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REPORT

on the Commission communication to the Council and the European Parliament on a Community strategy for endocrine disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife
(COM(1999) 706 – C5-0107/2000 – 2000/2071(COS))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Torben Lund

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PROCEDURAL PAGE

By letter of 17 December 1999, the Commission forwarded to Parliament a communication to the Council and the European Parliament on a Community strategy for endocrine disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM(1999) 706 – 00/2071(COS)).

At the sitting of 13 March 2000 the President of Parliament announced that she had referred the communication to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Industry, External Trade, Research and Energy for its opinion (C5-0107/2000).

The Committee on the Environment, Public Health and Consumer Policy appointed Torben Lund rapporteur at its meeting of 22 March 2000.

It considered the Commission communication and the draft report at its meetings of 19 April, 19 June and 11 July 2000.

At the latter meeting it adopted the motion for a resolution unanimously with 2 abstentions.

The following were present for the vote: Alexander de Roo, acting chairman;Torben Lund, rapporteur; Per-Arne Arvidsson, Maria del Pilar Ayuso González, Emmanouil Bakopoulos (for Mihail Papayannakis), Hans Blokland, David Robert Bowe, John Bowis, Philip Rodway Bushill-Matthews (for Marielle de Sarnez), Dorette Corbey, Chris Davies, Avril Doyle, Carlo Fatuzzo (for Cristina Gutiérrez Cortines), Marialiese Flemming, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Françoise D. Grossetête, Roger Helmer, Mary Honeyball (for Anneli Hulthén), Marie Anne Isler Béguin, Hedwig Keppelhoff-Wiechert (for Caroline F. Jackson), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Paul A.A.J.G. Lannoye (for Hiltrud Breyer), Peter Liese, Jules Maaten, Minerva Melpomeni Malliori, Maria Martens (for Giuseppe Nisticò), Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Karl Erik Olsson, Béatrice Patrie, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Ursula Schleicher, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Bart Staes (for Patricia McKenna), Cathrine Stihler, Antonios Trakatellis, Kathleen Van Brempt (for Carlos Lage), Phillip Whitehead.

The opinion of the Committee on Industry, External Trade, Research and Energy is attached.

The report was tabled on 13 July 2000.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the Commission communication to the Council and the European Parliament on a Community strategy for endocrine disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM(1999) 706 – C5-0107/2000 – 00/2071(COS))

The European Parliament,

– having regard to the Commission communication (COM(1999) 706 – C5-0107/2000[1]),

– having regard to the hearing held by the Committee on the Environment, Public Health and Consumer Policy on 18 April 2000 and the submissions received from interested parties,

– having regard to its resolution of 20 October 1998[2] on endocrine-disrupting chemicals,

– having regard to the Commission's communication on the precautionary principle (COM(2000) 1)[3],

– having regard to Rule 47(1) of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Industry, External Trade, Research and Energy (A5-0197/2000),

A. whereas the European Parliament needs to give a political response to the debate on endocrine disruption and to the Commission communication and to give a signal as to the direction the debate needs to take to be translated into action; Parliament also needs to reflect public concern,

B. whereas arguments in this debate should be based on facts,

C. whereas limitations and uncertainties in the available scientific data and, consequently, discrepancies in the observed effects - linked with stated disagreement between scientists as to the importance and/or interpretation of data - must all lead to the application of the precautionary principle,

D. whereas since the EU Scientific Committee on Toxicity and the Environment (SCTEE) has noted that for wildlife "there is a potential global problem", the use of the precautionary principle requires the introduction of quick measures to avoid possible irreversible damage to wildlife,

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[1] OJ C ....
[2] OJ C 341, 9.11.1998, p. 11.
[3] OJ C …

E. whereas a multidisciplinary approach to the issue is needed to better understand the mechanisms and the consequences; the identification of endocrine disrupters is the key; conclusive standardisation of tests is urgent; short-term tests are useful for screening purposes, but the methods must be further validated; these outstanding requirements are not a sine qua non for taking action,

