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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Tobias Bahr
Organisation/company	ACEA
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.	0649790813-47
Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.	My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q5: Please indicate whether you are replying to this questionnaire as:	An industry association
Q6: If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:	Manufacture of motor vehicles, trailers and semi-trailers (C29)
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	4
Protecting the environment	4
Ensuring a well-functioning internal market**	4
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	4
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	2

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

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

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please	Classification, labelling and packaging (Regulation No (EC) 1272/2008)

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.

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

,

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

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

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Inland transport of dangerous goods (Directive 2008/68/EC)

,

Chemical Agents (Directive 98/24/EC),

Asbestos (Directive 2009/148/EC),

Carcinogens and mutagens at work (Directive 2004/37/EC)

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Young people at work (Directive 1994/33/EC),

Pregnant workers (Directive 1992/85/EEC),

Signs at work (Directive 92/58/EEC),

Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)

,

Waste framework (Directive 2008/98/EC) and List of Waste

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Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)

,

Water Framework (Directive 2000/60/EC),

Urban Waste Water (Directive 91/271/EEC),

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

,

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

Batteries (Directive 2006/66/EC),

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

,

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

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

Aerosol dispensers (Directive 75/324/EEC),

Explosives (Directive 93/15/EEC),

General Product Safety (Directive 2001/95/EC),

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

PAGE 5: Effectiveness

Q14: In the EU legislative framework for chemicals, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations (e.g. widespread exposure or exposure of vulnerable groups), which justify the automatic adoption of such measures. In other cases, the risk management measures are determined by a specific risk assessment that assesses the probability of adverse health and environmental effects resulting from the specific exposure scenarios associated with the proposed use(s) of the chemical. In your view, do you think EU chemical and chemical-related legislation should, in general:

a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged discussions and implementation delays)

,

If you answered a or b, please explain
In an industrialized society we need substances that may be hazardous or reactive for a resource efficient production. A risk based approach is compared to a purely hazard based approach preferable as this is guaranteeing the definition of the most precise and efficient risk-management-option and thus avoiding unnecessary efforts for a globally engaged industries and the creation of competitive disadvantages. Such an approach will furthermore generate a high level protection of human health and the environment. In this regard it has to be considered that a proper risk-management strongly depends on a sound identification of related hazards. E.g. CLP is substance intrinsic and should describe only the related hazards – also for the future.

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

No,

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.
• In particular combination effects of chemicals are not well evaluated yet. The onus has been on industry to control this, however, for smaller businesses without the expertise there is only rudimentary guidance. • Protection of human health is predominantly hazard based. Many companies, particularly SME's, lack the knowledge to implement the legislation practically. • A more balances and risk related approach is required to ensure EU's competitiveness with other regions in the world. • Micro management of substances (e.g. specific lead restriction – like particular exemptions in the ELV directive - for a total utilization of lead in all EU volume manufacturing of 0.2 t/a) should be avoided. • Continuous revisions are posing very high administrative burden for the Commission and industry stakeholders while having only and very limited effects because a technical feasible phase out already reached its boundaries in most cases. Existing remaining exemptions without negative effects for people and environment should also be considered as frozen or review periods have to be extended until technical achievements are made and thoroughly

tested and evaluated. • Respective R&D costs for industry to further reduce undesirable substances in remaining applications below a technical feasible limit are disproportionately high. • A variety of options for the future have been considered and evaluated. Significant changes to the ELV directive would probably not be beneficial. In the future, it will be difficult to identify, test and approve alternatives for all of the remaining exemptions that do not have expiry dates, so there would be beneficial cost savings for both the EU and to industry from a freeze or at least longer periods between exemption reviews and for some exemptions much longer periods, without loss of the incentive to continue efforts to replace lead. • Experiences with carefully evaluated and proven solutions from other material and substance related legislations should be taken into account in the development or adoption of chemical legislation without additional and costly administrative burden for authorities and industry. • The granted exemptions under the ELV directive are providing a good example in acknowledging the process related challenges of the industry while implementing new legislative obligations in ongoing production and supply of spare parts for vehicles that might already have ceased mass production (“repair as produced principle”). • This problem was initially raised and resolved during discussion and implementation of the EU End of Life Vehicle (ELV) Directive (2000/53/EC) and the exemption for legacy spare parts under the ELV Directive was confirmed by Member States, Parliament and the EU Commission. • CLP is the source for criteria describing the hazards of chemicals. Required data are obtained by the REACH registration dossiers. Many of the published REACH dossiers are not sufficient in CLP classification (inconsistency of data).

