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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Sylvie Lemoine
Organisation/company	Dow Corning Europe
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.**	55291765363-39
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 other chemical products (C20.5) , Manufacture of rubber and plastic products (C22) , Other (please specify) Manufactue of specialty chemical substances and mixtures in different forms (silicones)

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	3
Protecting the environment	3
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 adapted to the issues at stake
Protecting the environment	The legislation is not adapted to the issues at stake
Ensuring a well-functioning internal market	The legislation is not effectively implemented
Stimulating competitiveness and innovation	The legislation is unclear

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

EU-level legislation adds value to national level action	5

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.For other stakeholders - Please select the legislation you are familiar with.

Classification, labelling and packaging (Regulation No (EC) 1272/2008)
,

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

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

Chemical Agents (Directive 98/24/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
,

Waste shipments (Regulation (EC) No 1013/2006),

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)
,

Packaging and Packaging Waste (Directive 94/62/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)

,

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)

,

Other (please specify)
Construction legislation (emissions from building materials)

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
Regulatory decision-making should systematically rely on risk assessment (see above). Risk assessment is central to industry's chemicals management approach in order to determine how and under what conditions a chemical can be safely used. The risk associated with each chemical is dependent on the specific use for which it is intended, as well as the conditions for use (e.g. amount, containment, personal protection measures, packaging, and awareness of user). Therefore a specific risk assessment is in general more appropriate to define the most effective risk management measure whilst preserving societal benefits. Risk assessments should be based on the weight of all available evidence and consider the specific characteristics of each individual substance. There are situations such as for PBT/vPvB substances where meeting or exceeding the generic numerical threshold (the bioconcentration factor in particular) does not imply that there will be exposures leading to adverse outcomes in the environment. This is because default criteria do not adequately predict the behavior of a substance in real life and consideration should be given to the full range of scientific studies, including environmental measurement, metabolism etc, before a decision for regulatory action is taken. Areas where decisions are in practice more driven by hazard than risk, even when risk assessments are carried out include: the selection of priority substances under the Water Framework Directive and setting Environmental Quality Standards; the nominations of substances to the Stockholm Convention on Persistent Organic Pollutants (POPs) and subsequent evaluations by the POP Review Committee; and the consideration of environmental properties under the Seveso III Directive.

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. IMPACTS ON COMPETITIVENESS of EU industry are generally not considered in the context of regulatory decision making on risk management. At best, these impacts are estimated before the main legislative act is proposed by the Commission to Parliament and Council – but not necessarily considered when the rules are finally adopted and become law or when they are implemented. TECHNICAL FEASIBILITY AND ECONOMIC IMPACT should be fully and systematically considered (e.g. for harmonised classification decisions under CLP because of the downstream consequences of such classifications). Similarly, societal benefits of products are insufficiently considered in the decision-making process. Finally, where a COST-BENEFIT ANALYSIS has taken place these are not always considered during the final voting stage of new legislation. Any change of scope of a regulatory proposal, or any significant change in the proposed provisions (e.g. at REACH Committee level), should take into account cost-benefit aspects.

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	4
Time to allow duty holders to adapt	3
Predictability of the outcomes	1
Stability of the legal framework	2
Clarity of the legal texts	3
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	4
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.	TRANSPARENCY OF PROCEDURES: While most ECHA procedures are transparent (rating 4), this is not always the case for other institutions e.g. European Commission or EU Council (rating 2). For example, in March 2016, the European Commission proposed to the

European Council to nominate one of Dow Corning's key raw material (substance "D4") as a Persistent Organic Pollutant under the Stockholm Convention. This came without prior notice, in parallel to the on-going D4/D5 REACH Restriction process, with a very short time for decision-making within Council. Industry has never been informed, let alone consulted. Documents and discussions taking place at EU Council level also lack transparency. Even at ECHA level, more transparency is desirable in relation to specific procedures (e.g. harmonized C&L decisions, decisions on CoRAP listing of substances, on screening process etc). PREDICTABILITY / STABILITY: Areas where a lack of stability and predictability have been noticed include: - Agreements on interpretation and technical/regulatory guidance are constantly changing sometimes with very tight deadlines for application. - The RMOA process is not consistently applied or followed. So in practice, a substance subject to regulatory action under one piece of EU legislation could be subject to scrunity or regulatory action under another piece of EU legislation at any time (e.g. REACH restriction and POP Regulation). - The CoRAP and PACT lists are updated at a pace that does not allow predictability (hence investment) for the chemical industry. A formulator or chemical user cannot be certain that a substance that is available now will be allowed for use in the next years. In other words, there is a "sword of Damocles" constantly hanging above almost every chemical substance. - The lack of clarity of the legal text can be a reason for poor predictability (e.g. PBT, vPvB criteria of REACH Annex XIII). GUIDANCE DOCUMENT AND SUPPORT: Significant efforts have been made to provide support to industry (and authorities) in the form of Helpdesks, Guidance, Tool, Manuals etc. There is one area where Guidance is still missing, which is the practical application of weight-of-evidence to multiple pieces of data. Guidance is needed for a more scientifically robust weight-of-evidence approach, including an objective scoring methodology that allows selecting the most reliable, relevant and highest quality data at different levels including environmental measurements. This will increase predictability. At present there is a divergence between the commitment to weight-of-evidence (WoE) consideration and how substances are being identified in practice. For example, existing guidance explicitly refers to the need to "use all available data for assessing B" but it unfortunately is always followed by "the WoE and all the available data need to be compared back to the criteria defined in the legal text" which for B is only the surrogate