F. whereas the Commission communication provides a good basis for understanding the problem and the difficulties inherent in it; it provides a good, complete overview; the communication is a direct response to Parliament's resolution of October 1998, but it does not answer the specific questions nor does it present precise proposals and timetables for action aimed at regulating the use of substances known as causing endocrine disruption,

G. whereas international co-operation in this field focuses on two issues: (1) agreement on a list of reference of endocrine disrupters with which to validate individual endocrine disruption tests (2) the design of a screening and testing programme for endocrine disrupters, including the development of new and review of existing test guidelines to detect endocrine disrupters; programmes to address both human and wildlife effects,

H. whereas it recognises that this is a global issue, with potentially global consequences; however, the EU must show responsibility and lead the way; it is deeply worried about the full consequences and the uncertainty about the scope of the problems related to endocrine disrupters; it is deeply concerned at the many documented examples of endocrine disrupters' impact on wildlife and demands prompt action based on the precautionary principle; it is concerned about the increased incidence of adverse human health effects, such as increased incidence of breast cancer and other cancers in the reproductive organs, lower sperm counts, testes cancer, which might be linked to endocrine disrupting substances,

I. whereas it welcomes the Commission initiative to set out a strategy, in particular the need for precautionary action, but is disappointed with the proposed strategy’s lack of ambition, concerning the need to reduce human exposure to endocrine disrupters and protect wildlife,

J. whereas many substances suspected to be EDs have already been identified and included in other priority chemicals lists for their negative effects on human health and wildlife without concrete action to be taken; the European Parliament reiterates its assessment that the existing Community chemicals legislation does not sufficiently address risks for health and wildlife and needs urgent thorough revision,

K. whereas it recommends that the strategy should consider all aspects of the suspected consequences of endocrine disruption – problems for wild life, adverse human health effects, sources of exposure, how these are avoided/removed and how to prevent new endocrine disrupting substances from being put on the market,

L. whereas it is concerned about the decline in EU funding for EDs research in the framework of the 5th Community Framework Programme on Research and Development**,**

M. whereas it recommends that the strategy be organised in a way that makes it possible to constantly adapt to new knowledge/scientific evidence,

N. whereas it draws attention to the fact that experience with voluntary agreements shows that they are not appropriate for short-term/prompt action and are often in general without effect; if such a strategy is chosen it is imperative to establish effective monitoring programmes;

Immediate action:

1. Supports the Commission strategy on establishing by the end of 2000 a list of substances, which are or are suspected of being endocrine-disrupting substances; the Commission must ensure that the necessary resources are available to include on the list all 560+ substances which have been identified by the Commission consultants; all of these substances must be scrutinised and categorised;

2. Calls upon the Commission to identify the substances on this list, which should be intervened against on the basis of the precautionary principle, without awaiting further tests. As for these substances, intervention – ban, phasing out and/ or limiting the use – should be decided upon before mid-2001, ***taking into account the fact that it is almost impossible to set limit values for hormone-mimicking substances***;

3. Supports the ongoing international cooperation and co-ordination through the OECD and with US and Japanese authorities in both the area of research and in the process to identify endocrine-disrupting chemicals;

4. Urges the Commission and the Member States to establish a European screening and testing strategy; the number of chemicals which are to be tested requires the possibility of group-testing/screening, which must be based on the biological or chemical characteristics of the substances; calls on the institutions involved to secure the funds for such a strategy;

5. Finds that the strategy must recognise that several endocrine disrupters (EDs) have now been found to cause effect at a very low dose level and that there is uncertainty about effects of a mixture of EDs and synergetic effects;

6. Calls on the Commission to set up European scientific research programmes aimed at gathering as much information, scientific knowledge and evidence as possible and encouraging the exchange of information, identification of endocrine disrupters and updating of validated testing methods***;***

