfactory	Neutral	Rather satisfactory	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				
Prioritisation 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)

Our members' experience with REACH tells us 3 improvements are needed in this regard.

1. The enforcement of REACH must be improved. This is especially the case for EU REACH restrictions, which, if not enforced, are a de facto competitive advantage to noncompliant European and third country industries. The lack of enforcement of REACH and its restrictions greatly impacts the competitiveness of EU-based manufacturing. An illustrative example is in the tyre sector and the related Annex XVII restriction of PAHs in their oils. Compliance with this restriction mobilised huge amounts of R&D and testing resources in the oil, polymer and tyre companies manufacturing in Europe, including American ones. The tyre industry has estimated that this restriction costs them over €100 million. This granted a first competitive advantage to producers from other regions of the world importing their finished products into the EU. Without having made this investment, these producers benefitted from the R&D of the European industry and a new supply of compliant oils. A second competitive advantage is granted to non-compliant actors in that they continue to have access to the European market without having made the necessary investment to meet the new REACH obligations. After the 2010 REACH restriction, the tyre industry ran its own testing campaign to check the compliance of tyres on the EU market. Over 10% of tyres were not compliant with the restrictions, representing exclusively cheap imports from outside the EU. De facto, non-compliant actors who have not had to pay REACH compliance costs are given a competitive advantage over those who are compliant.

2. All Competent Authorities, in particular staff directly in charge of enforcement activities, must be constantly updated on the most recent interpretation of the REACH Regulation, and apply guidelines agreed at EU level. Officials in charge of enforcement must be better trained.

3. Different departments of national Competent Authorities must be better coordinated. In each Member State, all departments involved in or impacted by REACH (health, environment, industry, trade and customs, labour, etc…) should organise communication platforms in order to secure the consistency and practicality of decisions.

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 duty holders).

☒ 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?

	Not significant at all	Rather not significant	Neutral	Rather significant	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		
Stimulating international trade between the EU and other countries		X				

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

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?

	Not at all	Slightly	Somewhat	Substantially	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					
Authorisation	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 authorisation		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

☐ 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	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:

	Strongly disagree	Disagree	Neutral	Agree	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…)	X					
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)	X					
The implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), contributes to coherent implementation of authorisation 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)

AmCham EU believes that two of the main issues to be addressed by the REACH REFIT evaluation are the lack of predictability and overlaps with other pieces of legislation. Despite efforts made by the Commission, ECHA and Member States, the implementation of REACH processes remains somewhat chaotic, and in several cases can lead to inconsistencies or contradictions.

Inconsistencies in REACH implementation

In some cases the same substance is subject to different processes simultaneously (eg. evaluation and RMOA, or authorisation and restriction). Such processes would generally be led by different Member States and there is no mechanism to prevent two Member States from running two RMOAs in parallel and reach different conclusions. We also deplore significant regulations being advanced outside of the traditional REACH framework (see the recent example of the CMR fast track process for chemicals in textiles). This type of extraordinary action jeopordises the legitimacy of the entire REACH framework. In addition, compliance checks (dossier evaluation) can in some cases lead to multi-year processes, potentially requiring extensive testing or data development, with no predictability on whether the submissions made at the end of the process will lead to compliance. While the objectives of REACH are agreed, the regulation should be a means to an end and not an end it itself.

Overlaps with other legislation

Although efforts have been made by the Commission and some Member States in that regard (eg. common understanding papers), overlaps continue to exist and often lead to inconsistencies and deadlocks that jeopardise the smooth implementation of EU legislation. A striking example is that of REACH and OSH legislation, where RAC and SCOEL continuously apply different limit values as their methodologies differ, as in the NMP example.

We have also observed inconsistencies between REACH and CLP, where multiple REACH and CLP processess can be invoked on a substance at any time. Member States can initiate harmonised classification proposals under the CLP without any apparent reference to the REACH dossiers. There should be consultation between the relevant Member State and the affected registrants to ensure that the CLP proposal is scientifically justified. Given that REACH registrants are required to agree on classification, there should also be a requirement for CLP inventory notifiers (as required under the CLP) to consult with REACH registrants.

The current revision of the waste framework directive also gives rise to potential inconsistencies. References made to hazardous chemicals in amendments tabled by Members of the European Parliament are inconsistent with existing chemical legislation. We caution against this trend of including chemical measures which may differ from obligations foreseen under REACH in waste and product legislation. The Commission has announced an analysis on that particular point under the Circular Economy Action Plan and AmCham EU hopes it will lead to clarifications on how chemical, product and waste legislation can constitently coexist. It is crucial that measures taken under chemical legislation such as REACH and CLP serve as a basis for any chemical-related measures taken under product and waste legislation.

We have also noticed major inconsistency between REACH and some international processes. A substance assessed as a PBT under REACH and subject to a targeted REACH restriction becomes systematically a potential candidate for nomination as a POP under the Stockholm Convention. This process aims at eliminating a chemical unless an exemption is granted, rather than restricting a specific use. This has happened regardless of whether the technical criteria differ under each regulatory framework (long-range transport properties and air fate are not assessed in detail under REACH). The

Commission's 'Common Understanding' paper that establishes a link between the REACH restriction process and the Stockholm Convention needs to address these shortcomings.

