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Towards a comprehensive European Union framework on endocrine disruptors

INTRODUCTION

Endocrine disruptors are chemical substances that alter the functioning of the endocrine system and negatively affect the health of humans and animals. They may either be of synthetic or natural origin. Exposure to endocrine disruptors can occur from different sources, such as residues of pesticides or consumer products used or present in our daily life.

What is the endocrine system?

The endocrine system is a messenger system of the body. It uses hormones, signalling molecules which travel through the bloodstream, as a communication tool and to produce effects on distant cells, tissues and organs. Hormones are essential for controlling a large number of processes in the body, from early ones such as embryonic development and organ formation, to the control of tissue and organ functions in adulthood.

Concerns about endocrine disruptors have been growing since the 1990s[1]. Following the adoption by the European Parliament of a Resolution on endocrine disruptors in 1998[2], in December 1999 the Commission adopted the Community Strategy for endocrine disruptors[3], which has been taken forward since then through action in the fields of research, regulation and international cooperation.

Significant progress in understanding and regulating endocrine disruptors has been made, and the EU is today recognised as one of the global leaders in dealing with these chemicals. At the same time, societal concerns remain high.

The Commission has always been and will remain committed to protect EU citizens and the environment from all hazardous chemicals. In this context, almost twenty years after the adoption of the Community Strategy of 1999, there is a need to update the EU approach on endocrine disruptors so that it remains state-of-the-art and continues to coherently address these substances across different areas, building on the increased knowledge, the achieved results and gained experience. To this end, the Commission is today outlining its strategic approach to endocrine disruptors for the years to come, with the ultimate overall goal to ensure a high level of protection of EU citizens and the environment and, at the same time, to preserve an internal market which delivers for consumers and where all EU business can thrive.

This Communication addresses the requests of the European Parliament and the Council[4], follows up from the 7th Environment Action Programme[5] and is framed by the international commitments to act on hazardous chemicals[6].

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[1] See for example the workshop held in 1996, *The Impact of Endocrine Disruptors on Human Health and Wildlife*, co-supported by the European Commission.
[2] OJ C 341, 9.11.1998, p. 37.
[3] COM(1999) 706.
[4] See for example the European Parliament's resolutions of 14 March 2013 (P7_TA(2013)0091) and 8 June 2016 (P8_TA(2016)0270) and the Council conclusions on the protection of human health and the environment through the sound management of chemicals (19.12.2016).
[5] Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 (OJ L 354, 28.12.2013, p. 171).
[6] See in particular: the United Nations' 2030 Agenda for Sustainable Development (2015), the Parma declaration (2010) and the Ostrava declaration (2017) by countries in the European Region of the World Health Organisation (in particular, in the Parma declaration, endocrine disruptors were listed among the "*key environment and health challenges of our time*") and the conclusions of the third and fourth sessions of the International Conference on Chemicals Management.

Section 1 describes the scientific progress made on endocrine disruptors in the past twenty years. Section 2 summarizes the actions the EU has taken so far and section 3 outlines the Commission's proposed approach to effectively take forward the EU's policy on endocrine disruptors in the future.

1. THE SCIENCE OF ENDOCRINE DISRUPTORS

In the past decades, science on endocrine disruption has advanced significantly. Many thousands of peer-reviewed scientific publications have become available since the adoption of the Community Strategy of 1999, investigating the nature of endocrine disruption, its causes and its consequences for human health and wildlife populations. Progress has also been reported in publications by the European Commission, EU agencies, or in the context of activities co-ordinated by the Commission.

Since 1999, **the scientific evidence linking exposure to endocrine disruptors with human diseases or negative impact on wildlife has become stronger**. Furthermore, scientific progress has brought agreement on a number of issues which are relevant to understand endocrine disruption. There is now broad consensus on the **definition** provided in 2002 by the International Programme on Chemical Safety, a joint programme of various United Nations Agencies, including the World Health Organisation, whereby an endocrine disruptor is defined as "*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*"[7].

