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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Johanna Löfbom
Organisation/company	Swedish Chemicals Agency
Country	Sweden
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.	*Respondent skipped this question*
Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.	My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q5: Please indicate whether you are replying to this questionnaire as:	A government or public authority
Q6: If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:	*Respondent skipped this question*
Q7: For businesses, please indicate the size of your business:The definition of small and medium-sized enterprises depends on the staff headcount and either the annual turnover or the balance sheet of the company. Please consult the following website: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm	*Respondent skipped this question*

Q8: Please indicate the level at which your organisation is active:	National

PAGE 3: Part II – General Questions

Q9: How important is it in your view that there is chemical and chemical-related legislation* at EU-level in order to achieve the following objectives? (1 = not important; 5= very important)*This comprises the chemical-related provisions in all legislation within the scope of this fitness check. It encompasses legislation governing hazard identification and classification, as well as risk management measures, including chemical-related aspects of legislation on worker safety, transport, environmental protection, chemicals controls and supporting legislation, excluding REACH. The full list of legislation can be found here.The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals.**

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	3

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	4
Protecting the environment	3
Ensuring a well-functioning internal market	4
Stimulating competitiveness and innovation	2

Q11: If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

Protecting human health	The legislation is unclear, The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
Protecting the environment	The legislation is unclear, The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
Ensuring a well-functioning internal market	The legislation is unclear
Stimulating competitiveness and innovation	The legislation is not adapted to the issues at stake

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

EU-level legislation adds value to national level action	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)
,

Export and import of hazardous chemicals (Regulation No 649/2012)
,

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

Safety of toys (Directive 2009/48/EC),

Detergents (Regulation (EC) No 648/2004),

Test methods (Regulation (EC) No 440/2008),

Other (please specify)
We have selected the legislations that the Swedish Chemicals Agency is responsible for. However, our comments refer sometimes to other legislations too. This is because we have knowledge of other legislations due to the fact that they are adjacent to our areas of responsibility, that we get questions on them from stakeholders and that we collaborate on them closely with other authorities.

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
We consider that the legislation in general should be oriented towards generic risk considerations for a more effective and efficient legislation. Classification according to CLP provides basic information that not only triggers hazard communication in the form of labels and safety data sheets but also several other kinds of risk reduction measures in a number of downstream legislations, including REACH. . We consider this to be a good approach since it allows flexibility according to the specific sector under discussion. For this approach to work it is absolutely vital that the classification remains based on intrinsic hazardous properties and nothing else. Risk and socioeconomic factors may influence which risk reduction measures are applied in downstream legislation, but the hazard information is known and common for all use sectors. The balance between generic risk considerations and specific risk assessment should also be decided at the level of the downstream legislation. Generic risk considerations as applied in the BPR and PPR, are more economical in terms of resources and time, where substances that have X hazardous property are not normally considered appropriate for a Y exposure (to children, to consumers or to the outdoor environment, for example). Whether derogations should be allowed is for lawmakers to decide in each sector. Specific risk assessment methods are burdensome for both industry and Member States. They are also proving rather unpredictable where problems with substances can be identified at quite a late stage of evaluation or even during the decision-making process (as has occurred with BPR). Since companies ask for a greater predictability in legislation then this would be an advantage of generic approaches since companies would know from the beginning which types of substances were likely to be allowed for certain uses and which would not be.

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. The provisions of the chemicals legislation are not sufficiently updated in relation to new scientific data about risks and the development of safer alternatives both for human health and the environment. Some examples that are not taken into account are shown below; - Combination toxicity effects, both via dietary and non-dietary exposure; - Cumulative effects between different legislations; - Risks from manufactured nanomaterials; - Environmental effects in cosmetics and pharmaceutical products; - Satisfactory specific provisions for the protection of vulnerable groups such as born and unborn children and youths in all legislation and not only for toys; - Sufficient sources and uses in the approval of active substances in the BPR for products and treated articles . The methods of legislating in complex areas such as chemicals in articles should be reassessed in order to find more efficient ways of regulating. A suggestion is a new product safety directive that applies even to environmental risks.

