Endocrine Disruptors: Industry workshop outcomes

Markus Junker, BASF SE

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Industry Workshop

Industry Workshop on Endocrine Disruption & Developing European Regulatory Policy

3 May 2012, Brussels

- One day cross-industry workshop organized by CEFIC EMSG (Endocrine Modulators Steering Group)

- Presenters:
  EU Law Attorney
  American Chemistry Council
  ECETOC
  Exponent
  CEFIC LRI (Long-range Research Initiative)
  CEFIC MIAT (Mixtures Industry Ad-hoc Team)

Industry Workshop

- **First half of the day**
  a) Political background
  - Commission strategy
  - Global developments

  b) Scientific background
  - Proposals from various competent authorities and stakeholders especially the approach developed by industry

Presentations are available under the following link:
http://sendit.cefic.org/DMZ/DownLoad.aspx?UID=72b4d5b2-a08d-4df0-9293-e0f79c0600bd

- **Second half of the day**
  Four break-out sessions:
  Develop Industry Engagement and Advocacy Positions – Answer four relevant controversial issues for the further EU process

Break-out session 1

What are the health effects / new endpoints?

- Is there is evidence supporting that industrial chemicals are responsible for increased occurrence of diseases, e.g. obesity, diabetes, ..?
  - no robust data indicating exposure to industrial chemicals are associated with conditions such as obesity or diabetes
  - Some epidemiology studies are available but not pass quality criteria
- Testing methods have been proposed by OECD: should the industry embrace these endpoints? Why (not)?
  - Studies to detect E-A-T modes of action have been established and applied to toxicology investigations
  - Industry follows developments of new test methodologies and will embrace and use new methods and technologies when scientifically justifiable and provide accurate and reproducible toxicological effects

Break-out session 2

How do we deal with threshold / low dose question?

- Is “threshold” or “low dose” the correct term?
  - Need to keep the concept of threshold alive, it is the concentration above which a noticeable effect is triggered
  - Still no definition for “low dose” is available
- How to prove an absence of low dose effects?
  - It is difficult to prove the absence of effects
- Examples for postulated low dose effects? Where is the evidence for both environment and human? Where is the control?
  - There are still no scientific proves for low dose effects
- What about independent replication of low dose effects?
  - Nothing is proven without independent replication

Break-out session 3

What are our proposed regulatory approaches?

- What additional steps can be taken to operationalize the ECETOC approach for regulatory application and advocacy during the Commission process?
- Consider e.g. adversity, potency, specificity, severity, irreversibility ?
- Highlight areas of agreement and conflict with MS proposals
  - The group agreed that the ECETOC approach is scientifically sound and a good basis for technical discussions. Additional technical support may be required around the questions of thresholds for endocrine effects.
  - However, it should be acknowledged that the different legislative texts vary so that some differentiation of approach may be required but the basic scientific principles should be the same.

Break-out session 4

Classification: is it necessary, is it possible for EDs?

- Does CLP already cover ED?
  - Preferred position: Yes, no specific new C&L changes needed
  - Compromise positions:
    a) If CLP change is needed, synchronization within GHS needed, will take long time
    may broaden / globalise ED focus?
    b) Modified STOT and CR as tool for covering endocrine?
    New H-phrases incl. specification like “H3XXFE”?
    added to existing endpoint; E and e for potency differentiation
    What about ecotoxicology? Should be adverse effect driven incl. taxonomic group

THANK YOU FOR YOUR ATTENTION !