Contribution as Public authority

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Organisation name: Answers of the Belgian authorities coordinated by the Federal Public Service for health, food chain safety and environment.

Country of origin of your organisation: Belgium

Scope: international

Organisation size: Large (250 or more)

Publication privacy settings:

The Commission will process the responses of this stakeholders survey for the purpose of the Fitness Check on the EU legislation on endocrine disruptors. This includes the publication of a summary report of the survey. You can choose to give your consent to publish your personal details, or to remain anonymous.
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SURVEY

1) How familiar are you with the following pieces of legislation? Very familiar (for all)

Horizontal approach to the identification of endocrine disruptors

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

It is an important problem, leading to incoherent identification of endocrine disruptors across sectors

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

The ED WHO (2002) definition can be seen as a common basis for all chemical legislations. However to ensure a coherent approach for ED identification, we need a common understanding of what is needed to meet the definition (criteria). If the data set requirements do not allow to get the necessarily info (ED MoA, adverse effect and biological plausible link) it will not be possible to conclude (e.g. answer 11d)

A chemical can have different uses leading to different exposure. A same chemical can be covered by different legislations (e.g. REACH and cosmetics). We need horizontal criteria for ED identification, to

avoid incoherencies across sectors. The criteria should take into account the possibility or not to get data. All data available should be taken into account (e.g. for ingredients used in cosmetics, it should be possible to use animal data generated for other uses). When data are not sufficient to conclude, a precautionary approach to protect vulnerable population is needed.

The Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) set rules for the classification and labelling of hazardous substances, based on their physical, health or environmental hazards.

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

Yes

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

Yes

Please explain your answers to questions 3 and 4, if possible indicating the sector(s) in which this problem occurs.

We need one specific forum where ED identificat° can be concluded for all legislat°. CLP can be a good way forward, also to allow inclusion of an additional cat. "suspected" as for CMRs, which can be very useful for toys, cosmetics… We also need a platform to share the info used for ED identificat° or other info used in the risk assessment (RA) within the specific legislations. For RA and risk management, one very important issue is the possibility or not to set a safe threshold for a substance identified as ED. While identificat° is based on specific test results, assuming (no-)threshold is a scientific issue and also a political one (taking into account the growing knowledges on EDs, test methods'sensitivity, gaps in test methods, growing evidence of adverse endocrine related effects in HH and ENV, the remaining high uncertainties, including cocktail effects). We need coherency and avoid assuming a threshold in one legislat° and no-safe threshold for the same ED in other legislat°

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

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

Yes

This will allow their management using the precautionary principle.

Clear criteria will be needed to identify a substance as a "suspected ED", like those we currently have for CMR cat.2.

The data on which ED identification is based upon are quite divergent. Except for data-rich evaluation settings, it is in many cases not possible to come to a conclusion and therefore to take appropriate

measures (i.e.: protect the consumer like it is done with suspected CMR or protect vulnerable populations. The adoption of a **list** of "suspected" EDs (rather than a C&L "**category**") on the basis of lower tier studies could alleviate this gap, prompting notifiers/industry to engage in higher-tier studies to refine the assessment.

Rationale and consequences of different regulatory approaches

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

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

Yes

After ED identification, RA and risk management are carried out taking into account specific uses and exposures. For RA and risk management, one very important issue is the possibility or not to set a safe threshold for an ED substance (see also answer 4). Given the lack of specific measures in legislations , the detect° (and thus control) is not ensured in sectors others than PPP's and biocides (like medicines, contaminants, food contact materials, detergents etc…). In cases where ED assessment was performed and EDs identified (e.g. DEHP) they remain on the market and exposure remains possible A political decision should be taken on risk management approach. When the principle of no or negligible exposure (PPP, biocide) is adopted for one sector, consideration should be given to the extent to which this approach should be applicable in other sectors, except for medicines (for HH), where the risk for the patient is always related to the benefit conferred on the patient and is modulated by the indication and frequency of treatment (one-time or lifetime). For pesticide MRLs, an agreement has not yet been reached at EU level whether non-compliance of an active substance with the hazard-based 'cut-off criteria' stipulated in Reg. (EC) No 1107/2009 (PPP) should automatically lead to lowering of all EU MRLs, including existing import tolerances (ITs)and CXLs (Codex MRLs). If an active substance is not approved in the EU due to application of hazard-based criteria, while ITs for this a.s. would be maintained in the EU on the basis of a favourable RA, this could lead to a different level playing field, i.e. the competitiveness of EU growers/producers could be negatively impacted. The concept of negligible exposure should also be applied in the context of MRLs.

