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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Lara Carrier
Organisation/company	IMA-EUROPE aisbl
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.**	14190001484-01
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]:**	Mining and quarrying (B)
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**	Small enterprise (under 50 employees)

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	4
Protecting the environment	4
Ensuring a well-functioning internal market**	4
Stimulating competitiveness and innovation	3

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 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	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.	*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:	*Respondent skipped this question*
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.	*Respondent skipped this question*
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)	*Respondent skipped this question*

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.)	3
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)	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.	Hazard assessment correctly addresses the intrinsic properties of a chemical substance. However, in order to develop an appropriate risk management tool and ensure a proper control of the substance uses, the joint consideration of the exposure and hazard parameters is essential. In overall, regulators and stakeholders often lack a broad perspective about the existing vertical and horizontal interlinkages between the different chemical legislations. The current fact that substances are only classified according to their intrinsic properties, lead to a purely hazard-based approach in policy-making. This said, it is therefore very difficult to determine if chemical legislation is appropriate in achieving human health and environmental protection, since exposure and actual risk parameters are not taken into account by regulators. IMA-Europe wants to highlight that the hazard properties of a substance should be the starting point only for deciding the launching (or not) of risk management measures and that these former ones should be based on exposure aspects in order to ensure a risk-based decision-making. For this purpose, we want to stress the importance of the Risk Management Option Analysis (RMOa) tool developed by regulators but often not used. In this context, we strongly believe that if the RMOa tool was regularly employed whenever searching for an appropriate risk management measure for specific uses of a hazardous substance, the outcome of the process would be more targeted and, therefore, more efficient regarding the guarantee of having a high-level protection system for the environment and the targeted public (consumers, workers, etc.).

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?	*Respondent skipped this question*

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)	*Respondent skipped this question*
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)	*Respondent skipped this question*
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	*Respondent skipped this question*
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	*Respondent skipped this question*

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)	*Respondent skipped this question*

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	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.

Overlaps	Integrating the two Directives in a single instrument covering all chemicals at work could be the best option to solve incoherencies and helping for simplification provided the single instrument would define appropriate measures/obligations for the different kinds of substances covered. This unique instrument should provide a system of obligations based on the nature/hazard of the substances. In addition, it would allow to address the risk management of substances for which no effect can be observed below a certain limit (e.g. threshold carcinogens) more proportionately, in particular when addressing substitution under the CMD.
Inconsistencies	IMA-Europe identified some inconsistencies within one of the OSH Directives, which is aimed at protecting workers against health and safety risks from exposure to carcinogens or mutagens at work. Issues arising from the Carcinogens and Mutagens Directive (CMD) 2004/37/EC: ¬ There is a need to distinguish between substances having a threshold limit of effect (i.e. no effect can be observed below the limit) and non-threshold substances (i.e. substances for which a residual risk can be expected at a very low concentration). ¬ The hierarchy principle of the CMD needs to be redefined. As an example, substitution is not appropriate for chemical agents with a threshold of effect that can be managed as any other substance, provided that exposure is controlled below the defined safe limit value. ¬ Article 5 on risk management is unclear for some situations and inconsistent with the Chemical Agents Directive (CAD) 98/24/EC. Indeed, whenever a binding OEL value (BOELV) exists under Annex III of the CMD and the requirement to eliminate or reduce exposure “as low as technically possible” applies, the existence and validity of the BOELV may be questioned. It is unclear how far below the OEL the exposure needs to be reduced. In addition, the concept of lowering exposure level as low as technically possible does not take into account economic and feasibility factors. Therefore, the strict requirements of the CMD are not appropriate for less potent (and threshold) carcinogens. In this context, the terminology of reducing exposure levels “as low as reasonably practicable” would be more feasible and appropriate as it would take into account economic factors. Currently, there is no adequate legislative framework to regulate occupational exposure to threshold

carcinogens. Our first choice as a solution to this problem would be to consider the joining of the Chemical Agents Directive (CAD) and CMD into a single instrument that would not only define appropriate measures/obligations for all chemicals at work, but also be based on the nature/hazard of the substances. Another possibility would also be to restrict the scope of the CMD to non-threshold carcinogens and to regulate threshold carcinogens through BOELVs in the CAD. Indeed, the CAD, which is based on the concept of risk assessment and risk minimization coupled with its Annexed lists of limit values, would be more appropriate and provide the right and proportional level of intervention to ensure adequate worker protection and prevention to hazardous substances. More particularly, we would advocate for a pragmatic approach where not only it would be acceptable to reduce exposure to the level of the BOELV and not any lower, but also that the substitution and closed systems principles would not apply if exposures are controlled adequately (below the BOELV).

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 (EC 1907/2006) and EU OSH Directives
We invite regulatory bodies to recognize workplace legislation, instead of REACH Candidate listing and Authorisation, as the most effective risk management option for substances where there is a need to address a risk limited to the workplace:
a. When authorities identify a risk, but find that it is limited to the workplace, then workplace specific legislation offers, in our view, the most targeted, effective and proportionate regulatory risk management approach. Moreover, it should be ensured that no additional and unnecessary regulatory measures are applied, i.e.:
i. When the identified risk for all uses of a substance can be more effectively addressed by workplace legislation, the substance should not be included within the Candidate list. In the event of a substance that has already been included in the list but meets the criteria established by the workplace legislation, it should not be prioritised for Authorisation purposes under REACH.
ii. When the identified risk for some uses of the substance can be more effectively addressed by the workplace legislation, those uses should be exempted from Authorisation under REACH pursuant to Article 58(2) of this former legislation.
b. The setting of EU-wide OELs for substances where a risk is identified at the workplace, is an essential step to achieve better regulation.
c. As mentioned already in Question 17, IMA-Europe stresses the importance of the Risk Management Option Analysis (RMOa) tool whenever searching for an appropriate risk management measure for specific uses of a hazardous substance. We firmly believe that the outcome of the RMOa process would be more targeted and, therefore, more efficient regarding the guarantee of having a high-level protection system both for the environment and human health.

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)	*Respondent skipped this question*
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)	*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)	*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?	*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.	*Respondent skipped this question*