European Commission

Targeted Stakeholder Consultation

in the context of a Fitness Check of the EU legislation with regard to Endocrine Disruptors

Factual Summary Report

EUR 30125 EN

Joint Research Centre

The Joint Research Centre (JRC) is the European Commission's science and knowledge service and provides evidence-based scientific support to the European policymaking process. This report has been produced by the JRC to provide a brief factual overview of the open targeted stakeholder consultation conducted in context of the Fitness Check of EU legislation pertaining to Endocrine Disruptors. The results and summary presented do not imply a policy position of the European Commission. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use that might be made of this publication.

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PART 1.

Introduction

Introduction

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 step to collect evidence for any Fitness Check. It aims at gathering inputs from a broad range of stakeholder groups as well as citizens to ensure that relevant evidence and views from all interested parties are considered in the evaluation. This ED Fitness Check includes two open consultations, notably a public consultation (designed from a citizen's perspective) and a stakeholder consultation (designed for stakeholders and experts). There is also a survey aimed to collect the views of micro, small and medium-sized enterprises (SMEs).

This factual summary report provides a brief factual overview of the **open targeted stakeholder consultation**, with information on the respondents as well as the number of responses and range of opinions.

The aims of the stakeholder consultation were:

- To collect views on possible lack of legislative coherence of EU legislation with respect to EDs and possible impacts on stakeholders;
- To collect information on the effectiveness of the current EU legislation for the identification and risk management of endocrine disruptors;
- To collect information on the efficiency of procedures for the identification and risk management of EDs (e.g. duplication of efforts) and to identify opportunities for improvement.

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

The survey was an open consultation posted on the European Commission's endocrine disruptor webportal[2] for a period of 8 weeks from 06/12/2019 to 31/01/2020.

The questionnaire was structured into different parts. The first section concerned information about the respondents such as category of stakeholder, country of origin and residency, and regulatory sector of interest. The second section asked about the level of familiarity with the different pieces of legislation within the scope of the Fitness Check and then went on to ask questions, seeking views and information on different aspects of coherence, effectiveness, efficiency, relevance and EU-added value of the current approaches to identification, assessment and management of endocrine disruptors in the EU legislation.

Apart from the introductory section related to respondent characteristics, the survey did not include any mandatory field. It was therefore possible for respondents to leave one or more questions unanswered. As a result, the total number of responses to each question varied.

Some questions were aimed at specific categories of stakeholders: questions 25, 26 and 29 were intended for business associations, company/business organisations and public authorities; questions 27, 28 and 35 were intended for business associations and company/business organisations. These questions did not appear to respondents identifying themselves in other categories.

The survey consisted of both closed and open questions, including closed questions followed by an open field for explanation of the answer.

Overall 183 replies were received. A quality check of the responses evidenced a few replicates in the answers that will be taken into account during the final analysis. These replicate

2 *https://ec.europa.eu/info/policies/endocrine-disruptors_en*

answers, accounting for less than 15% of the total number of responses and being spread across the different stakeholders categories, are not expected to have a statistical impact on the numbers presented in this report.

This document reports the answers to the closed questions and provides an indication of the number of responses to the open questions. Responses to both closed and open questions will provide an essential input to the Fitness Check carried out by the European Commission. A more detailed analysis of the responses to the three consultations will be published in a synopsis report along with the Fitness Check evaluation at the end of the process.

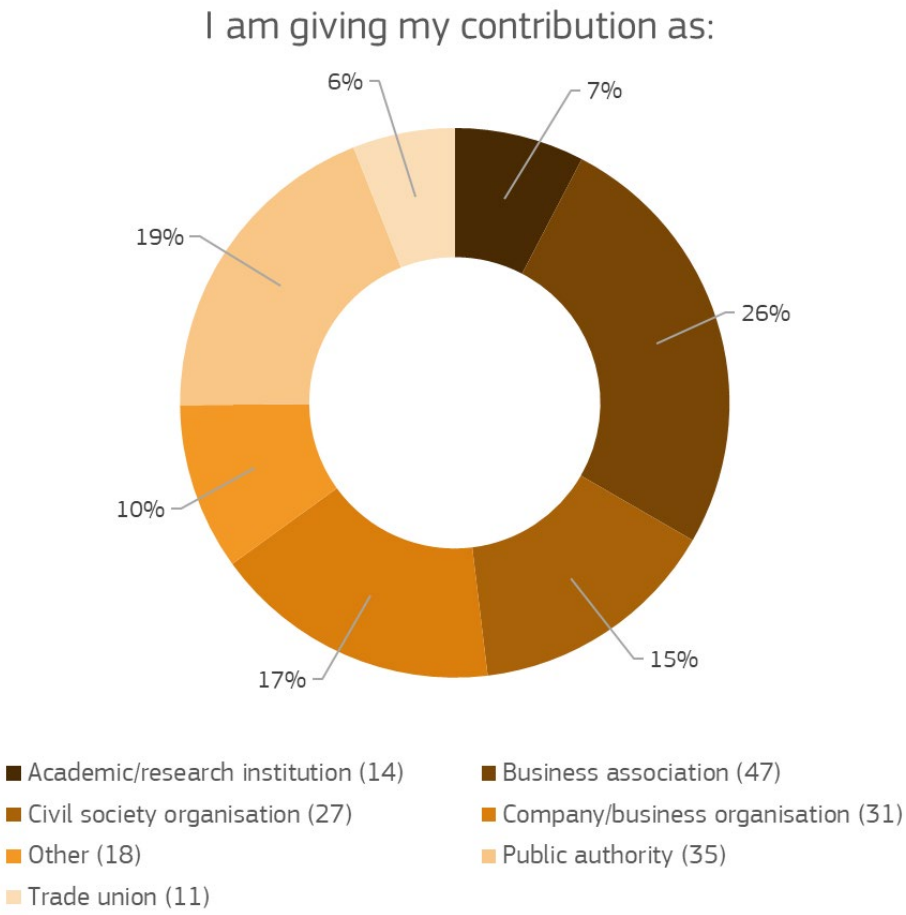
PART 2.

Who responded to the survey

Who responded to the survey

Replies provided to the survey cover all categories of respondents with respect to their stakeholder category:

- 47 come from Business associations
- 35 come from Public authorities
- 31 come from Company or business organisations
- 27 come from Civil society organisations
- 14 come from Academic/Research institutions
- 11 come from Trade unions



This document should be regarded solely as a summary of the contributions made by respondents to the targeted stakeholder consultation on the Fitness Check of the EU legislation on endocrine disruptors. It cannot in any circumstances be regarded as the official position of the European Commission or its services.

