REPORT

on the protection of public health from endocrine disrupters
(2012/2066(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Åsa Westlund
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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on the protection of public health from endocrine disrupters

(2012/2066(INI))

The European Parliament,


– having regard to Regulation (EU) No 528/2012⁴ of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products,


– having regard to the Commission proposal for a directive of the European Parliament and of

¹ OJ L 36, 5.2.2009, p. 84.
the Council amending Directives 2000/60/EC and 2008/105/EC as regard priority substances in the field of water policy,

– having regard to the OECD conceptual framework for testing and assessment of endocrine disrupters,

– having regard to the draft guidance document on standardised test guidelines for evaluating chemicals for endocrine disruptions (2011).

– having regard to the draft detailed review paper entitled ‘State of the sciences on novel in vitro and in vivo screening and testing methods and endpoints for evaluating endocrine disruptors’,

– having regard to the upcoming Commission proposal on a ‘Blueprint to safeguard Europe’s water resources’,


– having regard to the Commission Staff working paper ‘4th Report on the implementation of the “Community Strategy for Endocrine Disrupters” – a range of substances suspected of interfering with the hormone systems of humans and wildlife’ (COM (1999)0706), (SEC(2011)1001),

– Having regard to the European Environment and Health Strategy and the EU Action Plan on Environment and Health (2004-2010), which, inter alia, recognise a need to take into account combined exposure of chemicals in risk assessments,

– having regard to the Commission’s communication to the Council on the precautionary principle (COM(2000)0001),


– having regard to its report of 20 October 1998 on endocrine-disrupting chemicals¹,

– having regard to its report of 6 May 2010 on the Commission communication entitled ‘Action against cancer: European partnership’²,

– having regard to its report of 20 April 2012 on the review of the 6th Environment Action Programme and the setting of priorities for the 7th Environment Action Programme – A better environment for a better life³,

– having regard to the ‘Study on the scientific evaluation of 12 substances in the context of

the endocrine disrupter priority list of actions’,
– having regard to the Study of DHI Water and Environment on enhancing the endocrine disrupter priority list with a focus on low-production-volume chemicals,
– having regard to the definition for endocrine disrupting chemicals developed by the World Health Organisation (WHO) and the International Programme on Chemical Safety (IPCS)\(^1\);
– having regard to Rule 48 of its Rules of Procedure,
– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0027/2013),

A. whereas hormone-related disorders and illnesses in humans have increased over the last 20 years, including impaired sperm quality, early onset of puberty, increased incidence of deformed sexual organs, increased incidence of certain forms of cancer, and metabolic diseases; whereas certain neurological disorders and neurodegenerative diseases, impacts on neurodevelopmental functions, the immune system or epigenetics, might be linked to exposure to chemical substances with endocrine-disrupting properties; whereas further research is needed to obtain a better understanding of the causes of such diseases;

B. whereas chemical substances acting as endocrine disrupters can have oestrogenic or anti-oestrogenic effects which interfere with the function of the female reproductive system, altering hormone concentrations and menstrual cycles of women, as well as their fertility, favouring the development of uterine diseases, such as fibroids and endometriosis, and affecting breast growth and lactation; whereas such substances have been identified as risk factors responsible for premature puberty in girls, breast cancer, miscarriage and impaired fertility or infertility;

C. whereas an increasing number of scientific studies have suggested that endocrine disrupting chemicals, particularly in combination, play a role in both chronic diseases, including hormone related cancers, obesity, diabetes, cardiovascular disease and also in reproductive problems;

\(^1\) Definition from the WHO/IPCS (2002) report: "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.” A potential endocrine disruptor is "an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations." (http://www.who.int/ipcs/publications/en/ch1.pdf)
D. whereas there is now significant scientific evidence that hormone-related disorders in wildlife – including reproductive abnormalities, the masculinisation of gastropods, the feminisation of fish or the decline of many mollusc populations in various parts of the world – are linked to the impact of chemicals with endocrine-disrupting properties;

E. whereas there are many possible causes for the growing frequency of hormone-related disorders in humans; whereas there is now significant scientific evidence that this is partly due to the impact of chemicals with endocrine-disrupting properties;