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	3
Speed with which identified risks are addressed	3
Time to allow duty holders to adapt	2
Predictability of the outcomes	2
Stability of the legal framework	4
Clarity of the legal texts	2
Guidance documents and implementation support	2
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	4

Public awareness and outreach	2
International collaboration and harmonisation	2
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	ACEA agrees that EU chemical legislation is important or even very important in some cases. However, improvements could be made with regard to transparency and national implementation and enforcement in a consistent way. The speed for assessment of hazards might be appropriate but this is not the case for risk related assessments. § 174 of the EU Treaty is calling for a Union policy on the environment that shall contribute to the preservation, protection and improvement of the quality of the environment with prudent and rational utilization of natural resources. In preparation of such a policy available scientific and technical data shall be taken into account as well as potential benefits and costs of action or lack of action. This obligation should be more thoroughly considered and a more impact oriented approach should be chosen. The cost to benefit ratio as outlined in art §174 and § 175 of the EU treaty needs to be considered more thoroughly. In the example of RoHS or ELV-directive-Annex II a very tight and increasingly disaggregated approach is chosen only providing minor improvements while generating high administrative and operational burden. Transparency of all EU legislations as well as their interaction is paramount for a sustainable implementation in industrial processes – in particular for complex products with long and complex supply chains and production cycles. 1. the process of amending the EU POP Regulation is rather in-transparent (e.g. compared to REACH) and thus the possibility for Stakeholders to comment and contribute to implementable legislation is not sufficient. 2. Sufficient transition periods are needed and impact oriented acting is necessary. 3. Existing legislation covering a sector specific use of substances needs to be accepted as appropriate RMO (e.g. use of lead in vehicle application should not interfere with REACh) 4. Qualification of consultants (e.g. for stakeholder consultations). Consultants should have a professional experience in that field that is assessed eg. for chemical hazard assessment there should be at least a scientific based university education with chemistry and toxicology and additional 3 years of relevant professional experience or 5 years of professional experience in the field they assess. 5. Cross sector specific timelines should be considered more thoroughly in implementation. The differences of e.g. packaging-materials in comparison to durable and complex products have to be considered with regard to lead-time and specific

	derogations (see comment above for spare parts). With regard to transparency ACEA is concerned about late notification/publication of specific obligations. Just recently the revised Annex II of the ELV directive has been published in May 2016 with a phase out date on 1 January 2016 for lead in particular applications (exemption 8h). A publication date after a phase out date is makes it extremely difficult for OEMs and impossible for suppliers (in particular if they are deeper in the supply chain) to adjust processes accordingly. Also phase-out dates for new vehicle types up from 2017 (8fa and 10d) are difficult to handle when published only 7 month before introduction as the development of vehicles launched in 2017 has already been started around 2014. Sufficient lead time has to be considered a crucial prerequisite to adjust industrial processes in order to ensure compliance throughout the supply chain.

