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COMPLETE

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IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address

Contact name	Ole Schrader
Organisation/company	Henkel AG & Co. KGaA
Country	Germany
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.

To be filled

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 business

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 soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4)
,
Manufacture of other chemical products (C20.5),
Other,
Other (please specify)
Adhesives & sealants, surface treatments, biocidal products

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

Large company (250 employees or more)

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

Global

PAGE 3: Part II – General Questions

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

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	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	2
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:

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

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

EU-level legislation adds value to national level action	5
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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)
,
Chemical Agents (Directive 98/24/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),
Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
,
Waste framework (Directive 2008/98/EC) and List of Waste
,
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
,
Water Framework (Directive 2000/60/EC),
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),
Packaging and Packaging Waste (Directive 94/62/EC)
,
Export and import of hazardous chemicals (Regulation No 649/2012)
,
Persistent organic pollutants (Regulation (EC) 850/2004)
,
EU Ecolabel (Regulation (EC) 66/2010),
Safety of toys (Directive 2009/48/EC),

Cosmetic products (Regulation (EC) No 1223/2009) ,
Detergents (Regulation (EC) No 648/2004) ,
Drinking Water (Directive 98/83/EC) ,
Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)
,
Aerosol dispensers (Directive 75/324/EEC) ,
Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
,
General Product Safety (Directive 2001/95/EC) ,
Test methods (Regulation (EC) No 440/2008) ,
Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
,
Protection of animals used for scientific purposes (Directive 2010/63/EU)

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
Most chemical products for end users, especially for consumers, have a well defined use and associated exposure. For some of those product categories safety assessments are well established, e.g. cosmetics , detergents and biocidal products. Such use specific safety assessments should always overwrite generic risk considerations based on hazard classification. Especially, chemicals should not be generally banned for defined uses based on hazard classification without taking into consideration use specific risk assessments (e.g. BPR Art.5 Exclusion criteria; cmr substances in cosmetics).

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.

Combined effects of chemicals and vulnerable populations are addressed where necessary, e.g. under the Cosmetic Products Regulation. However, impact assessments, especially economic (e.g. jobs and competitiveness), are lacking. For example, the BPR bans active substances from approval based on hazard classification ("exclusion criteria"), without assessing potential benefits to society .

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	4
Speed with which hazards/risks are identified	5
Speed with which identified risks are addressed	5
Time to allow duty holders to adapt	2
Predictability of the outcomes	2
Stability of the legal framework	2
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	2
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.

Whilst the overall framework is satisfactory, it is generally not acceptable when regulatory requirements, or their interpretation by authorities, change in a way that ongoing approval or assessment processes are effected without adequate time to adapt by industry. Examples are a) changes to rules and technical/regulatory guidelines under BPD affecting dossiers submitted years before; b) change of interpretation of Article 15, Cosmetic Products Regulation, automatically banning cmr cat. 2 substances upon entry into force of the CLP classification, not providing for enough time to obtain a positive SCCS opinion. Furthermore, relevant regulations are partly unclear and/or requirements are differently interpreted and enforced by member states, e.g. definition of "placing on the market", deviating acceptance of hazard classification based on DetNet data and related assessment methodology by member states.

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	4
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	2
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	4
Risk management measures restricting or banning the use of chemicals	1
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	5

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.

The hazard classification criteria for skin and eye irritation/corrosion are more stringent under CLP than under DSD. This results in more severe hazard labeling under CLP. A hand dish wash product may be labelled as skin corrosive in the same way as a drain cleaner. As a conclusion, consumers cannot distinguish the hazard potential anymore, and even severe hazards may not be identified and taken for serious adequately. In contrary, for cosmetic products, the communication to consumers is risk-based and this works very well. Furthermore, hazard identification criteria simply do not work for some chemicals (e.g. PBTs and vPvBs criteria for silicones and resulting impact on cosmetic products). Regarding risk management measures restricting or banning the use of chemicals in please see the comment under question 14 + 16 above.

