EDC Targeted Consultation

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Introducing Standard Information Requirements for Endocrine Disruption

REACH Registration requires manufacturers and importers of substances in quantities greater than 1 tonne per year to collect and share information on the properties and uses of such substances. Registrants must assess the intrinsic properties of their substance and whether the substance may cause an adverse effect on human health or the environment. This information is communicated to ECHA in their Registration dossier, and for substances manufactured or imported in quantities greater than 10 tonnes per year, the chemical safety report. Standard information requirements are the minimum required to meet REACH Registration obligations and are dependent on the tonnage that is manufactured or imported into the EU/EEA.

The European Commission has been investigating the regulation of endocrine disruptors for a number of years. In 1999, the EU Commission adopted the Community Strategy for endocrine disruptors, which has led to action in the fields of regulation, research, and international cooperation. Despite significant improvements in our understanding and regulation of endocrine disruptors, there remains a need to update the EU approach in order to ensure that it continues to build on existing knowledge and coherently address these substances throughout the chemical legislative framework.

The Commission Communication 'Towards a comprehensive European Union framework on endocrine disruptors'[1] confirmed the commitment of the Commission to update data requirements in the different legislative frameworks to improve identification of endocrine disruptors. The 2020 Fitness Check on Endocrine Disruptors noted that questions had been raised by stakeholders on the overall coherence of the EU legal framework in relation to EDCs. Building on this, the Chemicals Strategy for Sustainability seeks to "*ensure that sufficient and appropriate information is made available to authorities [on the intrinsic properties of a substance] to allow the identification of endocrine disruptors [which may cause adverse effects on human health and the environment] by reviewing and strengthening the information requirements across legislation*" [2]. To do this, the European Commission shall "*update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH*".

In order to meet the ambition of Chemicals Strategy for Sustainability to ensure sufficient and appropriate information for identification of endocrine disruptors, the Commission proposes to update:

- Annex I - General provisions for assessing substances and preparing chemical safety reports
- Annex VII - Standard information requirements for substances manufactured or imported in quantities of one tonne or more
- Annex VIII - Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more

- Annex IX - Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more.
- Annex X - Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more.[3]

Options for introducing standard information requirements for endocrine disruptors at each tonnage level were presented at the 3rd meeting of the CASG-ED in October 2020. Following the advice of the subgroup of the Competent Authorities for REACH and CLP on endocrine disruptors (CASG-ED) experts, the Commission has developed two different options for adaptations of the Annexes, which will include new standard tests providing information on endocrine disrupting properties. Before the potential revision of the REACH Annexes, the Commission following its guidelines on Better Regulation conducts an Impact Assessment of the relevant regulatory options. The purpose of this consultation is to gather the views of key stakeholders on the costs and benefits of including in REACH standard information requirements for endocrine disruption.

[1] COM(2018) 734

[2] COM(2020) 667

[3] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

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3

Your role – what you can do to help us and the EU

We would like to enlist your help in understanding the range of potential impacts (cost and benefits) of the two proposed options for introducing standard information requirements for endocrine disruptors to REACH Annexes VII-X.

Your views and expertise will contribute to our ongoing work on an Impact Assessment of possible revisions to the information requirements of the REACH Regulation.

The Targeted Consultation questionnaire shall run from 3rd August 2021 – 8th October 2021.

Content of this consultation

This **Targeted Consultation** is divided into **seven parts**:

- Part 1 asks for some information about you, such as which country you come from.
- Part 2 aims to gather information on general awareness and views of the impacts of endocrine disruptors and the measures to manage these and existing legislation.
- Part 3 contain more detailed questions about the ambitions and relevance of chemical legislation in the EU and views on the revision of REACH Annexes.
- Parts 4, 5, 6 and 7 aim to gather evidence of the potential baseline direct and indirect economic, social and environmental impacts of the proposed changes to REACH Annexes to include standard information requirements for endocrine disruption.

Please also note that there will be also be follow-on **Targeted Stakeholder online Focus Groups for experts** (11th October 2021 – 29th October 2021). At the end of this survey, you are welcomed to let us know if you would like to participate in the follow-on Targeted Stakeholder online Focus Groups.

At the end of the questionnaire, you will also be able to upload one document (e.g. technical information, Position Paper, etc.) supporting and detailing your views.

If your would like to save the questionnaire and come back to it later please use the "Save and Continue" function at the bottom of the page. Once you have submitted your answers, you will receive an email with your completed questionnaire.

If you have any questions, please contact the European Commission at this dedicated email address:

ENV-EDC@ec.europa.eu

Please contact the study team at:

becca.johansen@ricardo.com

Your opinion matters, and we are very grateful to you for taking the time to answer these questions.

4

Part One - About You

5

Language of my contribution

*

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

LOGIC Show/hide trigger exists.

ID 6

I am giving my contribution as

*

- Business association
- Chemical manufacturer/ formulator
- Downstream user
- Consumer organisation
- Laboratory
- Non-governmental organisation (NGO) with a focus on human health
- Non-governmental organisation (NGO) with a focus on the environment
- Non-governmental organisation (NGO) with a focus on Animal Welfare organisation
- Public authority including ECHA
- Trade union
- Research institute/Scientific organisation
- Other

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Other")

ID 7

Please specify your choice of other

*

ID 8

Please complete: *

First name

Surname

EmailThis will not be published

9

Organisation/association/institution/authority name

*

10

Scale of your operation

*

- International
- National
- Regional
- Local

11

Organisation size

*

- Micro (1 to 9 employees or €2 million or less turnover/ balance sheet total)
- Small (10 to 49 employees or €10 million or less turnover/ balance sheet total)
- Medium (50 to 249 employees or €50 million or less turnover/ balance sheet total)
- Large (250 or more or more than €50 million turnover/ balance sheet total)

12

EU Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision making.

LOGIC Show/hide trigger exists.

ID 13

Country of origin

Please add your country of origin, or that of your organisation.

*

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus Malta
- Czechia
- Denmark
- Estonia
- Finland
- France Slovakia
- Option 2
- Germany
- Greece Spain
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Netherlands
- Poland
- Portugal
- Romania
- Slovenia
- Sweden
- United Kingdom
- Other

LOGIC Hidden unless: Question "Country of origin

Please add your country of origin, or that of your organisation.

" is one of the following answers ("Other")

ID 14

Please specify your country of origin *

15

Publication - Privacy settings

16

The Commission will publish the responses to this public consultation. Please choose whether you would like your details to be made public or to remain anonymous.

*

- [ ] PLEASE TICK THIS BOX if you are happy to make your submission **Public**.
We will publish your identification details (name, organisation name and size, transparency register number, country of origin) and your contribution.

- [ ] PLEASE TICK THIS BOX if you wish to remain **Anonymous**.
We will only publish your type of respondent, country of origin and contribution. We will not publish any other details (name, organisation name and size, transparency register number, etc).

