European Parliament
2014-2019

TEXTS ADOPTED
Provisional edition

P8_TA-PROV(2019)0441

A comprehensive European Union framework on endocrine disruptors

European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors (2019/2683(RSP))

The European Parliament,

– having regard to the Commission communication of 7 November 2018 (COM(2018)0734) entitled 'Towards a comprehensive European Union framework on endocrine disruptors' (hereinafter 'the Communication'),

– having regard to the Treaty on the Functioning of the European Union (TFEU) and, in particular, Article 191(2) thereof,

– having regard to 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 and repealing Council Directives 79/117/EEC and 91/414/EEC[1],

– having regard to Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties[2],

– having regard to 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[3],

– having regard to Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council[4],

– having regard to 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

1 OJ L 309, 24.11.2009, p. 1.
2 OJ L 101, 20.4.2018, p. 33.
3 OJ L 167, 27.6.2012, p. 1.
4 OJ L 301, 17.11.2017, p. 1.

food and repealing Directives 80/590/EEC and 89/109/EEC[1],

– having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[2],

– having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[3],

– having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (hereinafter 'the CLP Regulation')[4],

– having regard to 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' (hereinafter 'the 7th EAP'), and in particular Point 54 (iv) thereof[5],

– having regard to the Sustainable Development Goals, in particular target 3.9[6];

– having regard to the report by the UN Environment Programme (UNEP) and the World Health Organisation entitled 'State of the science of endocrine disrupting chemicals – 2012'[7],

– having regard to its resolution of 14 March 2013 on the protection of public health from endocrine disruptors[8],

– having regard to the study of 15 January 2019 entitled 'Endocrine Disruptors: from Scientific Evidence to Human Health Protection', commissioned by Parliament's Policy Department for Citizen's Rights and Constitutional Affairs'[9],

– having regard to Rule 123(2) of its Rules of Procedure,

A. whereas the UNEP/WHO report of 2012 called endocrine disruptors ('EDCs') 'a global threat', and refers *inter alia* to the high incidence and the increasing trends of many endocrine-related disorders in humans, as well as noting that endocrine-related effects have been observed in wildlife populations;

---

1 OJ L 338, 13.11.2004, p. 4.
2 OJ L 342, 22.12.2009, p. 59.
3 OJ L 170, 30.6.2009, p. 1.
4 OJ L 353, 31.12.2008, p. 1.
5 OJ L 354, 28.12.2013, p. 171.
6 https://unstats.un.org/sdgs/METADATA?Text=&Goal=3&Target=3.9
7 WHO/UNEP, 'State of the Science of Endocrine Disrupting Chemicals – 2012', World Health Organisation, 2013, http://www.who.int/ceh/publications/endocrine/en/
8 OJ C 36, 29.1.2016, p. 85.
9 Study – 'Endocrine Disruptors: from Scientific Evidence to Human Health Protection', European Parliament, Directorate-General for Internal Policies, Policy Department for Citizens' Rights and Constitutional Affairs, 15 January 2019, available at: http://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU(2019)608866_EN.pdf

B. whereas according to the report, there is emerging evidence of adverse reproductive outcomes (infertility, cancers, malformations) from exposure to EDCs, and there is also mounting evidence of the effects of these chemicals on thyroid function, brain function, obesity and metabolism, and insulin and glucose homeostasis;

C. whereas the fact that this class of chemicals induces adverse effects on human health and wildlife by interfering with the hormonal system is no longer disputed; whereas, therefore, there is no valid reason to postpone effective regulation;

D. whereas the most recent study by the Institute for Risk Assessment Sciences, entitled 'Health costs that may be associated with Endocrine Disrupting Chemicals', found, when assessing five potentially EDC-related health effects, that 'according to currently available literature, the socio-economic burden of EDC associated health effects for the EU may be substantial', with estimates ranging from EUR 46 billion to EUR 288 billion per year[1];

E. whereas the UNEP/WHO report states: 'Close to 800 chemicals are known or suspected to be capable of interfering with hormone receptors, hormone synthesis or hormone conversion. However, only a small fraction of these chemicals have been investigated in tests capable of identifying overt endocrine effects in intact organisms';

F. whereas the Communication states in the context of the proposed Union Framework that 'since 1999, the scientific evidence linking exposure to endocrine disruptors with human disease or negative impact on wildlife has become stronger';

G. whereas according to the 7th EAP, 'in order to safeguard the Union's citizens from environment-related pressures and risk to health and well-being, the 7th EAP shall ensure that by 2020 safety concerns related to endocrine disruptors are effectively addressed in all relevant Union legislation';

H. whereas according to the 7th EAP, this requires in particular 'developing by 2018 (…) building on horizontal measures to be undertaken by 2015 to ensure (…) the minimisation of exposure to endocrine disruptors';

I. whereas to date the Commission has not adopted a Union strategy for a non-toxic environment, nor did it take horizontal measures by 2015 to ensure the minimisation of exposure to EDCs;

J. whereas the revision of the 1999 Community strategy for EDCs is long overdue;

K. whereas in the absence of a revised Union strategy for EDCs, Member States such as France, Sweden, Denmark and Belgium have taken steps at national level with a view to increasing the level of protection for their citizens through a variety of national measures;

---

[1] Rijk, I., van Duursen, M. and van den Berg, M, *Health cost that may be associated with Endocrine Disrupting Chemicals – An inventory, evaluation and way forward to assess the potential health impact of EDC-associated health effects in the EU*, Institute for Risk Assessment Sciences, University of Utrecht, 2016, available at: https://www.uu.nl/sites/default/files/rijk_et_al_2016_-_report_iras_-_health_cost_associated_with_edcs_3.pdf

