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PAGE 2: Part I – General Information about Respondents

Q1: Address

Contact name	Ninja Reineke
Organisation/company	CHEM Trust
Country	UK
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.

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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: 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 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	4
Stimulating competitiveness and innovation	3

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
Stimulating competitiveness and innovation	The legislation is not effectively implemented

Q12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

EU-level legislation adds value to national level action	5
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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)
,
Waste framework (Directive 2008/98/EC) and List of Waste
,
Water Framework (Directive 2000/60/EC),
Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
,
Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
,
Safety of toys (Directive 2009/48/EC),
Cosmetic products (Regulation (EC) No 1223/2009),
Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
,
General Product Safety (Directive 2001/95/EC),
Test methods (Regulation (EC) No 440/2008),
Other (please specify)
Food contact materials Regulation 2004/1935

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
General comment: the formulation of the answer b) itself is rather biased ('despite the possibility that certain uses of a chemical that are in the interest of society might be restricted'). It would have been appropriate to qualify the question from a different perspective, e.g. 'use generic risk considerations in order to take a pragmatic approach to avoid harm before it occurs, thus reducing the disease burden of society' or 'in order to provide clear incentives for

society ... or in order to provide clear incentives for chemical producers and users to move away from chemicals with unwanted properties in uses leading to consumer and environment exposure.' In fact, all EU laws already foresee sufficient clauses for exemptions and derogations which ensure that uses essential to society can be continued as long as no safer alternatives exist. CHEM Trust supports the approach to use generic risk considerations instead of specific risk assessments, in particular for all substances which may lead to serious and irreversible effects to human health or the environment. This includes endocrine disrupters, carcinogens, mutagens, reprotoxic substances, PBT/vPvB chemicals, neurodevelopmental and immunotoxic substances. Lessons from the past have shown that specific risk assessments are often flawed and that risk assessments have many uncertainties, which can be greater for some types of chemicals. Therefore, in cases where there is the potential for serious and irreversible damage the stakes are too high to rely on an assumed safe level which is often not protective of vulnerable groups or the unborn. See this CHEM Trust brief for more details (<http://www.chemtrust.org.uk/wp-content/uploads/CHEM-Trust-Briefing-on-REACH-EDC-review-FINAL.pdf>) One of the most important lessons from the Existing Substance Directive was that even in cases where serious hazards had been identified for PBT chemicals, it was difficult to accurately predict the risk over time because of both uncertainties of the effects due to long term exposure and uncertainties as to exposure over time. This is why PBT chemicals obtained a specific emphasis in Annex XIII of REACH, combined with a special authorisation requirement. However, under REACH we are concerned that PBT chemicals are inadequately regulated because the evidence requirement for the identification and conclusion of a PBT assessment is so high, while on the other hand there is insufficient effort to ensure that industry's PBT assessments are of an adequate quality to make an accurate determination. EU chemical and chemical-regulated legislation should incorporate more generic risk considerations for chemicals with harmful properties in uses leading to consumer exposure (e.g. cut-off of CMRs in the cosmetics regulation without a specific additional risk assessment check because it is obvious that exposure takes place by the use itself; introducing a phase-out for CMR and EDCs in medical devices and food contact materials or expanding the Carcinogens and Mutagens at work Directive to include reproductive toxins). In addition, legal requirements to move towards a group approach for chemicals affecting common adverse outcomes are needed to address various exposures from multiple sources. The fact that chemicals can act together is another reason why specific risk assessments for individual chemicals are very problematic. Moving to more generic risk considerations for certain types of chemicals would give a clear signal to companies and investors that chemicals with such dangerous properties are not wanted in these open uses. Many

leading companies have benefitted from providing solutions and alternative processes. Currently there is still too much focus on rewarding company laggards by not regulating instead of rewarding those companies who have successfully invested in safer alternatives. <http://www.chemtrust.org.uk/replacing-chemicals-with-safer-alternatives-or-protecting-dirty-industry/>

Q15: In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.

No,

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.

There is a clear need to move forward to address risks from cumulative exposures (simultaneous and/or subsequent exposures to multiple chemicals). So far EU chemicals policy has failed to develop a response to the potentially very harmful combination effect from chemicals. Wildlife and humans are now exposed to many different substances from a whole range of consumer and other products. This means they are exposed, amongst others, to industrial chemicals, pesticides and biocides with endocrine disrupting properties. Many of these chemicals will have additive action at specific endpoints. Single substance risk assessment is not adequately protective to account for possible mixture effects, see e.g. Martin et al. Environmental Health 2013, 12:53 <http://www.ehjournal.net/content/12/1/53>. Additional uncertainty factors are needed to address risks from cumulative exposures for some substance groups. In other cases, for some substance groups, additional generic risk considerations should lead to the implementation of 'hazard based' cut off or bans to prevent continued exposures. Moreover, CHEM Trust is very concerned about the high burden of proof needed in decision making and the very few cases where decisions are taken based on the precautionary principle (to address remaining uncertainty). The BPA ban in baby bottles from 2011 was one of the very few examples, and thus contradicts the claim that current decision making on chemicals in the EU is 'over-precautionary'. We are seeing that it is taking many years for effective controls to be brought into place, for example, in the case of Deca-BDE, Alkylphenols or perfluorinated chemicals. This is particularly relevant for the potential serious and irreversible effects on the developing child in the womb or in the further development of children. EU chemical laws should be better equipped to provide special protection for future generations.