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PLEASE TICK THIS BOX to state that you agree with the personal data protection provisions

*

- [ ] I agree

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Part 2 – General awareness and views on the impacts of endocrine disruptors and existing legislation

This section asks about your general awareness of the chemicals industry, endocrine disruptors, and existing legislation to gather general views on revising the information requirements, especially under REACH; to improve the identification and management of endocrine disruptors and, in doing so, protecting citizens and the environment better against associated hazards whilst encouraging innovation for the development of safe and sustainable alternatives.

In each question, please select the answer which best represents your views.

Please also note that you do not need to answer all the questions in any of the sections.

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1. How familiar are you with the potential role of chemical substances in affecting the endocrine systems of humans and wildlife?

Familiarity with the role of chemicals affecting the endocrine system of **humans**

- Expert
- Very familiar
- Somewhat familiar
- Not familiar
- Don't know

Familiarity with the role of chemicals affecting the endocrine system of **animals**

- Expert
- Very familiar
- Somewhat familiar
- Not familiar
- Don't know

22

2. For the products that you use (consumer goods) or work with (e.g. manufactured substances, testing chemicals, products for professional or industrial use) on a day-to-day basis, how familiar are you with the chemical components and their potential positive or negative impacts on human and wildlife?

Familiarity with chemicals used and/or worked with and **potential positive impacts on human health**	Expert Very familiar Somewhat familiar Not familiar Don't know
Familiarity with chemicals used and/or worked with and **potential negative impacts on human health**	Expert Very familiar Somewhat familiar Not familiar Don't know
Familiarity with chemicals used and/or worked with and **potential positive impacts on wildlife**	Expert Very familiar Somewhat familiar Not familiar Don't know
Familiarity with chemicals used and/or worked with and **potential negative impacts on wildlife**	Expert Very familiar Somewhat familiar Not familiar Don't know

31

3. Do you have practical experience with registering substances and engaging with the REACH Annexes that outline the existing information requirements?

Annex I General provisions for assessing substances and preparing Chemical Safety Reports	Highly experienced Somewhat experienced Limited experience No experience Don't know
Annex VII Standard information requirements for substances manufactured or imported in quantities of one tonne or more	Highly experienced Somewhat experienced Limited experience No experience Don't know
Annex VIII Standard information requirements for substances manufactured or imported in quantities of 10 tonne or more	Highly experienced Somewhat experienced Limited experience No experience Don't know
Annex IX Standard information requirements for substances manufactured or imported in quantities of 100 tonne or more	Highly experienced Somewhat experienced Limited experience No experience Don't know
Annex X Standard information requirements for substances manufactured or imported in quantities of 1000 tonne or more	Highly experienced Somewhat experienced Limited experience No experience Don't know

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Public authority including ECHA","Other")

ID 42

4. How many employees currently work on REACH Registration within your organisation?

Average number of employees per annum working on REACH Registration over the last five years

- 0 FTE
- 1-25 FTE
- 26-50 FTE
- 51-75 FTE
- 76-100 FTE
- 101+ FTE
- Don’t know

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Part 3 – Views on the revision of REACH Annexes I, VII to X to include standard information requirements for endocrine disruption

As outlined in the introduction, in order to meet the ambition of the Chemicals Strategy for Sustainability to ensure sufficient and appropriate information for identification of endocrine disruptors, the Commission proposes to update:

- Annex I - General provisions for assessing substances and preparing chemical safety reports
- Annex VII – Standard information requirements for substances manufactured or imported in quantities of one tonne or more
- Annex VIII - Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
- Annex IX - Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
- Annex X - Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more.[1]

This part seeks to gather detailed information on the potential costs and benefits of the two options (Option 1, Option 2 ?If you cannot access the document please ensure you are not using an Advertisement Blocker, if the issue persists please contact becca.johansen@ricardo.com) presented by the Commission for revision of the standard information requirements to include endocrine disruption. This data shall be assessed against the baseline.

Baseline Scenario

Current REACH standard information requirements, as published in Annexes VII-X of REACH, including all amendments up to and including Regulation 2018/1881.

Please select the answer that best represents your views. Please note that not all questions need to be answered.

[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

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5. REACH Registration is the first step in the regulation of endocrine disruptors. How important would you say the addition of standard information requirements for the testing of endocrine disruption under REACH could be to inform of their properties?

Addition of standard information requirements for endocrine disruption testing under REACH to inform about endocrine disrupting properties with human health effects	Very important Somewhat important Hardly important Not important Don't know
Addition of standard information requirements for endocrine disruption testing under REACH to inform about endocrine disrupting properties with environmental effects	Very important Somewhat important Hardly important Not important Don't know

52

6. Testing for endocrine disruption is currently mainly limited to animal testing due to current knowledge and available test methods for endocrine activity. Use of alternative test methods such as (Q)SAR, read-across and grouping and in vitro studies that could reduce animal testing are available or are under development. **Would a greater focus on alternative test methods lead to greater innovation in this field, and a reduction in reliance on in vivo methods?**

Strongly agree
Moderately agree
Neither agree nor disagree
Moderately disagree
Strongly disagree
I don't know

53

7. Which of the following in vivo tests can possibly be replaced by non-animal testing methods?

	QSARs	Read-across/ Grouping	In vitro tests
Short-term toxicity testing on fish (OECD TG 203)	☐	☐	☐
Uterotrophic Bioassay in Rodents (OECD TG 440)	☐	☐	☐
Hershberger Bioassay in Rats (OECD TG 441)	☐	☐	☐
Fish Short Term Reproduction assay (OECD TG 229)	☐	☐	☐
Amphibian Metamorphosis Assay (OECD TG 231)	☐	☐	☐
Fish early-life stage (FELS) toxicity test (OECD TG 210)	☐	☐	☐
Fish, juvenile growth test (OECD TG 215)	☐	☐	☐
Fish Sexual Development Test (OECD TG 234)	☐	☐	☐
Fish Life Cycle Toxicity Test (OPPTS 850.1500)	☐	☐	☐
Medaka Extended One-Generation Reproduction Test (OECD TG 240)	☐	☐	☐
Zebrafish Extended One-Generation Reproduction Test	☐	☐	☐
Larval Amphibian Growth and Development Assay (OECD TG 241)	☐	☐	☐

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8. Please state any additional non-animal testing methods that can be used or other in vivo tests that could be replaced.

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9. For substances to be ‘fully registered’ under REACH, the information in REACH Annexes VII-X must be submitted with the registration. If in vitro testing for EDs was added to the REACH information requirements as indicated in the options, **for what percentage of these ‘fully registered substances’** (including identified EDs or substances for which available classification provides information e.g. tests for reprotoxicity that provide information on ED effects) would you estimate the in vitro tests would provide an indication for an ED mode of action, sufficient information on the ED mode of action or on ED related effects?

