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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Stéphanie Brochard
Organisation/company	American Chamber of Commerce to the EU (AmCham EU)
Country	Belgium
Email Address	
Q2: If you have a Transparency Register ID number, please provide it below. If your organisation is not registered, you have the opportunity to register now by following this link. 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.	5265780509-97
Q3: 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 of 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 such cases, 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
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q5: Please indicate whether you are replying to this questionnaire as:	An industry association
Q6: If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:	Other, Other (please specify) AmCham EU is a cross-sectoral association and gathers many of the above.

Q7: For businesses, please indicate the size of your business:The definition of small and medium-sized enterprises depends on the staff headcount and either the annual turnover or the balance sheet of the company. Please consult the following website: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm	*Respondent skipped this question*
Q8: Please indicate the level at which your organisation is active:	EU

PAGE 3: Part II – General Questions

Q9: How important is it in your view that there is chemical and chemical-related legislation* at EU-level in order to achieve the following objectives? (1 = not important; 5= very important)*This comprises the chemical-related provisions in all legislation within the scope of this fitness check. It encompasses legislation governing hazard identification and classification, as well as risk management measures, including chemical-related aspects of legislation on worker safety, transport, environmental protection, chemicals controls and supporting legislation, excluding REACH. The full list of legislation can be found here.The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals.**

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	5

Q10: Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.

Protecting human health	3
Protecting the environment	3
Ensuring a well-functioning internal market	2
Stimulating competitiveness and innovation	1

Q11: If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

Protecting human health	The legislation is not adapted to the issues at stake
Protecting the environment	The legislation is not adapted to the issues at stake
Ensuring a well-functioning internal market	The legislation is unclear, The legislation is not effectively implemented
Stimulating competitiveness and innovation	The legislation is unclear, The legislation is not adapted to the issues at stake, The legislation is not effectively implemented

Q12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

EU-level legislation adds value to national level action	4

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.For other stakeholders - Please select the legislation you are familiar with.

Classification, labelling and packaging (Regulation No (EC) 1272/2008)
,

Plant protection products (Regulation (EC) No 1107/2009)
,

Biocidal products (Regulation (EU) No 528/2012),

REACH, Annex XIII (Regulation (EC) No 1907/2006)
,

Inland transport of dangerous goods (Directive 2008/68/EC)
,

Chemical Agents (Directive 98/24/EC),

Carcinogens and mutagens at work (Directive 2004/37/EC)
,

Young people at work (Directive 1994/33/EC),

Pregnant workers (Directive 1992/85/EEC),

Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
,

Waste framework (Directive 2008/98/EC) and List of Waste
,

Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
,

Water Framework (Directive 2000/60/EC),

Urban Waste Water (Directive 91/271/EEC),

Marine Strategy Framework (Directive 2008/56/EC),

Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
,

End of life vehicles (Directive 2000/53/EC),

Batteries (Directive 2006/66/EC),

Packaging and Packaging Waste (Directive 94/62/EC)
,

Export and import of hazardous chemicals (Regulation No 649/2012)
,

Persistent organic pollutants (Regulation (EC) 850/2004)
,

EU Ecolabel (Regulation (EC) 66/2010),

Safety of toys (Directive 2009/48/EC),

Cosmetic products (Regulation (EC) No 1223/2009),

Drinking Water (Directive 98/83/EC),

Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)
,

Pressure equipment (Directive 2014/68/EU),

Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
,

General Product Safety (Directive 2001/95/EC),

Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
,

Other (please specify)
Fluorinated greenhouse gases regulation (517/2014/EU)

PAGE 5: Effectiveness

Q14: In the EU legislative framework for chemicals, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations (e.g. widespread exposure or exposure of vulnerable groups), which justify the automatic adoption of such measures. In other cases, the risk management measures are determined by a specific risk assessment that assesses the probability of adverse health and environmental effects resulting from the specific exposure scenarios associated with the proposed use(s) of the chemical. In your view, do you think EU chemical and chemical-related legislation should, in general:

a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged discussions and implementation delays)
,

If you answered a or b, please explain
Risk assessment has been successfully applied to chemicals with widely differing toxicity profiles and characteristics of human exposures used over the last 30 years. However, AmCham EU sees that in many areas in the EU, decisions are driven by hazard rather than risk, even when risk assessments are carried out. Examples include: the Water Framework Directive, PBT assessments, BPR, PPPR, nanomaterials. In the context of identification of endocrine disruptors (ED) for instance, we believe risk assessment is a crucial element. Classification as CMRs (based on hazard) cannot automatically lead to prohibition of key substances without considering risk, including risk/benefit ratio (e.g. BPR). Stakeholders do not have the possibility to raise any points related to socio-economic impacts and emphasise risk-based approaches before their products are affected by harmonised classification. Similarly, ED identification based solely on hazard should not lead to an automatic prohibition of these substances in a range of products. Appropriate identification including potency and risk management must be part of the solution.

