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Collector: Web Link 1 (Web Link)
Started: Wednesday, May 18, 2016 2:16:04 PM
Last Modified: Friday, May 27, 2016 1:43:03 PM
Time Spent: Over a week
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	ELISABETTA SCAGLIA
Organisation/company	UNIC
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.	Unic1946
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 leather and related products (C15)
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**	4
Stimulating competitiveness and innovation	4

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	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	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 adapted to the issues at stake
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	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.

Classification, labelling and packaging (Regulation No (EC) 1272/2008)
,

Biocidal products (Regulation (EU) No 528/2012),

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
,

Water Framework (Directive 2000/60/EC),

Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
,

End of life vehicles (Directive 2000/53/EC),

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

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

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

Safety of toys (Directive 2009/48/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)

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
PFOS risk assessment has been made on REACH basis, it has never been calculated for specific articles (i.e. leather. In addition, PFOS has been moved to POP Regulation without any further socio-economical assessment, neither the related impact on industry.

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.
Specific adverse effects on the competitiveness of EU Industry, especially for SME, on minor economic activities or on particular products and some general principles are not adequately considered or translated. e.g. in POP Regulation the restriction on PFOS it establishes a threshold for non-intentional contamination that shall be assessed on the mass, except for textiles and "other coated materials" where the value is transferred to the surface area. This generic reference to "other coated materials" leads to legal uncertainty (what other coated materials?), is not justified (are all coated materials equal?) and therefore discriminatory (the threshold of 1 microgram/m2 is so low that the unintentional determination on material with a significant thickness overtakes the limit. Moreover, as far as reach REACH is concerned, the threshold of unintentional use is clearly identify at 0.1%, because it corresponds to the treaceability threshold of the substances. Often unintentional use and “absence” are improperly confused. This is the case of PFOS in POP regulation. POP foresees restriction on use of some persistent organic pollutant because their environmental diffusion can create problem to environment and to human health. This is also the reason why the art. 4 (comma 1), lett. b) of POP clarifies that the prohibition of the “production, placing on the market and use of substances listed in Annex 1 shall not apply in the case of: (a)…. (b) a substance occurring as an unintentional trace contaminant in substances, preparations or articles”. So, why for PFOS two different limitations are in force? Why one of them (restriction for textile and other coated material: 1µg/m2) does not considered the exemption of art. 4? The legislation should not be source of a discrimination related to different interpretations. How can it be that a material (i.e. leather) could be considered at the same time both an article and a “coated material”? How can it be at the same time compliant or not compliant, depending on the fact that the threshold of 0.1% can take into consideration “the possibility of an unintentional trace contaminant while”

possibility of an unintentional trace contaminant while 1 microg/m2 excludes, de facto, that same possibility? Furthermore, the method used (EN/TS 15968) to evaluate its concentration, as a TS, has not been validated, notably at that low concentrations. As consequence, many laboratories in Europe developed their own method, situation that does not guarantee at all the reproducibility (so the correct assessment) of results. This situation has, of course, heavy repercussions on the market. To solve all these problems, POP regulation should not refer to “coated materials”, because that leads to both an uncertainty of identification and a difficult assessment of PFOS presence. As alternative, only the following should be considered: • substrate (articles, whose limit is 0.1%) and • coating mixtures, whose limit is 0.05%. Producers should be able to demonstrate the respect of 0.05% content in the mixtures they use, on the basis of SDS and of recipes they use in leather production.

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	4
Time to allow duty holders to adapt	3
Predictability of the outcomes	2
Stability of the legal framework	4
Clarity of the legal texts	3
Guidance documents and implementation support	3
Effective implementation and enforcement across Member States	4
Consistent implementation and enforcement across Member States	I don't know
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.	Specific legislation in mind: POP Regulation with regard to PFOS. Indeed, with the ban of intentional use of PFOS, industry sectors that don't use them understand that they should be safe. Environmental contamination through diffuse presence of PFOS in waterways, may, however, contaminate products requiring water for their processing. Such risks have not been correctly assessed, addressed or predicted. The legal text (art.4) excludes unintentional traces but the threshold of 1microgram/square meter for (generic) coated material excludes, de facto, this prevision. In addition, the mention of the generic term "other coated materials" next to textiles for assessing PFOS on the surface rather than on the mass, lends to different interpretations on the materials that should be considered. This is also a problem for the effective and consistent implementation and enforcement of the rules applying to certain materials, coated or not. Finally, imported products are likely not to be assessed at entrance of the European market,, as there is no designated nor standard method for the assessment. The protection of the EU market is, at a certain extent, an illusion. And the objiectives of the Regulation are not necessarily met.

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	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.)	4
Risk management measures restricting or banning the use of chemicals	4
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	4
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 proof that restricted or banned chemicals are still provoking risks to people and/or the environment is RAPEX. The risk that imported products fail legislative requirements is extremely high, or in other words, the risk that non compliant imported products are caught before they could cause damage, is very small. And the chance for an extra-EU producer to be prevented from causing further damage is close to nil. There is still a big gap in the protection of people and the environment (and EU industry) from the risks of non-compliant imported products. As long as enforcement is left to the will and capacity of Member States, a uniform efficient and consistent enforcement is not secured. In addition, in RAPEX should be indicated not only the provenience of the article, but also the country of origin of component/material when the chemical content of materials is the source of the RAPEX alert. It could be also useful for EU enterprise to know the name of providers of the dangerous component.
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?	I don't know

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 society in general
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 , Inspections and administrative requirements, Other (please specify) The implementation of EU Chemical legislation has led to a certain extent to the relocation of chemical suppliers in extra-EU for servicing a market without restrictions. This has led to a reduction of the offer of chemicals in certain sectors and a consequent reduction of choice and increase in prices for EU companies, while imported products did not experience any of these adverse effects. EU consumers do not benefit necessarily from the stricter legislative framework if no control on imported goods is put in place. Extra-EU imports, notably in mass consumer products (textiles/leather/wood/etc), affect adversely the competitiveness of EU industry. Chemical analyses to assess the compliance of articles have an economical impact up to 1.5% the turnover of a SME.
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

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	Neutral
The EU chemicals legislation framework has overlaps	Neutral
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.

Inconsistencies	i.e. Inconsistency of the restrictions in the POP regulation

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.

The non-intentional contamination of industrial products is inconsistent with other regulations. One example is the thresholds of PFOS in POP in Food legislation. You can legally drink water that contains PFOS, but you cannot put on the market a coated leather that has been processed in that water and fails the POP Reg. limit expressed over the surface area of the leather. This is, because the operators of market can choose the limitation to consider.

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?	5
To what extent are CLP labels effective in communicating hazards to consumers?	3

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	No experience
Industry association guidance and materials	5
Other (training, conferences, etc.)	3

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	I don't know

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	I don't know
Appropriateness of classification criteria and methods for substances	I don't know
Appropriateness of classification criteria and methods for mixtures	4
International harmonisation through the Globally Harmonised System (GHS)	4

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

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	2
Quality of scientific data and related information	3
Speed of the procedure	I don't know

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	Since 2010, with the Regulation 757/2010 EC the PFOS have been included in Annex I to the Regulation (EC) No. 850/2004 on persistent organic pollutants (POP Regulation). It bans the placing on the market of articles, in which the concentration of PFOS is higher than 0.1 % by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is higher than 1 µg/m2. The notion "other coated materials" is unfortunate and discriminatory, as it is unfair treating all coated materials like textiles (e.g. leather) independently of the thickness. Unintentionally contaminated leathers (e.g. through the medium "water") will pass or fail the area requirement depending on their thickness. This is not the intention of the law!