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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Cristina Arregui
Organisation/company	IFRA (International Fragrance Association)
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.**	14130436110-87
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]:**	Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4) , Manufacture of other chemical products (C20.5) , Other (please specify) Manufacturers, importers and downstream users of fragrance chemical substances and “intermediate” mixtures.

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	Micro-enterprise (under 10 employees)
Q8: Please indicate the level at which your organisation is active:	Global

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	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	5
Protecting the environment	5
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	2

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	No opinion or not applicable
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 not adapted to the issues at stake

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)
,

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),

Signs at work (Directive 92/58/EEC),

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

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

Water Framework (Directive 2000/60/EC),

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

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),

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

Drinking Water (Directive 98/83/EC),

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

Test methods (Regulation (EC) No 440/2008) ,

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

Protection of animals used for scientific purposes (Directive 2010/63/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 is central to industry's chemicals management approach in order to determine how and under what conditions a chemical can be safely used. The risk associated with each chemical is dependent on the specific use for which it is intended, as well as the conditions for use (e.g. amount, containment, personal protection measures, packaging, and awareness of user). Therefore a specific risk assessment is in general more appropriate to define the most effective risk management measure whilst preserving societal benefits. Areas where decisions are in practice more driven by hazard than risk, even when risk assessments are carried out include: the selection of priority substances under the Water Framework Directive and setting Environmental Quality Standards; the evaluations by the POP Review Committee; and the consideration of environmental properties under the Seveso III Directive.

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. Impacts on competitiveness of EU industry are generally not considered in the context of regulatory decision making on risk management. At best, these impacts are estimated before the main legislative act is proposed by the Commission to Parliament and Council – but not necessarily considered when the rules are finally adopted and become law or when they are implemented. Where a cost-benefit analysis has taken place these are not always considered during the final voting stage of new legislation. For example in the case of CLP Regulation Article 45, several outputs of the cost benefit study as well as the discussions amongst various stakeholders on the draft proposal now seem to be disregarded during the final REACH Committee process.

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	5
Speed with which hazards/risks are identified	3
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	2
Predictability of the outcomes	2
Stability of the legal framework	3
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	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.	Implementation support: in the space of the notifications to the C&L Inventory, solutions supporting bulk notifications are not very efficient. This leads to significant burden in complying with the C&L Inventory notification obligations. In addition there is no possibility for obsoleting notifications and no clarity on the obligations related to substances no longer present in a company's portfolio. Guidance documents: guidance should be provided on a more scientifically robust weight-of-evidence approach, including an objective scoring

methodology that allows selecting the most reliable, relevant and highest quality data at different levels including environmental measurements. At present there is a divergence between the commitment to weight-of-evidence consideration and how substances are being identified in practice. Existing guidance explicitly refers to the need to “use all available data for assessing B” but it unfortunately is always followed by “the WoE and all the available data need to be compared back to the criteria defined in the legal text” which for B is only Bioconcentration Factor. Consistent implementation & enforcement: enforcement across Member States varies across many chemicals and chemical-related legislation, particularly under environmental protection legislation. International harmonisation: the regional differences in GHS implementation add complexity to supply chain communication. In this context what is often mentioned is lack of harmonization in the applied hazard classes and categories. It cannot be however forgotten that some of the major differences in C&L under various GHS implementations stem from the differences in the implemented generic concentration limits. Stability of the legal framework: Whilst the overall framework is satisfactory, there is one aspect which is of high concern to the industry, namely the process regarding CMR substances and the link to the Cosmetics Regulation. The cosmetics legislation was designed to operate on the basis of risk assessments, a ban entering into effect only after an amendment of the relevant annexes based on a risk evaluation by the Scientific Committee for Consumer Products (SCCS) or the fact that the industry has no interest in the continued use of the substance. The CMR-related provisions of the cosmetics legislation did not undergo substantial changes with the recast (Cosmetic Products Regulation published in December 2009). Nevertheless, since 2010 a new interpretation of these provisions (Article 15) is being applied by the Commission whereby a substance classified as CMR category 2 under the CLP becomes automatically banned upon the entry into force of the CLP classification with no amendment to the annexes of the Cosmetic Products Regulation; the only accepted exception to this automatic ban is for industry to obtain a positive opinion from the SCCS. However, the timeline (i.e. the time between the publication of the classification in CLP and its entry into force) available to the cosmetics industry to submit a dossier, for the SCCS to evaluate it and for the annexes of the Cosmetic Products Regulation to be amended is not workable. Regarding CMRs category 1A and 1B, clarity and a workable application of

