



Guidance Document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors

Dr. José V. Tarazona
Head Pesticides Unit

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1. BACKGROUND

- The legislations on **pesticides** and **biocides** include both hazard and risk based criteria for pre-marketing approval
- The hazard based criteria are leading **to non- approval without risk assessment** or approval under restricted conditions
- The hazard criteria includes substances **identified as endocrine disruptors**
- In June 2016 EC published a proposal for establishing science-based criteria



2. HUMAN HEALTH DRAFT CRITERIA

- **Endocrine disrupting properties that may cause adverse effect in humans**
- it shows an **adverse effect** in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
- it has an **endocrine mode of action**, i.e. it alters the function(s) of the endocrine system;
- **the adverse effect is a consequence of the endocrine mode of action.**



2. WEIGHT OF EVIDENCE APPROACH

- relevance of the study designs; quality and consistency of the data; positive and negative results; coherence of the results within and between studies and across different species; route of exposure, toxicokinetic and metabolism studies;
- the **biological plausibility of the link** between the adverse effects and the endocrine mode of action;
- the concept of the limit dose, guidelines on maximum recommended doses and for assessing **confounding effects of excessive toxicity**;
- adverse effects that are **non-specific secondary consequences** of other toxic effects shall not be considered



3. MANDATE

- EFSA and ECHA (European Chemicals Agency responsible for biocides) were mandated on 18 October 2016 to produce a **join guidance document**
- The guidance will be applicable to **pesticides and biocides**
- The guidance covers the **hazard identification**
- The public consultation on the draft guidance should be conducted after publication of the final criteria
- The scientific principles are common and can be relevant for other chemicals if a decision on the hazard properties, not the risk, is relevant



4. SCOPING PAPER

Scoping paper, published in December 2016

- Process for drafting the guidance
- Consultations
 - EFSA and ECHA bodies
 - MS
 - Other stakeholders
 - Public
- Finalisation of the guidance
- Adoption for regulatory use



5. DRAFTING PROCESS

- Drafting group of ESFA/ECHA/JRC scientific staff
- Comments from ECHA/EFSA Consultation Group:
 - EFSA MS risk assessors and Stakeholder experts
 - ECHA ED Expert group
- Possible *ad hoc* involvement
 - PPR Panel and their WGs on request, targeted according to the expertise
 - To be extended to the SC
- Supported by a grant with BfR



5. CONSULTATIONS & FINALISATION

- Public consultation
 - Option for a dissemination activity (Meeting/Web)
- Workshop with MSs
 - RMS to present and discuss case-studies
- Formal consultation (for comments, not for endorsement)
 - EFSA SC and PPR Panel, Pesticides Steering Network
 - ECHA Committees (BPC)
- Finalisation by EFSA and ECHA
- Adoption process to be further defined



5. SCOPE

- Limited scope: due to short timeline
 - Focus on EATS pathways (Estrogen, Androgen, Thyroid and Steroidogenesis) in line with SC recommendations
 - For (non-target) organisms limited to vertebrates, including mammals, fish, birds, amphibians and reptiles.
- Use of OECD 150 GD and other available documents
- Description of the information sources for ED identification
- Hazard identification strategy for endocrine disrupting properties (how to construct the WoE)



6. UPDATE ON CURRENT STATUS

■ First consultation (MS and stakeholders) concluded in early May

1. [Placeholder for introduction]
2. [Placeholder for the scope]
3. [Placeholder for definitions]

4. Information sources for ED identification

5. Hazard identification strategy for endocrine disruptors

6. [Placeholder for recommendations]

Comments without duplications	1320
Ch4	590
Ch5	638
General excl Ch4 Ch5	72
General incl Ch4 Ch5	103
Annexes incl. Examples	7
References	2



6. UPDATE ON CURRENT STATUS

■ Next steps

- ECHA/EFSA/JRC drafting group already considering the comments
- Next draft (full guidance document) expected to be ready for the second consultation by mid July
- 2nd Consultation (MSs and stakeholders) to be launched from Mid July to end of August
- Draft for public consultation expected by early October



Thank you