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	3
Speed with which hazards/risks are identified	2
Speed with which identified risks are addressed	1
Time to allow duty holders to adapt	4
Predictability of the outcomes	3
Stability of the legal framework	3
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	2
Public awareness and outreach	2
International collaboration and harmonisation	3
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	These comments explain the basis of our choices in the table above: Transparency of procedures The transparency varies depending on the procedure. In general it is better than before. However, there are some areas for improvements such as the following; - Legal interpretations from the commission are seldom

put in writing and are usually vaguely motivated. Or if they are put in writing it is not easy to find them on CIRCABC. - A significant number of legal acts under the chemicals legislation are adopted through “comitology” and delegated acts. Despite recent improvements, the transparency of these processes still remains poor. - Complicated legislations such as BPR need better transparency throughout the whole process to enable especially SME’s to follow the process and understand what is expected of them to comply to the legislation. - The process of identification of SVHC substances (which includes substances fulfilling the PBT/vPvB of REACH Annex XIII) is in itself quite transparent. However, it is probably not transparent for the general public. Speed of hazard and risk identification With specific substance risk assessments it can take years to work through the process to identify hazards and risks. Even if legislation is implemented as intended it can take 2-3 years. For pesticide legislation it has often taken longer because of implementation problems. Speed with which identified risks are addressed This varies. It can be quick if it is a risk that has been identified through the reporting of adverse symptoms through exposure. In most cases for general chemicals it takes an extremely long time since registration, evaluation and classification comes first before limitations or restrictions. The advantage with the PPR and BPR legislation is that the hazard identification, risk assessment and decisions around risk reduction measures all occur as part of the same process instead of having the divisions that REACH has. Predictability of the outcomes - REACH Annex XIII; REACH Annex XIII includes strict numerical criteria but also allows for weight of evidence assessment taking all relevant information into account. This is necessary to enable proper identification of PBT/vPvB substances, but as it involves expert judgment (and experts may have different opinions) and as science is evolving in some cases this makes the outcome less predictable. - PPP; One of the intentions with the approval criteria in Annex II, points 3.6.3-3.6.5 was to make the approval procedure of active substances predictable by early in the process identifying substances with certain unwanted properties as decided upon by the Member States. By widening the definition of ‘negligible exposure’ compared to what is written in the regulation, the unpredicted effect of now allowing derogations for substances with these unwanted toxicity profiles is seen. - BPR. There are particular problems with predictability in the biocide area. First, the scope of the Biocidal Products Directive was not very clear. The

scope of the Biocidal Products Regulation is an improvement but inevitably involves changes in scope from the Directive which the sector is having to adapt to. Then there are both “external” and “internal” borderlines. There are external borderlines with other chemical legislation. It can be very difficult for the borderline to be drawn and it takes a lot of resources for companies, authorities and, in some cases, users to work out whether a product is a biocidal product or, for example, a medicine (disinfectant). Internal borderlines come in at least two dimensions, those between different product types for biocidal products and the borderlines between what is a biocidal product, what is a treated article and what should lie outside of the scope of the Regulation (note a recent decision on flower bags). One advantage of the Regulation is that decisions can now be made by the Commission that give legal certainty. Unfortunately, sometimes it is only when evaluators are conducting in depth risk assessments that they find unexpected problems, sometimes at the last minute, where the evaluator finally understands the use of the product and realises that it maybe has not been attributed to the right product type by the company or might not even be considered a biocidal product any longer! In future it should be avoided that a scope is defined as being everything that isn’t within the scope of other legislation (which was particularly the case with the Biocidal Products Directive). Clarity of the legal text There is still need for improvements in the field of legal drafting. Many problems of interpretation arises from the lack of understanding of the relationship between different legal acts, i.e. it is often difficult to seize or understand the exact scope of single provisions or even entire legal acts especially in relation to other legal acts (e.g. Art. 1(5) CLP). Regarding the PPP it is sometimes the wording of certain provisions are in conflict with the intended functioning of the legislation and it may be assumed that this is not the intention. Some provisions are too vague and need to be elaborated on further. The lack of clarity leads to attempts to find solutions in Guidance documents for example, which sometimes has resulted in incorrect interpretations. It is important to use simple language as far as possible for the majority to understand and comply with the legislation. For example, the legal text of BPR is very long, complicated and unclear. Furthermore the linguistic/legal check carried out on translations of proposals for regulations and directives is insufficient as an examination of the legal integrity of a proposed legislation and closer legal scrutiny of proposals should be made after working group discussions. Guidance

