EDC Targeted Consultation

1. Page 1

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 inquantities 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 intothe 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 ofa 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 chemicalsafety reports

Annex VII - Standard information requirements for substances manufactured orimported in quantities of one tonne or more

Annex VIII - Standard information requirements for substances manufactured orimported in quantities of 10 tonnes or more

Annex IX - Standard information requirements for substances manufactured orimported in quantities of 100 tonnes or more.

Annex X - Standard information requirements for substances manufactured orimported 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. Beforethe 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).

2. Page 2

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 REACHRegulation.

The Targeted Consultation questionnaire shall run from 3rd August 2021 – 8thOctober 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 ofchemical 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 thissurvey, 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 thisdedicated 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.

3. Page 3

Part One - About You

Language of my contribution

English

I am giving my contribution as

Non-governmental organisation (NGO) with a focus on the environment

Please complete:

First name : Helene
Surname : Loonen
EmailThis will not be published : helene.loonen@eeb.org

Organisation/association/institution/authority name

European Environmental Bureau (EEB)

Scale of your operation

International

Organisation size

Small (10 to 49 employees or €10 million or less turnover/ balance sheet total)

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

06798511314-27

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

Belgium

Publication - Privacy settings

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 to state that you agree with the personal data protection provisions

I agree

4. Page 4

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 againstassociated 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.

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

	Expert	Very familiar	Somewhat familiar	Not familiar	Don't know
Familiarity with the role of chemicals affecting the endocrine system of humans		X			
Familiarity with the role of chemicals affecting the endocrine system of animals		X			

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?

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

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

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

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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).

4. 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?

	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 human health effects	X				

Addition of standard information requirements for endocrine disruption testing under REACH to inform about endocrine disrupting properties with environmental effects	**X**				

5. 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?

Moderately agree

6. 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)			

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

Animal free approaches can be potentially used if they are sufficiently validated and sufficiently sensitive to identify ED properties in accordance with the protection goals and overall aims of the CSS and Green Deal. The current state of science does not allow to make general statements on the replacement of in vivo tests in this respect. Read-across and grouping approaches could be used potentially provided that sufficient, reliable and relevant data are available across the group. The use of read-across and grouping should be allowed only in a precautionary way: use of read-across and grouping should be restricted to confirm ED properties, whereas it is not acceptable to waive testing with the aim to conclude that the substance does not have ED properties.

8. 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?

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

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, 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)?

10. 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 theymight have ED properties.

Please upload any evidence or sources to support your response.

11. 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	X					
Systematic literature review						X
In silico methods						X
Estrogen receptor transactivation assay (OECD TG 455)						X
Androgen receptor transactivation assay (OECD TG 458)						X
H295R steroidogenesis assay (OECD TG 456)						X
Aromatase assay (OPPTS 890.1200)						X
Short-term toxicity testing on fish (OECD TG 203)						X
Uterotrophic Bioassay in Rodents (OECD TG 440)						X
The output data from the ToxCast ER Bioactivity Model						X
Hershberger Bioassay in Rats (OECD TG 441)						X
Fish Short Term Reproduction assay (OECD TG 229)						X
Fish early-life stage (FELS) toxicity test (OECD TG 210)						X
Fish, juvenile growth test (OECD TG 215)						X
Fish Sexual Development Test (OECD TG 234)						X
Fish Life Cycle Toxicity Test (OPPTS 850.1500)						X
Amphibian Metamorphosis Assay (OECD TG 231)						X
Medaka Extended One-Generation Reproduction Test (OECD TG 240)						X
Zebrafish Extended One-Generation Reproduction Test						X
Larval Amphibian Growth and Development Assay (OECD TG 241)						X

12. 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

Animal welfare

Don't know

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

It is important to increase the level of information for low tonnage chemicals to allow for the identification of ED properties, which is not possible with the current standard information requirements of Annex VII.

13. 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.	X		

14. 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 invitro 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	X		

15. For substances registered in the tonnage band of 10 tonnes or more, Option 2 requests in vivo mechanistic studiesas 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 tonnageband 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 2

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

The EU Green Deal and the CSS aim at increasing the level of protection of human health and the environment against the threats of EDs. The revision of the REACH annexes should help to provide a strong basis of evidence that allows the identification of EDs. Option 2 is better equipped to meet this goal as it may identify a greater proportion of the substances that are EDs.

