Regulatory Update

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Food Packaging Forum
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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
  - 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