



**European Committee
of the Regions**

NAT-VI/040

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OPINION

Towards a comprehensive EU framework on endocrine disruptors

THE EUROPEAN COMMITTEE OF THE REGIONS

- calls on the Commission not to further delay the development and adoption of the new strategy on endocrine disruptors and demands that it be accompanied by a detailed timetable to make progress in reducing exposure;
- calls on the Commission to address as soon as possible existing differences across the EU laws and to harmonise the way in which endocrine disrupting chemicals are treated, namely with a presumption that no safe threshold for exposure can be set with sufficient certainty;
- calls on the Member States and the Commission to give priority to citizens' health outcomes while also taking into account the interests of consumers and the industry and to significantly increase funding for independent, public research into endocrine disruption and into safe substitutes and other innovative solutions;
- calls for a ban on bisphenols and phthalates in all food contact materials;
- highlights the initiatives such "EDC-Free cities and territories", "non-hazardous cities", "pesticides-free cities", adopted by local and regional authorities to reduce the exposure of their inhabitants to endocrine disrupting chemicals, in particular for the most vulnerable groups, children and pregnant women.

Rapporteur

Uno Silberg (EA/EE), Chairman of Kose Municipal Council

Reference document

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 European Union framework on endocrine disruptors – COM(2018) 734 final

Opinion of the European Committee of the Regions – Towards a comprehensive EU framework on endocrine disruptors

I. POLICY RECOMMENDATIONS

THE EUROPEAN COMMITTEE OF THE REGIONS

General comments

1. considers it important that the Commission has launched a comprehensive review of the existing EU legislative framework on endocrine disruptors, and agrees that it is necessary to update the EU's approach to dealing with endocrine disruptors based on the increase in knowledge, findings and experience, so that it can continue to keep pace with the latest technology and enables consistent treatment of these substances across the various fields;
2. is concerned to note that there has been increasingly compelling scientific evidence since 1999 on the link between exposure to endocrine disruptors and disorders in humans or adverse effects on flora and fauna;
3. is concerned about the superficial nature of the information on endocrine disruptors that has so far been addressed to the public, as the terms "endocrine function" and "endocrine disruptors" are likely to be unfamiliar to many people;
4. supports the Commission's initiatives to provide a high level of protection for EU citizens and the environment while at the same time adapting the single market to take account of new circumstances and benefit consumers;
5. draws attention to the conflict that could arise between a high level of protection for people and the environment and profit-driven businesses; this must be addressed by taking into account beforehand the consequences of the measures and the risks to business;
6. calls on the Commission not to further delay the development and adoption of the new strategy on endocrine disruptors;
7. demands that the new strategy be accompanied by a detailed timetable to implement appropriate criteria for endocrine disruptors in all relevant EU laws and make progress in reducing exposure to these chemicals, in particular for the most vulnerable groups;
8. calls on the Commission to address as soon as possible existing differences across the EU laws and to harmonise the way in which endocrine disrupting chemicals are treated, namely with a presumption that no safe threshold for exposure can be set with sufficient certainty;
9. calls on the Member States and the Commission give priority to citizens' health outcomes while also taking into account the interests of consumers and the industry and to significantly increase funding for independent, public research into endocrine disruption and into safe substitutes and other innovative solutions;

10. believes that Europe has a leading role in terms of international collaboration on testing, screening and identification of endocrine disrupting chemicals (EDCs); is in favour of improved data collection and sharing and supports the idea of international classification of EDCs;

Research into endocrine disruptors

11. is convinced that public authorities at all levels of governance should contribute to financing research on EDCs, filling the knowledge gaps and providing much needed evidence;
12. stresses the need for information on how and to what extent people and other living organisms are exposed to endocrine disruptors, how these substances are spread, and what impact they have on human health and flora and fauna;
13. very much supports the proposal laid out in the communication to finance through Horizon Europe research activities focusing on the cocktail effect, hazard and risk assessment; on elimination of substances of concern in the production and end-of-life phases; on eco-innovation and remediation of environmental pollution and on interference between chemicals, products and waste;
14. calls on the European Food Safety Agency (EFSA) and the European Chemicals Agency (ECHA) to cooperate and coordinate their work more closely in an effort to make effective use of the resources available to carry out comprehensive assessments;
15. draws attention to the report "The Cost of Inaction"¹ commissioned by the Nordic Council of Ministers that estimates the (undiscounted) costs linked to the effects of endocrine disrupting substances on male reproductive health in the EU-28 at EUR 1 267 million per year;
16. highlights the findings of another study² linking endocrine disrupting chemicals with IQ loss and associated intellectual disability; autism; attention deficit/hyperactivity disorder; endometriosis; uterine fibroids; childhood obesity; adult obesity; adult diabetes; cryptorchidism; male infertility, and increased mortality associated with reduced testosterone. This study estimates that the annual cost for Europe will reach EUR 163 billion (equivalent to 1.28% of EU GDP);
17. has doubts about the definition set out in 2002 under the International Programme on Chemical Safety – a joint programme of various UN Agencies, including the World Health Organization – according to which "an endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations". Based on current evidence, this definition is too narrow and does not take sufficient account of the impact on flora and fauna;
18. proposes that consideration be given to the following definition of endocrine disruptors based on the current state of knowledge: "Endocrine disruptors are exogenous chemicals or mixtures

1 <https://www.norden.org/en/publication/cost-inaction>.

