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EXECUTIVE SUMMARY OF THE FITNESS CHECK

on endocrine disruptors

of the

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

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Endocrine disruptors are chemical substances of synthetic or natural origin that adversely affect the health of people and animals by altering the functioning of the endocrine system. Exposure to endocrine disruptors can occur from different sources, such as food or everyday consumer products. Different regulatory approaches to managing the risks posed by endocrine disruptors exist because sector-specific regulations have been developed at different points in time and, in some cases, incorporate different specific considerations. This raises questions about the overall coherence of the EU's legal framework on endocrine disruptors. The fitness check focussed on the coherence of EU legislation in this area, and looked at whether the legislation is effective in delivering on its objective to protect human health and the environment by identifying and minimising exposure to these chemicals. The other evaluation criteria (efficiency, EU value added and relevance) are also covered, but less extensively.

Definition and horizontal approach to identifying endocrine disruptors

The definition of endocrine disruptors used by the International Programme on Chemical Safety/World Health Organisation (IPCS/WHO) is broadly accepted in EU legislation. It provides the basis for the criteria used to identify endocrine disruptors under the Plant Protection Products Regulation and Biocidal Products Regulation. The IPCS/WHO definition is also used to identify substances of very high concern for human health and/or the environment due to their endocrine disrupting properties under the legislation on the registration, evaluation, authorisation and restriction of chemicals (REACH).

Many stakeholders have criticised the lack of a horizontal approach to identifying endocrine disruptors. Based on the limited number of substances that have been identified as endocrine disruptors or as not being endocrine disruptors, the fitness check could find no evidence of inconsistent identification across the legislation. Nevertheless, the lack of a unified approach to identifying endocrine disruptors renders decision-making less transparent and more complex. The criteria for identifying them under the Plant Protection Products Regulation and Biocidal Products Regulation may provide a starting point for a future cross-sectorial definition in EU legislation.

Data requirements for identifying endocrine disruptors

Overall, the findings of the fitness check show that there are differences in data requirements across different sectors. These reflect differing intended uses and exposure scenarios contributing to risk, as well as the need to take into account proportionality with respect to socio-economic and laboratory animal welfare considerations.

The regulatory testing of chemicals relies predominantly on the use of OECD test guidelines which are not currently sufficient for addressing all the different ways in which the endocrine system might be disrupted, which therefore limits the ability to identify endocrine disruptors. A combination of testing methods is usually required to generate data relevant to both the adverse effect and the endocrine activity, and which can then be used to identify a substance as an endocrine disruptor. However, data generated by so-called 'mechanistic' tests, which can determine specific endocrine activity, are currently not required under any of the legislative instruments that have provisions on data submission. This gap has been recognised and work is currently in progress to update the data requirements under the Plant Protection Products Regulation, the Biocidal Products Regulation and REACH. The findings of the fitness check show that ready access to such data would also be helpful in other policy areas that have provisions for ensuring the safety of products placed on the EU market, but no specific data requirements.

Risk assessment and management

One challenge for risk assessment is whether the effects of an endocrine disruptor are considered to have a threshold or not, and whether this can be established using current assessment methodology. In the absence of scientific consensus on the threshold question, the policy options for managing endocrine disruptors include either a generic approach to risk management with derogations (as for plant protection and biocidal products) or a case-by-case evaluation of whether a specific risk-based approach can be applied, as done under REACH. Certain pieces of sectorial legislation (e.g. for cosmetic products and food contact materials) lack not only specific provisions for assessing endocrine disruptors, but also specific guidance on how to deal with endocrine disruptors for which it is not possible to quantify a safe (or acceptable) threshold. In practice, in cases where a threshold cannot be established, the regulatory approach followed under EU legislation is to minimise exposure as far as possible, including the option to prohibit the use of a substance.

There are only a few examples of risk assessments based on endocrine disrupting properties. In this limited number of cases, risks were identified following the standard risk assessment approach based on exceedance of a safe threshold for endpoints, which were not necessarily specific to endocrine disruption. Regulatory guidance does not specify how potential non-threshold and non-monotonic dose-response properties of endocrine disruptors should be considered in a risk assessment, except through the possible inclusion of additional uncertainty factors defined on a case-by-case basis.

