#1

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Thursday, April 28, 2016 10:07:54 AM
Last Modified: Friday, May 27, 2016 9:39:04 PM
Time Spent: Over a week
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Jutta Klasen
Organisation/company	Environment Agency
Country	Germany
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.	85428576646-51
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 government or public authority
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]:	*Respondent skipped this question*
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:	EU

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 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 the environment	I don't know
Stimulating competitiveness and innovation	4

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 the environment	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	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) , Plant protection products (Regulation (EC) No 1107/2009) , Biocidal products (Regulation (EU) No 528/2012), REACH, Annex XIII (Regulation (EC) No 1907/2006) , Persistent organic pollutants (Regulation (EC) 850/2004) , Detergents (Regulation (EC) No 648/2004), Drinking Water (Directive 98/83/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:

If you answered a or b, please explain
The questionnaire outlines the difference between generic and specific risk considerations and refers to risk management measures based on hazard. We assume that the questionnaire reflects on areas where a hazard base risk management is applied which – with regard to the environment - are: - non approval of plant protection products and biocides (Regulation (EC) No 1107/2009) and (EU) No 528/2012) for persistent, bioaccumulative and toxic (PBT) substances, very persistent and very bioaccumulative (vPvB) substances and endocrine disruptors (for the environment) - SVHC identification under REACH ((EC) No 1907/2006) for persistent, bioaccumulative and toxic (PBT) substances, very persistent and very bioaccumulative (vPvB) substances and endocrine disruptors with scientific evidence for probable serious adverse effects to the environment - Restriction or ban of persistent organic pollutions under Regulation (EC) 850/2004. - Management measures stipulated by other legislation, but based on hazard classification and labeling according to Regulation No (EC) 1272/2008. In short, UBA explicitly supports a general hazard identification for all chemicals and subsequent hazard-based risk management measures with regard to the hazards and legislation described above. Where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment may be inconsistent with the high level of protection chosen for the Community, we agree with the Commission that the precautionary principle should apply. Hazard based risk management is thus considered imperative. Hazard identification of substances being persistent, bioaccumulative and toxic (PBT) and endocrine disrupters acting via a specific toxic mode of action should be consistent among all pieces of legislation summarized above. This should also be true for pharmaceutical substances, which can be defined as highly potent chemicals,. However risk management measures may differ and do so in practice. Thus, with regard to Endocrine Disruptors under Regulations for plant protection products and biocides, UBA favors approaches for regulatory decision making which focus on the overall environmental burden which should not increase by replacing an Endocrine Disruptor by an environmentally even more harmful but eventually not endocrine disrupting substance. Compounds with at least two of three PBT criteria are considered for substitution under the biocide regulation and a comparative assessment has to be conducted to find suitable alternatives. Hence, the two additional hazards related to persistence and bioaccumulation (including the terrestrial compartment) might be included in the CLP system for consistency. In addition to the hazard based regulation already in place, a hazard and environmental risk assessment for detergents and cosmetics should be implemented.

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.
in general regulatory decision making on risk management is constricted by the legislative context and thus per se cannot take into account all relevant considerations, yet. It might be appropriate that all chemical substances, which have potential to reach the environment will be subject to hazard identification and risk assessment to determine appropriate risk management measures, if necessary (especially human pharmaceuticals). Substances of concern are for example those: • which have PBT properties • which are persistent, mobile and toxic (PMT) and hence can contaminate groundwater bodies • which have potential to select for resistances or can change the behavior. In cases where objective scientific evaluation indicates that risks are not appropriately addressed by current legislation, additional considerations are needed e.g. registry for products containing nanomaterials to enhance transparency on application and uses of nanomaterials. A harmonised definition of nanomaterials within the various legislations of chemical safety is needed to be able to identify nanoscale forms of substances. For this aim, a proper characterization of physical chemical have to be mandatory within the regulatory requirements. Environmental risks arising from combination effects and exposures to technical mixtures are and/or may be currently addressed during product authorization for plant protection products, biocides as well as veterinary pharmaceuticals. This is not the case for human pharmaceuticals. REACH addresses the safe use of substances in technical mixtures, but not explicitly possible risks arising from joint effects and exposures of components. Potential gaps or needs in CLP were stated and partly evaluated in Kienzler et al 2014, Kortenkamp et al. 2009, Bunke et al. 2014, Rheilen et al 2012). Main gaps with respect to an assessment of technical mixtures are e.g. tank mixtures and subsequent or parallel applications of PPP, which currently are not considered. The combined effects and exposures of more complex environmental mixtures (e.g. sequential/parallel applications, discharge, coincidental or environmental mixtures) are not adequately addressed in all respective substance regulations as well as across legislations. Moreover, different uses of the same compound under different legislations as well as the concurrent uses of thousands of compounds in commerce that can result in spatial and temporal peak exposures that might have been acceptable for the respective authorized use, however, in sum being an overall environmental concern. This fact is not yet covered by any of the current risk assessment procedures. There are still gaps to be closed for technical as well as complex mixtures to be sufficiently addressed. These are for complex mixtures for example the prioritisation of substances/mixtures for

