



# *Activities under the Community Strategy for Endocrine Disruptors*

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# Background

- 1996 – Weybridge workshop on impacts of endocrine disruptors on human health and environment
- 1998 – Resolution of European Parliament – call upon the Commission to take specific action in particular with a view to improve the legislative framework, to reinforce research efforts and to make information available to the public
- 1999 – Opinion of SC for Toxicity, Ecotoxicity and the Environment: *“Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods”*
  - ➔ ***Potential global problem***
  - ➔ ***Impaired reproduction and development causally linked to endocrine disrupting chemicals are well-documented***

# Community Strategy for Endocrine Disrupters



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*

# Strategy on Endocrine Disrupters

## ■ Objectives of the paper were:

- To identify problem of endocrine disruption, its causes and consequences
- To identify appropriate policy action on the basis of the precautionary principle

## ■ Four key elements/needs were identified:

- The need for further research
- The need for international cooperation
- The need for communication to the public
- The need for policy action

# Actions

- 6 short term actions
- 3 medium term actions
- 1 long term action

# Establishment of priority list of substances

- 575 substances were nominated by stakeholders as suspected endocrine disruptors in 1999
- 4 contracts (one in 2000, two in 2002 and one in 2007) were commissioned by the Commission to gather scientific evidence on the endocrine disruption of these chemicals
- The reports are available on the DG ENV website

→ [http://ec.europa.eu/environment/endocrine/documents/index\\_en.htm](http://ec.europa.eu/environment/endocrine/documents/index_en.htm)

# Establishment of priority list of substances

## ■ Substances were categorized into 3 classes:

- 1 – At least one study published providing **evidence of endocrine disrupting effects in an intact organism**. Not a formal weight of evidence approach. On the basis of the precautionary approach, substances with insufficient evidence, but chemically closely related to category 1 substances, have been categorized as category 1
- 2 – **Potential for endocrine disrupting effects**. *In vitro* data indicating potential for endocrine disruption in intact organisms. Also includes effects *in-vivo* that may, or may not, be ED-mediated. May include structural analyses and metabolic considerations.
- 3a – **substances with no scientific basis for inclusion in list** (ED studies available but no indications on ED effects)
- 3b – **substances with no or insufficient data gathered.**

# Establishment of priority list of substances

- Database currently contain 428 substances
  - Category 1 – 194 substances
  - Category 2 – 125 substances
  - Category 3a and 3b – 109 substances



# Establishment of priority list of substances

- Transfer of the database to DG JRC
- Change of format and creation of web portal access
- Mechanism for updating, further content, functionalities of the information system need to be decided
- It should serve to all stakeholders (EC, MSs, ECHA, EFSA, EEA, NGOs, Industry, Scientists)
- It should become a living database/information system

# Establishment of monitoring programmes

- Working group on integrated environment and health monitoring for EDs was set-up under the European Environment and Health Strategy in 2003
- Baseline report was prepared
- Recommendations given to develop the Commission's Environment and Health Action Plan 2004-2010
- Financing of human biomonitoring project
- Further integration of environment and health monitoring

# Communication to the public

EUROPA - Environment - Endocrine disrupters - Windows Internet Explorer

http://ec.europa.eu/environment/endo/index\_en.htm

Environment

EUROPA > European Commission > Environment > Chemicals > Endocrine Disrupters

Home Who's who Policies Integration Funding Resources News & Developments

## Endocrine Disrupters Website

How the European Commission uses the precautionary principle to

**Definitions**

- What is the endocrine system?
- Why is it important for life?
- What are endocrine disrupters?
- What areas might they affect?

**Strategy**

- Introduction
- What is being done?/Priority list
- What is the existing approach in the European Community?
- Which programmes/actions are being developed at international level?

**Documents**

- Commission documents
- Studies / Research
- Workshop reports

**Conscious of the potential th...**  
**European Commission adopte...**  
**issue. The subject matter is c...**  
**principles on endocrine disru...**  
**as well as the Commission's s...**

**News & agenda**

- The priority list of substan... as an Access-Database. Th... but also the scientific infor...
- A study to complement the completed end of Decemb... Report: see Strategy - Wh...
- The third implementation r... November 2007 (SEC (20...

Research - Endocrine Disrupters - Homepage - Windows Internet Explorer

http://ec.europa.eu/research/endo/index\_en.html

RESEARCH

European Commission > Research > Endocrine Disrupters

Contact Search

BACKGROUND INFORMATION	EU ACTIVITIES	EU-FUNDED RESEARCH PROJECTS
<ul style="list-style-type: none"> <li>What is endocrine system?</li> <li>What is endocrine disruption?</li> <li>Health effects</li> <li>Useful links</li> </ul>	<ul style="list-style-type: none"> <li>Institutional framework</li> <li>EU strategy on endocrine disruption</li> <li>Environment and health strategy</li> <li>Reach</li> <li>Environment DG</li> <li>Research DG</li> <li>Useful links</li> </ul>	<ul style="list-style-type: none"> <li>Framework programmes</li> <li>Completed projects</li> <li>Ongoing projects</li> <li>CREDO cluster</li> <li>New opportunities</li> <li>More information</li> </ul>

Welcome to the website of the European Commission's Directorate-General of Research which focuses on endocrine disrupter research in Europe. The purpose of this website is to give you an overview of the European Union's many activities in this field.

**NEWS & EVENTS**

- The two FP6 funded projects ECNIS and NewGeneris organize a stakeholder workshop on "Food and Environmental Cancer Risks for Adults and Children", in Brussels, in the context of ECNIS 4<sup>th</sup> Annual meeting in Brussels.

