Endocrine Disrupting Chemicals

– *the European regulatory environment*

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Endocrine Disrupting Chemicals
– the European regulatory environment

European Crop Protection

- **WHY –** ***Background***
- **HOW –** ***Impact assessment***
- **WHAT –** ***Proposal***
- **WHO –** ***…will be impacted –sectors***
- **WHEN –** ***Timelines for adoption***

Health warning!

- **The European Union has introduced legislation which include hazard based criteria for endocrine disruption**
  - There will be regulatory consequences and an impact on business
  - current policy discussions will determine what those consequences and impacts will be…

Background (2002)

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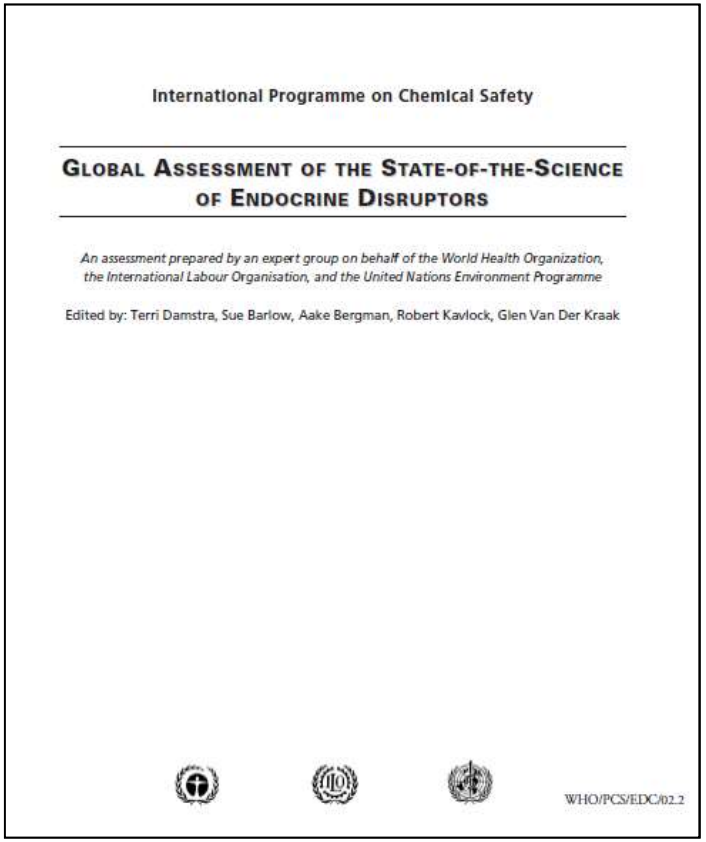
WHO-IPCS

Includes definition of EDCs:

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


International Programme on Chemical Safety

GLOBAL ASSESSMENT OF THE STATE-OF-THE-SCIENCE OF ENDOCRINE DISRUPTORS

An assessment prepared by an expert group on behalf of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme

Edited by: Terri Damstra, Sue Barlow, Aake Bergman, Robert Kavlock, Glen Van Der Kraak

WHO/PCS/EDC/02.2

Background (2009)

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Pesticides Regulation (1107/2009)

- *By 14 December 2013, the Commission shall present […] a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties […]*

- **Similar measure in Biocides Regulation (528/2012)**

Background (2012)

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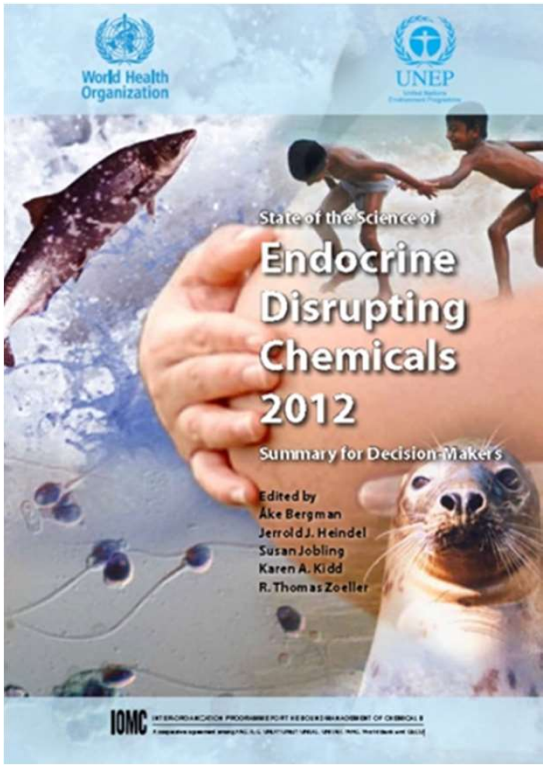
- **WHO/UNEP report in 2012 raised global concerns on ED chemicals**



Background (2013)