Consensus also exists that the **most sensitive window of exposure** to endocrine disruptors is during important periods of development, such as foetal development and puberty[8]. Exposure to endocrine disruptors during these periods may cause permanent effects and result in increased susceptibility to diseases later in life. It is also generally recognised that **endocrine disruptors can interfere with the endocrine system in different ways**. So far, science has focused mainly on a limited number of endocrine modalities[9]. However, in recent years, it has been shown that other aspects of the endocrine system can be sensitive to endocrine disruptors as well. There is also increasing evidence showing that endocrine disruptors can work together to produce additive effects ("**mixture effect**", or "**cocktail effect**") so that exposure to a combination of endocrine disruptors may produce an adverse effect at concentrations at which individually no effect has been observed[10] (even if this effect is not specific to endocrine disruptors)[11].

However, **knowledge gaps still exist**. These relate in particular to:

- the impact that **exposure to endocrine disruptors has on the development of diseases and on wildlife**. In this context, there is limited understanding of the specific

[7] International Programme on Chemical Safety (IPCS) (2002), *Global Assessment of the state-of-the-science of Endocrine Disruptors*.

[8] United Nations Environment Programme (UNEP) / World Health Organization (WHO) (2012), *State of the science of endocrine disrupting chemicals*.

[9] Oestrogen, androgen, thyroid hormone or steroidogenesis (EATS).

[10] UNEP / WHO (2012). See also for example Thrupp TJ et al. (2018), *The consequences of exposure to mixtures of chemicals: Something from 'nothing' and 'a lot from a little' when fish are exposed to steroid hormones*, Science of the total environment, volumes 619–620, 1 April 2018, pages 1482-1492.

[11] The European Food Safety Authority is preparing guidance on harmonised risk assessment methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals; European Food Safety Authority (EFSA) (2013), *Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile*.

contribution of chemical exposure and the way to separate it from other possible causes of the negative impacts being investigated. Other factors are indeed also at play in the development of such endocrine-related disorders (such as genetics, nutrition, lifestyle, or other environmental factors) or impacts on wildlife (e.g. overexploitation, climate change);

- **the existing controversy as to whether and how certain toxicological principles, such as the "safe threshold" principle –** i.e. the dose below which no adverse effect is expected to occur **– are applicable to assess the safety of endocrine disruptors**[12]. A share of scientists is of the view that a safe threshold cannot be established for endocrine disruptors;
- **fully understanding combined exposure** ("mixture/cocktail effect");
- the **development of safer alternatives** (including non-chemical approaches) to substitute endocrine disruptors;
- the **mechanism** of endocrine disruption.

Testing and the extent to which the science is able to inform regulators

Another area where science has significantly progressed but needs to advance further is that related to the **development and validation of tests methods**. Reliable testing is indeed necessary to identify endocrine disruptors, taking account of the different ways in which endocrine disruptors can interfere with the endocrine system, and manage them appropriately. The Organisation for Economic Co-operation and Development is the leading recognised body for developing internationally agreed test guidelines[13], which are transposed into relevant EU legislation as appropriate. The European Food Safety Authority looked into existing test guidelines for endocrine disruptors in 2013. It concluded[14] that a variety of tests were (or would soon be) available for certain endocrine modalities that can be affected by endocrine disruptors[15] in mammals and fish, with fewer tests available for birds and amphibians. The Authority also found that: tests covering other aspects of the endocrine system or other animal groups still needed to be developed and/or validated; that there are no suitable predictive models for some endocrine-related diseases such as certain hormonal cancers, or metabolic disorders/obesity and that no single study existed to assess the effects of exposure of mammals through the complete life cycle[16].

Furthermore, as in other fields of scientific research, also for endocrine disruptors there is the need to progress in the development of alternatives to animal testing: this would imply better

[12] Another example is the dose-response relationship for endocrine disruptors. On all these aspects, see in particular: Joint Research Centre (JRC) (2013), *Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group;* JRC (2013), *Thresholds for Endocrine Disrupters and Related Uncertainties - Report of the Endocrine Disrupters Expert Advisory Group*; Beausoleil et al. (2016), *Review of non-monotonic dose-responses of substances for human risk assessment*; Solecki et al. (2017), *Scientific principles for the identification of endocrine-disrupting chemicals: a consensus statement*.