Full details of the event, including the programme and registration details is available at <http://www.newgeneris.org/>

More events

**ENDOCRINE DISRUPTER RESEARCH**  
in the European Union



# Research and development

- More than 80 projects funded via the Community Framework Programme for R&D
- The support started under FP4 programme
- Continued under FP5 and FP6
- Support of research focused on effects, identification and assessment of endocrine disrupting chemicals continues under the 7th Framework Programme
- [http://ec.europa.eu/research/endocrine/index\\_en.html](http://ec.europa.eu/research/endocrine/index_en.html)

# Legislative action

- **REACH (1907/2006) – Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals**

- Most of the provisions currently in force
- Implementation period

- **Regulation on Plant Protection Products 1107/2009**

- Comes into force on the 20<sup>th</sup> day of the publication (24 November 2009)

- **Regulation on biocides**

- Commission proposal in 2009

# Authorisation under REACH

- Substances to be included in Annex XIV (Article 57)
  - CMR cat. 1 or 2
  - PBT (criteria in Annex XIII)
  - vPvB (criteria in Annex XIII)
  - Substances – such as those **having endocrine disrupting properties** or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) – **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 the procedure set out in Article 59.

# Authorisation under REACH

- Identification of substance as Substance of Very High Concern (SVHC)
- Listing of substance in Annex XIV
- Application for authorisation
- Granting the authorisation
  - If risks are adequately controlled (not applicable for PBT, vPvB and non-threshold CMs)
  - Socio-economic benefits outweigh the risks and there are no alternatives available

# Authorisation under REACH

- **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**



# Regulation on Plant Protection Products

- “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, .....
- Within four year from the entry into force of this Regulation, the Commission shall present to the Committee referred to in Article 79 (1) a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79 (4)
- Pending the adoption of these criteria, substances classified as Carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties

# Regulation on Plant Protection Products

- “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 on non-target organism, .....”

# Contract 'State-of-the-art of the assessment of endocrine disruptors'

- Signed in December 2009; Ends August 2011
- The contractor is expected to
  - Analyze scientific literature on endocrine disruptors
  - Analyze approaches to assess endocrine disruptors
  - Draw conclusions and answering policy relevant question

# Contract 'State-of-the-art of the assessment of endocrine disruptors'

- Scientific review of the state-of the art – December 2010
- Overview of assessment methodologies and initiatives – December 2010
- Draft Final report – June 2011
- Final report – August 2011
  
- Consultations of (draft) final report ECHA, EFSA, EMEA, OECD – June 2011

# Identification and assessment of EDs

- Harmonization and validation of testing methods for endocrine disruptors
  - OECD – Working group ‘National Co-ordinators for Test Guidelines’
  - OECD – EDTA AG
- 6 test methods adopted
  - Uterotrophic Bioassay in Rodents: A short-term screening test for oestrogenic properties
  - Repeated Dose 28-Day Oral Toxicity Study in Rodents
  - The Stably Transfected Human Estrogen Receptor- $\alpha$  Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals
  - The 21-day Fish Assay: A short-term screening for endocrine or reproductive activity
  - The Hershberger Bioassay in rats: a short term test for (anti)androgenic properties
  - The Amphibian Metamorphosis Assay

# OECD EDTA AG

- The mandate has been slightly changed
  - ➔ Provide advice to WNT on development of tiered approaches for endocrine disrupters testing and assessment
  - ➔ Regulatory aspects of test guidelines development for endocrine disrupters
- OECD-EDTA Workshop on OECD Countries Activities Regarding Testing, Assessment and Management of Endocrine Disrupters (22-24 September 2009, Copenhagen)
  - ➔ To identify current activities on ED chemicals in the different countries
  - ➔ To analyse how the test guidelines and other tools/data/information are used for different types and levels of decision making concerning identification, assessment and management of endocrine disrupters

# OECD EDTA AG

- 1st meeting of EDTA AG
  - **Development of a draft Guidance document on the assessment of Endocrine Disrupter Chemicals**
  - **Development of a Detailed Review Paper on new Endocrine endpoints**

# Reports on the implementation of Strategy

## ■ June 2001

→ Communication on the implementation COM (2001) 262

## ■ October 2004

→ Staff Working Document on the implementation SEC (2004) 1372

## ■ November 2007

→ Staff Working Document on the implementation SEC (2007) 1635

## ■ December 2010

→ Staff Working Document on the implementation – in preparation



# 2010 report on the implementation of Strategy

- **Progress achieved since 2007**
- **Council Conclusions on Combination Effects of Chemicals (December 2009) in which the Council invites the Commission**
  - to make recommendations as to how exposure to multiple endocrine disruptors should be further addressed within relevant existing Community legislation, inter alia in the context of its forthcoming report on the implementation of the Community strategy on endocrine disruptors to be completed by 2010,

## Next steps

- Further development of the information system on endocrine active substances
- Continue to support research in the field of endocrine disruptors
- Development of harmonized scientific criteria and assessment methodology for identification of endocrine disruptors
- COM proposal of scientific criteria for PPPR
- Review and possible proposals in accordance with Art 138.7 of REACH

# Next steps

- Continue working with OECD
  - **test method validation**
  - **EDTA AG**
- Next report on implementation of EU ED strategy
  - Containing an assessment of how combined effects of EDs are currently addressed
  - Consideration of the need for revision of the EU ED strategy

# ONLY ONE EARTH



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<http://ec.europa.eu/environment/>

