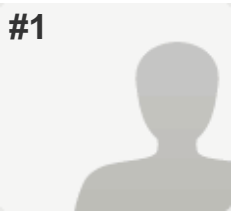

#1

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Monday, May 16, 2016 6:50:55 PM
Last Modified: Friday, May 27, 2016 4:25:31 PM
Time Spent: Over a week
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Vito Buonsante
Organisation/company	ClientEarth
Country	Belgium
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.	96645517357-19
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 non-governmental organisation (NGO)
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:	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	3
Protecting the environment	3
Ensuring a well-functioning internal market	5
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 human health	The legislation is not effectively implemented
Protecting the environment	The legislation is not effectively implemented
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

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)
,

Plant protection products (Regulation (EC) No 1107/2009)
,

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

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

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

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

Residues of pesticides (Regulation (EC) No 396/2005)
,

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

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:

b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted)
,

If you answered a or b, please explain
To fulfil the aim of ensuring a high level of protection to human health and the environment, the use of hazardous substances should be discouraged and the burden of proving that substances of concern do not cause harm should be placed on the economic operator. However, due to the enormous limitation of exposure assessment for chemicals with a widespread exposure, risk management measures should be taken based on the identified hazard classification using generic risk considerations. This is because specific risk assessments are not suitable for all uses of hazardous substances. First, generic risk considerations are especially important in regards to substances that are not controlled and cannot be easily traced. Endocrine disrupting Chemicals (EDCs) and Persistent, Bioaccumulative and Toxic (PBT) substances require a hazard-based approach due to the uncertainty in predicting exposure and effects. For example, in relation to EDCs, substances can have

delayed effects at very low doses making it difficult to calculate no-effect of exposure. Moreover, for PBTs, it may not be possible to calculate “safe” levels due to their persistence and the potential to accumulate in the environment, hence risk assessments are not reliable in managing the risks as long-term toxicity is difficult to predict. Second, generic risk considerations will not generally result in an automatic ban. In most cases generic risk considerations will lead to a reversal of proof on the economic operator to establish that the intrinsic hazard of the substance can be managed, or the socio-economic benefits outweigh a ban. Positive examples of chemical legislation that are based on generic risk considerations are the Plant Protection Product (Regulation (EC) 1107/2009) (PPPR) and the Biocidal Products Regulation (Regulation No 528/2012) (BPR). Under the PPPR there is a “cut-off criteria” for the approval of substances based on their intrinsic hazardous properties. Hence, if a substance fulfils the EDC criteria laid out in Annex II 3.6.5 (humans) or Annex II 3.8.2 (non-target organisms) it will not be approved (Article 4(1)). However, the Regulation foresees exceptions to this rule if, under realistic conditions of use, exposure would be negligible or a derogation applies (Annex II 3.6.5 and 3.8.2; Article 4(7)). An EDC may therefore be approved if “on the basis of documented evidence” the substance is “necessary” to control a serious danger to plant health, and for no longer than five years (Article 4(7)). In addition, in special circumstances, Member States may also authorise a plant protection product for a maximum period of 120 days and for limited and controlled use, where such a measure is needed to control a serious danger that cannot be controlled by any other reasonable means (Article 53(1)). Similarly, under the BPR an active substance that falls under the PBT criteria as defined in REACH Annex XIII will not be approved (Article 5(e)). However, the substance may be approved if it is established that either: a) risk to humans, animals or the environment is negligible; b) approval is essential to prevent or control danger; c) not approving the active substance would have a disproportionate socio-economic impact (Article 5(2)). The PPPR and the BPR provide an effective way to regulate the manufacture and use of EDC and PBT substances by ensuring that substances are not put on the market, unless the economic operator can prove that a specific exception applies. The negative impact of relying on risk-based approach to regulating hazardous chemicals is illustrated in the adverse effects that the pesticide Dibromochloropropane (DBCP) has had on male fertility. The pesticide was approved in the US in 1955 for agriculture, and in 1964 for use as a fumigant. However, in 1977, an emergency study by a US government agency discovered that workers in production plants were suffering from deficient or absent sperm, and the use of DBCP was banned in 1979. Nevertheless, DBCP continued to be marketed and used in plantations around the world. As a consequence, by the 1990s tens of thousands of plantation workers alleged to

tens of thousands of plantation workers alleged to have suffered adverse reproductive effects from the use of DBCP. Moreover, although the use of DBCP in agriculture has been banned in the US for more than 20 years, the pesticide persists in the environment and in water across many states. The long-lasting and irreversible effects of that DBCP has had on human health and the environment was due in part because exposures below the lowest dose tested in animal studies were mistakenly assumed to be safe. (European Environment Agency, 'Late lessons from early warnings: science, precaution, innovation', 23 January 2013, available at: http://www.eea.europa.eu/publications/late-lessons-2/#parent-fieldname-title) Finally, using a hazard-based approach to risk management measures results in legislative framework that is predictable and clear for investors and the chemistry industry. A risk-based approach, on the other hand, means more uncertainty and can have a negative impact on investment. As argued by the European Commission when proposing the criteria for the approval of active substances in plant protection products (see the explanatory memorandum of (COM(2006) 388 final, 2006/0136 (COD)): "The establishment of criteria will also enable industry to take an informed decision before investing in the development of new active substances or to support the renewal of approval of existing active substances." Indeed cut-off criteria have the advantage of giving clear guidance to industry. If those properties are fulfilled it would be a business risk to invest in the marketing of substances that have hazardous criteria hoping that a risk assessment would find that they can be properly managed.

