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## COMPLETE

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### PAGE 2: Part I – General Information about Respondents

#### Q1: Address

Contact name	Luca Nava
Organisation/company	Cosmetica Italia - Federchimica
Country	Italy
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:**

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)

**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](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:** 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	5
Protecting the environment	5
Ensuring a well-functioning internal market	5
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:**

Stimulating competitiveness and innovation	The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
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**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.**

Classification, labelling and packaging (Regulation No (EC) 1272/2008)  
,  
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) ,  
Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)  
,  
Waste framework (Directive 2008/98/EC) and List of Waste  
,  
Packaging and Packaging Waste (Directive 94/62/EC)  
,  
EU Ecolabel (Regulation (EC) 66/2010) ,  
Cosmetic products (Regulation (EC) No 1223/2009) ,  
Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)  
,  
General Product Safety (Directive 2001/95/EC) ,  
Aerosol dispensers (Directive 75/324/EEC)

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**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  
Cosmetic products have a well defined use and associated consumer exposure. The safety assessment (for human health) of each cosmetic product is required by the Cosmetics Regulation before the product is placed on the market. The environmental safety of substances used in cosmetic products is addressed under REACH, which enables the assessment of environmental safety in a cross-sectoral manner. This also ensures the environmental safety of substances at consumer use level. In those cases where concerns are identified in relation to specific uses (including in cosmetics) risk management measures must be identified and communicated through the supply chain, via the extended Safety Data Sheets of substances. These risk management measures ensure occupational and environmental safety. Safe use of substances in cosmetic products is demonstrated in the Chemical Safety Report and environmental concerns are addressed through the restriction or authorisation process which apply to substances used to formulate cosmetic products.

**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.  
Combined effects of chemicals and vulnerable populations are addressed under the Cosmetic Products Regulation. However, impact assessments, especially economic (e.g. jobs and competitiveness), are lacking.

**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	4
Speed with which hazards/risks are identified	5
Speed with which identified risks are addressed	5
Time to allow duty holders to adapt	1
Predictability of the outcomes	1
Stability of the legal framework	4
Clarity of the legal texts	4
Guidance documents and implementation support	1

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

Effective implementation and enforcement across Member States	1	
Consistent implementation and enforcement across Member States	1	
Public awareness and outreach	2	
International collaboration and harmonisation	1	
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.		<p>Whilst the overall framework is satisfactory, there is one aspect which is of high concern to the cosmetics industry, namely the process regarding CMR substances. 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.</p>

**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 4

Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.) 5

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 1

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.

The hazard identification criteria applicable to PBTs and vPvBs do not work (e.g. for silicones). For cosmetic products, the communication to consumers is risk-based and this works very well. Regarding risk management measures restricting or banning the use of chemicals in cosmetic products please see the comment under question 16 above.

**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.

**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, Costs for consumers

## 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?**

Training staff to ensure compliance with legal requirements

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Understanding and keeping up-to-date with changes in legal requirements

,

Risk management measures under the different legislation

**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 5

### 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 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.**

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

**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.**

Please see the answer to question 16

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**PAGE 9: Part IV: Specific questions on the CLP Regulation**

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<b>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)</b>	<i>Respondent skipped this question</i>
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<b>Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?</b>	<i>Respondent skipped this question</i>
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<b>Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)</b>	<i>Respondent skipped this question</i>
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<b>Q31: To what extent is CLP enforced in a harmonised manner across Member States?</b>	<i>Respondent skipped this question</i>
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<b>Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)</b>	<i>Respondent skipped this question</i>
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<b>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?</b>	<i>Respondent skipped this question</i>
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<b>Q34: To what extent are the current elements of the procedures for harmonised classification &amp; labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)</b>	<i>Respondent skipped this question</i>
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**PAGE 10: Part V: Additional comments**

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<b>Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.</b>	<i>Respondent skipped this question</i>
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