EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Directorate F - Health, Consumers & Reference Materials
Chemicals Safety & Alternative Methods

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Fitness Check of the EU legislation with regard to Endocrine Disruptors - SME Panel Consultation

Report on the results of the consultation

The European Commission is taking a cross-cutting look at the approach to the assessment and management of endocrine disruptors (EDs) in a broad range of legislation through what is described as a Fitness Check[1]. The goal is to analyse the coherence of the different approaches to this topic, identify possible gaps and synergies, and assess their collective impact on human health and the environment.

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. This ED Fitness Check includes three consultations, a public consultation (designed from a citizen's perspective) a stakeholder consultation (designed for stakeholders and experts) and a consultation to collect the views of micro, small and medium-sized enterprises (SMEs).

The aims of this **SME consultation** were:

- 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.

The consultation was conducted through the Enterprise Europe Network and was open from 01/02/2019 to 09/03/2020.

This summary report provides a brief factual overview of the 70 replies received from the SME consultation, with information on the respondents as well as the number of responses and range of opinions. The replies gathered through the consultation will help the Commission to understand the experiences of SMEs and constitute an important contribution to the Fitness Check evaluation on

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2142-Fitness-Check-on-endocrine-disruptors

endocrine disruptors. A more detailed analysis of the responses to all three consultations will be published in a synopsis report along with the Fitness Check evaluation at the end of the process.

Respondents

Eighty-one percent of the respondents have micro enterprises (23), small enterprises (13) or medium enterprises (19); four percent are self-employed (3), and fifteen percent have large enterprises (10).

Most answers were received from respondents in Romania (27%), Bulgaria (20%), Poland (14%) and Portugal (11%). The other respondents are based in Italy (7%), Greece (6%), France (4%), Latvia (4%), Czech Republic (3%), Belgium (1%) and Spain (1%).

Sixty-five respondents regularly sell products in all the EU with the exception of Ireland and Luxembourg. The main countries where products are sold are Romania (26), Germany (17), Bulgaria (16), Italy (14), Poland (13) and the United Kingdom (12).

Most of the respondents describe themselves as downstream users (29), followed by suppliers (19), distributors (12), formulators (9), importers (8), manufacturers of chemical substances (6) or only representatives (2). Six respondents declared another role (e.g. water treatment, security service provider, construction works).

Respondents are involved in almost all of the chemical sectors listed with the exception of aerosols and cleaning services. The sectors most reported are metals (12), paints, inks and coatings (12), plastics (11), dyes and pigments (11), and polymers (10).

Relevant legislation

The five pieces of EU legislation affecting most respondents are: Directive 2008/98/EC on Waste (34 being familiar with its content vs. 14 being not familiar); REACH Regulation (EC) No 1907/2006 (33 familiar vs. 5 not); Classification, Labelling and Packaging of substances and mixtures (EC) No 1272/2008 (32 familiar vs. 3 not); Chemical Agents Directive at Work (98/24/EC) (25 familiar vs. 10 not); and Pregnant Workers Directive (1992/85/EEC) (24 familiar vs. 6 not).

The five pieces of EU legislation affecting the least respondents are: Veterinary Medicinal Products Regulation ((EU) 2019/6) (54 not being familiar with its content vs. 6 being familiar); Regulation (EU) 2017/746 on in vitro Diagnostic Medical Devices (56 not familiar vs. 4); Medicinal Products for Humans (Directive 2001/83/CE) (54 not familiar vs. 4); Regulation (EU) 2017/745 on Medical Devices (53 not familiar vs. 6); and Toy Safety Directive 2009/48/EC (53 not familiar vs. 6).

Information in the company about endocrine disruptors

The five sources of information most used by the respondents are safety data sheets from business partners (43 often use this source and 7 sometimes); manufacturers or suppliers of chemicals (32 often, 6 sometimes); national authorities (16 often, 12 sometime); customers (16 often, 11 sometimes); and industry associations (16 often, 10 sometimes).

The five sources of information least used by the respondents are: EU Agencies (18 never use this source and 7 rarely); European Commission (20 never, 9 rarely); authorities at local level (19 never,

8 rarely); authorities at regional level (19 never, 9 rarely); and consultants including law firms (14 never, 10 rarely).

The respondents are divided in their views on whether the information at their disposal helps their company to comply with legal requirements for endocrine disruptors, with 12 replying not at all and 25 to a small extent; 23 to a large extent and 8 completely.