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.
1. Vulnerable groups In general, risk assessments fail to do not take into account the specific risk that chemical substances, including EDCs, pose to women and children. For instance, under the Pregnant Workers (Directive 92/85/EEC) EDC substances are not even identified as a risk and therefore there is no obligation on employers to reduce exposure. Under Directive 92/85/EEC, an employer shall take all necessary measures to avoid the risk of exposure of pregnant or breastfeeding women to “agents” in Annex I, or prohibit exposure entirely to “agents” in Annex II, sections A and B (Article 5; Article 6). However, EDC substances are not specifically identified as "agents" in Annex I, or Annex II. Instead substances in Annex I are limited to those that fulfil the Carcinogenic, Mutagenic or Toxic for Reproduction (CMR) criteria as defined by the Classification, Labelling and Packaging Regulation (CLP) (Regulation No (EC) 1272/2008) (CLP) (Annex I - as amended by Directive 2014/27/EU, Article 2). Given that prenatal and neonatal exposure to EDC substances can have a heightened effect on human health and the development of children, it is of particular concern that there is no obligation to identify and prohibit exposure to EDCs under the Pregnant Workers Directive. 2. Mixtures Risk assessments do not generally take into account exposure to multiple substances, but rely on the assessment of individual substances. However, in “real life” we are exposed to mixtures of chemicals, and the harmful effects of unintentional mixtures are not effectively assessed and risks are not managed. In 2015, the Joint Research Centre published a report on the regulation of mixtures in the EU and found that the majority of legislation did not require mixture assessment. For instance, though the Water Framework (Directive 2000/60/EC) (WFD) takes families or groups of chemicals into consideration, the Directive does not address chemical mixtures or mixture effects. The failure to regulate mixtures across chemical legislation is of particular concern due to the potential enhanced effect that EDC substances may have in a mixture. (Aude Kienzler, Elisabet Berggren, Jos Bessems, Stephanie Bopp, Sander van der Linden and Andrew Worth, ‘Assessment of mixtures - Review of regulatory requirements and guidance’, European Commission Joint Research Centre, 2014, available at: https://eurl-ecvam.jrc.ec.europa.eu/news/assessment-mixures-report)

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	2

Speed with which hazards/risks are identified	1
Speed with which identified risks are addressed	1
Time to allow duty holders to adapt	5
Predictability of the outcomes	4
Stability of the legal framework	5
Clarity of the legal texts	3
Guidance documents and implementation support	2
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	3
Public awareness and outreach	1
International collaboration and harmonisation	4
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	1. Transparency The European Food Safety Authority (EFSA) lacks transparency and accountability, especially in relation to their procedures of approving plant protection products. In 2011, a PAN Europe study revealed links between members of an EFSA expert group and the industry lobby. Whilst in 2015 ClientEarth and PAN Europe brought a successful challenge before the EU Court of Justice for EFSA's lack of transparency in revealing the input of scientists in drafting guidance on identifying studies for inclusion in applications for approvals. The lack of transparency in EFSA's decision making procedures was ignited on 12 November 2015, when EFSA published the findings of its peer review assessing the risks posed by glyphosate, stating that it is "unlikely to pose a carcinogenic hazard to humans". However, this contradicted the conclusion reached by the International Agency for Research on Cancer (IARC), which in July 2015, classified glyphosate as a "probable carcinogen". The conclusion that EFSA reached has caused widespread suspicion as reliance was placed upon unpublished, industry-generated studies, which are not available for independent scientific review. Moreover, whereas the entire IARC panel that reviewed glyphosate were screened for possible conflicts of interest, not all of the 80 EFSA toxicology experts filed a declaration of interests, and some of those that were submitted were dated. (PAN Europe, 'A toxic mixture? Industry bias found in EFSA working group on risk assessment for toxic chemicals', 2011, available at: http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202011%20-%20A%20Toxic%20Mixture%20-

