

Opinion of the European Economic and Social Committee on the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — Towards a comprehensive EU framework on endocrine disruptors

(COM(2018) 734 final)

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1. Conclusions and recommendations

1.1. The European Economic and Social Committee (EESC) welcomes the Commission communication on Endocrine Disruptors (EDs), which aims to better protect human and animal health. In particular, the EESC considers it necessary to carry out a complete fitness check on current legislation, including the social and economic impact, in order to establish the real state of play. A holistic approach is crucial to supporting a long-term strategy which makes it possible to deal with EDs in a coherent, consistent and scientific way. Nevertheless, the Committee considers that this strategy should be reinforced with a realistic action plan which sets targets and deadlines.

1.2. The Committee supports the proposal which aims to define a more coherent legislative framework. In this framework it will be important to respect the principle '*one substance, one toxicology*' and to base the new strategy on harmonised use of the *precautionary principle*, in line with the effective provisions already adopted on biocides and pesticides ⁽¹⁾. The new strategy could be included under the 'cross-sectoral umbrella' represented by REACH.

1.3. The mechanism of governance should be science-based, in order to ensure transparency for citizens and stakeholders. For this reason, public and independent research should be supported by an adequate budget. In particular, independent research could provide agreed scientific criteria and/or methods to address, support and stimulate European industrial R&I activity and production. The EESC recommends that this budget should not be lower than the current budget under Horizon 2020. In particular, the Committee recommends establishing a specific budget line for early identification of EDs and the risks for animal and human health, identification of safe alternative substances and environmental remediation.

1.4. Bans or restrictions on some substances or products, once they are plausibly identified as EDs, could have a relevant impact on enterprises and workplaces. For this reason, the EESC recommends that the Commission provide for a specific financial mechanism to support the transition towards more sustainable production, in order to improve industries' production techniques and mechanisms and update workers' skills.

1.5. The EESC supports the proposal for an Annual Stakeholder Meeting. Nevertheless, the Committee considers that the dialogue between stakeholders and the European Commission should include a permanent, structured system of information exchange and consultation, in order to be really effective.

⁽¹⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 167, 27.6.2012, p. 1); Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 309, 24.11.2009, p. 1).

1.6. The Committee asks that the broad awareness campaign on POPs which the Commission will be organising at EU level be developed with reference to a similar approach focused on EDs. The EESC also reiterates its recommendation to create an open data bank for POPs and EDs in order to provide a useful tool for enterprises and consumers.

1.7. The Committee firmly believes that the European strategy on EDs should have an international dimension in order to effectively protect citizens' health against potentially unsafe products from third countries. For this reason, the EESC endorses the Commission proposal for a more proactive EU role at global level, supporting the OECD in improving its tests. Moreover, the EESC believes that the EU should promote sustainability and the upholding of ED provisions in bilateral and multilateral trade agreements. In this context, the EU could work in cooperation with the WHO and UNEP to sign a global convention on EDs, as it has already done for POPs (Stockholm Convention), and based on the existing UN list of identified or potential EDs. These initiatives will also be useful to create a level playing field and protect the European production model from unfair competition.

1.8. The EESC supports the open strategy undertaken by the Commission and considers that organised civil society could play a crucial role in developing national awareness campaigns, in order to inform a wider population base about the activities taken by the EU to protect the health of citizens. Such initiatives should start in schools in order to reduce the risks of exposure to EDs and to promote safe behaviour. In particular, the EESC recommends that education and training initiatives be harmonised and considered part of the same strategy under a lifelong learning approach. Specific training courses should be compulsory and available for all European workers whose job is directly or indirectly related to EDs.

2. Introduction

2.1. **Endocrine disruptors (EDs)** are synthetic or natural chemical substances that alter the way in which the endocrine system works, and consequently they negatively affect the health of humans and animals, including metabolism, growth, sleep and mood. Exposure to EDs is due to a number of different sources, such as residues of pesticides, metals and additives or contaminants in food and cosmetics. Some EDs are substances naturally present in the environment. Humans and animals may be exposed to endocrine disruptors through food, dust or water, by inhaling gases and particles in the air, or simply through skin contact (personal care products). Sometimes, the effects caused by an endocrine-disrupting substance are only seen long after exposure ⁽²⁾. It should be noted that items with ED properties can include substances present in specific foodstuffs (e.g. vegetables), some vitamins and other food supplements, as well as key pharmaceuticals, (e.g. for the treatment of cancer, and especially female birth control): EU citizens may be exposed to large quantities of ED through such items.

