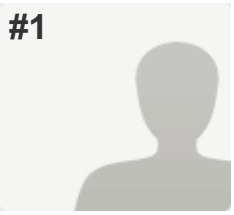

#1

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Collector: Web Link 1 (Web Link)
Started: Tuesday, May 17, 2016 9:05:20 AM
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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Dr Albrecht Tribukait
Organisation/company	Corporate Regulatory, COTY
Country	Switzerland
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.	474640321962-16
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 business
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]:	Other (please specify) Manufacture of cosmetic products
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	Large company (250 employees or more)

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	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:

Protecting human health	No opinion or not applicable
Protecting the environment	No opinion or not applicable
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	The legislation is unclear, 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)
,

REACH, Annex XIII (Regulation (EC) No 1907/2006)
,

Inland transport of dangerous goods (Directive 2008/68/EC)
,

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),

Aerosol dispensers (Directive 75/324/EEC),

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 CMR substances are classified as such based on their intrinsic properties (“hazard”). However, the European Economic and Social Committee welcomed the introduction of a differentiated regime based on risk assessment: CMR substances of category 1A or 1B may be used in cosmetic products by way of exception where all of the conditions set forth in Article 15.2 of the Cosmetics Regulation are fulfilled, including that the application for exemption is made for a particular use of the product category with a known exposure. It is important to note that, as stated in the Impact assessment report on simplification of Directive 76/768/EEC (COM(2008)49 final) (SEC(2008)118), the two conditions established in paragraphs (a) and (b) of Article 15.2 are “mere “gatekeepers””, specifically intended to avoid a situation where the SCC[S] is systematically seized on the safety of CMR 1, 2 substances. A blanket, i.e. hazard-based prohibition of CMR 1A and 1B substances in cosmetic products would lead to absurd situations, for example with ethanol (alcohol). Ethanol is widely used in cosmetic products, and its classification as CMR of category 1 has been proposed several times over the past years. Without an exemption from the terms of Art. 15.2 based on risk assessment, such classification would result in the prohibition of the use of ethanol in cosmetic products, whilst alcohol-containing food and beverages would not be affected by this classification, and consumers could continue to use such products and expose themselves to much higher quantities of ethanol than through the application of perfumes and other ethanol-containing cosmetics on the skin.
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, there are no provisions that require the impact on jobs and competitiveness of EU industry to be assessed and considered.

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
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.	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 assessment, with ingredient bans being imposed only after an amendment to the relevant annexes based on a risk assessment by the Scientific Committee on Consumer Safety (SCCS). The CMR-related provisions of the cosmetics legislation did not undergo substantial changes with the recast (Cosmetic Products Regulation published in December 2009). Nevertheless, a new interpretation of these provisions (Article 15) has been applied by the Commission since 2010, according to which substances classified as CMR of category 2 under the CLP are automatically banned upon the entry into force of the CLP classification, with no amendment to the annexes of the Cosmetic Products Regulation; except if industry obtains a positive opinion from SCCS. The timeline (between the publication of the classification in CLP and its entry into force) for industry to submit a dossier, SCCS to evaluate it, and the annex(es) of the Cosmetic Products Regulation to be amended, is not workable. For substances classified as CMR of category 1, a sound and objective application of the exemption criteria set froth in the regulation is 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 a particular 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	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.	CMR classification is based on hazard. However, as stated in the Cosmetic Products Regulation (CPR), a hazardous property of a substance does not necessarily always entail a risk. The link between the CMR classifications under CLP and the risk-based approach under the CPR is inappropriately applied in our view, particularly in the case of the use of Formaldehyde in nail hardeners. The SCCS has issued a positive Opinion at the request of the Commission, after the Commission considered that the substantiation of the three first conditions of Article 15.2 were fulfilled. However, a report openly based on marketing claims and arbitrary interpretation that was submitted to the Commission on behalf of a non-EU Member State's authority after the SCCS had already been requested to issue an Opinion triggered opposition from EU Member States to the exemption that is now warranted under the terms of Art. 15.2 of the CPR. The CPR fails to provide for a definition of the term "suitable alternative substances" as used in Art 15.2 (b) thereof. Given the identical definition of the term "substance" in both regulations, the REACH Regulation may validly be used to construe the CPR and provide for the absent definition and clarify its meaning – as to exclude any "technologies" or "mechanisms".
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?	Other (please specify) Given the high diversity of cosmetic products in scope of the definition in Art. 2 of the Cosmetic Products Regulation, and the resulting complexity of the logistics involved in their manufacture and supply to markets, any requirement to add consumer information to the labeling and packaging of cosmetic products should be implemented in the spirit of Better Regulation and foresee options for compliance that are cost-efficient and contemporary, such as the possibility to make consumer information available to the consumer electronically, instead of printing it on the label. Without such options, additional consumer information will require an increase in the size of packaging at a significant impact for industry in terms of cost, and for the environment in terms of raw materials and waste.
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	By 11 January 2014, the Commission should have made available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. At the latest on 11 January 2015, the Commission should have reviewed the Regulation with regard to substances with endocrine-disrupting properties.

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.

Inconsistencies	The hazard-based 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)	
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?	4
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	3
Helpdesks	1
Industry association guidance and materials	3
Other (training, conferences, etc.)	1
Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is 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	3
Appropriateness of classification criteria and methods for mixtures	3
International harmonisation through the Globally Harmonised System (GHS)	3
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 , Please elaborate if you answered that the transition period is too short or too long. See our comment under item 16 regarding the time needed for the defense of CMRs for use in cosmetic products.

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

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*