%20Industry%20bias%20found%20in%20EFSA%20working%20group%20on%20risk%20assessment%20for%20toxic%20chemicals..pdf; Arthur Neslen, 'EU scientists in row over safety of glyphosate weedkiller, The Guardian, 13 January 2016, available at:http://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-of-glyphosate-weedkiller) 2. Effective and consistent implementation and enforcement across Member States Under the Rapid Alert System for non-food dangerous products, national authorities of Member States can circulate notifications of non-compliant products to other participating countries for appropriate action. However, a report by the European Commission revealed that the presence of dangerous chemicals in products remains high, and notifications are not made, or acted upon, consistently by Member States. In 2015, dangerous chemicals in products have been the most frequently notified risk with 572 notifications, 25%. Though the majority of dangerous products notified originated outside the EU, 313 notifications (15%) were made regarding products made in Europe, including 63 from products of German origin, 46 products from the UK, 35 from Italian origin and 34 products from Poland. The frequency of notifications across Member States varies with national authorities in Spain notifying 12% and Bulgaria 7%, thus indicating that some Member States lack sufficient or suitably qualified inspectors. Moreover, the not all national authorities follow up on notifications of non-compliant products, with approximately 50% of notifications in the system being acted upon by another Member State. (See also Question 32) (European Commission, 'Rapid alert system 2015 results: full report', 2015, available at: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/docs/rapex_annual_report_2015_en.pdf) 3. Public awareness and outreach There is worrying little understanding of the hazardous nature of many chemicals that are commonly used by people across Europe. The last EU-wide study on consumer understanding of labels and the safe use of chemicals was conducted by the Joint Research Centre in 2011, and found that most respondents only felt moderately informed about the risks associated with chemical products. Moreover, many respondents did not recognise and could not understand the meaning of the CLP hazard symbols. For example, only 19% understood the carcinogenicity symbol and in the Netherlands and Sweden 68% of respondents mistakenly believed it to refer to a potential respiratory hazard. The lack of awareness and understanding of the CLP symbols is

	particularly problematic as 65% of the people in the survey relied on warning symbols, and 66% read instructions. (See also Question 30) (European Commission, 'Consumer understanding of labels and the safe use of chemicals', May 2011, available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_360_en.pdf)

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	2
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	2
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	3
Risk management measures restricting or banning the use of chemicals	2
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	2
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.	1. Hazard identification a. Inconsistent criteria used to identify EDC substances There is no uniform assessment to identify EDC substances in the EU, and some relevant legislation does not regulate EDCs at all. Out of 17 pieces of chemical legislation analysed, including the Registration, Evaluation, Authorisation and restriction of Chemicals (Regulation (EC) No 1907/2006) (REACH), only 3 included criteria to identify EDC specifically. These are REACH, PPPR and the BRD. Amongst the legislation that does specifically identify EDCs, this is done via a hazard-based assessment. However, the criteria applied varies across the legislation, and is based on either scientific criteria (REACH, PPPR, WFD), CMR criteria as defined by CLP (BPR) or entry on REACH Candidate List (BPR). The analysis revealed that most of the 17 pieces of EU legislation examined did not identify EDC properties when assessing a substance, including legislation covering cosmetics products. Of great concern is the fact that legislation governing products that are exempted from both registration and authorisation requirements under REACH, such as medicinal products for human and veterinary use and food or feeding stuffs, also failed to identify EDC. Moreover, whereas the identification of an EDC substance via Candidate Listing under REACH in the BPR appears to harmonise the process of hazard classification, this is not the case as biocides are exempted from registration under REACH.

Therefore, substances that are used exclusively in a biocide product will not be assessed according to scientific criteria under REACH Article 57(f), and this creates a gap in the level of protection afforded by different legislative frameworks. In fact, the absence of scientific criteria in the BPR has resulted the approval of biocides that are potential EDCs. A study conducted by PAN Germany in 2014, found that 10% of biocides submitted for notification or approved are possible EDCs under alternative priority lists, such as the EU priorities list (ED categories 1 and 2). (PAN Germany, 'Endocrine disrupting biocides', 2014, available at: http://www.pan-germany.org/download/biocides/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf) b. Inconsistent criteria used to identify PBT substances There is no uniform assessment to identify PBT substances in the EU, and the vast majority of relevant legislation do not cover PBTs. Out of 17 pieces of chemical legislation analysed, including REACH, PBTs were only dealt with or mentioned in five (REACH; CLP; PPPR; BPR; WFD). Among the legislation that referred to PBT substances, however, the criteria for identifying and classifying PBTs differ. Two pieces of legislation rely on the criteria established in REACH Annex XIII (BPR; WFD Daughter Directive, the Environmental Quality Standards (Directive 2008/105/EC), whilst the PPPR establishes its own independent criteria. Again the majority of the legislation analysed failed to identify PBTs, including legislation waste in the EU. The analysis revealed the inconsistent approach to identifying PBT substances in REACH, the BPR and PPPR, which undermines the protection afforded to health and the environment as well as the predictability of regulatory action. Under REACH, identification of PBT substance is based on scientific criteria as defined in REACH Annex XIII (Article 5(e)). This includes scientific criteria and toxicity criterion, including CMR and Specific Target Organ Toxicity-Repeated Exposure Category 1 or 2 as defined in the CLP. In addition, if the criteria in Annex XIII are not met, a substance may be classified as a PBT to if there is "scientific evidence of probable serious effects to human health or the environment" (REACH, Article 57(f)). The BPR follows this approach and the hazard identification of a PBT substance is based on PBT scientific criteria as defined in REACH Annex XIII (Article 5(e)). However, Annex 3.7.2 of the PPPR establishes different scientific criteria to identify PBT substances, which though similar to REACH Annex XIII differs in important respects. For example, the hazard assessment under the PPPR does not take into

