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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Joerg Seifert
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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.**	20132976103-18
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]:**	Agriculture, forestry and fishing (A) , Other (please specify) Feed additives and Premixtures

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	4
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	4
Ensuring a well-functioning internal market	3
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	No opinion or not applicable
Protecting the environment	The legislation is unclear
Ensuring a well-functioning internal market	The legislation is unclear, The legislation is not effectively implemented
Stimulating competitiveness and innovation	No opinion or not applicable

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

EU-level legislation adds value to national level action	3

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)
,

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

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

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

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

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

Pregnant workers (Directive 1992/85/EEC),

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

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

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

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

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

Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
,

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

Drinking Water (Directive 98/83/EC),

Pressure equipment (Directive 2014/68/EU),

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

Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
,

Protection of animals used for scientific purposes (Directive 2010/63/EU)
,

Other (please specify)
Inland transport of dangerous goods (2008/68)

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
The hazard classifications that companies assign their products has to be more properly controlled. There are many companies in the EU that don't properly classify their products as dangerous to the environment (hiding behind the intended use that seems to be exempt, while the product is very similar/the same as included) and there is no control over this. This creates an uneven playing field. Hazard classifications should be regulated and policed. Specific risk assessment changes in the exposure scenario or any future/new (not yet known) exposure scenario would lead to a long process of risk assessment. A generic approach is more convenient to maintain innovation and competitiveness for a sustainable risk management. However the generic approach has to be proportionate and should not overuse the "precaution principle" or overestimate exposure. There could be difficulties with both systems of risk assessment depending on the sectors represented, knowing that the human health and environment protection requires always the same level. A continuum system might be best: generic approach as a basis, amended/completed by a specific approach when data are available, and/or when it is appropriate/relevant. Risk assessment should be more intended for use orientation (14a). The current matrix with partial scope exclusions creates confusion in agencies like ECHA and EFSA. Although not optimal it might be better and would be fully an EFSA responsibility for Food and Feed products evaluated by EFSA for placing on the market (eg. including the SDS – transport risk – using the best practices developed by other agencies).

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.
When arriving at a hazard classification is it the substance itself or the active substance (mineral) that should be used for the classification? This aspect is unclear in the legislation when referring to trace elements. Calculation within CLP is very difficult. We calculate our finished products ourselves. There are many suppliers of software. But I really doubt the correctness of this software. Another point for the calculation within CLP: laboratories perform a tests for skin corrosion which can change the product classification from the calculated corrosive to irritant. In some situations risk management can be too political or driven by poorly informed committees, and not consistent across different applications for the same active substance, and it should be largely based on solid scientific facts. Other considerations taken in the risk management are poorly documented. Hence, it is difficult to know to which extent the other relevant considerations are taken into account, to compare the risk assessments (evaluating part of the hazard and/or risk of a chemical substance or mixture). The laboratory performs many tests for skin corrosiveness according to prescribed testing methods (OECD 431). The calculation methods from the CLP regulation are too strict. The outcome of the calculation of a lot of products (for example premixtures) is corrosive, but according to the prescribed tests they are not. The products are irritants. The labelling of the product is then not corrosive but an irritant and is also much easier to transport which leads to no ADR requirements.

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	3
Predictability of the outcomes	2
Stability of the legal framework	2
Clarity of the legal texts	1
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	I don't know
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.	The framework could be functioning better with respect to how companies classify the hazards for their chemical products. Specifically this relates to the feed additive sector which is probably not a high priority but companies need to be made to classify their products responsibly. Time to allow duty holders to adapt: Transitional measures are increasingly systematically included in regulations. Stability of the legal framework: Stability might not lead to a legislation in step with market evolution, or could lead to a legislation that hinders safe innovation. Clarity of the legal texts: Not easy to identify, understand and comply, with overlaps. Guidance documents and implementation support: The guidances may not represent over regulation unless they are clearly identified as having a legal binding effect. Their update shall be linked to the related regulation.