Indication for ED mode of action	0 1-5% >5-10% >10-25% >25-50% >50-75% >75-100% Don’t know
Sufficient information on the ED mode of action	0 1-5% >5-10% >10-25% >25-50% >50-75% >75-100% Don’t know
Sufficient information on ED related effects	0 1-5% >5-10% >10-25% >25-50% >50-75% >75-100% Don’t know

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10. For substances to be ‘fully registered’ under REACH, the information in REACH Annexes VII-X must be submitted with the registration. If in vitro testing for EDs was added to the REACH information requirements as indicated in the options, and if the in vitro testing results in indication of an ED mode of action or ED related effects, **what percentage of these ‘fully registered substances’ would be confirmed as actual EDs by further (in vivo) testing** (100% = all ‘fully registered’ substances)?

0
1-5%
>5-10%
>10-25%
>25-50%
>50-75%
>75-100%
Don’t know

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11. Please provide an explanation for your response that is supported by evidence and sources (including whether or not your assessment is based on the portfolio of substances you are producing/ using). We would especially welcome any evidence on substances you have identified and/or have evidence to suspect that they might have ED properties.

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Please upload any evidence or sources to support your response.

Browse...

81

12. When considering the possible new information requirements to identify substances

that may have endocrine-disrupting properties, how would you assess their importance?

	Very important	Important	Hardly important	Not important	Don't know	Clear answer not possible/answer is case-dependent
Literature review	☐	☐	☐	☐	☐	☐
Systematic literature review	☐	☐	☐	☐	☐	☐
In silico methods	☐	☐	☐	☐	☐	☐
Estrogen receptor transactivation assay (OECD TG 455)	☐	☐	☐	☐	☐	☐
Androgen receptor transactivation assay (OECD TG 458)	☐	☐	☐	☐	☐	☐
H295R steroidogenesis assay (OECD TG 456)	☐	☐	☐	☐	☐	☐
Aromatase assay (OPPTS 890.1200)	☐	☐	☐	☐	☐	☐
Short-term toxicity testing on fish (OECD TG 203)	☐	☐	☐	☐	☐	☐
Uterotrophic Bioassay in Rodents (OECD TG 440)	☐	☐	☐	☐	☐	☐
The output data from the ToxCast ER Bioactivity Model	☐	☐	☐	☐	☐	☐
Hershberger Bioassay in Rats (OECD TG 441)	☐	☐	☐	☐	☐	☐
Fish Short Term Reproduction assay (OECD TG 229)	☐	☐	☐	☐	☐	☐
Fish early-life stage (FELS) toxicity test (OECD TG 210)	☐	☐	☐	☐	☐	☐
Fish, juvenile growth test (OECD TG 215)	☐	☐	☐	☐	☐	☐
Fish Sexual Development Test	☐	☐	☐	☐	☐	☐

Development Test (OECD TG 234)	☐	☐	☐	☐	☐	☐
Fish Life Cycle Toxicity Test (OPPTS 850.1500)	☐	☐	☐	☐	☐	☐
Amphibian Metamorphosis Assay (OECD TG 231)	☐	☐	☐	☐	☐	☐
Medaka Extended One-Generation Reproduction Test (OECD TG 240)	☐	☐	☐	☐	☐	☐
Zebrafish Extended One-Generation Reproduction Test	☐	☐	☐	☐	☐	☐
Larval Amphibian Growth and Development Assay (OECD TG 241)	☐	☐	☐	☐	☐	☐

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13. With regards to animal welfare considerations or costs to companies, do you believe it is proportionate to require in vivo animal, testing for low tonnage (<10 tonnes) substances?

Cost to companies

Yes
No
Don’t know

Animal welfare

Yes
No
Don’t know

Please explain your answer with reference to any evidence that may support it

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14. A weight of evidence approach uses a combination of information from several independent sources to give sufficient evidence to fulfil an information requirement. This approach is beneficial when the information from a single piece of evidence alone is not sufficient to fulfil an information requirement. Option 1 suggests in Annex VIII to trigger in vivo studies informing on endocrine mechanisms or adverse effects using a weight-of-evidence approach. What would be – in your view – sufficient information in a weight-of-evidence approach for requesting further tests?

	Agree	Disagree	Don't know/neither agree or disagree
A single positive in vitro assay	○	○	○
At least two positive in vitro assays pointing to the same mechanisms	○	○	○
A single positive in vitro assay plus some other information (e.g. either QSAR, in vivo effect data, read-across …)	○	○	○
Read-across to another substance with known mode of action	○	○	○
QSAR	○	○	○
In vivo effect data that give reasonable cause for assuming an ED mode of action.	○	○	○
The information needed is case dependent. It is not possible to set clear rules.	○	○	○

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15. For substances registered in the tonnage band of above 1 tonnes and below 10 tonnes (low tonnage substances), Option 2 requests in vivo mechanistic studies on the basis of a single positive result in any of the in vitro assay. Do you agree or disagree to the following statements?

	Agree	Disagree	Don't know/neither agree or disagree
A single positive in vitro assay sufficiently justifies requesting an in vivo mechanistic test	○	○	○
The trigger for in vivo testing should be strengthened	○	○	○
The positive in vitro assay should be confirmed by a second in vitro assay before triggering in vivo testing	○	○	○
A positive in vitro assay sufficiently evidences an ED mode of action – no confirmation with an in vivo test required	○	○	○

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16. For substances registered in the tonnage band of 10 tonnes or more, Option 2 requests in vivo mechanistic studies as well as in vitro tests. Option 1 requests in vivo mechanistic studies on the basis of a weight of evidence (WoE) approach that takes account of available information. Thus Option 1 may be less expensive than Option 2 but Option 2 may identify a greater proportion of the substances that are EDs

Which would be your preferred option for substances registered in the tonnage band of 10 tonnes or more?
Details of Option 1 and Option 2 ?If you cannot access the document please ensure you are not using an Advertisement Blocker, if the issue persists please contact becca.johansen@ricardo.com

- Option 1
- Option 2
- No preference
- Don't know

Please provide an explanation for your response that is supported by evidence and sources.

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Please upload any supporting evidence

Browse...

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17. The Options list several established in vitro assays. As any test method, in vitro assays can lead to false positive and false negative results. If you have suitable expertise, could you provide an estimation for the prevalence of false positive and false negative results for the following assays?

False positive

<2%
<5%
<10%
<20%
<30%
<50%
Don’t know

Estrogen receptor transactivation assay (OECD TG 455)

<2%
<5%
<10%
<20%
<30%
<50%
Don’t know

Androgen receptor transactivation assay (OECD TG 458)

<2%
<5%
<10%
<20%
<30%
<50%
Don’t know

H295R steroidogenesis assay (OECD TG 456)

<2%
<5%
<10%
<20%
<30%
<50%
Don’t know

Aromatase assay (OPPTS 890.1200)

False negative

<2%
<5%
<10%
<20%
<30%
<50%
Don’t know

Estrogen receptor transactivation assay (OECD TG 455)

<2%
<5%
<10%
<20%
<30%
<50%
Don’t know

Androgen receptor transactivation assay (OECD TG 458)

Don't know

<2%
<5%
<10%
<20%
<30%
<50%
Don't know

H295R steroidogenesis assay (OECD TG 456)

<2%
<5%
<10%
<20%
<30%
<50%
Don't know

Aromatase assay (OPPTS 890.1200)

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18. Please provide an explanation for your response that is supported by evidence and sources.