account the possible formation of breakdown products or metabolites with possible PBT properties, whereas this is included in REACH Annex XIII and thus also the BPR. There appears to be no justification for this divergence, which would lead to a PBT substance being approved under the PPPR and not under the BDR. Identification of EDCs and PBTs is the first critical step towards introducing effective risk management measures. However, EU chemical legislation is not coherent thereby undermining the effectiveness of the legislation as well as the risk management measures to be introduced. Therefore, although PBT substances may differ in their properties, uses, exposure pathways and regulatory consequences, the outcome of an assessment should not depend on the framework under which they are evaluated, since the protection goals do not differ. (Fleur van Broekhuizen, Martien Jansen, Marino Marinković, Caroline Moermond, Dick Sijm, Eric Verbruggen and Peter van Vlaardinge, 'PBT or vPvB substances and the possible added value of Candidate listing under REACH: Thought starter for discussion at the PBT Workshop 2015', Ministry of Health, Welfare and Support, March 2015, available at: http://reachhelpdesk.nl/dsresource?type=pdf&disposition=inline&objectid=rivmp:274229&versionid=&subobjectname=) 2. Risk management The horizontal effects of the CLP Regulation are not timely in ensuring a high level of protection to human health and the environment. Under the CLP Regulation, a substance will be classified as CMR based on the intrinsic hazardous properties of the substance. Under certain legislation the classification triggers certain risk management measures. However, there is no procedure to implement these risk management measures. For instance, if Glyphosate was to be classified as Carcinogenic category 1B under the CLP while it is still authorised in the EU, there is no automatic mechanism that would trigger the CLP results to be applicable for Plant Protection. Hence, where a substance meets the criteria for classification as CMR under CLP (e.g. it is listed in the Classification & Labelling Inventory as a CMR) and considered as having EDC properties (in case horizontal criteria for EDCs will be established) there is no procedure to trigger the risk management measures under the BPR and other related chemical legislation.

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?

No,

If you answered no, please explain your answer
Using GLP standards for all safety data is not enough, as they do not guarantee the quality of the study. This is because GLP standards focus on general practices, such as record-keeping, sample sizes and the training of technicians. Moreover, due to their cost, most independent academic and government research does not follow GLP standards and there is an over-reliance on industry-funded studies, which undermine the objectivity and reliability of assessments. The conflicting conclusion that the EFSA and IARC reached on the carcinogenicity of glyphosate also triggered concerns regarding the reliance on GLP studies. This is because, the German Federal Institute for Risk Assessment responsible for the assessment, failed to take into account a number of studies with evidence of the harmful effects of glyphosate as they did not follow the GLP standards. In November 2015, a group of international scientists openly criticised EFSA's decision, due to the lack of transparency and the exclusion glyphosate-induced carcinogenic findings from non-GLP studies. In 2014, PAN Europe analysed the authorisations of 7 pesticides under the PPPR and found that most of independent studies were dismissed in the assessment despite an obligation to carry out a literature review under that regulation. (PAN Europe and Generations Futures, 'Missed & dismissed: Pesticide regulators ignore the legal obligation to use independent science for deriving safe exposure levels', 2014, available at: http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20Missed%20and%20dismissed.pdf)

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. , 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
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 authorities at EU level, Costs for authorities at national level, Costs for small and medium sized 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?	We do not view the business costs of meeting EU chemicals legislation to be significant , Other (please specify) The answer depends on the definition of costs, which should include external costs to society and the environment. In regards to pesticides, there are four main areas of external costs that mean that society as a whole pays for the use of pesticide products: 1) human health, 2) environment, 3) regulation, such as decontamination and monitoring, 4) defensive measures, such as buying protective clothing or organic food to prevent exposure to pesticides. As a result, it has been calculated that the financial gains from using pesticides in terms of agricultural productivity are 30% lower than the external costs. (Denis Bourguet and Thomas Guillemaud, 'The Hidden and External Costs of Pesticide Use', Sustainable Agriculture Reviews, 20 February 2016 (19), available at: http://www.springer.com/cda/content/document/cda_downloaddocument/9783319267760-c2.pdf?SGWID=0-0-45-1549473-p177802456) Robust legislation is necessary to manage the external costs of using chemicals, which in any case outweighs the costs of regulation. This was confirmed by the

Department for Environment and Rural Affairs in the UK in 2012, that concluded that for every £1 spent on regulation, there is a £3 return to society as a result of economic benefits to business and the public and environmental and health benefits. (Department for Environment and Rural Affairs, 'Emerging findings from Defra's regulation assessment', February 2015, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/406225/defra-regulation-assessment-2015.pdf) Moreover, the cost of regulation for the chemical industry is not significant when compared to the enormous costs of cleaning up pollution caused by the most hazardous chemicals. For instance, though the contraceptive pill has provided significant benefits to society, exposure to Ethinyl estradiol (EE2), the main active ingredient of the pill, has sublethal effects on aquatic animals. As a result, it has been estimated that it could cost over £30 billion to clean up the UK's rivers, streams and drinking water supplies that have been contaminated by EE2. Placing the environmental and societal costs on the chemical industry is therefore the biggest incentive to prevent negative impact that chemicals can have on human health and the environment. (European Environment Agency, 'Late lessons from early warnings: science, precaution, innovation', 23 January 2013, available at: http://www.eea.europa.eu/publications/late-lessons-2/#parent-fieldname-title; Robin McKie, '£30bn bill to purify water system after toxic impact of contraceptive pill, The Guardian, 2 June 2012, available at: http://www.theguardian.com/environment/2012/jun/02/water-system-toxic-contraceptive-pill)