Across the EU's legislation on chemicals, the co-legislators have opted for different approaches to risk management, depending on specific policy considerations (generic risk approaches, specific risk approaches or risk/impact-benefit-based approaches). This situation has been criticised by many stakeholders, who expressed concerns that differences in risk management measures may not be justified. Indeed, the rationale for some of the differences should be made more transparent (e.g. possibilities for derogation from the exclusion criteria for biocidal products and cut-off criteria for plant protection products). Despite differences in risk management approaches, however, this fitness check found no cases of inconsistent risk management for specific substances based on the lack of a horizontal approach to identification or any other consideration specific to endocrine disrupting properties. This finding has to be qualified, however, by the limited number of endocrine disruptors risk managed due to their ED properties as examined in this Fitness Check.

In view of the above and the Commission’s ambition to develop a 'one substance-one assessment' process, including a horizontal approach to endocrine disruptors, consolidation and simplification options should be explored, as should better communication of the approach to the public and stakeholders. Consolidation would also provide the groundwork for systematically assessing and possibly managing the risks resulting from aggregate and combined exposures (mixtures) to different endocrine disruptors. A comprehensive framework for integrated exposure assessment would enable improved coordination of risk assessment and risk management measures across sectors.

Many sector-specific and product-specific pieces of legislation have provisions in place to address risks posed by hazardous substances, but do not require the generation of toxicity data necessary to identify the hazard. Some pieces of sectorial legislation rely primarily on REACH for identifying endocrine disruptors (e.g. the Medical Devices Regulation and the Water Framework Directive), whereas others have further data requirements but do not yet specifically address endocrine disruption (such as the Food Contact Materials, Food Additives and Cosmetic Products Regulations). There may therefore be a need to strengthen the links between legislation that includes provisions for generating

data on substances, such as REACH, and sector- and product-specific legislation that relies on such data for risk management purposes. Possibilities for improved data sharing across legislation should also be explored.

The findings of the fitness check suggest that differences in regulatory approaches between regulatory areas have had an impact on regulatory efficiency, particularly in cases where multiple assessment and management procedures have focused on the same substances. The Commission and EU agencies working in this area have recognised the problem, and are increasing their efforts to coordinate across sectors. Additional efficiency gains could be obtained by further developing a horizontal approach to endocrine disruptors, including an increased use of new methodologies and grouping approaches, in line with the objectives to minimise animal testing where possible.

Protecting people and the environment

The EU's strategic approach to endocrine disruptors aims to ensure a high level of protection by minimising overall human and environmental exposure. Increasing trends in some non-communicable diseases have been observed, and are suspected to be associated with exposure to endocrine disrupting substances. However, it is difficult to determine to what extent exposure to endocrine disrupting substances from products used and placed on the EU market contributes to these observed adverse effects. Consequently, the fitness check could not draw conclusions on the effectiveness of legislation in reducing the potential impact of endocrine disruptors on these trends. For some endocrine disruptors, environmental monitoring data and/or human biomonitoring data have shown that the restriction measures put in place have been successful in reducing releases into water bodies and/or people's exposure, respectively. Information on substances with endocrine disrupting properties gathered under biomonitoring programmes will be essential for understanding the effectiveness of control measures. Information on the levels of different substances in the body (including endocrine disruptors and mixtures of endocrine disruptors) may also be useful for establishing links with biomarkers of effects related to endocrine system-related diseases.

Vulnerable groups

The critical role of hormones during sensitive life stages (such as embryonic development, puberty, pregnancy and menopause) means that foetuses, infants, adolescents, pregnant women and the elderly are potentially at higher risk than average from exposure to endocrine disruptors. Moreover, early exposure during critical periods of development can affect health at a later stage of life. Since any age group, including the unborn, can be exposed to chemicals in consumer products, the default approach is to consider all ages when conducting a risk assessment. In practice, the extent to which this is possible depends on the data available. It is therefore important that data requirements for assessing endocrine disruptors include methods that address sensitive life stages. Risks to vulnerable groups are currently addressed on a case-by-case basis, based on guidance available for specific legislative sectors. This indicates that there is an opportunity to introduce and improve the consistency of definitions of vulnerable groups across legislation, and to clarify the scientific rationale (degree of exposure or biological susceptibility) for triggering specific provisions for vulnerable groups.