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.)	3
Risk management measures restricting or banning the use of chemicals	2
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	2
If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.	Regulated hazard classification procedures are needed because too many companies are flouting the rules and getting away with it. There is a lack of consistency in risk management measures set by different legislation. Regulated hazard classification is needed. Risk management measures are dispersed in several legislations.

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 more important that the use of EU Test Methods or OECD Test Guidelines are adhered to. Other equivalent quality systems might be evaluated and accepted in EU.

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 EU level , Costs for authorities at national level , 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
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. The main cost of the authorities should be to ensure controls for the implementation of the regulations. However there is a tendency to charge companies for compliance inspections (additional tax burden).

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	1
Please comment	The legislation deals with areas which are identified by industry as needing approval to place on the market. Little known initiatives for addressing innovation, new technologies through EU legislation – the effect of legislation tends to be to stifle and discourage innovation and new technologies.

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	Gaps/Inconsistencies. For example: Directive 2002/32 Contaminants In Feed: Toxins are described but no microbiological criteria evaluated as the source of the toxins (to deal with feed safety criteria and feed hygiene criteria).
Inconsistencies	Inconsistences exist whereby it is EFSA and the SCoPAFF who deliver the re-authorization using safety-related sentences that are similar to CLP but do not use the CLP criteria. This leads to labelling difficulties, especially for Feed Additives many of which are chemicals.

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.

Certain substances having multiple uses (e.g pesticides and veterinary medicines), may have different MRLs for the same type of products.
Safety for workers is described in regulation 1831/2003 on feed additives, evaluated by EFSA, and in parallel safety for workers is evaluated by REACH, and CLP is evaluated by ECHA. There are too many different and independent evaluations for the same substance chemical. A suggestion is to make the evaluation for placing on the market the leading principle for the applications of adjacent/overlapping regulations.

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?	5
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	Yes
Physical	Yes
Human health	Yes

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

Guidance documents	2
Helpdesks	4
Industry association guidance and materials	4
Other (training, conferences, etc.)	No experience
Please add further details as necessary	The guidance documents and the legislation are overly cumbersome to navigate and as such it does not encourage compliance. More focus on guidance documents for the feed sector would help. The guidance documents are very difficult to follow (for example the “Guidance of Application of CLP, 1.6.4.1 the calculation of a mixtures”). It would be very helpful if EU entities (particularly ECHA) would provide more guidance specifically aimed at the feed sector.

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 There is poor harmonization: In Holland for example they require all feed additives, premixtures and supplementary feeds to be labelled according to CLP even though supplementary feeds are not required to be labelled according to CLP.

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	3
International harmonisation through the Globally Harmonised System (GHS)	I don't know
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Calculation of mixtures is too complicated, and too complex, often making it necessary to make use of consultants. Too strict rules for certain mixtures (e.g. mixtures containing zinc and/or copper). For chemicals which do not have a harmonised classification, it is difficult to determine the correct classification since there may be several self-classifications available on the ECHA website. CLP: can be too complicated when you need to calculate the final status of the finished product: is it corrosive (GHS 05) or irritating (GHS 07) and maybe there is also an “environmental hazard” (GHS09). There are too many steps in this calculation (pH, specific concentration limit, general concentration limit, calculation of the raw materials together). There are many software suppliers, but there are doubts if they have implemented the calculation methods correctly. SDS: many customers asks for an SDS for non-hazardous products. There is a big difference in the quality of the SDS from the different suppliers (even for the same product) and also from suppliers within the EU. The REACH regulation states how to prepare an SDS but feed is excluded from REACH. Differences between small and big companies in how they approach the SDS preparation. Examples: copper sulphate: In some finished feed additive products copper sulphate is still copper sulphate (according to the SDS from the suppliers copper sulphate is dangerous for the environment). Some companies take the level of the copper sulphate in the end product. When this higher than 0.1% then they will mention GHS 09 environmental hazard on the label (CLP 1.1.2.2.2. table 1.1, blz 66).

