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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Prof. Christina Rudén
Organisation/company	Stockholm University
Country	Sweden
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.**	514687319814-91
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:**	Academia or a research or educational institute
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]:**	*Respondent skipped this question*
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:	Not applicable

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	2
Protecting the environment	2
Ensuring a well-functioning internal market	I don't know
Stimulating competitiveness and innovation	I don't know

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 unclear, The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
Protecting the environment	The legislation is unclear, The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

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	5

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)
,

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),

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

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

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),

Detergents (Regulation (EC) No 648/2004),

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)
,

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

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:	b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted) , If you answered a or b, please explain Risk based assessment approaches require access to more data and are more time consuming. Exposure assessments also need to be updated on a regular basis, and are needed for different scenarios. Hazard based assessment approaches consider the intrinsic properties of a substance, which is not expected to change over time.
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. Mixture assessment (needed across legislation). Endocrine disrupting chemicals (criteria and suitable test methods are needed across legislation). Endpoints not covered by guideline studies should be included in chemical assessments. Children and pregnant women are not protected sufficiently across legislation.

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	1
Speed with which identified risks are addressed	1
Time to allow duty holders to adapt	5
Predictability of the outcomes	I don't know
Stability of the legal framework	5
Clarity of the legal texts	4
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	I don't know
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	2
International collaboration and harmonisation	3
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	Raw data and other underlying data for assessments should be made available to the public. Assessments should be performed for groups of chemicals with similar properties to speed up the process. An increased effort to get US and China to adapt to the EU legislation is needed. The TTIP agreement risk weakening the EU legislation and thereby the protection of human health and the environment. Global agreements like the GHS is a good start for collaborations across borders.

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

Hazard identification criteria	1
Risk assessment and characterisation	1
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	2
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	2
Risk management measures restricting or banning the use of chemicals	1
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	2
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.	Mixture assessment (needed across legislation). Endocrine disrupting chemicals (criteria and suitable test methods are needed across legislation). Endpoints not covered by guideline studies should be included in chemical assessments. Children and pregnant women are not protected sufficiently across legislation. Time consuming processes (e.g. assessment of biocides and plant protections products with very specific data submitted). Politicized process where decision are not based on scientific studies (e.g. endocrine disrupting chemicals). Few number of restricted or banned substances (slow process with a too high standard of proof). Table of contents is missing for consumer products and food items. Risk based assessment approaches require more data and are more time consuming. Exposure assessments also need to be updated regularly. Hazard based assessment approaches consider the intrinsic properties of a substance, this is not expected to change over time.

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 is important to prevent cheating by industry. However, it is important that GLP is not used to exclude peer-reviewed academic studies from the assessment process. In addition, performing studies according to GLP does not guarantee the reliability of studies (see reference below). Myers, John Peterson, Frederick S. vom Saal, Benson T. Akingbemi, Koji Arizono, Scott Belcher, Theo Colborn, Ibrahim Chahoud, et al. 2009. “Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A.” Environmental Health Perspectives 117 (3): 309–15. doi:10.1289/ehp.0800173.

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. , Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals 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
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)	I don't know
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	We do not view the business costs of meeting EU chemicals legislation to be significant , Other (please specify) Costs for human health and the environment is difficult to estimate but there are several examples that show that this is a significant aspect to consider. Olsson, Ing-Marie. 2014. “The Cost of Inaction.” Nordic Council of Ministers. http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A763442&dswid=1741. UNEP. 2013. “Costs of Inaction on the Sound Management of Chemicals.” http://www.unep.org/chemicalsandwaste/Portals/9/Mainstreaming/CostOfInaction/Report_Cost_of_Inaction_Feb2013.pdf. http://chemsec.org/publication/chemicals-business/cry-wolf-2015/

Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	Yes, If you answered yes, please indicate what these are. Risk based assessments take longer time.

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	2

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	2
Please comment	The process take too long time, it is politicized and scientific studies are excluded from the decision-making. Examples include restrictions of PFAS-substances, management of pharmaceuticals within the WFD, deciding on a defintion for EDC and relevant testing proposals, assessment and management of nanomaterials.

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 contains gaps and missing links	Strongly Agree
The EU chemicals legislation framework has overlaps	Neutral
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.

Gaps or missing links	Children are living in the same environment as adults, therefore the restrictions that apply in the Toys Directive must be implemented in all legislation. Additional references: Molander, Linda, Magnus Breitholtz, and Christina Rudén. 2011. “Missing Links in the Regulatory Chain Controlling Life Cycle Emissions of Hazardous Chemicals from Articles.” Toxicol. Lett. 205: S243–S243. Molander, L., and C. Rudén. 2012. “Narrow-and-Sharp or Broad-and-Blunt - Regulations of Hazardous Chemicals in Consumer Products in the European Union.” Regulatory Toxicology and Pharmacology 62 (3): 523–31. doi:10.1016/j.yrtph.2011.11.003.
Inconsistencies	Reference: Sobek, A., S. Bejgarn, C. Rudén, L. Molander, and M. Breitholtz. 2013. “In the Shadow of the Cosmetic Directive - Inconsistencies in EU Environmental Hazard Classification Requirements for UV-Filters.” Science of the Total Environment 461-462: 706–11. doi:10.1016/j.scitotenv.2013.05.074.

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.

Children are exposed to the same environment as adults, therefore the restrictions that apply in the Toys Directive must be implemented in all legislation. Additional references: Molander, Linda, Magnus Breitholtz, and Christina Rudén. 2011. “Missing Links in the Regulatory Chain Controlling Life Cycle Emissions of Hazardous Chemicals from Articles.” Toxicol. Lett. 205: S243–S243. Molander, L., and C. Rudén. 2012. “Narrow-and-Sharp or Broad-and-Blunt - Regulations of Hazardous Chemicals in Consumer Products in the European Union.” Regulatory Toxicology and Pharmacology 62 (3): 523–31. doi:10.1016/j.yrtph.2011.11.003.
Sobek, A., S. Bejgarn, C. Rudén, L. Molander, and M. Breitholtz. 2013. “In the Shadow of the Cosmetic Directive - Inconsistencies in EU Environmental Hazard Classification Requirements for UV-Filters.” Science of the Total Environment 461-462: 706–11. doi:10.1016/j.scitotenv.2013.05.074.

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?	2
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?

Environmental	No
Physical	I don't know
Human health	No
Please list any hazard classes that are not covered	Endocrine disrupting chemicals. Fate (Persistence and bioaccumulation). Terrestrial effects. Also, untested chemicals are treated as harmless.

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

Guidance documents	No experience
Helpdesks	No experience
Industry association guidance and materials	No experience
Other (training, conferences, etc.)	No experience

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	I don't know

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

Ease of implementation for duty holders	I don't know
Appropriateness of classification criteria and methods for substances	3
Appropriateness of classification criteria and methods for mixtures	3
International harmonisation through the Globally Harmonised System (GHS)	2
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Non-standard studies from academia should be included (if relevant and reliable) in assessments.

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?	Transtion period is too long

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	3
Quality of scientific data and related information	2
Speed of the procedure	I don't know

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
Raw data should be made available to the public. Non-standard studies from academia should be used in assessments. Tests for EDCs are missing.

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	It is crucial that the EDC definition is put in place, and that the TTIP agreements are not allowed to jeopardize the current level of protection in the EU.