* Contribution ID: 036603c9-e511-495f-ad42-e0d0406c7939
Date: 31/01/2020 23:36:43

Fitness Check of the EU legislation with regard to Endocrine Disruptors - Stakeholders Survey

Fields marked with * are mandatory.

Introduction

Scope and objectives

In its Communication (https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF) 'Towards a comprehensive European Union framework on endocrine disruptors', adopted on 7 November 2018, the Commission confirmed its commitment to protect EU citizens and the environment from endocrine disruptors by minimising human and wildlife exposure to these substances. The Communication outlines a comprehensive set of actions including a cross-cutting Fitness Check of the relevant legislation.
The Fitness Check aims at analysing the coherence of the different regulatory approaches to the assessment and management of endocrine disruptors and at assessing whether legislation delivers on its objectives to protect humans and the environment.
The legislative measures constituting the EU legal framework regulating chemicals have been developed at different points in time and have, in certain cases, different objectives. This has resulted in different approaches to regulating endocrine disruptors, depending on the sector, and has raised questions as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent. The Fitness Check aims to assess specifically the consequences of the absence of common criteria to identify endocrine disruptors across the different legal frameworks, and different regulatory approaches for managing substances identified as endocrine disruptors. More information is available in the published Roadmap (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en).
Stakeholder consultation is an essential step to collect evidence for the Fitness Check. It aims at gathering inputs from a broad range of stakeholder groups as well as citizens to ensure that relevant evidence and views from all interested parties are considered in the evaluation. The consultation activities solicit input to the analysis of the coherence of the EU framework, as well as, to the extent possible, its effectiveness, efficiency, relevance and EU added value.

The aims of this stakeholder survey are:

- To collect views on possible legislative inconsistencies and to assess their impact on stakeholders;
- To collect information from stakeholders on the effectiveness of the current EU legislation for the identification and risk management of endocrine disruptors;
- To collect information on the efficiency of procedures for the identification and risk management of endocrine disruptors (e.g. duplication of efforts) and to identify opportunities for improvement.

Target audience

This survey is addressed to **stakeholder organisations** such as businesses, public authorities, academia research and NGOs, and to **experts** working in such areas responding in their professional capacity. If you would like to comment in your personal capacity from a citizen's perspective, please respond to the public survey. (https://ec.europa.eu/eusurvey/runner/ED_FC_PublicConsultation)

Instructions

Respondents are encouraged to explain their answers providing examples and data in the open fields provided. However, there is no mandatory field in the main survey section.
Answers should be in **English**.

Information on respondent

I am giving my contribution as:

Some questions are specific to certain stakeholders group(s) and will be visible according to your answer to this question

- ○ Academic/research institution
- ○ Business association
- ○ Company/business organisation
- ○ Civil society organisations
- ◉ Public authority
- ○ Trade union
- ○ Other

First name

50 character(s) maximum

Pierre

Surname

50 character(s) maximum

de Franclieu

Email

50 character(s) maximum

pierre.defranclieu@developpement-durable.gouv.fr

Organisation name

50 character(s) maximum

France - Government

Country of origin of your organisation

- ○ Austria
- ○ Belgium

- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- Other (Please specify)

In which sector does you organisation operate?

Tick all that apply

- [x] Plant Protection Products
- [x] Biocidal products
- [x] General chemicals
- [x] Toys
- [x] Detergents
- [x] Fertilisers
- [x] Electric and electronic equipment
- [x] Food contact materials
- [x] Food additives
- [x] Cosmetics
- [x] Medical devices
- [x] Human and veterinary medicines
- [x] Water industry
- [x] Waste/recycling industry

Scope

- International

- National
- Regional
- Local

Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- 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.

- **Anonymous** - Only your stakeholder group, country of origin, sector, scope and size of your organisation may be published. Your personal details will not be published.
- **Public** - Your personal details may be published with your contribution.

☑ I agree with the following personal data protection provisions

Personal data protection provisions

Privacy_statement.pdf

Survey

1) How familiar are you with the following pieces of legislation?

