Endocrine disruptors – references in EU law

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Outline

1. Legal references
2. Developments so far
3. What can be expected?
1. References to endocrine disruptors in EU law
Overview

- Action on endocrine disruptors is requested in four Regulations under EU law
  - REACH Regulation ((EC) No 1097/2006)
  - Biocidal Products Regulation (BPR) ((EU) No 528/2012)
  - Cosmetics Regulation ((EU) No 1223/2009)

- These are legislative acts (adopted by the European Parliament and EU Council (composed of Member States representatives)
REACH Regulation

- **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).
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

(…) 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).
Biocidal Products Regulation

**Article 5(1)** on exclusion criteria: “…*the following active substances shall not be approved: […]* (d) active substances which, on the basis of the criteria specified pursuant to […] 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 No 1907/2006 as having endocrine disrupting properties.”

**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”
Cosmetics Regulation

- **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 criteria 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 Cosmetics Regulation – if scientific consensus, or at the latest by January 2015

- What has the European Commission done so far?
2. Developments So Far
Developments So Far

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

1. European Food and Safety Agency

- **March 2013**: Scientific Opinion
  - Endorsing WHO definition, recognizing the possibility of threshold effects

- **21 September 2015**: Report on assessment of endocrine disrupting properties in EFSA conclusions

- **23 September 2015**: EFSA Press release on work advancement
Scientific bodies/advisers to the European Commission

2. Scientific advisers

- **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)
Scientific bodies/advisers to the European Commission

3. ECHA Endocrine Disruptors Working Group

2015

- 4th meeting: 24-25 February 2015
- 5th meeting: 2-3 September 2015
- 6th meeting: 21-22 October 2015

2016 – upcoming meetings

- 7th meeting: 21-22 April 2016 (TBC)
- 8th meeting: 28-29 September 2016 (TBC)
- 9th meeting: 10-11 November 2016 (TBC)
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
  - case pending

- **October/November 2014**: Open letter by Sweden and other Nordic States to the Commission urging for action on endocrine disruptors.
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 26 September 2014 to 16 January 2015.
  - Over 27,000 replies received (over 25,000 replies via NGO campaigns)

- **October 2015** European Commission Work Programme 2016
  - Commission will “conclude” complex preparatory work and “follow up on it”
3. What Can be Expected?
What Can Be Expected?

REACH

- Continued activity in the ECHA Working Group on ED, resulting in
  - New inclusions in the [SVHC list](#) (a number of substances identified already) and
  - New inclusions in the [Authorisation list](#) - DEHP was identified as an “endocrine disruptor” in Annex XIV to the REACH Regulation
  - Continued investigation of suspected ED under REACH Substance Evaluation procedure (initiated by [CoRAP listing](#))

PPPR/BPR

- AS evaluations / EFSA conclusions - may need to be re-evaluated

Action by individual Member States?

- In principle not, because EU law fully harmonized (no scope for national legislation) – but…
What To Be On The Look-out For?

- Any discussions in formal committees/groups referring to your substance as an identified/potential ED
  - In particular, discussions in the ECHA Working Group on ED (check agenda, request access to documents if not available)

- Evaluation of active substances (pesticides or biocides) by Member States or ECHA

- REACH Annex XV dossiers for inclusion of a suspected ED on the SVHC list or on Annex XVII (restrictions)

- Inclusion on the CoRAP as a suspected ED
Take Away Messages

- European Commission Roadmap:
  
  « *The first problem addressed in this initiative is the absence of criteria for ED in the BPR and the PPPR, while ED are regulated in these pieces of legislation.* »

- High degree of (legal) uncertainty!

- Processes feed into one another – build up a consistent scientific/technical/legal argumentation early on

- Opportunities to comment and remedies are available
Questions?