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

Committee on the Environment, Public Health and Food Safety

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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 (EC) No 1907/2006¹ of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC(7) ('the REACH Regulation'),
- having regard to Regulation (EU) No 528/2012² 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 Directive 2000/60/EC³ of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ('the WFD'),
- having regard to Directive No 2009/128/EC⁴ of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides,
- having regard to the Commission proposal for a directive of the European Parliament and of 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 upcoming Commission proposal on a 'Blueprint to safeguard Europe's water resources',
- having regard to the Commission Staff working paper 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), (COM(2001)0262 and (SEC(2004)1372),
- 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),

¹ OJ L 36, 5.2.2009, p. 84.

² OJ L 167, 27.6.2012, p. 1.

³ OJ L 327, 22.12.2000, p.1.

⁴ OJ L 309, 24.11.2009, p. 71.

- having regard to the Commission’s communication to the Council on the precautionary principle (COM(2000)0001),
 - having regard to EEA Technical Report No 2/2012 ‘The impacts of endocrine disrupters on wildlife, people and their environments’,
 - 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 disruptor 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 ‘State-of-the-art assessment of endocrine disrupters’, Project Contract Number 070307/2009/550687/SER/D3,
 - having regard to ‘The impacts of endocrine disrupters on wildlife, people and their environments’, the Weybridge+15 (1996–2011) report (ISSN 1725-2237),
 - 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 (A7-0000/2012),
- 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 many cases of metabolic illnesses;
- B. whereas there are many possible causes for a 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;
- C. 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;
- D. 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:

¹ Texts adopted, P4_TA(1998/0608).

² Texts adopted, P7_TA(2010)0152.

³ Texts adopted, P7_TA(2012)0147.

- a long time may elapse between exposure and effect;
 - 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 disruptors can interact with each other and with the body's own hormones;
 - endocrine disruptors 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;
- E. whereas EU legislation contains no criteria for determining whether a substance should be regarded as having endocrine-disrupting properties;
- F. whereas, as things stand at present, it is not legally possible to consider combination effects between endocrine disruptors released by products governed by different sets of regulations;
- G. whereas the standard data requirements in EU chemicals legislation do not contain any information on endocrine-disrupting properties;
1. Considers, on the basis of an overall assessment of the state of knowledge, that the precautionary principle requires us as legislators to take measures to reduce human exposure to endocrine disruptors to a minimum;
 2. Takes the view that the feared effects of endocrine disruptors are so serious that the absence of precise knowledge, including exact knowledge of causal links, should not prevent us from taking measures to protect humans and animals;
 3. Calls, therefore, on the Commission to submit as soon as possible proposals for overarching criteria 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 disruptor' as a regulatory hazard class;
 4. Stresses that it is important for the criteria for endocrine-disrupting chemicals to be based on a comprehensive hazard assessment;
 5. Takes the view that the criteria for defining endocrine disruptors should be based on criteria for defining 'adverse effect' and 'endocrine mode of action'; considers that both these criteria must be weighed up in parallel in order to carry out a comprehensive assessment; considers that proven effects should be assumed to be harmful as long as there is no scientific data to indicate the opposite; stresses that any possible combination effects should be taken into consideration;

6. Stresses that the criteria determining what constitutes an endocrine disruptor should be scientifically based and that the precautionary principle should be applied; considers that a socio-economic assessment should then be carried out in accordance with the relevant legislation;
7. Takes the view that all peer-reviewed scientific 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;
8. 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 validated and internationally recognised testing methods that have been developed in (for example) the OECD 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 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 disruptors, possible low-dose effects and non-monotonic dose-response relationships;
9. Considers that it should be possible for decision-making bodies to deal with substances having similar chemical structures on a group basis if the manufacturer or importer cannot demonstrate that the chemical is safe in spite of its structural similarity, with a view to providing the public as quickly as possible with protection from exposure to endocrine disruptors and restricting the number of experiments on animals;
10. Calls on the Commission, in its review of EU strategy on endocrine disruptors, to place greater emphasis on the precautionary principle and work towards reducing human exposure to endocrine disruptors;
11. Considers that the data base on hormonally active substances, developed as part of the current strategy, should be continually updated;
12. Calls on the Commission to carry out a systematic examination of all relevant current legislation and, where necessary, to propose new legislation so as to reduce the exposure of human beings, particularly fetuses, babies, children and teenagers, to hormone disruptors; calls on the Commission to submit legislative proposals for chemicals in textiles and building materials, and stresses in particular the importance of reviewing legislation on materials and products intended to come into contact with food, so as to reduce human exposure to endocrine disruptors;
13. Takes the view that endocrine disruptors should be regarded as Substances of Very High Concern within the meaning of the Reach Regulation; considers, therefore, that endocrine disruptors should be subject to authorisation or restriction with a view to substitution;
14. Stresses that endocrine disruptors should be regarded as substances for which it is not possible to set a limit value at which effects may occur ('non-threshold' substances) and that any exposure to such substances may entail a risk;

15. Calls on the Commission to support targeted research projects on endocrine disruptors, including the development of new testing and analysis methods;
16. Calls on the Commission to include all relevant stakeholders in cooperation seeking to adopt the necessary legislative changes to improve protection of human health from hormone-disrupting chemicals;
17. Calls on the Commission to ensure that the criteria for identifying endocrine disruptors are applied horizontally to all current and future legislation;
18. 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 disruptors can interact with each other and with the body's own hormones;
- endocrine disruptors 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:

- Kortenkamp et al. *State of the art assessment of endocrine disruptors*, Project Contract Number 070307/2009/550687/SER/D3
- The impacts of endocrine disruptors on wildlife, people and their environments. The Weybridge+15 (1996–2011) report. ISSN 1725-2237

- Diamanti-Kandarakis E et al. 2009 *Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement*. Endocrine Reviews 30(4):293-342
- Linda Birnbaum. *Environmental Chemicals: Evaluating Low-Dose Effects*. doi:10.1289/ehp.1205179
- Richard Sharpe. *Male Reproductive Health Disorders and the Potential Role of Exposure to Environmental Chemicals*. Commissioned by CHEM Trust.
- 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
- Survey and Health Assessment of the exposure of 2 year-olds to chemical substances in Consumer Products. Kathe Tønning, Eva Jacobsen and Eva Pedersen. Danish Technological Institute. Marianne Strange and Pia Brunn Poulsen. Force Technology. Lise Møller and Helle Buchardt Boyd, DHI group. Survey of Chemical Substances in Consumer Products, No. 102 2009
- Vandenberg et al: Hormones and endocrine-disrupting chemicals: Low dose effects and nonmonotonic dose responses, Endocrine Reviews, online March 2012, in print June 2012.