2.2. Concerns about EDs have been growing since the 1990s. In December 1999, the Commission adopted the Community Strategy for endocrine disruptors ⁽³⁾, which has been developed since then by action in the fields of research, regulation and international cooperation. A broad study by the World Health Organisation (WHO) raised the problem of the wide impact of endocrine disruptors on a large number of humans and animals, in particular on foetuses and pregnant women (preterm birth and low birth weight, malformations and neurodevelopmental disorders), children and adolescents (alteration of normal development and functioning of reproductive system, such as earlier onset of breast development in young girls), but also on adults (loss of fertility, obesity, cancer) ⁽⁴⁾.

2.3. A large number of man-made and natural chemicals are known to interact with hormone synthesis, activity or metabolism, but only a small fraction of them have been properly investigated for their potential to induce adverse effects through endocrine-related mechanisms as outlined also by a recent UN Report. The speed with which the increases in disease incidence have occurred in recent decades rules out genetic factors as the sole plausible explanation. Environmental and other non-genetic factors, including nutrition, age of mother, viral diseases and chemical exposures, are also at play, but are not always easy to identify ⁽⁵⁾.

⁽²⁾ ECHA website. <https://chemicalsinourlife.echa.europa.eu/endocrine-disrupters-and-our-health> According to the widely recognised WHO definition (WHO-IPCS) of 2002, an endocrine disrupting chemical (EDC), 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'.

⁽³⁾ COM(1999) 706.

⁽⁴⁾ World Health Organisation, State of the Science of Endocrine Disrupting Chemicals, 2012, pages VII-XII.

⁽⁵⁾ <https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/scientific-knowledge-endocrine-disrupting>

2.4. Significant progress in understanding and regulating EDs has been made, and the EU is now recognised as a global leader in dealing with these chemicals, while its legislation is among the most protective in the world. Specific provisions are now included in legislation on pesticides and biocides, chemicals in general (the 'REACH Regulation'), medical devices and water ⁽⁶⁾. Other legislation, such as that on food contact materials, cosmetics, toys or protecting workers in the workplace ⁽⁷⁾, does not contain specific provisions on EDs. However, substances with endocrine disrupting properties are subject to case-by-case regulatory action on the basis of the general requirements of the legislation. Nevertheless, the lack of coordination has made the current legislation fragmented and sometimes incoherent (e.g. Bisphenol A is a raw material broadly used in several manufacturing sectors. It is prohibited in cosmetics and baby bottles but still permitted in other food and feed contact materials and in thermal paper.)

3. Gist of the proposal

3.1. Coming almost 20 years after the adoption of the Community Strategy, the communication notes that the Commission intends to carry out a *fitness check* on current legislation, in order to establish the state of play. This should be the first step towards updating EU legislation and making it coherent and coordinated with regard to three crucial aspects: definition, identification and regulatory consequences (in particular on protection measures).

3.2. A common definition of EDs is the starting point for the horizontal approach and it is a key element of the new path. It will be based on the WHO definition of endocrine disruptors ⁽⁸⁾. A common definition is necessary to establish a harmonised method for identifying EDs.

3.3. With regard to identification, the Commission is seeking to enhance three lines of action:

- a horizontal mechanism for identifying EDs,
- updating data requirements in legislation to identify new endocrine disruptors more accurately,
- improving communication throughout the supply chain with regard to endocrine disruptors under REACH (safety data sheets).

3.4. The third aspect consists of implementing the same measures and provisions in line with the *precautionary principle*, in order to protect the public from exposure to harm, when scientific investigation has found a plausible risk. This should entail banning the production of such substances with limited possibilities for derogations. For this reason, the *fitness check* will pay specific attention to the consistency and intensity of measures to protect all citizens, with a specific focus on vulnerable population groups that are particularly sensitive to EDs when the endocrine system is in a phase of change, such as foetuses, adolescents and pregnant women.