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

	Very negatively	negatively	No effect	positively	Very positively	Don't know
HH protection				■		
ENV protection				■		
Functioning of the internal market						■
Competitiveness and innovation						■

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

	Very negatively	negatively	No effect	positively	Very positively	Don't know
HH protection						
ENV protection						
Functioning of the internal market						
Competitiveness and innovation						

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

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

Yes

Plant protection products:

During the evaluation of the ED properties of thiram under the PPP regulation, we were aware of an earlier evaluation under REACH and the conclusion to consider the a.s. NOT an ED. It was proposed to request additional information in order to clarify uncertainties about the ED status taking into account data in the open public literature. It is anticipated that taking into account the current GD, less inconsistencies will be encountered.

Biocides:

According to biocide legislation (BPR), all co-formulants of biocidal products have to be assessed regarding their ED properties. As data are usually lacking for co-formulants - applicants having only access to the data related to the active substances- it was decided to rely on REACH work. However according to the BPR, a clear conclusion on ED properties has to be reached for both human health and environment while in the REACH legislation such assessment is not mandatory.

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

Yes

We consider that there should be a scientific consensus on the evaluation of EDs.

Problems could occur from any non-EU imported goods, especially from countries having no specific legislation regarding ED (regulation but also identification). Moreover given the volume of goods imported into Europe, it is impossible to control the quality of all products. Therefore a risk could always occur.

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

Where consumers/ENV exposure is possible, the risk has to be correctly assessed, taking into account ED properties of the substance, all exposure routes, vulnerable groups, cocktail effects… The current regulat° on food additives and contaminants do not contain specific provisions for EDs. However, the risks related to the proven or presumed ED properties of the substances are taken into account and are part of the assessment made by EFSA (e.g. case of zearalenone and the guidance for submission for food additive evaluations). Food contaminants are not intentionally added. They result from various causes and sources of contamination and the possibilities/levels of control may be different. The risk needs to be correctly assessed and specific approaches for the risk management may be needed or justified.
PPP : It has been asserted that, where consumers/ENV exposure is possible, a hazard-based approach to decision-making is needed. However, the generally accepted paradigm of RA is based upon the concept of acceptable exposure, where a safe exposure level is possible (and enforceable by assessing exposure vs. dietary, occupational and ENV reference values). It is recommendable to harmonise the various regulations in order to obtain a fair and transparent view on the EDs for HH and ENV assessment. For PPP's, there was a decision to adopt a hazard-based decision-making process. While obviously, the absence of (exposure to) EDs is maximally protective for HH and ENV, it remains plausible that a risk-based decision-making would be protective as well. The condit° is, however, that the (eco)toxicological database is sufficiently robust to support a risk-based decision making. A hazard-based approach could at first sight negatively affect competitiveness (compared to third-country competitors). However, innovat° is not necessarily negatively affected, as a stringent regulatory context will positively influence the development of more sustainable alternatives.

Effectiveness in achieving policy objectives

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

11) Do you agree with the following statements?