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

Hazard identification criteria	3
Risk assessment and characterisation	2
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	4
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	3
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.	We are concerned about the lack of impact orientation in recent decisions and conclusions from consultants and legislators. Waste related legislation like ELV or RoHS are very detailed and restricting even for very low amounts of remaining heavy metals. After very successful reduction and phase out of heavy metals in most applications other major sources are handled not in the same manner. A cost calculation on the yields of each legislative measure should be a mandatory part of decisions e.g. avoidance cost per g and affected sector. Calculation models for cost avoidance should be developed and used in a coherent and transparent manner. They also should reflect the endpoints of a product and specific regulation. E.g. for vehicles the end points and the utilization are regulated very well in the EU and waste categories according European waste catalogue enable a tracking of

	volumes and end points. An end-of-life vehicle is going defined ways as a valuable source of secondary raw materials. Products should be considered as one waste stream that can be handled and treated according to best management practices. Micro management on subcomponent level is not effective at our opinion. Distinctions with regard to the particular application of products are often not fully consistent. E.g. very energy efficient lamps containing mercury are restricted under ELV legislation but welcomed /tolerated in buildings and public illumination as energy saver even Hg amounts are higher. E.g. exemptions under ELV / RoHS regulate a total EU use of 0.2 t lead in a specific application whereas thousands of tons of lead ammunition are used per year and legally accepted directly released and dissipated into the environmentally sensitive areas. Safety data sheets and labelling are often of bad quality. Even if we well understand the question and its scope, due to the fact that REACH is not on the scope of the consultation we would like to emphasize that efficient tools to communicate safety data is of paramount importance for downstream user companies – in particular with long and complex supply chains. The quality of this information has to evaluated and checked thoroughly to enable safe handling. Errors and inconsistencies are compromising can lead to risk to human health and to the environment which could lead to legal penalties and loss of company reputation. To reduce this, companies must undertake burdensome checks and engagement with suppliers. Even if the situation is not yet satisfactory, we would like to emphasize that REACH and CLP obligations are improving significantly the quality of the safety data for chemicals from a downstream user perspective although the quality of SDS is still lacking to some extend and increased enforcement is required.
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 Good laboratory practice is at our opinion a suitable way to determine concentrations and responsible care. Additional market specific analysis methods should be transposed into global standards like ISO and harmonized between global markets.

PAGE 6: Efficiency

Q19: In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)	Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.
Q20: In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)	Costs for small and medium sized enterprises, Costs for large enterprises
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Classification requirements for substances and mixtures , Chemical labelling and packaging requirements, Risk management measures under the different legislation , Understanding and keeping up-to-date with changes in legal requirements , Training staff to ensure compliance with legal requirements , Inspections and administrative requirements, Other (please specify) It should be defined when a target is achieved. Eliminating the very last impurity or element is extremely cost intensive and ubiquitous background concentration levels or impact of transboundary emissions/immissions need to be considered. If there are non-anthropogenic natural emission levels a legal measure for anthropogenic emissions of a chemical substance derived should reflect this in an appropriate manner.

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. Very high sophisticated and too detailed regulation like e.g. RoHS are very difficult for being crosschecked. Enforcement of regulations for less than one microgram inside an electronic component is requiring enormous effort in analytics. Cut- off criteria and tolerated background concentration levels on component or article level are required to reduce costs for industry and monitoring authorities. The CLP/GHS method of ATEmix-calculation results in new burdensome administrative data collection of acute toxicity data. This could be improved by offering an Acute Toxicity data base on European level. Data could be collected out of the REACH dossiers for registered substances. Consortium can already flag the relevant key study for calculation the ATEmix for mixtures already during the registration process. This would help to improve data quality also for the SDS SECTION 11 and 12. On the long term perspective shortening of SECTION 11 and 12 could be considered if such a data base is implemented and operational. A similar way forward could be implemented for the exposure scenarios (comprehensive overview in one data base) and on basis of the safety-data-sheets (SDS) to shorten the process and to improve the quality.

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	3
Please comment	The Framework has led to a reduction in the number and/or use of hazardous chemicals. However, we are recognizing an increasing number of chosen substitutes to be regulated after substitution as well which leads to continuous substitution of substitutes and thus to a lack of planning certainty. The promotion of proven safer alternatives is something that needs to be optimised. Every substitution process costs money with regard to new release processes that have to be started. Substance assessment based on a unified system (REACH) helps to identify potential future risks if new substances are developed and intended to enter volume production. Taking nanomaterials as an example, legislation was slow to react (i.e. incorporation into the general framework) but member states are now taking a different route (e.g. registers) to deal with the situation. This lack of harmonized actions is posing a risk to EU competitiveness and is making adaptation even more difficult for global acting companies.