3.5. Research will be crucial in the future legislative framework, because there are still several knowledge gaps, such as:

- precisely how exposure to EDs contributes to the development of diseases,
- whether a 'safe threshold' can be established for EDs under which no adverse effect occurs,
- which mixture can produce a 'cocktail effect' and how 'mixtures' work in general,
- how we can make our testing methods more efficient.

3.6. Since 1999, over 50 projects on EDs have been funded under the EU framework programmes for research and development (over EUR 150 million in funding ⁽⁹⁾). A further EUR 52 million have been allocated under Horizon 2020. New projects will be financed under the Horizon Europe Programme ⁽¹⁰⁾. In particular, the Commission proposes the following lines of research:

⁽⁶⁾ Regulation (EC) No 1107/2009; Regulation (EU) No 528/2012; Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 1); Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 117, 5.5.2017, p. 1); Directive 2000/60/EC of the European Parliament and of the Council (OJ L 327, 22.12.2000, p. 1).

⁽⁷⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council (OJ L 338, 13.11.2004, p. 4); Regulation (EC) No 1223/2009 of the European Parliament and of the Council (OJ L 342, 22.12.2009, p. 59); Directive 2009/48/EC of the European Parliament and of the Council (OJ L 170, 30.6.2009, p. 1); Council Directive 98/24/EC (OJ L 131, 5.5.1998, p. 11); Directive 2004/37/EC of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 50).

⁽⁸⁾ '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'.

⁽⁹⁾ EC data.

⁽¹⁰⁾ COM(2018) 435 final and COM(2018) 436 final — see in particular, in the second pillar on Global Challenges and Industrial Competitiveness, the Health cluster (with a proposed budget of EUR 7,7 billion) and the Non-nuclear direct actions of the Joint Research Centre cluster (with a proposed budget of EUR 2,2 billion).

- further development of hazard assessment, risk assessment and management of chemicals, including as regards cocktail effects, and the collection, sharing and combination of required data,
- elimination of substances of concern in the production and end-of-life phases; support for the development of safe substitutes, and safe and cost-efficient production technologies,
- eco-innovation to prevent and remedy environmental pollution from hazardous substances and chemicals which are now deemed to be of concern, while also considering the interface between chemicals, products and waste.

3.7. In order to make the new strategy more effective, the Commission is envisaging a more proactive role for the EU at global level and an open dialogue with stakeholders and the general public. Such activities will be structured around four initiatives:

- a Forum on EDs will be organised on an annual basis. The Forum will enable scientists and public and private stakeholders to exchange information and best practices, identify challenges and build synergies, in order to support the Commission's work,
- enhanced support for the work of relevant international organisations, with a specific focus on providing the Organisation for Economic Cooperation and Development (OECD) with the necessary support to make progress in the development of internationally agreed test guidelines,
- exploring possibilities for the inclusion of EDs in the existing international system for classifying chemicals. This would provide a global solution for the identification of endocrine disruptors (similar to the system already in place for other hazard classes such as mutagens, carcinogens, and substances toxic for reproduction),
- a one-stop-shop web portal to inform individuals, enterprises and stakeholders about this topic. Since there are different levels of information and awareness in Europe, Member States will be encouraged to develop specific campaigns with a special focus on vulnerable groups.

4. General comments

4.1. The EESC welcomes the Commission communication on EDs. In particular, the Committee considers it necessary to carry out a complete *fitness check* on current legislation, including the social and economic impact, in order to establish the real state of play. A holistic approach is crucial to supporting a long-term strategy ⁽¹¹⁾ which makes it possible to deal with EDs in coherent, consistent and scientific way.

4.2. The Committee agrees with the Commission that endocrine disruptors are substances of particular concern. For this reason, the Committee supports the proposal to create a coherent legislative framework and harmonised use of the *precautionary principle*, in line with the effective provisions already adopted on biocides and pesticides ⁽¹²⁾.

4.3. In particular, the EESC considers that the coherence of the new legislative framework will be the main challenge for the EU, because several substances, such as 'bisphenol A', broadly used as additives in various sectors, are considered in a very different way. For this reason, it is important to respect the scientific principle '*one substance, one toxicology*' ⁽¹³⁾. This means that the criteria for identifying a substance as an ED must be consistent and coherent across all regulatory fields in the EU. Then, even if exceptions may be possible, the regulatory decisions should in general be coherent and coordinated. Last but not least, the new strategy could be included under the 'cross-sectoral umbrella' provided by REACH to ensure consistency.