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

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)	<p>Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.</p> <p>,</p> <p>Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.</p> <p>,</p> <p>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.</p>
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)	<p>Costs for small and medium sized enterprises ,</p> <p>Costs for large enterprises, Costs for consumers</p>
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	<p>Classification requirements for substances and mixtures</p> <p>,</p> <p>Chemical labelling and packaging requirements ,</p> <p>Risk management measures under the different legislation</p> <p>,</p> <p>Understanding and keeping up-to-date with changes in legal requirements</p> <p>,</p> <p>Training staff to ensure compliance with legal requirements</p>
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	<p>I don't know</p>

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

Novel areas of concern sufficiently addressed by framework 4

Please comment

Emerging areas of concern are sufficiently addressed. As a principle, regulatory action should not be taken on the basis of pre-mature scientific knowledge and without adequate definition of the regulated topic, e.g. implementation of requirements on “nano” and “endocrine disrupters” in several pieces of legislation without a definition of “nano” and “endocrine disrupter”.

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 Disagree

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.

Overlaps

Restrictions/bans in sector legislation based on CLP classification, e.g. the incorrect application of Article 15 of the Cosmetic Products Regulation – see detailed answer to question 16.

Inconsistencies

Labelling requirements under BPR, Detergents regulation and CLP ,e.g. labeling of preservatives

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.

Overlap, potentially resulting in inconsistencies, between risk management measures/precautionary phrases under CLP and occupational health requirements on the one hand and REACH safety assessment/safe use communication on the other hand (e.g. OEL vs DNEL).

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? 2

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 4

Helpdesks 4

Industry association guidance and materials 5

Other (training, conferences, etc.) 5

Q31: To what extent is CLP enforced in a harmonised manner across Member States?

Enforcement is not harmonised across most Member States

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Please add further details as necessary
Significantly missing harmonization of enforcement between Member states was identified with respect to - Implementation deadline for GHS classification of mixtures ("placing on the market") - Acceptance of hazard classification and labeling of detergents based on DetNet ^{aa} Member States' competent authorities interpret CLP differently. In some countries authorities do not take into account that the decision tree for classification has been changed under CLP compared to DPD, i.e. test data on mixtures/similar mixtures have now prevalence before the additivity approach. Furthermore, experience from inspections shows that the application of Bridging Principles and Weight of Evidence determinations including expert judgement as well as data from certain in vivo and in vitro tests are not accepted every in the same way leading to stricter classification in some Member States than in others. ^{aa} Lack of harmonization results in a fragmented approach towards classification and labelling of the same product type. This leads to disruptions in the free movement of goods. In addition, higher costs for businesses occur when selling the same product type in various Member States.

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 3

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) 3

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

Hazard classification criteria for mixtures with respect to skin and eye irritation of surfactants result in inappropriate hazard classification and labeling of detergents and cleansers.
International harmonization is the main benefit from GHS implementation and should be further improved with respect to -
Harmonization of mandatory national classification lists (e.g. CLP Annex VI) -
Harmonization of implemented building blocks and UN GHS revision number (e.g. harmonization of national update frequencies -
Harmonization of the use of GHS for consumer products (not implemented in e.g. USA)

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 too short,

Please elaborate if you answered that the transition period is too short or too long.
Revision of CLP covers changes in legal classification of substances (Annex VI), as well as e.g. editorial changes in H and P phrases without impact on safety information communicated (taken over from UN GHS). However, any change triggers massive workload with respect to review and update of all relevant product labels. Whereas the transitional periods may be considered adequate for safety relevant changes, the transitional periods are inadequate with respect to editorial changes, especially, taken into account the biannual frequency of UN GHS updates. As a conclusion, the update frequency and transitional periods should differentiate between "major changes" and "minor changes".

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

Transparency of the procedures	3
Involvement of stakeholders	3
Quality of scientific data and related information	4
Speed of the procedure	3

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

With regard to harmonized classification and labeling (CLH) public consultations, the commenting period of 45 days is too short. If companies have available relevant data for the respective substance, e.g. due to REACH registration, more time is needed to adequately review the CLH dossier, and to identify relevant new data and prepare for scientifically valid argumentation.

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 approach of analyzing efficiency and effectivity of existing legislation, before generating new regulatory requirements, is highly welcomed.