2 <https://www.ncbi.nlm.nih.gov/pubmed/27003928>.

of chemical substances that alter the functioning of hormones and the endocrine system, and negatively affect physiological and developmental processes, including the health of humans and animals or their offspring";

19. stresses that it is not enough to investigate just the link between endocrine disruptors and disorders in humans; the matter must be handled specifically from the angle of human health, flora, fauna and the environment and the need to avoid possible consequences – both social and economic – for society more broadly;
20. stresses that, while it is agreed that the most critical window of exposure to endocrine disruptors are key development stages, such as the development of the foetus and puberty, it is nevertheless worrying that such exposure in these periods can have lasting effects and lead to increased susceptibility to disorders in later life;
21. recommends deepening our knowledge of the causes underlying the development of medical conditions, for example the increase in children born with autism or the rising incidence of testicular cancer, and publicising this information;
22. stresses equally that current science does not provide a sufficient basis for setting a limit value below which adverse effects do not occur. Endocrine disruptors should therefore be regarded as "non-threshold" substances, which means that any exposure to such substances may entail a risk, especially during critical windows of development (prenatal, postnatal and puberty), and that the effects of mixtures should be taken into particular account;
23. is concerned that research has so far concentrated in essence on a limited number of endocrine modes of action: in recent years, however, it has been demonstrated that there are other areas of the endocrine system that could be susceptible to endocrine disruptors and that together these disruptors have an additive ("combining" or "cocktail") effect, so that exposure to a combination of endocrine disruptors at sufficient concentrations can provoke an adverse effect not established for such disruptors individually;
24. sees a need for further research, financed notably under the Horizon 2020 programme, that could clarify the effects of exposure to endocrine disruptors in relation to the aetiopathogenesis and development of disorders, including in the case of flora and fauna;
25. sees a need for research leading to the design, development and validation of test methods and for the development of predictive models;
26. supports the fact that, under the auspices of the Organisation for Economic Cooperation and Development (OECD), a concentrated effort is being made to make test guidelines for the identification of endocrine disruptors more available and to eradicate at EU and international level the shortfalls identified in the test methods;
27. calls on the Commission to support targeted research projects, including the development of new testing and analysis methods, on substances likely to affect the endocrine system and to emphasise the adverse effects at low concentrations or through combined exposure;

28. calls on the Commission to develop *in vitro* and *in silico* methods in order to minimise animal testing for endocrine disruptor screening;
29. is pleased to learn about research funded and committed to date and hopes to see a significantly larger envelope earmarked for future funding for research on endocrine disrupting chemicals;

Current EU policy and regulation of endocrine disruptors

30. welcomes the Commission's various initiatives and proposals regarding the management of endocrine disruptors, including the proposal for a regulation on the transparency and sustainability of the EU risk assessment model, the European strategy for plastics, the Drinking Water Directive, the New Deal for Consumers, the Goods Package and the updating of the existing legal framework in the area of health and safety at work;
31. notes, however, that in 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 "Living well, within the limits of our planet" the Commission committed itself to have undertaken – by 2015 – horizontal measures on "minimisation of exposure to endocrine disruptors" and to have a full EU strategy ready by 2018; in this respect, the CoR expresses its regret that the current document falls short of the promise made in 2013;
32. points out that "Better Regulation" principles should not delay any measure aimed at averting or reducing potentially serious or irreversible consequences for human health and/or the environment, as compelled by the precautionary principle enshrined in the EU Treaties;
33. reiterates that the European Union has committed itself to act on hazardous substances internationally and points to the WHO Europe Parma and Ostrava declarations;
34. applauds the direction taken by France, Sweden, Denmark and Belgium to increase the level of protection for their citizens through comprehensive sets of national measures restricting use of EDCs; calls on the Commission to draw inspiration from these leading Member States and deliver the highest possible level of protection to all Europeans;
35. considers that all legislation needs to focus more on upstream activities, in other words that stricter requirements need to be imposed on chemicals manufacturers, the pharmaceuticals industry, etc. It is not cost-effective to focus on additional purification steps in drinking water plants and sewage works;
36. is concerned that – unlike in the case of e.g. tobacco – it is not possible to avoid endocrine disrupting chemicals entirely as they are found everywhere and contaminate European citizens' bodies without their knowledge and consent;
37. urges the Commission and the Member States to provide Europeans with reliable information – presented in an appropriate form and in a language that they can understand – about the dangers of endocrine disruptors, their effects, and possible ways of reducing exposure;