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	I don't know
Speed of the procedure	I don't know

PAGE 10: Part V: Additional comments

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

Question 9: The EU legislation has a key role in the management of the protection of human health and environment. The legislation should be a tool to achieve a stimulating competitiveness and innovation with fair, applicable and predictable rules. Question 11:Legislation is not always uniformly implemented by the EU Member States, which leads to disruption of the internal market. The European Commission should have a more active role to ensure uniform implementation of legislation. Ineffectiveness due to the partial exclusion of the scope of certain applications. For example in REACH Feed Additives are excluded from the submission of a dossier however the provisions for the obligations of SDS apply. Some of the elements in the SDS depend on the provisions of CLP where again the formulation of the exclusion of eg. Feed Additives is inconsistent with the restrictions of a Feed Additive in the sense that it cannot be directly fed to the end user. The ineffectiveness of the chemicals-regulations especially for chemical-substances with a use different than industrial-chemicals is that the reference regulation (eg. 1831/2003 for feed additives) doesn’t give clear guidance on how to use specialized regulations like eg. CLP or ADR. Add to this DG Sante/EFSA (who cover Feed Additive Legislation) seem not fully to accept/understand what their colleagues in ECHA have developed. There is a lack of communication between the different reviewing agencies. In short, ineffectiveness from complexity & network of regulations. There are overlaps of legislation: not clear what is applicable to what, some discrepancies. Question 12: National legislation can increase complexity of the EU legal environment and it does not contribute to a well-functioning EU internal market. EU Chemical and chemical-related legislation: can add value to national level actions, without it national governments could avoid their responsibilities. Question 13: Regulation 396/2005 establishes MRLs for raw materials like wheat or corn. However, for processed commodities (e.g. wheat gluten) it is very important EU authorities establish processing factors to allow the determination of MRLs for those commodities. At the moment Member States use different processing factors with no consistency which causes problems for the internal market. Regulation 396/2005: feed is included in the spirit of this legislation even though there are no

stated MRL's. Question 25:The risk assessment looks inconsistent (either generic approach or specific approach). Question 35: In some Member States (e.g BE, PT, RO, HU) premixtures are not considered to fall under the scope of CLP despite according to EU 1831/2003 premixtures cannot be subministered directly to animals (B2B products). The formulation of the exclusion in the CLP regulation appears inconsistent with the product definitions in EU 1831/2003. This situation can create some confusion with the Directive on Inland Transport of Dangerous Goods since premixtures may have to be classified as ADR. Regulation on feed additives (as for food additives) may also be considered as legislations covering hazard identification and classification and covering risk management measures as identified in point 1 and 2 of the legislation covered by this questionnaire. Other: Trace elements Zinc and Copper can be dangerous to the environment. When labelling one needs to take account of the levels in the product and properly label according to the risks. Should they be labelled based on the level of active substance that is the cause of the risk (i.e. the element) or does one label according to the level of the 'compound present' in the bag (i.e. the zinc and copper salts)? Some companies label according to the level of the element, but it is not clear if this is stated in the regulations. SUMMARY: The REFIT of Chemicals legislation should overcome the matrix-type regulation and assign more clearly a reference legislation that is leading for a certain product. Specifically for Feed Additives we would expect that the 1831/2003 Regulation with the associated regulations on the contents of Feed Additive dossiers is the leading reference. These regulations should leverage other regulations (eg. CLP) to allow consistency and best practices. This way for a feed additive, CLP would be an instrument within the Feed Additive legislation and it could overcome the confusion of the exclusions. At the same time, using the best practices from CLP in the worker risk assessment paragraph of the Feed Additive evaluation, inconsistency can be avoided with other legislation (in a similar way that the dangerous goods transport regulation can be applied). This approach should allow producers and users a clearer basis for compliance – reference regulation and guidance documents should help in the application of regulations that interfere with Feed Additives (eg. The drinking water legislation overlap which is relevant and overlaps in some situations).