SME panel consultation on Endocrine Disruptors

Fields marked with * are mandatory.

Scope and objectives

Endocrine Disruptors (EDs) are chemical substances that interfere with hormones (endocrine system) and in so doing negatively affect the health of humans and animals. They may either be synthetic or of natural origin. Exposure to endocrine disruptors can occur from different sources, such as from residues of pesticides in our food or from other types of products used or present in our daily life.
In its Communication 'Towards a comprehensive European Union framework on endocrine disruptors', adopted on 7 November 2018, the European Commission confirmed its commitment to protect EU citizens and the environment from endocrine disruptors (EDs), by minimising human and wildlife exposure to these substances. The Communication outlines a comprehensive set of actions including a cross-cutting Fitness Check of the relevant legislation.

EU legislation regulating chemicals has been developed at different points in time and has, in certain cases, different objectives. This has resulted in different approaches to regulating endocrine disruptors, depending on the sector, and has raised questions as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent. The Fitness Check aims at analysing the coherence of the different regulatory approaches to the assessment and management of endocrine disruptors and to assess whether legislation delivers on its objectives to protect human health and the environment. The outcome of the Fitness Check will inform potential improvements of the regulatory framework with regard to endocrine disruptors. More information is available in the published Roadmap[1].

Stakeholder consultation is an essential component of the Fitness Check. It aims at gathering inputs from a broad range of stakeholder groups as well as citizens to ensure that views from all interested parties are considered in the evaluation.

The aims of this survey are:
To identify any legal incoherencies and their consequences for small companies To review the efficiency of procedures for the assessment and risk management To identify opportunities for improvement.

Survey Instructions.
We encourage you to give explanations in open fields to questions. However, there is no mandatory field.

[1] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en

EEN partner identification

* Please enter you 7-digit organisational ID Number

Text of 7 to 7 characters will be accepted

This question is only for the members of the Enterprise Europe Network . The number is the 7 digit number next to your name in Merlin in the format of XY12345 where XY stands for your country code.

Company profile

1) Size – Please indicate which of the following best describes the size of your company/your group of companies?

- Self-employed: 0 employees
- Micro enterprises: with 1-9 persons employed
- Small enterprises: with 10-49 persons employed;
- Medium-sized enterprises: with 50-249 persons employed;
- Large enterprises: with 250 or more persons employed.

2) Geographical location - Please indicate the main country of business of your company:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- Iceland

- Liechtenstein
- Norway
- Switzerland
- Other

3) Please indicate in which country/ies your company regularly sell products and/or services:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- Iceland
- Liechtenstein
- Norway
- Switzerland
- Other

4) Role of company (tick all that apply)

[2] Manufacturer means any natural or legal person established within the EU who manufactures a substance within the EU

[3] Importer means any natural or legal person established within the EU who is responsible for import

[4] Formulators produce mixtures (e.g. paints, adhesives, detergents, biocides, plant protection products), which are usually supplied further downstream.

[5] Distributor means any natural or legal person established within the EU, including a retailer, who only stores and places on the market a substance, on its own or in a mixture for third parties

[6] Non-EU suppliers may appoint an only representative for the purpose of acting as a registrant established in the EU

[7] Downstream user (industrial or professional user) means any natural or legal person established within the EU, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of their industrial or professional activities. Industrial users are workers who use chemical products in an industrial site, large or small. Professional users are workers who use chemical products outside an industrial setting (e.g. workshop, client site, educational or healthcare establishment) such as construction, mobile cleaning companies or professional painters.

[8] Article means an object given a special shape, surface or design that determines its function to a greater extent than its chemical composition does (e.g. clothing, furniture, electronics and practically all objects of modern life)

- ☐ Manufacturer of chemical substances[2]
- ☐ Importer[3]
- ☐ Formulator[4]
- ☐ Distributor[5]
- ☐ Only representative[6]
- ☐ Downstream user (industrial or professional user)[7]
- ☐ Supplier (producer/importer/ wholesaler/retailer) of articles[8]
- ☐ Other (please specify)

Other, please specify:

5) In which of the following chemical sectors are you involved? Please tick all that apply.

