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## COMPLETE

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

#### Q1: Address

Contact name

Hazel Doonan

Organisation/company

Crop Protection Sector, Agricultural Industries Confederation

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.**

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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:**

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]:**

Agriculture, forestry and fishing (A),  
Transporting and storage (H),  
Professional, scientific and technical activities (M)

**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)

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	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	5
Protecting the environment	5
Ensuring a well-functioning internal market	3
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:**

Ensuring a well-functioning internal market	The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
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	I don't know
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PAGE 4: Part III - Specific Questions

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**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)  
,  
Inland transport of dangerous goods (Directive 2008/68/EC)  
,  
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)  
,  
Water Framework (Directive 2000/60/EC),  
Residues of pesticides (Regulation (EC) No 396/2005)  
,  
Drinking Water (Directive 98/83/EC)

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PAGE 5: Effectiveness

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**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  
Directive 98/83/EC (Drinking Water Directive) sets quality standards for pesticides applicable to water intended for human consumption at a maximum of 0.1 µg/l. This standard takes no account of the variation in chemical properties of the 484 substances currently approved as pesticides in the EU. An individual standard for each pesticides based on its hazard would be more scientific and present cost savings for water treatment across the EU.

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**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.

Whilst the individual impacts of a piece of legislation may be considered, the added impacts and unintended consequences of more two or more pieces of chemicals legislation are rarely considered. The collective impacts of 1107/2009, 2000/60/EC and 485/2013 on the approval of neonicotinoids were considered in 'The Effect of the Loss of Plant Protection Products on UK Agriculture and Horticulture and the Wider Economy'

<https://www.nfuonline.com/andersons-final-report/> .

This indicated the cumulative impacts on crop production, farm profitability and jobs along the supply chain.

**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	I don't know
Speed with which hazards/risks are identified	I don't know
Speed with which identified risks are addressed	5
Time to allow duty holders to adapt	3
Predictability of the outcomes	3
Stability of the legal framework	I don't know
Clarity of the legal texts	3
Guidance documents and implementation support	1
Effective implementation and enforcement across Member States	I don't know
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	2
International collaboration and harmonisation	3

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

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.

Speed with which identified risks are addressed: Immediate withdrawal with no grace periods exists where severe safety concerns come to light regarding an active substance. Time to allow duty holders to adapt: When an active substance is withdrawn from the market the standard 6+12 month grace periods may be insufficient to allow the product to be used without incurring disposal costs for the supply chain. PPP use is weather dependent and seasonal. The start of a grace periods should be timed to allow maximum opportunity for use of the active substance including the consideration that in some years weather conditions may prevent use of the active substance within the approved periods. In this way disposal via legitimate or illegitimate routes would be minimised. Predictability of the outcomes: See response to Q15. Clarity of the legal texts: It would be helpful if definitions were listed alphabetically in the relevant Article on Definitions. Guidance Documents and implementation support: The European Food Safety Authority (EFSA) provides technical guidance on how risk assessments included in approval dossiers should be undertaken. The Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) has undergone much revision and debate since it was first published and is estimated to impact on 95% of active substances approved under 1107/2009. A high investment would be required to meet the proposed new studies required in this guidance document, which it is estimated would take 24 years to complete. Guidance documents continue to be developed and appear to increase regulatory costs. Public Awareness and outreach: Public not involved with the chemical industry have no awareness of the checks and controls in place around the approval and use of chemicals to protect them and the environment. International collaboration and harmonisation 107/2009 Mutual recognition is not fully enacted.

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

Hazard identification criteria	2
Risk assessment and characterisation	4
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	4
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	4

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.

Hazard Identification criteria: 1107/2009 the development of a definition for endocrine disrupting properties has taken some time due to the complex nature of the subject. There was no provision in the regulation for carrying out an impact assessment. However following the decision to carry out an impact assessment in 2013, a Commissionaire commented that the impact assessment was 'a useful and even essential tool to guide its future decision on the criteria'. This would point to the need for consideration of an impact assessment before criteria for hazard identification are developed in the future to inform the decision and lead to a pragmatic outcome.

**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)**

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.

,

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.

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

**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 national level ,  
Costs for small and medium sized enterprises ,  
Costs for large enterprises, Costs for consumers

**Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?**

Chemical labelling and packaging requirements ,  
Risk management measures under the different legislation  
,  
Understanding and keeping up-to-date with changes in legal requirements  
,  
Training staff to ensure compliance with legal requirements  
,  
Inspections and administrative requirements

**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. Directive 98/83/EC (Drinking Water Directive) sets quality standards for pesticides applicable to water intended for human consumption at a maximum of 0.1µg/l. This standard takes no account of the variation in chemical properties of the 484 substances currently approved as pesticides in the EU. An individual standard for each pesticides based on its hazard would be more scientific and present cost savings for water treatment across the EU.

### 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 3

Please comment

Improving analytical techniques are able to detect increasingly smaller amounts of chemical residues, which are not an issue for human health. We would not like to see a decrease in MRLs under 396/2005 due to this ability to detect lower levels of chemicals where there is no issue for human health. Minor uses under 1107/2009 also should consider the need for pesticides to tackle new weed, pest and disease issues due to, for example, changing climate.

## 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? 3

To what extent are CLP labels effective in communicating hazards to consumers? 3



**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	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	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)	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?**

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	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.**

*Respondent skipped this question*