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

Yes,

If you answered yes, please indicate what these are. One example is the costs of cleaning up pollution, which places a significant burden on authorities. Therefore, a better implementation of the polluters pay principle is needed in order to ensure that negative externalities are covered by chemical companies that make the profit. In addition, the extended producer responsibility should be included across chemical legislation to displace the economic burden of recycling, clean-up costs and regulation on the chemical industry. The extended producer responsibility already exists in the Batteries (Directive 2006/66/EC), where producers are responsible for financing waste battery collection and recycling. Given the costs and complications of enforcing and implementing cut-off criteria and exposure limits by Member States, it would be preferable to restrict the approval of substances to ensure that health and the environment are better protected. Under the Chemicals Agents (Directive 98/24/EC), for example, Member States have the obligation to enforce employers' obligations to eliminate exposure to certain chemicals. However, due to the lack of resources and decreases in public funding, there has been a trend of Member States of downsizing labour inspections. In Spain for example, there is a shortage of suitably qualified inspectors to supervise companies, and a new focus on "reducing accidents [rather] than reducing chemical exposure". Research revealed that across the EU, there has been a shift towards a more "soft" approach to regulation through the provision of guidance and support, which has replaced more sophisticated inspection techniques. The Chemicals Agents Directive, which aims to protect workers from risks to their safety and health from the effects of chemical at work (Article 1), is based on limiting exposure to certain chemical substances. Therefore, in order to ensure that the aims of the Directive are achieved, it would be preferable that hazardous substances are not approved in order actually protect workers from exposure. (Dr. Lothar Lißner et al. 'Evaluation of the implementation of Directive 98/24/EC (Chemical Agents at Work) in the EU-Member States', August 2010, available at: ec.europa.eu/social/BlobServlet?docId=10152&langId=en)

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	3

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	2
Please comment	1. Endocrine disrupting chemicals, Persistent, Bioaccumulative and Toxic substances and life-cycle management Overall, the legislative framework fails to address emerging areas of concern, such as EDC and PBT substances. As already discussed in Question 17 there are significant gaps and inconsistencies in the regulation and prohibition of EDCs in chemical control legislation, and similar deficiencies are also found in environmental protection legislation. For instance, in the Waste Framework (Directive 2008/98/EC) EDC and PBT properties are not taken into account when classifying “hazardous waste” and the Directive does not address the life-cycle risk management of these substances. Under the Waste Framework Directive, “hazardous waste” means waste that displays one or more of the hazardous properties listed in Annex III. Annex III, (replaced by Commission Regulation (EU) No 1357/2014) is aligned with CLP hazard classifications. However, no account is taken in Annex III whether waste has EDC and PBT properties. The absence of precise criteria to identify these properties in the Waste Framework Directive, or the CLP, is a significant gap as the more stringent risk management measures for “hazardous waste” will not apply to waste that may have EDC or PBT properties. Such risk management measures would include for example ensuring that production, collection, transportation, storage and treatment is carried out in conditions that provide sufficient protection to human health and the environment (Article17, with reference to Article 13). The failure to identify and manage the risks of EDC properties under the Waste Framework Directive is especially problematic as the different categories of “waste” in the Directive can be excluded from registration, downstream users’ obligations and evaluation under REACH. Moreover, the EU’s push towards a transition towards a circular economy will require that hazardous substances are not approved in the first place, and products that contain EDCs and

	PBTs are classified appropriately across their life cycle. 2. Nanomaterials Nanomaterials give rise to concern as a result of their new physico-chemical properties compared to the same chemical in its conventional form. However, in the EU, there is no definitive legal definition of nanomaterials and only a few pieces of legislation specifically address or regulate the manufacture and use of nanomaterials. Therefore, whereas REACH, CLP and the Cosmetic Products (Regulation (EC) 1223/2009) do apply to nanomaterials, the PPPR and environmental legislation does not. Due to the uncertain effect of exposure to nanomaterials during manufacturing, use or disposal, a specific legislative framework is needed or relevant pieces of legislation must be amended. Given the scientific evidence pointing to nanomaterials altering the endocrine system, any changes to the regulation must include specific hazard-based assessment of potential EDC properties of nanomaterials. 3. Mixtures See Question 15

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	Disagree
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.