38. calls for a ban on bisphenols and phthalates in all food contact materials;
39. points out that Bisphenol A (BPA) is often replaced with Bisphenol S (BPS), Bisphenol F (BPF) and Bisphenol HPF (BHPF), which are less studied but appear to have similar hormone-disrupting effects; is therefore of the opinion that co-legislators should regulate groups of related chemicals, rather than taking a substance by substance approach. In the absence of good data to the contrary, chemicals with a similar structure should be assumed to have toxicological properties as harmful as those of the most toxic known substance in the group;
40. observes that an approach based on, and strict adherence to, the precautionary principle is also in the interests of the (chemical) industry, contributes to investment in research into and development of innovative, environmentally friendly products and safe, sustainable alternatives, and thus has a positive impact on the development of the single market and the wider economy;
41. proposes that the EU's legal framework and safeguards related to endocrine disruptors, which have a direct effect on human health, be updated so that, for example, legislation and guidelines on cosmetics also cover the protection of pregnant women;
42. suggests identifying high-risk areas and territories, such as agricultural land and grassland fertilised with sewage sludge, areas around landfills and incinerators and, more broadly, regions such as the Baltic, the Mediterranean and the Danube Region;

Promoting EU policy on endocrine disruptors – the impact of the planned measures at local and regional level

43. welcomes the Commission's introduction of a fitness test to gauge whether the existing EU legislation on endocrine disruptors achieves the overall objective of protecting human health and the environment by minimising exposure to these substances;
44. welcomes an understanding of endocrine disruptors based on the latest scientific evidence available and the framing of policy on this basis;
45. considers it essential for the public to be given as much information as possible about endocrine disruptors, their spread, and the dangers they pose;
46. considers it important for the Commission to make every effort to identify toxic chemicals, including endocrine disruptors, in products, and to establish and implement appropriate informative product labelling etc.;
47. takes the view that, although local and regional authorities usually lack the powers to adopt legislation on endocrine disruptors (in most EU Member States it is the regional level that is responsible for health services), they are nonetheless obliged to attend to the well-being of their populations;

48. considers it therefore both crucial and ethically and economically important for the local and regional level to take a stance on endocrine disruptors, given that they are known to affect the health of present and future generations;
49. is in no doubt that local and regional authorities are prepared to protect future generations and will not be thwarted by increasing pressure from a powerful industry and some of the EU's trading partners;
50. In the absence of adequate and comprehensive national and European legislation on endocrine disruptors, highlights the initiatives such "EDC-Free cities and territories", "non-hazardous cities", "pesticides-free cities", adopted by local and regional authorities to reduce the exposure of their inhabitants to endocrine disrupting chemicals, in particular for the most vulnerable groups, children and pregnant women;
51. considers it essential that EU policy on endocrine disruptors is taken forward and the impact of the planned measures at local and regional level analysed;
52. points out that the use of certain phthalates is currently necessary in healthcare, to make medical devices sufficiently soft. It is important to push forward with the development of new products with the same properties before reducing phthalate content. While these substances remain in use, it is also important to ensure that the devices are properly disposed of after use, by means of effective collection systems and destruction;
53. is convinced that prioritising human health indicators over the interests of industry and the single market will entail new challenges for the development and use of sustainable technologies for health and the environment and would probably improve the competitiveness of companies by pushing them to innovate and invest in smarter long-term solutions. It must, however, be based on sound science and matched by an analysis of socio-economic consequences.

Brussels, 26 June 2019

The President
of the European Committee of the Regions

Karl-Heinz Lambertz

The Secretary-General
of the European Committee of the Regions

Jiří Buriánek

II. PROCEDURE

Title	Towards a comprehensive EU framework on endocrine disruptors
Reference(s)	
Legal basis	Article 307 TFEU
Procedural basis	Rule 41 b) i) of the Rules of Procedure
Date of Council/EP referral/Date of Commission letter	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 European Union framework on endocrine disruptors – COM(2018) 734 final
Date of Bureau/President's decision	29/11/2018
Commission responsible	Commission for Natural Resources
Rapporteur	Uno SILBERG (EA/EE)
Analysis	21/12/2018
Discussed in commission	29/01/2019
Date adopted by commission	28 and 29/03/2019
Result of the vote in commission (majority, unanimity)	unanimous
Date adopted in plenary	26/06/2019
Previous Committee opinions	N/A
Date of subsidiarity monitoring consultation	No subsidiarity or proportionality issues – own initiative opinion