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

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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	4
Clarity of the legal texts	3
Guidance documents and implementation support	3
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

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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

General comment: We doubt that any meaningful interpretation can be derived from such an aggregated response table. The responses are very different from legislation to legislation and our examples just give a few illustrations. Transparency: Transparency varies with regulatory system. REACH tends to be reasonably transparent, while systems that involve EFSA – including pesticides and food contact chemicals – tend to be rather intransparent. Non-industry stakeholders also have reasonable access in the REACH system, but virtually no access in the chemicals in food contact area (which does however allow some access by industry stakeholders). Stability: up to now the legislation has been relatively stable, but now there is a process of destabilisation with REFIT. Speed: Although policymakers decided in 2009 that no CMR, PBT or EDC pesticide should be on the market, there has been long delays and not one decision, yet, to decide a non-approval based on this hazard based cut-off provision. The goal of the Water Framework Directive for progressively reducing pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances is a long way from being achieved for the majority of substances. Moreover, the EU strategy on pharmaceuticals is still missing; the Commission had promised progress on tackling risks from cumulative effects from chemical mixtures and nothing has happened over the last 5 years; and the delay on the adoption of EDC criteria has now been nearly 3 years. During all this time, exposure continues and leaves human health and wildlife at risk. All in all it is a disgrace how Europe fails its citizens on this issue and instead carries out a 'REFIT'-exercise which aims for 'better legislation' and seems to suggest that the burden on companies is too high while the increasing toxic burden in people can be disregarded.

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.)	3
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

If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of

The implementation of risk management measures in the EU restricting or banning the

legislation), please explain your answers.

use of chemicals are insufficient to protect the population and the environment and need to be strengthened to increase the long term benefits for society as a whole. One obvious area of neglect are the provisions for minimising exposures to endocrine disrupting chemicals (EDCs) due to the Commission's delay in adopting the EDC criteria as mandated by the pesticides and biocides laws. Moreover, CHEM Trust sees the need to widen the range of uses that are covered by generic risk assessments (or hazard based cut-offs), particularly focussing on situations where there is exposure of the general public and the environment. Important areas for extension include, but are not limited to, food contact materials, toys, furniture, carpets, certain construction materials and the general product safety directive. Furthermore, a greater emphasis should be put on adequate implementation and enforcement to ensure consumer protection. The large number of notifications through the EU Rapid Alert System for dangerous products (RAPEX) regarding harmful chemicals in consumer products which pose a serious risk highlight that there are still many gaps that need to be closed, see http://europa.eu/rapid/press-release_IP-16-1507_en.htm One option would be to introduce more controls such as testing by a third party, as now required in the US for children's products.

<https://www.cpsc.gov/en/Business--Manufacturing/Testing-Certification/Third-Party-Testing/Third-Party-Testing-FAQ/> In addition, in CHEM Trust's view it is very important to improve consumer information and transparency for chemicals in products. We believe the pictogram and hazard statements process is useful, but more targeted awareness raising activities are needed, as recommended in ECHA's study from 2012 'Communication on the safe use of chemicals.'

(https://echa.europa.eu/documents/10162/13559/clp_study_en.pdf Most importantly, more information is needed on which chemicals are contained in consumer products to allow for an informed consumer choice. A positive example is the mandatory ingredient list for cosmetics and personal care products. In contrast, one negative example is the limited amount of consumer information that needs to be provided for selling products online (e.g. for biocidal products only the pictograms are required and no information on active ingredients or advice for safe handling). In addition, more efforts and further studies are needed in relation to ECHA's very useful classification and labelling inventory. New databases and technologies will hopefully facilitate this process further. We consider that apps that assist the public in finding out about SVHCs in articles are an

important start in this area. For more points regarding the hazard identification criteria also see question 31 (missing endpoints in CLP classification criteria) and question 16 (delay re adopting EDC criteria).