Gaps or missing links	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); Pregnant workers (Directive 1992/85/EEC); Waste framework (Directive 2008/98/EC); Water Framework (Directive 2000/60/EC); Cosmetic products (Regulation (EC) No 1223/2009); Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009); Chemical Agents (Directive 98/24/EC); Carcinogens and mutagens at work (Directive 2004/37/EC); Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC). There are critical gaps when it comes to identifying and introducing risk management measures in regards to EDC and PBT substances. For example, the Cosmetics Regulation aims to ensure the functioning of the internal market and a high level of protection of human health (Article 1). However, the Regulation does not establish criteria to identify or restrict EDC or PBT substances. Moreover, substances identified as an EDC in accordance with REACH Article 57(f) due only to their hazards to human health are exempted from the authorisation requirements when used in Cosmetic products (REACH Article 56(5)(a)). According to Article 15(4) of the Cosmetics Regulation, the Commission was required to review the criteria for identifying substances with endocrine-disrupting properties by 11 January 2015. However, this deadline has not been met. There is clearly a failure to regulate EDC and PBT substances, or to draw on existing evidence and regulatory frameworks to prohibit the use of such substances in cosmetic products.
Inconsistencies	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); Pregnant workers (Directive 1992/85/EEC); Waste framework (Directive 2008/98/EC); Water Framework (Directive 2000/60/EC); Cosmetic products (Regulation (EC) No 1223/2009); Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009); Chemical Agents (Directive 98/24/EC); Carcinogens and mutagens at work (Directive 2004/37/EC); Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC). EU chemical legislation is inconsistent in how hazardous substances are regulated and risks are managed at work. For example, robust regulation of EDC and PBT substances is

excluded from the scope of the Carcinogens and Mutagens (Directive 2004/37/EC) and the Chemical Agents Directive. However, even if EDC and PBTs were included in the scope of either Directive, the two are inconsistent in their approach to regulating SVHC, which undermines the protection afforded to workers. For example, under the Chemical Agents Directive employers have an obligation to eliminate exposure through substitution, whereas under the Carcinogens and Mutagens Directive there is weaker obligation to "protect" workers from exposure. (Jorge Costa-David, 'EU legislation on reproductive risks ad EU practical guidance relevant for exposure to work' January 2014, available at: https://osha.europa.eu/sites/default/files/seminars/documents/presentation-costa-david_0.pptx) Derogations The criteria for permitting derogations under the PPPR and the BPR are not the same, which leads to an incoherent approach to approving the use of substances identified as EDC and PBTs. Under the PPPR, an EDC or PBT substance may be approved if it is 'necessary to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, not exceeding five years' (Article 4(7)). The BPR however, also permits the approval of an EDC or PBT substance based on socio-economic considerations (Article 5(2)(c)). The criteria for allowing derogations across chemical legislation should be consistent to guarantee a high level of protection to health and the environment, as well as ensuring legal certainty and predictability. Moreover, when considering the possible "disproportionate" socio-economic benefits of not approving an EDC or PBT substance under the BPR, the "disproportionate" impact should be clearly defined. The BPR is underpinned by the precautionary principle (Article 1), and an EDC or PBT substance should only be approved if an economic operator can establish a clear societal benefit.

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.

1. Food contact material framework (Regulation 1935/2004)
The fitness check currently includes Food Contact Materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009). However, the Food Contact Materials (Regulation (EC) No 10/2011) is limited to the composition of plastic FCMs, and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. Whilst Regulation (EC) No 450/2009) regulates the active and intelligent materials and articles intended to come into contact with food.

To ensure a coherent approach to the regulation of chemicals in the materials that come into contact with food, the Food Contact Material Framework (Regulation 1935/2004) should also be included within the scope of the fitness check. Currently, only 17 groups of food contact materials and articles are listed in Annex I of the Framework Regulation, and leaves paper, card, ink, coatings & adhesives in food contact materials unregulated. Moreover, EDC and PBT substances are neither identified nor are risks managed under the Framework Regulation. Individual Member States

substances are neither identified nor are risks managed under the Framework Regulation. Individual Member States have introduced regulations in relation to some materials, however, there are piecemeal and vary in terms of their scope and level of protection. Therefore, the Framework Regulation should be included within the fitness check to harmonise the regulation of EDC and PBT substances in all food contact materials to ensure a high protection to human health and the environment, and the functioning of the internal market.

(ChemTrust, 'Chemicals in food contact materials: A gap in the internal market, a failure in public protection', January 2016, available at: http://www.chemtrust.org.uk/wp-content/uploads/chemtrust-foodcontactchemicals.pdf)

2. Medicinal products for human or veterinary use (Regulation 726/2004; Directive 2001/82/EC; Directive 2001/83/EC)
Water pollution by medicines is a complex problem that requires action both at EU and Member State level. However, there are significant gaps in how medicinal products for human or veterinary use are regulated in the EU, and the WFD, which necessitates its inclusion in the fitness check.
Moreover, medicinal products for human or veterinary use are exempted from Titles II, V, VI and VII of REACH, meaning an exemption from registration (Article 2(5)(a). Therefore, where a substance is only used in medicinal product for human or veterinary use, it will not be registered under REACH and environmental risks associated with the life-cycle of a medicinal product may be missed due to the gaps in the environmental risk assessment for medicinal products for human or veterinary use.

