Endocrine Disruptors – Developments in EU Law

Ruxandra Cana

Annual Chemicals Regulation Seminar
Product Defense for REACH and Biocides
April 1, 2015 – Brussels

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

Steptoe
STEPTOE & JOHNSON LLP

Content

- **Status quo**
- **Developments so far**
- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

Status Quo

Status Quo

- Endocrine disruptors are referred to in four legal acts under EU law
  - REACH ((EC) No 1097/2006)
  - EU Plant Protection Products Regulation (PPPR) ((EU) No 1107/2009)
  - EU Biocidal Products Regulation (BPR) ((EU) No 528/2012)
  - EU Cosmetics Regulation ((EU) No 1223/2009)
- These are legislative acts (adopted by the European Parliament and EU Council (composed of Member States representatives))

Status Quo

REACH

- **Article 57(f):** "*The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:* […] *(f) 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 to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59" (emphasis added).*

- **Article 138(7):** "*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) 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*" (emphasis added).

Status Quo

EU Plant Protection Products Regulation

- **Article 23(1):** *"For the purpose of paragraphs 2 to 6, a basic substance is an active substance which: ([…];(b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects"* (emphasis added).

- **Section 3.6.5 of Annex II on the procedure and criteria for the approval of active substances, safeners and synergists**

- *An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.* ***By 14 December 2013, the Commission shall present*** *to the Standing Committee on the Food Chain and Animal Health 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 that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008,* ***as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties****. In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as* ***toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered*** *to have such endocrine disrupting properties" (emphasis added).*

Status Quo

EU Biocidal Products Regulation

Article 5(1) on exclusion criteria: "*Subject to paragraph 2, the following active substances shall not be approved: (d) active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties*" (emphasis added).

- **Article 5(3):** "***No later than 13 December 2013, the Commission shall adopt*** *delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties. Pending the adoption of those criteria, active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as* ***carcinogen category 2 and toxic for reproduction category 2 shall be considered*** *as having endocrine-disrupting properties. Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as* ***toxic for reproduction category 2 and that have toxic effects on the endocrine organs may be considered*** *as having endocrine-disrupting properties*" (emphasis added).

- **Article 19(4):** "*A biocidal product shall not be authorised for making available on the market for use by the general public where:* […] *(d) it has endocrine-disrupting properties*"

Status Quo

Cosmetics Regulation (EU) No 1223/2009

- **Article 15(4):** "*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*".

Status Quo - Conclusions

- The European Parliament and the EU Council have requested the European Commission to adopt “delegated acts” relating to endocrine disruptors
  - To adopt the definition for pesticides (agricultural and non-agricultural) – by December 2013
  - To decide whether ED should be restricted automatically under REACH – by June 2013
  - To review the EU Cosmetics Regulation – if scientific consensus, or at the latest by January 2015
- What has the European Commission done so far?

Developments So Far

Developments So Far

- Scientific bodies / advisors to the European Commission
- The European Commission
- Member States

Developments So Far

Scientific bodies/advisers to the European Commission

- March 2013: Scientific Opinion by EFSA
  - Endorsing WHO definition, recognizing the possibility of threshold effects
- 18 June 2013: Letter to Ann Glover, Chief Scientist to the European Commission President Barroso
  - Letter signed by 70 scientists highlighting the lack of consultation of scientists in defining a regulatory framework for endocrine disruptors
- 24 October 2013: Minutes from meeting between Ann Glover and experts
- 16 December 2014 Memorandum by Scientific Committee on Consumer Safety (in the framework of the EU Cosmetics Regulation)

Developments So Far

Scientific bodies/advisers to the European Commission (cont'd)

- ECHA Endocrine Disruptors Working Group (independent experts)

2014

- 1st meeting: 13-14 February 2014
- 2nd meeting: 22-23 May 2014
- 3rd meeting: 11-12 November 2014

2015 – Upcoming meetings

- 4th meeting: 24-25 February 2015
- 5th meeting: 3-4 September 2015 (tbc)
- 6th meeting: 21-22 October 2015 (tbc)

Developments So Far

European Commission

- April 2014 European Commission conclusions on the opportunity of reviewing the REACH Regulation to include non-threshold concept for EDs (no review necessary at this stage, see minutes of Caracal meeting of 2-3 April 2014)

- June 2014 European Commission Roadmap for criteria for EDs for Plant Protection Products and Biocidal Products
  - Public consultation open from September 26, 2014 to January 16, 2015.

Developments So Far

Member States

- June 2014: France urges action from Commission on EDC in a Council document (supported by the Swedish and Danish delegations)
  - Explaining the importance of endocrine disrupting properties in France

- 4 July 2014: Legal action introduced by Sweden against the European Commission, before the EU General Court, for failure to adopt ED criteria under the EU BPR – pending

- October/November 2014: Open letter by Sweden and other Nordic State to the Commission urging for action on endocrine disruptors.

Questions?