document and implementation support It is still difficult to find and understand relevant guidance documents published on the Commission's web site (e.g. RoHS, Detergent, Persistent Organic Pollutants). It would be best to gather this kind of guidance documents in a way that they could be easy to find. There is also a need to review the current guidance documents and their design so that their content become more accessible. In this, one might have a look at Echa's guidance documents. - Regarding BPR, there are lots of guidance documents but some are old and have not been revised since the Regulation came into force. Some are revised but not very transparent. There is loads of useful information in CA meeting documents available to the public. These are loaded up on to CIRCA so that they are publically available, which is good. However, the information is not ordered in any way to facilitate parties trying to find it. Several documents can deal with the same issue and the provision of information would be much more effective (especially for companies) if someone at the Commission had the time to combine relevant documents into one coherent document. This would also help identify inconsistencies and loopholes. Some ECHA documents are good but they are difficult to find on their website and they are too long. Effective implementation and enforcement across Member States For the BPR, the Commission and MS put a lot of effort in to discussing and documenting common interpretations, especially regarding borderline issues. Even so, the legislation is so complicated that a lot of room for diverging interpretation exists. A particular problem even with the new Regulation is that when it was written insufficient attention was paid to writing clear provisions on legal administration. The lack of precision in these provisions have caused a lot of problems for authorities trying to authorise products. It is something the Commission should understand better in the future now that they will also be authorising products (Union Authorisations). This point also relates to the comment made on the need for legal scrutiny of text made elsewhere. Regarding PPP, the Commission have to take action when it is obvious that Member States are too generous in granting emergency authorisations according to Article 53. Consistent implementation and enforcement across Member States The quality and the frequency of enforcement differs in different Member States. Partly it has to do with interpretation of legislation, guidance documents and borderline issues (for BPR particularly with medicines and treated articles/biocide products) and partly it has to do with resources. The Commission has made

efforts to help Member States with this by enabling the formation of the Co-ordinating Group (even before it was based in law) and now the Biocides Enforcement Group. Even so, more co-operation is needed. Public awareness and outreach Given the technical complexity of the legislation it is not surprising that people are not aware of the implications of chemicals legislation thereby affecting their possibility of understanding their rights and obligations. For example BPR is too complicated. It is very difficult and resource intensive to describe to the general public the consequences of the legal text and reasons behind decisions. The BPR is to protect the public's health, their environment, in some context companies' intellectual property rights, and to defend the harmonised market even if it means not allowing a low risk product that doesn't fulfil the extensive requirements. The consequences can be difficult to explain. However, the power of the public to impel innovation by making it easier for them to take informed decision on what products to buy should not be underestimated. International collaboration and harmonisation The level of international collaboration and harmonisation varies a lot depending on legislation. GLP, CLP and Test Methods are examples of high collaboration and harmonisation. For many other legislations the level is low. Increased efforts are needed to increase harmonisation without compromising the level of protection of human and animal health and the environment. A constructive approach which should be encouraged is to seek out good approaches to particular issues in the different global regions (for example, biocidal treated articles) and to work for harmonisation using the best regulatory practices so that both authorities and companies benefit from them.

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

Hazard identification criteria	4
Risk assessment and characterisation	3
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	3
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	4
Risk management measures restricting or banning the use of chemicals	4
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	4

If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.

These comments explain the basis of our choices in the table above: Hazard identification criteria: There are well-established for most endpoints but there are some missing: - We are still awaiting criteria for endocrine disrupting substances which should have been established in 2013. According to Regulations (EC) no 1107/2009 and no 528/2012 the criteria for identifying chemicals with endocrine disrupting property shall be based on science, not socioeconomic considerations although the Commission seem reluctant to adhere to this. The success with other classification endpoints in having purely scientific categories upon which risk reduction is decided downstream is equally possible here. Such an approach is transparent and avoids pressures to manipulate conclusions on hazard identification on the basis of socioeconomic need. The consequences of a constant and increasing exposure of humans and the environment to endocrine disrupting chemicals can be anticipated to be of such importance as to generally outweigh the benefits. - REACH Annex VIII; the criteria works well but criteria for e.g. terrestrial bioaccumulation and substances not bioaccumulating via lipid partitioning are missing and should be developed if possible. Risk assessment and characterisation: - For new active substances under Reg (EC) no 1107/2009 a harmonized classification should be available before decision on approval is taken. Also, in case of uncertainties and data gaps in the basis for decision it should be possible to await for such issues to be resolved before decision-taking. Hazard and risk communication: - While risk communication is good for pesticides and chemical products (although it could perhaps be clearer) it is insufficient for articles both for professionals and consumers. - Although basic information in safety data sheets has improved, the extension of the safety data sheets with REACH driven information (e.g. exposure scenarios) has perhaps had the effect that the important basic information in these sheets are even - REACH Annex VIII; Almost non-existent. There are no labels/pictograms for PBT/vPvB substances. - However, identification of a substance as PBT/vPvB and subsequent listing as SVHC on the candidate list means that consumers, upon request, have the right to be informed if an article contains SVHC substances, which is a very weak measure. Risk management measures We think that the integrated approach of PPR and BPR where risk management is decided as part of a continuous process that began with hazard identification works much better than legislation where risk management procedures are kept separate.

