Implementing the EDC criteria – an NGO perspective

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Contents

- Critical points in the guidance for ED identification
- The new EU Framework on EDs - what to expect?
- Priorities for speeding up regulatory controls
• Involved in ED criteria debate since the beginning
• JRC Advisory group on ED criteria (2012-2013)
• ECHA ED expert group
• OECD EDTA
e.g. EFSA, 2013:
´101 out of 287 screened pesticides affecting thyroid system´

Critique ED criteria

- Denmark + Sweden: *no satisfactory level of protection*
- Endocrine Society: *no categories, unrealistic amount of evidence required*
- NGOs: *too high burden of proof (paralysis by analysis)*

The original text of EU law required pesticides not to be approved if they had ED properties *that may cause adverse effects.*
ED Guidance: 3 major concerns

1. Role of mode of action analysis in the identification

2. Due consideration of multiple modes of endocrine action

3. Sufficient data to conclude?
1. Mode of action analysis

- Finding out detailed mechanism can take decades (e.g. TBT)
- Regulators must not require each step in a MoA to be known, before the adverse effects can be judged to be a plausible consequence of the endocrine activity

- Final guidance contains the following useful clarifications:
Key Paragraphs in the EU Guidance on Identifying EDCs (1)

• “To conclude on the biological plausibility of the link, it may not be necessary to have demonstrated for the substance under evaluation the whole sequence of events leading to the adverse effect (p37).”
Key Paragraphs in the EU Guidance on Identifying EDCs (2)

• “In the case of adversity based on EATS mediated parameters, the underlying knowledge of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis (p40)”
2. Multiple modes of action

- Is it really feasible to investigate each ED mode of action in isolation?

- Many substances seem to interfere with more than one pathway and have multiple MoAs

- Crucial for ED identification are the effects on hormone sensitive tissues, irrespective if one or several MoAs

> Final guidance contains the following useful clarification:
“There may be also situations where an adverse effect has been identified which, based on current knowledge, is highly likely to be E, A or S but due to the complexity and cross talk of the endocrine system it is difficult to identify the specific modality. In such cases, this should be considered an ED regardless through which modality the substance causes adversity.” (p40)
3. Sufficient data to conclude?

- Ambiguity: data from old versions of test guidelines often not sufficient to identify or rule out ED properties

- Delays expected for requiring new information during the assessment
General limitation: EATS focus

The EU Guidance document largely refers to EATS modalities. However:

- “It may, in some cases, be already possible to reach a conclusion on a non-EATS endocrine modality” (p6)
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The new EU framework on EDs - what to expect?

Relevant for EDs beyond biocides and pesticides, e.g. in toys, cosmetics, food contact materials

EC Communication, 7th November:
Towards a EU Framework on EDs
Overview of past and current activities +
New initiatives as part of strategic approach for years to come:

- Fitness check: identify gaps and synergies in EU laws
- Stakeholder Forum on EDs
- Explore inclusion of ED in GHS
- EU Webportal and information campaigns

CHEM Trust view

- **minimising overall exposure** of humans and the environment to EDs

- Lack of targets, specific measures and timelines

- Lack of focus on addressing cumulative exposures

8 Points for a new EU EDC Strategy

1. Protect public health and reduce exposures to EDCs
2. Increase citizen`s awareness
3. Improve laws: Close gaps for cosmetics, food packaging, consumer products, toys
4. Tackle combination effects and move to mixture assessment
5. Speed up testing and screening of EDCs
6. Work towards a non-toxic circular economy
7. Promote safer substitutes
8. Monitor health and environmental effects

Critical points in the guidance for ED identification
The new EU Framework on EDs - what to expect?
Priorities for speeding up regulatory controls
Speed up testing and screening

a) Adapting test requirements in biocides and pesticides law with more sensitive ED endpoints

b) Develop more tests with endpoints relevant to human diseases (useful work at OECD and new EU Horizon2020 projects)

Need more non-animal tests  ↔  Need to show adversity in intact organism
Setting priorities for further development and validation of test methods and testing approaches for evaluating endocrine disruptors

Final Report

Need for group approach

- CHEM Trust “Toxic Soup” report, on regrettable substitution of one bisphenol by another

- Important for a circular economy with confidence in recycled products

www.chemtrust.org/toxicsoup
Some companies are fighting yesterday`s battles instead of moving to safer alternatives

Plastics Europe started 3 court cases against ECHA in 2017 and 2018 for identifying BPA as

- reprotoxic chemical
- an ED for human health
- an ED for the environment

@pcbpagroup (BPA manufacturers)

Is this a sustainable and responsible approach?
Conclusions

- ED guidance: useful basis, remaining concern over amount of evidence required to make conclusion
- Work on identifying EDs will be very slow and EDs will remain on the market for many years
- Initiative for new ED framework lacks targets and measures
- Need more effective regulatory controls (including grouping)