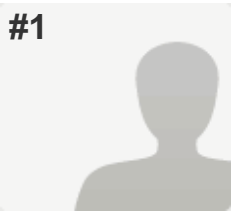

#1

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Monday, May 23, 2016 12:52:49 PM
Last Modified: Tuesday, May 24, 2016 2:41:55 PM
Time Spent: Over a day
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Ewa Starzyk
Organisation/company	Polish Union of Cosmetics Industry
Country	Poland
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.	329994521912-92
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) , Other (please specify) Manufacture of cosmetic products as defined in the regulation 1223/2009/EC

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	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 unclear, The legislation is not adapted to the issues at stake, 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

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
,

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

Packaging and Packaging Waste (Directive 94/62/EC)
,

Persistent organic pollutants (Regulation (EC) 850/2004)
,

EU Ecolabel (Regulation (EC) 66/2010) ,

Cosmetic products (Regulation (EC) No 1223/2009) ,

Aerosol dispensers (Directive 75/324/EEC),

Explosives (Directive 93/15/EEC),

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)

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 Cosmetic products have a well defined use and consumer exposure scenarios. 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 metodology of safety assessment of both finished cosmetic products and ingredients used in cosmetics is subject to a detailed and well-defined methodology. The safety assessment of a cosmetic product is equivalent to the risk assessment process. It includes hazard identification as a first step, following by the detailed exposure assessment and risk assessment at the end. In case of cosmetics ingredients hazard identification (asssessment) is related to intrinsic properties of the substance only and does not necessarily corresponds to the risk posed by this substance. For example, a substance classified as hazardous may be safe when used in cosmetics taking into consideration route of exposure, exposure level etc. Therefore, any legal provisions related to the safety of cosmetic product for the human health should be based on risk assessment but not on hazard assessment. 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	3
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	2
Clarity of the legal texts	3
Guidance documents and implementation support	2
Effective implementation and enforcement across Member States	2
Consistent implementation and enforcement across Member States	4
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.	Whilst the overall framework for CLP is satisfactory, there is one aspect posing high concerns to the cosmetics industry in the EU, namely the CMR substances and practical application of the provisions of art. 15 (regulation 1223/2009/EC). The cosmetics legislation was designed to function based on 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 regulation 1223/2009, art. 15, envisages that substances classified as CMR under CLP are banned from use in cosmetic products. However, it envisaged at the same time the possibility of derogation under certain conditions, different for CMR's cat. 2 and 1A or 1B. For all CMR a necessary condition is that risk assessment by the SCCS has to confirm that the substance is safe when used in cosmetic product. Then, the Commission could adopt regulatory measures allowing for the use of substance in cosmetics. Unfortunately, the Commission adopted an interpretation that substances classified as CMR's are considered as automatically banned in cosmetics after 15 months of publication of CMR classification under CLP if safety assessment by the SCCS is not finished until this date. 15 months is not a sufficient time for preparation of a safety dossier by the industry, its subsequent assessment by the SCCS and preparation of regulatory measures by the Commission. The current situation has already led to significant legal uncertainty: substance is considered banned on the basis of CLP classification and at the same time is listed as allowed in the annexes of the Cosmetic Products Regulation. Such situation led to contradictory enforcement at national level and loss of ingredients without any evidence of health issues (risks for human health) related to the use of the substance in cosmetic products. Therefore, the interpretation of art. 15 regulation 1223/2009/EC is unworkable both for industry and competent authorities in Member States. Clarity and a workable application of the exemption criteria are particularly important for CMRs category 1A and 1B, as this group is subject to additional exemption criteria, beside SCCS safety assessment and regulatory measures: compliance with food law, acceptable overall exposure and the notion of suitable alternatives).

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.	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. The hazard identification criteria applicable to PBTs and vPvBs do not work (e.g. for silicones). Risk management measures are not always proportionate and adequately chosen to address identified risks. An examples might be regulatory measures for D4 and D5 silicones planned to be introduced in the EU. There are two options considered at EU level. One regulatory option is introduction of the restrictions under REACH. RAC Committee identified main sources of environmental exposure on D4 and D5. There are mainly washed off personal hygiene cosmetic products. Restrictions of D4 and D5 use in these products reflects identified risks and seems to be a proportionate regulatory measure, providing added value and being in line with Better Regulation Policy. At the same time (the second regulatory scenario) D4 was proposed to be included into the Stockholm Convention for Persistent Organic Pollutants, because it fulfils the classification criteria for POP's (which reflects purely a hazard identification), but not because it represents risks when used in any products or processes. Stockholm Convention for POP's is purely based on the Precautionary Principle and potential risks, but not on the proportionality rule and existing / identified risks. Inclusion of any substance into the Stockholm Convention lead in practice to its complete withdrawal from all existing technological processes, even if the substance is not directly banned. Following D4 inclusion in the Stockholm Convention there is high probability of subsequent inclusion D5 into the Stockholm Convention, where D5 is an important and unreplaceable cosmetic ingredient. Stockholm Convention seems not to be a proportionate regulatory measure for D4 or D5 environmental risks.
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, Costs for consumers
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	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 , Other (please specify) in order to get detailed costs characterization the Union recommends to contact with individual companies.
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
Please comment	Novel / emerging areas of concern are often too excessively addressed in the regulatory measures. An example is a notification system of cosmetic products containing nanomaterials according to art. 16 of the regulation 1223/2009/EC. All products containing nanomaterials shall be notified 6 months before placing on the market with very detailed physical and chemical specification, hazard identification, exposure scenarios and risk assessment of the finished product containing nanomaterial. This is the only group of substances regulated in such manner in the regulation 1223/2009/EC. At the same time, most of the nanomaterials is subject to the Scientific Committee on Consumer Safety risk assessments and subsequent regulation by the Commission - inclusion into the annexes of the regulation, providing restrictions for use of certain cosmetics ingredients. The work - risk assessment of the ingredient is done twice - by the company notifying and then by the SCCS. This represents a significant regulatory burden for the companies and lack of added value from safety perspective. Is should be mentioned that the regulation 1223/2009/EC was drafted in 2006-2008, at the time of quick development of industrial and consumer use of nanomaterials, when many stakeholders raised concerns on the safety of these ingredients and technologies. In 2009, SCHENIHR adopted the scientific opinion on Risk Assessment of Products of Nanotechnologies, stating that: “However, it should be noted that not all nanomaterials induce toxic effects. Some manufactured nanomaterials have already been in use for a long time (e.g. carbon black, TiO2) showing low toxicity. Therefore, the hypothesis that smaller means more reactive, and thus more toxic, cannot be substantiated by the published data. In this respect nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not.” Those nanomaterials, which are being a subject to the detailed SCCS risk assessment and subsequent regulation in the annexes of the regulation 1223.2009/EC should be excluded from the notifications required in the art. 16 of this regulation.

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 above.

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*