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PAGE 2: Part I – General Information about Respondents

Q1: Address

| | |
|----------------------|---------------|
| Contact name | Guy Buckenham |
| Organisation/company | EDF Energy |
| Country | UK |
| 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.

Respondent skipped this question

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]:

Electricity, gas, steam and air conditioning supply (D)

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: National

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 | 4 |
| Protecting the environment | 4 |
| Ensuring a well-functioning internal market** | I don't know |
| Stimulating competitiveness and innovation | I don't know |

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

| | |
|---|--------------|
| Protecting human health | 4 |
| Protecting the environment | 4 |
| Ensuring a well-functioning internal market | I don't know |
| Stimulating competitiveness and innovation | I don't know |

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 | 2 |
|--|---|

PAGE 4: Part III - Specific Questions

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

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),

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

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Asbestos (Directive 2009/148/EC),

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),

Marine Strategy Framework (Directive 2008/56/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
 EDF Energy has found that in some instances, large amounts of EU resources are being spent registering, investigating and regulating obviously low risk activities. Recent changes to the Biocidal Products Regulations which have required operators of electrochlorination plants who produce active chlorine solely for their own consumption to submit a dossier under BPR to register as a producer in the same manner as a major chemical supplier. In this instance, the production of a biocide has been identified as a generically hazardous activity, and as such operators are all regulated in the same way regardless of their product, its intended use, their productions volumes, or whether or not they intend to sell their product. We believe that registration is an excessive requirement for production for own consumption on site. This is burdensome for the operator, for the national regulators, and for the European Chemicals Agency. We believe that a more specific risk assessment would demonstrate that production for self-consumption is relatively low risk and would allow our regulators and ECHA to focus their efforts on higher risk operations.

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.

Yes

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 | I don't know |
| Speed with which identified risks are addressed | I don't know |
| Time to allow duty holders to adapt | I don't know |
| Predictability of the outcomes | 2 |
| Stability of the legal framework | 4 |
| Clarity of the legal texts | 2 |
| Guidance documents and implementation support | 2 |
| Effective implementation and enforcement across Member States | 4 |

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

| | |
|---|---|
| Consistent implementation and enforcement across Member States | I don't know |
| Public awareness and outreach | I don't know |
| International collaboration and harmonisation | I don't know |
| Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it. | <p>EDF Energy has found some aspects of the EU's chemical legislation are unclear and that there is a lack of guidance for users/producers of some chemicals. This lack of guidance means that outcomes of legislation are also difficult to predict. Our experience is of the process of notifying ECHA of our intention to submit a dossier in line with the Biocidal Products Regulations. As we produce biocide for our own consumption only and do not 'place it on the market', the language in the legal text has been confusing as it tends to refer to manufacture placing substances on the market. Guidance documents are similarly confusing, and are aimed at manufactures of biocides as opposed to 'in-situ generator/users' such as ourselves, and advice from national helpdesks was also unclear. We found ECHA's helpdesk to be the only source of clear information on this issue. EDF Energy believes that legislation such as the Biocides Products Regulation is not very transparent in part due to the lack of clarity in the legislation and guidance mentioned above, but also due to the charging regimes. Whilst the charges themselves are clearly set out, the rationale behind them is not. We believe that in some instances charges are highly disproportionate. For example, the in-situ generator/user of a low volume of a low risk substance is required to pay the same fees as the producer of a high risk substance on an industrial scale. We believe that where such fees are paid, it should be made clear where they are spent, so that organisations can better understand how their fees are calculated.</p> |

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

| | |
|--|--------------|
| Hazard identification criteria | I don't know |
| Risk assessment and characterisation | I don't know |
| Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.) | I don't know |
| Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.) | I don't know |
| Risk management measures restricting or banning the use of chemicals | I don't know |
| Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment) | I don't know |

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

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? I don't know

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) I don't know

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 large enterprises

Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies? Understanding and keeping up-to-date with changes in legal requirements
,
Other (please specify)
EDF Energy has found registration fees in line with the Biocidal Products Regulations to be a significant cost. We are required to pay these fees as we produce our own biocide at some sites. We believe that it is disproportionate that low volume manufacturers of biocides who consume these on-site are required to follow the same process and pay the same fees as major chemicals manufacturers.

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 I don't know

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 | Neutral |

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.

Respondent skipped this question

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? | 4 |
| 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 | I don't know |
| Physical | I don't know |
| Human health | I don't know |

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 | 4 |
| Industry association guidance and materials | 2 |
| Other (training, conferences, etc.) | No experience |
| Please add further details as necessary | EDF Energy has found that guidance documents and industry association materials are typically useful resources for routine compliance issues. However, we have found that there is very little guidance (and what there is can seem contradictory) for infrequent issues such as the notification of intention to submit a dossier under Biocidal Products Regulations for an in-situ manufacturer/user. In our experience, national regulators were also unsure as to how the regulations applied in a more exceptional scenario such as ours; however, the ECHA helpdesk proved to be a very useful resource. |

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

I don't know

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 | I don't know |
| Appropriateness of classification criteria and methods for substances | I don't know |
| Appropriateness of classification criteria and methods for mixtures | I don't know |
| International harmonisation through the Globally Harmonised System (GHS) | I don't know |

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?

I don't know or have no opinion

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 | I don't know |
| Involvement of stakeholders | I don't know |
| Quality of scientific data and related information | I don't know |
| Speed of the procedure | I don't know |

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

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

Respondent skipped this question