L. whereas it is in the interests of all to ensure that an effective and comprehensive European approach to EDCs is put in place in order to guarantee a high level of protection of human health and the environment;

M. whereas a robust Union framework on EDCs and its effective implementation are crucial for the EU to contribute to fulfilling its commitment to target 3.9 of the Sustainable Development Goals, namely to 'substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water, and soil pollution and contamination';

N. whereas a robust Union framework on EDCs is also required to lay the foundations for a non-toxic circular economy, encouraging industrial innovation through safer substitution;

O. whereas it is welcome that the Communication recognises the adverse effects of EDCs on human health and the environment, including mixture effects, highlights the objective of minimising overall exposure and recognises the need to have a horizontal approach for the identification of EDCs;

P. whereas, however, the Communication lacks both a concrete action plan to minimise exposure to EDCs and a timeline for the next steps to move forward;

Q. whereas key Union legislation in sensitive areas still lacks specific provisions on EDCs (e.g. for cosmetics, toys, or food contact materials);

R. whereas the Commission has announced a Fitness Check to assess whether the relevant EU legislation on EDCs delivers its overall objective of protecting human health and the environment by minimising exposure to these substances; whereas the cross-cutting nature of the Fitness Check, as well as the Commission's commitment that particular attention will be paid to the protection of vulnerable groups, are to be welcomed; whereas, however, this assessment should have been conducted years ago and it is regrettable that the Commission has only now decided to proceed with such a Fitness Check; whereas, therefore, the Fitness Check should not provide a justification for prolonging the delivery of concrete legislative and other actions;

S. whereas the scientific criteria developed for the determination of EDCs in pesticides and biocides lack a category of 'suspected EDCs' and are therefore not fit for horizontal application; whereas this is not consistent with the classification of substances that are carcinogenic, mutagenic or toxic for reproduction (CMRs) under the CLP Regulation and the 7th EAP; whereas the ability to identify suspected EDCs is extremely important, all the more so because both the Cosmetics Regulation and the Toy Safety Directive not only restrict known and presumed CMRs (categories 1A and 1B), but also suspected CMRs (category 2);

T. whereas there is a lack of adequate tests and data requirements to identify EDCs in the relevant Union legislation;

U. whereas the Communication points to increasing evidence concerning mixture effects for EDCs (i.e. exposure to a combination of EDCs may produce an adverse effect at concentrations at which, individually, no effect has been observed), yet it does not make any proposals to address this issue;

V. whereas the project 'EDC-MixRisk' under Horizon 2020 concluded that 'current regulations of man-made chemicals systematically underestimate health risks associated with combined exposures to EDCs or potential EDCs'[1];

W. whereas the failures in the implementation of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (high percentage of non-compliant registration dossiers, slow evaluations due to missing data and failure to take regulatory action on substances found following evaluation to pose a serious risk to human health or the environment) also lead to a failure to minimise exposure to known or suspected endocrine disruptors;

1. Considers that the Union framework for EDCs as suggested by the Commission in the Communication is not adequate to address the threat to human health and the environment due to exposure to EDCs, and that it does not deliver what is required pursuant to the 7th EAP;

2. Considers that EDCs are a class of chemicals that is of equivalent concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR substances), and should therefore be treated identically in Union legislation;

3. Calls on the Commission to swiftly take all necessary action to ensure a high level of protection of human health and the environment against EDCs by effectively minimising overall exposure of humans and the environment to EDCs;

4. Calls on the Commission to develop a horizontal definition based on the WHO definition for suspected EDCs as well as for known and presumed EDCs in line with the classification of CMRs in the CLP Regulation, no later than June 2020;

5. Calls on the Commission to ensure that the horizontal definition is accompanied by proper guidance documents;

6. Calls on the Commission to make legislative proposals no later than June 2020 to insert specific provisions on EDCs into Regulation (EC) No 1223/2009, similar to those on CMR substances;

7. Calls on the Commission to draw up legislative proposals no later than June 2020 to insert specific provisions on EDCs into Directive 2009/48/EC, similar to those on CMR substances but without any reference to thresholds of classification, as such thresholds are not applicable for EDCs;

8. Calls on the Commission to revise Regulation (EC) No 1935/2004 no later than June 2020 in order to effectively reduce the content of hazardous substances therein, with specific provisions to substitute the use of EDCs;

9. Considers that there is an urgent need to accelerate test development and validation in order to properly identify EDCs, including new approach methodologies;

10. Calls on the Commission to ensure that data requirements are continuously updated in all the relevant legislation in order to take account of the latest technical and scientific

---

[1] https://edcmixrisk.ki.se/wp-content/uploads/sites/34/2019/03/Policy-Brief-EDC-MixRisk-PRINTED-190322.pdf

progress, so that EDCs can be properly identified;

11. Calls on the Commission to take mixture effects and combined exposures into account in all relevant EU legislation;

12. Calls on the European Chemicals Agency, the Commission and the Member States to take all necessary measures to ensure the compliance of registration dossiers with the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation by the end of 2019, to accelerate substance evaluation and to implement effectively the final conclusions of substance evaluations under REACH as an important means of minimising exposure to endocrine disruptors;

13. Calls on the Commission to ensure adequate bio-monitoring of EDCs in human and animal populations, as well as the monitoring of EDCs in the environment, including in drinking water;

14. Calls on the Commission to ensure that the Union framework on EDCs becomes an effective contribution to the Union strategy for a non-toxic environment, to be adopted as soon as possible;

15. Calls on the Commission to promote research into EDCs, in particular with regard to their epigenetic and transgenerational effects, their effects on the microbiome, novel EDC modalities and characterisation of dose-response functions, as well as safer alternatives;

16. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.