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	Legacy spare parts (repair as produced) principle under ELV but not under POP regulation. Gap between CLP and REACH
Overlaps	Overlaps of various chemical regulations and restrictions. Overlaps of ELV directive and Battery diretive (see below)

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.

Exemptions for legacy spare parts granted under the ELV directive but still not granted under the EU POP Regulation. Use of lead in vehicle applications is restricted by ELV legislation and the necessary use (regulated in particular exemptions) is periodically tracked and reviewed. If lead use will be regulated under REACh-authorization the ELV directive is (until now) not considered as an appropriate RMO and may lead to a double assessment. This will only lead to additional administrative burdens only and multiplication of workload.

It remains an open question what level on influence the fact of “unknown toxicity” obtained by CLP, might have. This also might be considered for a safe-use/work-place and environmental safety- in particular if considerable lack of data results in a non-classification and therefore a real risk assessment cannot be carried out.

There is a gap between REACH and CLP: REACH allows exposure based data waiving whereas under CLP such data waiving results in “data lacking”. This lack of data may result in the CLP requirement of “unknown acute toxicity”. CLP does not use the terminology “exposure” because it’s hazard based only.This might lead to serious problems if lack of data results in more stringent classification of mixtures, e.g. acute toxic vs. harmful.

The automotive industry is phased with an increasing number of partly overlapping and conflicting substance related regulation (ELV, Battery, Stockholm Convention, REACH…). Together with similar but partly deviating regulation from non-European markets it is more and more difficult to handle the substantial complexity of related requirements by internal compliance processes.

The End-of-Life Vehicle (ELV) Directive 2000/53/EC regulates all recycling relevant items around the design/production-, use/repair- and end-of-life-phase of vehicles and its components. All batteries and accumulators used in a vehicle are included.The battery directive (2006/66/EC) affects all batteries in cars, light vehicles as well as heavy vehicles, starting batteries as well as others.
The directive however clearly states in Article 2 that the ELV directive should be taken into account in the implementation. Other aspects of this are mentioned in e g Articles 8.4 and 16.2 and others.
ACEA sees contradictions and double-regulation regarding the battery directive and the ELV directive. Therefore ACEA sees the need to exempt cars from the battery directive in the following areas:
• Collection system :
Cars should be exempted from the battery directive concerning collection requirements as the same is already achieved by ELV-directive Art 5 and a collection is done more environmentally friendly and cost-effective if done together with the ELV.
• Treatment and recovery targets :
Cars should be exempted from the battery directive as treatment and recovery targets are already defined in the ELV-directive.
• Heavy metal thresholds :
The Battery directive is defining max. thresholds of Cd and Hg - however, without prejudice to Directive 2000/53/EC where thresholds for heavy metals are already covered for the automotive sector. Therefore the respective provisions of article Art 4.1 should not apply to the automotive industry to avoid contradictory regulation.
• Cost free take-back :
Cost-free take back for cars is already covered by the ELV-directive, Art 5.4 and the battery directive is not providing more specific regulations. Cost-free take back is based on the assumption of a complete vehicle, i.e. including all batteries.
• Battery Removal :
Art 11 of battery directive is suggesting that end-users should be instructed how to remove batteries. However, batteries are removed according to ELV Directive 2000/53/EC by authorized end-of-life operators. Batteries in vehicles should therefore be exempted from the battery directive

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	Yes
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	Hazard class for endocrine disruptor and corrosive to the respiratory system (should be an own hazard class and NOT a special labelling EUH071 only) are missing in GHS.