The most represented country is Belgium with 48 respondents, followed by France (27), Germany (18) and Spain (11).

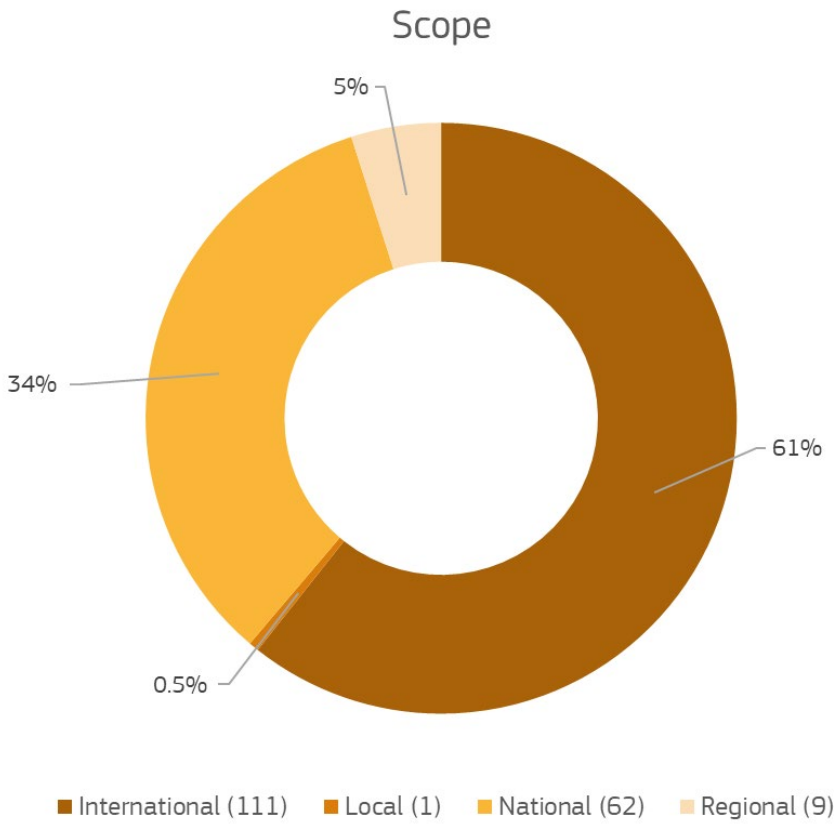
	Answers	*Percentage*
Belgium	48	26%
France	27	15%
Germany	18	10%
Spain	11	6%
Denmark	8	4%
Italy	7	4%
United Kingdom	6	3%
Sweden	5	3%
Austria	4	2%
Bulgaria	4	2%
Luxembourg	4	2%
Finland	3	2%
Hungary	3	2%
Ireland	3	2%
Portugal	3	2%
Latvia	2	1%
Netherlands	2	1%
Poland	2	1%
Romania	2	1%
Slovenia	2	1%
Croatia	1	1%
Cyprus	1	1%
Lithuania	1	1%
Malta	1	1%
Slovak Republic	1	1%
Other (Please specify)	13	7%

Respondents outside of the EU are from Switzerland (6), USA (3), Norway (2), Japan (1) and Turkey (1).

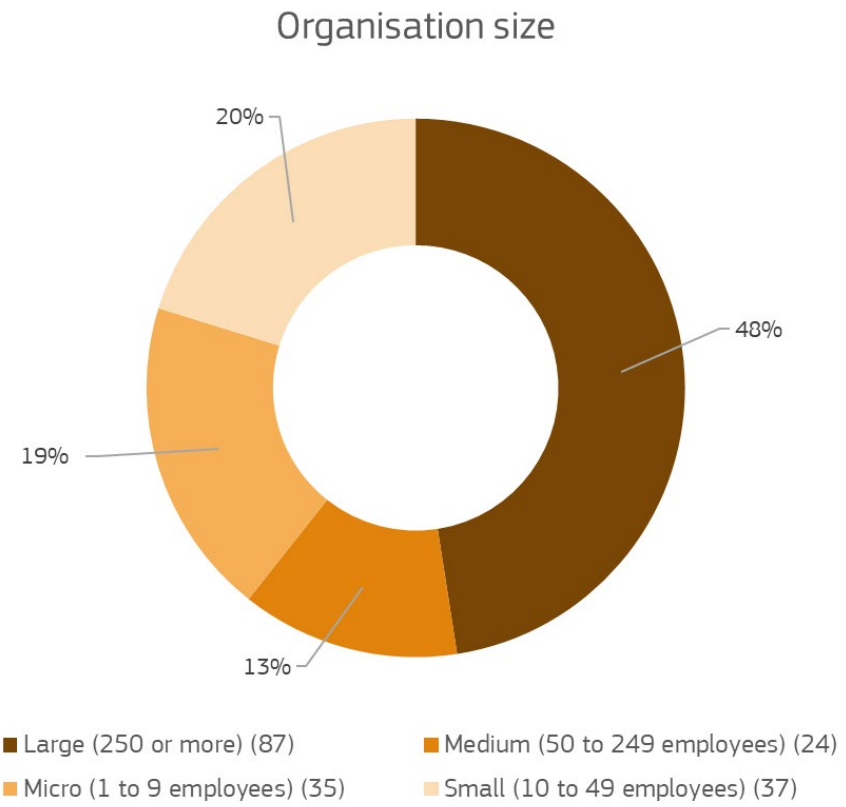
Among economic operators (companies and business associations) and public authorities, the main sectors of interest are General Chemicals (14%), Biocidal Products (12%) and Cosmetics (11%).

	Answers	*Percentage*
General chemicals	51	14%
Biocidal products	43	12%
Cosmetics	40	11%
Plant Protection Products	33	9%
Food contact materials	30	8%
Detergents	28	8%
Food additives	25	7%
Medical devices	24	6%
Human and veterinary medicines	20	5%
Fertilisers	16	4%
Water industry	16	4%
Waste/recycling industry	16	4%
Electric and electronic equipment	15	4%
Toys	14	4%

The geographical scope of the respondents is 61% international and 39% national, regional or local.



The size of the respondents' organisations is large for almost half of the respondents (48%), others being medium (20%), small (20%) or micro (19%). The Fitness Check also includes a survey of small and medium-sized enterprises (open from 1 February to 9 March 2020) the outcome of which will be reported separately.



