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## COMPLETE

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### PAGE 2: Part I – General Information about Respondents

#### Q1: Address

Contact name	Michael Gillen
Organisation/company	BioPharmaChem Ireland
Country	Ireland
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 other chemical products (C20.5),  
Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)

**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](http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm)**

Medium-sized enterprise (under 250 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**	4
Stimulating competitiveness and innovation	2

**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	4
Ensuring a well-functioning internal market	2
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	2
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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)  
,  
REACH, Annex XIII (Regulation (EC) No 1907/2006)  
,  
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  
,  
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)  
,  
Water Framework (Directive 2000/60/EC) ,  
Export and import of hazardous chemicals (Regulation No 649/2012)  
,  
Persistent organic pollutants (Regulation (EC) 850/2004)  
,  
Pressure equipment (Directive 2014/68/EU) ,  
General Product Safety (Directive 2001/95/EC)

**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 need to properly risk assess is critical to the effective implementation of chemical legislation. Where a more generic approach is adopted, situations develop whereby properly controlled chemical use is prohibited. This leads to the unfortunate scenario where processes that do use hazardous chemicals are prohibited from happening in Europe and they end up being relocated to other jurisdictions where the level of national control is much lower. This has two very serious consequences; loss of competitiveness for Europe and greater level of exposure to less developed jurisdictions. Where a pragmatic specific risk assessment is allowed in Europe, the level of control is capable of ensuring the health and well being of those working with the chemical. Risk assessment is key.

**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.  
The one area that is increasingly being ignored is the impact on competitiveness and jobs

**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	4
Speed with which hazards/risks are identified	3
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	4
Predictability of the outcomes	2
Stability of the legal framework	3
Clarity of the legal texts	2
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	3
International collaboration and harmonisation	3

**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	3
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	4
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	4
Risk management measures restricting or banning the use of chemicals	3
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	3

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**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

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## PAGE 6: Efficiency

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<b>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)</b>	<p>Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.</p> <p>,</p> <p>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.</p>
<b>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)</b>	Costs for small and medium sized enterprises
<b>Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?</b>	We do not view the business costs of meeting EU chemicals legislation to be significant
<b>Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?</b>	<p>Yes,</p> <p>If you answered yes, please indicate what these are. Costs associated with Registration and Authorisation under REACH</p>

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## 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 5

Please comment Beacuse of the need to identify hazards and assess risk, there is an onus on all users of chemicals, irrespective of their physical form (including nano), to esnure adeqaute controls. Correct risk assessment also addresses the issue of potency and this faciliates the provision of proper control measures.

## 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	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.**

Overlaps	there are some overlaps between CLP, chemical agents and REACH
Inconsistencies	some pieces of legislation are very hazard centric to the detriment of risk assessment

**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.**

there are some overlaps between CLP, chemical agents and REACH  
Much of what is covered under REACH only considers the hazard. This results in very anti-competitive legislation.

## 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? 4

**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 4

Helpdesks 5

Industry association guidance and materials 4

Other (training, conferences, etc.) 4

**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 4

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) 4

**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 4

Involvement of stakeholders 4

Quality of scientific data and related information 4

Speed of the procedure 2

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

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*Respondent skipped this question*