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PAGE 2: Part I – General Information about Respondents

Q1: Address

Contact name	David Azoulay
Organisation/company	Center for International Environmental Law (CIEL)
Country	Switzerland/US
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 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:

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	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	No opinion or not applicable
Protecting the environment	No opinion or not applicable
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

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

EU-level legislation adds value to national level action	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)

,

Plant protection products (Regulation (EC) No 1107/2009)

,

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

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

,

Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)

,

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

,

Cosmetic products (Regulation (EC) No 1223/2009),

Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)

,

General Product Safety (Directive 2001/95/EC),

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:

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 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. It is not possible to achieve a high level of protection of human health and the environment through a risk-based approach. Risk assessments are notoriously slow processes and a systematic lack of exposure data frequently leads to high levels of uncertainties meaning that the establishment of acceptable exposure levels are ultimately political, rather than scientific, decisions. 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 uncertainties or not dealt with adequately and decisions are rarely based on the precautionary principle. For nanomaterials information on hazard properties of most nano-forms is missing

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

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

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.

Transparency on nanomaterials has been non-existent. An example of this 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 banning products from the market if information is not available. Speed: in relation to nanomaterials the speed in which the policies are developed is, to say the least, unsatisfactory. There is no systematic system that ensures the protection from the risks of nanomaterials, although industry had repeatedly assured that REACH would provide all the necessary data in relation to nanomaterials, this is not the case as demonstrated in the dossiers and substance evaluation context. The experience with cosmetics and the lack of a transparency register to trace the presence of nanomaterials in products shows a bias towards keeping unregulated substances on the market despite the possible health and environmental implications. Examples of wide differences among MS is given by the fact that lacking EU wide initiative as a consequence of the strong lobby from the chemicals industry, Member States have started to regulate independently on nanomaterials so that several registers have been enacted and more will come given the Commission deregulation agenda in favor of SMEs and chemicals industry interests

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 due to the lack of reliable hazard characterization for nanomaterials forms, risk characterization and risk management are not at all satisfactory. Also, appropriate information on uses and routes of exposure are lacking.

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 is not a measure for the quality of research studies. GLP is a measure of good laboratory practice, not good study design, execution or interpretation. Myers et al. Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A. Environmental Health Perspectives 117, 3. March 2009 vom Saal and Myers. Good Laboratory Practices Are Not Synonymous with Good Scientific Practices, Accurate Reporting, or Valid Data. Environmental Health Perspectives 118, 2. February 2010. doi:10.1289/ehp.0901495

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.

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Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy

Q20: In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)

Costs for authorities at EU level ,

Costs for authorities at national level ,

Costs for small and medium sized enterprises

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)

There is no evidence that the cost for companies to implement EU environmental and chemicals legislation is higher than the burden that society has to suffer from the negative consequences of chemicals. Placing the burden on companies is the biggest incentive to prevent negative effect on the public. The example of nanomaterials clarifies the need to place the burden on companies. Without legal obligations clearly applying on companies, these tend to elude the obligation to provide safety data and place on the market chemicals that, when they will be properly assessed may be found to have caused significant harm. The Commission, national authorities and different stakeholders conducted several studies on cost and benefits of regulating chemicals in the frame of the REACH regulation development that highlighted the overall benefits for society are way over the costs for certain industry sectors. For example: - Pearce- Koundouri, 2003. The social cost of chemicals. WWF - University of Sheffield, 2005 The Impact of REACH on occupational health. 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

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. In relation to nanomaterials, lacking harmonized data requirements for companies to comply with, member states 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 shifted to the polluter.

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

1

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 has shown to be clearly insufficiently to address emerging areas of concern such as nanomaterials, endocrine disrupters, mixture toxicity, low dose exposure, combined risks, pharmaceuticals etc.

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

The regulation of nanomaterials is patchy. There are different definitions in different pieces of legislation and a harmonized definition that is not legally enforceable as it is only contained in a recommendation (though it has been used in the biocides regulation). 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. The precautionary principle is therefore not applied and the legislation is incoherent.

Inconsistencies

Given that nanomaterials are not consistently covered 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.

In relation to nanomaterials basically every piece of legislation is incoherent with the next one. For example the biocides and pesticides regulations, although regulating similar categories of products treat nanomaterials in completely different way. Every nano specific provisions in EU law (e.g.: in Biocide regulation, Cosmetic regulation, Novel food regulation) is based on a different definition of nanomaterials.

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
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To what extent are CLP labels effective in communicating hazards to consumers?	I don't know
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Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	No
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Physical	Yes
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Human health	No
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Please list any hazard classes that are not covered	several environmental haz class were lost when adapting to GHS, Human health: no hazard classes for immunotoxicity, neurotoxicity, endocrine disruption. No specific nano hazards
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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
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Helpdesks	3
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Industry association guidance and materials	No experience
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Other (training, conferences, etc.)	No experience
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Please add further details as necessary	National helpdesks are a key tool to provide support for companies, however many Member states do not have sufficient resources for them. Indeed for nanomaterials there is limited guidance coming from the EU Commission on how to deal with them in each regulatory context. There is no specific guidance that relates to the classification of nanomaterials.
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Q31: To what extent is CLP enforced in a harmonised manner across Member States?

	I don't know
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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	In relation to nanomaterials none of these elements have proven satisfactory

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 long,

Please elaborate if you answered that the transition period is too short or too long.
We believe that the time for companies to adapt to technical progress is more than sufficient taking in account it takes several years since a substance is proposed for a harmonised classification, it is 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	4
Involvement of stakeholders	3
Quality of scientific data and related information	2
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 in classification and labelling related 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.

We would like to highlight that the replies to this questionnaire are meant to relate only to nanomaterials in the context of non-REACH chemicals legislation. Therefore the comments on the complete inadequacy of chemicals legislation does not automatically extend to the regulation of all chemical substances and to the management of all hazards. However it is clear that placing the burden on the economic operator to provide safety data about uses of all chemicals is a basic principle that maximises the benefits from the use of hazardous chemicals and minimizes the costs for society.