- ☐ Basic chemicals
- ☐ Speciality chemicals
- ☐ Formulation of chemical products
- ☐ Metals
- ☐ Kitchenware
- ☐ Adhesives and glues
- ☐ Fertilisers
- ☐ Polymers
- ☐ Cosmetics
- ☐ Personal care products
- ☐ Retail
- ☐ Textiles
- ☐ Automotive
- ☐ Plastics
- ☐ Toys
- ☐ Synthetic Rubber
- ☐ Veterinary medicines
- ☐ Human medicines
- ☐ Lubricants and oils
- ☐ Dyes and Pigments
- ☐ Crop protection
- ☐ Paper and pulp
- ☐ Consumer chemicals
- ☐ Aerosols
- ☐ Fuels
- ☐ Electronics
- ☐ Detergents and cleaning products
- ☐ Paints, inks and coatings
- ☐ Auxiliaries for industry
- ☐ Aerospace and Defence
- ☐ Biocidal products
- ☐ Other manufacturing
- ☐ Agriculture
- ☐ Construction
- ☐ Motor vehicle repair
- ☐ Professional painting or decoration
- ☐ Cleaning services
- ☐ Other professional users of chemicals
- ☐ None of the above

Relevant legislation

6) Which of the following statements apply to each of the pieces of legislation listed?

	Affects my business and I am familiar with the content	Affects my business but I am not very familiar with the content	Does not affect my business but I am familiar with the content	Does not affect my business and I am not familiar with the content

Plant Protection Products Regulation (EC) 1107/2009				
Residues of Pesticides Regulation (396/2005/EC)				
Biocidal Products Regulation (528 /2012/EU)				
REACH Regulation (EC) No 1907 /2006				
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) No 1272/2008				
Persistent Organic Pollutants Regulation (850/2004/EC and (EU) 2019/1021)				
Food Contact Materials legislation – Regulation (EC)1935/2004				
Contaminants in Food and Feed Regulation (315/93/EEC) and Directive (2002/32/EC)				
Food Additives Regulation (1333 /2008/EC)				
Cosmetic Products Regulation (EC) No 1223/2009				
Regulation (EU) 2017/745 on Medical Devices				
Regulation (EU) 2017/746 on in vitro Diagnostic Medical Devices				
Toy Safety Directive 2009/48/EC				
Fertilisers (Regulation (EC) No 2003/2003 and Regulation (EU) 2019/1009)				
Detergents Regulation (648/2004 /EC)				
Medicinal Products for Humans (Directive 2001/83/CE)				
Veterinary Medicinal Products Regulation ((EU) 2019/6)				
General Product Safety Directive (2001/95/EC)				

Water Framework Directive (2000/60/EC)				
Priority substances Directive (39/2013/EC)				
Drinking Water Directive (98/83/EC)				
Groundwater Directive (2006/118/EC)				
Marine Strategy Framework Directive (Directive 2008/56/EC)				
Urban Waste Water Directive (91/271/EEC)				
Chemical Agents Directive at Work (98/24/EC).				
Carcinogens and Mutagens at Work Directive (2004/37/EC)				
Pregnant Workers Directive (1992/85/EEC)				
Young People at Work Directive (1994/33/EC)				
Directive 2008/98/EC on Waste				
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment (Directive 2011/65/EU)				
Industrial emissions (Integrated Pollution Prevention and Control) Directive (2010/75/EU)				
Seveso-III-Directive (2012/18/EU)				
Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on Ambient Air Quality and Cleaner Air for Europe				
Regulation (EC) No 66/2010 on the EU Ecolabel				

Information in the company about endocrine disruptors

7) Which sources of information on endocrine disruptors does your company use most?

	1 Never used	2 Rarely used	3 Sometimes used	4 Often used	I am not aware of this source of information
Business partners - Manufacturers or suppliers of chemicals					
Business partners - Safety data sheet					
Business partners - Customers					
Business partners - Consultants including law firms					
Industry Associations					
Authorities at national level					
Authorities at regional level					
Authorities at local level					
EU level - EU Agency					
EU level - European Commission					
Other, please specify					

Please specify other source of information:

100 character(s) maximum

None of the above, I do not look for information on endocrine disruptors

- None of the above
- Not applicable

8) To what extent does the information at your disposal help your company to comply with legal requirements for endocrine disruptors?

- Not at all
- To a small extent
- To a large extent
- Completely

Regulatory approaches to the identification, assessment and management of endocrine disruptors

Recently the European Commission published criteria for the determination of endocrine disrupting properties of substances under:
Biocidal Products Regulation ((EU) 2017/2100) and Plant Protection Products Regulation ((EU) 2018/605)
Both are based on the WHO definition[1]. Other EU laws related to human health and environmental protection from manufactured chemicals do not contain such criteria.

[1] An endocrine disruptor is defined as “an exogenous substance or mixture that alters function(s) of the endocrine systems and consequently causes adverse health effects in an intact organism, or its progeny, or sub(populations)”.

Does the absence of criteria for ED identification in chemical control legislation other than pesticides and biocides pose a problem for identifying endocrine disruptors?

- It is an important problem, leading to an incoherent identification of endocrine disruptors.
- It is not a problem, the criteria should be sector specific
- I do not know.