PART 3.

What did the respondents say?

Q 01 How familiar are you with the following pieces of legislation?

The familiarity of the respondents with the pieces of EU legislation included in the scope of the Fitness Check is considered relevant to the interpretation of the replies provided to the other questions in the survey.

Among the listed legislative instruments, the respondents are most familiar with the following pieces of legislation:

	Very familiar	*Fairly familiar*	*A little familiar*	*Not at all familiar*
REACH Regulation (EC) 1907/2006	122	32	20	2
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008	113	35	17	10
Biocidal Products Regulation (EU) 2012/528	60	57	42	13
Cosmetic Products Regulation (EC) 1223/2009	59	35	35	40
Plant Protection Products Regulation (EC) 1107/2009	51	41	42	38

The respondents are least familiar with the following legislative instruments:

	Very familiar	*Fairly familiar*	*A little familiar*	*Not at all familiar*
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009	21	18	36	91
Medicinal Products for Humans Directive 2001/83/EC	15	23	52	77
Marine Strategy Framework Directive 2008/56/EC	15	16	48	85
Urban Waste Water Directive 91/271/EEC	21	9	44	90
Veterinary Medicinal Products Regulation (EU) 2019/6	16	14	40	97
In vitro Diagnostic Medical Devices Regulation (EU) 2017/746	14	12	45	94

Horizontal approach to the identification of endocrine disruptors

The European Commission has published criteria for the identification of endocrine disruptors under both the Biocidal Products Regulation and the Plant Protection Products Regulation, which are very similar to each other and based on the WHO definition[3]. Other pieces of EU legislation related to human health and environmental protection from manufactured chemicals do not contain such criteria.

3 "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."

Q 02

To what extent does the absence of harmonised criteria pose a problem to a coherent approach for the identification of endocrine disruptors?

Ninety-three percent of the respondents consider that the absence of harmonised criteria poses a problem to the identification of endocrine disruptors across sectors.

	Answers	*Percentage*
It is an important problem, leading to incoherent identification of endocrine disruptors across sectors	150	93 %
It is not a problem, the criteria should be sector specific	11	7 %

The Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures and 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.

Q 03

Do you think that 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?

Opinion is divided on this topic with roughly half of the respondents (53%) thinking that this is a problem for a coherent ED identification.

	Answers	*Percentage*
Yes	94	53 %
No	83	47 %

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

Q 04

On this topic, opinion is also divided with half of the respondents (51%) thinking that the lack of a hazard category is a problem for coherent risk management.

	Answers	*Percentage*
Yes	86	51 %
No	84	49 %

The CLP Regulation applies different approaches to categorise hazards depending on the endpoints, which may include aspects related to severity of effects or strength of evidence. Some stakeholders have suggested to classify endocrine disruptors in one of three categories based on the level of evidence: i.e. known, presumed or **suspected**.

Do you think that a category of suspected endocrine disruptor should be introduced?

Q 05

With regard to the need of a category of suspected endocrine disruptors, opinion is again divided with a bit more than half of respondents (53%) being in favour of introducing a category for suspected endocrine disruptors.

	Answers	*Percentage*
Yes	89	53 %
No	79	47 %

Rationale and consequences of different regulatory approaches

Under some pieces of legislation, endocrine disruptors are regulated based on their hazardous properties, whereas under others they are regulated on the basis of risk.

Q 06

Are you aware of any inconsistencies in the way chemicals are identified and controlled with regard to endocrine disrupting properties across regulated areas in the EU?

Seventy-three percent of respondents are aware of inconsistencies in the way endocrine disruptors are identified and controlled in the European Union.

	Answers	*Percentage*
Yes	123	73 %
No	45	27 %

Q 07a

In your opinion, how do hazard-based criteria for identifying endocrine disruptors in combination with a hazard-based approach to decision-making affect the following objectives?

A majority of respondents consider that the use of hazard-based criteria for identifying endocrine disruptors in combination with a hazard-based approach to decision making would affect (very)

positively[4] human health protection (93) and environmental protection (92) compared with 58 and 54 who viewed these impacts (very) negatively[5].

The effects on "competitiveness and innovation" and on the "functioning of the internal market" are viewed more negatively than positively, although higher numbers of respondents indicate "no effect" or "don't know".

	Very positively	*Positively*	*No effect*	*Negatively*	*Very negatively*	*Don't know*
Human health protection	60	33	5	24	34	15
Environmental protection	62	30	9	26	28	15
Competitiveness and innovation	33	16	10	21	46	45
Functioning of the internal market	34	9	19	29	23	56

In your opinion, how do hazard-based criteria for identifying endocrine disruptors in combination with a risk-based approach to decision-making affect the following objectives?

Q 07b

Of those respondents expressing an opinion, the majority view positively or very positively a risk-based approach to decision making in relation to human health and environmental protection.

4 Sum of respondents agreeing very positively or positively.

5 Sum of respondents agreeing very negatively or negatively.

The effects on "competitiveness and innovation" and on the "functioning of the internal market" are also viewed more positively than negatively, although higher numbers of respondents indicate "no effect" or "don't know".

	Very positively	*Positively*	*No effect*	*Negatively*	*Very negatively*	*Don't know*
Human health protection	60	51	3	32	10	14
Environmental protection	60	49	4	33	10	13
Competitiveness and innovation	37	42	15	29	4	43
Functioning of the internal market	32	28	18	28	5	56

Chemicals are managed under different EU regulations according to their uses and the environmental media into which they are released during their life cycle (production, use, recycling/disposal).

Q 08 Are you aware of any gaps or overlaps in the way endocrine disruptors are regulated in the EU?

Seventy-three percent of respondents consider that there are gaps or overlaps in the EU legislation on endocrine disruptors.

	Answers	*Percentage*
Yes	127	73 %
No	46	27 %

Have you experienced issues or problems because endocrine disruptors are regulated differently in the EU compared with non-EU countries?

Q 09

On this topic, opinion is divided with half of the respondents (51%) not experiencing issues or problems due to endocrine disruptors being regulated differently in the EU compared to non-EU countries.

	Answers	*Percentage*
Yes	81	49 %
No	85	51 %

Do you have further comments on the coherence of the EU legislation with regard to endocrine disruptors?