example the prioritisation of substances/mixtures for an assessment of combined effects and exposures, the identification of the most relevant substances/mixtures from the hazard and exposure side (e.g. substance groups, uses, exposures, properties), the responsibility for an assessment, possible exposure scenarios, the communication and quality of data and a link to retrospective assessment frameworks (e.g. assessment methods for mixtures are included under WFD). (References: Frische, T., Matetzi, S. Wogram, J. 2014: Environmental risk assessment of pesticide mixtures under regulation 1107/2009/EC: a regulatory review by the German Federal Environment Agency (UBA) DOI 10.1007/s00003-014-0916-6; Kortenkamp, A., Backhaus, T., Faust, M. (2009): State of the Art Report on Mixture Toxicity; study contract No. 070307/2007/485103/ETU/D.1; Aude Kienzler, Elisabet Berggren, Jos Bessems, Stephanie Bopp, Sander van der Linden, Andrew Worth (2014): “Assessment of Mixtures - Review of Regulatory Requirements and Guidance”, Joint Research Centre (JRC) Science and Policy report EUR 26675 EN; 2014doi:10.2788/84264; Antonia Reihlen, Dirk Jepsen, Olaf Wirth (2012) Consolidation of Information for Mixtures under REACH - Analysis of the DPD+ Method - Executive Summary, Project No. FKZ 3710 63 403 (summary and full report available on request); Dirk Bunke, Rita Groß, Fritz Kalberlah, Jan Oltmanns, Markus Schwarz, Antonia Reihlen, Ninja Reineke: “Mixtures in the Environment – Development of Assessment Strategies for the Regulation of Chemicals under REACH” (short title: 4M: Mixtures under REACH. Concepts and Options to act, project number 3711 63 429), UBA, Texte 65/2014). In order to achieve the goal of consistent hazard identification for PBT properties or endocrine disruptors across legislations, the generation of classification criteria for hazardous substance properties of endocrine disruption, PBT/vPvB or mobility (M), as well as the potential to select for resistances might be a solution. In addition in some areas specific endpoints from additional OECD guidelines are needed to improve hazard and/or risk assessment such as long-term effects on invertebrates and endangered species or on special forms of substances like nanomaterials. There are also some sustainability aspects which are not reflected in the chemicals legislation so far. In order to achieve a sustainable European society it is not sufficient to phase out chemicals of very high concern and to curb chemicals exhibiting risks. Question 15 refers to potential positive economic effects of a chemical (“jobs or the competitiveness of EU industry”) and asks if such criteria should be considered in regulatory decision-making. In view of ensuring a high level of protection for the environment, we appreciate that, regulation (EC) 1107/2009 does not support such an approach regarding PPP. Irrespective of that, our opinion is that as a general rule, a socio-economic analysis of chemicals should equally consider both, the potential benefit and the disadvantages for the society, especially the – mostly