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
It is very important that chemical assessments and classification are not just based on studies done to 'Good Laboratory Practice'(GLP), as other studies may examine endpoints that are not covered by established GLP methods, and can be of equal or higher scientific quality. Many useful studies relating to a chemical's toxicity may be done, for example, in an academic laboratory without GLP accreditation and it is vital to understand that the purpose of GLP is not to assess the intrinsic scientific value of a study. Thus, although GLP creates the semblance of reliable and valid science, it actually offers no such guarantee. GLP specifies nothing about the quality of the research design, the skills of the technicians, the sensitivity of the assays, or whether the methods employed are current or out-of-date. GLP simply indicates that the laboratory technicians/scientists performing experiments follow highly detailed OECD requirements for record keeping, including details of the conduct of the experiment. These record-keeping procedures in GLP were, incidentally, instituted because of widespread misconduct being committed by commercial testing laboratories. CHEM Trust would particularly like to highlight that there is a need to update existing test methods required in all relevant regulatory frameworks to include additional endpoints for endocrine disrupters, as well as a need to new tests to cover 'new' endocrine disrupting mechanisms.

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.

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Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.

,

Reducing the damage to the environment and to ecosystems 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

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)

General comment: We did not provide an answer to question 20 as we think it is badly designed and impossible to interpret without providing further information. For example, the 'costs for society' due to ineffective implementation of chemical legislation are enormous as has been shown in several studies previously. Here we would like to share just 3 recent examples: - The cost of inaction – A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Nordic Council report, November 2014 <http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf> The Norden Study estimated the cost of male reproductive health problems from yearly exposure to EDCs: Assuming that EDs constitute 2, 20 or 40% the total costs for the selected health effects are 3.6, 36.1 or 72.3 million Euros/year of exposure in the Nordic countries, this corresponds to 59, 592 and 1,184 million Euros/year at EU-level. - Health costs in the EU - How much is related to EDCs, Health and Environment Alliance (HEAL), June 2014 http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_related_to_edcs.pdf The HEAL study estimated that if EDCs contribute to only 2-5% of the total health costs from endocrine-related chronic diseases, EU policy change such as the phasing out of these hazardous substances and promoting safer alternatives could save Europeans up to €31 billion each year in health costs and lost productivity. - A series of papers published in March 2015 in the Journal of Clinical Endocrinology and

Metabolism looked at a variety of health conditions that can partly be attributed to EDC exposure. These ranged from infertility and male reproductive dysfunction, birth defects, obesity, diabetes, cardiovascular disease and neurobehavioural and learning disorders. It finds that the costs across the EU of exposure to hormone disrupting chemicals could be over €150 billion annually in health care expenses and lost earning potential. The papers can be found here under the following links: overview, neurobehavioral, male reproduction and obesity & diabetes. Experience from e.g. the debate on REACH has shown that industry-based cost estimates are often extremely inflated (as has been the case in the ADL and Mercer studies). We would therefore urge that the results of these questionnaires are treated with caution (see also

<http://chemsec.org/publication/chemicals-business/cry-wolf-2015/>) . We consider there is also a need to focus on the benefits for companies in different scenarios, e.g. reduced costs for disposal of hazardous waste after switching to non-CMR chemicals. There are numerous success stories of successful substitution which deserve a closer look. For example, for a start check out the following compilations of case studies:

http://echa.europa.eu/view-article/-/journal_content/title/echa-newsletter-highlights-substitution

<http://www.ecocouncil.dk/releases/articles-pressreleases/chemicals/1905-new-publication-on-the-substitution-of-hazardous-chemicals>

http://chemsec.org/wp-content/uploads/2016/03/The_bigger_picture_160217_print.pdf In addition, it is important to enlarge the view on the health costs borne by the health care systems and the society as a whole.

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. It is obvious that authorities have costs in running the system effectively and we believe better mechanisms for ensuring the 'polluter pays' principle should be developed, e.g. a tax for continued use of harmful chemicals in certain sectors or certain products. The work by national authorities is essential, and it is vital that it is not cut in times of austerity and pressures on public budgets. It's already clear that monitoring and enforcement of EU laws on chemicals is ineffective in many countries – this work needs more resources and priority. Member states also have an important role in conducting assessments, performing evaluations, organising monitoring surveys (environmental monitoring, food residues control) and proposing control measures, again this requires more resources not less. Without such work many chemicals will be used on the basis of inaccurate industry assessments of their safety (e.g. the example of the Deca-BDE registration dossier that claimed there was no hazard, and there are more examples in the other legislations). To say it in a nutshell: All citizens have a right not to have ill health inflicted upon them in the interest of others and they have the right to know what is in their products so that they can avoid exposure. And the unborn has the right to normal development. To ensure this, is the one of the main tasks of the authorities and should guide their actions (and budgets).