7. Calls on the Commission and the Member States to ensure that sufficient resources from the forthcoming 6th Framework Programme on Research and Development are allocated to independent research; such research should cover ED test methods (including in vitro/invivo tests); risks; behavioural consequences; low-dose, synergistic and long-term effects; the effects of exposure to a mixture of substances; toxicological mechanisms of impacts on wildlife and humans (including mixtures of man-made chemicals and natural substances); effects on oestrogen-, androgen- and thyroid hormone-related processes;

8. Recommends that the Commission initiates an investigation into the number of

endocrine-disrupting substances and the quantity of EDs which humans and wildlife are exposed to, including an investigation into the quantities of EDs in foodstuffs;

9. Recommends to the Commission that research projects should be co-ordinated, inter-disciplinary and cross-border and should involve independent participants of different scientific backgrounds;

10. Urges the Commission to encourage industry and agriculture to develop and use alternative substances to endocrine disrupters

11. Calls on the Commission to help ensure that the issue of endocrine disrupters is on the agenda in international for a such as the WTO and the WHO.

Further action

12. Calls on the Commission to elaborate by mid-2001 an analysis of existing legal instruments relating to EDs, including a presentation of EDs which already or during the year 2000 have been classified under Directive 67/548/EEC or dealt with according to other existing Community legislation, and an analysis of specific measures introduced by Member States;

13. Considers that a future legal framework for chemicals should include specific legislation (e.g. in an annex to framework legislation or specific sectoral legislation) dealing with endocrine disruption; such legislation should be based on the precautionary principle and the shifting of the burden of proof; when a product is put on the market the manufacturer must prove at least a "reasonable certainty of no harm"; a future legal framework must also include a mechanism which puts the onus on manufacturers of existing chemicals to test their chemicals to the standards required for new chemicals and a timetable for this action;

14. Calls upon the Commission to ensure the internal market's functioning is based on a high level of protection; the institutions must agree to take a progressive view on "any new development based on scientific facts" (Article 95) of the TEC;

15. Recommends that the Commission give special consideration to sensitive groups (children, pregnant women) and their exposure to EDs in the workplace; stresses the need to focus on the numerous adverse female health effects linked to exposure to EDs;

16. Calls on the Commission to take into account that the chemical substances giving rise to concern may have totally different effects on embryos, foetuses and young babies by comparison with their effects on adults;

17. Reiterates its request that the Commission must, in co-operation with Member States' authorities, monitor the levels of "releases" of endocrine disrupters into the environment by requesting industry to report which chemicals are put on the market and in what quantities;

18. Reiterates its request that EU-labelling requirements should be reviewed to ensure that

each chemical product is labelled in an easily understandable way to show what level of substances it contains and that the hazard category for those substances is displayed; substances which have been subjected to a risk analysis/assessment should be labelled to show their effects;

19. Recommends that the Commission gather information from all parties – environmental organisations, industry and researchers and others – in the process;

20. Requests that Member States and the Commission make information on EDs widely available on the basis of the "right-to-know" principle; this principle is the best way of enabling people to maintain control over their own health rights and to obtain information about the impact on wildlife; such information should also seek to accurately communicate all the uncertainties to the public and the actions that are being taken to address the uncertainties and the problem in general;

21. Instructs its President to forward this resolution to the Council, the Commission, the Economic and Social Committee, the Committee of the Regions and to the governments and parliaments of the Member States and those of the applicant countries.

EXPLANATORY STATEMENT

This report is prompted by the Commission communication of 17 December 1999 to the Council and the European Parliament on a Community strategy for endocrine disrupters. At the same time, it is a follow-up to Parliament's resolution of 20 October 1998 on endocrine-disrupting chemicals and the hearing held by Parliament on this subject on 18 April 2000.

The hearing clarified the existing know-how on endocrine disrupters and their effect on the health and reproduction of human beings and wildlife. The Commission communication sets out a three-pronged strategy for resolving the difficult problems entailed by the use of substances that interfere with hormone systems.

The strategy contains many important initiatives for further action but, on a number of points, lacks the necessary ambition and drive. The many recommendations and proposals in this report are intended to provide this drive and ensure pro-active application of the precautionary principle in this area. At the same time, attention is drawn to the requirements in terms of resources that need to be provided in order to implement effective action.

