Basic information

2012/2066(INI) INI - Own-initiative procedure	Procedure completed
Protection of public health from endocrine disrupters **Subject** 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 4.20 Public health 4.20.01 Medicine, diseases	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Public Health and Food Safety	WESTLUND Åsa (S&D)	12/04/2012
		Shadow rapporteur KLASS Christa (PPE) LEPAGE Corinne (ALDE) SCHLYTER Carl (Verts /ALE) RIVASI Michèle (Verts/ALE) OUZKÝ Miroslav (ECR) SOUSA Alda (GUE/NGL)	

European Commission	**Commission DG**	**Commissioner**
	Health and Food Safety	BORG Tonio

Key events

Date	Event	Reference	Summary
20/04/2012	Committee referral announced in Parliament		
23/01/2013	Vote in committee		
30/01/2013	Committee report tabled for plenary	A7-0027/2013	Summary
12/03/2013	Debate in Parliament		
14/03/2013	Decision by Parliament	T7-0091/2013	Summary
14/03/2013	Results of vote in Parliament		

14/03/2013	End of procedure in Parliament		

Technical information	
Procedure reference	2012/2066(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/08967

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE496.297	15/11/2012	
Amendments tabled in committee		PE500.605	27/11/2012	
Amendments tabled in committee		PE502.204	22/01/2013	
Committee report tabled for plenary, single reading		A7-0027/2013	30/01/2013	Summary
Text adopted by Parliament, single reading		T7-0091/2013	14/03/2013	Summary

Protection of public health from endocrine disrupters

2012/2066(INI) - 30/01/2013 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted the report drafted by Åsa WESTLUND (S&D, SE) on the protection of public health from endocrine disrupters.

Members highlight that 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. 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. These substances acting as endocrine disrupters can have oestrogenic or antioestrogenic 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. Furthermore, 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 and cardiovascular disease.

Application of the precautionary principle: in the abovementioned context, Members consider that the **precautionary principle should be applied**. It 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. Members take the view that where adverse effects of endocrine disrupting substances can reasonably be presumed, measures to protect human health have to be implemented in line with the precautionary principle.

Protecting women: Members consider that protecting women from potential risks of endocrine disrupters for their reproductive health is of utmost importance and call on the Commission to support long-term studies monitoring women's health over large spans of their lives. The report 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-theart science, taking into account potential combination effects as well as long-term effects and effects during critical windows of development.

The Commission is called upon 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.

Defining the main sources of endocrine disrupters: Members take the view that the criteria for defining endocrine disrupters should be based on criteria for defining 'adverse effect' and 'endocrine mode of action'. They stress that any possible combination effects, such as mixtures or cocktail effects, should be taken into consideration. The criteria determining what constitutes an endocrine disrupter must be scientifically based and horizontal. **Members strongly disagree 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. The Commission is called upon to introduce in all relevant EU legislation **appropriate testing requirements** for the identification of substances with endocrine-disrupting properties – such as those developed by the OECD, the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM). The development of non-animal test methods should be promoted.

Members propose the development of **registers of reproductive health disorders** to fill the existing data gap at EU level as well as reliable data on the socioeconomic impacts of hormone-related disorders and illnesses.

Towards a EU strategy on endocrine disrupters: given that 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, Members call 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.

In this context, the Commission is called upon 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;
- 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**;
- 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;
- lay down an exact timetable, specifying the intermediate stages, for the purposes of: (i) applying the future criteria serving to identify possible endocrine-disrupting chemicals; (ii) reviewing the relevant legislation; (iii) publishing a **regularly updated list of priority endocrine disrupters**, the first version of which should be published by 20 December 2014; (iv) taking all measures necessary to **reduce the exposure of the EU public and the environment to endocrine disrupters**.

No limit value setting: Members stress that current science does not provide sufficient basis for setting a limit value below which adverse effects do not occur. 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.