Q15: In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.

No,

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.
The science is not clear on combined effects and is not at a stage where regulatory action can be taken. Furthermore, economic and technical feasibility as well as impact on jobs, innovation and competitiveness should be fully considered.

Q16: In your view, to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory? (1= not satisfactory, 5= very satisfactory)

Transparency of procedures	2
Speed with which hazards/risks are identified	3
Speed with which identified risks are addressed	3
Time to allow duty holders to adapt	2
Predictability of the outcomes	1
Stability of the legal framework	2
Clarity of the legal texts	3
Guidance documents and implementation support	4

Effective implementation and enforcement across Member States	2
Consistent implementation and enforcement across Member States	1
Public awareness and outreach	2
International collaboration and harmonisation	2
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	A lot of effort has been made, by ECHA as well as by the Commission, to develop comprehensive tools such as guidance, helpdesks and tools for SMEs. For example, the RoHS guidance is a solid example of good support provided to companies for implementation of EU legislation. Effectiveness in the implementation and enforcement of EU legislation varies across Member States and there is no consistency. AmCham EU believes that predictability and legal certainty are key to ensuring competitiveness of industry in Europe. Yet, legal uncertainty remains in the EU, particularly surrounding which chemical substances will be targeted, when, and under which regime (also in relation to the interface with REACH). Multiple regulatory processes under REACH in addition to the CLP results in the fact that dossiers never seem to be 'closed', even after extensive evaluations have been conducted. This lack of predictability means that companies producing in Europe cannot be certain that a substance which is allowed now, will be available for use in 3, 5 or 10 years when a new product range is ready to be released on the market, and even beyond that, during the product's life. Unfortunately, too often predictability is seriously undermined by political considerations and interferences which have nothing to do with sound science. With regard to international collaboration and harmonisation, AmCham EU members believe that developing common principles for information sharing, prioritising chemicals for review and evaluation, protecting commercial and proprietary interests and, ensuring coherence in hazard and risk assessment would dramatically improve the international regulatory environment on chemical policy. Several EU-like legislation are developing in third countries but without full understanding of the EU system which therefore leads to serious inconsistencies in the application of these laws. This is something AmCham EU has observed with RoHS. For example, RoHS-like initiatives have spread in countries like Kosovo, India, China, the United Arab Emirates and the Customs Union (with includes Russia, Belarus and Kazakhstan) but with substantial differences in terms of scope and annexes. Furthermore, AmCham EU members have

	varying experiences with international frameworks. While the Montreal Protocol works well, the Stockholm Convention has in some cases lacked coherence with EU developments under REACH, for example. In addition, there is little stakeholder consultation and limited transparency in the Stockholm Convention process. More generally, some EU decisions are not transparently made or communicated. This is evident in biocides or CLP, as decisions are made in closed sessions, without a systematic application of weight-of-evidence).

Q17: In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)

Hazard identification criteria	3
Risk assessment and characterisation	2
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	4
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	4
Risk management measures restricting or banning the use of chemicals	2
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	4
If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.	Hazard identification criteria are clear but often subject to different interpretations. The creation of an RMOA step, even if voluntary, is an important and practical innovation in seeking the best regulatory outcome for managing risks associated with the use of hazardous substances. AmCham EU members therefore see room for improvement in the RMOA process. However, AmCham EU considers that the new RMOA process has elements which overlap or are akin to actions within substance evaluation which has its own separate process under REACH. AmCham EU believes that the Commission, ECHA and the Member States, in the interest of regulatory efficiency, should work to ensure that the processes are well coordinated.

Q18: Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?	No, If you answered no, please explain your answer GLP can be important and sometimes necessary, but is not in itself sufficient to ensure good quality decision-making because it does not assess the robustness, weight of evidence and human and environmental relevance of data.