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

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors						
Protecting workers by minimising						

exposure to endocrine disruptors						
Protecting citizens by minimising exposure to endocrine disruptors via the environment						
Protecting wildlife by minimising exposure to endocrine disruptors via the environment						
Improving the functioning of the internal market						
Enhancing competitiveness and innovation						
Promoting alternatives to animal testing						

Please explain your answers
2000 character(s) maximum

Biocide ED assessment is based on particularly data rich dossiers for HH (somehow less for ENV), which include the highest tier studies in order to conclude on ED. However, further refinement of ED Guidance is still needed in order to investigate non-EATS modalities. Next, further investigation is needed to further characterize the (eco)toxicological relevance of findings "*sensitive to but not diagnostic of*" ED perturbation.

Please note that for active substances for which the assessment of ED properties has not been conducted (e.g. because they are no longer supported in the EU), an effective human and environmental exposure could not be optimally guaranteed. Therefore, the BE position is that the concept of negligible exposure should also be applied in this context. The application of ED criteria to treated articles - and the regulatory consequences - is also unclear.

For HH, the regulatory process is effective (due to the exclusion criteria), unless derogation criteria are applied. The regulatory process does not protect correctly the environment - ED for the ENV is only candidate for substitution. The substance which is candidate for substitution is authorized for 7 years (instead of 10 years) and there is no limit in the number of renewal.

Proposal: Exclusion criteria should be for HH and ENV. Derogation should be case by case. Authorisation should only be given for one specific product by the country where the product is used and for a limited time period.

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

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors						
Protecting workers by minimising exposure to endocrine disruptors						
Protecting citizens by minimising exposure to endocrine disruptors via the environment						
Protecting wildlife by minimising exposure to endocrine disruptors via the environment						
Improving the functioning of the internal market						
Enhancing competitiveness and innovation						
Promoting alternatives to animal testing						

Please explain your answers
2000 character(s) maximum

For ENV: 'moderately agree'. For older active substances (a.s.) the necessary studies are currently lacking, but will be required in the periodic review. More complete datasets are expected for future applications.

For HH, the regulatory process is effective (due to the exclusion criteria), unless derogation criteria are applied.

However, the EU approach for dealing with existing import tolerances (ITs) and Codex MRLs (CXLs) following non-approval in the EU of an a.s. due to ED exclusion criteria still has to be agreed upon. If ITs and CXLs are maintained as EU MRL at a level based on RA (and possibly an incomplete hazard/ED assessment if no longer supported in EU), the consumer exposure to EDs will not be minimised. Therefore, the concept of negligible exposure stipulated in Reg.1107/2009 should also be applied in the context of MRLs, i.e. EU MRLs for a.s. considered in the EU as ED should not exceed 0.01 mg/kg.

Hazard: Under Reg no 1107/2009, the PPP RA is based on particularly data rich dossiers for HH (somehow less for ENV), which include the highest tier studies (like 2G studies) in order to conclude on ED. However,

further refinement of the ED GD is still needed in order to investigate non-EATS modalities. Next, further investigation is needed to further characterize the (eco)toxicological relevance of findings *"sensitive to but not diagnostic of"* ED perturbation. ***Exposure:*** In cases where ED criteria are met, but the a.s. remains on the market pursuing art.4.7 ("essential use"), the exposure to human and wildlife should be minimised and particular RM measures should be put in place for this goal. If *"negligible exposure"* is claimed, the use of the a.s. can only be allowed if the release in food, feed and ENV can be lowered to a degree as low as meant by the regulation, *i.e.* excluding exposure to humans and wildlife (*e.g.* closed circuits), and not using the rule "<10% of reference values", as the latter cannot be considered a typical negligible exposure

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

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors						
Protecting workers by minimising exposure to endocrine disruptors						
Protecting citizens by minimising exposure to endocrine disruptors via the environment						
Protecting wildlife by minimising exposure to endocrine disruptors via the environment						
Improving the functioning of the internal market						
Enhancing competitiveness and innovation						
Promoting alternatives to animal testing						

Please explain your answers
2000 character(s) maximum

We need to include an obligation in REACH to provide for all substances ED-related *in vitro* data. This needs to be included in the core data set. The process to identify a substance as ED in REACH is currently too slow. We need to speed up the identification. Industry has to proof that their substances are not EDs.

