January 2014

EU MILESTONES ON ENDOCRINE DISRUPTING CHEMICALS (EDCS): OFFICIAL COMMITMENTS AND LEGISLATIVE ACTION ON EDCS IN THE EU

October 1998 - the European Parliament adopted a Resolution calling upon the European Commission (EC) to take action on the issue of endocrine disrupting chemicals (EDCs). Among the aims of the Resolution were:

- an improvement in the legislative framework,
- reinforcement of research efforts and
- an increased effort to make information available to the public.

March 1999 - report by the EU Scientific Committee for Toxicity, Ecotoxicity and the Environment (SCTEE). This report, "Human and wildlife health effects of endocrine disrupting chemicals with emphasis on wildlife and on ecotoxicology test methods" identified a potential global problem for wildlife. It stated:

- "Impaired reproduction and development causally linked to endocrine disrupting substances are well-documented in a number of wildlife species and have caused local and population changes."

December 1999 - EC published Community Strategy on EDCs.
"Community Strategy for Endocrine Disruptors - a range of substances suspected of interfering with the hormone systems of humans and wildlife. COM(1999)706" sets out a general framework for studying EDCs.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1999:0706:FIN:EN:PDF

i. **June 2001 - EC adopted a Communication on implementation of the Strategy.** COM(2001)262 covered the time period 1999 to 2001.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0262:FIN:EN:PDF

ii. **October 2004 - the EC published a Staff Working Document on the implementation of the Strategy. SEC(2004)1372** covered the period 2001 to 2003.
http://ec.europa.eu/environment/endocrine/documents/sec_2004_1372_en.pdf

iii. **November 2007 – the EC published a Staff Working Document on the implementation of the Strategy. SEC(2007)1635** covered the period 2004 to 2006.
http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.pdf

iv. **August 2011 - the EC published a Staff Working Document - the 4th report on the implementation of the Strategy. SEC(2011)1001**
http://ec.europa.eu/environment/endocrine/documents/sec_2011_1001_en.pdf

The establishment of a priority list of substances for further evaluation of their role in endocrine disruption has been the key short term action under the Community Strategy. Four studies were published to develop a priority list of substances and to collect hazard information on individual chemicals.

This first step resulted in a study entitled "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting". This is the so-called BKH report.
http://ec.europa.eu/environment/archives/docum/pdf/bkh_main.pdf
It also has 15 annexes which can be found on the following web page:-
http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

A second step resulted in a study entitled "Study on gathering information on 435 substances with insufficient data". Finally a third step resulted in a study entitled: "Study on enhancing the endocrine disruptor priority with a focus on low production volume chemicals". Both of these can also be found on http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

The results of all these studies have now been compiled in a database. This is available for downloading on the following web page:-
http://ec.europa.eu/environment/endocrine/strategy/short_en.htm

December 2006 – Adoption of EU Regulation on industrial chemicals
Regulation EC 1907/2006 deals with the Registration, Evaluation, Authorisation and Restriction of CHemical (**REACH**) substances.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF
It entered into force in June 2007 and one of its aims was to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemicals used in industry. REACH therefore requires a certain amount of pre-market testing of substances, so that there is some information on their toxicity.

Under REACH, chemicals with endocrine disrupting (ED) properties can be brought under strict control by subjecting them to the authorization procedure on a case by case basis (on the initiative of the regulators) (Article 57(f)). Each use of such a chemical would then have to be specifically authorized, although it could be authorized if there was 'adequate control of the risk'. Before being brought through for authorization, chemicals which are agreed to meet the criteria for authorization – the so-called substances of very high concern (SVHC) - can be put on the 'Candidate List'. REACH also mandated a specific review (originally June 2013, now delayed) of how EDCs, subject to the authorization procedure, should be treated, and whether they should all be considered 'non-threshold substances' and blocked from the 'adequate control of the risk' route to authorization (Article 60(3)). This would mean that they could only

be authorized if the socio-economic benefits outweigh the risk *and* if there is no available alternative. (This is the so-called 'socio-economic route') (Article 138(7)).