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
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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

CHEM Trust has often criticised that over the last years Europe's efforts in adapting EU chemicals legislation to new scientific developments have been a story of delays and setbacks. The existing EU legislative framework does not sufficiently address emerging areas of concern such as risks from nanomaterials, endocrine disrupters, mixture toxicity, low dose exposures, epigenetic effects. Although such issues have been mentioned multiple times in legislation, they are not being effectively addressed by or included in regulations. This means that the public and environment are not being properly protected. An additional topic that deserves urgent regulatory attention in CHEM Trust's view is pharmaceuticals in the environment (see CHEM Trust report written by G. Lyons: "Pharmaceuticals in the Environment: A growing threat to our tap water and wildlife" (<http://www.chemtrust.org.uk/wp-content/uploads/CHEM-Trust-Pharma-Dec14.pdf>))

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	Strongly Agree
The EU chemicals legislation framework has overlaps	Disagree
The EU chemicals legislation framework is internally inconsistent	Disagree

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

Chemicals in food contact materials: - Currently there is no harmonised EU-level legislation on food contact chemicals permitted in paper, card, ink, glues or coatings. In addition, there is no EU legislation on safe use of recycled materials in such food contact applications. This is in contrast to chemicals in plastic food contact materials, where there is a harmonised list and approval of recycling processes - There is no linkage between REACH SVHC designation and any of the legislation on chemicals in food contact materials. - There is no provision for a generic risk assessment approach in the food contact legislation

Chemicals in consumer articles: In general the issue of chemicals in most consumer articles is not covered well by EU regulations, for example there is a lack of control on chemicals in home furnishings and carpets, in spite of the fact that these could easily be exposing children to as much chemical exposure as toys do (as can be seen from chemical contaminants in dust). This needs to be urgently addressed in product specific and sectorial legislation.

Inconsistencies

While we agree it can be useful to look for current gaps and missing links in current legislation, we hold the view that not all inconsistencies are bad by definition. There can be good reasons to adapt rules to specific chemical uses or intrinsic hazardous properties. For example, the use of generic risk assessments to phase out chemicals with the most harmful properties from applications with clear exposure of people, including children.

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.

Just as on additional particular example: Regulations promote the recycling of packaging waste, yet there are no regulations ensuring that the use of recycled material in e.g. paper and card food contact material is chemically safe.

PAGE 9: Part IV: Specific questions on the CLP Regulation

Q28: CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very effective)

To what extent are CLP labels effective in communicating hazards to workers? 4

To what extent are CLP labels effective in communicating hazards to consumers? 4

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

Environmental	No
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	CHEM Trust advocates the expansion of the CLP classification criteria to also address additional properties, which are currently not covered in CLP. This includes: • POPs, PBTs/vPvBs • Biodegradation (Persistence) • Immunotox, including allergenic properties • Nanoforms • EDCs • Environmental endpoints, including those lost in the transition to GHS (e.g. soil)

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

Please add further details as necessary
We are aware that the monitoring and enforcement of chemical safety legislation varies considerably between member states and that there are considerable efforts ongoing to improve the harmonisation across Member States.

Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)

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

In CHEM Trust's view hazard based identification and classification provides a scientific base for identifying hazardous properties of substances, thus establishing a clear, predictable and systematic approach for identification. This system is very important for workers and occupational health and safety legislation, ranging from communication about hazards and risks to providing comparable data sets for alternatives assessment and replacement with safer alternatives. It is also the appropriate base for taking measures for consumers and environmental protection.

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 2

Speed of the procedure 1

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

While the current procedures for harmonised classification have led to several new classifications over recent years CHEM Trust takes the view that current test methods needs to be updated to better address endocrine disrupting endpoints. This also means that the test requirements in various EU laws have to be adapted accordingly to ensure that these data are generated. We also consider that far too few chemicals undergo testing for effects on developmental neurotoxicity and immunotoxicity and are thus not identified. In general, the wider use of non-animal tests will have to be accompanied by changes in classification criteria to enable these tests to be used for classification and regulatory decisions. Given the long list of chemicals pending classification, the process for adopting EU wide harmonised classifications needs to be accelerated and there should be additional efforts for harmonising industry's self-classifications.

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

We consider the questionnaire itself to be confusing and likely to lead to ambiguous interpretation. In many cases it is impossible to provide a meaningful answer by ticking one box, and free text fields are not always available. In addition, most questions are very broad in scope and the aim of the exercise is unclear. Moreover, in several places the questions appear biased towards the interests propagated by certain industry sectors. We had also expressed our general concern in a letter to Commission Vice President Timmermans (see <http://www.chemtrust.org.uk/wp-content/uploads/Letter-to-Vice-President-Timmermans-on-chemicals-refit.pdf>).