PAGE 6: Efficiency

Q19: **In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)**	Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.
Q20: **In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)**	Costs for small and medium sized enterprises, Costs for large enterprises
Q21: **In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?**	Classification requirements for substances and mixtures , Chemical labelling and packaging requirements, Risk management measures under the different legislation , Understanding and keeping up-to-date with changes in legal requirements , Training staff to ensure compliance with legal requirements , Inspections and administrative requirements, Other (please specify) - Supply chain management costs - Alternative substance qualification for use in final articles (to ensure same or better electro-technical properties from the alternative substance) - Article substance disclosure/restriction implementation IT tools - Costs of external consultants - Safety Data Sheet update - Generation and maintenance of registration dossiers under REACH, and associated testing costs
Q22: **Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?**	I don't know

PAGE 7: Relevance

Q23: To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	3

Q24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)

Novel areas of concern sufficiently addressed by framework	3
Please comment	New and emerging scientific issues present the EU with opportunities to align regulations with other major international partners and prevent divergence prior to their enactment. AmCham EU believes that nanotechnologies for example could be the competitive industry of the future for the US and Europe given that the global market for nanomaterials is estimated at a market value of €20 billion. If the regulation framing this new technology and the materials and products it produces is too rigid, it could stifle its development and impact the competitiveness of European industry.

PAGE 8: Coherence

Q25: Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

The EU chemicals legislation framework has overlaps	Strongly Agree
The EU chemicals legislation framework is internally inconsistent	Strongly Agree

Q26: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

Overlaps	CLP and Seveso III (for environment) Changes in CLP environmental classification automatically triggers requirements under Seveso III. CLP classification has therefore a direct impact on the downstream level. AmCham EU believes there should be a step in between to assess whether the requirements, created because of the classification, make sense.
Inconsistencies	CLP labelling vs sectorial labelling CLP requires the presence of some substances to be labelled but this is also the case of some sectoral legislation such as biocides, detergents, and both are not always consistent with each other. For instance there are inconsistencies in terms of thresholds and position of the label on packaging. CLP vs waste management CLP classification can trigger different waste related requirements at the national level. This is an important issue in terms of alignment and market distortions.

Q27: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

REACH/RoHS: ensuring coherence
If analysis shows that key environmental and health concerns are related to the use of the substance in EEE, RoHS should be considered an appropriate regulatory tool to address these concerns, as it addresses both environmental and health while considering industry specific needs for the continued use of a substance. This is particularly important for EEE, where new technologies and applications are constantly developed.
Clearly-defined scopes are also critical to a coherent system. For instance, when substances are being assessed under REACH but have already been addressed under RoHS, the scope of uses/applications under REACH should clearly exclude EEE products already regulated by RoHS. This is aligned with the Commission's common understanding paper.
In cases where the review of a substance has already taken place under REACH or RoHS, it is critical that the knowledge already generated be used to draw the new regulatory conclusions. For example, information generated under REACH on substances, their classification, uses, exposure and best risk management options should be fully taken into consideration in the context of RoHS. To maximise the necessary synergies with REACH, we recommend that all relevant opinions from the Risk Analysis Committee (RAC) and Socio-Economic Analysis Committee (SEAC), as well as the regulatory decision of the Commission, are taken into account. At the same time, RoHS granted exemptions should be recognised as grounds for a possible exemption from REACH authorisation obligations.

REACH/ OSH: avoid overlap and select the best risk management measure
While REACH is the cornerstone of EU chemicals management and has contributed to unrivalled data collection about the use and effects of substances, AmCham EU members believe that REACH Candidate Listing and Authorisation should not be considered as the preferred option when potential risks from a substance have found to be limited to the workplace and can be more effectively addressed by workplace-specific legislation. Referring to the Commission's Roadmap on Substances of Very High Concern (SVHC Roadmap), we would like to stress that Risk Management Option Assessments (RMOAs) are rightly aimed at identifying the best regulatory option to manage the risk 'either in REACH […] or outside of REACH'.

REACH/Water Framework Directive: potential overlap and inconsistencies
Substances proposed for inclusion as priority substances, or priority hazardous substances, under the Environmental Quality Standard (EQS) Directive have already been subject to other pieces of EU legislation that introduced specific risk management measures. For example, substances that have been included in REACH Authorisation Annex XIV cannot be produced, imported or used by companies unless a 'use specific' authorisation is granted. Prioritising one of these substances as priority hazardous substance (PHS) under the EQS Directive can therefore be perceived as incoherent with the REACH Authorisation process. Indeed the PHS status under the EQS Directive means that the substance needs to be eliminated from surface waters, while REACH Authorisation allows companies to continue using the substance.