[13] The test guidelines relevant to endocrine disruptors are listed in the Conceptual Framework for Testing and Assessment of Endocrine Disrupters.

[14] EFSA (2013), *Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment*.

[15] Oestrogen, androgen, thyroid hormone or steroidogenesis (EATS).

[16] Scientific guidance exists on how to interpret the results of individual tests and compile all the available evidence on a substance to evaluate it for endocrine disruption. At international level, the reference is the document from OECD (2012), *Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption*. At EU level, specific guidance exists in the context of the different legal frameworks.

reliance on existing data (and further using extrapolation techniques[17]) and giving more weight to mathematical modelling and new *in vitro* methods.

2. EU POLICY AND REGULATION OF ENDOCRINE DISRUPTORS SO FAR

Following the Community Strategy of 1999, the EU has developed a policy response to endocrine disruptors that is focused on **promoting scientific research**, effectively **regulating endocrine disruptors** and developing **international cooperation** in the field.

EU research and development of test guidelines on endocrine disruptors

Since 1999, the European Union's Framework Programmes for Research and Technological Development have been key instruments for supporting scientific progress in the field of endocrine disruptors. Over 50 multinational collaborative projects have been funded, receiving over €150 million from the EU. These projects aim to improve understanding of the endocrine mechanism of action, to identify adverse effects on human health and wildlife from exposure to endocrine disruptors, and to develop tools for identification of endocrine disruptors and exposure assessment. A further €52 million has been allocated under Horizon 2020 for projects on new testing methods for endocrine disruptors, to be attributed by the end of the year.

In addition to research funded under Horizon 2020, a special effort was made in recent years to further improve the availability of test guidelines for identification of endocrine disruptors and address the testing weaknesses identified at EU and international level, under the auspices of the Organisation for Economic Co-operation and Development. More authoritative testing is an important way to improve the effectiveness of control. The European Commission has funded several activities focusing on identifying gaps in test guidelines, on identifying possible ways to fill in these gaps, on setting priorities for further development of test guidelines, and on enhancing existing test guidelines or designing new ones[18].

How EU legislation addresses endocrine disruptors

In parallel with scientific progress, in the past decades the EU has progressively updated its body of laws regulating chemicals, with the aim of ensuring a high level of protection of human health, animal health and the environment, while ensuring the smooth functioning of the internal market. EU legislation is today recognised as among the most protective in the world and applies to all chemical substances, including those with endocrine disrupting properties.

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. When 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

[17] One example is "read-across", which allows to predict information for one substance by using data from another substance.

[18] Examples include: *Setting priorities for further development and validation of test methods and testing approaches for evaluating endocrine disruptors* (2018); *Development of a study protocol for thyroid disruptor testing in the mammalian system* (to be finalised in 2019); *Validation study to assess in vitro methods for thyroid disruptors* (launched in 2017, ongoing).

facilitates exchange of information between national competent authorities to improve their enforcement activities[19].

Over recent years, the Commission has taken action against endocrine disruptors in line with the different requirements laid down in the relevant legislation. Specific provisions on how to address endocrine disruptors are now included in the legislation on pesticides[20] and biocides[21], chemicals in general ("REACH Regulation")[22], medical devices[23] and water[24]. These requirements vary depending on the specific legislation. Other legislation, such as that on food contact materials[25], cosmetics[26], toys[27] or protecting workers at the workplace[28], does not contain specific provisions for endocrine disruptors. However, substances with endocrine disrupting properties are subject to case-by-case regulatory action on the basis of the general requirements of the legislation.