F. whereas there are major difficulties in proving the causal link between exposure to individual chemicals and disruption of the hormonal balance with risk of health impacts;

G. whereas, in the case of chemicals with endocrine-disrupting properties, the difficulties of proving a causal link are exacerbated by a number of factors, such as that:

- a long time may elapse between exposure and the epigenetic effects, and endocrine disrupters can have a detrimental effect several generations into the future;
- the risk of a negative impact varies in magnitude at different stages of development, and critical windows, e.g. during foetal development, may be very short;
- during their lives, people are exposed to a large number of chemicals in complex mixtures;
- endocrine disrupters can interact with each other and with the body’s own endocrine system;
- endocrine disrupters can act at extremely low concentrations and thus cause adverse effects at a low dosage; where the dose-response relationship is non-monotonic, the difficulty of prediction increases still further;
- our knowledge of human and animal endocrine systems is still limited;

H. whereas EU legislation contains legal provisions concerning endocrine disrupters, but lacks criteria for determining whether a substance should be regarded as having endocrine-disrupting properties, which undermines proper application of the legal provisions; whereas a timetable should be set up to ensure the swift application of the future criteria;

I. whereas, at EU level, there are no coordinated or combined monitoring programmes specifically dedicated to endocrine disrupters;

J. whereas there is little if any co-ordination regarding the way that data are collected, managed, assessed and reported across the different monitoring programmes;

K. whereas, as things stand at present, it is not legally possible to consider combination effects between endocrine disrupters released by products governed by different sets of regulations;

L. whereas the standard data requirements in EU chemicals legislation are insufficient to
identify endocrine-disrupting properties in an adequate manner;

M. Whereas a number of EU laws are aimed at protecting citizens from exposure to harmful chemicals; whereas current EU legislation, however, assesses each exposure individually and does not provide for a comprehensive, integrated assessment of cumulative effects that takes into account different routes of exposure or different product types;

1. Considers, on the basis of an overall assessment of the state of knowledge, that the precautionary principle, in accordance with Article 192 (2) of the Treaty on the Functioning of the EU (TFEU), requires the Commission and the legislators to take adequate measures to reduce short- and long-term exposure of humans to endocrine disrupters where necessary, while undertaking a much greater research effort to improve the state of the scientific knowledge on the impact of endocrine disrupters on human health;

2. Points out that the precautionary principle applies in a world of scientific uncertainty, in which a risk can be characterised only on the basis of imperfect knowledge – neither set in stone nor beyond challenge – but in which it is necessary to act in order to avert or reduce potentially serious or irreversible consequences for human health and/or the environment;

3. Takes the view that where adverse effects of endocrine disrupting substances can reasonably be presumed, measures to protect human health have to be implemented; stresses, moreover, given the potential of endocrine disrupting substances to cause harmful or irreversible effects, that the absence of precise knowledge, including final proof of causal links, should not prevent health protection measures to be taken in line with the precautionary principle, keeping in mind the principle of proportionality;

4. Considers that protecting women from potential risks of endocrine disrupters for their reproductive health is of utmost importance; calls, therefore, on the Commission to prioritise research funding to study the effects of hormone disrupters on women’s health, and to support long-term studies monitoring women’s health over large spans of their lives, thus allowing an evidence-based assessment of the long-term and multi-generational effects of exposure to endocrine disrupters;

5. Calls, therefore, on the Commission to submit, as soon as possible, proposals for overarching criteria based on the definition of endocrine disrupters prepared by the World Health Organisation’s International Programme on Chemical Safety (WHO/IPCS), together with testing and information requirements for chemicals on the commercial market, and for EU legislation to make clear what is regarded as a substance with endocrine-disrupting properties; advocates considering the introduction of ‘endocrine disrupter’ as a regulatory class, with different categories based on the strength of evidence;