external – costs due to risks to the environment and to human health. The latter costs should not only take into account environmental and health damages but also the costs of efforts done to prevent them (official inspection and monitoring, etc.). With respect to (EC) 1107/2009: A high proportion of the terrestrial environment in the EU Member States is directly exposed to plant protection products (PPP) which constitutes considerable risks to a wide spectrum of organisms. Although long since several groups of organsims are known to be overlooked in the environmental risk assessment of PPP, to date it has not been achieved to integrate those taxa into the praxis of the assessment and management of risks. Some – wild bees, amphibians and reptiles – are explicitly referred to in regulation (EC) 1107/2009 or subordinated regulations and guideance documents, but the risk characterization and management regarding those taxa has not been put into effect. The same applies to the assessment and management of indirect effects on higher trophic levels via an alteration of the food web, being explicitly demanded by regulation (EC) 283/2013. Other potential subjects of protection – bats, fungi species and their function in the soil – are not even considered in the referring regulations and guidance documents. Greater effort should be made to integrate those “known unknowns” into the praxis of environmental risk assessment and management. Another shortcoming of the regulation of PPP is that for so-called non-relevant metabolites in the ground water, no mandatory EU-harmonized threshold values exist. We consider this a considerable gap in the regulation as contaminations even whith quite low levels of such metabolites are considered unacceptable by the suppliers of drinking water (as well as their customers). In addition, a lack of harmonized rules generally provokes a distortion of competition and hampers the required co-operation of the Member States in the course of the zonal authorization of PPP. With respect to biocides (Regulation 528/2012), until now there exists no harmonised approach to minimise hazards and risks of biocides to human health and the environment during the use phase and on sustainable use of biocidal products. While the Biocide Regulation 528/2012 focusses on the procedure for including active substances in the Union list of approved active substances and the authorisation of biocidal products, there are no concrete requirements for the use phase of biocidal products. Additionally, authorization procedure can only cover the acceptable risks for a single product, not overall risks. Instruments for improving sustainable use of pesticides are described in Directive 2009/128/EC. It seems to be sensible that such an approach is appropriate for biocides as well, as authorised biocides are still biocides - which means that they keep their ability in killing living organisms. In our point of view the structure of certain instruments in Directive 2009/128/EC can be transferred to the biocide area, but some biocide specific adaptations are required, not only for biocides in general, but also

for the several Product Types or specific applications. There are also gaps in the Regulation concerning treated articles. Under the Biocidal Product Directive it was possible to have risk mitigation measures e.g. for treated wood within the authorization of a product. Now, under the Regulation, it is not possible to consider risk reduction measures for treated articles, even if they get obvious during authorization of the biocidal product. This leads to the fact that chances are given away to reduce risks of the use of biocidal products and leads to known and unnecessary burden of humans and the environment. Also regulation is missing for cases of import of treated articles from other EU member states when a substance is not allowed for special use in one member state but not in another. The state where the substance is not allowed for that use can only restrict placing of the market of the product for that use, but not the treated article (relevant e.g. for creosote).REACH ((EC) No 1907/2006). With regard to REACH socio-economic considerations are an important part of authorization and restriction of chemicals including those identified according to Annex XIII of REACH legislation as substances of very high concern. However, in most cases it is not possible to quantify the benefit for the environment of not authorizing or of restricting a chemical. Thus socio-economic considerations may underestimate the benefits for the environment caused by restricting or not authorizing chemicals – especially on the long-term. Good examples are the socio economic cost of remediating dioxins and other persistent pollutants. Furthermore, REACH (Annex XIII) has shortcomings with regard to the protection of drinking water from exposure to chemicals. Persistent chemicals, with a high mobility in the aqueous environment might have the potential to contaminate drinking water resources when released into the environment. If these chemicals have toxic effects on human health this is of high concern and should be addressed by hazard assessment and risk management.. An EU wide harmonized regulation for material in contact with drinking water is still missing. According to the drinking water directive 98/83/EC this is in the responsibility of member states but this is not in line with regulation 2679/98 on the functioning of the internal market in relation to the free movement of goods among the Member States. Consumption of resources should also play a role. Against the background of the rising global population the amounts of chemicals used have to be limited.

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)

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.