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

The European Commission has published criteria for the determination of endocrine disrupting properties of substances under the Biocidal Products Regulation ((EU) 2017/2100) and the Plant Protection Products Regulation ((EU) 2018/605), both of which are based on the World Health Organization (WHO) definition of ED[2]. Other EU laws related to human health and environmental protection from manufactured chemicals do not contain such criteria.

The absence of criteria for ED identification in chemical control legislation other than plant protection products and biocides was reported to be an important problem by 40% of the respondents, not a problem for 22% while the remaining 38% did not know.

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, human health or environmental hazards.

The lack of a hazard category covering endocrine disrupting properties in the CLP Regulation and/or GHS poses a problem for the coherent identification of endocrine disruptors according to 82% of respondents, and also causes a problem for the coherent risk management of endocrine disruptors according to 84% of respondents.

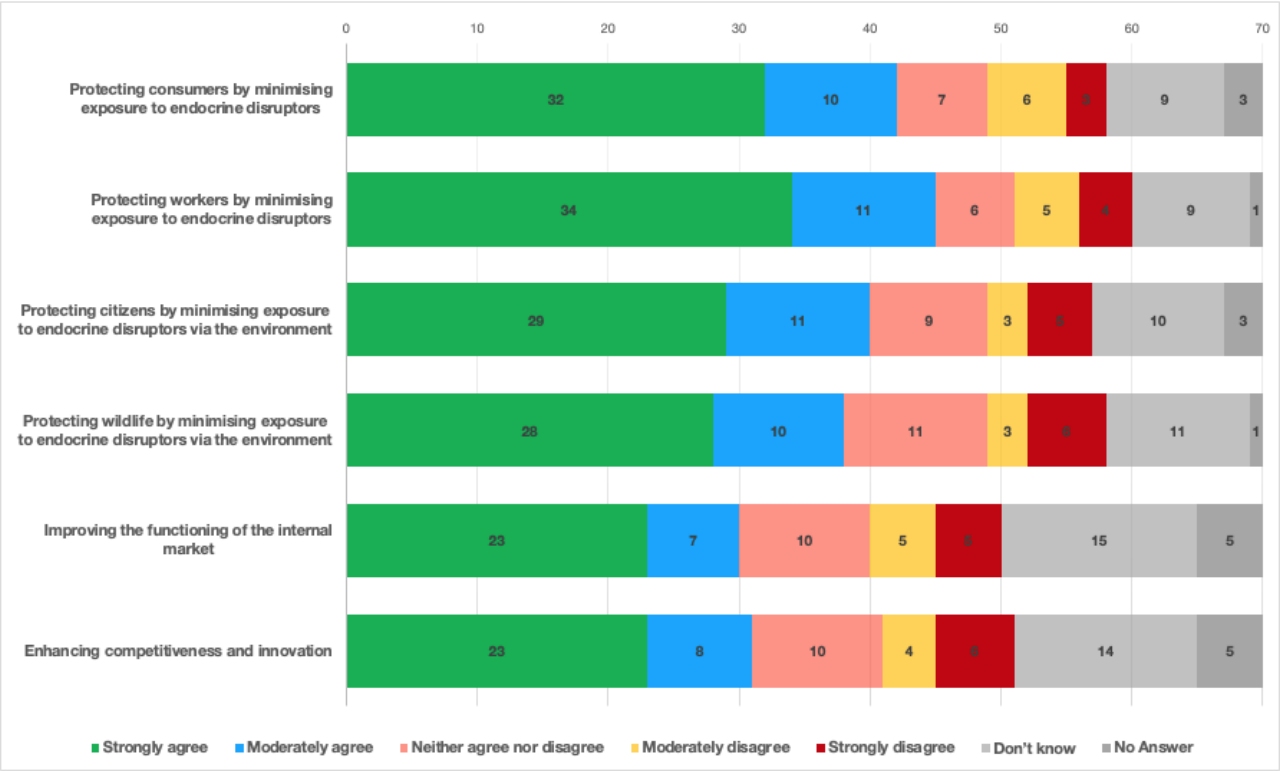
Sixteen percent of the respondents reported being aware of inconsistencies in the way chemicals are addressed with regard to endocrine disrupting properties across regulated areas in the EU.