6. Stresses that it is essential to base the criteria for determining endocrine disrupting properties on a comprehensive hazard assessment carried out on the basis of state-of-the-art science, taking into account potential combination effects as well as long-term effects and effects during critical windows of development; the hazard assessment should then be utilized in the risk assessment and risk management procedures as prescribed in various relevant legislation;
7. Calls on the Commission to take further action in the field of chemicals policy and step up research that provides both for the assessment of the endocrine disrupting potential of individual chemicals as well as the possibility to assess the cumulative impact of identified combinations of substances on the endocrine system;

8. Takes the view that the criteria for defining endocrine disrupters should be based on criteria for defining ‘adverse effect’ and ‘endocrine mode of action’; the WHO/IPCS definition being the appropriate basis for that purpose; considers that both ‘adverse effect’ and ‘endocrine mode of action’ must be examined and weighed up in parallel in a comprehensive assessment; considers that observed effects should be assumed to be harmful if there is scientific data to indicate this; stresses that any possible combination effects, such as mixtures or cocktail effects, should be taken into consideration;

9. Stresses that the criteria determining what constitutes an endocrine disrupter must be scientifically based and horizontal; considers that a weight-of-evidence approach should be used and that no single criterion should be seen as cut-off or decisive for the identification of an endocrine disrupter; considers that a socio-economic assessment should then be carried out in accordance with the relevant legislation;

10. Strongly disagrees with the attempts to introduce the criterion of ‘potency’ as a cut-off for the definition of endocrine disrupters, as this would unduly limit the definition of endocrine disrupters, and make it scientifically flawed and not coherent with the classification of Carcinogenic, Mutagenic and Reprotoxic (CMR) substances which is based on strength of evidence;

11. Takes the view that all peer-reviewed scientific data and information, including a review of the scientific literature and non-GLP studies, should be taken into account, subject to their strengths and weaknesses, in assessing whether a substance does or does not have endocrine-disrupting properties; further considers it important to take account of modern methods and up-to-date research;

12. Calls on the Commission to introduce in all relevant EU legislation appropriate testing requirements for the identification of substances with endocrine-disrupting properties; considers that the most recently validated and internationally recognised testing methods – such as those developed by the OECD, the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) or the US Environmental protection Agency (EPA) Endocrine Disruptor Screening Program – must be implemented; notes that the OECD programme of testing methods covers sex hormones and thyroid hormones as well as steroidogenesis; points out, on the other hand, that there are no tests for many other areas of the endocrine system, e.g. insulin and growth hormones; considers that testing methods and guidance documents should be developed so as to take better account of endocrine disrupters, possible low-dose effects, combination effects and non-monotonic dose-response relationships, in particular with regard to critical windows of exposure during development;

13. The development of non-animal test methods should be promoted in order to produce safety data relevant to humans and to replace animal studies currently in use;

14. Believes that the use of non-animal test methods and other risk assessment strategies
should be promoted, and that animal testing should be minimised and tests on vertebrates should be undertaken as a last resort; recalls that, in accordance with Directive 2010/63/EU, tests on vertebrate animals must be replaced, restricted or refined; calls, therefore, on the Commission to lay down rules to avoid duplicative testing and to ensure that duplication of tests and studies on vertebrates is prohibited;

15. Invites the Commission and the Member States to develop registers of reproductive health disorders to fill the existing data gap at EU level;

16. Invites the Commission and the Member States to develop reliable data on the socio-economic impacts of hormone-related disorders and illnesses;

17. Considers that it should be possible for decision-making bodies to deal with substances having the same modes of action and properties on a group basis when sufficient data is available, while in the absence of sufficient data it may be useful to group substances on the basis of structural similarity, for example in order to establish priorities for further testing, in order to protect the public as quickly and effectively as possible from the effects of exposure to endocrine disruptors, and limiting the number of animal tests; takes the view that grouping chemicals with structural similarity should be applied if the manufacturer or importer is unable to demonstrate the safety of a chemical to the satisfaction of the relevant decision making bodies; points out that, in such cases, these bodies may use information from chemicals of similar structure to complement the available data on a given chemical that is being considered by the bodies in order to reach conclusions regarding which subsequent steps need to be taken;