⁽¹¹⁾ EESC opinion on 'Drinking water directive' (OJ C 367, 10.10.2018, p. 107); EESC opinion on *EU actions to improve environmental compliance and governance* (OJ C 283, 10.8.2018, p. 83); EESC opinion on *The current system guaranteeing food safety and security of the food supply in the EU and ways to improve it* (OJ C 268, 14.8.2015, p. 1); EESC opinion on *Toys' safety* (OJ C 77, 31.3.2009, p. 8); EESC opinion on 'Civil society's contribution to the development of a comprehensive food policy in the EU' (OJ C 129, 11.4.2018, p. 18).

⁽¹²⁾ Regulation (EU) No 528/2012; Regulation (EC) No 1107/2009; EESC opinion on 'Biocidal products' (OJ C 347, 18.12.2010, p. 62).

⁽¹³⁾ 'Scientific principles for the identification of endocrine-disrupting chemicals: a consensus statement', Solecki, 2017. <https://link.springer.com/article/10.1007/s00204-016-1866-9>

4.4. In the new context, the mechanism of governance should be science-based, in order to ensure transparency for citizens and stakeholders. For this reason, it is important to establish an adequate budget to support public and independent research. The EESC believes that *agreed scientific criteria and/or methods* based on independent research data could address, support and stimulate European industrial R&I activity and production.

4.5. The Committee considers that the ban or restrictions imposed on some substances or products, once plausibly identified as EDs, could have a relevant impact on the enterprises and workplaces. For this reason, the Commission should provide for a specific financial mechanism to support the transition towards more sustainable production, both for enterprises, in order to make their production techniques and mechanisms more innovative, and for workers, in order to update their skills ⁽¹⁴⁾.

4.6. Independent research is crucial to improve and complete our knowledge of EDs. The Committee notes that the Commission proposal does not specify the exact budget for research and innovation on EDs in the Horizon Europe Programme. The EESC recommends that this budget should not be lower than the current budget under Horizon 2020.

4.7. The EESC agrees with the Commission proposal on investments in research and innovation, but considers that some other fields will be crucial in the coming years and should therefore be financed:

- (a) early identification of EDs. According to the WHO, there are more than 800 substances that are potential EDs ⁽¹⁵⁾. Due to their broad use, it is important to invest in speeding up scientific individuation techniques and mechanisms for data analysis (in order to achieve better interpretation of the existing data);
- (b) identification of safe alternative substances and methods. The new pathway undertaken by the EC could drive the discovery of many new EDs. Some of these substances are particularly useful in many productive sectors, therefore it is important to invest in researching safe alternatives and safe production methods. The absence of data does not mean that a substance is safe, and for this reason it is important to increase scientific investigation. Efforts should be made to broaden the list of substances evaluated, not merely focusing on substances already widely tested;
- (c) environmental remediation. Once a new ED substance is plausibly identified, it is important to apply a specific procedure concerning risk assessment and management of such substances in the environment in order to plan, if needed (particularly due to its persistence), a specific strategy for *environmental remediation*.

4.8. The EESC supports the proposal for an Annual Stakeholder Meeting. Nevertheless, the Committee considers that the dialogue between stakeholders and the European Commission should include a permanent, structured system of information exchange and consultation, in order to be really effective. The EESC would like to participate in and contribute to the annual meeting.

4.9. EDs and Persistent Organic Pollutants (POPs) are different substances and have different effects on human beings and the environment, but they are equally dangerous to health and unknown to citizens. Because the EU strategy on POPs bears several similarities to the Commission communication on EDs, the Committee proposes to develop these strategies with a similar approach in order to enhance political and scientific process. In particular, in line with the EESC NAT/719 opinion on Recast of POPs, the Committee asks that particular attention be paid to EDs in the broad awareness campaign on POPs, to be organised by the Commission at EU level. The EESC also reiterates its recommendation to create an open data bank on POPs and EDs in order to provide a useful tool for enterprises and consumers.

5. Specific comments

5.1. The EESC sees the Commission communication as an important step towards better protection of citizens' health by defining a more sustainable manufacturing system. Nevertheless, the Committee considers that this strategy should be reinforced with a realistic action plan, which sets targets and deadlines.