Q 10

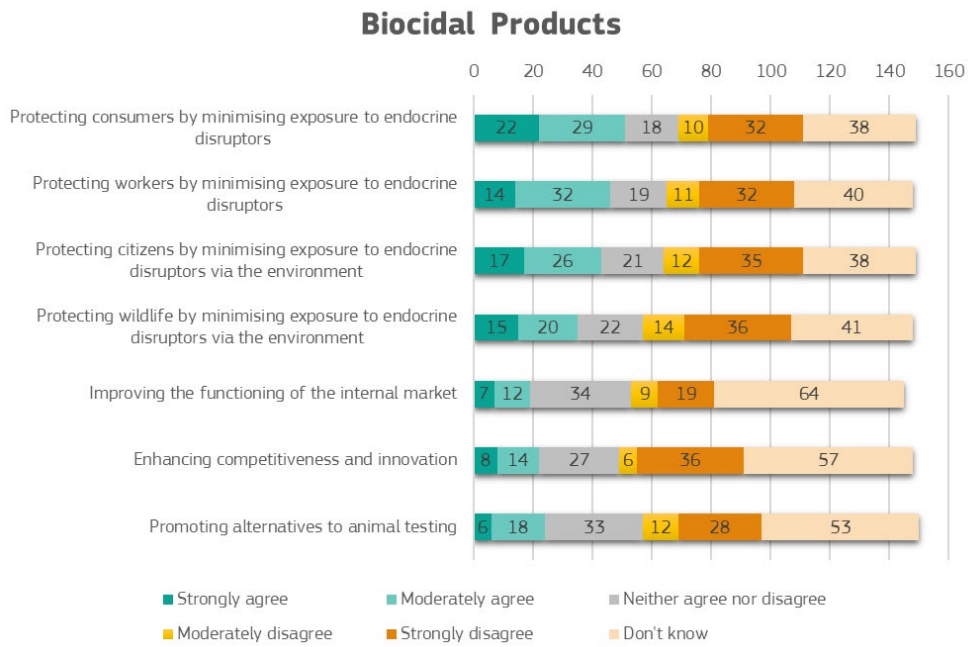
Ninety-four respondents provided answers to this open question. An analysis of the answers will be presented in the synopsis report.

Effectiveness in achieving policy objectives

A common goal of EU chemicals legislation is the protection of human and environmental health, by minimising exposure to hazardous chemicals, while at the same time improving the functioning of the internal market, enhancing competitiveness and innovation, and minimising animal testing. Some regulations have specific provisions for the identification and control of endocrine disruptors.

Q 11 Do you agree with the following statements?

a) The regulatory process to identify and control substances with endocrine disrupting properties in Biocidal Products is effective in:



With regard to biocidal products, of those expressing an opinion there is a roughly even split between those that consider the regulation is effective in protecting human health and those that do not when considering consumers (51 agree[6], 42 disagree[7], and 18 neither agree nor disagree), workers (46 agree, 43 disagree, and 19 neither agree nor disagree) or citizens exposed via the environment (43 agree, 47 disagree and 21 neither agree nor disagree). When it comes to protecting wildlife the number of

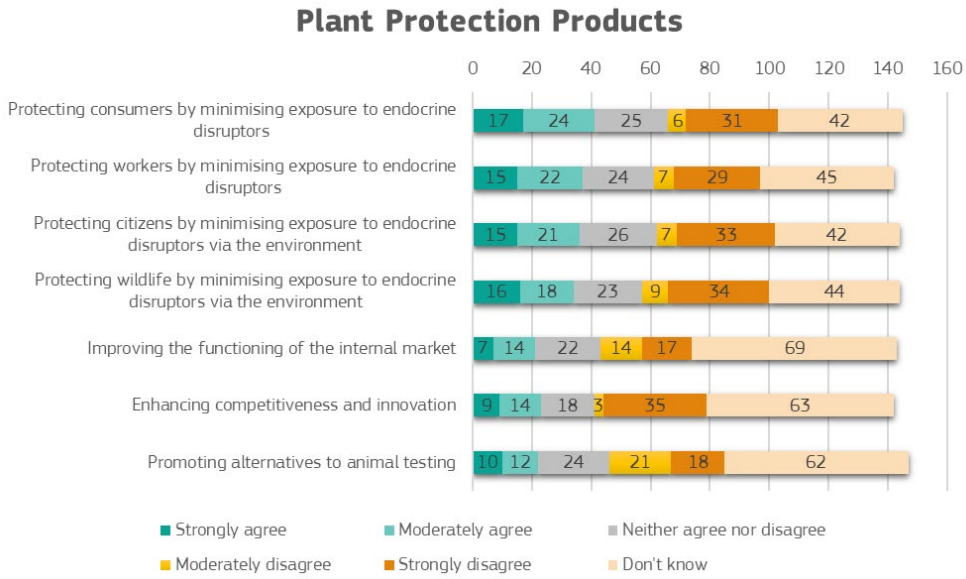
6 Sum of respondents who strongly or moderately agree.

7 Sum of respondents who strongly or moderately disagree.

respondents agreeing that the regulation is effective decreases (35 agree, 50 disagree and 22 neither agree nor disagree).

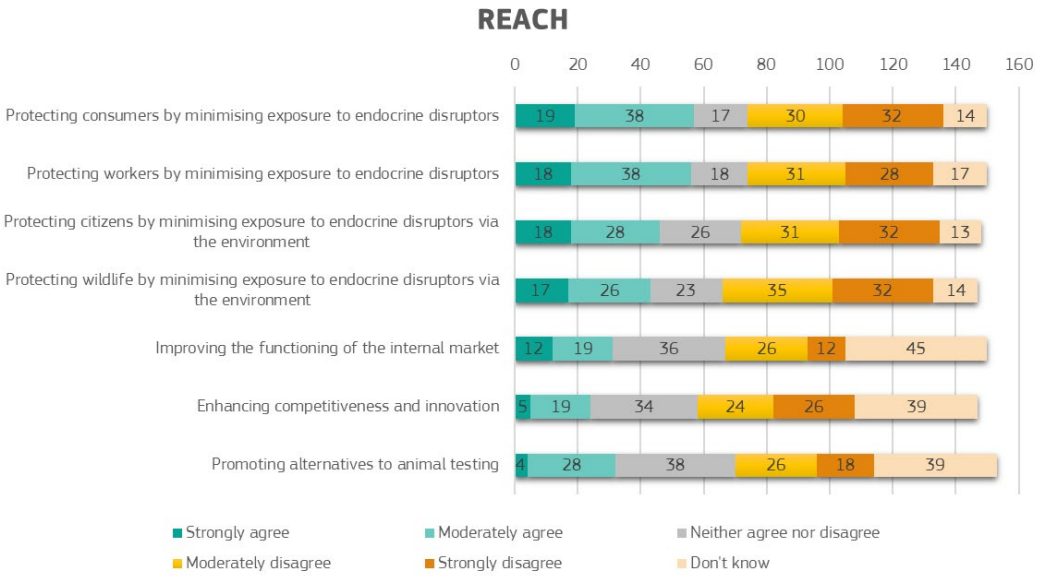
Of those expressing an opinion, more respondents disagree than agree that the provisions related to EDs have a positive effect on the functioning of the internal market (19 agree, 28 disagree and 34 neither agree nor disagree), on enhancing competitiveness and innovation (22 agree, 42 disagree and 27 neither agree nor disagree) and on promoting alternatives to animal testing (24 agree, 40 disagree and 33 neither agree nor disagree). However, to these questions there are many respondents choosing "neither agree nor disagree" or "don't know".