18. Calls on the Commission to revise its EU strategy on endocrine disrupters so that it delivers effective protection of human health by placing greater emphasis on the precautionary principle, while observing the proportionality principle, to work towards reducing human exposure to endocrine disrupters where necessary;

19. Urges the Commission and the Member States to take greater account of the fact that consumers need to have reliable information – presented in an appropriate form and in a language that they can understand – about the dangers of endocrine disrupters, their effects, and possible ways of protecting themselves;

20. Calls on the Commission to put forward a concrete timetable for applying the future criteria and modified testing requirements for endocrine disrupters in relevant legislation, including reviews of the approval of active substances used in pesticides and biocides, and a roadmap with specific actions and targets to reduce exposure to endocrine disrupters;

21. Considers that the database on hormonally active substances, developed as part of the current strategy, should be continually updated;

22. Calls on the Commission, as part of its current review of the 1999 Community strategy on endocrine disrupters, to carry out a systematic examination of all relevant current legislation and, where necessary no later than 1st of June 2015, to amend existing legislation or to come forward with new legislative proposals, including hazard and risk assessments, so as to reduce the exposure of humans – in particular vulnerable groups
such as pregnant women, babies, children and teenagers – to hormone disrupters as appropriate;

23. Calls on the Commission, when carrying out its future review of EU strategy on endocrine disrupters, to lay down an exact timetable, specifying the intermediate stages, for the purposes of:

– applying the future criteria serving to identify possible endocrine-disrupting chemicals;

– reviewing the relevant legislation referred to in paragraph 22;

– publishing a regularly updated list of priority endocrine disrupters, the first version of which should be published by 20 December 2014;

– taking all measures necessary to reduce the exposure of the EU public and the environment to endocrine disrupters;

24. Takes the view that endocrine disrupters should be regarded as Substances of Very High Concern within the meaning of the Reach Regulation, or the equivalent under other legislation;

25. Stresses that current science does not provide sufficient basis for setting a limit value below which adverse effects do not occur, and endocrine disrupters should therefore be regarded as ‘non-threshold’ substances, and that any exposure to such substances may entail a risk, unless the manufacturer can show scientific proof that a threshold can be identified, taking into account increased sensitivities during critical windows of development, and the effects of mixtures;

26. Calls on the Commission to support targeted research projects on substances likely to affect the endocrine system and to emphasise the adverse effects at low concentrations or through combined exposure, including the development of new testing and analysis methods, as well as supporting a new paradigm shift based on pathways of toxicity/adverse outcome pathways; calls on the Commission to incorporate endocrine disrupters, their combination effects, and related subjects in the priorities for the research and development framework programme;

27. Calls on the Commission to develop in vitro and in silico methods in order to minimise animal testing for endocrine disrupters screening;

28. Calls on the Commission to require all products imported from third countries to comply with all present and future EU legislation on endocrine disrupters;

29. Calls on the Commission to include all relevant stakeholders in cooperation efforts to introduce the necessary legislative changes, in order to improve protection of human health from hormone-disrupting chemicals, and to devise information campaigns;

30. Calls on the Commission to consider the possibility of establishing a research centre for endocrine disrupters which should research in and coordinate knowledge on endocrine disrupters at EU level;
31. Calls on the Commission to ensure that all relevant current and future legislation applies horizontally the criteria for identifying known, probable and potential endocrine disrupters, so as to achieve a high level of protection;

32. Stresses that while this resolution is limited to addressing the protection of human health from endocrine disrupters, it is equally important to take decisive action to protect wildlife and the environment from endocrine disrupters;

33. Urges the Commission to promote and finance public information programmes on the health risks of endocrine disrupters, so as to allow consumers, in full knowledge of the facts, to adapt their behaviour and lifestyles; these information programmes should, in particular, focus on the most vulnerable groups (pregnant women and children), so that precautionary measures can be taken in good time;

34. Calls on the Member States to improve training programmes for health professionals in this field;

35. Welcomes the inclusion of endocrine disrupting chemicals (EDCs) among the emerging policy issues managed under the Strategic Approach to International Chemicals Management (SAICM) policy framework; calls on the Commission and the Member States to support these SAICM activities, and to promote active policies to reduce human and environment exposure to EDCs in all relevant international forums, including the WHO and the United Nations Environment Programme (UNEP);

36. Instructs its President to forward this resolution to the Council and the Commission.
EXPLANATORY STATEMENT

The increased incidence of hormone-related disorders and illnesses in humans needs to be taken very seriously indeed. The endocrine system regulates much of what happens in the body, including reproduction, metabolism, growth, salt and water balance and cardiac function. There is a disturbing trend particularly with regard to human reproductive capacity, where endocrine disruptors are thought to be a contributory factor.

