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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Doreen Fedrigo-Fazio
Organisation/company	ECOS
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.**	96668093651-33
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 non-governmental organisation (NGO)
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]:**	*Respondent skipped this question*
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	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	5
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	The legislation is not effectively implemented
Protecting the environment	The legislation is not effectively implemented
Ensuring a well-functioning internal market	The legislation is not effectively implemented
Stimulating competitiveness and innovation	The legislation is not effectively implemented

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

EU-level legislation adds value to national level action	5

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please 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)
,

Chemical Agents (Directive 98/24/EC),

Asbestos (Directive 2009/148/EC),

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

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),

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),

Batteries (Directive 2006/66/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),

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)

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 This reply relates exclusively to the regulation of nanomaterials. Ongoing gaps in and poor quality of information on the characterization and properties, hazards and exposure scenarios of nanomaterials continues to result in scientific and regulatory uncertainty. A risk-based approach that provides for substances to be excluded from the market only when public authorities can prove harm would not deliver adequate human health or environmental protection. For nanomaterials, a more cautious approach is needed, given the high level of uncertainty due to poor and little scientific information. A more generic risk-oriented approach, giving more weight to hazard profiles of substances, would better ensure adequate protection, while encouraging developers (of substances, nano-particles, and products containing them) to improve scientific information prior to placing products on the market.
Q15: In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.	No, If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to. In relation to nanomaterials, the ongoing poor quality and low level of information provided by industry has not resulted in products being excluded from the market (e.g. Cosmetics Regulation, except in unusual situations such as Portugal being the only country to exclude products containing nanomaterials). Legislation is not implemented or enforced adequately to apply pressure on producers/importers to provide sufficient quality information before placing products on the market. Also, legislation does not address combination effects of chemicals.

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	1
Speed with which hazards/risks are identified	1
Speed with which identified risks are addressed	1
Time to allow duty holders to adapt	5
Predictability of the outcomes	2
Stability of the legal framework	5
Clarity of the legal texts	1
Guidance documents and implementation support	3
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	3
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	In relation to nanomaterials, transparency has been non-existent. An example of this lack of transparency is the Commission's refusal to publicly publish the catalogue of nanomaterials used in cosmetic products which was legally required by January 2014. It has also not submitted an annual status report to European Parliament, as legally required. No information has been made available from the Commission, ostensibly because the information provided has been so poor. This situation should be publicly communicated and the legislation enforced in terms of excluding products from the market if information is not available.

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

Hazard identification criteria	1
Risk assessment and characterisation	1
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.)	1
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)	1
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.	In relation to nanomaterials, the continuing lack of reliable hazard characterization for nano-forms results in poor to non-existent risk characterization and risk management. Also, appropriate information on uses and routes of exposure are lacking, and information becomes too generic to build trust in users/consumers.

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

GLP aims to ensure quality laboratory behaviour, but does not address study design, execution or interpretation of results. Many studies omit fundamental information such as characterisation of the tested nanomaterial and its preparation, hence very few studies are reproducible. There are serious gaps between: a) the complexity of the technologies (nanomaterials, nanoparticles) and their (potential) applications b) the quality of the scientific studies being delivered to identify hazard, exposure, key endpoints, etc. to feed into regulatory risk assessment c) the needs of regulators to take decisions based on hazard/risk assessment, within a precautionary background setting d) the information (quality and level) being made available from industry e) the products continuing to remain on the market and new ones continuing to be introduced.