Q18: Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?	Yes, If you answered no, please explain your answer It should be noted that test- and study reports can be taken into consideration even though they are not performed according to GLP if the studies, assessed on a case by case basis, is considered to be of acceptable quality. Such studies may be both reliable and relevant. GLP is useful in contributing to good scientific practice and thorough reporting so that even negative results can be considered reliable.

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
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 national level, Costs for small and medium sized enterprises, Costs for consumers
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Other (please specify) Obviously there are costs from these requirements on companies but we don't know exactly how they are divided up between these tasks. However, there are also benefits such as the level playing field, clear requirements on their duties as manufacturers/distributors and various stimulators for innovation.

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. We want the principle of polluter pays applied more widely than is the situation today. Some work is not covered by fees. See examples below; - Products authorisation under the legislations on PPP and BPR - PPP and BPR as part of the enforcement procedure. - To analyse articles during enforcement

PAGE 7: Relevance

Q23: To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	4

Q24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)

Novel areas of concern sufficiently addressed by framework	2
Please comment	The existing EU legislative framework does not sufficiently address areas like combination effects, nanomaterials, and endocrine disrupting chemicals. The process of developing legislation is too slow. Additionally, new test methods take a long time to be accepted etc. The methods of legislating in complex areas such as chemicals in articles should be reassessed in order to find more efficient ways of regulating. Alternative test methods: The classification criteria in the CLP-regulation are in general based on data from in-vivo studies. Although use of non-testing approaches, like read-across and in-vitro, is allowed, the current classification criteria can make them difficult to apply. In order to address this concern work within the OECD has been initiated with the main aim of examining whether new classification criteria, based on alternative approaches, should be developed in the GHS. This work would also consider the current development of new alternative test methods. This OECD initiative is a necessary step towards a further adaptation of the classification system into the technical progress.

PAGE 8: Coherence

Q25: Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

The EU chemicals legislation framework contains gaps and missing links	Agree
The EU chemicals legislation framework has overlaps	Agree
The EU chemicals legislation framework is internally inconsistent	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	Water bodies not fulfilling the quality criteria of the Water Framework Directive can lead to consequences in other legislations. It would be advantageous if this was highlighted in the Water Framework Directive. In general there should be more co-ordination between the WFD and other relevant legislation.--Article 1(5) CLP is not clear with regard to the scope of the exemption from CLP. --Article 1.5 CLP lists general derogations. Several acts are listed even though they do not give the same protection. E.g. cosmetics in relation to environmental hazard.--The derogation for medical devices which are invasive… (article 1.5.d) in CLP is not written in the same way as in REACH, which leads to the absurd situation that there is no labelling obligation for these hazardous products but still a need for safety data sheet. CLP needs to be corrected.--Better coordination is warranted with regard to the integration of the EU rules on chemicals, articles and waste in order to achieve a life cycle perspective.--There is a large gap with regard to information on chemicals used in cosmetics (covered by the cosmetics regulation). It is not possible for EU-authorities to get data on the use of ingredients in cosmetics. In addition, the cosmetics regulation should take into account professional use, however in practise, risk assessment within that framework does not cover professional use.--The term “ingredients” is not defined in CLP leading to unclear legal text within e.g. the use of the Bridging Principles for mixture classification.--It was said that the Toys Directive would cover the relevant aspects of the BPR for toys. Under closer examination we can now see that this is not the case and therefore there is a gap in the requirements for toys.--The same substance must be assessed for both PPP and BP Regulations. The risks may vary because of the different uses but the hazard identification should be the same based on a common data package instead of it depending on which companies submit their