The impact/possible impact of endocrine disrupters on the health and reproduction of human beings and wildlife is frightening. Even though our knowledge is not complete, there is more than enough evidence available of effects and correlations to justify the need for action here and now.

The Commission's strategy of establishing a priority list of known and suspected endocrine disrupters therefore deserves strong support. Such a list is a necessary basis for further action. However, it is essential that the list include the 560 or so substances which the Commission's consultants have identified as having or being suspected of having endocrine disrupting characteristics. The necessary resources to achieve this should be provided and the work should be pressed ahead with so that the list can be published by the end of the year. All the substances on the list should be investigated and categorised as soon as possible.

Through application of the precautionary principle, the Commission should at the same time identify those substances on the list requiring intervention in the form of bans, phasing out and/or setting limit values now - and by mid-2001 at the latest.

The Commission should analyse as soon as possible to what extent existing legislation can more generally be used as a basis for the decisions that need to be taken on endocrine disrupters.

The future legislative framework for chemicals should contain specific provisions guaranteeing the instruments necessary for regulating the use of endocrine disrupters. These provisions must be based on the precautionary principle, on the principle of the reversal of the burden of proof and on a system of approval for new substances and must at the same time contain a timetable showing when existing substances need to comply with the approval requirements applicable to new substances.

It was emphasised at Parliament's hearing of 18 April 2000 that a great deal of research is currently being carried out into the development of validated testing methods in the US, Japan and Europe. This work is being coordinated through the OECD but is making only slow

progress. There is a need to develop a European strategy so that the process can be expedited.

At the same time, there is a need to secure the necessary resources from the sixth framework programme on research and development to identify the endocrine characteristics and harmful effects of substances on human beings and wildlife, causal relationships, critical exposure periods, mixture and synergetic effects, low-dose effects, etc. Intensive international cooperation in this area can ensure effective action and swifter results.

Further know-how is essential in determining safe and effective regulation of endocrine disrupters in the future.

21 June 2000

OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Consumer Policy

on public health: effects of endocrine disrupters on human and animal heath (communication) (COM(1999) 706 – C5-0107/2000 – 2000/2071(COS))

Draftsman: Nuala Ahern

PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed Nuala Ahern draftsman at its meeting of 19 April 2000.

It considered the draft opinion at its meetings of 6 June 2000 and 21 June 2000.

At the last meeting it adopted the amendments unanimously.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman, Peter Michael Mombaur, vice-chairman, Nuala Ahern draftsman and vice-chairman, Gordon Adam (for Eryl Margaret McNally), Konstantinos Alyssandrakis, Eduard Beysen (for Willy C.E.H. De Clercq), Guido Bodrato, Yves Butel, Massimo Carraro, Gérard Caudron, Giles Bryan Chichester, Dorette Corbey (for Erika Mann), Claude J.-M.J. Desama, Harlem Désir, Concepció Ferrer, Francesco Fiori (for Renato Brunetta), Colette Flesch, Glyn Ford, Jacqueline Foster (for Godelieve Quisthoudt-Rowohl), Norbert Glante, Robert Goebbels (for Rolf Linkohr), Lisbeth Grönfelt Bergman (for Anders Wijkman), Malcolm Harbour, Bashir Khanbhai (for Christos Folias), Bernd Lange (for François Zimeray), Peter Liese (for Werner Langen), Caroline Lucas, Linda McAvan, Marjo Tuulevi Matikainen-Kallström, Elizabeth Montfort, Luisa Morgantini, Angelika Niebler, Giuseppe Nisticò (for Paul Rübig), Reino Kalervo Paasilinna, Yves Piétrasanta, Elly Plooij-van Gorsel, Samuli Pohjamo (for Nicholas Clegg), John Purvis, Alexander Radwan (for W.G. van Velzen), Mechtild Rothe, Christian Foldberg Rovsing, Umberto Scapagnini, Konrad K. Schwaiger, Astrid Thors, Claude Turmes (for Ilka Schröder), Jaime Valdivielso de Cué, Dominique Vlasto.