Nanomaterials in cosmetics/ REACH/medical devices/novel foods
There are different definitions of nanomaterials in specific/sectoral pieces of legislation.

PAGE 9: Part IV: Specific questions on the CLP Regulation

Q28: CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very effective)

To what extent are CLP labels effective in communicating hazards to workers?	4
To what extent are CLP labels effective in communicating hazards to consumers?	2

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?	*Respondent skipped this question*

Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)

Guidance documents	3
Helpdesks	4
Industry association guidance and materials	5

Q31: To what extent is CLP enforced in a harmonised manner across Member States?

Please add further details as necessary
It is unclear as to the degree of enforcement across Member States.

Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)

Respondent skipped this question

Q33: CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?

Transition period is too short,

Please elaborate if you answered that the transition period is too short or too long.
For predictability reasons, changes in criteria should only be done if there is a major justification and only then on an infrequent basis.

Q34: To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)

Transparency of the procedures	3
Involvement of stakeholders	2
Quality of scientific data and related information	2
Speed of the procedure	2

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
Procedures are not always transparent. For instance, minutes are not available, or only after they are edited and RAC refuses to participate in discussions. AmCham EU believes that the EU should be best-in class in this regard.

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.

AmCham EU would like to share some additional comments given that not all questions offered the possibility to comment and explain the answers.
Additional comments for Part II – General Questions
AmCham EU clearly sees value in having chemical management policies at the EU level rather than at 28 national levels. AmCham EU member companies are committed to protecting human health and the environment, not only through compliance, but also by developing voluntary industry initiatives. Regulation helps to achieve the objectives outlined in the questionnaire. Sometimes it works very well, in other cases less so, mostly because of lack of enforcement. Limited and uneven enforcement across the EU creates distortions in the Single Market. EU chemicals legislation in particular is strongly hazard-based and focuses on standardised lab testing. There is therefore

focuses on standardised lab-testing. There is therefore insufficient data to support the argument that EU chemicals legislation effectively protects human health and the environment. AmCham EU believes that proper risk assessment, coupled with hazard assessment, provides for a better protection and allows for a more targeted identification of the best risk management options. Regarding competitiveness, the preliminary results of the evaluation by the European Commission on the cumulative costs arising from existing EU chemicals legislation indicates that the total cost of legislation that companies from the chemical sector had to bear amounts to €10 billion per year on average, over the period 2004-2014. This represents 12% of the gross value added of the European chemicals' sector and is even higher in the specialty chemicals' sector. AmCham EU members take compliance very seriously and therefore implement EU chemicals policy. Member companies have, however, noted incoherent implementation of this legislation across Member States, as well as strong differences in terms of enforcement. AmCham EU also wants to stress that complying with the legislation is a licence to operate, and not a guarantee or an enabler for innovation. AmCham EU believes that the chemical regulatory framework does not properly address innovation. All too often the discussion on innovation and chemicals legislation gets truncated to regulation-mandated substitution, which is overly simplistic. For AmCham EU, impacts on innovation should be systematically considered ex-ante and ex-post. Regulatory certainty is also key to ensure long term investments in Europe. More specifically on the question of effectiveness, members believe that the current testing system tends to be disconnected from the issues at stake, for instance in terms of public health. In-lab tests are relevant as a starting point but the consideration of exposure should also be part of the hazard and risk assessment. Additional comments for Part III – Specific Questions It is difficult to answer to question 23 with a general assessment as each case is specific and has its own assessment. Industry applies risk assessment and risk management to the running of operations and the marketing of substances. If a substance can be used safely then it should not be substituted automatically based on hazard alone. The substitution of substances in the market place is a complex process depending upon performance, availability, technical and economic feasibility as well as regulatory drivers. Replacing major commodity chemicals, where justified, can take decades and billions of euros of investment – therefore this is not something which can be undertaken lightly. Substitution is not driven by legislation alone, but is influenced by many other drivers, which are very case-specific. For informed substitution to take place, a comprehensive comparison of substances or technologies to be substituted against their potential alternatives should be performed, covering their whole life-cycle, in a holistic manner.