Due to the diversity of legislations, answers to the questions are provided specifically for the different legislations and not in general. Some overarching issues are addressed. With respect to the overall EU legislative framework, transparency on nanoforms of substances are not addressed in most of the legislations

(exemption: Biocide Regulation and plant protection regulation). Therefore, transparency on nanomaterial is lacking and enforcement agencies are not able to identify them for an adequate hazard and risk assessment. Furthermore, in neither of the legislations nanomaterials an adequately description exists how to assess hazard and risk appropriately. A harmonised definition of nanomaterials within the various legislations are lacking. This in conclusion leads also to legal uncertainties. With respect to CLP cosmetics should not be exempted. Cosmetics often contain environmentally hazardous chemicals. They are used in high amounts, have a wide dispersive use pattern and may often reach the environment or at least wastewater treatment plants. Although the list of ingredients has to be indicated on the packaging of cosmetics, information is missing which of these chemicals are hazardous. Classification and labelling is necessary in order to ensure safe handling of cosmetics with environmentally hazardous substances, e.g. substances hazardous to water. Besides, consumers should be enabled to take an informed choice when they buy cosmetic products. Moreover, surfactants, which are not in the scope of detergents regulation should be required to be easily degradable. Wiith regard to REACH (EC) NO 1907/2006 clear hazard identification, effective risk management and risk communication in the product chain are hampered by a lack of data. This is – in part - due to the weak quality of registration dossiers which often does not allow a risk or hazard assessment. Although the EU Commission committed to regulating all relevant substances of concern until 2020, this commitment is thwarted by a prolongation of processes, e.g. due to missing data and process steps that were not implemented within the regulation originally, but turned out to be necessary . Furthermore, the consumer right on information on SVHC in articles is hardly feasible and should be amended by obligatory labeling. Although exposure of citizens is comparable, consumer information on substances in mixtures is missing completely.In general regulations for hazardous chemicals in articles imported into the EU is weak, leading to disadvantages for producers of in the EU compared to importers and to a reduced protection of human health and the environment. For example the REACH authorization system has certain flaws. It excludes SVHC in imported articles from authorization and allows an unlimited number of authorizations, because additive effects of all authorized uses are not considered. In general, environmental impacts seem to be considered of lower priority than economic impacts and

aspects of human health. As the healthy environment is the basis for healthy life, environmental impactsct are equally relevant as economic impacts for society as a whole. Even if hazardous substances are necessary to combat diseases, other regulative frameworks (e. g. the water framework directive, Drinking water directive and Groundwater Directive) have to address the environmental concerns of these substances adequately. With regard to e.g. endocrine disruptors scientific and horizontal criteria for their identification are needed to increase transparency and predictability of the outcome of the assessment of chemicals within the different pieces of legislation. OECD guidance documents providing technical guidance on how to identify such endocrine disruptors are available and should be implemented and expanded to other endocrine modes of actions. With respect to nanomaterials, specific guidance documents for adapted risk assessment and risk management procedures are still missing or still to general.

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

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.

Due to the diversity of legislations, answers to the questions are provided specifically for the different legislations and not in general. Some overarching issues are addressed. REACH ((EC) No 1907/2006): With regard to REACH criteria for hazard identification as well as risk characterization are well established. Although risk management measures restricting or banning the use of substances of very high concern are available in principle, they put a very high burden on authorities with regard to restriction measures and first experiences show, that substitution within a medium time horizon is hampered by the fact that benefits for the environment of non-authorization are not adequately taken into account during socio-economic analyses. Furthermore, authorization should also be applicable to imported articles. Chemicals in imported articles might be released into the environment, comprising an emission source. In addition to that, European manufacturers have a competiveness disadvantage compared to manufacturers outside the EU. There are also some sustainability aspects which are not reflected in the chemicals legislation so far. In order to achieve a sustainable European society it is not sufficient to phase out chemicals of very high concern and to curb chemicals exhibiting risks. Consumption of resources should also play a role. Against the background of the rising global population the amounts of chemicals used have to be limited. Biocide Regulation 528/2012: There are gaps in the Regulation concerning