Finally, as we move beyond CMR into endocrine disruptors and other sensitive endpoints, it becomes increasingly important to develop a common understanding of how to characterise 'equivalent level of concern' for SVHC identification under Article 57f of REACH. A broad consensus between academia, authorities and industry is needed. For example, for the assessment of endocrine disrupting chemicals or respiratory sensitisers under Article 57f, specific guidance is needed to clarify which health effects are considered similar to those of cancer, how much evidence is needed for such effects and whether a quantitative comparison ('equivalence') can be established. Such clarification would contribute to improving the predictability of the REACH processes for industry.

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			
Authorisation				X		
Restriction					X	

Part III. B

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

	Not at all satisfactory	Rather unsatisfactory	Neutral	Rather satisfactory	Very satisfactory	Do not know / not applicable
Awareness raising for duty holders on key obligations and			X			

deadlines						
Support for preparation of registration dossiers			X			
Participation in Substance Information Exchange Fora (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 SVHCs for the candidate list			X			
RMOA (Risk Management Option Analysis) process				X		
Prioritisation of			X			

SVHCs for authorisation						
Amendments to the list of substances subject to authorisation			X			
Substitution of SVHCs		X				
Support for applicants for authorisation		X				
Assessment of applications for authorisation by ECHA			X			
ECHA public consultations (e.g. in restriction or authorisation)		X				
Consideration of the availability and feasibility of alternatives		X				
Decision making by Commission on applications for authorisation		X				
Preparation of Annex XV dossiers to propose new restrictions		X				
Assessment of proposals for new restriction			X			
Decision making by Commission on new restrictions			X			
Exemptions for R&D activities				X		
Reduction of fees for			X			

SMEs						
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)

AmCham EU believes that several tools are easily accessible and implementable to counter-balance some of the unintended consequences of REACH raised in this consultation.

The use of guidance should be encouraged. In addition, roundtables with stakeholders who have provided comments would help to further explain and supplement provided input. This could be particularly helpful during the public consultation stage for the addition of substances on Annex XV, when some companies already are providing information about the use of a substance, a use which might be new to ECHA. We recommend the Commission and ECHA take on a more central role in coordinating the implementation of REACH by consulting with registrants and other stakeholders for major substances. With respect to scientific quality and robustness, ECHA should be the guardians of robust science in the regulatory process.

In some cases it should also be possible for dossiers to be closed once adequate evaluations have been completed and risk management measures implemented. Although there may not be many substances which have been fully evaluated yet, this option could restore some predictability. Only where substantial new scientific data comes forward should consideration be given to re-opening the file for such substances. More generally, AmCham EU is concerned by the absence of process to reassess or update the status of a chemical. There is no mechanism to reassess the SVHC status of a substance as new data become available. Similarly, updating a harmonised classification in the light of new data has proven difficult in practice. Progressive legislation must be able to cope with scientific updates, including at substance level, and ensure that information communicated in the supply chain.

There is strong agreement on the objectives of REACH i.e. ensuring a high level of protection of health and the environment, as well as supporting innovation and competitiveness. However, significant improvements are needed in predictability to support investment in existing and new substances. Policy objectives should not be confused with legislative means. It is essential that limited resources (from both natiaonal and EU administrations and industry) are used to address real problems. Improvements in this regard can be best achieved by formalising the RMOA process with a clear upfront dialogue with all relevant participants including registrants. In our view, the use of guidance or the development of a new REACH Annex seems like a relevant tool to formalise the RMOA process. Before a particular regulatory process is proposed, there should be a discussion between registrants, ECHA, interested Member States, the Commission, and other interested parties. Evaluations and risk management measures ongoing or already in place should be considered, to avoid overlaps and contradictions.

This should lead to prioritisation and focus on appropriate regulatory process: for instance authorisations for substances used only in the workplace should not receive a high priority if fully covered by the OSH legislation.

AmCham EU has provided detailed comments on the authorisation process (see paper attached). The REACH REFIT evaluation should also aim to address the following concerns:

- Authorisation is not adapted for process chemicals used in industrial settings that are not present in products placed on the market for industrial uses;
- Authorisation can be incompatible with long-term production planning for uses associated with time production of long lived products.

Where RMOAs identify authorisation as the best regulatory option, upstream applications are fundamental to the effective operation of REACH in the context of complex supply chains due to:

- The need to cover suppliers' uses in accordance with prime contractor specifications
- the lack of REACH know-how and resources in many small end-users, especially SMEs
- The need for supply chain flexibility

However, some larger companies which do not need to cover their supply chain are already making downstream user applications to obtain longer review periods, despite being also covered by upstream applications. A difference in review period is therefore distorting the market to the disadvantage of smaller companies and companies with complex supply chains.

Finally, AmCham EU would like to call on the Commission and Member States to promptly finalise the work on simplified authorisation procedures for low volumes and legacy/spare parts.

With respect to ensuring a well-functioning internal market even though regulations prior to REACH were supporting the internal market with limited barriers to trade, we believe REACH has more potential to support a well-functioning internal market provided enforcement and risk management are harmonized across Member States.

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

Attachments: REACH and competitiveness paper + REACH substance evaluation paper + authorisation paper

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

☒ Yes
☐ No