	Not at all familiar	A little familiar	Fairly familiar	Very familiar
Plant Protection Products Regulation (EC) 1107/2009				◉
Residues of Pesticides Regulation (EC) 396/2005				◉
Biocidal Products Regulation (EU) 2012/528				◉
REACH Regulation (EC) 1907/2006				◉
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008				◉
Persistent Organic Pollutants Regulation (EC) 850/2004 and (EU) 2019/1021				◉
Food Contact Materials Regulation (EC) 1935/2004				◉

Contaminants in Food and Feed Regulation (EEC) 315/93 and Directive (EC) 32/2002				
Food Additives Regulation (EC) 1333/2008				
Cosmetic Products Regulation (EC) 1223/2009				
Medical Devices Regulation (EU) 2017/745				
In vitro Diagnostic Medical Devices Regulation (EU) 2017/746				
Toy Safety Directive 2009/48/EC				
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009				
Detergents Regulation (EC) 648/2004				
Medicinal Products for Humans Directive 2001/83/EC				
Veterinary Medicinal Products Regulation (EU) 2019/6				
General Product Safety Directive 2001/95/EC				
Water Framework Directive 2000/60/EC				
Priority Substances Directive 2013/39 EC				
Drinking Water Directive 98/83/EC				
Groundwater Directive 2006/118/EC				
Marine Strategy Framework Directive 2008/56/EC				
Urban Waste Water Directive 91/271/EEC				
Chemical Agents at Work Directive 98/24/EC				
Carcinogens and Mutagens at Work Directive 2004/37/EC				
Pregnant Workers Directive 92/85/EEC				
Young People at Work Directive 94/33/EC				
Waste Directive 2008/98/EC				
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment - Directive 2011/65/EU				
Industrial emissions Integrated Pollution Prevention and Control Directive 2010/75/EU				

Seveso-III-Directive 2012/18/EU	○	○	○	◉
Ambient Air Quality and Cleaner Air for Europe Directive 2008/50/EC	○	○	○	◉
Regulation (EC) 66/2010 on the EU Ecolabel	○	○	○	◉

Horizontal approach to the identification of endocrine disruptors

Recently the European Commission published criteria for the identification of endocrine disruptors under both the Biocidal Products Regulation and the Plant Protection Products Regulation, which were very similar to each other and based on the WHO definition [1]. Other pieces of EU legislation related to human health and environmental protection from manufactured chemicals do not contain such criteria.

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

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
- ○ It is not a problem, the criteria should be sector specific

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

1,000 character(s) maximum

Hazard identification (ie caracterization of intrinsic properties of a substance) is the first step of risk management of chemicals. For the sake of consistency, it should be the same whatever the use. In other words, a same substance should not be identified differently among regulations.

The second step, risk evaluation, takes into account the identification and the exposure. The French authorities recommend the implementation of harmonized hazard-based identification criteria, in 3 categories (known, presumed and suspected) - integrating the level of evidence. This scheme would enable the application of a single classification and identification, leading to different consequences and ways of managing risks depending on the uses.

The French authorities suggest that hazard identification be under scrutiny of a single body at European level. For the time being, it is necessary for the Commission to encourage better coordination between the different European agencies.

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
- ( ) No

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
- ( ) No

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

1,000 character(s) maximum

EDC identification is currently not possible in CLP whereas it is essential. The implementation of hazard-based criteria to identify EDCs in the cross-cutting regulation CLP, based on the level of evidence, would facilitate the consideration of these hazardous substances in all regulations where the CLP Regulation is taken into account, e.g. similarly to CMR.

The French authorities recommend the implementation of the known, presumed and suspected categories to identify and manage the risk of EDCs. The suspected category is crucial for substances having an ED mode of action with nefast effect but with insufficient level of evidence to be classified in known or presumed catergories. With these three categories, risk management can be adapted according to the level of evidence and the precautionary principle applied (prohibition of suspected EDCs for uses exposing vulnerable populations).