Differences in the ways EDs are regulated between the EU and other jurisdictions (e.g. USA, China) affect five respondents to a significant extent, ten to some extent, five to a minor extent, sixteen not at all, while thirty-four respondents indicated that they didn't know.

Effectiveness in achieving policy objectives

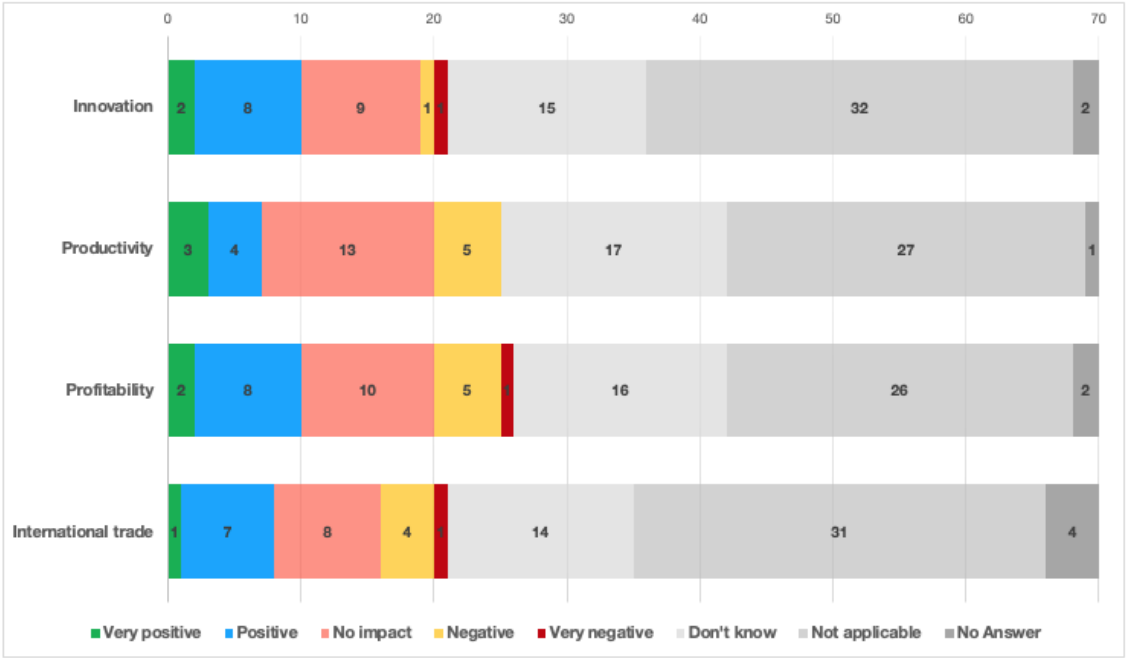
In general, respondents consider the regulatory process to identify and control chemicals with endocrine disrupting properties to be effective in protecting people and wildlife, in improving the functioning of the internal market, and enhancing competitiveness and innovation. This can be seen in the following figure since respondents more often agree than disagree.

[2] "An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations."



Efficiency of regulatory provisions for endocrine disruptors

Out of 70 respondents, the need to implement regulatory requirements for endocrine disruptors was reported to increase total operating costs by 25 respondents (3 to a significant extent, and 22 not to a significant extent), whereas 12 respondents reported no effect on operating costs. For the remaining 33 respondents, this question was either not applicable (30) or no answer was provided (3). Costs are related to: a) the replacement of substances (21 respondents); b) the preparation of registration or authorisation dossiers (14 respondents); c) the provision of test data (14 respondents); and d) the development of new testing methodologies (13 respondents).



In terms of the perceived impact of the provisions for endocrine disruptors on innovation, productivity, profitability and international trade within their sectors, as illustrated in the figure above few respondents (between 1 to 6) regarded the impact as negative or very negative and another minority (7 to 10) considered the impact as positive or very positive. The rest considered there was no impact (8 to 13), did not answer or did not know (14 to 17), or considered the question not applicable to them (26 to 32).

The costs of the provisions for ED identification and management in each respondents respective business sector were considered justified and proportionate for the benefits accrued by 23 respondents (3 fully and 20 to some extent), not at all justified or proportionate by 8 respondents, while 38 did not 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.

Ninety-six percent of the respondents reported that unilateral Member State actions did not affect their company.

Annex 1: Response to Closed Questions

Annex 2: Responses to Open Questions