Regulating endocrine disruptors: a few examples

- The Commission has recently established **criteria for identifying endocrine disruptors under the legislation on pesticides and biocides**, based on the definition of the World Health Organisation[29]. This development constitutes a milestone, as criteria to identify endocrine disruptors had never been set before in a regulatory context. In principle, no identified endocrine disruptor will be allowed to be used in these product categories in the future, except when very limited derogation possibilities apply.
- Under **REACH**, two endocrine disruptors have been placed in the list of substances requiring a specific authorisation to be placed on the market[30]. Another 13 substances have been identified as endocrine disruptors and are included in the *Candidate list* of substances for possible inclusion in the authorisation list in the future[31]. Substances

[19] For example through the Rapid Alert System for dangerous non-food products.
[20] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).
[21] Biocides are used to control harmful organisms (examples are disinfectants) - Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).
[22] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).
[23] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (OJ L 117, 5.5.2017, p. 1).
[24] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p.1).
[25] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (OJ L 338, 13.11.2004, p. 4).
[26] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009, p. 59).
[27] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p.1).
[28] See in particular Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p. 11) and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 158, 30.4.2004, p. 50).
[29] Commission Delegated Regulation (EU) 2017/2100 (OJ L 301, 17.11.17, p.1) and Commission Regulation (EU) 2018/605 (OJ L 101, 20.4.2018, p. 33).
[30] The *authorisation list* of Annex XIV of REACH – substances concerned are for example certain phthalates, ethoxylates of nonylphenol and octylphenol.
[31] More information on the *Candidate list* is available on the website of the European Chemicals Agency.

with endocrine disrupting properties are also subject to restrictions[32]. For example, the Commission has recently obtained Member States' support[33] on a proposal to **forbid the presence of four phthalates** – chemicals broadly used to make plastics softer[34]- in a variety of everyday products at levels of 0.1% or higher. Furthermore, more than 80 chemical substances are currently being evaluated due to concerns on their potential endocrine disrupting properties.

- Under the legislation on **water**, the Commission has **included several endocrine disruptors[35] in the list of "priority substances" of particular concern**[36] for which environmental quality standards and emission controls apply. Furthermore, the Commission has included three endocrine disruptors in the "watch list" of substances for which Union-wide monitoring data should be gathered[37].
- Due to concerns of endocrine disruption, the chemical **bisphenol A is banned from use in baby bottles and other containers for foods for infants and young children**, and very low migration limits are set for other food contact materials[38]. Bisphenol A is also **subject to limit values in toys** for young children under 36 months or intended to be placed in the mouth[39] and **paper** used in receipts[40]. Very low limits for bisphenol A have also been set to **protect workers from exposure** through inhalable dust[41].
- 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[42]. In addition, a substance used in sunscreens as a **filter for ultraviolet radiation has also been banned**[43] taking into account in particular its potential endocrine disrupting properties.

In order to realise the full potential of EU legislation that is relevant for endocrine disruptors, the Commission is currently working on actions in a number of areas. These include:

- aiming to develop 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 to improve identification of endocrine disruptors;

[32] See Annex XVII of REACH.
[33] The REACH Committee, composed of experts from all Member States, supported the proposed measure by unanimity on 11 July 2018.
[34] Bis(2-ethylhexyl) phthalate, Benzyl butyl phthalate, Di-n-butylphthalate, Di-iso-butylphthalate.
[35] Such as brominated diphenylether, bis-(2-ethylhexyl) phthalate and tributyltin compounds.
[36] Last updated by Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy (OJ L 226, 24.8.2013, p. 1).
[37] Commission Implementing Decision (EU) 2018/840 (OJ L 141, 7.6.2018, p.9). The substances are: 17-alpha-ethinylestradiol (EE2), 17-beta-estradiol (E2) and estrone (E1).
[38] Commission Regulation (EU) No 10/2011 (OJ L 12, 15.1.2011, p. 1) and Commission Regulation (EU) 2018/213 (OJ L 41, 14.2.2018, p. 6).
[39] Commission Directive (EU) 2017/898 (OJ L 138, 25.5.2017, p. 128).
[40] Commission Regulation (EU) 2016/2235 (OJ L 337, 13.12.2016, p. 3).
[41] 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). The latest review is based on the recommendation of 2014 of the Scientific Committee on Occupational Exposure Limits (SCOEL/SUM/113).
[42] 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).
[43] 3-Benzylidene Camphor - Commission Regulation (EU) 2015/1298 (OJ L 199, 29.7.2015, p. 22), following the opinion of the Scientific Committee on Consumer Safety SCCS/1513/13.