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
- ( ) No

What should be the regulatory consequences of such a category? What would be the consequences for protecting human health and the environment? What would be the economic consequences?

2,000 character(s) maximum

The French authorities underline the necessity of a suspected category for EDC regarding their specific properties : windows of exposition, cocktail effect, non-monotonous dose-response answer, long term and transgenerational effects.

The French authorities consider EDC as substances of very high concern (like CMR, PBT and vPvB). The categories will allow different levels of management according to the uses and exposed populations.

For EDCs, the French authorities support a principle of prohibition for uses exposing vulnerable populations (e.g. cosmetics), anf if needed with strict derogations. The scope of the derogation should be specified in each regulation, or within REACH, according to the products concerned and the level of exposure (population and environment).

Without reliable tests for the identification of endocrine disruptors, it is difficult for companies to demonstrate the safety of the products. Exemptions should be authorized for the suspected category.

The French authorities consider this way of managing EDC will stimulate innovation (alternatives development). Regarding competitiveness, consequences should be mitigated as the future framework could raise the costs of tests and studies required to demonstrate the safety of products. Morever a positive impact on companies competitiveness will depend on public authortities ability to ensure them a fair competitive environment with companies located outside the EU. It will be necessary to strengthen customs control and European coordination to ensure the conformity of products entering the European market.

The French authorities are not in favour of the regulatory framework taking into account a safe threshold, given that it is difficult for most EDCs to define a threshold below which the risk could be qualified as negligible.

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
- No

Please provide examples and describe the consequences.

2,000 character(s) maximum

The French authorities note there is no specific provision for EDC except in REACH,PPPR and BPR.

The French authorities also note that in food contact material regulations th e approach chosen to manage the risk of EDCs differs: from the theoritical pr ohibition of certain substances considered hazardous to an approach based on migration limits (e.g. : BPA). This latter approach based on migration limits is scientifically questionnable regarding the specific properties of EDCs and the difficulty to establish a hazard threshold. The French authorities point out that if the applicant does not succeed in demonstrating the existence of a safe thershold then the EU regulation should prohibit the intentional use o f these substances or the use of the substance should only be authorized for manufacture under special conditions ensuring total absence of migration such as behind a functional barrier.

Actually, the French authorities recall that it is often impossible to define a threshold below which the risk could be qualified as "negligible". These di fficulties are due to specificities related to EDCs ; the windows of vulnerab ility of exposed populations (humans and other living species), the synergist ic effects and the possibility of non-monotonous dose-response relationships.

Besides, although necessary for PPP and BP uses, the concept of non-target or ganism introduces a de facto distinction in how EDCs are dealt with between t hese two regulations and the other European regulations (REACh, cosmetics, et c.). In addition, for PPP and BP uses of the same chemical, the non-target or ganisms may differ.

Finally, the French authorities recall that the inconsistencies of identific ation, management and control globally concern all chemicals and their hazard ous properties (CMR, PBT, vPvB...).

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
Human health protection	○	○	○	○	◉	○
Environmental 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

Human health protection	○	○	○	◉	○	○
Environmental 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
- ○ No

Please provide examples and describe the consequences.

1,000 character(s) maximum

Most of the regulations don't take ED issue into account.

Besides, the effects of substances used in cosmetic and medical devices regulations are not evaluated for their effects on the environment and for the time being no specific requirement are included in the cosmetic regulation to address ED effects for human health. The requirements that could demonstrate the capability of cosmetic substances to have ED effect on wildlife are not in these regulations. It is in principle under REACH.

Other differences among regulations concern the provisions regarding required data.

The French authorities note that the risk assessment is limited to a substance-by-substance analysis whereas the use of substances lead to a combined exposure known as "cocktail effect". The French authorities request the EC to take into account the cocktail effect and apply the precautionnary principle in the risk assessment (ban principle with derogations, group approach, endocrine activity tests...).

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

- ◉ Yes
- ○ No

If yes, please provide examples and describe the consequences.

1,000 character(s) maximum

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

2,000 character(s) maximum

Regarding EDC, for hazard identification, the French authorities advocate for a CLP classification system coordinated by a single European body.