The simplified restriction procedure (art.68, §2)(for CMR cat1A or 1B in consumers products) should be extended to endocrine disruptors.

11.d) The regulatory process to identify and control substances with endocrine disrupting properties in **Cosmetics** [2] is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors						
Protecting workers by minimising exposure to endocrine disruptors						
Improving the functioning of the internal market						
Enhancing competitiveness and innovation						
Promoting alternatives to animal testing						

[2] Effects on the environment are regulated via REACH

Please explain your answers
2000 character(s) maximum

The Cosmetics regulation is promoting alternatives to animal testing for all cosmetic ingredients, as animal testing is forbidden. Considering that, for the time being, data for different toxicological endpoints cannot be generated by alternative methods, the identification and the risk assessment of EDs cannot be performed in the absence of pertinent/updated data generated before the animal testing ban or coming from other sources.

11.e) The regulatory process to identify and control substances with endocrine disrupting properties in **Medical Devices** [3] is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure						

to endocrine disruptors						
Protecting workers by minimising exposure to endocrine disruptors						
Improving the functioning of the internal market						
Enhancing competitiveness and innovation						
Promoting alternatives to animal testing						

[3] Effects on the environment are regulated via REACH

Please explain your answers
2000 character(s) maximum

Composition (substances of concern in the medical device) should be more transparent with systematic testing of the substances used, for possible ED concern.

Medical devices: a decent regulatory framework exists to address ED in medical devices using a risk-based approach. The main problems are a lack of clear data regarding individual endocrine disrupting chemicals to inform the overall biological safety analysis and perhaps underappreciation of endocrine disrupting effects as an endpoint to consider in evaluating the biological safety of a medical device. Apart maybe from labelling requirements, we would propose to rely on the upcoming Medical Device Regulation to address the issue of endocrine disruptors in medical devices. Furthermore it could be considered to implement specific medical device guidance on the European level and to include endocrine disruption as an endpoint to be considered in the next update of the ISO 10993-1 standard (a horizontal standard on the biological safety evaluation of medical devices).

Medicines for humans & animals: not under the scope of this discussion, but some elements are included to be complete:

-human use: non-clinical testing covers identification of pharmacology, pharmacokinetics and toxicity (includes environmental risk) of medicines (including also possible endocrine disrupting substances). Potential toxicity of the product and dangerous/undesirable toxic effects under the proposed conditions of use in human beings, in relation to the pathological condition concerned are identified.

Toxicological profile of identified leachable compound in pharmaceutical container (including reproductive/developmental toxicity) is required.

-veterinary use: No specific legal framework for EDS. Following Directive 2001/82/EC, to get a marketing authorization, if applicable, toxicological and pharmacological tests have to be provided. Any identified ED effect is assessed in a global risk/benefit balance with possible RMMs.

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

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting citizens by minimising exposure to endocrine disruptors via the environment						
Protecting wildlife by minimising exposure to endocrine disruptors via the environment						

Please explain your answers
2000 character(s) maximum

The Waterframework Directive aims at a good water quality and quantity. To tackle the problem of hazardous substances (including ED) in relation to water quality, Daughter Directives were launched (2008/105/EG and 2013/39/EG) which include environmental quality standards (EQS) for about 50 substances. In the derivation of these EQS's the effect of endocrine disruption is taken into account if data are available. The list contains PFOS, dioxins, brominated flame retardants, short chained chlorinated paraffins, nonylphenol and more, substances which were mostly included in the European list of EDs following the European ED strategy from 1999.

Further, measures applicable on the emissions, losses and discharges of these substances should help to obtain the goals of the WFD. These measures are to be included in the River basin district management plans. For the moment the plan 2016-2021 is valid and the plan for the period 2022-2027 is in preparation and will include specific measures for PFOS for instance.