b) The regulatory process to identify and control substances with endocrine disrupting properties in Plant Protection Products is effective in:



For plant protection products the pattern of responses is very similar to those given for biocidal products.

c) The regulatory process to identify and control substances with endocrine disrupting properties under REACH is effective in:

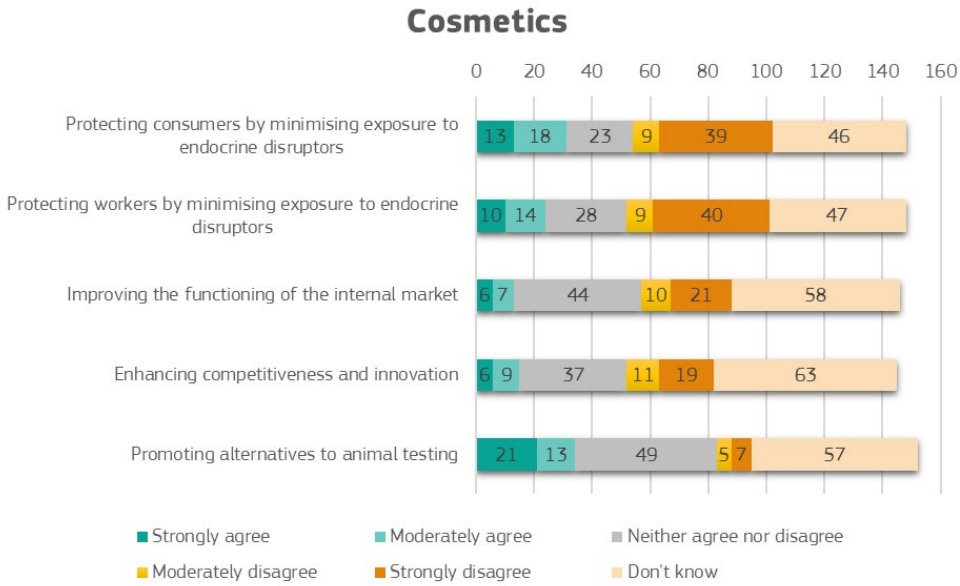


With regard to the effectiveness of REACH in protecting human health and the environment there are fewer respondents selecting 'neither agree nor disagree' or choosing to select 'don't know', than is the case for biocides or plant protection products.

Of those expressing an opinion there is a roughly even split between those that consider the regulation is effective in protecting human health and those that do not when considering consumers (57 agree, 62 disagree, and 17 neither agree nor disagree) or workers (56 agree, 59 disagree, and 18 neither agree nor disagree). A smaller proportion of respondents consider that the regulation is effective in protecting citizens exposed via the environment (46 agree, 63 disagree, and 26 neither agree nor disagree) or wildlife (43 agree, 67 disagree, and 23 neither agree nor disagree).

More respondents disagree than agree that the regulation (with respect to EDs) improves the functioning of the internal market (31 agree, 38 disagree, and 36 neither agree nor disagree) or enhances competitiveness and innovation (24 agree, 50 disagree, and 34 neither agree nor disagree) or promotes alternatives to animal testing (32 agree, 44 disagree, and 38 neither agree nor disagree). Again there are many respondents choosing "neither agree nor disagree" or "don't know" to this group of questions.

d) The regulatory process to identify and control substances with endocrine disrupting properties in Cosmetics is effective in:

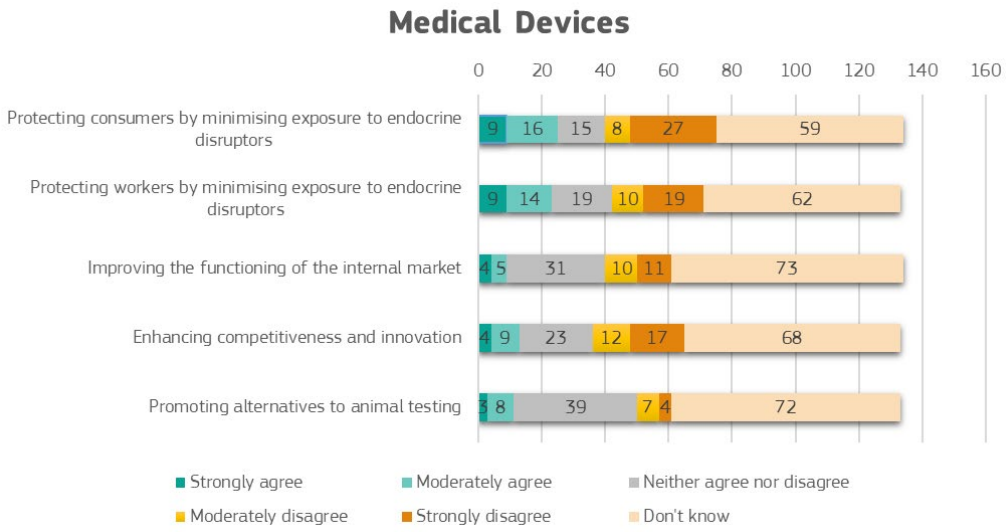


For cosmetics, more respondents disagree than agree that the regulation with respect to EDs is protecting consumer health (31 agree, 48 disagree, and 23 neither agree nor disagree) or worker health (24 agree, 49 disagree, and 28 neither agree nor disagree).