Do you know examples of false-negatives/positives?

153

Please upload any supporting evidence or sources.

Browse...

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19. The current options differ as regards in vitro thyroid assays to be introduced in Annex VII. Option 1 suggests the use of (multiple) thyroid assays in Annex VII that address different key events in the thyroid modes of action. Option 2 does not specify the assays yet but contains a placeholder. Which of the following key events do you think are important to address in in vitro assays?

	Very important	Important	Hardly important	Not important	Don't know
Binding to and (in)activation of thyroid hormone receptors;	○	○	○	○	○
Thyroid stimulating hormone receptor binding and (in)activation;	○	○	○	○	○
Thyroid releasing hormone receptor binding and (in)activation;	○	○	○	○	○
Binding to thyroid hormone serum transporters	○	○	○	○	○
Inhibition of thyroid hormone cellular transporters	○	○	○	○	○
Thyroid peroxidase inhibition	○	○	○	○	○
Sodium/iodide symporter inhibition	○	○	○	○	○
Deiodinase inhibition	○	○	○	○	○
Inhibition and/or induction of thyroid hormone biotransformation enzymes	○	○	○	○	○
Altering thyroid hormone levels affecting in vitro organ systems.	○	○	○	○	○

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Consumer organisation","Laboratory","Non-governmental organisation (NGO) with a focus on human health","Non-governmental organisation (NGO) with a focus on the environment","Non-governmental organisation (NGO) with a focus on Animal Welfare organisation","Trade union","Research institute/Scientific organisation","Other")

ID 165

20. How many of the thyroid assays listed in Q16 do you believe is appropriate to include in the standard information requirements?

None
1
2
3
4
5
6
7
8
9
10

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Public authority including ECHA")

ID 166

21. How many of the thyroid assays listed in Q17 do you believe is appropriate to include in the standard information requirements?

None
1
2
3
4
5
6
7
8
9
10

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22. Please provide an explanation for your response that is supported by evidence and sources, where possible.

186

Please upload evidence and sources, where possible.

Browse...

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23. Please mark in the table below those in vitro assays (or any combination) that **in your view provides sufficient information** to provide evidence on a thyroid mechanism for triggering further in vivo testing for thyroid disruption mediated effects.

- [ ] Binding to and (in)activation of thyroid hormone receptors;
- [ ] Thyroid stimulating hormone receptor binding and (in)activation;
- [ ] Thyroid releasing hormone receptor binding and (in)activation;
- [ ] Binding to thyroid hormone serum transporters
- [ ] Inhibition of thyroid hormone cellular transporters
- [ ] Thyroid peroxidase inhibition
- [ ] Sodium/iodide symporter inhibition
- [ ] Deiodinase inhibition
- [ ] Inhibition and/or induction of thyroid hormone biotransformation enzymes
- [ ] Altering thyroid hormone levels affecting in vitro organ systems.

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24. Are there any combinations of assays that should trigger further in vivo testing (please indicate combinations by using a ‘+’-sign and separate combinations by ‘;’. Examples: 1+7+8; 2+5)

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25. Please rank the different Commission options for introducing standard information requirements for endocrine disruption testing as regards the potential costs and benefits of each option.
If you would expect an action e.g. use of alternative test methods to have a high cost or benefit please select 5.
If you would expect a low cost or benefit, please select 1.

Details of Option 1 and Option 2 ?If you cannot access the document please ensure you are not using an Advertisement Blocker, if the issue persists please contact becca.johansen@ricardo.com

	Use of alternative test methods	Number of animal tests	Costs to Industry
Option 1 - Cost	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Option 1 - Benefit	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Option 2 - Cost	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Option 2 - Benefit	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

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26. Please provide an explanation for your response that is supported by evidence and sources, where possible.

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Please upload evidence and sources, where possible.

Browse...

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27. Finally, do you have any suggestions for changes to the options for new REACH Annex VII-X standard information requirements for endocrine disruption testing? E.g. different triggering system, use of different tests?

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Part 4 – Baseline

This part seeks to develop a quick baseline of the administrative activities and testing that may be required by the proposed changes to REACH Annexes and may have already been carried out by industry. Further, this part seeks to gather updated evidence on the general costs of Substance Registration.

Please note that not all questions need to be answered.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

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28. How many unique substances have you registered under REACH?

- 0
- 1-5
- 6-10
- 11-20
- 21-30
- 31-40
- 41- 60
- 61-80
- 81 – 100
- 101-250
- 251-500
- 501-750
- 751-1000
- 1000+
- Don’t know

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

190

29. Please indicate which of these tests and administrative activities you have already performed for your Registration, and on what percentage of your Registrations you

have performed this.

	Already performed			Select Ranges 0-100% Registrations
	Yes	No	Don't know	
Literature review on ED	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Systematic literature review on ED	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
In silico methods regarding ED	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
				0 1-10% 11-20% 21-30% 31-40%

Estrogen receptor transactivation assay (OECD TG 455)	○	○	○	41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Androgen receptor transactivation assay (OECD TG 458)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
H295R steroidogenesis assay (OECD TG 456)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Aromatase assay (OPPTS 890.1200)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
				0 1-10% 11-20% 21-30% 31-40%

Uterotrophic Bioassay in Rodents (OECD TG 440)	○	○	○	41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
ToxCast ER Bioactivity Model	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Hershberger Bioassay in Rats (OECD TG 441)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Fish Short Term Reproduction assay (OECD TG 229)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Fish early life stage (ELS) toxicity test (OECD TG				0 1-10% 11-20% 21-30% 31-40%

Fish early-life stage (FELS) toxicity test (OECD TG 210)	○	○	○	41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Fish, juvenile growth test (OECD TG 215)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Fish Sexual Development Test (OECD TG 234)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Amphibian Metamorphosis Assay (OECD TG 231)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
				0 1-10% 11-20% 21-30% 31-40%

Fish Life Cycle Toxicity Test (OPPTS 850.1500)	○	○	○	41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Medaka Extended One-Generation Reproduction Test (OECD TG 240)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Zebrafish Extended One-Generation Reproduction Test	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Larval Amphibian Growth and Development Assay (OECD TG 241)	○	○	○	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
				0 1-10% 11-20% 21-30% 31-40%

OECD 426 Developmental Neurotoxicity	○	○	○	41-50% 51-60% 61-70% 71-80% 81-90% 91-100%

LOGIC Show/hide trigger exists. Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 194

30. Please indicate the geographical area of the laboratories you use to perform (eco)toxicological testing for Registration purposes.