December 2009 Environment Council 17820/09
With regard to the combination effects of chemicals the ED was invited to to "make recommendations as to how exposure to multiple endocrine disruptors should be further addressed within relevant existing Community legislation" and outline this in the 4th report on the implementation of the Strategy (which was published, see above, in August 2011).
http://register.consilium.europa.eu/pdf/en/09/st17/st17820.en09.pdf

2009 Pesticide Regulation and 2012 Biocide Regulation
Regulation (EC) No 1107/2009 of October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. This regulation on pesticides applied from June 2011.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF

Regulation No 528/2012 of May 2012 concerning the making available on the market and use of biocidal products will apply from 1 September 2013.
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF

Both these regulations mandate the provision of criteria to identify chemicals with ED properties, and such chemicals are specifically subject to very stringent controls. These legislative instruments effectively require that pesticides and biocides with ED properties that may cause adverse effects will be banned unless exposure is negligible (which is very tightly defined for humans). The impact of this strict rule is that industry and industry-friendly policymakers are advocating criteria to identify EDCs that will be very hard to meet.

March 2013 - the EU Parliament adopted a Resolution on EDCs
This Resolution, amongst other things, stated:

- "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."
  http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-91

June 2013 – the 7th Environment Action Programme (7EAP)
The 7th Environment Action Programme was proposed by the Commission in November 2012 (IP/12/1271). In June 2013, Commissioners Janez Potočnik and Connie Hedegaard welcomed the trilogue agreement on the new Environment Action Programme, which identified

priority objectives for the period up to 2020, including addressing environment-related threats to health.

The 7EAP states that “Horizontal chemicals legislation (REACH and the Classification, Labelling and Packaging Regulations) provides baseline protection for human health and the environment and promotes the uptake of evolving non-animal testing methods. However, there is still uncertainty about the impacts on human health and the environment from the combined effects of different chemicals (mixtures), nanomaterials, chemicals that interfere with the endocrine (hormone) system (endocrine disruptors) and chemicals in products. In recent years, more information has come to light on the need for action to deal with these challenges, especially if the EU is to attain the goal agreed at the World Summit on Sustainable Development in 2002, and reaffirmed at the Rio+20 Summit, to have ensured ‘the minimisation of significant adverse effects’ of chemicals on human health and the environment by 2020 and to respond to new and emerging issues and challenges in an effective, efficient, coherent and coordinated manner. The EU will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors and set out a comprehensive approach for minimising adverse effects of hazardous substances, including chemicals in products, supported by a comprehensive chemical exposure and toxicity knowledge base.”

Commission web site for the new EU Environment Action Programme to 2020:
http://ec.europa.eu/environment/newprg/index.htm

THREE RECENT KEY EU PUBLICATIONS ON THE CRITERIA TO IDENTIFY EDCS

1. **In 2012, DG Environment published the “State of the Art of the Assessment of Endocrine Disruptors”** providing a basis for i) the development of scientific criteria for the identification of endocrine disruptors; and ii) the review and possible revision of the Community Strategy on Endocrine Disruptors. This review was undertaken by Professor Kortenkamp’s team.
   http://ec.europa.eu/environment/endocrine/documents/4_SOTA%20EDC%20Final%20Report%20V3%206%20Feb%2012.pdf
   Annex 1: Summary of the state of the science
   http://ec.europa.eu/environment/endocrine/documents/4_Annex%201%20Summary%20State%20of%20Science%20ED%20V6.pdf
   Annex 2: Summary of expert consultations on approaches to the regulatory assessment of endocrine disruptors
   http://ec.europa.eu/environment/endocrine/documents/4_Annex%202%20Summary%20of%20Expert%20Consultations%20V2.pdf
   Annex 3: Comparative analysis of endpoints and assays by human health and wildlife endpoint
   http://ec.europa.eu/environment/endocrine/documents/4_Annex%203%20Comparative%20analysis%20V%202.pdf