	data.--There is no provision within Regulation EC 396/2005 to enable MRLs to be set for BPR products as required by the BPR. The Commission has negotiated an interim solution which several MS consider inappropriate (possibly unworkable). It would be better that DGs were cooperative internally between different work areas and between different DGs.--The PFAS-group consists of >3,000 substances. Their properties do not fit in the criteria laid down by REACH Annex XVIII. All PFASs are vP (even vvP) either themselves or part of a degradation product. They are also mobile (M) in the environment. The P and M properties will result in a potential problem for the ground and drinking water.
Overlaps	Hazard assessment of the same substances under both Regulation (EC) no 1107/2009) and Regulation (EU) no 528/2012 should be avoided.--Article 69(1) BPR (Regulation EU no 528/2012) refers to the provisions of CLP, including requirements to have labels in the national languages (art. 17(2) CLP). The same issue is dealt with in art. 69(3) BPR giving the MS an option to adopt such provisions in their national legislation and thus creating a possible overlap.--The Detergent regulation has its own additional labelling requirements beyond what is required according to CLP. The demands are too detailed and unnecessary since CLP entered into force and it could be removed.--Both CLP and the plant protection regulation/biocidal products regulation have rules regarding for example advertising and labelling. The requirements are not the same and the period of grace for labelling is different between the legislations.--The RoHS directive and the Toys directive have the same substances regulated.--Creosote between BPR and REACH.

Inconsistencies	Article 4(1) of Reg (EC) 1107/2009 states that “The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.” Article 11 of Reg (EC) no 1107/2009 states that “Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment”. This indicates that the evaluation should be stopped when it has been established that substances fall for the so called ‘cut-off criteria’. The approach indicated by the legislator is not followed in practise.--Reg (EC) no 1107/2009 and Reg (EC) no 1272/2008 are vague as to the designating responsibility to produce classification dossiers and submitting these to ECHA. ---Same definitions can mean different things in different legislations, like the definition of “Placing on the market” which is a problem. Overall different definitions in different regulations cause problems. It is important that definitions and concepts are applied consistently from existing legislation to new legislation.--REACH Annex XIII: When it comes to PBT/vPvB criteria the consequences of fulfilling the criteria are very different. For REACH no immediate consequences (candidate listing and maybe subsequent inclusion in the authorisation list). For PPP, however fulfilling the PBT/vPvB criteria leads to non-authorisation. This difference may to some extent be justified by differences in exposure but far from always. The difference in consequences also leads to differences in interpretation of the criteria between the different legislations, which is very unfortunate.--The overall positive effects of the legislation thus becomes difficult to demonstrate. It is not clear that the legislation leads to that substances that stay on the market are safer than the one that are removed. For example, in the case of product authorisations of plant protection products.--Regulatory efforts and costs in comparison to efficiency in risk reduction and control varies significantly between different legislations.--In the BPR the risks from products might be the same but the extent to which they are regulated depends upon the claims made on the label.

Q27: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

• The evaluation process for active substances in PPP and the CLH process seem not to be totally coherent and should be re-examined.
• Limit values in different legislations are potentially overlapping and incoherent.
• Monitoring data, generated on priority substances within the Water Framework Directive, would be useful for other legislations e.g. REACH
• It would be very useful with a coordinated EU-database with regards to environmental monitoring data.
• It would be useful with access to data on accidents/incidents caused by chemical substances.
• The relative high standards of regulation of chemicals within EU should not be jeopardized or compromised through trade agreements with countries outside of EU.
• Clarification is needed regarding legislation covering treated seeds. The treatment itself is covered by Reg (EC) 1107/2009 whereas trade with pesticide-covered seeds is covered by another legislation.
• Although there are obvious gaps for chemical products (nanomaterial, combination effects etc.) and even more for articles (chemicals information) more efforts are needed to ensure a sufficient implementation of already existing legislation (enforcement, guidance, helpdesk and awareness). It does not help to fix gaps, missing links and overlaps if the legislation becomes too complicated and ignored.
• There are two current examples of new pieces of legislation that are poorly prepared in the sense that it is unclear how they relate to existing legislation. A new EU regulation on mercury is under negotiation (Proposal for a Regulation of The European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008; COM/2016/039 final - 2016/023 (COD), and there are virtually no investigation of how the proposals made should function in relation to existing legislation. This despite the fact that the new regulation will affect a number of different pieces of EU legislation (amongst others Reach). Another example is the new Tobacco Products Directive (2014/40/EU) which contains a provision that could be interpreted as double regulating the CLP Regulation (Art. 5(2)). The COM has promised that clarification should be made through guidance document. However, this development is unfortunate and will ultimately lead to the regulations as a whole becomes more ambiguous and difficult to interpret, which will take considerable resources not only from competent authorities but also from consumers, businesses and other stakeholders.