The precautionary principle is, and must remain, a major plank of the EU’s chemicals policy. The fact that we do not know everything cannot be used as a pretext for inactivity. The risks of irreversible damage to humans and the environment are simply too great.

At present there are some 27,000 research reports dealing with endocrine disruptors and their effects on humans and animals. A number of disturbing trends may be observed.

In the last twenty years, evidence has been mounting that hormone-related disorders in humans are on the rise. The diagnosis and incidence of a number of diseases have risen sharply all over the world. There has been a particularly noticeable increase in potential reproductive disorders in the form of impaired sperm quality, testicular cancer, early onset of puberty and deformities of the sexual organs, e.g. cryptorchidism, where the testicles do not descend into the scrotum when the foetus is developing, and hypospadias, in which the opening of the urethra is on the underside of the penis. We are also seeing a rise in the number of birth deformities, cancers and cases of diabetes, and the incidence of neurological development disorders such as autism and ADHD is also on the increase. The number of women diagnosed with breast cancer in the United Kingdom has nearly doubled since 1980. It is now estimated that one in nine women will have breast cancer at some point during their lives. Such a rapid change can only be explained by external environmental factors.

Our genes have not changed so much in such a short time. Accordingly, the increase in these disorders must be explained by external factors. This external influence comes from a number of different sources, including lifestyle factors, food and nutrition, pathogens, medicines, drugs, economic factors, and social causes such as stress. There are also a wide range of studies showing that exposure to chemicals is a contributory factor. All these factors may correlate with each other; for example, nutrition and stress can influence the body’s susceptibility to other factors.

The protection of human health is an important part of EU policy (Article 35 of the Treaty). In order to achieve this, it is important that the precautionary principle (Article 191 of the Treaty) should be applied in full.

Endocrine disruptors in the human environment, then, are one of the factors that influence this worrying development. However, it is impossible to know in detail exactly how a specific endocrine disruptor causes a specific disease. This is due to a number of factors.

– a long time may elapse between the exposure and the effect, very probably several decades or generations;
– the risk of a negative impact differs in magnitude at different stages of development, and critical windows during foetal development may be very short;
– during their lives, people are exposed to a large number of chemicals in complex mixtures;
– endocrine disrupters can interact with each other and with the body’s own hormones;
– endocrine disrupters can act at extremely low concentrations and can have a greater effect at a low dosage than at a high one. Where the dose-response relationship is non-monotonic the difficulty of prediction increases still further;
– our knowledge of the human and animal endocrine systems is still limited.

Endocrine disruptors are all around us in our everyday lives. They are present in food packaging, skin care products, cosmetics, building materials, electronic goods, furniture and floorings. Many products made of plastic in our homes and at our workplaces contain one or more types of chemicals which are suspected of having an endocrine-disrupting effect. As an individual consumer it is impossible to know what substances are present in what products, particularly in the case of goods with no list of contents.

Endocrine disruptors are released from materials and products and accumulate, for example, in dust in our homes. Consequently small children, who crawl on the floor and also like putting things in their mouths, are at special risk of exposure. Given that children are particularly susceptible to these substances’ effects, this is very worrying.

The substances suspected of having endocrine-disruptive properties are many and widespread, which means that it is impossible to protect oneself against them as an individual consumer. The quantity and widespread nature of these substances also makes it impossible to protect the most vulnerable groups, namely foetuses and children of all ages up to adult. Children, young people and women of child-bearing age are groups containing rapidly developing individuals for whom the correct balance of hormones is crucial. Accordingly they need special protection against exposure to endocrine disruptors. Society must be sufficiently safe for its most vulnerable members too.