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	3
Industry association guidance and materials	5
Other (training, conferences, etc.)	No experience
Please add further details as necessary	The advices from the help desks are not consistently accepted from MS authorities. The interpretation from local authorities differs sometimes substantially. More consistency and coherence is required to provide a reliable and useful source of information – maintaining a neutral position that is not influenced by any particular MS opinion. It is crucial to improve a manageable and sophisticated search-function and a related database. This would also support an enforcement of consolidated provision of accurate data by registrants – including the closing of existing data gaps. Comments to CLP Guidance, Modul 2: Following clarifications are required either in the CLP regulation itself or in the guidance: 1. Non-additivity concept for irritation/corrosion effects: It has to be clarified that this concept does not play any role at Europe. Alternatively, it has to be specified in more detail when it should be used (at the moment it's not clear enough stated resp. no sufficient support in the Guidance document 2. Clarification that the additivity formula for acute aquatic and chronic toxicity does not play a role in Europe or delete it completely, if comparable with building block approach. 3. Crucial need for clarification on the fact that the used ATE values for mixture classification (calculation of the ATEmix) are

	not in contradiction to the harmonized classification. Our industry experts are detecting many cases where legal classifications are ignored by using ATE values which can lead to ignorance of even the minimum classification. 4. The ATEmix calculation in Europe should be reconsidered with regard to the cut-off criteria. At the moment any substance with an ATE > 2000 mg/kg (e.g. oral exposure route) must not be considered for calculation and is therefore cut-off before calculation carried out. This result in different ATEmix values compared to those legal areas who decided to cut-off the category 5 after calculation of ATEmix (like USA and Canada). Fact is that this specific European approach results in a global lack of harmonization and should be eliminated! 5. Clarification that testing of physical-chemical data is required or sufficient justification for data waiving/non-classification must be submitted (see CLP Art. 8.2) 6. Clarification that in case of new information (for example obtained by restriction processes) manufacturers have the duty to initiate the change process of harmonization process according to CLP, Art. 37.6) immediately. This is often ignored in the supply-chain. With regard to this it remains unclear why these obligations is additionally put on the end-user. The obligation to comply should be detected already earlier in the supply-chain 7. The label of the “unknown acute toxicity/aquatic toxicity” should be deleted. It is sufficient to put this information into the SDS of mixtures as additional information to the classification. 8. It should be clear stated either in CLP or SDS guidance that all kind of SCLs are part of the classification of a substance and have to be communicated along the supply-chain (like already stated for M-factors).
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 Member states sometimes do have other opinions on the criteria because guidance documents leave room for interpretation. Enforcement is different in some member states. Particular member states have a much stronger enforcement and stringent interpretation than others

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	A useful provision of classification-relevant acute toxicity data for downstream-users (among them SMEs) and product manufacturers should be improved. It has to be avoided that various/all parts of the supply chain have to investigate toxicity data on their own to make Acute Toxicity Estimate of mixture (ATEmix) data coherent and comparable. The knowledge of data gaps has to be transparent to enable CLP classification and labelling (problem of unknown acute toxicity). See the points above

Q33: CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?

Transition period is sufficient

Q34: To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)

Transparency of the procedures	4
Involvement of stakeholders	4
Quality of scientific data and related information	4
Speed of the procedure	2

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

Registry of intention / annexe dossier ensures a quite good transparency, but took too much time - in some cases. There are examples where scientific data are collected and interpreted for a restriction proposal and did not directly resulted in a change of legal classification (e.g. D4/D5). In other cases very important data for correct classification are missing (e.g. acids and bases with regard to systemic acute toxicity). Process of harmonization of classification is often too long and leads to increasing uncertainties in initiating required substitution processes. Industry requires complete and scientific correct classification of substances and mixtures for sustainable release processes.

PAGE 10: Part V: Additional comments

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

The challenge of regrettable substitution is one of the major cost drivers in industry. We would like to reemphasize the importance of guidance to industry regarding the selection and use of safer alternatives to substances under legal scrutiny.