The French authorities ask the funds of the agencies to be increased, so that assessments could be carried out in certain cases independantly from the industries. It would also allow public agencies to carry out more expert appraisal. A contribution from industries should finance these funds. The French authorities recall that the burden of proof relies on industry.

The French authorities suggest to include the approach of essential use to phase out most hazardous chemicals (e.g.EDCs). This approach could be decline in 3 parts : 1/ Uses not essential for health, safety, or functioning of the society; 2/ Uses performing important functions but for which equally performant and safer alternatives exist; 3/ Uses considered essential because they are necessary for health, safety, or functioning of the society AND alternatives are not yet available.

Regarding the product-waste interface, the French authorities recommend harmonising the classification rules between the Waste Framework Directive and CLP. They are opposed to the practice of differentiated thresholds for hazardous substances according to whether or not products are derived from recycling. The French authorities also ask for the "exit from waste status" to be organised at European level for the sake of consistency.

The French authorities consider it is necessary to ensure timely regulation to restrict hazardous chemicals in imported products and promote ambitious standards beyond the Union and at international level to ensure safe management of chemicals and to preserve European competitiveness.

The French authorities will soon publish a position paper containing the proposed regulatory amendments needed to take EDCs into account in all relevant regulations.

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

2,000 character(s) maximum

The French authorities note that the procedure for identifying active substances as EDCs is not yet fully effective in the BPR. They also note that tests are still lacking to identify all EDCs MoA and effects.

The French authorities regret the failure to take into account the suspected EDCs in the light of the current possibilities for derogation already provided for in the regulation. The French authorities recall the importance to allow the identification in BPR of the suspected EDCs and to apply the precautionnary principle. Indeed, the hazards of EDCs have been known for more than 20 years but their identification is still complicated by their intrinsic properties: effects that depend on the exposure window, cocktail effects that can lead to greater impacts, long-term and transgenerational effects, effects that depend on the period of exposure and also MoA that are not yet all known.

The French authorities also regret the lack of immediate re-examination of the active substances identified as EDC (known, presumed and suspected) in the impact study carried out by the EC on the occasion of the revision of the pesticide regulations (cf. the 2018 French positions regarding the re-evaluation of active substances).

The French authorities also wonder how the conclusions of the assessments of the ED property in the authorisation conditions as well as the assessment of the ED property of the co-formulants are effectively taken into account.

Finally, the French authorities, given the frequent absence of data on EDCs (namely the results of tests required by the regulations) in the dossiers submitted by manufacturers (e.g. recently: benalaxyl), ask that the absence of transmission of these data implies the non-approval of the substance.

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

2,000 character(s) maximum

The French authorities note that the procedure for identifying active substances as EDCs is not yet fully effective for PPP. They also note that tests are still lacking to identify all EDCs MoA and effects. Besides, they note, despite scientifc consensus on certain EDC, that the application of the ED criteria of the Regulation and the required tests leads to a non-ED classification (e.g. chlorpyrifos) : consideration of independent scientific studies should be effectively taken into account and the guidance on the application of the ED criteria may need to be updated.

The French authorities also wonder how the EC consider the withdrawals of authorisations at national level, particularly for the epoxiconazole. The EC should therefore specify the consequences provided for in this case and apply them.

The French authorities regret the failure to take into account the suspected EDCs. The French authorities recall the importance to allow the identification in PPPR of the suspected EDCs by applying the precautionnary principle. Indeed, the hazards of EDCs have been known for more than 20 years but their identification is still complicated by their intrinsic properties: effects that depend on the exposure window, cocktail effects that can lead to greater impacts, long-term and transgenerational effects, effects that depend on the period of exposure and also MoA that are not yet all known.

The French authorities also wonder how the conclusions of the assessments of the ED property in the authorisation conditions as well as the assessment of the ED property of the co-formulants are effectively taken into account.