Further actions are called for at EU level such as:

- supporting targeted research projects on substances likely to affect the endocrine system;
- requiring all products imported from third countries to comply with all present and future EU legislation on endocrine disrupters;
- ensuring 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;
- including 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;
- considering the possibility of **establishing a research centre for endocrine disrupters** which should research in and coordinate knowledge on endocrine disrupters at EU level;
- promoting and financing 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 (in particular pregnant women and children);
- improving training programmes for health professionals in this field.

Lastly, Members call on the Commission and the Member States to support Strategic Approach to International Chemicals Management (SAICM) activities and to promote active policies to reduce human and environment exposure to EDCs in all relevant international forums, including the WHO.

Protection of public health from endocrine disrupters

2012/2066(INI) - 14/03/2013 - Text adopted by Parliament, single reading

The European Parliament adopted by 489 votes to 102, with 19 abstentions, a resolution on the protection of public health from endocrine disrupters.

Parliament highlights that 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. 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. These substances acting as endocrine disrupters can have oestrogenic or antioestrogenic 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. Furthermore, 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 and cardiovascular disease.

Application of the precautionary principle: in the abovementioned context, Parliament considers that the **precautionary principle should be applied**. It 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. Members take the view that where adverse effects of endocrine disrupting substances can reasonably be presumed, measures to protect human health have to be implemented in line with the precautionary principle.

Protecting pregnant women and babies: Members consider that protecting women from potential risks of endocrine disrupters for their reproductive health is of utmost importance and call on the Commission to support long-term studies monitoring women's health over large spans of their lives.

Parliament 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.

The resolution 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 Commission is called upon 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.

Defining the main sources of endocrine disrupters: Parliament takes the view that the criteria for defining endocrine disrupters should be based on criteria for defining 'adverse effect' and 'endocrine mode of action'. It stresses that any possible combination effects, such as mixtures or cocktail effects, should be taken into consideration. The criteria determining what constitutes an endocrine disrupter must be scientifically based and horizontal. 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. However, Plenary did not accept the measure proposed by the committee responsible which refused **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.

Parliament is favourable to establishing testing methods such as those developed by the OECD, the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) covering sex hormones and thyroid hormones as well as steroidogenesis. The development of non-animal test methods should be promoted. Members also propose the development of **registers of reproductive health disorders** to fill the existing data gap at EU level as well as reliable data on the socioeconomic impacts of hormone-related disorders and illnesses.

Towards a EU strategy on endocrine disrupters: given that 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, Parliament 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.

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: (i) a long time may elapse between exposure and the epigenetic effects, and endocrine disrupters can have a detrimental effect several generations into the future; (ii) 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; (iii) endocrine disrupters can act at extremely low concentrations and thus cause adverse effects at a low dosage.

In this context, the Commission is called upon 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;
- 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**;
- 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;
- lay down an exact timetable, specifying the intermediate stages, for the purposes of: (i) applying the future criteria serving to identify possible endocrine-disrupting chemicals; (ii) reviewing the relevant legislation; (iii) publishing a **regularly updated list of priority endocrine disrupters**, the first version of which should be published by 20 December 2014; (iv) taking all measures necessary to **reduce the exposure of the EU public and the environment to endocrine disrupters**.

No limit value setting: plenary 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.

Further actions are called for at EU level such as:

- supporting targeted research projects on substances likely to affect the endocrine system;
- requiring all products imported from third countries to comply with all present and future EU legislation on endocrine disrupters;

- ensuring 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;
- including 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;
- considering the possibility of **establishing a research centre for endocrine disrupters** which should research in and coordinate knowledge on endocrine disrupters at EU level;
- promoting and financing 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 (in particular pregnant women and children);
- improving training programmes for health professionals in this field.

Lastly, Parliament calls on the Commission and the Member States to support Strategic Approach to International Chemicals Management (SAICM) activities and to promote active policies to reduce human and environment exposure to EDCs in all relevant international forums, including the WHO.

It should be noted that an alternative motion for a resolution tabled by the ECR Group was rejected in Plenary.