The WFD gives quality objectives for water: in case of exceedence, the regional authority can limit permits for discharge in water (then you can have sanctions for industries), but it's not practicable for domestic discharges that are better prevented at source.

Community wide measures should also be decided to prevent emissions in case of concern (e.g. via REACH restriction…).

Aggregated exposure and combined effects

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

12) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know

Humans are protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources						
Wildlife is protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources						

Please explain your answers and provide examples
1000 character(s) maximum

In biocides, aggregated exposure is not applied (due among other to a lack of guidance). In PPPs, there is no method to evaluate an "aggregated exposure" . In general, the different procedures are working in silo and cocktail effect from the use of different products (e.g. in a crop protection program, where different molecules are used to avoid resistance) is never assessed, neither within the same legislation, nor for substances covered by different legislations

In cosmetic products, risk assessment taking into account aggregate exposure from all sources is only foreseen for CMR 1A and 1B substances.

There are some values which are stated for instance in the biocide product regulation: e.g. in the BPR, the authorised concentration of biocides in the groundwater has to be below 0.1 **µg/L** for each substance of concern (active substance, metabolite…) with a maximum of 0.5 **µg/L** for all substances together.

Moreover, a precautionary level should also be set for suspected EDs.

13) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Humans are protected by the current regulatory framework from the risks associated with						

the combined exposure to different substances with endocrine disrupting properties (combined effects)						
Wildlife is protected by the current regulatory framework from the risks associated with the combined exposure to different substances with endocrine disrupting properties (combined effects)						

Please explain your answers and provide examples
1000 character(s) maximum

For PPP's, the active substance is tested, and also the product (Active substance together with the other substances in the product). But in general, the combined exposure is not addressed with the current legislative tools.

For PPP's, there is for the moment no Cumulative Risk Assessment (CRA), although EFSA is working on a database to evaluate cumulative assessment groups, with the aim to apply CRA for dietary RA. The concept is for the overall toxicological RA, and should be applicable to ED RA too. Except for situations of essential use or negligible exposure, no (cumulative) exposure is expected for PPP or biocides since EDs cannot be allowed for neither professional nor general public users, and residues should in our opinion not occur at levels above 0.01 mg/kg in food imported from third countries.

For the other legislations, combined exposure are currently not taken into account.

Could the use of a precautionary value for the sum of all EDs be a good way forward?

Vulnerable groups

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

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

	Yes	No	Don't know
unborn through exposure during pregnancy			
newborn up to the age of 3			
children until puberty			
young persons around the age of puberty			

pregnant women			
adults in general			
people at work			
elderly			
people with illnesses			

The question regarding "people with illness" is difficult to answer, as the answer is heavily dependent on the severity. In addition, a general question regarding the impact of ED on vulnerable groups is also difficult, as under some legislations (like PPP) all phases are virtually tested, including foetuses.

It was considered by some experts that effects on thyroid may not be sufficiently covered, as some uncertainties exist on the risk of mental deficiencies when thyroid is affected in critical windows of exposure. Since there are major differences in testing strategies depending on the sector, the level of concern may be lowered if the possibility exist to run adequate tests. Further refinement in testing strategies is necessary if thyroid functions are affected.

It should also be noted that in PPPR, BPR and REACH, only EATS modalities are covered. Non-EATS effects are not covered, leading to a potential exposure of the population as well as of the environment to other possible EDs..

Data requirements and available regulatory test methods

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

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

No

PPP & biocides:

In principle for EATS enough **scientific tests** are available, but some reservation exists on the effects on thyroids. It was considered by some experts that effects on thyroid may not be sufficiently covered, as some uncertainties exist on the risk of mental deficiencies when thyroid is affected in critical windows of exposure. Since there are major differences in testing strategies depending on the sector, the level of concern may be lowered if the possibility exist to run adequate tests. Further refinement in testing strategies is necessary if thyroid functions are affected. In addition, non-EATS modalities are not comprised in the latest RD GD, although in our opinion obvious non-EATS effects (*e.g.* retinoic acid pathway) may be identified on the basis of existing scientific literature.