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	Yes
Please list any hazard classes that are not covered	Environmental hazards: Besides “hazardous to the ozone layer” environmental hazards according to CLP only cover the open water aquatic compartment. We consider that sediment and terrestrial ecosystems should be covered as well. One simple way of including other compartments could be to add e.g. tests on terrestrial organisms and to broaden the class from “Hazardous to the aquatic environment” to simply “Hazardous to the environment”. Especially since there is no longer any indication of danger as we had in the older classification and labelling system as “Dangerous to the environment”. However, we appreciate that this would require changing GHS before we could change CLP.

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

Guidance documents	3
Helpdesks	4
Industry association guidance and materials	3
Other (training, conferences, etc.)	3
Please add further details as necessary	Guidance doc.: These are quite heavy and could preferably be simplified where possible. Nevertheless, they are helpful not only directly for companies, but also indirect through use within helpdesks and they include a number of good examples. There are, however, areas where more guidance is needed, e.g. health classification of solid metals, strategy for classifying alloys (health and environment), bridging principles, weight of evidence, a more clear definition of bioavailability. Helpdesks are highly appreciated and effective. It is important to sustain good cooperation between helpdesks, e.g. HelpNet. Training and conferences are always appreciated. But the need for more seems endless and often at a deeper level than our resources allow. It is particularly beneficial when guidance is made available centrally (via the Commission or ECHA) because it strengthens harmonisation and reduces double work across MS.

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is harmonised across most Member States , Please add further details as necessary There are common enforcement projects and groups like the Forum for enforcement and the Cleen network. Enforcement is a national matter and it differs in resources and organisation between different Member States. However, there are many questions in the legislation which are open to interpretation and it is highly desirable that interpretations are coordinated and harmonized between the countries as far as possible.

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	2
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	4
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	CLP is a very technical legislation which requires high level of knowledge and experience for companies as well as for authorisations. The company managements needs to assign appropriate resources and smaller enterprises often engage consultants. With regards to GHS, it gives harmonised criteria but due to the building block approach it is not implemented in a fully harmonised way. It is important to realise that for development (including simplifications) of classification and labelling criteria (CLP) and for rules related to safety data sheets (REACH), EU MSs and the Commission need to allocate proper resources at the UN level.

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	3
Speed of the procedure	3

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

Transparency of the procedures and involvement of stakeholders: Measures under the procedure for harmonisation of classification and labelling of substances are still adopted through the old so called “regulatory procedure with scrutiny (RPS or “PRAC”) but are likely to be adopted through delegated acts under Art. 290 TFEU. In spite of improvements and the recent Interinstitutional Agreement on Better law-making (IIA) these procedures are still too anonymous for actors not directly involved. The same is true with regard to stakeholders making their participation depending on the vagaries of national authorities. As the dossier submitter is given a very small role at the RAC meetings, it would be advantageous to introduce a step in the ’classification process’ under Reg (EC) no 1272/2008 where the dossier submitter is allowed to review and comment upon the draft opinion and classification proposal of the RAC rapporteur ahead of the RAC meeting to avoid misunderstandings concerning the decision forming basis. Quality The quality of CLH-dossiers varies a lot. There is a need for a better accordance check. In addition, it would be valuable if Echa would provide a better indication of their time planning for accordance check after submission of the dossier.

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

Directives vs. Regulations:Most of the chemical related legislation is highly technical and some of it is subject to continuous amendments. It creates a lot of work in the Member States to implement changes in directives in their national legislation. The Commission should, therefore, consider the difference and the choice to be made between regulations and directives in accordance with the statements made in the interinstitutional agreement on better regulation (Art. 25).