The main concern is that the WFD, which is designed to deal with chemicals that pollute water, does not take medicinal products into account. Pharmaceuticals are not listed in Annex I of the WFD, as amended by the Environmental Quality Standards (Directive 2008/105/EC) (EQSD) in 2013, which contains 45 'priority substances' that are subject to emission controls. Neither are pharmaceuticals included in Annex II, which defines threshold values.

This is of particular concern due to the fact that the legislative framework that regulates medicinal products for human or veterinary use requires a narrow environmental risk assessment and the weight granted to the assessment is not consistent across the legislation.

First, the legislation on medicinal products for human and veterinary use aims to safeguard public health, thus the information provided for the risk assessment is primarily directed towards ensuring a high degree of human health protection. As a consequence, the environmental risk assessments required under both Directives are limited and do not include risks in the entire life cycle stages of the product.

Second, the weight granted to the environmental risk assessment is different if authorising a medicinal product for human or a product for veterinary use. The outcome of the environmental risk assessment of medicinal products for veterinary use is grounds for the refusal of an authorisation. This is because the risk-benefit balance laid out in Directive 2001/82/EC includes the quality, safety and efficacy of the veterinary medicinal products as regards to animal or human health and environmental risks (Article 1(20), with reference to Article (19)). On the other hand, the risk-benefit balance of products for human use does not include effects on the environment, and therefore the outcome of the environmental assessment may not provide a basis for refusing the authorization (Directive 2001/83/EC, Article 1(28)(a) with reference to Article 1(28)).

Moreover, though it is foreseen that a MS may refuse market authorisation via the in mutual recognition and decentralised procedure, environmental concerns are not a legitimate ground for non-recognition of an authorization of products for human use. According to Article 33(1) of Directive 2001/82/EC, a concerned Member State may refuse an approval under the mutual recognition and decentralised procedure on the grounds of "risk to human or animal health or the environment". In comparison, Article 29(1) of Directive 2001/83/EC stipulates that a product may only be refused on the grounds of "potential serious risk to public health".

The WFD is intended as a safety against the risk posed by harmful substances. However, the Framework cannot compensate the gaps in the regulation of medicinal products at the "source", thereby creating significant gaps in the level of protection from exposure to pharmaceutical chemicals in the water.

(Dr. Andrea Keessen, 'The legal instruments for the control of emissions of medicines for human and veterinary use', May 2012, available at: http://www.uu.nl/en/file/39117/download?token=csBp-w-b)

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?	3

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

Environmental	No
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	1. Human health The CLP Regulation does not include scientific criteria for identifying EDC and PBT substances or mixtures. Instead, under the Regulation, EDC substances are identified based on CMR criteria (Carcinogen, Annex I s, 3.6.1.1; Mutagenicity Annex I s,3.5.1.1; Reproductive toxicity, Annex I s,3.7.1.1). However, relying on the CMR classification is not an adequate substitute for clear, predictable or robust criteria for identifying and labelling EDC substances. Additional health hazards that are not covered by the CLP are: allergenic properties and nanoforms/nanomaterials. 2. Environment The CLP does not establish clear scientific criteria for PBT substances and PBTs are only mentioned in Recital 75 and Article 53(2) of CLP for inclusion at a later stage. The absence of clear criteria to identify the PBT substance under the CLP means that substances with PBT properties do not carry appropriate precautionary statements to protect workers, consumers and the environment. Additional environmental hazards that are not covered by the CLP are: Persistent Organic Pollutants (POPs), Very Persitent and Very Bioaccumulative substances (vPvBs) and nanoforms/nanomaterials. 3. Gaps and inconsistencies The absence of clear scientific criteria for identifying EDC and PBT substances creates gaps in regards to the implementation of risk management measures across chemical legislation. This is seen, for example, in the Pregnant Workers Directive, the BPR and REACH. Moreover, the UK has pointed to the absence of classification of PBT substances under the CLP has hampered the inclusion of such substances in the Candidate List under REACH. (ChemicalWatch, ‘Member states have other priorities besides candidate list, 31 January 2012, available at: https://chemicalwatch.com/9799/member-states-have-other-priorities-besides-candidate-list?q=member-states-have-other-priorities-besides-candidate-list) In addition, the CLP

	excludes a number of products from the scope of the Regulation, including medicinal products for human and veterinary use and cosmetic products (Article 1(5)(a)(b)(c)). This leads to gaps in the information available to consumers as regards to the presence of hazardous chemicals in products. In 2012, an independent study reviewed 41 cosmetic products according to the criteria for classification and labelling under the CLP and found that the signal word WARNING would have to be on the labels of 64%, DANGER would have to be included on 33% of the products. Therefore, as long Cosmetics Regulation does not guarantee effective labelling requirements to communicate risks to consumers, the exemption of cosmetic products in the CLP means there are serious gaps in consumer awareness. (Ursula Klaschka, 'Dangerous cosmetics - criteria for classification, labelling and packaging (EC 1272/2008) applied to personal care products', Environmental Sciences Europe, December 2012, 24(37) DOI: 10.1186/2190-4715-24-37, available at: http://link.springer.com/article/10.1186/2190-4715-24-37)

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?