- ☐ EU-27
- ☐ EEA
- ☐ Eastern Europe (non-EU-27)
- ☐ North America (USA, Canada)
- ☐ Central and South America
- ☐ Middle East
- ☐ Africa
- ☐ Oceania
- ☐ UK
- ☐ East Asia (Peoples Republic of China, Japan, North Korea, South Korea, Macau, Mongolia, Taiwan)
- ☐ South Asia (Afghanistan, Bangladesh, Bhutan, India, Nepal, Pakistan, Sri Lanka, the Maldives)
- ☐ South East Asia (Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand, Vietnam)
- ☐ Central Asia (Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, Uzbekistan)
- ☐ Other

LOGIC Hidden unless: #30 Question "Please indicate the geographical area of the laboratories you use to perform (eco)toxicological testing for Registration purposes.

" is one of the following answers ("Other")

ID 195

Please specify the geographical area of the laboratories you use to perform (eco)toxicological testing for Registration purposes.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 197

31. Please provide your best estimates of the average costs of Registration-related administrative activities per Registration, across all Registrants.
Where no cost applies, please indicate “0”.

	Annex VII >1 tonne	Annex VIII >10 tonnes	Annex IX >100 tonnes
Cost for preparing the Registration Dossier	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Physicochemical requirement study costs	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Toxicological	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 €

requirement study costs	>5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	>5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	>5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Ecotoxicological requirement study costs	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Costs of read across and QSARs	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Costs for a chemical safety assessment / report	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 €

	>100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	>100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	>100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Costs of letter of access	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Cost of legal support	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Costs of training or changes to company systems	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €

	>1 000 000 €	>1 000 000 €	>1 000 000 €
Updating dossier as a result of new information (historical)	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €
Other	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €	0 >0-100 € >100-500 € >500-1 000 € >1 000-5 000 € >5 000-10 000 € >10 000-20 000 € >20 000-50 000 € >50 000-100 000 € >100 000-250 000 € >250 000-500 000 € >500 000-1 000 000 € >1 000 000 €

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 223

If you have entered costs under "Other" please add detail on the "Other administrative activities".

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 224

32. Please provide any evidence and sources as well as the general time frame in which these costs may have been incurred.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 225

Please upload any evidence and sources to support this.

Browse...

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Laboratory","Research institute/Scientific organisation","Other")

226

33. Does your laboratory currently perform/ intend to perform the following tests which can be used to identify endocrine disrupting properties?
Also, if you intend to introduce these tests, what is your estimated timeline for introduction?

	Currently perform	Test capacity per year	Intend to perform	Planned test capacity per year (including existing ones)	Timeline for introduction of testing
In silico methods	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Estrogen receptor transactivation assay (OECD TG 455)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Androgen receptor transactivation assay (OECD TG 458)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
H295R steroidogenesis assay (OECD TG 456)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Aromatase assay (OPPTS 890.1200)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years

					5 years to 10 years 10 years +
Short-term toxicity testing on fish (OECD TG 203)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Uterotrophic Bioassay in Rodents (OECD TG 440)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Hershberger Bioassay in Rats (OECD TG 441)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Fish Short Term Reproduction assay (OECD TG 229)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Fish early-life stage (FELS) toxicity test (OECD TG 210)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Fish, juvenile growth test (OECD TG 215)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Fish Sexual Development	Yes No		Yes No		<6 months 6 months – 1 year 1 year – 2 years

Development Test (OECD TG 234)	No Don't know		No Don't know		1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Fish Life Cycle Toxicity Test (OPPTS 850.1500)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Amphibian Metamorphosis Assay (OECD TG 231)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Medaka Extended One-Generation Reproduction Test (OECD TG 240)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Zebrafish Extended One-Generation Reproduction Test	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
Larval Amphibian Growth and Development Assay (OECD TG 241)	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +
OECD 426 Developmental Neurotoxicity	Yes No Don't know		Yes No Don't know		<6 months 6 months – 1 year 1 year – 2 years 2 years to 5 years 5 years to 10 years 10 years +

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Laboratory","Research institute/Scientific organisation","Other")

ID 241

34. Please can you provide an estimate of the average cost per substance of the following activities you currently perform?

	Average cost per unique substance (€)
In silico methods	
Estrogen receptor transactivation assay (OECD TG 455)	
Androgen receptor transactivation assay (OECD TG 458)	
H295R steroidogenesis assay (OECD TG 456)	
Aromatase assay (OPPTS 890.1200)	
Short-term toxicity testing on fish (OECD TG 203)	
Uterotrophic Bioassay in Rodents (OECD TG 440)	
Hershberger Bioassay in Rats (OECD TG 441)	
Fish Short Term Reproduction assay (OECD TG 229)	
Amphibian Metamorphosis Assay (OECD TG 231)	
Long-term toxicity testing on fish	
Fish early-life stage (FELS) toxicity test (OECD TG 210)	
Fish, juvenile growth test (OECD TG 215)	
Fish Sexual Development Test (OECD TG 234)	
Fish Life Cycle Toxicity Test (OPPTS 850.1500)	
Medaka Extended One-Generation Reproduction Test (OECD TG 240)	
Zebrafish Extended One-Generation Reproduction Test	
Larval Amphibian Growth and Development Assay (OECD	

TG 241)	
OECD 426 Developmental Neurotoxicity	

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Laboratory","Research institute/Scientific organisation","Other")

ID 244

35. Please provide an indication (in months) of the time it takes to complete the following tests and the number of animals needed per test (where relevant)

	Time to complete (months)	Number of animals needed per test
Estrogen receptor transactivation assay (OECD TG 455)		
Androgen receptor transactivation assay (OECD TG 458)		
H295R steroidogenesis assay (OECD TG 456)		
Aromatase assay (OPPTS 890.1200)		
Short-term toxicity testing on fish (OECD TG 203)		
Uterotrophic Bioassay in Rodents (OECD TG 440)		
Hershberger Bioassay in Rats (OECD TG 441)		
Fish Short Term Reproduction assay (OECD TG 229)		
Amphibian Metamorphosis Assay (OECD TG 231)		
Fish early-life stage (FELS) toxicity test (OECD TG 210)		
Fish, juvenile growth test (OECD TG 215)		
Fish Sexual Development Test (OECD TG 234)		
Fish Life Cycle Toxicity Test (OPPTS 850.1500)		
Medaka Extended One-Generation Reproduction Test (OECD TG 240)		
Zebrafish Extended One-Generation Reproduction Test		
Larval Amphibian Growth and Development Assay (OECD TG 241)		
OECD 426 Developmental Neurotoxicity		

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36. Do you offer in vitro thyroid assays that address one of the following key events in the thyroid modes of action? If yes, please indicate costs and assay capacity. Do you intend to offer in vitro thyroid assays that address one of the following key events in the thyroid modes of action if those tests would become a standard information requirement under REACH? Please indicate approximate costs and assay capacity.