SHORT JUSTIFICATION

The endocrine system, in association with the nervous and immune systems, regulates the body's internal activities so as to preserve a balanced internal environment. Hormones are produced and released into the bloodstream by a variety of glands, such as the testes, ovaries, the adrenal gland, the pancreas, and the pituitary, thyroid and parathyroid glands. In recent decades growing evidence has accumulated on the hormone-like effects of a number of industrial chemicals that appeared in the environment. These types of substances have been termed endocrine disrupters, or EDs. The internationally agreed working definition of EDs is the following:

'An endocrine disrupter 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'.

'Endocrine disruption is not in itself an adverse outcome but a mechanism which may have carcinogenic, reproductive, developmental or behavioural effects. Some of these effects can already be detected using current testing procedures, even though it may not be clear whether the disorder has been brought about through endocrine disruption.' (Report EP SACO 100 EN, October 1997).

It was known as early as the 1930s that some man-made chemicals discharged into the environment could mimic oestrogens. In the 1970s disruption in the endocrine systems in birds was found in the US and this was attributed to exposure to chemicals. In the 1980s and 1990s, a series of studies on wildlife served to polarise the issue and indicated that reproduction and development were impaired in a variety of wildlife species around the world as a result of exposure to environmental chemicals. The animal species ranged from marine molluscs (Europe) to fish (both freshwater and marine, UK and US), frogs (US), alligators (US), and mammals (US and Europe). Much of the wildlife affected lived in, or was closely associated with, the aquatic environment. The reasons why aquatic wildlife may be more predisposed to endocrine disruption may include the fact that freshwater and marine environments act as repositories for discharges of large volumes of chemicals, uptake of EACs in many aquatic animals will occur via the gill and skin surfaces, as well as via the diet, and eggs (and subsequent embryos) deposited into the aquatic environment will be exposed to EACs at vulnerable life stages. Most field studies on endocrine disruption have been conducted at 'chemical hot spots', that is areas that are known to be heavily contaminated with chemical discharges. Recent work on fish in UK rivers, however, has established that disruption in sexual development, as a result of exposure to discharges from sewage treatment works, is widespread in the ambient riverine environment (Dr Charles Tyler).

Wildlife effects

The EU Scientific Committee on Toxicity and the Environment (CSTEE) has noted that for wildlife 'there is a potential global problem'.

The CSTEE report states that:

'There is strong evidence obtained from laboratory studies showing the potential of several environmental chemicals to cause endocrine disruption at environmentally realistic exposure levels. In wildlife populations, associations have been reported between reproductive and developmental effects and endocrine disrupting chemicals. (…) For most reported effects in wildlife, however, the evidence for a causal link with endocrine disruption is weak or non-existing. (…) Impaired reproduction and development causally linked to endocrine disrupting chemicals are well documented in a number of species and have resulted in local or regional population changes.'

The CSTEE Opinion on Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with Emphasis on Wildlife and Ecotoxicological Test Methods, by the European Scientific Committee for Toxicology, Ecotoxicology and the Environment (CSTEE), EC-DG Consumer Policy and Consumer Health Protection, Brussels, 1999.

Human health effects

The CSTEE report says that 'although there are associations between endocrine disrupting chemicals, so far investigated, and human health disturbances, a causative role of these chemicals in diseases and abnormalities possibly related to an endocrine disturbance has not been verified.' In general, scientists are suspicious of certain organochlorine compounds such as PCBs.

New European research funded at European level

The report 'Endocrine Disrupters – How to address the challenge?' (proceedings of the Joint Conference of the European Commission, DG XI, and the Austrian Presidency, Vienna, 18-19 November 1998) presents the research funded by the Fourth European Framework Programme for RTD. This research addresses mostly environmental aspects of endocrine disruption, but some started to investigate the links between endocrine disruption and human health. One project in particular attempted to test the hypothesis according to which possible decreases in human sperm counts and increases in testicular cancer could be associated with exposure to endocrine disrupters. Another project developed a bioassay to detect EDs in the environment.

