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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Dr. Ehrhard Anhalt
Organisation/company	Bundesverband der Arzneimittel-Hersteller
Country	Germany
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:	An industry association
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 medical and dental instruments and supplies (C32.5)
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	Small enterprise (under 50 employees)

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	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	3

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	5
Protecting the environment	5
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:

Ensuring a well-functioning internal market	The legislation is not adapted to the issues at stake
Stimulating competitiveness and innovation	The legislation is not adapted to the issues at stake

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)
,

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

Chemical Agents (Directive 98/24/EC),

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

Young people at work (Directive 1994/33/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) ,

Water Framework (Directive 2000/60/EC) ,

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

Batteries (Directive 2006/66/EC),

Packaging and Packaging Waste (Directive 94/62/EC)
,

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

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)
,

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)
Medicinal Products (Dir 2001/83/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
The current REACH Regulation exempt medical devices which are invasive or used in direct physical contact with the human body from Title IV (Regulation (EC) 1907/2006, Art. 2 No. 6 (c)). Risks arising from use of medical devices to human health shall not be considered for authorization (Regulation (EC) Art. 60 No. 2, 2nd paragraph). Applications for authorization shall not include risks to human health arising from the use of substances used in medical devices. Additionally the CLP Regulation exempts substances or mixtures used in medical devices (Regulation (EC) 1272/2008, Art. 1 No. 5 (d)). These provisions show that especially human health risks are regarded by the chemical legislation to be covered by the medical device legislation (REACH exemption from Title IV and from authorization based on human health risks). Otherwise, the general exemption from CLP and the exemption to communicate even environmental risks in the supply chain indicates that environmental risks are covered for these products by the risk management system for medical devices based on EN ISO 14971. That means, to demonstrate the conformity with the basic requirements of the medical device directive any medical device must be subject of a risk management system based on the harmonized EN ISO 14971 (EN ISO 14971: 2012 corresponding to ISO 14971: 2007). This standard requires not only the analysis of risks to patient's health (even if this is its primary focus – see introduction, paragraph 3) but also the managing of any environmental risk arising from the use of the device. The Annex C of EN ISO 14971 (Questions for risk identification) substantiates this request by question C.2.16: "Does the medical device influence the environment? Factors that should be considered include: □ the effects on power and cooling supplies; □ emission of toxic materials; □ the generation of electromagnetic disturbance." Based on this the medical device legislation requests a detailed analysis not only on human health risks arising from the use of medical devices but also of environmental risks, even if these risks are probably low, due to the low volume of substances used normally in medical devices. In conclusion, if the requirements of REACH are more specifically risk orientated a full exemption of medical devices from the provisions of REACH (as given e.g. for medicinal products) would be appropriate, providing reduced bureaucratic effort for authorities and manufacturers and more legal certainty for manufacturers.

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, If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to. Concerning medical devices all relevant considerations are taken in account especially by harmonized standard EN ISO 14971: 2012 (risk management for medical devices), as well as by the harmonized standard series EN ISO 10993 (biological/ toxicological evaluation and testing).

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	2
Speed with which hazards/risks are identified	4
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	2
Predictability of the outcomes	2
Stability of the legal framework	3
Clarity of the legal texts	3
Guidance documents and implementation support	5
Effective implementation and enforcement across Member States	5
Consistent implementation and enforcement across Member States	5
Public awareness and outreach	4
International collaboration and harmonisation	5
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	There are conflicts regarding regulations on chemicals and regulations on medical devices, (see e.g. Comment indicated at question 14).

Q17: In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)	
Hazard identification criteria	4
Risk assessment and characterisation	4
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	5
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	5
Risk management measures restricting or banning the use of chemicals	5
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	5
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

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, 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?	Classification requirements for substances and mixtures , Chemical labelling and packaging requirements , Risk management measures under the different legislation , Inspections and administrative requirements , Other (please specify) Transportation and storage of chemicals.
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	5

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	5

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	Disagree
The EU chemicals legislation framework has overlaps	Disagree
The EU chemicals legislation framework is internally inconsistent	Disagree

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.

See comment to question 14, relates to "Overlaps"

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?	5
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	5
Helpdesks	3
Industry association guidance and materials	4
Other (training, conferences, etc.)	3

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is 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	4
Appropriateness of classification criteria and methods for mixtures	4
International harmonisation through the Globally Harmonised System (GHS)	3

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 sufficient

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	5
Involvement of stakeholders	4
Quality of scientific data and related information	4
Speed of the procedure	3

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	If CLP classification and labeling is used for products like medical devices that are addressed to less trained (regarding chemical legislation) persons (like medical/ dental personnel). The misunderstanding between hazard and risk communication often leads to many questions. Hazards indicated by CLP labeling are understood as risks by this personnel. The communication of risks as required by medical device legislation (e.g. by instructions for use) is better understood. Conclusion: more helpful for medical/ dental users is a communication of potential risks in the manner as requested by medical device directive and not as requested by CLP (hazard based communication).