	Currently offer such assay	Current Costs per assay	Current Assay capacity per year	Intend to offer such assay	Intended Costs per assay	Intended Assay capacity per year
Binding to and (in)activation of thyroid hormone receptors;	Yes No Don't know			Yes No Don't know		
Thyroid stimulating hormone receptor binding and (in)activation;	Yes No Don't know			Yes No Don't know		
Thyroid releasing hormone receptor binding and (in)activation;	Yes No Don't know			Yes No Don't know		
Binding to thyroid hormone serum transporters	Yes No Don't know			Yes No Don't know		
Inhibition of thyroid hormone cellular transporters	Yes No Don't know			Yes No Don't know		
Thyroid peroxidase inhibition	Yes No Don't know			Yes No Don't know		
Sodium/iodide symporter inhibition	Yes No Don't know			Yes No Don't know		

inhibition						
Deiodinase inhibition	Yes No Don't know			Yes No Don't know		
Inhibition and/or induction of thyroid hormone biotransformation enzymes	Yes No Don't know			Yes No Don't know		
Altering thyroid hormone levels affecting in vitro organ systems.	Yes No Don't know			Yes No Don't know		

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Part 5 – Costs Related to Inclusion of ED Testing in REACH Annexes VII-X

This part seeks input on regulatory costs that may be associated with administrative and testing activities that will be required upon the introduction of the legislative options considered herein.

Please note that not all questions need to be answered

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 260

37. On average, what is the cost of preparing and submitting new testing proposals to ECHA for in vivo tests in Annexes IX and X?

	Values	Don't know
Costs of preparing (€/proposal)		☐
Costs of submitting (€/proposal)		☐

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Public authority including ECHA","Other")

ID 267

38. On average, what is the cost and time taken of reviewing new proposals for additional in vivo testing in Annex IX and X?

	Values	Don't know
Costs of reviewing (€/proposal)		☐
Time taken to review proposals (hours/proposal)		☐

ID 270

39. If the following tests were introduced as a result of standard information requirements under REACH, would you expect the costs of testing to increase or decrease? Please refer to your previous answers for the current costs of these tests against which we should consider this question.

Decrease by >50%
Decrease by >40%-50%

In silico methods	Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Estrogen receptor transactivation assay (OECD TG 455)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Androgen receptor transactivation assay (OECD TG 458)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
H295R steroidogenesis assay (OECD TG 456)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20%

	Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Aromatase assay (OPPTS 890.1200)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Short-term toxicity testing on fish (OECD TG 203)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Uterotrophic Bioassay in Rodents (OECD TG 440)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
	Decrease by >50% Decrease by >40%-50%

Hershberger Bioassay in Rats (OECD TG 441)	Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Fish Short Term Reproduction assay (OECD TG 229)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Amphibian Metamorphosis Assay (OECD TG 231)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Fish early-life stage (FELS) toxicity test (OECD TG 210)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20%

	Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Fish, juvenile growth test (OECD TG 215)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Fish Sexual Development Test (OECD TG 234)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Fish Life Cycle Toxicity Test (OPPTS 850.1500)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
	Decrease by >50% Decrease by >40%-50%

Medaka Extended One-Generation Reproduction Test (OECD TG 240)	Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Zebrafish Extended One-Generation Reproduction Test	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
Larval Amphibian Growth and Development Assay (OECD TG 241)	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20% Increase by >20%-30% Increase by >30%-40% Increase by >40%-50% Increase by >50%
OECD 426 Developmental Neurotoxicity	Decrease by >50% Decrease by >40%-50% Decrease by >30%-40% Decrease by >20%-30% Decrease by >10%-20% Decrease by >0%-10% No change Increase by >0%-10% Increase by >10%-20%

Increase by >20%-30%
Increase by >30%-40%
Increase by >40%-50%
Increase by >50%

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 289

40. Based on your costs of updating a registration dossier recently, what would be the likely cost of updating the dossier as a result of EDC testing?

Note that the costing of updating the dossier should include the cost of testing that has not been carried out previously for the substance. Previous studies have indicated the costs of updating registration dossiers to lie within the €1000-10,000 range.

	More than the historical Dossier Updating costs	Similar to the historical Dossier Updating costs	Less than to the historical Dossier Updating costs	Don't know
Annex VII	☐	☐	☐	☐
Annex VIII	☐	☐	☐	☐
Annex IX	☐	☐	☐	☐
Annex X	☐	☐	☐	☐

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 301

41. Please provide any evidence and sources.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 302

Please upload any evidence and sources.

Browse...

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Laboratory","Research institute/Scientific organisation","Other")

ID 303

42. Would you need to employ additional staff **as a result of introducing** EDC testing requirements and the need for updating Registration dossiers?

0 FTE
1-25 FTE
26-50 FTE
51-75 FTE
76-100 FTE
101+ FTE
Don't know

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Public authority including ECHA","Other")

ID 304

43. Would you need to employ additional staff **as a result of introducing** EDC testing requirements and the need for updating Registration dossiers?

Additional staff that may be needed to manage/ review/ approve Registration updates	0 FTE 1-25 FTE 26-50 FTE 51-75 FTE 76-100 FTE 101+ FTE Don't know
Additional staff that may be needed to manage/ review/ approve new Registration	0 FTE 1-25 FTE 26-50 FTE 51-75 FTE 76-100 FTE 101+ FTE Don't know
Additional staff that may be needed to assess proposals for additional animal testing	0 FTE 1-25 FTE 26-50 FTE 51-75 FTE 76-100 FTE 101+ FTE Don't know
Further regulatory action as a result of identification of ED properties	0 FTE 1-25 FTE 26-50 FTE 51-75 FTE 76-100 FTE 101+ FTE Don't know

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Laboratory","Research institute/Scientific organisation","Other")

ID 311

44. Would you need to purchase new equipment in order to perform the following

tests? Please indicate the cost of doing so.

	New equipment required		Cost of equipment (€)
	Yes	No	
Estrogen receptor transactivation assay (OECD TG 455)	○	○	
Androgen receptor transactivation assay (OECD TG 458)	○	○	
H295R steroidogenesis assay (OECD TG 456)	○	○	
Aromatase assay (OPPTS 890.1200)	○	○	
Short-term toxicity testing on fish (OECD TG 203)	○	○	
Uterotrophic Bioassay in Rodents (OECD TG 440)	○	○	
Hershberger Bioassay in Rats (OECD TG 441)	○	○	
Fish Short Term Reproduction assay (OECD TG 229)	○	○	
Amphibian Metamorphosis Assay (OECD TG 231)	○	○	
Fish early-life stage (FELS) toxicity test (OECD TG 210)	○	○	
Fish, juvenile growth test (OECD TG 215)	○	○	
Fish Sexual Development Test (OECD TG 234)	○	○	
Fish Life Cycle Toxicity Test (OPPTS 850.1500)	○	○	
Medaka Extended One-Generation Reproduction Test (OECD TG 240)	○	○	
Zebrafish Extended One-Generation Reproduction Test	○	○	
Larval Amphibian Growth and Development Assay (OECD TG 241)	○	○	
OECD 426 Developmental Neurotoxicity	○	○	

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Public authority including ECHA","Other")
ID 315

Part 6 – Costs Related to Further Regulation of ED

This part seeks evidence on the likely implications of substance registration, especially for industry.