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

No

PPP & biocides:

In principle for EATS enough **scientific tests** are available, but some reservation exists on the effects on thyroids. It was considered by some experts that effects on thyroid may not be sufficiently covered, as some uncertainties exist on the risk of mental deficiencies of thyroid is affected in critical windows of exposure. Since there are major differences in testing strategies depending on the sector, the level of concern may be lowered if the possibility exist to run adequate tests. Further refinement in testing strategies is necessary if thyroid functions are affected. In addition, non-EATS modalities are not comprised in the latest RD GD, although in our opinion obvious non-EATS effects (e.g. retinoic acid pathway) may be identified on the basis of existing scientific literature.

However, the different legislations involve different data requirements, thus from a regulatory point of view some sectors may not be regulated in a sufficient way.

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

Yes

Please explain your answer and provide examples.
1000 character(s) maximum

There are differences in the core data set when all chemical regulatory contexts are considered.

Conclusion on ED is not mandatory on all substances in the 3 legislations (only for PPPs and biocides)

Under REACH, the level of testing depends on the volumes put on the market.

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

2000 character(s) maximum

PPP and Biocides:

Above all, existing data requirements like those imposed by the PPP and biocide regulation for instance, should be extended to the other legislations.

Currently, only EATS modalities are covered because the tests on EATS are the best validated. It is already a good starting point. Progress should however be made for endpoints which are currently not enough covered: e.g obesogen, neurodevelopmental aspects, immunodevelopmental aspects (although NT and immunotox are already assessed for PPPs where relevant). Mandatory in vitro assays should be added to the core data set. Moreover, we should make a better use of toxicological data to reduce animal testing (e.g. literature, in vitro results, Adverse Outcome Pathways…).

The available data should be shared between authorities E.g. data available for the plant protection products should also be available for the authorities assessing biocides. Co-formulants in biocides or plant protection products should be included in a database which could be consulted by authorities.

In addition, from the general point of view, only co-formulants that are sufficiently tested/evaluated should be allowed in final PPP and biocidal products. It is noted that there is a widespread use of

insufficiently evaluated co-formulants (*i.e.* potentially substances which are non-HPV), which poses a problem when it comes to assess actives in final products.

Regulatory testing and animal welfare

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

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

Strongly agree

Please explain your answer.
1000 character(s) maximum

For any substance, first tier studies should be made available.

We also need *in vitro* test requirements in standard test package to speed up the screening.

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

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

Minimized to the extent possible

21) Do you have recommendations on how to further minimise the impact of assessing chemicals for endocrine disrupting properties on animal welfare?
1000 character(s) maximum

We should make a better use of toxicological data to reduce animal testing (e.g. already available *in vivo* data, indicators, literature, *in vitro* results, Adverse Outcome Pathways…).

However, we should recognise that this is not an issue particular to ED assessment, but also for any other (eco)toxicological endpoint. It is important to acknowledge the current limitations of *in vitro* tests as well. The use of low-tier tests is advantageous for animal welfare, but any outcome is freight by the limitation that it may not be representative for the *in vivo* situation, and that the likelihood to collect 'false positive' outcomes will be high, and that decision-making on this base could be overly conservative. It should thus be decided if any decision based on *in vitro* data alone would be desirable for the HH and ENV perspective.

Effectiveness of regulatory procedures

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

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

	Yes	No
Workers protection		
Toys		
Detergents		
Fertilisers		
Electrical and electronic equipment		
Food contact materials		
Food additives		
Cosmetics		
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)		
Human and veterinary pharmaceuticals (only for effects on the environment)		
Water		
Waste/recycling		
Other (please specify)		

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

	Yes	No
Workers protection		
Toys		
Detergents		
Fertilisers		
Electrical and electronic equipment		
Food contact materials		
Food additives		
Cosmetics		
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)		
Human and veterinary pharmaceuticals (only for effects on the environment)		
Water		
Waste/recycling		
Other (please specify)		

The question on “issues aware of” is too vague. The issues are very depending on the type of legislations, being more relevant in cases of low data submission (see above).