Please upload any supporting evidence

16. 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)							
Androgen receptor transactivation assay (OECD TG 458)							
H295R steroidogenesis assay (OECD TG 456)							
Aromatase assay (OPPTS 890.1200)							

False negative

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

17. Please provide an explanation for your response that is supported by evidence and sources.Do you know examples of false-negatives/positives?

Question 16 is redundant. Systematic validation of any test method should be performed in broader context, e.g. in the context of the OECD framework. Individual expertise has no meaning in this respect and is of no relevance for the impact assessment.

Please upload any supporting evidence or sources.

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

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

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

Please upload evidence and sources, where possible.

21. 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.

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

23. 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			
Option 1 - Benefit			
Option 2 - Cost			
Option 2 - Benefit			

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

Please upload evidence and sources, where possible.

25. 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?

Detailed suggestions for improvement have been provided by NGOs to the Commission earlier in the process. Suggestions included:
- put emphasis on triggers rather than waivers
- the literature screening should cover non EATS endpoints
- The in vitro testing battery proposed under Annex VII is adequately followed up on, especially regarding the known risks of false negatives
- in the context of grouping and read-across: positive in vitro results for one substance can be informative for the assessment of other substances of the same family and contribute to more efficient assessments.

For further details see we refer to:
https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_draft-final.pdf

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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 updatedevidence on the general costs of Substance Registration.

Please note that not all questions need to be answered.

26. 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;						
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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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 administrativeand 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

27. 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.

									Incre
	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%	>10 20
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)									
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									
Zebrafish Extended One-Generation Reproduction									
Larval Amphibian Growth and Development Assay (OECD									
OECD 426 Developmental									

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Part 7 – Other economic, social and environmental impacts

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

Please note that not all questions need to be answered.

Economic impacts

28. 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.	X					
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	X					

Social impacts

29. 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.	X					
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.	X					

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

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

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

32. 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.

Please note that there are very many sources on the links between EDCs and adverse effects of human health and the environment. We would like to refer you in this respect to the work of the Endocrine society and research institutes involved in the EURION project.
The burden of disease and costs of exposure to EDCs was amongst others analysed in the following reference: https://doi.org/10.1111/andr.12178

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.

Environmental impacts

33. 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

34. 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 wildlifeexposure to substances with endocrine disrupting properties registered under REACH on the following environmental effects?

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

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

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

We would like to refer you to existing evidence and sources. There are very many sources publicly available demonstrating the the links between EDCs and their adverse effects on wildlife.

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

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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.

37. Please add any additional comments here.

In the CSS, the Commission committed to update data requirements under REACH to improve identification of endocrine disruptors. This update is urgently needed given the current absence of adequate data requirements to identify EDs under REACH. The adverse effects of EDs on human health and the environment are well established and described in scientific literature, including infertility, obesitas, diabetes, IQ loss, cancers, thyroid disruption and impaired immune system. The impact assessment should give due consideration to the societal and environmental benefits of improving the identification and regulation of EDs. A conservative analysis of the EDC associated health costs estimated that a reduction of exposure to the EDCs could save billions of Euros on health costs alone (ref: https://onlinelibrary.wiley.com/doi/10.1111/andr.12178).

Options for introducing standard information requirements for endocrine disruptors at each tonnage level were discussed at the 3rd meeting of the CASG-ED in October 2020 and we understand that experts of this subgroup of the Competent Authorities for REACH and CLP on endocrine disruptors, were very clear in their strong support for option 2. This strong support for option 2 by experts is not reflected in the present questionnaire. We recommend that comments and proposals made at the 3rd CASG meeting and forwarded in writing to the Commission following this CASG meeting are fully taken into consideration in the impact assessment.
We would like to refer you in this respect to the following document:
https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_draft-final.pdf

38. Please upload any supporting documents here

39. 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.

Thank you

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

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

ENV-EDC@ec.europa.eu

Please contact the study team at:

becca.johansen@ricardo.com

11. Thank You!

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

European Environmental Bureau

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