Enforcement is not harmonised across most Member States

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Please add further details as necessary
In order for the CLP to achieve its aims of ensuring a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles in the EU (Article 1), it must be systematically enforced across the EU. However, there is evidence that companies are failing to fulfil their obligations and Member States are not enforcing the Regulation systematically or effectively across the EU. Under the Dangerous Substances (Directive 67/548/EEC) in 2004, a project conducted by the Chemicals Legislation European Enforcement Network found very high deficiencies in the quality of material safety data sheets throughout the EU, including wrong classification of substances and mixtures. (ECLIPS Working Group, 'European classification and labelling inspections of preparations, including safety data sheets. FINAL REPORT', Chemicals Legislation European Enforcement Network, 2004, available at: http://www.cleen-europe.eu/projects/ECLIPS.html) In 2013, the REACH-En-Force-2 published a report that examined the compliance and enforcement of two provisions under the CLP: • Article 40 - obligation to notify substances to Classification and Labelling Inventory at ECHA, if the downstream user is also a manufacturer or importer of substances • Article 49 – duty for suppliers to collect and maintain information as required by CLP for at least 10 years after the substance or the mixture was last supplied by that supplier The report found that 15% of companies did not comply with the duty to notify substances to ECHA and 20% of companies did not comply with duties to collect and store information. The Report highlighted the need to improve the provision of support and information via helpdesks, and recommended strengthening cooperation between enforcement authorities in different Member States to facilitate the enforcement of companies active in several Member States. (ECHA, 'Forum REACH-EN-FORCE 2 Project Report: Obligation of downstream users - formulators of mixtures', 2013, available at: https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf) In the UK, enforcement of the CLP Regulation remains extremely low and there has been no formal enforcement of the CLP since the provisions on mixtures came into force last year in June 2015. (Anita Lloyd, 'CLP – where have we got to?', British Safety Council, 4 April 20116, available at: https://sm.britsafe.org/clp-%E2%80%93-where-have-we-got#)

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	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	1. Appropriateness of classification criteria and methods for substances The current criteria under the CLP provide a scientific base for identifying hazardous properties of some substances, thus establishing a clear, predictable and systematic base for identification. However, a more precautionary approach is needed when applying the criteria, as well as better use of the available epidemiological data. Moreover, scientific criteria and categories should be established for: EDCs, PBTs, POPs, vPvBs and nanoforms/nanomaterials and allergenic properties. (See Question 29) 2. Appropriateness of classification criteria and methods for mixtures There is a need to update existing test methods, as most of the existing test methods are dated and fail to take into consideration many new scientific insights such as vulnerable windows in development or epigenetics. Available tests should be introduced for additional endpoints, such as: immunotoxicity, neurotoxicity, endocrine disruption and persistence. There is also a need to update testing methods to avoid non-genotoxic carcinogens being undetected.

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,

Please elaborate if you answered that the transition period is too short or too long.
We believe that the time for companies to adapt to technical progress is more than sufficient. It takes several years for substances to be classified and then transition periods are considered. Perhaps better information for companies in early stages is required, instead of considering giving longer periods to adapt to changes. Longer transitional periods would only be at the detriment of the regulatory objectives of the CLP.

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	2
Speed of the procedure	1

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

1. Transparency See Question 17 - "Risk management" 2. Involvement of stakeholders The lack of capacity and resources within CSO and SMEs hinders their capacity to participate in the CLH process. By contrast, chemical manufacturers have the capacity to follow and influence the outcome of each classification dossier. This situation is affecting the consistency and objectiveness of the process and should be tackled. 3. Quality of scientific data and related information Independent academic data are given a lower value than industry data that conforms GLP procedures, which undermines both transparency and the quality of data. (See Question 18) 4. Speed of the procedure The harmonised classification and labelling (CLH) procedure is extremely slow, for example, and only 13 substances have been classified (harmonised) as carcinogens in the last five years. A good indicator of the problems with the CLH procedures is the fact that industry is self-classifying more substances as carcinogens than the authorities. ECHA's Classification and Labelling inventory shows that 1017 substances have a harmonised classification as Category 1 carcinogens, however, industry has notified this classification for over 2400 substances.

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.

We would like to highlight that the questions raised during this public consultation seem biased towards establishing the costs of chemicals legislation to the chemical industry rather that focusing on the overall picture. The public consultation and the REFIT exercise should be aimed at understanding to what extent the existing regulatory approaches are efficient, effective, coherent in achieving the objectives of protecting human health and the environment. The consultation needs to assess whether citizens, workers, downstream companies and authorities are sufficiently protected and if the underlying principles of EU legislation are being implemented adequately, such as the precautionary principle or the polluter pays principle. However, instead the questions in the consultation have the objective of questioning the current regulatory approached to chemical safety. These approaches, based on generic risk considerations, reversal of the burden of proof and the polluter pays principle have been chosen due to decades of failure of expensive and burdensome detailed risk assessments Given the complexity of the issues, the use of multiple choice questions are not appropriate or useful, see for example Question 23 on safer alternatives. Moreover, where text boxes are allowed, the questions are so broad that it is almost impossible to provide a meaningful answer that covers all relevant points.