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

	Yes	No	Don’t know

Plant Protection Products			
Biocidal products			
General chemicals			
Toys			
Detergents			
Fertilisers			
Electrical and electronic equipment			
Food contact materials			
Food additives			
Cosmetics			
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)			
Human and veterinary pharmaceuticals (only for effects on the environment)			
Waste/recycling			
Other (please specify)			

Efficiency of regulatory provisions for endocrine disruptors

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

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

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

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

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

Please explain your answers
1000 character(s) maximum

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

* Not at all

* To some extent
* Fully
* Don't know

Please explain your answer
1000 character(s) maximum

Adequacy of legislation to address needs and concerns on endocrine disruptors

In 1999 the European Commission published a Community strategy on endocrine disruptors, reflecting public concerns that these substances might cause diseases/disorders in humans and affect wildlife populations and biodiversity. Diseases/disorders in humans that are endocrine-related (i.e. via effect on the endocrine system) might result from a combination of factors such as genetic origin, diet, lifestyle, exposure to endocrine disruptors and other chemical stressors. Effects on wildlife populations and biodiversity might be caused by a combination of factors such as habitat loss, climate change, exposure to endocrine disruptors and other chemical stressors.

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

To a significant extent

In recent literature, several papers (see for instance the WHO 2012 state of the science of EDC) have showed that the incidence and/or prevalence of health problems potentially associated with endocrine disruption have increased during the last decades. Even if we cannot say to which extend does ED exposure contribute to the increase in these diseases, there are enough evidence to say that ED could contribute to health problems like cancer, diabetes, obesity, metabolic syndrome or infertility via interference with the neuro-endocrine system.

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

To a significant extent

In recent literature, several papers have showed that pollution of aquatic environment by ED (mainly via sewage) could lead to interferences with the reproductive system (sexual differentiation, infertility, abnormalities of reproductive organs, interference with hormonal system, problems during embryonic development) causing change in anatomy and behaviour of aquatic species. These changes could themselves lead to increased sensitivity to environmental stressors, reduction in reproductive success, reduction of genetic diversity or even increased mortality. Even if the contribution of EDs alone is difficult to measure, it seems that EDs could clearly participate in the decline in biodiversity.

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

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

Yes

Please explain your answer with examples for specific regulated areas.

1000 character(s) maximum

The regulatory frameworks are flexible enough. Support to and awareness raising of the different authorities is important. This could be done, for instance, by updating some guidance(s) (e.g. how to use and interpret HBM4EU data…) and sharing data of the different hazard and/or risk evaluation in the different domains.

The "open-end" tests mainly used in research published in the open scientific literature are increasingly taken into account for RA of PPP's.

33) Do you have any further comments on the adequacy of legislation to address societal needs and concerns on endocrine disruptors?
2000 character(s) maximum

We need to speed up the identification of EDs (e.g. by grouping approach…) and we need to address the cocktail effects.

Added value of EU level intervention

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

It is important to have common criteria to identify ED. Decisions have to be taken preferably on a European level.

This is justifiable in some cases – protection of human health or the environment is more important than preserving the integrity of the single market. However, it should be followed by an EU wide action to preserve the integrity of the single market.

Under which circumstances do you think that a decision at national level would be justifiable?
1000 character(s) maximum

If a substance is identified as ED by a Member States and an action at EU level is not possible under a reasonable time period.

36) Do you have any further comments on the added value of regulating endocrine disruptors at EU level?
1000 character(s) maximum

Regulating ED at EU level has a higher impact compared to national level. But this should not slow down management of the risk. Member States can help to speed up the actions.