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 consumers, Costs for society in general

Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	We do not view the business costs of meeting EU chemicals legislation to be significant , Other (please specify) The Commission, national authorities and different stakeholders have conducted several studies on the costs and benefits of regulating chemicals when REACH was in development. These studies highlighted that the overall benefits to society are far beyond the costs for certain industry sectors. These include: - Pearce- Koundouri, 2003. The social cost of chemicals. WWF - University of Sheffield, 2005 The Impact of REACH on occupational helath.ETUC. - RPA, 2003. Assessment of the Impact of the New Chemicals Policy on Occupational Health. Commissioned by DG Environment. - DHI, 2004. The impact of REACH on the environment and human health. Commissioned by DG Environment. - KPMG, 2005. REACH- further work on impact assessment A case study approach. - European Commission, 2003. REACH Extended Impact Assessment.COM(2003)644final In particular, in relation to nanomaterials, it is up to a company to decide whether to include nanomaterials in its product portfolio, knowing that nanomaterials are complex materials with many ongoing uncertainties (scientific and regulatory). Costs to prove human health and environmental safety are therefore inherent. Beyond nanomaterials, the same logic applies to (potentially) problematic substances. Legislation should encourage industry to innovate away from problematic substances, which in principle it does, but regulatory uncertainty enters when enforcement and implementation are not strictly delivered.
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. For nanomaterials, as harmonized data requirements for companies to comply with are lacking, member state authorities have a daunting task in trying to gather sufficient information in order to protect the citizens, workers and the environment from the possible negative consequences of nanomaterials. In general for chemicals, the polluter pays principle has not been fully applied as costs are still borne by authorities and society rather than by the polluter, i.e. industry.

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	2

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 existing EU legislative framework (implementation) has proven to be clearly insufficient in addressing emerging areas of concern such as nanomaterials, endocrine disrupters, mixture toxicity, low dose exposure, combined risks, pharmaceuticals etc. In principle, these are addressed in the legal text, but implementation particularly by the European Commission has been deplorable, particularly in terms of unexplained and unjustified delays.

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	Disagree
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	Nanomaterials regulation is patchy and incoherent, from definitions used (biocides, pesticides, cosmetics, REACH) and an overarching definition is not legally bindingon that is not legally binding. Also, only certain pieces of legislation specifically seek to assess the risks from nanomaterials as distinct from the correspondent bulk substance. Therefore for nanomaterials the legislation is completely inconsistent and the precautionary principle is not applied.
Inconsistencies	Given that nanomaterials are not consistently addressed by different pieces of legislation, there is a clear need to have a reliable and coherent legislation that can be provided by a horizontal piece of legislation.

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.	*Respondent skipped this question*

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?	I don't know
To what extent are CLP labels effective in communicating hazards to consumers?	I don't know

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	No
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	Environmental: no hazard classes for PBT or EDC. Also several environmental hazard classes were lost when adapting to GHS. Human health: no hazard classes for inmunotoxicity, neurotoxicity, endocrine disruption.

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

Guidance documents	No experience
Helpdesks	No experience
Industry association guidance and materials	No experience
Other (training, conferences, etc.)	No experience

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

I don't know,

Please add further details as necessary
The ECLIPS project report shows very high deficiencies in quality of MSDS sheets throughout the EU, including wrong classification of substances and mixtures (see ECLIPS Working Group. European Classification and Labelling Inspections of Preparations, including Safety Data Sheets. FINAL REPORT. CLEEN, 2004. http://www.cleen-europe.eu/projects/ECLIPS.html). Also, through informal conversations with individual nanomaterial producers, feedback received by the producer on the information provided through SDS routes included a 200-page report on potential RMMs to be identified and selected by downstream user employers. This high amount of generic information renders OSH efforts impossible and unattractive for any company, thereby placing workers at risk.

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	1
Appropriateness of classification criteria and methods for substances	1
Appropriateness of classification criteria and methods for mixtures	1
International harmonisation through the Globally Harmonised System (GHS)	1
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Nanomaterials are not yet addressed appropriately.

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?

Transtion period is too long,

Please elaborate if you answered that the transition period is too short or too long.
The time for companies to adapt to technical progress is more than sufficient, particularly as it takes several years for a substance to be proposed for harmonised classification, to be included in the CLP Regulation and then transition periods are considered. Perhaps better information for companies in early stages is required, instead of considering giving longer periods to adapt to 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	1
Involvement of stakeholders	1
Quality of scientific data and related information	1
Speed of the procedure	1

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
No experience yet in relation to nanomaterials.

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