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PAGE 2: Part I – General Information about Respondents

Q1: Address

Contact name	Marie Cardfelt
Organisation/company	Swedish Work Environment Authority
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.

Respondent skipped this question

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 government or public authority

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	I don't know
Ensuring a well-functioning internal market	3
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	No opinion or not applicable
Ensuring a well-functioning internal market	The legislation is not effectively implemented
Stimulating competitiveness and innovation	The legislation is unclear

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

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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)
,
Chemical Agents (Directive 98/24/EC),
Asbestos (Directive 2009/148/EC),
Carcinogens and mutagens at work (Directive 2004/37/EC)
,
Young people at work (Directive 1994/33/EC),
Pregnant workers (Directive 1992/85/EEC),
Signs at work (Directive 92/58/EEC),
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
,
Residues of pesticides (Regulation (EC) No 396/2005)
,
Cosmetic products (Regulation (EC) No 1223/2009)

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:

c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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. Specific uses, instead of substances, should be regulated more frequent. The obligation for employers to assess the risk of the combination of all present chemical agents is difficult to implement. There is a need of more guidance on how this shall be done.

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	5
Predictability of the outcomes	I don't know
Stability of the legal framework	4
Clarity of the legal texts	1
Guidance documents and implementation support	1
Effective implementation and enforcement across Member States	I don't know
Consistent implementation and enforcement across Member States	I don't know
Public awareness and outreach	3
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 remarks concerns mainly the directives on worker safety. The carcinogen and mutagen directive is an example with lacking clarity in the text. The chemical agents directive is more understandable but the implementation is not clear. The transposition and implementation of the signs at work directive is not consistent among the Member States.

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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

Hazard identification criteria	5
Risk assessment and characterisation	3
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	I don't know
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	5
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	3
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.	Safety data sheets often contain inconsistencies and only provide general information. They are not sufficient for the employer's risk assessment.

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? Yes

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.

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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 small and medium sized enterprises

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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)

When all business fulfil their parts the burden on each actor is not un reasonable, but it can lead to significant costs when other parts of the supply chain do not fulfil their obligations.

Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?

No

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 4

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 5

Please comment

There is a clear ambition to adress emerging risks in good time but until the hazards are known specific measures cannot be implemented. The implementation can therefore be lacking when there is uncertainty.

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 Disagree

The EU chemicals legislation framework has overlaps Strongly Agree

The EU chemicals legislation framework is internally inconsistent Neutral

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.

Respondent skipped this question

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 overlaps the chemical agents directive and the carcinogen and mutagen directive instead of just supporting the implementation. The obligation to develop a DNEL when there is an OEL leads to inconsistent obligations for the employer.

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?	5
To what extent are CLP labels effective in communicating hazards to consumers?	I don't know

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

Environmental	I don't know
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	Criteria for classification of endocrine disruptors are missing. Information on the labels on hazardous substances formed during intended use would help to bring attention to the risk to the users.

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

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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	2
Appropriateness of classification criteria and methods for mixtures	I don't know
International harmonisation through the Globally Harmonised System (GHS)	I don't know
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Despite the fact that cyanoacrylates causes many allergies they are not classified as allergens. The method or the implementation of the criteria can be the cause to this.

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?

I don't know or have no opinion

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	5
Involvement of stakeholders	5
Quality of scientific data and related information	I don't know
Speed of the procedure	5

PAGE 10: Part V: Additional comments

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

Respondent skipped this question