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PAGE 2: Part I – General Information about Respondents

Q1: Address

Contact name	Therese Jacobson
Organisation/company	The Swedish Society for Nature Conservation
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.

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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:

A non-governmental organisation (NGO)

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: National

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	5
Stimulating competitiveness and innovation	3

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 effectively implemented
Protecting the environment	The legislation is not effectively implemented
Stimulating competitiveness and innovation	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	5
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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.

Respondent skipped this question

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)

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If you answered a or b, please explain
For safeguarding human health and the environment, a hazard-based approach is safer and more appropriate. A hazard- based approach decreases uncertainties in both evaluation of chemicals and implementation of protective measurements. As has been shown many times, it is not possible to eliminate the risk posed by hazardous chemicals to human health and the environment through risk management practices. It requires an unfeasible level of control and compliance throughout the life history of the chemicals used, from initial production, through use and in the end waste management. Furthermore, there are hazardous properties which cannot be adequately addressed via risk based management. Such as, endocrine disruptive properties, CMRs, low dose effects, non-linear dose-response and combination effects of chemicals. A risk-based approach would increase the risk posed by hazardous chemicals to human health and the environment.

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 solid foundation of the precautionary principle approach is not fully implemented in the regulatory decision making on risk management. There is a big lack of knowledge concerning the hazardous properties of numerous chemicals on the market today. Chemicals that are present in consumer goods all over Europe and could potentially cause negative effects on human health and the environment. And since requirement of content declaration is only present for a few product groups, people can in most cases not choose to avoid chemicals that could pose a threat to their health or to the environment. There is an urgent need to address the lack of data on combined exposures, vulnerable time windows, endocrine disruption, neurotoxicity, nanomaterials and much more.

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	1
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	5
Stability of the legal framework	5
Clarity of the legal texts	3
Guidance documents and implementation support	3
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	3
Public awareness and outreach	1
International collaboration and harmonisation	4

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.

The slowness of implementation of the chemical regulations is a big problem and exposes people and the environment to unacceptable risks of negative impacts. One striking example is the unreasonable prolongation of the process to develop scientific criteria for Endocrine disruptors. The process has taken several years longer than expected and during this period effective measurements to protect the population and ecosystem from the adverse effects caused by endocrine disruptors has been stalled. The implementation and efficacy of the chemical regulations must be improved to fulfill the precautionary principle that the European leaders have decided to safeguard human health and the environment. There is a need to strengthen the "Right to know"-principle in the EU legislative framework. Customers should be able to get full content declaration for all articles and goods they buy. Only then can customers make informed decisions on what products to buy and use their customer influence.

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

Hazard identification criteria	2
Risk assessment and characterisation	2
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.)	3
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)	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.

Risk management has not adequately protected the people and environment from risks posed by hazardous chemicals. The process is so slow that known substances of very high concern can still be widely used even in consumer articles and goods, and with little regard to the public's right to know. That is an unacceptable risk to human health and the environment. There are too few chemicals being restricted, the process is too slow and too little attention is directed towards hazardous chemicals in imported products and goods. Risk assessment and characterization is not addressing the issues of combined exposures, low dose exposures, sensitive exposure windows, endocrine disruption, neurotoxicity or immunotoxicity.

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 only reflects good laboratory practice and do not reflect the quality of study design, interpretation on execution.

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.

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Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.

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Reducing the damage to the environment and to ecosystems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.

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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

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 authorities at EU level ,

Costs for authorities at national level ,

Costs for small and medium sized enterprises

Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?

Other (please specify)

This needs to be put in context with high costs to society, human health and the environment from exposure to hazardous chemicals.

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. There are significant costs to authorities from implementing and managing chemicals regulations. These costs should be more evenly distributed between companies and authorities, in accordance with the polluter pays principle. A suggestion could be that companies pay a fee to the authorities or a third party for burden sharing of costs.

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)

Respondent skipped this question

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 existing EU legislative framework has been too slow in addressing emerging areas such as endocrine disruptors, nanomaterials, combination effects and sensitive exposure windows. This needs to speed up significantly to adequately protect human health and the environment.

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 Agree

The EU chemicals legislation framework has overlaps Disagree

The EU chemicals legislation framework is internally inconsistent 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

Current gaps in the legislation include lack of implemented protection against endocrine disruptors, nanomaterials, polymers, combined effects, mixture effects and low-dose exposure to name a few. There is also a significant gap in the current legislation concerning chemicals in low volumes with lack of evaluation and reporting. There is also a gap in chemical regulations and content information to customers when it comes to the majority of consumer goods, for example textiles and building materials. The exposure of customers to hazardous chemicals in imported articles and goods is also not adequately addressed.

Inconsistencies

Lists of substances in different legislations should be harmonised.

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.

Respondent skipped this question

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? 4

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental No

Physical Yes

Human health No

Please list any hazard classes that are not covered

A significant lack in relevant hazard class is the risk connected to uncertainties. Today, the absence of hazard label could both be due to an extensive evaluation not resulting in hazard classification or a non-conclusive or non-existing evaluation due to lack of quality data. For workers and consumers, this is not possible to separate and there is no possibility to take protective measures from the risk of using products with unknown exposure risks. We suggest an added hazard class clearly stating lack of knowledge. Other hazard classes that are missing are endocrine disrupting properties, neurotoxicity, nanomaterials and immunotoxicity.

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

Respondent skipped this question

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

Respondent skipped this question

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

Appropriateness of classification criteria and methods for substances 3

Appropriateness of classification criteria and methods for mixtures 3

If you answered 1, 2 or 3 and would like to provide further information, please explain your answer

Hazard classes that are missing are for example endocrine disrupting properties, neurotoxicity, nanomaterials and immunotoxicity. There should also be a hazard class for uncertain data and unknown risk.

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?

Respondent skipped this question

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

Respondent skipped this question

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 premature to do the re-fit evaluation of the EU legislative framework concerning chemicals. The legislation is not yet fully implemented and it is therefore hard to evaluate it properly. There should instead be an overview to see if the legislation is on the right track to adequately protect human health and the environment from adverse effects of hazardous chemicals. We are still far from seeing all chemicals being evaluated and reported within the REACH system. There is a need to strengthen the "Right to know"-principle in the EU legislative framework. Customers should be able to get full content declaration for all articles and goods they buy. Only then can customers make informed decisions on what products to buy and use their customer influence.
