



Endocrine disruptors

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DG Environment, Sustainable chemicals

Outline

What are endocrine disruptors

Policy background

Achievements

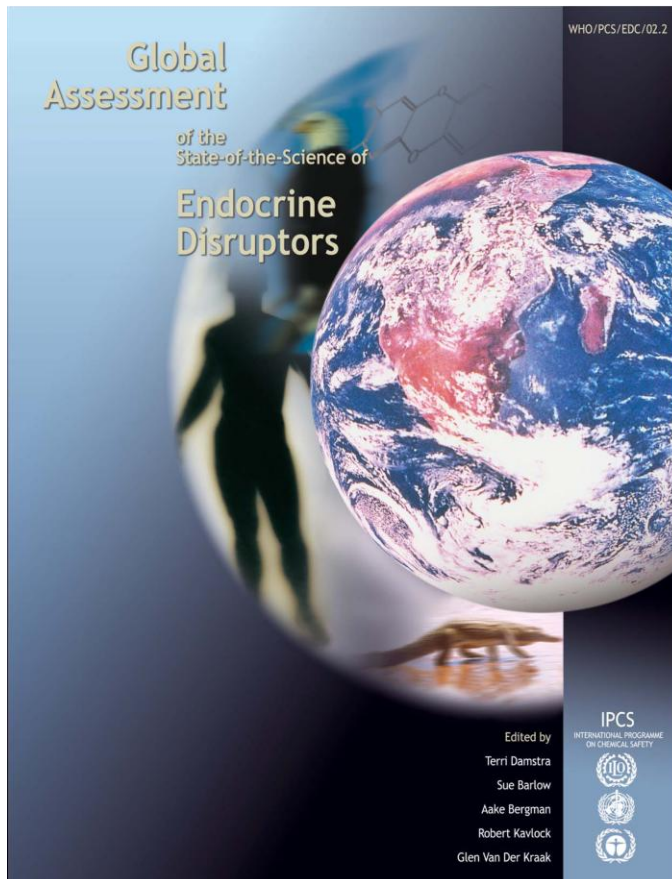
Activities external to the Commission

Current focus

The WHO IPCS Definition

"An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub)populations."


Science reviews



Temporal trends in sperm count: a systematic review and meta-regression analysis

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average decline in mean total sperm count of 1.6% per year and overall decline of 59.3% between 1973 and 2013

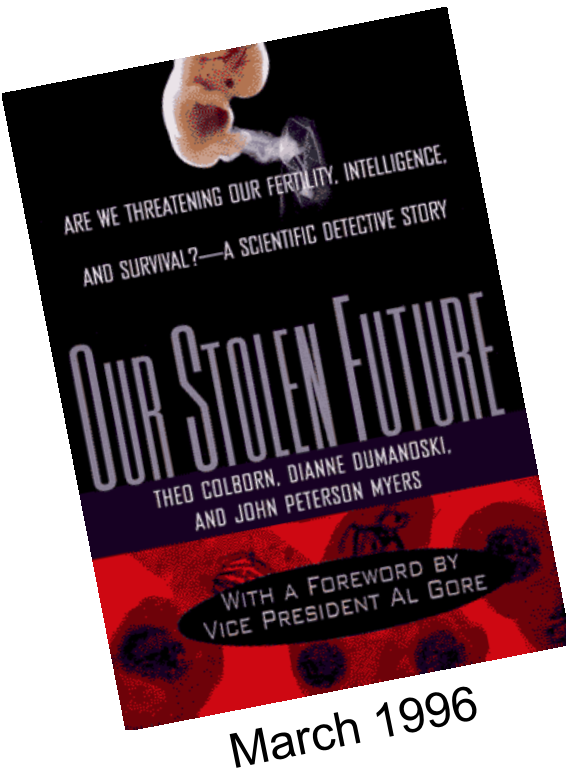
December 1996
Weybridge
Workshop



October 1998
Parliament resolution



March 1999
Scientific Committee



Community Strategy for Endocrine Disruptors



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.12.1999
COM(1999) 706 final

**COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

Community Strategy for Endocrine Disruptors

*a range of substances suspected of interfering with the hormone systems
of humans and wildlife*

