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IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address

Contact name	Gerard Luijkx
Organisation/company	Unilever
Country	Netherlands
Email Address	

Q2: If you have a Transparency Register ID number, please provide it below. If your organisation is not registered, you have the opportunity to register now by following this link. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and, as such, will publish it separately.

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Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.

My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication

Q4: We might need to contact you to clarify some of your answers. Please state your preference below:

I am available to be contacted

Q5: Please indicate whether you are replying to this questionnaire as:

A business,
Other (please specify)
Note: The questionnaire is completed for the Unilever Home and Personal Care 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)

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	5

Q10: Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	1

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, The legislation is not effectively implemented
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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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)
,
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),
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),
Packaging and Packaging Waste (Directive 94/62/EC)
,
EU Ecolabel (Regulation (EC) 66/2010),
Cosmetic products (Regulation (EC) No 1223/2009),
Detergents (Regulation (EC) No 648/2004),
Aerosol dispensers (Directive 75/324/EEC),
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)

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
For home care products CLP is the leading legislation which is purely based on labelling on hazard. For consumers this leads to confusion as to how to use the products safely based on the assessment of risk, taking into account exposure. So a more risk based approach would be desirable. Cosmetic products have a well defined use and associated consumer exposure. The human safety of cosmetics products is addressed under the Cosmetic Regulation. It requires a safety assessment of each cosmetic product before the product is placed on the market and demonstration of the safe use of substances in the Cosmetic Product Safety Report. The environmental safety of substances used in cosmetic products is addressed under REACH, which enables the assessment of environmental safety in a cross-sectoral manner. This also ensures the environmental safety of substances at consumer use level. In those cases where concerns are identified in relation to specific uses (including in cosmetics) risk management measures must be identified and communicated through the supply chain, via the extended Safety Data Sheets of substances. These risk management measures ensure occupational and environmental safety. Environmental concerns are addressed through the restriction or authorisation process which apply to substances used to formulate cosmetic products.

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.
For home care products the implementation of EU regulations affects competitiveness. Member states often have different interpretations of the regulatory text and enforces the requirements differently. This stifles harmonisation. Even Commission rulings are sometimes not adhered to and there is no mechanism to impose such rulings onto the member states. For cosmetics, the combined effects of chemicals and vulnerable populations are addressed under the Cosmetics Products Regulation. However impact assessments, especially economic (e.g. jobs and competitiveness), are lacking.

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

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

Speed with which identified risks are addressed	5
Time to allow duty holders to adapt	1
Predictability of the outcomes	1
Stability of the legal framework	4
Clarity of the legal texts	2
Guidance documents and implementation support	1
Effective implementation and enforcement across Member States	1
Consistent implementation and enforcement across Member States	1
Public awareness and outreach	2
International collaboration and harmonisation	1

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

For Home Care products the main issues lie in the timelines to allow industry to adapt to changes in the regulations. When different timelines exist for substances and mixtures, intended to allow down stream users to get data on substances before they apply these in mixtures, it should be realized, that often mixtures are also used as ingredients, hence putting deadlines on top of each other, which does not allow the whole supply chain to adapt sequentially. An even more important issue is the fact that the legal text leaves ample room for interpretation, which leads to disharmonisation due differences in interpretation by member state authorities. Guidance prepared should be more clear and in line with the objectives of the legislation. The overall regulatory framework for substances in cosmetic products is designed to operate based on a risk assessment and is satisfactory. For cosmetic products, first, the risk is evaluated by the Scientific Committee for Consumer Safety (SCCS), and then translated into a regulation (i.e. restriction, ban, authorization) entering into force after publication of an amendment to the Regulation. Not satisfactory, however, is the approach to substances classified as CMR under CLP. This is caused by a new interpretation of the 2009 Cosmetics Regulation vs the original Cosmetics Directive, which is not supported by substantial changes in the CMR related provisions. Because of this new interpretation, a substance classified as CMR 1 or 2 under the CLP becomes automatically banned upon the entry into force of the CLP classification without an amendment of Cosmetic Products Regulation anymore. The only accepted exception is for industry to obtain a positive opinion from the SCCS. However, the time available is insufficient (i.e. cosmetics

industry to submit a dossier, SCCS to evaluate it and then Commission to regulate in the Cosmetic Products Regulation). Next to this, further guidance is needed regarding the specific exemption criteria for CMR1, for example regarding overall exposure (how to assess and split between various product groups using the ingredient), suitable alternatives and compliance with food safety criteria requirements. The current situation has already led to legal uncertainty where substance considered banned are at the same time positively listed in the Annex or where industry needs to (prepare for) move out, while at the same time work is ongoing to demonstrate safe use of an ingredient. Also, ingredients are lost for use without any evidence of health issues related to the use of the substance in cosmetic products. In our view the Cosmetic Product Regulation should drive risk assessment and management process based on clear timelines and criteria, while hazard-based approaches banning potential safe uses must be avoided. This ensures a fair chance to defend safe ingredients without unnecessary disruptions in the market, while if needed also appropriate restrictions and transition times can be put in place.