Few respondents agree that it is improving the functioning of the internal market (13 agree, 31 disagree, and 44 neither agree

nor disagree) or enhancing competitiveness and innovation (15 agree, 30 disagree, and 37 neither agree nor disagree). However the agree to disagree ratio changes around with respect to promoting alternatives to animal testing, where 34 moderately or strongly agree compared with 12 that strongly or moderately disagree. The number that "don't know" or "neither agree nor disagree" is rather high.

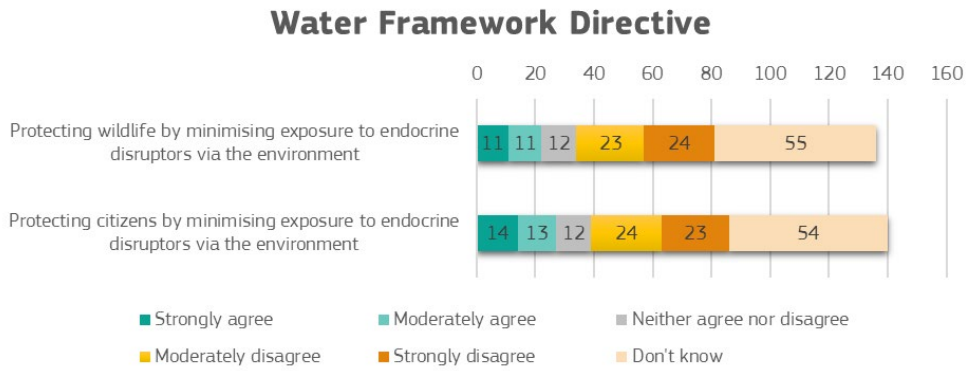
e) The regulatory process to identify and control substances with endocrine disrupting properties in Medical Devices is effective in:



For medical devices, a large proportion of respondents say they do not know about the effectiveness of the regulatory process (ranging from 59 to 73). Of those expressing an opinion, more respondents disagree than agree that it is protecting consumers (25 agree, 35 disagree, and 15 neither agree nor disagree), protecting workers (23 agree, 29 disagree, and 19 neither agree nor disagree) or enhancing competitiveness and innovation (13 agree, 29 disagree, and 23 neither agree nor disagree).

More respondents neither agree nor disagree that it is improving the functioning of the internal market (9 agree, 21 disagree, and 31 neither agree nor disagree) or promoting alternatives to animal testing (11 agree, 11 disagree, and 39 neither agree nor disagree) compared with those that agree or disagree.

f) The regulatory process to control substances with endocrine disrupting properties under the Water Framework Directive is effective in:



Regarding the Water Framework Directive, more respondents disagree than agree that the directive is effective in minimising the exposure of citizens (22 agree, 47 disagree, and 12 neither agree nor disagree) or wildlife (27 agree, 47 disagree, and 12 neither agree nor disagree) to endocrine disruptors via the environment. However, the numbers of "don't knows" are relatively high.

Aggregate exposure and combined effects

Humans and wildlife can be exposed to the same endocrine disruptor via various sources (aggregate exposure) if this substance is present in different types of products. Humans and wildlife can also be exposed to a combination of multiple endocrine disruptors from one or multiple sources, which may lead to combined effects (mixture/cocktail effect). Such effects may include additive and synergistic effects.

Q 12

Aggregate exposure to one substance from all exposure sources — Do you agree with the following statements?

More respondents disagree than agree that the current regulatory framework protects humans (60 agree, 96 disagree, and 6 neither agree nor disagree) or wildlife (39 agree, 92 disagree, and 14 neither agree nor disagree) from the risks associated with the aggregate exposure to one substance with endocrine disrupting properties from all exposure sources.

	Strongly agree	*Moderately agree*	*Neither agree nor disagree*	*Moderately disagree*	*Strongly disagree*	*Don't know*
Humans are protected by the current regulatory framework	25	35	6	33	63	8
Wildlife is protected by the current regulatory framework	19	20	14	23	69	24

Combined exposure to multiple substances from all sources — Do you agree with the following statements?

Q 13

Compared with Q12, a larger proportion of respondents disagree that the current regulatory framework protects humans (46 agree, 100 disagree, and 14 neither agree nor disagree) or wildlife (27 agree, 95 disagree, and 23 neither agree nor disagree) from the risks associated with the combined exposure to different substances with endocrine disrupting properties (combined effects).

	Strongly agree	*Moderately agree*	*Neither agree nor disagree*	*Moderately disagree*	*Strongly disagree*	*Don't know*
Humans are protected by the current regulatory framework	14	32	14	24	76	9
Wildlife is protected by the current regulatory framework	9	18	23	15	80	21

Vulnerable groups

The endocrine system controls a large number of processes in the body throughout life from early stages such as embryonic development, to later ones such as puberty, reproductive life and old age. It controls formation and functions of tissues and organs, as well as homeostasis of physiological processes.

Q 14

Do you think that the following groups are sufficiently protected from exposure to substances with endocrine disrupting properties?

For all population categories, the level of protection is regarded as insufficient by about two thirds of respondents (ranging between 56%[8] for adults in general to 66% for the unborn exposed during pregnancy).

	Yes	*No*	*Don't know*
unborn through exposure during pregnancy	47	90	34
newborn up to the age of 3	49	90	30
children until puberty	49	90	30
young persons around the age of puberty	48	91	30
pregnant women	52	87	29
adults in general	63	80	26
people at work	54	85	30
elderly	56	78	34
people with illnesses	46	81	43

8 Percentage of "No" answers, excluding respondents who don't know.

Data requirements and available regulatory test methods

Several EU regulations require registrants or applicants to perform some tests on the toxicity of their substance. These tests should be run according to validated test methods that are accepted by the authorities (Test Guidelines adopted at international level such as the OECD, or methods laid down in the Commission Regulation (EC) 440/2008 on test methods). Several of these tests can be used to identify endocrine disruptors.

Are available regulatory tests sufficient to identify endocrine disruptors for humans (including vulnerable groups) as well as wildlife? Q 15

A majority of respondents (74%) consider the available regulatory tests insufficient to identify EDs.

	Answers	*Percentage*
Yes	41	26 %
No	116	74 %

Q 16

Are current provisions for data requirements laid down in relevant legislation (REACH, Biocidal Products Regulation, Plant Protection Products Regulation) sufficient to identify endocrine disruptors for humans (including vulnerable groups) as well as wildlife?

Similarly, a majority of respondents (71%) consider that the data requirements laid down in relevant legislation (REACH, Biocidal Products Regulation, Plant Protection Products Regulation) are insufficient.