Finally, the French authorities, given the regular absence of data on EDCs (namely the results of tests required by the regulations) in the dossiers submitted by manufacturers (e.g. recently: benalaxyl), ask that the absence of transmission of these data implies the non-approval of the substance.

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

2,000 character(s) maximum

The REACH Regulation allows EDCs to be identified and managed when they are SVHC. The main issue regarding EDCs in REACH is the absence of sufficient required tests allowing the identification of EDCs.

The French authorities ask for the implementation of more required tests, taking into account at least the exposure window, the long-terme effect and the transgenerational effect, to identify known, presumed and suspected EDC. Besides, as provided for in the regulation, all scientific studies carried out by independent researchers should be taken into account (e.g. BPB).

The French authorities recommend, for protecting consumers, that restriction and authorisation dossiers for each EDC should be implemented. Actually, if it is difficult to identify the ED property (or hazard category), it is even more difficult to perform an appropriate risk assessment and identify a potential risk.

However, even when the EDC is identified as SVHC and is submitted to authorisation, the French authorities point out at least two major issues to say the population is not being protected as expected:
- A substance could be submitted to authorisation (Annex XIV) for properties other than its ED property (e.g. phthalates for reprotoxic effects), which means that ED effects are not taken into account in the exposure and /or CSR scenarios – even though they are a determining factor in the risk assessment and in the socioecological analysis leading to the granting of authorisation;
- the methodology for the SEA pathway specific to non-threshold substances remains to be developed.

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

2,000 character(s) maximum

The French authorities note that the approach currently provided for in the Cosmetics Regulation for EDCs is based on risk and on a substance-by-substance analysis. This approach is inconsistent with what is done with CMRs in the same regulation. This approach is also contrary to the will of the legislator who has put in the same article the provisions that apply to CMRs and EDCs. The French authorities advocate for a ban principle with the possibility of derogations.

Besides, the French authorities recall that the ban on animal testing is a limitation for the EDCs to be identified in an acceptable way, as recalled by endocrinologists. Also the population using these products as well as the workers in contact with them may be exposed and impregnated with EDC with potentially non-threshold and transgenerational effects. Moreover, the in vitro/in silico tests carried out by industries in the framework of the Cosmetics Regulation are not validated at the international level. Thus, it means that the data currently collected in the framework of the Regulation do not allow to conclude with certainty on the ED property of a substance. Therefore, without going back on the prohibition of animal tests, the French authorities require, regarding the exposure of sensitive populations and workers to potential EDC (young people of childbearing age, parents...), the application of the precautionary principle in the Cosmetics regulation as soon as endocrine activity is detected in vitro or in silico or in the scientific literature.

The French authorities also refer to its comments on essential uses. The EDC questioned the paradigm of toxicity, also identification and risk management paradigm for EDC should changed too and the precautionnary principle applied.

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

2,000 character(s) maximum

```
The regulation on medical devices will come into force in May 2020, so it is
complicated at this stage to give an opinion on the implementation of this re
gulation.

However, The French authorities ask for the implementation of more required t
ests to be able to identify EDCs. Besides, as provided for in the regulation,
all sientific studies carried out by independent researchers should be taken
into account.

The French authorities recall the necessity to assess the impact of possible
alternatives on the functionality, performance and overall risk-benefit ratio
of the medical device.
```

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

2,000 character(s) maximum

The establishment of the list of priority substances in the Water Framework Directive does not take into account the EDC issue. The establishment of the environmental quality standards used to assess good water status rarely takes into account the ED activity (cf. INERIS work in progress). The substance-by-substance approach is not consistent with the ED issue. The watchlist introduced in 2015 is a useful adaptive tool to implement monitoring of ED activity with existing tools. The review of the Directive is an opportunity to develop methods for monitoring and assessing the chemical quality of water by taking into account scientific advances in this field (use of bioassays in particular). The European water directors expressed the wish for a pragmatic approach taking into account the cocktail effect for the future of the directive. A European working group issued recommendations in this direction, endorsed by the Strategic Coordination Group.