- 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[44];
- taking forward the scientific assessment of endocrine disruptors in order to take further regulatory action;
- supporting data sharing and monitoring activities;
- preparing guidance documents and reports;
- and organising training for risk assessors and risk managers.

Furthermore, a number of ongoing Commission initiatives currently being considered by the European Parliament and Council, or in the process of being implemented, will provide additional tools to deal with endocrine disruptors once fully in place. These include:

- the proposal for a Regulation on **transparency and sustainability of risk assessment** under EU food law[45], which aims at increasing trust in the regulatory process, including for the assessment of substances suspected to be endocrine disruptors;
- the **European Plastics Strategy**[46], which aims to accelerate the substitution of substances of concern, including endocrine disruptors, in order to promote recycling;
- the proposal to revise the **Drinking Water Directive**[47]**,** which adds three endocrine disruptors[48] to the list of parameters for determining the safety of drinking water;
- the **New Deal for Consumers**[49] and the **Goods package**[50], which will improve enforcement of product safety requirements and will address the illegal presence of endocrine disruptors in a variety of products[51];
- and the update of the existing legal framework on **Occupational Safety and Health** on the basis of robust scientific advice to protect workers exposed to hazardous chemicals, some of which have endocrine disrupting properties.

International cooperation on endocrine disruptors

The Commission and Member States actively participate to the work of the Organisation for Economic Co-operation and Development, thus contributing to the Organisation's efforts in developing internationally agreed test guidelines on endocrine disruptors and improving coordination on the international scene.

The Commission and Member States support the work of the World Health Organisation[52], the Strategic Approach to International Chemicals Management and the United Nations Environment Programme. The Commission and Member States also cooperate and exchange

[44] Safety Data Sheets are documents provided to downstream users which include information about the properties of substances or mixtures. See the review of the REACH Regulation (COM(2018)116).
[45] COM(2018) 179.
[46] COM(2018) 28 and COM(2018) 32 – following up from the Circular Economy Action Plan COM(2015) 614.
[47] COM(2017) 753.
[48] Beta-estradiol; nonylphenol; bisphenol A.
[49] COM(2018) 183.
[50] In particular the Commission's proposal for a Regulation on compliance with and enforcement of legislation (COM(2017) 795).
[51] A market surveillance exercise coordinated by the European Chemicals Agency's Enforcement Forum in 2018 (Forum REF-4 Project Report - Harmonised Enforcement Project on Restrictions, ECHA-18-R-03-EN) revealed that 19.7% of the inspected toys and 3.6% of the inspected childcare articles contained levels of phthalates not complying with the legislation (mainly coming from outside the European Economic Area or of unknown origin). In 2017, more than 170 notifications relating to non-compliant products as regards phthalates were exchanged between Member States via the Rapid Alert System for dangerous non-food products.
[52] As mentioned before, the criteria to identify endocrine disruptors under the legislation on pesticides and biocides are based on the definition of the World Health Organisation.

information with international partners under the auspices of the World Trade Organisation as regards EU regulatory developments which might affect trade[53]. In addition, on a bilateral basis, information exchanges have taken place with international partners, in particular the United States, Canada, Japan and recently also China. While having different approaches on how to deal with endocrine disruptors, all partners agree on the importance of addressing the matter as a priority[54]. Bilateral co-operation agreements with trade partners have also included setting up discussions on matters related to endocrine disruptors.

3. TAKING FORWARD THE EU'S POLICY ON ENDOCRINE DISRUPTORS

The Commission has always been and will remain committed to ensuring a high level of protection of EU citizens and the environment from endocrine disruptors and, at the same time, to preserve an internal market which delivers for consumers and where all EU business can thrive.

The implementation of the Community Strategy of 1999 has put the EU at the forefront in understanding and regulating these hazardous chemicals. But in order to further progress and maintain the expected high level of protection, it is important to ensure that the EU framework continues to coherently address endocrine disruptors across different areas.

The EU strategic approach on endocrine disruptors for the years to come should be based on the application of the precautionary principle and aim at:

- **minimising overall exposure** of humans and the environment to endocrine disruptors, paying particular attention to exposures during important periods of development of an organism, such as foetal development and puberty;
- **accelerating the development of a thorough research basis** for effective and forward-looking decision-making;
- and **promoting an active dialogue** allowing all stakeholders to be heard and to work together.