	Answers	*Percentage*
Yes	46	29 %
No	114	71 %

Q 17

Considering the information requirements of REACH, the Biocidal Products Regulation and the Plant Protection Products Regulation, do you think the likelihood of identifying a substance as an endocrine disruptor is lower under one of these regulations compared to the others?

The likelihood to identify an endocrine disruptor under REACH, the Biocidal Products Regulation and the Plant Protection Products Regulation is about the same, according to 53% of respondents.

	Answers	*Percentage*
Yes	65	47 %
No	74	53 %

Do you have any further comments on available regulatory test methods and data requirements under REACH, the Biocidal Products Regulation, the Plant Protection Products Regulation, and other sector specific legislation?

Q 18

Sixty-three respondents answered to this open question. An analysis of the answers will be presented in the synopsis report.

Regulatory testing and animal welfare

Data generation according to standard information requirements is expensive, time consuming and requires the use of animals. The recently adopted criteria for identifying endocrine disruptors require information on endocrine activity and adverse effects.

Do you agree with the following statement? *In vitro* and/or *in silico* methods are not used systematically enough to prioritise further investigations.

Q 19

Among those who expressed an opinion, a majority of respondents think that *in vitro* and/or *in silico* methods are not used systematically enough to prioritise further investigations (80 agree, 7 disagree, and 38 neither agree nor disagree).

	Answers
Strongly agree	39
Moderately agree	41
Neither agree nor disagree	38
Moderately disagree	5
Strongly disagree	2
Don't know	41

Regulations requiring testing for endocrine disrupting properties of a substance (Biocidal Products Regulation, Plant Protection Products Regulation, REACH) specifically require the use of vertebrate animals to be minimised, in accordance with Directive 2010/63/EU on the protection of animals used for scientific purposes.

Q 20

In your opinion, is the impact of assessing chemicals for endocrine disrupting properties on animal welfare minimised in the EU?

A bit more than half of the respondents expressing an opinion (54%) think that the impact of assessing chemicals for endocrine disrupting properties on animal welfare is minimised in the EU to the extent possible.

	Answers
Not at all	12
Insufficiently minimised	43
Minimised to the extent possible	64
Don't know	51

Do you have recommendations on how to further minimise the impact of assessing chemicals for endocrine disrupting properties on animal welfare?

Q 21

One hundred and eight respondents answered to this open question. An analysis of the answers will be presented in the synopsis report.

Effectiveness of regulatory procedures

The following sectors are regulated via sector-specific legislation as well as by horizontal/other legislation (e.g. REACH, Biocidal Products Regulation, CLP Regulation).

Are you aware of issues that result from the lack of specific provisions for identifying endocrine disruptors in sector-specific legislation for the following areas:

Q 22

A majority of respondents are not aware of issues resulting from the lack of specific provisions for identifying endocrine disruptors in sector-specific legislation (from 60% to 70%).

	Yes	*No*
Human and veterinary pharmaceuticals (only for effects on the environment)	39	80
Electrical and electronic equipment	40	81
Other (please specify)	33	65
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	42	81
Waste/recycling	42	81
Food additives	43	78
Toys	45	77
Workers protection	47	78
Detergents	46	75
Fertilisers	46	74
Cosmetics	52	83
Food contact materials	52	79
Water	51	77

Q 23

Are you aware of issues that result from the lack of specific provisions for managing endocrine disruptors in sector-specific legislation for the following areas:

For all categories, between 60 and 70% of respondents are not aware of issues resulting from the lack of specific provisions for managing endocrine disruptors in sector-specific legislation.

	Yes	*No*
Electrical and electronic equipment	39	81
Food additives	40	80
Fertilisers	41	79
Human and veterinary pharmaceuticals (only for effects on the environment)	41	79
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	43	82
Waste/recycling	42	78
Detergents	44	76
Workers protection	45	77
Toys	45	75
Water	49	76
Cosmetics	53	81
Food contact materials	51	76
Other (please specify)	32	72

In your view, on which areas should market surveillance authorities focus their activities to effectively enforce chemical safety of products as regards endocrine disruptors?

Q 24

A majority of respondents (80 to 90% of those who expressed an opinion) indicated that authorities should focus on market surveillance across all sectors listed.

	Yes	*No*	*Don't know*
Toys	88	10	44
Food contact materials	99	12	37
General chemicals	93	13	40
Cosmetics	92	13	37
Human and veterinary pharmaceuticals (only for effects on the environment)	75	11	52
Food additives	90	14	40
Waste/recycling	80	13	50
Plant Protection Products	87	16	39
Fertilisers	74	14	49
Biocidal products	88	17	38
Detergents	76	16	48
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	71	15	53
Electrical and electronic equipment	65	15	61
Other (please specify)	27	13	63

Efficiency of regulatory provisions for endocrine disruptors

Benefits of regulatory intervention include human health and environmental protection, smooth functioning of the internal market, 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.

Has the implementation of regulatory requirements for endocrine disruptors increased your total operating costs?

Q 25

Eighty-eight percent of the concerned respondents report an increase of costs related to regulatory requirements for endocrine disruptors. Forty-eight percent consider the increased costs to be significant.

	Answers
Yes, to a significant extent	29
Yes, but not to a significant extent	24
No	7
Not applicable	42

Has the assessment of substances for endocrine disrupting properties delayed your assessment work in other areas of human health or environmental protection?

Q 26

Of those respondents to whom the question is applicabile, about 80% reported a delay in their assessment work in other areas of human health or environmental protection. Half of these reported the delay to be significant.