Besides, there is only one restriction (on BPA) related to the presence of EDCs in water for human consumption. The French authorities welcome the implementation of a watch list in the water for consumer use. The French autorities indicate to the European Commission that measures must be rapidly implemented to identify the hazard posed by the presence of EDCs in aquatic environments.

The French authorities ask for the polluter pays principle to be applied. Indeed, the treatment and decontamination of water pollution should weigh on the industry and not on the society.

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

1,000 character(s) maximum

Aggregated exposure within one regulation is theorically taken into account (but there is no guidelines). However the aggregated exposure across regulatio n is not taken into account. A first approach should be to implement tests to detect endocrine activity.

In this context, the French authorities insist on the general objective of mi nimising exposure. They recall the importance of identifying suspected EDCs a nd of applying the precautionnary principle (ban principle, group approach...).

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

1,000 character(s) maximum

Regulations deal with individual substances. Most of the time - except in cas es of Product approval under PPPR and BPR where calculation (additive approac hes) are conducted or rare restriction under REACH (on more than one substanc e) - combined exposure is not taken into account.

This is an important gap when one considers the synergistic effect between ED Cs and the ubiquitous exposure to these substances to which we are subjected.

The French authorities note the risk assessment is currently limited to a sub stance-by-substance analysis whereas the conditions of use of the substances lead to a combined and cumulative exposure of the environment and the populat ion to these substances known as the "cocktail effect". The French authoritie s request the EC to take into account the cocktail effect (e.g. : group appro ach, test to indentify ED activity) in the risk assessment of the various re gulations mentioned in this survey and to apply the precautionnary principle (ban principle).

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	○	◉	○

Please give examples of regulatory sectors in which a group is not sufficiently protected from exposure to endocrine disruptors and explain why.

2,000 character(s) maximum

The French authorities note that, on the whole, the EDCs are insufficiently taken into account in the regulations in view of their specific nature. The French authorities stress the importance of having tests to study the effects of chemicals according to the periods of exposure, the long term effects and the transgenerational effects.

The known deleterious effects of EDCs on children when compared to currently published impregnation studies (notably ESTEBAN in France) are worrying as they show that children impregnate at higher levels compared to adults. Moreover, citizens are exposed to a large number of substances whose synergistic harmful effects are not known. However, tangible scientific data on the hazard of EDCs have been available for more than 20 years (developmental disorders, hormone-dependent cancer ...). These data raise serious public health concerns which must be solved as quickly as possible. Indeed, in addition to the generalised ED-impregnation of the population, there is a lack of knowledge of the cocktail-effects.

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?

- Yes
- No

Which tests should be developed?

1,000 character(s) maximum

E, A & S are relatively well covered (if the tests are run with the current standard), T is partially evaluated and for the other MoA, they are mainly not investigated in regulatory tests. Some of the adverse effects related to E, A, S are observable in standard reproductive studies. Some of the effects on T can be observed in a neuro-developmental study. Effects on metabolism (obesity) are not standardised. This question is technic and should be developed in details by experts. The development of tests for the EAS axis should be continued in order to improve their sensitivity and their design to correspond to the realities of exposures.

Besides, sientific studies carried out by independent researchers should be taken into account.

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?

- Yes
- No

Please specify what requirements you would add or modify in each piece of legislation.

1,000 character(s) maximum

There is so far no sufficient specific requirement regarding ED properties in the current provisions for data requirements, whatever the regulation (REACH, PPP, BP...).

The current requirement are far from being exhaustive : it should be reminded that so far, only EATS (estrogen, androgen, thyroid and steroidogenesis) modalities are covered by the ECHA-EFSA guidance for PPP and BP.

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
- No

Please explain your answer and provide examples.

1,000 character(s) maximum

The French authorities underline that EDC identification is not harmonized so far which necessarily implies differences in the likelihood of identifying an EDC in the sectoral and REACH regulations. The French authorities also note that the test requirements have to be reinforced in REACH regulation. This work has just been initiated by the EC which is positive signal.

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?

2,000 character(s) maximum

Scientific studies carried out by independent researchers should be taken into account.