treated articles. Under the Biocidal Product Directive it was possible to have risk mitigation measures e.g. for treated wood within the authorization of a product. Now, under the Regulation, it is not possible to consider risk reduction measures for treated articles, even if they get obvious during authorization of the biocidal product. This leads to the fact that chances are given away to reduce risks of the use of biocidal products and leads to known and unnecessary burden of humans and the environment. Also regulation is missing for cases of import of treated articles from other EU member states when a substance is not allowed for special use in one member state but not in another. The state where the substance is not allowed for that use can only restrict placing of the market of the product for that use, but not the treated article (relevant e.g. for creosote). Detergents Regulation: The criteria which are basis for classification as “corrosive” do not allow a differentiation between slightly corrosive and strongly corrosive. Thus final consumers can be misleaded. E.g. concentrates of hand dishwashing detergents are as well classified as “corrosive” if classified on the basis of the calculation method (because of the high content of surfactants) as pipe cleaning products (because of the content of sodium hydroxide). According to Regulation (EC) No 648/2004, article 15 (Safeguard clause) Member States are entitled to withdraw a specific detergent from the market, if it constitutes a risk to the safety or health of humans or of animals or a risk to the environment although it is in compliance with the requirements of the Detergents Regulation. The interpretation that a detergent has to be in compliance before being withdrawn based on the Safeguard clause is not always useful. If a risk of a product is stated based on its ingredients it makes no sense to request the manufacturer to bring it in compliance first and to withdraw it afterwards. It is a disadvantage that the withdrawal can be made only for one specific detergent and not for an identified hazard ingredient. Furthermore the Commission Implementing Decision on the temporary prohibition of the placing on the market is time restricted and not in correspondence with risk management procedures of REACH and CLP. In addition the following overarching aspects are considered relevant: • For many applications or uses of substances, effective risk management measures are not yet available; e.g. effective risk management measures for endocrine disruptors are hampered by the lack of criteria to identify them • With regard to nanomaterials: Elements of hazard identification, risk assessment and characterisation are not

	sufficient addressed in the various legislations as they do not consider NM adequately. With regard to safety data sheets (as part of hazard communication), specific provisions are needed to be able to identify nanomaterials and describe their specific properties in the safety data sheet.
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, If you answered no, please explain your answer Standardized quality requirements such as GLP are important instruments to ensure reliability of information used for risk and hazard assessment. GLP ensures a sufficiently detailed description of experimental studies. However, it does not guarantee the reliability and relevance of the study results for the risk assessment. With regard to risk assessment and management reproducibility and standardization of study designs is much more important and thus standardized protocols such as OECD guidelines are generally preferred (with regard to their comparability), as they have internationally been harmonized among experts from concerned states. However, if it comes to identifying risks and hazards, all information including non-GLP and non guidelines studies need to be taken into account using a weight of evidence approach. This holds especially true if the hazards/risks to be regulated are not assessable by standardized studies . For instance regarding nanomaterials, adaptation of standardized test methods are needed which cover the specifics of nanomaterials. New endpoints without respective harmonized OECD guidelines are generally supported by the Commission or Industry, but might be ignored due to validity and plausibility issues.

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 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. , Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy , Stimulating competition and trade within the EU single market , Stimulating international trade between the EU and other countries

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)	*Respondent skipped this question*
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Other (please specify) Question 20 and 21 are biased toward costs of chemicals legislation for society (including authorities, industry, consumers). Although legislation puts a monetary burden on authorities, industry, society and consumers, those costs would need to be compared to benefits for man and the environment. With regard to the environment it is our understanding that benefits of current chemicals legislation - are outweighing costs. It is a well-known fact that cheap production is possible in our society, because costs caused by e.g. environmental pollution or efforts done to prevent them are usually not paid by the polluter, but by the society as a whole (so called external costs). Against this background we consider the costs incurred by the producer of chemicals as a consequence of the polluter pays principle. The burden for MS authorities caused by legislations could be reduced by close cooperation, transparency and communication.

Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?

If you answered yes, please indicate what these are.
see also answer to question 21. Identification of hazardous properties and respective legal classification by competent authorities would save costs. With regard to the identification of PBT, various agencies are responsible under the different legislations concerned (Biocides, PPP). We are aware of concerns regarding the composition of members of some of these committees, e.g. EFSA is selecting their members, while in the RAC Committee, each member state sends his representative, being considered more transparent. Biocide Product Regulation: The Regulation introduced the instrument of a product family. With the experiences so far this instrument is more attractive for industry than for authorities. Because the definition is very wide and allows to merge products even from different product types, the complexity of environmental risk assessment is an unacceptable burden for the authorities. Drinking Water Directive: Missing harmonized regulation for material in contact with drinking water cause costs for authorities. Plant Protection Products: The so-called “unless-clause” in the uniform principles for the decision-making in the framework of the authorization of PPP opens the floodgates to an excessive use of more and more complex and extensive higher tier methods by the applicants in their dossiers. This has lead to a considerable increase in the expenditure of the competent authorities in the risk assessment, partly exceeding the limits of their capacity. In principle, we support effects towards a more focused and realistic risk assessment, but we think that binding criteria should be established regarding the implementation of new and complex methods by the applicants in order to support a harmonized risk assessment and to minimize the regulatory effort in that context. Most complaints by the authorities concerning detergents refer to the website according to annex VII D. of the Regulation (EC) No 648/2004. Sometimes the access to the website is not given without any restriction, in other cases the website does not exist or information is difficult to find. This is time and cost consuming. A complete declaration of all ingredients at the packaging as necessary for cosmetics would be desirable for detergents as well as for all other chemical household products. So the consumer is enabled to make an informed choice.