There are measures which can be adopted rapidly to increase protection for the most vulnerable groups. The most important thing to do is to restrict the use of endocrine disruptors in products aimed at specific target groups, such as skin care products, textiles and toys with specific areas of application. More stringent safety requirements could also be applied when building and furnishing pre-schools and schools and other premises where children stay for prolonged periods. But because children, young people and particularly women of child-bearing age form a large and integral part of the population, it is necessary to protect the population as a whole.

It is crucial that appropriate tests for identifying endocrine disruptors should be implemented in existing EU legislation, particularly in the Classification, Labelling and Packaging (CLP) Regulation, Reach, the Plant Protection Products Regulations (PPPR), the Biocide Directive and the Cosmetics Directive.
Criteria need to be developed on how the interpretation of these tests in conjunction with other relevant research should be translated into concrete legislative measures. Because endocrine disruptors are thought to affect humans and the environment at very low concentrations and therefore no safe level of exposure can be established, limitation of approval on the basis of socio-economic considerations, in combination with substitution plans, should be the principal approach within Reach. The development of criteria and testing requirements should be guided by the precautionary principle. It is important that the criteria and methodology underlying the decision on whether a substance is deemed to have endocrine-disrupting properties should be as transparent as possible.

The Commission should also take the initiative of reviewing and developing all relevant legislation so as to take account of the risks of endocrine disruptors. There is a need for a broader review of the various legislative acts than has so far been announced or is required under the respective acts.

Much of the debate on endocrine disruptors concerns products and substances found in cosmetics, furniture, electronic goods, building products, toys, textiles and food – including packaging. It is therefore important that the Commission should review the existing legislation and propose new legislation in these areas so as to protect people from substances with endocrine-disrupting properties.

It is particularly important that there should be chemicals requirements concerning categories of goods that children come into contact with. Textiles are one such category for which at present there are no separate rules, in spite of the fact that small children often put textiles in their mouths and we have textiles next to our skin. We are therefore proposing the development of specific chemicals legislation for textiles.

This report is based on evidence from a number of sources. At the Commission’s Conference on Endocrine Disruptors held in Brussels in June 2012, several presentations were given that were of value for this report, including the one by Linda Birnbaum, head of the US National Institute of Environmental Health Sciences, Tracey J Woodruff, Professor at the University of California, Laurence Musset from the OECD and many others. In September 2012 the Committee on the Environment, Public Health and Food Safety held a workshop at the European Parliament entitled ‘Endocrine disruptors and impact on health’. Participants in this workshop included representatives of the Commission, researchers, stakeholder organisations and the chemical industry, and all of these provided valuable input into this report. Valuable information and viewpoints were also gathered from a number of individual meetings with researchers, representatives of industry, NGOs and public authorities. The Commission’s website on endocrine disruptors was also drawn on for information.

http://ec.europa.eu/environment/endocrine/index_en.htm

The following reports constituted important reference documents:


- Breast cancer and exposure to hormonally active chemicals: An appraisal of the scientific evidence. A background briefing paper by Professor Andreas Kortenkamp, Head of the Centre for Toxicology, The School of Pharmacy, University of London April 2008


- Vandenberg et al: Hormones and endocrine-disrupting chemicals: Low dose effects and nonmonotonic dose responses, Endocrine Reviews, online March 2012, in print June 2012.
RESULT OF FINAL VOTE IN COMMITTEE

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<td>Substitute(s) present for the final vote</td>
<td>Margrete Auken, Minodora Cliveti, José Manuel Fernandes, Vicky Ford, Gaston Franco, Judith A. Merkies, Miroslav Mikolášik, Vittorio Prodi, Christel Schaldemose, Birgit Schneiber-Jastram, Renate Sommer, Alda Sousa, Rebecca Taylor, Vladimir Urtuchev, Anna Záborská, Andrea Zanoni</td>
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<td>Substitute(s) under Rule 187(2) present for the final vote</td>
<td>Olle Ludvigsson</td>
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