It is difficult to observe EDC MoA (at low doses) and adverse effects (visible at higher doses) within a single study run with 3 doses. Given the particularity of EDCs, a single study does not allow to conclude with absolute certainty, or rarely, in the current state of knowledge, about MoA and the adverse effects of a substance. The European Commission has to take into account the specificity of EDCs and thus request several tests to identify long-term effects, effects according to the exposure window and finally transgenerational effects. The tests currently required do not take into account these specificities, which have been known for several decades. This situation is not acceptable.

The French authorities reiterate they are in favour of the creation of a European mechanism to enable the European and national agencies, to carry out independent studies on potential EDCs. This work consists, in cases justified by scientific controversy, in an impartial assessment of the evaluations provided by industry, without calling into question the general principle of the industries first responsibility for producing the data. This work should be financed by an increase in the fees charged by the agencies to industries.

Finally, the French authorities recall the importance of developing tests to cover all MoA (not just EATS) and effects of EDCs (long-term, cocktail, transgenerational...). In addition, the French authorities annnouce the setting up of a public-private platform aiming at the pre-validating methods and tests relevant for the characterisation of EDCs and thus accelerate their final validation at international level.

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

Please explain your answer.

1,000 character(s) maximum

In vitro and/or in silico methods are used as often as possible to focus in v ivo investigations on the relevant endpoints. In vitro and/or in silico metho ds can also be used to prioritise substance evaluation. However, they are not predictive of the ability of a substance to be an EDC. Indeed, endocrine syst ems can be disrupted through different MoA and no battery of test is covering all the possibilities MoA and effects.

For the REACH registration, the French authorities invite the EC to study the feasibility, within the framework of the fitness-check, that an "in vitro scr eening" (less costly than in vivo) be carried out systematically for substanc es by industries ; if this "screening" shows an endocrine disrupting effect, more complete tests would then have to be carried out. This is the minimal re quirement in terms of identification of EDCs.

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?

- Not at all
- Insufficiently minimised
- Minimised to the extent possible
- Don't know

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

1,000 character(s) maximum

Some of the Mode of Action (MoA) analysis can be performed through a battery of in vitro testing. However, level 3 tests (OECD conceptual framework) are n ecessary to strengthen this screening. In addition, level 4 &
5 tests are necessary to evaluate adverse effects on endocrine endpoints (lev el 4) and in more extensive part of life cycle (level 5) as most of these adv erse effect appear at long-term.

The application of the precautionary principle coupled with an approach by gr oup of substances will make it possible to limit the use of animal testing an d improve the animal welfare.

However, it should be kept in mind that for now only animal testing allows to have confirmation of many ED effects and MoA (which is a prerequisite for the identification of an ED).

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)	◉	○

Please explain your answers, including the consideration of sector-specific interconnections with horizontal legislation (e.g. REACH).

1,000 character(s) maximum

A position paper will soon be published by France to point out the shortcomings identified and identufy concrete solutions.
The second national strategy on EDC and the positions defended by France at Community level on the issue of the EDCs are available here: https://www.ecologique-solidaire.gouv.fr/strategie-nationale-sur-perturbateurs-endocriniens

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)	◉	○

Please explain your answers, including the consideration of sector-specific interconnections with horizontal legislation (e.g. REACH).

1,000 character(s) maximum

A position paper will be published by France in parallel to this questionnaire to point out the shortcomings identified and identify concrete solutions. The second national strategy on EDC and the positions defended by France at EU level on the issue of the EDCs are available here: https://www.ecologique-solidaire.gouv.fr/strategie-nationale-sur-perturbateurs-endocriniens.

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

1,000 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

1,000 character(s) maximum

Negative externalities linked to EDCs have a cost for the society, which is difficult to estimate precisely, but which some studies estimate to be at least more than €160 billion per year for the European health system. This estimation focuses only on few pesticides and flame retardants, on BPA and on phtalates. Besides,this estimation does not take into account the environmental costs, linked to hormone-dependent cancers, immune system disorders and thyroid disorders, which would lead to a cost of several hundred billion euros.

