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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Kirsty Reid
Organisation/company	Eurogroup for Animals
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.**	6809935493-49
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**	4
Stimulating competitiveness and innovation	4

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	3
Stimulating competitiveness and innovation	4

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	4

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

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 We support that chemicals are tested for their specific uses and effects on humans, environment and wildlife. For generating data requirements there should not be a tick the box approach of all tests, only those which are relevant to each chemical. Moreover, the use of modern animal free testing strategies should be enforced.
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.	I don't know

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	3
Time to allow duty holders to adapt	I don't know
Predictability of the outcomes	I don't know
Stability of the legal framework	2
Clarity of the legal texts	2
Guidance documents and implementation support	3
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	2
International collaboration and harmonisation	2
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	With regard to animal welfare, procedures and decisions need to be more transparent. Guidance and understanding of the legal texts needs to be described in greater detail and within the languages of the member states. Proper, speedy checks need to take place on transposition of various legislations (directives) and also on the implementation and enforcement across member states. International collaboration is essential in the sharing of data and testing techniques.

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

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 GLP ensures a high standard of practice within laboratories

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
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	I don't know
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	I don't know

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	1. Emerging areas of concern include nanomaterials and endocrine disrupters. Discussions and decisions and the development and acceptance of animal free testing strategies on these areas are lagging behind. 2. For risk assessments we would encourage a paradigm shift away from the desire to use animals and instead look at using methods, technologies, techniques and tools that do not relay on the use of animals and provide more accurate results.

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	Agree
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	European Union (EU) legislation on the protection of animals used for scientific purposes requires that alternative methods must be used instead of animal tests wherever they are available. Unfortunately, this provision is not implemented to its full extent when it comes to risk assessment of chemicals and new products prior to their authorization and placing on the market in the EU. Recent uptake of the latest test methods, not entailing the use of animals, under the REACH regulation need to be immediately considered for inclusion and uptake in other chemical legislation. A paper which highlights the problem of lack of harmonisation of data requirements in more detail: Wagner et al 2012. Inconsistencies in data requirements of EU legislation involving test on animals Altex 29. 3/12
Overlaps	Chemicals may be borderline or used for multiple purposes. When this happens (eg reach and Plant Protection Products or Biocides legislations), chemicals may be required to be tested under the requirements of each legislation resulting in duplicate testing and unnecessary animal use.

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.

Uptake of the latest test methods, not entailing the use of animals under certain legislations need to be immediately considered for inclusion and uptake in other chemical legislation. A paper which highlights the problem of lack of harmonisation of data requirements in more detail: Wagner et al 2012. Inconsistencies in data requirements of EU legislation involving test on animals Altex 29. 3/12

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	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	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
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

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	Relevant to Part II, General Comments: When the Lisbon Treaty came into force in 2009 it amended the 'Treaty on the Functioning of the European Union' (TFEU) and introduced the recognition that animals are sentient beings. Article 13 of Title II states that: "In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage." Animal welfare is an essential part under many of the chemical legislations. More efforts should be made to properly implement these measures to avoid animal testing. Chemical legislations which take up animal welfare, animal use only as a last resort and promotion of alternatives include REACH, biocidal products, cosmetics, Plant protection Products and the directive 2010/63/EU on the protection of animals for scientific us, while all the rest which fall into this discussion have very little focus or totally lack any recognition of the need to decrease the use of testing on vertebrates, they have to take this up in any amendments proposed to the legislations. Alternative methods should be promoted for assessment of substances and animal testing should take place only as a last resort with vertebrate test data shared. We therefore believe that missing in Part II under the general questions is focus on animal welfare.