Overview of activities under the Community Strategy for ED

19 February 2014, Brussels

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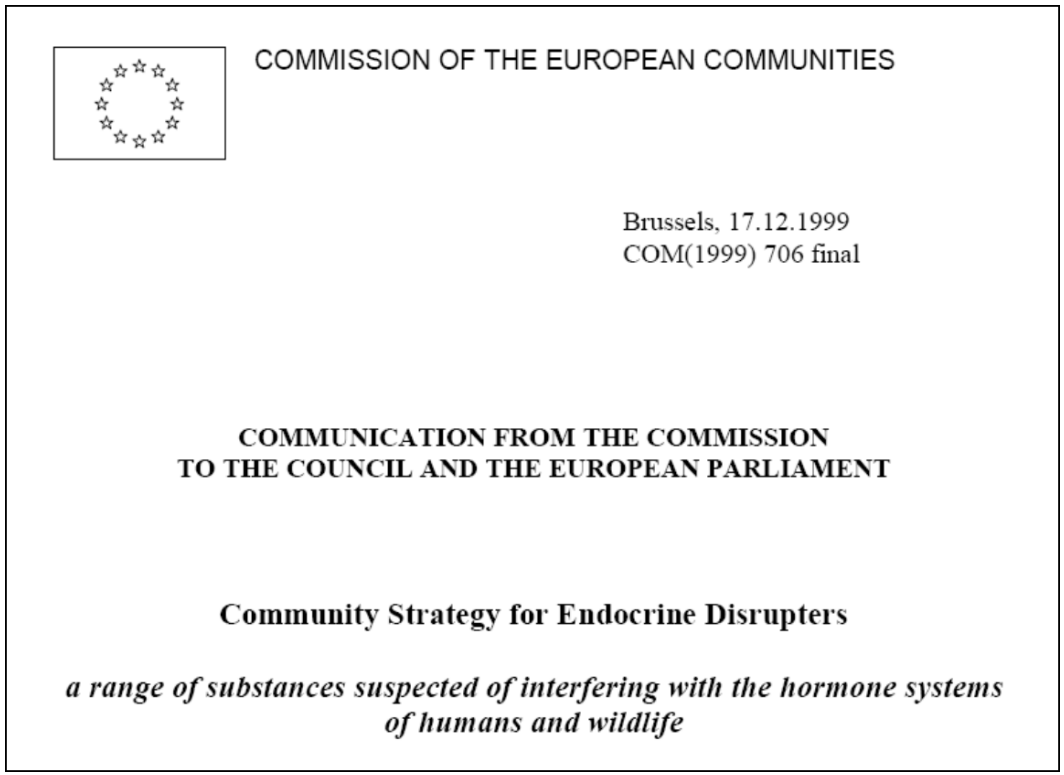
Community Strategy for Endocrine Disruptors



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 Disrupters

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*

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 with ……Article 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 ……..*
- *Provisional criteria*
  - ***carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.***
  - ***toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such 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*
- *Provisional criteria*
  - ***The same as in PPP Regulation***

Test method development

- *OECD Conceptual Framework for Testing and Assessment of EDs*
- *12 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*

Priority list of substances

- *Priority list of substances for their further evaluation of endocrine disruption; database contains some 420 substances*
  - *Class 1 - At least one study published providing evidence of endocrine disrupting effects in an intact organism.*
  - *Class 2 - In vitro data indicating potential for endocrine disruption in intact organisms.*
  - *Class 3 - data with no information in ED or insufficient data*
- *Time for something new*
  - *Endocrine active substances Web Portal (EASIS)*
  - *Change of format and creation of web portal access*
  - *Mechanism for updating and data sharing*
  - *Update of the DG ENV database by new data*
  - *To become a living database/information system*

Current activities

- *REACH review as regards endocrine disruptors*
  - **Required to review the way how endocrine disruptors can be authorised**
- *Development of criteria for identification of endocrine disruptors*
  - **Required by regulations on plant protection products and biocides**
- *Review and possible revision of the strategy*
  - **Need to review whether strategy is fit for purpose**
- Development of test methods under OECD
  - **Although good progress, still a lot to do; need to set priorities**
- Legislative action
  - **Proposal for the medical devices**
- Development and update of EASIS

Process

- *Scientific review*
  - Contract 'State of the art of the assessment of endocrine disruptors', January 2012
- *EU Conference on EDs: current challenges in Science and Policy, June 2012*
- *Consultation bodies: Ad hoc group, Expert group*
- *EFSA's opinion (2013)*
- *Several scientific reports published*
  - EEA, WHO, WHO/UNEP, EFSA, JRC
- Impact assessment for the criteria

Expected Outcome

- *REACH review as regards endocrine disruptors*
  - **In the form of Commission Communication**
- *Criteria for identification of endocrine disruptors*
  - **Implementing measures for BPR and PPPR**
- *Review and possible revision of the strategy*
  - **Commission Staff Working Paper - review**
  - **Commission Communication - revision**
- *EASIS make available for ECHA ED Expert group and update of the data*
- *Workshop/meeting on setting priority for development of test methods*
- *Medical devices legislation to be adopted*

Thank you for your attention