Commission Communication on endocrine disruptors: Questions and Answers

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How does the EU protect its citizens and the environment when it comes to chemicals?

Chemical substances are regulated extensively under different areas of EU law, such as Occupational Safety and Health, food and feed safety, consumer products and environmental protection. In addition, the REACH Regulation lays down the general EU framework applicable to chemicals.

Overall, the EU regulatory framework on chemicals, based on high level scientific advice and application of the precautionary principle, is considered to be one of the strictest - if not the strictest – in the world. It ensures a high level of protection of human health and the environment.

EU legislation regulates chemicals differently depending on the area of use, the specific objectives and the general approach of the sectorial legislation. For example, in the area of pesticides or biocides, all active substances used in these products can only be put on the market and used after it is demonstrated that the specific use does not pose a risk to humans and the environment (the approvals of all active substances are periodically reviewed at EU level). Under REACH, the use of hazardous chemicals can be subject to an authorisation requirement and, if the chemicals pose an unacceptable risk, their use can be restricted.

In the area of cosmetics, certain chemicals are banned by default, some must be pre-authorised based on risk assessment and others can be used unless a risk is identified.

What are endocrine disruptors and what are their effects?

Endocrine disruptors are chemical substances that alter the functioning of the endocrine (hormonal) system and, as a consequence, negatively affect the health of humans and animals in different ways (for example by negatively affecting reproductive health or having a role in the development of hormone-related cancers).

Endocrine disruptors may be of synthetic or natural origin and exposure to endocrine disruptors can occur from different sources, such as residues of pesticides or consumer products used or present in our daily life. The main characteristic of endocrine disruptors compared to other toxicological classes of chemicals is that we do not only look at the toxic effect, but also at the mechanism how they affect us by interfering with the functioning of the hormonal system. The usual approach to defining the toxicity of chemical substances is based on "end points", i.e. whether there is an adverse effect. The additional element for endocrine disruptors is the concept of "mode of action", i.e. the way in which a chemical substance impacts us.

How are endocrine disruptors regulated under EU law?

Endocrine disruptors are regulated under different areas of EU law. While the regulatory approaches differ, all legislations have allowed to effectively take actions on endocrine disruptors to avoid risks for human health and the environment.

Specific provisions on how to address endocrine disruptors are included in the Regulations on pesticides and biocides, chemicals in general ("REACH Regulation"), medical devices and water. By way of example, under the Regulations on pesticides and biocides, a substance identified as endocrine disruptor cannot be approved as a general rule. There are very limited derogation possibilities and in those cases the substance is approved as a so-called *candidate for substitution* and for a shorter period compared to standard approvals. The Commission has recently established criteria for identifying endocrine disruptors under the Regulations on pesticides and biocides, based on the definition of the World Health Organisation.

Under REACH, endocrine disruptors are specifically mentioned as substances that can be identified as Substances of Very High Concern (SVHCs) and can therefore be subject to authorisation requirements. Identification of substances with endocrine disrupting properties under REACH is also based on the definition of the World Health Organisation. The authorisation process aims to ensure that SVHCs are properly controlled and progressively replaced by less hazardous alternatives, where technically and practically feasible. Industry is required to apply for authorisation if it intends to use a substance placed on the *Authorisation List* (Annex XIV of REACH). In recent years, REACH identified already 13 substances as SVHCs with endocrine disrupting properties (first step of the authorisation procedure)

and two endocrine disruptors have already been placed in the *Authorisation List* (one example is nonylphenol). Several substances with endocrine disrupting properties such as bisphenol A are also subject to restrictions under REACH in order to address unacceptable risks (Annex XVII of REACH).

Other legislative instruments, such as the Regulations on cosmetics or food contact materials, and the legislative framework on Occupational Safety and Health, although they do not mention endocrine disruptors specifically, consider them like other substances that can negatively affect human health. They are therefore subject to case-by-case regulatory action on the basis of the requirements of the legislation. For example, under the legislation on cosmetics, specific restrictions or bans have been set on a number of preservatives with endocrine disrupting properties, in particular to protect infants and young children[1]. Under the legislative framework on Occupational Safety and Health, very low limits for bisphenol A have been set to protect workers from exposure through inhalable dust[2].

How are decisions taken in this field? Who provides scientific advice for them?

Rules and procedures vary depending on the specific legislation/sector regulated.

In general terms, the EU approach is based on high-level scientific advice from the relevant EU risk assessment bodies, such as the European Chemicals Agency, the European Food Safety Authority or the Scientific Committee on Consumer Safety, and risk management decisions taken by the Commission, in agreement with Member States, under the so-called Comitology rules.

When the scientific evaluation cannot conclude with sufficient certainty, the Commission is guided by the so-called *precautionary principle* to take protective measures for its citizens and the environment. Enforcement of legislation is carried out by the Member States, and the Commission facilitates exchange of information between national competent authorities to improve their enforcement activities.

How will the existing legal framework on endocrine disruptors be reviewed?