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
- Not to a significant extent
- Not at all
- Don't know

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
- Not to a significant extent
- Not at all
- Don't know

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
- No

Please explain your answer with examples for specific regulated areas.

1,000 character(s) maximum

Theorically, if well described, any piece of information can be added to the weight of evidence and has to be taken into account, at least under REACH, PPPR and BPR. But this possibility should be an obligation, regarding the few situations where it is effectively done. The PPP and BP that were identified as EDC in the JRC impact assessment at the time of the revision of the pesticide regulations should also be re-evaluated as soon as possible, as provided for in the regulations. The French authorities have already expressed this request in a position paper.

Studies from the scientific literature, carried out by independent laboratories and published in peer-reviewed scientific journals, should also be taken into account.

Finally, the conclusions of international bodies (WHO, IARC in particular) should also be taken into account in order to improve the efficiency of the substance evaluation process.

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

2,000 character(s) maximum

The French authorities consider that the European Commission should establish a prioritised list of potential EDCs for evaluation. This list would be made available to stakeholders.They also consider that in order to have a synthetic vision and to allow a better management, a European list of known, presumed and suspected EDCs should be established and enriched by the EC in the light of the assessment work already carried out by certain member states.

The French authorities call for an extension to EDCs of management principles that have been adopted for the most dangerous substances : introducing a principle of prohibition with possible derogations when alternatives are not available or when the socio-economic consequences of a ban is disproportionate.

The French authorities consider that, on the basis of these lists, the EC should implement information measures for the public, including mandatory labelling of the presence of EDC in everyday products. The credibility of the institutions is at stake. The French authorities believe that direct information for the public is crucial to enable informed choice. The French authorities therefore consider that, if the EC were to choose other options than the ban principle with derogation, the introduction of compulsory labelling indicating the presence of EDCs should be implemented regarding the risks resulting from exposure to these substances.

The French authorities suggest that the European Commission set up a Datathon with the aim of cross-referencing different sets of data. (environmental contamination, economic activity, socio-professional category, practices, etc) to produce a mapping and highlight spatial, temporal and socio-economic trends in the
environmental contamination by EDCs and population exposure to EDCs.

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 (http://www.senat.fr/petite-loi-ameli/2012-2013/9.html), applicable from July 2015.

34) Do you think:

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

Under which circumstances do you think that a decision at national level would be justifiable?

1,000 character(s) maximum

When the European Commission, despite the scientific proof of the hazard of a substance (known, presumed, suspected ED), does not implement risk management measures to protect the environment or the substance.

The French authorities recall that CLP and REACH are cross-cutting regulation referred to in the sectoral regulations. A hazard-based categorization of EDCs in REACH and/or CLP will identify the hazard in one cross-sectorial regulation. Thus a single European body will deal with the identification of EDCs, which will be beneficial in terms of public expenditure and consistency. Indeed, it will avoid differences of opinion between agencies on a substance evaluation as was the case on BPA between ECHA and EFSA.

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

1,000 character(s) maximum

The European regulatory framework is the right one and France will continue to play a leading role in it.

Besides, within the ECHA Forum, the French authorities will ask for the implementation of coordinated controls on endocrine disruptors (in particular for imported products).

The French authorities remind the importance to develop and support a European infrastructure for chemical exposome analysis. This infrastructure will for example develop screening methods to explore the chemical exposure and identify emerging substances.

The French authorities also ask that the EC to develop biomonitoring of the population regarding EDCs and to increase the funds of the agencies so that they can carry out more expert appraisal and assessement work independently of the industries. A contribution from industries could finance these funds.

Useful links

European Commission central information portal on endocrine disruptors (https://ec.europa.eu/info/policies/endocrine-disruptors_en) (https://ec.europa.eu/info/policies/endocrine-disruptors_en)

Harmful chemicals – endocrine disruptors, review of EU rules (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en) (https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en)

Contact

JRC-F3-ENQUIRIES@ec.europa.eu