Please explain your answer; indicating the sector(s) in which this problem occurs (max 1000 characters)

1000 character(s) maximum

The Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures ((EC) No 1272/2008) or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) set rules for the classification and labelling of hazardous substances, based on their physical, health or environmental hazards.

9) Do you think that the lack of a hazard category in the CLP Regulation and/or GHS covering endocrine disrupting properties poses a problem for the coherent identification of endocrine disruptors?

- Yes
- No

10) Do you think that the lack of a hazard category in the CLP Regulation and/or GHS covering endocrine disrupting properties poses a problem for the coherent risk management of endocrine disruptors?

- Yes
- No

The EU laws regulating chemicals have been developed at different points in time and have, in certain cases, different objectives. Because of this, endocrine disruptors are approached differently in different sectors. This causes doubts about whether the EU legal framework regulating endocrine disruptors is sufficiently coherent.

11) Are you aware of inconsistencies in the way chemicals are addressed with regard to endocrine disrupting properties across regulated areas in the EU?

- yes
- no

If yes, please provide examples explaining how it affects your business. (max 1000 characters)

12) How strongly do the differences in the ways EDs are regulated between the EU and other jurisdictions (e.g. USA, China) affect your business?

- To a significant extent
- To some extent
- To a minor extent
- Not at all
- Don't know

Please provide examples explaining how it affects your business. (max 1000 characters)

1000 character(s) maximum

Effectiveness in achieving policy objectives

EU legislation aims to protect human and environmental health, through reducing the exposure to toxicants, while at the same time improving the functioning of the internal market.

13) Do you agree with the following statements about your business sector?
The regulatory process to identify and control chemicals with endocrine disrupting properties is effective in:

	1 Strongly agree	2 Moderately agree	3 Neither agree nor disagree	4 Moderately disagree	5 Strongly disagree	6 Don't know
Protecting consumers by minimising exposure to endocrine disruptors						
Protecting workers by minimising exposure to endocrine disruptors						
Protecting citizens by minimising exposure to endocrine disruptors via the environment						
Protecting wildlife by minimising exposure to endocrine disruptors via the environment						
Improving the functioning of the internal market						
Enhancing competitiveness and innovation						

Efficiency of regulatory provisions for endocrine disruptors

Benefits of regulatory intervention include human health and environmental protection, smooth functioning of the internal market, and enhancing innovation and competitiveness. Costs can be economic (time, resources) as well as ethical (e.g. use of laboratory animals for testing). Efficiency considers the benefits in relation to costs.

14) Has the need to implement regulatory requirements for endocrine disruptors increased your total operating costs?

- Yes, to a significant extent
- Yes, but not to a significant extent
- No
- Not applicable

15) What is the cost increase for your company to comply with the regulatory requirements (e.g. testing, restriction or ban) specifically related to endocrine disruptors?

	1 More than 10%	2 Between 5 and 10%	3 Between 1 and 5%	4 Below 1%	I don't know	Not applicable
Investment in the development of new testing methodologies for endocrine disrupting properties						
Costs related to the provision of test data on endocrine disrupting properties						
Costs related to the preparation of registration or authorisation dossiers on endocrine disrupting properties						
Cost to replace substances due to endocrine disrupting properties (e.g.as a producer or user)						

16) What impact have the provisions for endocrine disruptors had on your sector of activity?

	Very negative	Negative	No impact	Positive	Very positive	Don't know	Not applicable
Innovation	○	○	○	○	○	○	○
Productivity	○	○	○	○	○	○	○
Profitability	○	○	○	○	○	○	○
International trade	○	○	○	○	○	○	○

Other, please specify max 100 characters

Please explain your answers (max 1000 characters)

17) In your view, are the costs of the provisions for ED identification and management in your business sector justified and proportionate for the benefits accrued?

- Fully
- To some extent
- Not at all
- Don't know

Added value of EU-level intervention

In some instances Member State authorities have taken unilateral action on endocrine disruptors, before the EU made a decision on them. For example, in October 2012, the French authorities introduced a ban of Bisphenol A in all Food Contact Materials, applicable from July 2015.

18) Have these Member State initiatives affected your company?

- Yes
- No

If yes, please provide examples explaining how it affects your business. (max 1000 characters)

1000 character(s) maximum

Open question

19) Please provide any additional comment or suggestion that you consider relevant for the ED Fitness Check. For example, suggestions to help SMEs comply with regulatory requirements, suggestions to reduce any burdens while keeping the objective of reducing exposure of humans and wildlife to endocrine disruptors. (Max 2000 characters)

2000 character(s) maximum

Thank you for your participation!