	the exemption criteria (i.e. with regard to the SCCS safety assessment, compliance with food law, acceptable overall exposure and the notion of suitable alternatives) are needed. The current situation has already led to legal uncertainty (substance banned under CLP and at the same time listed as allowed in the annexes of the Cosmetic Products Regulation), contradictory enforcement at national level and loss of ingredients without any evidence of health issues related to the use of the substance in cosmetic products.

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

Hazard identification criteria	4
Risk assessment and characterisation	4
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.)	5
Risk management measures restricting or banning the use of chemicals	3
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	5
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.	IFRA considers that CLP labels are effective tools in order to communicate hazards to professional users. However, the current system is not adapted to the issues at stake when it comes to communicating hazards to consumers. Labels appear confusing, overloaded and may not provide the consumer with relevant and meaningful information about safe use of the product. The industry is committed to participate in the development of an alternate option, and supports changes which would ensure that: - consumers notice the safety information, understand it, take it into account and act upon it to ensure safe use; - new labels/communication tools (e.g. QR tags, online information) can be developed in a resource efficient way for industry, thus enabling greater flexibility and innovation in Europe; - the information is proportionate to the product's actual risks. IFRA calls onto the European Commission to take the opportunity of the ongoing REFIT exercise and upcoming Staff Working Document to address the topic of consumer understanding and relevance of safety information on product labels, for the benefit of consumers, industry, and society at large.

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. , 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
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	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	4
Please comment	The current EU legislative framework is appropriate to address emerging areas of concern. The framework should however consider the latest scientific advances with regards to new test methods, new methodologies, and ensure required testing is linked to clear human health or environment emerging concerns.

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	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	-Seveso: With the inclusion of tighter hazard categories in the Seveso Directive from CLP, the expectation is that many more substances will fall under the Seveso requirements resulting in additional obligations and compliance costs. Automatic legal consequences in downstream legislation without risk assessment should be avoided. -Labelling requirements under the different pieces of legislation (cf. F-gas Regulation, REACH Annex XVII), could be better integrated to facilitate compliance.
Overlaps	The incorrect application of Article 15 of the Cosmetic Products Regulation creates an overlap with CLP which leads to inconsistency (conflicting requirements for the same substance between CLP and the Cosmetic Products Regulation) – see detailed answer to question 16.
Inconsistencies	At present there is a divergence between the commitment to weight-of-evidence considerations and how substances are being identified as PBTs/vPvBs.

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.

Overlapping requirements between REACH and occupational health legislation as well as between REACH and RoHs

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?

Environmental	Yes
Physical	Yes
Human health	Yes

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

Guidance documents	4
Helpdesks	4
Industry association guidance and materials	4
Other (training, conferences, etc.)	4

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is not harmonised across most Member States

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	3
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	2
International harmonisation through the Globally Harmonised System (GHS)	2

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 sufficient, Please elaborate if you answered that the transition period is too short or too long. For editorial changes to the text of H and P statements stemming from revisions of the UN GHS Model Regulation longer transitional periods would be beneficial for the industry.

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	4
Involvement of stakeholders	3
Quality of scientific data and related information	3
Speed of the procedure	4

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

There are some inefficiencies in the CLH process with respect the changes that affect the existing elements of harmonized C&L from Annex VI. Such changes can be brought by industry only to the attention of a Member State Competent Authority but not directly to ECHA. Unlike for the CLH Intentions that are submitted to ECHA for these intentions there is no publicly available registry of intentions. This means that if a given intention for a change of an existing Annex VI element for a substance was reviewed by a MSCA and was not found justified (thus it is not in the ECHA registry of intentions) this decision/conclusion cannot be readily accessed by e.g. downstream users.

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*