An approach that is coherent in regulating endocrine disruptors

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 endocrine disruptors, depending on the sector being regulated, and has raised questions as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent. Two points in particular deserve special attention:

Horizontal approach to the identification of endocrine disruptors: the Commission considers that there should be a coherent approach to the identification of endocrine disruptors across all relevant Union legislation, based on the broadly accepted definition of the World Health Organisation.

The recently established criteria for pesticides and biocides constitute a first step in that direction but EU legislation in other fields does not contain such criteria.

[53] This was for example the case when criteria were developed to identify endocrine disruptors under the legislation on pesticides and biocides.

[54] The U.S. Environmental Protection Agency operates the Endocrine Disruptor Screening Program. In Japan, the Ministry of Health, Labour and welfare established a Committee on Health Effects of Endocrine Disruptors.

It has been argued that horizontal criteria for the identification of endocrine disruptors should be laid down in the legislation, for reasons of legal certainty and to avoid the potential risk that a substance is identified as endocrine disruptor under one piece of legislation and not under another one. This matter should be further considered.

Regulatory consequences for endocrine disruptors: different regulatory approaches exist in different pieces of legislation for substances identified as endocrine disruptors.

For pesticides and biocides, the co-legislators adopted specific provisions "*underpinned by the precautionary principle*"[55] and based on a number of considerations. Taking for example into account the specific nature of the products in question, that endocrine disruptors are substances of particular concern, and that scientific uncertainty remains regarding their assessment (for example as regards the existence of a safe limit of exposure), they decided that once it is proven that a substance is an endocrine disruptor, the substance in principle cannot be authorised for use. There are very limited derogation possibilities.

Under REACH, endocrine disruptors are specifically mentioned as substances that can be identified as Substances of Very High Concern and, if prioritised, are subject to authorisation requirements. Restrictions can also apply to endocrine disruptors.

Other legislative instruments, such as for example the Regulation on cosmetics, although they do not mention endocrine disruptors specifically, consider them like other substances that can negatively affect human health.

Some stakeholders have argued that, in some areas, EU legislation does not provide adequate regulatory approaches to address endocrine disruptors effectively. This matter deserves further examination.

In line with the Commission's Better Regulation agenda and the commitment to ensure that EU laws remain fit for purpose, different evaluations have been carried out or are under way which are relevant, to different extents, for the topic of endocrine disruptors[56]. However, no single evaluation has so far covered all the different vertical and horizontal aspects of endocrine disruptors.

➔ The Commission will **launch a Fitness Check** to assess whether relevant EU legislation on endocrine disruptors delivers its overall objective to protect human health and the environment by minimising exposure to these substances.

The Fitness Check will for the first time 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. It will allow an analysis of how the different provisions/approaches on endocrine disruptors interact, identify any possible gaps, inconsistencies or synergies, and assess their collective impact in terms of costs and benefits for human health and the environment, the competitiveness of EU farmers and industry, and international trade. It will pay particular attention to those areas where legislation does not contain specific provisions for endocrine disruptors, such as toys, cosmetics and food contact materials.

[55] Article 1(4) of Regulation (EC) No 1107/2009 and Article 1(1) of Regulation (EU) No 528/2012.

[56] 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 materials and the evaluation of the legislation on toy safety.

Particular **attention will be paid to the consistency and intensity of actions** to protect vulnerable population groups that are particularly sensitive to endocrine disruptors, such as the foetus or adolescents. The Fitness Check will allow for a comprehensive consultation of EU citizens and stakeholders, including through a public consultation. Overall, it will help assess whether legislation is fit for purpose in line with Better Regulation requirements and feed into the reflection on whether legislative changes are necessary.

An approach based on the most up-to-date scientific evidence

EU decision-making is evidence-based. Continued support to research is therefore essential if the EU wants to further deepen understanding of endocrine disruptors and constitute a strong basis for effective policy-making.

➔ In its future framework programme for research and innovation, Horizon Europe[57], the Commission will continue to ensure the necessary **support to research on protecting citizens and environment from exposure to harmful chemicals, including endocrine disruptors**, building on the work under the current framework programme, Horizon 2020.