Objectives:

- *To identify problem of endocrine disruption*
- *To identify appropriate policy action*

11 actions specified:

- *7 short-term actions*
- *3 medium-term actions*
- *1 long-term action*

Main achievements

- *Endocrine specific provisions in WFD, REACH, Plant protection product and Biocidal regulations*
- *12 OECD test methods for identification of EDs developed + guidance document*
- *Much greater scientific understanding of EDs achieved via EU support of research and development in this field*
- *Priority list of substances for further testing of their role in endocrine disruption established*

Main achievements

- Legislative measures



- Test methods



- Research





Water Framework Directive (2000)

- *Annex VIII to the WFD provides an indicative list of main pollutants that should be particularly addressed by Member States in relation to the quality of surface and ground water and includes inter alia*
 - **“substances and preparations, or the breakdown products of such, which have been proved to possess properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment”**



REACH (2006)

- *Authorisation provisions of REACH may apply also to endocrine disruptors:*
 - **Substances – such as those having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern as CMR, PBT and vPvB and which are identified on a case-by-case basis in accordance withArticle 59.**
- *Review clause*
 - **By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60 (3) (socio-economic route) to substances identified under Article 57 (f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals**

Plant Protection Product Reg. (2009)



- *An active substance, safener or synergist shall only be approved if,.....it is not considered to have endocrine disrupting properties that may cause adverse effect in humans or non-target organism, unless the exposure.....is negligible.*
- *The Commission shall (by 13.Dec.2013) present a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties
.....*



Cosmetic Regulation (2009)

- *When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties*



Biocidal Product Reg. (2012)

- *Active substances shall not be approved if they are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Article 57(f) and 59(1) of REACH as having endocrine disrupting properties”*
- *A biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine disrupting properties*
- *No later than 13 December 2013, the Commission shall adopt scientific criteria for the determination of endocrine disrupting properties*



Medical Devices Reg. (2017)

- *Devices that are invasive and come into direct contact with the human body, administer medicines, body liquids,, shall only contain endocrine disruptors in a concentration that is above 0,1% where justified.*
- *The instructions for use shall contain information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. The information shall cover precautions related to materials incorporated in the device that contain or consist of endocrine disruptors*
- *Additional information shall require justification for use of endocrine disruptors*



Test method development

- *OECD Conceptual Framework for Testing and Assessment of EDs*
- *13 OECD TGs specifically developed or updated for detecting potential EDs*
- *OECD Guidance document No. 150 on standardised test methods for the evaluation of chemicals for endocrine disruption*
- *OECD Fish toxicity testing framework, No. 171 - contains elements for testing for endocrine disruption*
- *OECD Detailed Review Paper on the State of the Science on Novel In Vitro and In Vivo Screening and Testing Methods for Evaluating Endocrine Disruptors, No. 178*
- *DG ENV contractor's analysis of endpoints covered and not-covered by existing test methods*

Research



- Much greater scientific understanding of Eds achieved via EU support of research and development in this field
- Over €120 millions spent in R&D
- Support continues in Horizon 2020

7th Environment Action Programme to 2020

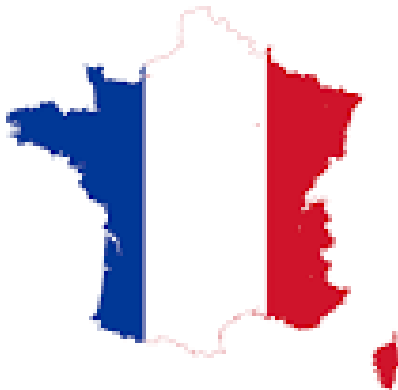


Actions on endocrine disruptors

Member States actions



Parabens



Council Conclusions (2016)



Main current focus

- *Identification of EDs under REACH for 2020*
- *Adoption of the ED criteria*
- *Finalisation of the review of the cosmetics regulation*
- *Progress in test methods and test guidelines*
 - **Series of workshops organised**
- *Supporting research in EDs*
- *Streamlining science to regulatory processes*
 - **EASIS + IPCHEM**



**Thank you for your
attention**