⁽¹⁴⁾ EESC opinion on *Protection of workers from the risks related to exposure to carcinogens or mutagens at work* (OJ C 288, 31.8.2017, p. 56); EESC opinion on the *Recast of Persistent Organic Pollutants (POPs)* (OJ C 367, 10.10.2018, p. 93).

⁽¹⁵⁾ According to TEDX (the Endocrine Data Exchange) that list includes more than 1 000 substances.

5.2. A well-designed circular economy, with a specific focus on secondary raw materials ⁽¹⁶⁾, could become a vehicle for minimising the exposure of EU citizens to endocrine disruptors. The Committee considers that the Commission proposal needs to be clearly and strictly linked to the current legislation developed under the 7th Environment Action Plan ⁽¹⁷⁾ and the other crucial policy initiatives for sustainability, such as the Circular Economy Action Plan and the Plastic Strategy seeking to exclude the production of toxic products. This issue is very sensitive, particularly concerning cocktail effects which are a cause of disease in human beings and harmful for the environment.

5.3. The EESC encourages the Commission to define more accurately the proposal to organise a public consultation on EDs. The Committee is convinced that more than individual people, organised civil society itself could play an important role, chiefly because specific knowledge and experience are necessary to give useful, reliable and science-based advice ⁽¹⁸⁾.

5.4. The Committee firmly believes that any European strategy on EDs should have an international dimension and be developed at international level in order to effectively protect citizens' health against potentially unsafe products from third countries. For this reason, the EESC endorses the Commission proposal for a more proactive EU role at global level, supporting the OECD in improving its tests. Moreover, the EESC believes that the EU should promote sustainability and the upholding of ED provisions in bilateral and multilateral trade agreements. In this sense, the EU could work in cooperation with the WHO and UNEP to sign a global convention on EDs, as it has already done for POPs (Stockholm Convention), based on the existing UN list of identified or potential EDs ⁽¹⁹⁾. These initiatives will also be useful to create a level playing field and protect European production model against unfair competition ⁽²⁰⁾.

5.5. The EESC supports the *open strategy* undertaken by the Commission and considers that organised civil society could play a crucial role in developing national awareness campaigns in order to inform a wider population base about the activities taken by the EU to protect the health of citizens. An effective awareness campaign should start in schools in order to reduce the risks of exposure to EDs and to promote safe behaviour ⁽²¹⁾. In particular, the EESC recommends that education and training initiatives be harmonised and considered part of the same strategy under a lifelong learning approach. Furthermore, the Committee considers that specific training courses should be compulsory and available for all European workers whose job is directly or indirectly related to EDs ⁽²²⁾.

Brussels, 21 March 2019.

The President
of the European Economic and Social Committee
Luca JAHIER

⁽¹⁶⁾ EESC opinion on an *Interface between Chemicals, Products and Waste legislation* (OJ C 283, 10.8.2018, p. 56).

EESC opinion on a *Strategy on Plastic in a Circular Economy (including action on marine litter)* (OJ C 283, 10.8.2018, p. 61).

⁽¹⁷⁾ Decision No 1386/2013/EU of the European Parliament and of the Council (OJ L 354, 28.12.2013, p. 171).

⁽¹⁸⁾ EESC opinion on 'Recast of Persistent Organic Pollutants (POPs)' (OJ C 367, 10.10.2018, p. 93).

⁽¹⁹⁾ In August 2018, the UN published a list of 45 chemicals, or groups of chemicals, that have been identified as EDs or potential EDs following a thorough scientific assessment based on the WHO/IPCS 2002 definitions of EDs and potential EDs. Unfortunately, the absence of an international convention on EDs does not make it possible to establish an agreed international procedure to protect human and animal health from exposure to such substances. <https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/scientific-knowledge-endocrine-disrupting>

⁽²⁰⁾ EESC opinion on 'Transition towards a more sustainable European future' (OJ C 81, 2.3.2018, p. 44).

⁽²¹⁾ E.g. Decalog for citizens on EDs. <http://old.iss.it/inte/index.php?lang=2&id=289&tipo=29>

⁽²²⁾ EESC opinion on the *Recast of Persistent Organic Pollutants (POPs)* (OJ C 367, 10.10.2018, p. 93).