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	3
Please comment	Emerging areas are addressed in legislations but due to the need of predictability of regulatory decisions this usually takes a (too) long time and is often hampered by scientific and/or regulatory controversies including political discussions about impacts of addressing emerging areas of concern. Thus, in our point of view the principle of precaution is essential in order to address emerging areas of concern in a sufficient time frame. It should be implemented more consequently in the risk assessment efforts under the different legislations. Nanomaterials feature a good example to demonstrate the shortcoming of the EU legislative framework to address emerging areas of concern in a timely and content-related acceptable manner: In principle, nanomaterials are covered by the current legislations on chemical safety. However, there are still no specific regulatory obligations for an adequate risk assessment of nanomaterials although we long since know which information is needed to assess the environmental hazard and risk. Even though discussion at the EU level regarding the adaptation of REACH to nanomaterials are going on for years, nearly no adaptation took place yet. In addition, neither CLP, PPP, nor the pharmaceutical directives feature specific provision for nanomaterials. Only the BP regulation includes a definition of nanomaterials and states that a separate risk assessment has to be performed. However, no guidance is developed yet how to perform this and which elements need to be considered. In the sense of legal clarity, equal treatment and for the fulfillment of the precautionary principle it is needed that these obligations are clearly specified. Since 1998 harmonization of rules for material in contact with drinking water are discussed but without conclusion. This result in essential gaps in the regulation of such material. Regarding the regulation of PPP, we highly appreciate that Regulation (EC) 1107/2009 demands an assements and management of effects on the biodiversity, including indirect effects on higher trophic levels via alterations of the food web. However, to date this important innovation in the risk assessment has not become effective in the praxis of the approval of substances and the authorization of products.

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	Neutral

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	Please note that the answer to this question is restricted to the following legislation: Plant protection products, biocides and REACH Annex XIII, detergents regulation, CLP and Drinking water directive 98/83/EC. While Regulations (EC) No 1107/2009 and (EU) No 528/2012 cover the application of plant protection products and biocides they do not cover manufacture and formulation of such products and at the same time these substances are exempted from REACH registration requirements. There are gaps in the Biocide Regulation 528/2012 concerning treated articles. Under the Biocidal Product Directive it was possible to have risk mitigation measures e.g. for treated wood within the authorization of a product. Now, under the Regulation, it is not possible to consider risk reduction measures for treated articles, even if they get obvious during authorization of the biocidal product. This leads to the fact that chances are given away to reduce risks of the use of biocidal products and leads to known and unnecessary burden of humans and the environment. Also regulation is missing for cases of import of treated articles from other EU member states when a substance is not allowed for special uses in one member state but not in another. The state where the substance or product is not allowed for that use can only restrict placing of the market of the product for that use, but not the treated article (relevant e.g. for creosote). Refill sale as a new selling method of detergents shows a gap in the Regulation (EC) No 648/2004. Article 11 (2) determines that certain information must appear in legible, visible and indelible characters on the packaging in which the detergents are put up for sale to the consumer. In the refill case it is not sufficient if the large containers/bulks, in which the detergents are stored in the shops, are correctly labeled. The detergents regulation does not ensure that these obligations need to be fulfilled directly after the detergent is filled up from the bulk. A change to Article 11 of the detergents regulation would be necessary to close this gap. It is not sufficient to amend the Regulation No (EC) 1272/2008 because not all detergents are hazard substances ore mixtures. An EU wide harmonized regulation for material in contact with drinking water is still missing. According to the drinking water directive 98/83/EC this is in the responsibility of member states but this is not in line with regulation 2679/98 on the functioning of the internal market in relation to the free movement of goods among the Member States.