2. **February 2013 – EU Endocrine Disruptor Expert Advisory Group (ED EAG)**
   The ED EAG was established in November 2011 as a sub-group of the ad hoc group of EC Services, EU Agencies and Member States. It included participants from various Member States and stakeholders and was chaired by the Joint Research Centre (JRC) of the EC. Its report entitled "Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances" accepted that the elements for identification of an EDC were demonstration of an adverse effect for which there was convincing evidence of a biologically plausible causal link to an endocrine disrupting mode of action and for which disruption of the endocrine system was not a secondary consequence of other non-endocrine-mediated systemic toxicity. It concluded that factors such as potency, severity, irreversibility and lead toxicity were not considered part of the identification of an EDC.
   http://ec.europa.eu/dgs/jrc/index.cfm?id=1410&dt_code=NWS&obj_id=16530&ori=RSS

   2b. ED EAG Report on Thresholds
   This was originally planned to be included in the main report of the group, but due to time constraints it was finalised later. A draft of the report is available on the Commissions web site called 'CIRCABC' and can be found by searching for the document entitled "Thresholds for Endocrine Disrupters and Related Uncertainties." Unfortunately, as of the start of 2014 the final version was still not on the JRC website.

3. **March 2013 – European Food Safety Authority (EFSA) scientific opinion on EDCs.**
   The EFSA opinion on "Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment".
   http://www.efsa.europa.eu/en/efsajournal/doc/3132.pdf
   It made 2 particularly controversial or contentious points. Firstly, the definition of endocrine active substances (EASs) is different to that of EDCs, in that it said an EAS was a substance having the inherent ability to interact or interfere the endocrine system resulting in a biological effect, but which need not necessarily cause adverse effects, whereas for a chemical to be considered an EDC there would need to be reasonable evidence for a biologically plausible causal relationship between the endocrine activity and the induced adverse effect(s) seen in an intact organism. Secondly, despite the EU Pesticide and Biocide Regulations having already agreed to a hazard based approach, this EFSA opinion suggested that EDCs can "be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment."

EUROPEAN COMMISSION WORKSHOPS & CONFERENCES

WEYBRIDGE - December 1996
European Workshop on the impact of endocrine disruptors on human health and wildlife
This invitee only workshop was supported by the EC, the European Environment Agency (EEA), the WHO, OECD, national authorities and agencies of the UK, Germany, Sweden (Chemicals Inspectorate) and The Netherlands, as well as CEFIC and ECETOC.

- Conclusions and Recommendations
  http://ec.europa.eu/environment/endocrine/documents/reports_conclusions_en.htm

ARONSBORG - June 2001
European Workshop on endocrine disruptors
This invitee only workshop was held by the EC with sponsorship from Swedish Ministry for Environment, Swedish National Chemicals Inspectorate (KEMI), OECD, WHO and the EEA.

- Conclusions and Recommendations
  http://ec.europa.eu/environment/endocrine/documents/workshop_conclusions_en.htm

HELSINKI – November 2006
An international conference (dubbed Weybridge +10) was held under the auspices of the Finnish EU presidency in November 2006. This workshop organised by the Academy of Finland, European Commission's Directorate-General for Research and the EEA (European Environment Agency) brought together international experts and policy-makers from EU Member States to assess new research findings, identify knowledge gaps, define future research priorities and consider the implications for policy-making and chemicals regulation. However, it did not release a consensus statement as such.

BRUSSELS – June 2012
The European Commission organized a conference on "Endocrine Disruptors: Current challenges in science and policy" in 2012. This was to feed into the review of the European Commission's strategy on endocrine disruptors and to provide input to the Commission's proposal for criteria for the identification of substances with endocrine disrupting properties.

Gwynne Lyons
gwynne.lyons@chemtrust.org.uk