In the Fifth Framework Programme, a new project just started (funded under the 'Environment and Health' key action of the Quality of Life programme) will attempt to identify the dietary and environmental factors that could be responsible for male urogenital malformations and low sperm counts. Additional projects will be funded through future FP5 calls over the next three years in both the Quality of Life and the Environment programmes.

CONCLUSIONS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its draft resolution:

A. In view of the complexity of the issue, better understanding will only arise from a very broad multidisciplinary approach covering epidemiology, physiology, environmental

sciences, medicine, genetic studies, toxicology, organic and analytical chemistry, and many other fields. However, the importance of the identification of endocrine disrupters underlies this whole approach.

B. There are no generally accepted, adequately validated methods for routine identification or monitoring of EDs. A recent study comparing different oestrogenicity tests concluded that careful standardisation is necessary. Similar methods vary in their sensitivity to oestrogenic compounds. Short-term tests are useful for screening purposes, but the methods must be further validated.

C. The various *in vitro* and *in vivo* screening assays available to date do not address the full range of putative actions of EDs. The assessment of hormonally active substances is hampered by the complexity of the molecular effects and control mechanisms.

D. There is a requirement to fully scrutinise all 560-plus suspected endocrine disrupting substances that have been identified by the Commission's consultants from other lists of EDCs, and to fully evaluate those to which humans and/or wildlife are exposed. To date, experts have only investigated the available literature on 116 of these substances, which include those that are high production volume chemicals (HPVs) and some metals.

E. There is a requirement to ensure that there is a screening and testing strategy to investigate the bulk of chemicals (to which there is exposure in the EU) for their ability to disrupt endocrine systems.

Your draftsman therefore proposes that research should address the following points and that they be included in the Sixth Research Programme:

1. To enhance *in vitro/in vivo* tests to improve significantly the identification of endocrine disrupters. This will set up a framework for research, monitoring and testing. Conclusive standardisation of testing is important.

2. To improve monitoring of EDs in the environment and to understand better the long-term consequences of their presence. This entails determining particular chemicals, levels of exposure, geographical areas, sources of contamination, and populations at risk.

3. To identify known and suspected toxicological mechanisms of impacts on wildlife and humans (including any uncertainties, limitations and weaknesses of the data). And in particular to tease out the role of endocrine disrupters in human health problems.

4. To identify and mitigate toxicological problems, particularly in relation to combined exposures and mixtures of man-made chemicals (e.g. pesticides) and natural substances (e.g. phytoestrogens).

5. To investigate the bulk of chemicals in our environment for their ability to disrupt the endocrine system, to avoid the risk that many substances to which there is current exposure may be left unevaluated.

6. To fully scrutinise all 560-plus suspected endocrine disrupting substances that have been identified by the Commission's consultants from other lists of EDCs, including their cumulative effect, and to fully evaluate those to which humans and/or wildlife are exposed.

7. To determine which modes of action are important for human and wildlife disease, including reproduction and development and the impact of hormones and hormone-like agents on disease. And to evaluate the human and ecological (wildlife) effects.

8. To examine effects on oestrogen-, androgen- and thyroid hormone-related processes.

9. To evaluate endocrine disrupting of both single chemical substances and common mixtures, and particularly to evaluate the combined effects.

10. To evaluate the chronic and acute effects of long-term exposure.

To make a rapid and full evaluation of the available scientific information relating to individual endocrine disrupting substances.

12. To establish an acceptable definition of an ED.

13. Urges the Commission:
- to require industry to provide information on which chemicals are being used and in what quantities;
- to consult industry in the formulation of policy and in research in the field of endocrine disrupters;
- to encourage industry and agriculture to develop and use alternative substances to endocrine disrupters.

14. Foreign trade:
Calls on the Commission to help ensure that the issue of endocrine disrupters is on the agenda in international for a such as the WTO and the WHO.