	Answers
Yes, to a significant extent	24
Yes, but not to a significant extent	27
No	13
Not applicable	40

Q 27

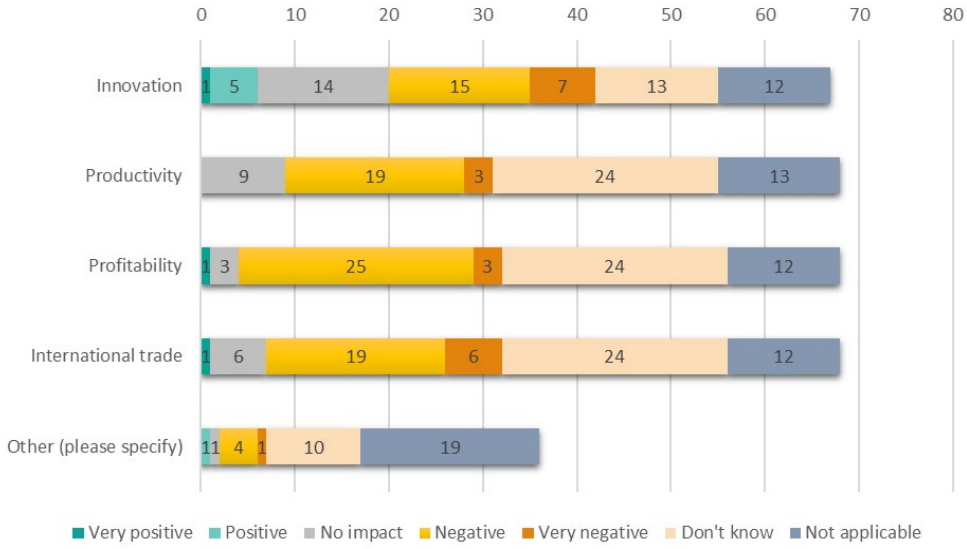
What is the cost increase for your company (companies your association is representing) to comply with the regulatory requirements (e.g. testing, restriction or ban) specifically related to endocrine disruptors?

Few respondents replied to this question. The type of costs incurring the highest cost increase was most commonly reported to be related to the provision of test data on endocrine disrupting properties.

	More than 10%	*Between 5 and 10%*	*Between 1 and 5%*	*Below 1%*	*Don't know*	*Not applicable*
Costs related to the provision of test data on endocrine disrupting properties	14	2	4	1	27	20
Cost to replace substances due to endocrine disrupting properties (e.g. as a producer or user)	7	4	7	1	27	19
Investment in the development of new testing methodologies for endocrine disrupting properties	6	8	3	0	25	26
Costs related to the preparation of registration or authorisation dossiers covering endocrine disrupting properties	5	7	6	4	22	24

What has been the impact of the provisions for endocrine disruptors on the sector you represent?

Q 28



More of the respondents expressing an opinion report the impact to be negative rather than positive, impacting productivity (0 positively, 22 (very) negatively, and 9 no impact), profitability (1 very positively, 28 (very) negatively, and 3 no impact) and international trade (1 very positively, 25 (very) negatively, and 6 no impact) and to a lesser extent innovation (6 (very) positively, 22 (very) negatively, and 14 no impact).

Q 29

Are the costs of the provisions for endocrine disruptor identification and management, for the sector(s) you operate in, justified and proportionate to the benefits accrued for society and the environment?

Of those respondents expressing an opinion, 79% consider the costs for endocrine disruptor identification and management to be to some extent or fully justified and proportionate to the benefits accrued for society and the environment in their sectors.

	Answers
Not at all	12
To some extent	28
Fully	17
Don't know	40

Adequacy of the legislation to address needs and concerns on endocrine disruptors

In 1999 the European Commission published a Community Strategy on endocrine disruptors[9], reflecting public concerns that these substances might cause diseases/disorders in humans and affect wildlife populations and biodiversity. Diseases/disorders in humans that are endocrine-related (i.e. via effect on the endocrine

9 *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:1999:0706:FIN*

system) might result from a combination of factors such as genetic origin, diet, lifestyle, exposure to endocrine disruptors and other chemical stressors. Effects on wildlife populations and biodiversity might be caused by a combination of factors such as habitat loss, climate change, exposure to endocrine disruptors and other chemical stressors.

To what extent do you think exposure to endocrine disruptors is contributing to the increase in endocrine-related human diseases/disorders, in the EU, in comparison with other factors?

Q 30

Sixty-two percent of respondents who expressed an opinion think that exposure to endocrine disruptors is contributing to a significant extent to the increase in endocrine-related human diseases/disorders in the EU, in comparison with other factors.

	Answers
To a significant extent	75
Not to a significant extent	40
Not at all	6
Don't know	46

To what extent do you think exposure to endocrine disruptors is contributing to the decrease in aquatic and terrestrial biodiversity in the EU, in comparison with other factors?

Q 31

Sixty-four percent of respondents who expressed an opinion think that endocrine disruptors are contributing to a significant

extent to the decrease in aquatic and terrestrial biodiversity in the EU, in comparison with other factors. However, a relatively large number of respondents selected 'don't know'

	Answers
To a significant extent	70
Not to a significant extent	36
Not at all	3
Don't know	57

The 1999 Community Strategy highlighted the need for research and development of new tools to understand the mechanisms of endocrine disruption.

Q 32

Is the regulatory framework flexible enough to take into account new scientific information and methods in the assessment of endocrine disrupting properties (e.g. new toxicological tests, (bio)monitoring data, (eco)epidemiology)?

Fifty-three percent of respondents think that the regulatory framework is not flexible enough to take into account new scientific information and methods in the assessment of endocrine disrupting properties.

	Answers
Yes	73
No	84

Do you have any further comments on the adequacy of legislation to address societal needs and concerns on endocrine disruptors?

Q 33

Sixty-four respondents answered to this open question. An analysis of the answers will be presented in the synopsis report.

Added value of EU level intervention

There have been instances where Member State authorities have taken unilateral action on endocrine disruptors before a decision has been taken at the EU level. For example, in October 2012, the French authorities introduced a ban of Bisphenol A in all Food Contact Materials, applicable from July 2015.

With regard to unilateral action on endocrine disruptors by Member States Authorities, do you think this is justifiable?

Q 34

Thirty-two percent of the respondents think it is not justifiable at all. Another thirty-two percent think it is justifiable but should be followed by an EU wide action. Twenty-four percent think that this is justifiable in some cases, while 2% consider EDs should not be regulated at EU level.

	Answers
This is not justifiable – decisions should be taken at EU level and all citizens of the EU should be protected in an equal way, while preserving the integrity of the single market.	59
This is justifiable, but it should be followed by an EU wide action to preserve the integrity of the single market.	59
This is justifiable in some cases – protection of human health or the environment is more important than preserving the integrity of the single market.	44
This is justifiable – endocrine disruptors should not be regulated at EU level.	4

Q 35 Has your organisation been impacted by unilateral actions at national level?

Of those who answered, 48% of respondents consider that their organisations have been impacted by unilateral actions at national level.

	Answers
Yes	30
No	33

Q 36 Do you have any further comments on the added value of regulating endocrine disruptors at EU level?

Seventy-eight respondents answered to this open question. An analysis of the answers will be presented in the synopsis report.

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