Particular attention should be paid to areas where knowledge gaps on endocrine disruptors still exist, as identified in Section 1, and where more scientific evidence can best support improved policies.

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

- research for the further development of hazard assessment, risk assessment and management of chemicals, including for cocktail effects, and for the collection, sharing and combination of required data;
- research on elimination of substances of concern in the production and end-of-life phases; support to the development of safe substitutes, and safe and cost-efficient production technologies;
- research on eco-innovation for prevention and remediation of environmental pollution from hazardous substances and chemicals of emerging concern; looking also at the interface between chemicals, products and waste.

An inclusive approach

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. The Commission stands ready to listen thorougly, dialogue cooperatively and communicate proactively.

This is also relevant for international cooperation with partners outside the EU, in order to keep abreast of research results, ensure efficient use of resources worldwide, guarantee regulatory consistency reducing barriers to trade and ensure continued global leadership of the EU.

[57] COM(2018) 435 and COM(2018) 436 – see in particular, in the second pillar on Global Challenges and Industrial Competitiveness, the "Health" cluster (with a proposed budget of €7.7 billion) and the "Non-nuclear direct actions of the Joint Research Centre" cluster (with a proposed budget of €2.2 billion).

➔ The Commission will organise a **Forum on endocrine disruptors** on an annual basis. The Forum will allow scientists and public and private stakeholders with expertise on endocrine disruptors to come together to exchange information and best practices, identify challenges and build synergies, in order to inform the Commission's reflections.

➔ The Commission will **step up its support to the work of relevant international organisations** and encourages Member States to do the same. Of particular importance is the need to provide the Organisation for Economic Co-operation and Development with the necessary support to progress in the development of internationally agreed test guidelines.

➔ The Commission will also explore possibilities for the inclusion of endocrine disruptors in the existing **international system for classification of chemicals**. This would bring a global solution to the identification of endocrine disruptors (similar to what already exists for other hazard classes such as mutagens, carcinogens, and substances toxic for reproduction).

➔ In order to provide EU citizens with clear and comprehensive information they can rely on, the Commission will launch **a one-stop shop web portal on endocrine disruptors**. The portal will consolidate and streamline all the information on endocrine disruptors currently present in different websites managed by the Commission and EU agencies. It will therefore constitute a single access point to information on endocrine disruptors, and will make it easier and more transparent for citizens and stakeholders to remain updated on the subject. In line with subsidiarity considerations, **the Commission** will **encourage Member States which deem it necessary to develop specific information and educational campaigns** on endocrine disruptors for the general public and vulnerable groups.

4. CONCLUSION

Almost twenty years after the Community Strategy for endocrine disruptors of 1999, endocrine disruption remains a global challenge and a source of concern for many EU citizens. While significant progress has been achieved over the past two decades to better understand and manage endocrine disruptors, it is important to step up the EU's efforts.

The Commission remains committed to protecting EU citizens and the environment from endocrine disruptors. To this end, the strategic approach outlined above aims to ensure a high level of protection of EU citizens and the environment and, at the same time, to preserve an internal market which delivers for consumers and where businesses can thrive.

In line with the Commission's Better Regulation agenda and the commitment to ensure that EU laws remain fit for purpose, the Commission is **launching a comprehensive screening of the existing legislative framework on endocrine disruptors**. This reflection exercise will allow an assessment of whether EU legislation on endocrine disruptors delivers on its overall objectives to protect human health and the environment. It will ensure citizens' involvement and stakeholders' participation, including through a public consultation, and will support the Commission in bringing the debate forward and deciding whether changes to the legislative framework are necessary.

In addition, the initiatives announced in this Communication will **support the continuous progress of relevant scientific research**, **foster inclusive dialogue** and cooperation with all interested parties and allow the **stepping up of the implementation of existing policies** on endocrine disruptors.

The Commission invites the Parliament and the Council to support the initiatives outlined in this Communication and bring their own contribution to the debate, and similarly invites input from the European Economic and Social Committee and the Committee of the Regions.