

Regulatory Update

Gregory Moore
Food Packaging Forum
Zurich
8 October 2015

About Kemi

- Swedish Agency under the Environment and Energy Department
- Established in 1986
- National, EU and international work
- Human Health and Environment
- Competent Authority for PPPR, BPR, REACH, CLP
- Approvals, Risk Assessment/Management, Enforcement, development of regulations
- Non-Toxic Environment (2010 - - 2020)
- ca 250 employees
- www.kemi.se

Content

- What has been happening since 2009
- Commission's activities on development of criteria
- Sweden's activities in dealing with EDs criteria work

Basic requirements

- Definition
 - What to regulate
- Test information
 - How to detect it
- Criteria
 - How to translate test outcomes into regulation

REGULATION (EU) No 1107/2009

Plant Protection Products Regulation (1)

- **Interim criteria:** *“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.”* [see art 3.6.5. and 3.6.4]
- **Scientific Criteria:** *“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 “*

COMMISSION REGULATION (EU) No 528/2012 Biocide Products Regulation

- Active substances which, on the basis of the criteria 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;.....
- **Interim criteria** apply for Human Health
- 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.**

Development of criteria up to the end of 2013

- DG ENV (2011-2014), DG SANCO
 - Revision of Community strategy for ED (2011)
 - Endocrine Disruptors Expert Advisory Group
 - *”State of the Art Assessment on Endocrine Disruptors”*, Kortenkamp *et al.* 2012
 - WHO/UNEP report (*”State of the Science of Endocrine Disrupting Chemicals”* 2012)
 - EFSA Scientific Committee (Opinion, March 2013)
 - **June 2013, Stop!**
 - October 2013, Scientific Agreement (Anne Glover)
 - Scientific Critique and Rebuttal (2013--)

Sweden's reaction

- Sweden Sues COM
 - Letter to Commissioners for the Environment, and for Industry and Entrepreneurship from SE and DK Environmental Ministers, Oct. 2013
 - Swedish government lawsuit against the EU Commission for failure on developing EDC criteria, July 2014
 - Council, Parliament, FR, FI, DK, NL join EDC court case 2015
 - ... and now?

Other reactions, changes and actions

- NGOs accuse COM of Die Spiegel accusation/rebuttal
- DG SANTE responsible 2014 (Junker COM)
 - Road Map 2014
 - Impact Assessment
 - Definition
 - Criteria options
 - Regulatory Options

Other reactions, changes and actions

- Public Consultation 2014
- Meetings 2015:
 - Roundtables (x3): NGOs, MS, MEPs
 - EDC Conference, June 2015
 - Screening methodology, Nov 2015
- Criteria by...2017

The WHO IPCS Definition (2002)

- *“An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub)populations.”*

Commission's proposal of criteria

- Option 1. No change (keep interim rules)
- Option 2. WHO/IPCS definition
- Option 3. WHO/IPCS definition including division into three categories based on strength of evidence for EDCs
- Option 4. WHO/IPCS definition, limited by a substances having a specified potency

Regulatory Options

Three alternatives for implementation of criteria:

- Option A – Implement criteria without other changes of the regulations
- Option B – Implement criteria combined with additional requirements for risk assessment
- Option C – Implement criteria combined with requirements for further socio-economic considerations

Summary/Conclusion

- Criteria are urgently required
- Await conclusion on Swedish lawsuit
- KemI (SE) supports Criteria Option 3
 - WHO/IPCS definition including division into three categories based on strength of evidence for EDCs
- Open meeting for scientific experts needed
- IA should be Transparent, Thorough and Objective