Please note that not all questions need to be answered.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Public authority including ECHA","Other")
ID 316

45. What might be the implications for industry of the positive indication of endocrine disrupting properties of substances as a result of the testing carried out for REACH Standard Information Requirements, where the substance is then classified under the CLP Regulation?

	Very likely	Likely	Possible	Limited likelihood	Unlikely	Don't know
Applications for derogations or for authorisation in REACH or downstream legislation e.g. sector specific legislation under the premise that EDC are regulated as CMRs as announced in the CSS. Legislation may includeREACH Regulation (EC) No 1907/2006 Regulation (EC) No 1223/2009 on cosmetic products Directive 2009/48/EC on the safety of toys Regulation (EC) No 450/2009 on active and intelligent materials intended to come into contact with food Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food Regulation (EC) No 1107/2009 on plant protection products Regulation (EU) No 528/2012 biocidal products	☐	☐	☐	☐	☐	☐
Introduction of additional risk management measures where no previous hazard classification has warranted similar risk management measures	☐	☐	☐	☐	☐	☐
Identification of substance alternatives/ substitution	☐	☐	☐	☐	☐	☐
Discontinuation of manufacturing/ use of these substances	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐

LOGIC Hidden unless: Question "Other " is one of the following answers ("Very likely","Likely","Possible","Limited likelihood","Unlikely")

ID 338

46. Please add detail to the "other" implications referred to above.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 339

47. Let us assume that your business identifies 10 unique substances that may have endocrine disrupting properties, what would be your most likely response, on average? For example, 5 or 50% could be substituted/ alternatives would be found, a further 4 or 40% would be discontinued/ no longer manufactured as a result of a positive indication of endocrine disrupting properties under REACH Registration, and for the final 1 or 10% of substances, the company may seek derogation from restriction or prohibition of use in REACH or downstream legislation after harmonised classification and labelling introduced by the CLP Regulation.
Note, responses should add to 100%

Introduction of risk management measures after positive identification of endocrine disrupting properties via REACH Annexes VII-X

- 0
- 1-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71-80%
- 81-90%
- 91-100%

Identification of substance alternatives/ substitution after positive identification of endocrine disrupting properties via REACH Annexes VII-X

- 0
- 1-10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%

	61-70% 71-80% 81-90% 91-100%
Discontinuation of manufacturing/ use of these substances after positive identification of endocrine disrupting properties via REACH Annexes VII-X	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Applications for derogations or for authorisation after harmonised classification and labelling according to CLP and subsequent regulatory management under one or more of the legislations. Legislation may includeREACH Regulation (EC) No 1907/2006 Regulation (EC) No 1223/2009 on cosmetic products Directive 2009/48/EC on the safety of toys Regulation (EC) No 450/2009 on active and intelligent materials intended to come into contact with food Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food Regulation (EC) No 1107/2009 on plant protection products Regulation (EU) No 528/2012 biocidal products	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%
Other	0 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 347

48. Please provide the context/ reasoning behind your answer.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 348

49. Would this manifest in indirect regulatory/ compliance costs for your business?

- [ ] Yes, significantly
- [ ] Yes, moderately
- [ ] Yes, insignificantly
- [ ] No
- [ ] Don’t know

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 349

50. Please provide any evidence and sources for these indirect regulatory / compliance costs.

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Other")

ID 350

Please upload any evidence or sources for these indirect regulatory / compliance costs.

Browse...

Page 9

ID 353

Part 7 – Other economic, social and environmental impacts

Part 7 seeks input and evidence on other economic, social and environmental impacts, direct or indirect, that may be expected or result from the legislative options.

Please note that not all questions need to be answered.

355

Economic impacts

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Laboratory","Research institute/Scientific organisation")

356

51. How would you expect establishing additional standard information requirements for endocrine disruption testing under REACH to affect the following in the EU, directly and indirectly?

	Strongly positive	Weakly positive	No or limited impact	Weakly negative	Strongly negative	I don't know
Laboratory capacity and associated costs. For example, in this context, requiring more laboratory capacity in the EU could have a positive economic impact for the laboratory sector. Associated costs could have a negative impact on the EU chemical sector.	☐	☐	☐	☐	☐	☐

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Business association","Chemical manufacturer/ formulator","Downstream user","Consumer organisation","Non-governmental organisation (NGO) with a focus on human health","Non-governmental organisation (NGO) with a focus on the environment","Non-governmental organisation (NGO) with a focus on Animal Welfare organisation","Trade union")

ID 359

52. How would you expect establishing additional standard information requirements for endocrine disruption testing under REACH to affect the following in the EU, directly and indirectly?

	Strongly positive	Weakly positive	No or limited impact	Weakly negative	Strongly negative	I don't know
Research and Development / innovation for the chemicals industry. For example, increased R&D could have a positive social and economic impact. It could also have a negative impact through the diverting of funds for R&D in other areas.	☐	☐	☐	☐	☐	☐
Competitiveness of the EU chemicals sector and wider industry in the global market. For example, improving the industry's competitiveness could be a positive economic impact. Where costs are high, this could lead to a negative impact through decreased competitiveness	☐	☐	☐	☐	☐	☐

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Public authority including ECHA")

ID 362

53. How would you expect establishing additional standard information requirements for endocrine disruption testing under REACH to affect the following in the EU, directly and indirectly?

	Strongly positive	Weakly positive	No or limited impact	Weakly negative	Strongly negative	I don't know
Research and Development / innovation for the chemicals industry. For example, increased R&D could have a positive social and economic impact. It could also have a negative impact through the diverting of funds for R&D in other areas.	☐	☐	☐	☐	☐	☐
Competitiveness of the EU chemicals sector and wider industry in the global market. For example, improving the industry's competitiveness could be a positive economic impact. Where costs are high, this could lead to a negative impact through decreased competitiveness	☐	☐	☐	☐	☐	☐
Public Authority impacts, including administrative burden and enforcement requirements. For example, in this context, requiring more public resources for administration and enforcement activities could have a negative economic impact in the medium to longer term.	☐	☐	☐	☐	☐	☐

LOGIC Hidden unless: Question "I am giving my contribution as

" is one of the following answers ("Other")

ID 366

54. How would you expect establishing additional standard information requirements for endocrine disruption testing under REACH to affect the following in the EU, directly and indirectly?