Bioconcentration Factor. CONSISTENT IMPLEMENTATON AND ENFORCEMENT: enforcement across Member States varies across many chemicals and chemical-related legislation. In general, there are still too many divergences in implementation from one Member State (e.g. regulatory acceptance of in vitro alternatives or other alternatives to animal testing, application of Weight-of-Evidence and expert judgment, setting of specific concentration limits, downstream consequences of CLP classifications e.g. on waste or water management). INTERNATIONAL HARMONISATION: more international coherence, e.g. on common principles for hazard and risk assessment, application of weight-of-evidence, prioritization of chemicals, would improve the international chemical regulatory environment. Regional differences in GHS implementation add complexity to supply chain communication and in safety data sheet content management. In this context what is often mentioned is lack of harmonization in the applied hazard classes and categories, as well as in the regional application specific annexes (e.g. Annex 5 to GHS on ‘likelihood of injury’).

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.)	3
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	4
Risk management measures restricting or banning the use of chemicals	2
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.	Hazard identification is often based on laboratory testing conducted in conditions that have nothing in common with reality (excessive doses, irrelevant route of exposure, environmental testing artificially forcing stable concentrations of volatile substances in the medium, etc). Physico-chemical properties of substances that are the basis of 'real-life behaviour' (volatility, partitioning, molecular weight etc) and route of exposure should be taken into consideration to determine if hazard found under laboratory testing can materialize as real-life hazard. This would not be an issue if regulatory decision-making such as bans and restrictions, or labelling (for consumers and professional users), was not based on these theoretical data. Hazard assessment should be followed by risk assessment prior to envisaging risk management measures. Where technically possible and justified, quantitative risk assessment should always be applied e.g. for PBT substances. More specifically, in the case of PBTs, the REACH guidance documents indicates that other evidence cannot be used to override a valid Bioconcentration Factor (BCF). However, by using the BCF only, a highly liphophilic substance could be deemed bioaccumulative even if it is broken down and never increases in concentration in the food chain. Field studies are more appropriate in this context. Data on metabolism where available, should also be taken into account.

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 We would like to stress that GLP is not always sufficient to decide on the most relevant study/safety data (data-rich substances): relevance, robustness are criteria that should be equally considered. GLP only ensures reproducibility of the study. Scientific validity including the relevance and applicability of the methods for the chemistry set need to be considered.

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 systems linked to above
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	I don't know

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 current EU legislative framework is appropriate to address emerging areas of concern. The framework should however consider the latest scientific advances with regards to new test methods, new methodologies, and ensure required testing is linked to clear human health or environment emerging concerns.

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	Neutral
The EU chemicals legislation framework has overlaps	Neutral
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.

Inconsistencies	At present there is a divergence between the commitment to weight-of-evidence considerations and how substances are being identified as PBTs/vPvBs within Europe and at international level too.

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.

Overlapping requirements between REACH and occupational health legislation.

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?	3
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	4
Other (training, conferences, etc.)	4
Please add further details as necessary	.
Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is not harmonised across most 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	2
Appropriateness of classification criteria and methods for mixtures	2
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	We noted that criteria for hazard identification or for classification are sometimes based on outdated high dose animal testing that are often performed by a route of exposure not relevant to actual human exposure. Environmental classification is based on test methods that 'force' the presence of a chemical even when naturally it cannot stay in water (volatility, strong binding to sediment or organic matter etc). For comments on international harmonization, see our reply to Q16.

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. The typical 18-month transition period for new classification applies to all actors in the supply chain at the same date. 18 months is a realistic timeframe for the first actor in the supply chain. For downstream users, there should be a staged transition period to allow the information to be communicated in the supply chain.

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	3
Speed of the procedure	2

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
Procedures are transparent but the decision-making basis is not (or not always). There is too little discussion with the RAC and too little stakeholder engagement. Many discussions take place in closed sessions. It is not always clear on which scientific study basis a classification relies, nor the quality of this study.

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	In relation to Q11: The EU chemicals legislation is strongly hazard-based and focused on laboratory testing that does not reflect actual conditions of use or actual environmental conditions, therefore is disconnected from issues at stake if such data are used as basis for regulatory action without further consideration. In relation to Q28: The 2012 ECHA Eurobarometer study and ECHA's study on safe use communication have shown that GHS/CLP pictogrammes are poorly understood in particular in the general public.