Questions have been raised as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent. In particular, interested parties have regularly raised two issues that are of concern to them: the absence of horizontal criteria for the identification of endocrine disruptors in the legislation and the different regulatory consequences for substances identified as endocrine disruptors depending on the policy area in which they are regulated. It has been argued that these issues are a cause of legal uncertainty, might result in inconsistent identification of endocrine disruptors across policy areas and, in certain cases, in insufficient protection.

Different evaluations have been carried out or are under way which are relevant for the topic of endocrine disruptors[3]. For example, the evaluations under REACH noted that the approach taken under REACH is suitable to identify and regulate endocrine disruptors properly. However, no single evaluation has so far covered all different vertical and horizontal aspects of the topic for all legislations.

This is why the Communication has launched a **Fitness Check on endocrine disruptors**. For the first time, the Commission will take a cross-cutting look at endocrine disruptors, building on scientific evidence and the significant amount of data already collected and analysed in the context of finalised and on-going evaluations. The Commission will look into how different provisions interact, identify possible inconsistencies or synergies and assess their collective impact on human health and the environment, the competitiveness of EU farmers and industry, and international trade. In the context of the Fitness Check we will also carry out a public consultation.

Overall, this exercise will help assess whether EU legislation on endocrine disruptors is fit for purpose in line with Better Regulation principles and feed into the reflection on whether legislative changes are necessary.

Will the exposure to endocrine disruptors be minimised?

The overall aim of all EU legislation on chemicals is to achieve a high level of protection of human health and the environment by minimising exposure to hazardous substances and by stimulating substitution of hazardous substances by less hazardous chemicals, as far as technically and practically possible. This remains our overarching objective.

All the new actions outlined in the Communication will contribute to reaching that objective as regards endocrine disruptors. Furthermore, by stepping up the implementation of existing legislation and policies, the Commission will also provide a significant contribution to reach that objective.

Will the EU support the research on endocrine disruptors?

The Communication confirms the Commission's commitment to build on the existing EU-supported research and to use available funding opportunities, in particular in the future programme for Research and Technological Development, Horizon Europe, to fill knowledge gaps that are key to understand endocrine disruptors.

Some examples of these gaps are: the impact that exposure to endocrine disruptors has on the development of diseases and on wildlife; the applicability of certain toxicological principles, such as the "safe threshold" principle (i.e. the dose below which no adverse effect is expected to occur) to endocrine disruptors; the issue of combined exposure ("mixture/cocktail effect") or the development of safer alternatives to substitute endocrine disruptors.

Several proposed research strands across Horizon Europe are very relevant to endocrine disruptors. These include:

- research on assessment and management of chemicals and on data collection and sharing;
- research on elimination of substances of concern from products and support to the development of safe substitutes;
- research on eco-innovation for prevention and remediation of environmental pollution; looking also at the interface between chemicals, products and waste.

How will the EU promote dialogue on endocrine disruptors?

In order to be able to progress in effectively addressing endocrine disruptors, the Commission will follow an inclusive approach that is open, transparent and brings together all interested parties. We will organise a Forum on endocrine disruptors on an annual basis, inviting scientists and public and private stakeholders to exchange information and best practices, identify challenges and build synergies.

Together with Member States, we will also step up our support to the work of relevant international organisations, in particular the Organisation for Economic Co-operation and Development, which is responsible for developing internationally agreed test guidelines for endocrine disruptors.

We will also launch a one-stop shop web portal on endocrine disruptors to consolidate and streamline all the information on endocrine disruptors currently present in different websites managed by the Commission and EU agencies.

Will there be an improvement of the implementation of the existing EU legislation and policies that are relevant for endocrine disruptors?

The Commission will continue to implement and enforce the existing legislation and policies that are relevant for endocrine disruptors. In this context, in order to exploit the full potential of our legislative framework, the Commission is currently working on actions in a number of areas that aim at:

- developpng a horizontal approach for the identification of endocrine disruptors across EU legislation building on the criteria developed for pesticides and biocides;
- updating data requirements in the different legislative frameworks, in particular for pesticides, biocides and in REACH, to improve the availability of data for the identification of endocrine disruptors;
- assessing how to improve the communication through the supply chain for endocrine disruptors under REACH in the context of the work on Safety Data Sheets. Safety Data Sheets are documents provided to downstream users, which include information about the properties of substances or mixtures;
- takinging forward the scientific assessment of endocrine disruptors in a number of areas, such as cosmetics or food contact materials, in order to take further regulatory action.

[1] Certain so-called "parabens", via Commission Regulation (EU) No 358/2014 (OJ L 107, 10.4.2014, p. 5) and Commission Regulation (EU) No 1004/2014 (OJ L 282, 26.9.2014, p. 5).

[2] Commission Directives 2009/161/EU (OJ L 338, 19.12.2009, p. 87) and (EU) 2017/164 (OJ L 27, 1.2.2017, p. 115).

[3] Such as the REACH REFIT evaluation, the REACH Review on the authorisation route of substances with endocrine disrupting properties according to REACH Art. 138 (7), the Fitness Check of the chemicals legislation, the evaluation of the legal framework on pesticides, the evaluation of the 7th Environment Action Programme, the Fitness Check of the water legislation, the evaluation of the legislation on food contact materialsand theevaluation of the legislation on toy safety.

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