	Strongly positive	Weakly positive	No or limited impact	Weakly negative	Strongly negative	I don't know
Research and Development / innovation for the chemicals industry. For example, increased R&D could have a positive social and economic impact. It could also have a negative impact through the diverting of funds for R&D in other areas.	☐	☐	☐	☐	☐	☐
Competitiveness of the EU chemicals sector and wider industry in the global market. For example, improving the industry's competitiveness could be a positive economic impact. Where costs are high, this could lead to a negative impact through decreased competitiveness	☐	☐	☐	☐	☐	☐
Public Authority impacts, including administrative burden and enforcement requirements. For example, in this context, requiring more public resources for administration and enforcement activities could have a negative economic impact in the medium to longer term.	☐	☐	☐	☐	☐	☐
Laboratory capacity and associated costs. For example, in this context, requiring more laboratory capacity in the EU could have a positive economic impact for the laboratory sector. Associated costs could have a negative impact on the EU chemical sector.	☐	☐	☐	☐	☐	☐

371

Social impacts

373

55. How would you expect establishing additional standard information requirements for endocrine disruption testing under REACH to affect the following in the EU?

	Strongly positive	Weakly positive	No or limited impact	Weakly negative	Strongly negative	I don't know
Employment levels. For example, increased testing leading to a net increase in employment for laboratories and public authorities could have a positive social impact. An increase in costs of production may result in product withdrawal, leading to a negative impact on employment in the industry. An increase in dossier updates may lead to an increase in employment in the chemicals industry.	☐	☐	☐	☐	☐	☐
Public health and health system impacts associated with endocrine disruptors. For example, reducing incidence of endocrine-related human health impacts could have a positive social impact.	☐	☐	☐	☐	☐	☐

380

56. In the EU, what would you say is the contribution of human exposure to substances with endocrine-disrupting properties registered under REACH on the onset of the following diseases or health hazards?

	Significant	Moderate	Low	None	Don't know
Metabolic disorders -obesity	☐	☐	☐	☐	☐
Metabolic disorders -Type II diabetes	☐	☐	☐	☐	☐
Other cardiovascular disease not related to obesogenic and diabetogenic effects of ED	☐	☐	☐	☐	☐
Metabolic disorders -Thyroid disorders	☐	☐	☐	☐	☐
Neurodevelopmental disorders e.g. attention-deficit/hyperactivity disorders	☐	☐	☐	☐	☐
Diminished immunity response in children	☐	☐	☐	☐	☐
Hormone-dependent cancers – breast, ovary, testes, prostate	☐	☐	☐	☐	☐
Reproductive disorders – declining sperm count	☐	☐	☐	☐	☐
Congenital malformation in children e.g. hypospadias, cryptorchidism	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

LOGIC Hidden unless: Question "Other" is one of the following answers ("Significant","Moderate","Low")

391

Please specify the "other" diseases or health hazards referred to above.

392

57. If known, please provide examples of exposure to substances causing the following effects.

Metabolic disorders -obesity	
Metabolic disorders -Type II diabetes	
Other cardiovascular disease not related to obesogenic and diabetogenic effects of ED	
Metabolic disorders -Thyroid disorders	
Neurodevelopmental disorders e.g. attention-deficit/hyperactivity disorders	
Diminished immunity response in children	
Hormone-dependent cancers – breast, ovary, testes, prostate	
Reproductive disorders – declining sperm count	
Congenital malformation in children e.g. hypospadias, cryptorchidism	

393

58. Please provide any evidence and sources on the links between substances with ED properties and human health challenges (diseases and health hazards) and lifestyle factors, e.g. phytoestrogens from soy.

394

Please upload any evidence or sources on the links between substances with ED properties and human health challenges (diseases and health hazards) and lifestyle factors, e.g. phytoestrogens from soy.

Browse...

395

Environmental impacts

396

59. How would you expect that establishing additional standard information requirements for endocrine disruption testing under REACH to affect the environment in the EU?

- Strongly positive
- Weakly positive
- No or limited impact
- Weakly negative
- Strongly negative
- I don't know

ID 397

60. The table below lists some effects on wildlife organisms that are sometimes considered to be linked to exposure to endocrine disruptors. Some of the effects can also be caused by other mechanisms (e.g. exposure to chemicals exhibiting a mode of action that is not endocrine related; environmental conditions like temperature affecting developing of organisms). What would you say is the contribution in the EU of environmental and wildlife exposure to substances with endocrine disrupting properties registered under REACH on the following environmental effects?

	Significant	Moderate	Low	None	Don't know
Egg thinning	☐	☐	☐	☐	☐
Disturbed nesting behaviour	☐	☐	☐	☐	☐
Skeletal abnormalities - birds	☐	☐	☐	☐	☐
Skeletal abnormalities - frogs	☐	☐	☐	☐	☐
Skeletal abnormalities - other	☐	☐	☐	☐	☐
Imposex	☐	☐	☐	☐	☐
Feminisation - fish	☐	☐	☐	☐	☐
Impaired reproductive function – e.g. whales, seals polar bears	☐	☐	☐	☐	☐
Impaired immune system - seals	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐

LOGIC Hidden unless: Question "Other" is one of the following answers ("Significant","Moderate","Low")

ID 410

Please specify the "other" effects.

411

61. Please provide examples of substances registered under REACH causing the effects in case you answered ‘significant’, ‘moderate’ or ‘low’ previously.

Egg thinning	
Disturbed nesting behaviour	
Skeletal abnormalities - birds	
Skeletal abnormalities - frogs	
Skeletal abnormalities - other	
Imposex	
Feminisation - fish	
Impaired reproductive function – e.g. whales, seals polar bears	
Impaired immune system - seals	

412

62. Please provide any evidence and sources on the links between substances with ED properties and animal welfare/ wildlife.

413

Please upload any evidence or sources on the links between substances with ED properties and animal welfare/ wildlife.

Browse...

414

Any other comments

Please include any further information that would be useful for the ongoing impact assessments of revisions to the information requirements associated with the identification and management of endocrine disruptors in chemicals legislation, particularly under REACH. Where possible, provide public references to relevant studies, position papers, and case studies or alternatively, please upload relevant documents.

439

63. Please add any additional comments here.

440

64. Please upload any supporting documents here

Browse...

415

65. If you are familiar with the European Chemicals' legislation and the associated information requirements, please indicate if you are happy to be contacted to participate in targeted consultation activities.

- [ ] **YES, please include me** / **my organisation** in further consultation activities on the revision of information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH.

417

Thank you

On behalf of the DG Environment Chemicals Team and of the REACH unit of DG GROW, thank you very much for your contribution to this Consultation!

If you have any questions, please contact the European Commission at this dedicated email address:

ENV-EDC@ec.europa.eu

Please contact the study team at:

becca.johansen@ricardo.com

Thank You!

1

Thank you for taking our survey. Your response is very important to us.