Inconsistencies	A harmonised definition of nanomaterials within the various legislations of chemical safety is needed to be able to identify nanoscale forms of substances.

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.

Regarding consistencies: A harmonised definition of nanomaterials within the various legislations of chemical safety is needed to be able to identify nanoscale forms of substances.

Chemicals in articles are partly regulated in chemicals legislation, partly in other legislation. Consistent legislation for chemicals in articles is missing.
Cosmetics may contain environmentally hazardous substances, but are exempted from classification and labelling as e.g. “hazardous for the environment” according to Regulation No (EC) 1272/2008. They are chemicals with a wide spread use pattern and often end up in the environment or at least in wastewater. The list of ingredients which has to be supplied with cosmetics is a valuable information, but of no use for most consumers. Other mixtures like paints and varnishes have to bear respective precautionary statements in order to ensure appropriate handling by consumers. The same should be applied to cosmetics, in addition to the list of ingredients.

The intended use of human and veterinary pharmaceuticals causes contamination of water bodies and environmental effects are acknowledged. However, no limit values in groundwater, drinking water and surface water exist for pharmaceuticals. Both directives 2001/82/EC and 2001/83/EC (as amended) do not cover the manufacturing and formulation of such products and at the same time these substances are exempted from REACH legal requirements.

The Regulation (EG) Nr. 1223/2009 refers to REACH with regard to the protection of the environment. But cosmetics are exempted from labelling requirements of environmental hazards/risks under CLP. This exemption for cosmetics should be deleted.
In some areas, specific endpoints from additional methods OECD guidelines are needed to improve hazard and/or risk assessment, such as long-term effects on invertebrates and endangered species.
In order to achieve the goal of consistent hazard identification for PBT properties or endocrine disruptors across legislations, the generation of classification criteria for hazardous substance properties of endocrine disruption and, PBT, /vPvB or mobility (M), as well as the potential to select for resistances might be a solution.

Examples include pharmaceutical substances in the environment as well as personal care product ingredients. Therefore, restrictions under the REACH regulation should also apply e.g. for the manufacturing of pharmaceuticals.

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?	I don't know
To what extent are CLP labels effective in communicating hazards to consumers?	I don't know

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	No
Physical	I don't know
Human health	I don't know
Please list any hazard classes that are not covered	.In general, the hazard classes currently used are appropriate. Nevertheless, the environmental risks resulting from endocrine disruptors and PBT substances as well as those pertaining to the terrestrial compartment, e.g., bee toxicity, are currently not addressed and should be further considered. Furthermore, regarding the criteria, with a special view on the classification of nanomaterials, the correct material form employed in tests should be considered when assessing the validity of data. Pertaining to the classification of mixtures, the combined effects of chemicals are not adequately addressed.

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

Guidance documents	No experience
Helpdesks	No experience
Industry association guidance and materials	No experience
Other (training, conferences, etc.)	No experience

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	4
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
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Row #2 and Row#3: Please see our comment to question 29. Row #4: While in general, the harmonization approach is seen as proficient, there is often the problem of different interpretation of data and resulting divergent classifications. Potential gaps or needs in CLP have been evaluated in Kienzler et al 2014, Kortenkamp et al. 2009, Bunke et al. 2014, Rheilen et al 2012). E.g. hazards could be underestimated with the summation method when sum of components with a relevant aquatic toxicity is just below the threshold for classification. Moreover, synergistic effects should be addressed under CLP, but are not adequately covered when no data is available from tests with whole mixtures and assessment has to rely on a component-based approach. The availability, quality and communication of hazard data derived under CLP for substances in mixtures is important for other regulations, e.g. REACH and should be strengthened. (References above, see 15.)

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

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

Deadlines pertaining to the input of comments and information are appropriate but should be handled in a more strict fashion. The final inclusion into Annex VI takes too long

PAGE 10: Part V: Additional comments

Q35: **In case you have any additional comments with relevance for this public consultation, please insert them here.**	• Some of the questions in the questionnaires are very generic. Answering them having a wide variety of chemical legislations in mind seems not appropriate in our point of view.