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

Hazard identification criteria	2
Risk assessment and characterisation	4
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	1
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)	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.

For Home care products CLP prescribes a hazard based labelling, which does not inform consumers on real risks, and leads to confusion. Emphasis should be more on the risk based rather than on hazard and on clearer communication on how to use the products safely. For cosmetic products, the communication to consumers is risk-based and this works very well. However the risk management measures restricting or banning the use in cosmetics of substances classified as CMR in CLP are not satisfactory (see question 16). The hazard identification criteria applicable to PBTs and vPvBs need improvement.

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
For Home Care products and substances, GLP is critical to ensure reliability and reproducibility of data and further to ensure that any protocol deviations are captured for assessment. Here "safety data" would include toxicology, environmental fate, ecological effects and physical chemistry data (pH, octanol water partition coefficient etc). Not all of these are datapoints are always equally critical (e.g. pH for non-extreme pH formulations) In these cases GLP should not be an automatic requirement.

Q19: In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)

Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.

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

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Reducing the damage to the environment and to ecosystems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.

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, Costs for consumers

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)

Main costs are driven by administrative burden related to classifications, product labelling and information provision on websites and to e.g. authorities and poison control centers, as well as adapting to changes in substance classification and changes to regulatory requirements.

Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?

I don't know

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 5

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	Strongly Agree
The EU chemicals legislation framework is internally inconsistent	Strongly 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	For Cosmetics Products, the incorrect application of Article 15 of the Cosmetic Products Regulation related to ingredients classified as CMR 1 or 2 in CLP, creates an overlap between both regulations. This leads to legal uncertainty and conflicting requirements for the same substance. Further information is given in the answer of question 16. For Home Care there is significant overlap between REACH and BPR on the assessment of risks of substances. Additionally there are overlaps between Detergent Regulation, CLP and BPR w.r.t labelling of allergens and preservatives on pack. Furthermore CLP labelling of outercases overlaps with transport labelling.
Inconsistencies	The inconsistency in the framework is mainly driven by the risk based approach of REACH and BPR versus the hazard based approach of CLP.

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.

For cosmetic products we would like to refer to the answer of question 16

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? 1

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 2

Industry association guidance and materials 4

Other (training, conferences, etc.) No experience

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

Enforcement is not harmonised across most Member States
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Please add further details as necessary
There are different interpretations between Member States on the use of bridging and expert judgement in CLP for classification of mixtures, differences in views of what P statements should preferentially be used in CLP labels, and differences in enforcement of legislation especially 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 1

International harmonisation through the Globally Harmonised System (GHS) 2

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

Classification criteria for home care mixtures when it comes to use of in-vitro methods and bridging to data on similar mixtures , as well as the used of expert judgement and existing human data are in principle OK. When it however comes to practical implementation ambiguities exist, which are made worse by different interpretation by Member States and inadequate and restrictive guidance. The calculation method for skin and eye irritancy seems to be too conservative. The international harmonization through GHS is hampered by the different regions/countries adopting different 'building blocks' from GHS (e.g. when a country adopts hazard categories that are optional and not adopted by the majority of states).

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.
For Home Care Products too short transition periods are often linked to the fact that mixtures used as ingredients have the same deadlines as the final mixtures than contain these ingredients mixtures, putting pressure on the last actor in the chain to do very fast transitions. For cosmetic products the transition time is too short to ensure a fair chance to defend safe ingredients without unnecessary disruptions in the market (see answer to question 16).

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 2

Quality of scientific data and related information 2

Speed of the procedure 4

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

Recent CLH proposals by the RAC committee seem to indicate that CLH proposals are adopted which lack sufficient scientific support and seem to be more influenced by political arguments e.g. MIT on skin sensitisation

PAGE 10: Part V: Additional comments

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

Respondent skipped this question