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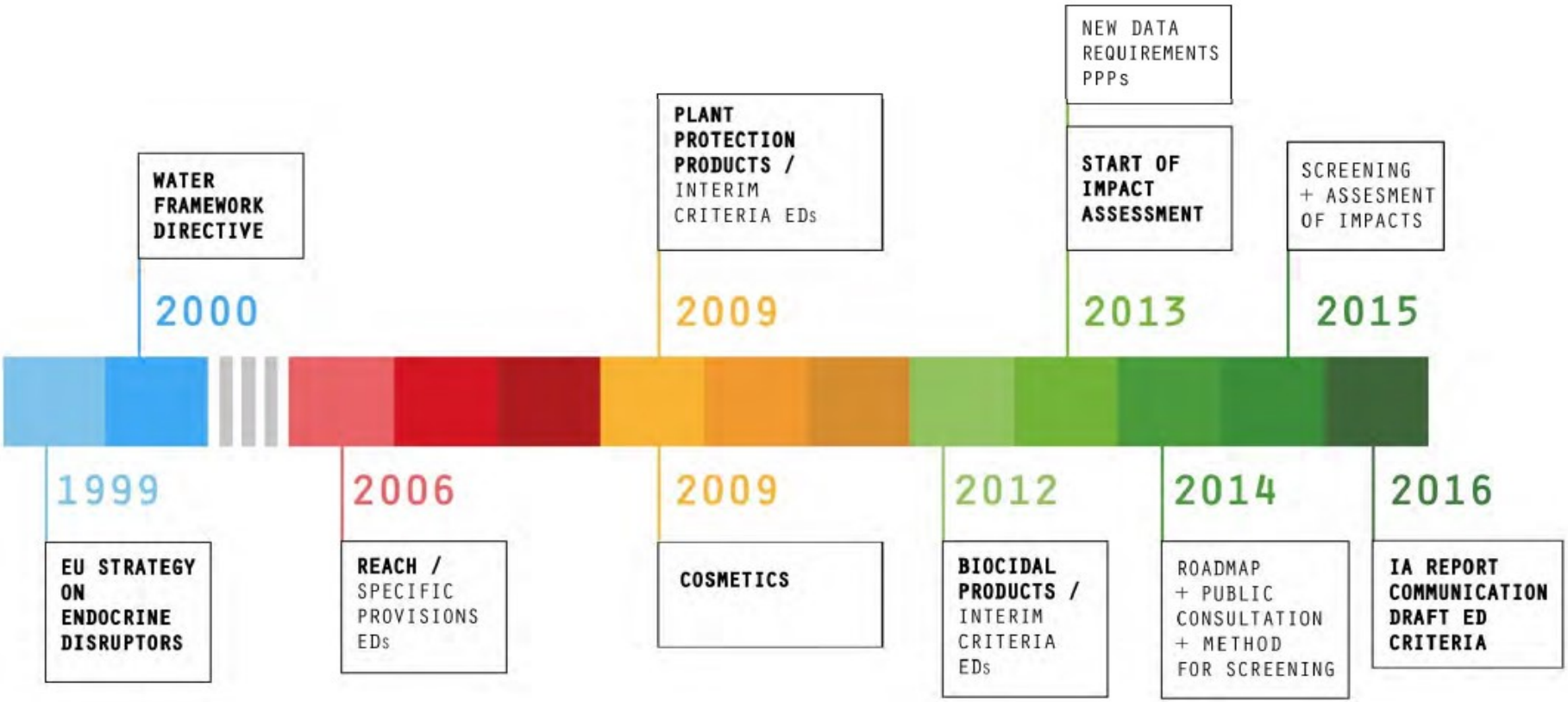
European Food Safety Authority:

Critical effect, severity, (ir)reversibility and potency aspects are part of the hazard characterisation of endocrine disruptors. To inform on risk and level of concern for the purpose of risk management decisions, risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information.

Endocrine disruptors can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment.

ED in EU legislation



Food Safety

Source: European Commission

Impact assessment
- *Options*

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Impact assessment looked at four policy options:

Option	Details/Comments
1	No criteria specified; the interim criteria apply (C2 and R2 or R2 with adverse endocrine effects)
2	Category based on WHO/IPCS definition
3	Multiple categories based on the WHO/IPCS definition. **(Category 1**: endocrine disruptors ; **Category 2**: suspected endocrine disruptors; **Category 3**: endocrine active substances);
4	WHO/IPCS definition to identify EDs and inclusion of potency (hazard identification and characterization)

Impact Assessment

- *Numbers of active substances*

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Detailed evaluation of substances

- ~700 substances screened:
  - **347 PPPs**
  - 98 biocides
  - ~250 sample of REACH and cosmetics substances

26 PPP substances 'caught' by option 2

- Less than expected – MoA data will identify more
- Actual evaluation more conservative…?
- ***Upper limit: 50% of all substances!***

Impact Assessment

- *How the options fared*

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Criteria	Most favorable	Least favorable
No substances impacted	4	1
No PPPs impacted	4	2/3
No crops impacted	4	2/3
Protection of human health	2/3/4	1
Micotoxins control in food	4	1
Overall environmental protection	Lack of indicators	
Water quality	1	4
Wildlife protection	2/3/4	1
Animal welfare	1/2/4	3
Competitiveness of EU agric	4	1
Sectorial competitiveness	4	1
International trade	4	2/3/1
PPP vs. BP coherence	4	1
Compliance with internat obligations	4	2/3/1

** Where option 3 is mentioned, category I is implied (= Option 2)*

Option 4 better than all others!

Commission proposal
- *Steps*

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- **June 2016:** Initial proposal (with impact assessment)
- **October 2016:** 1st revision (re-wording/clarification)
- **December 2016:** 2nd revision (split proposal…)

Commission proposal

- Key elements

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Criteria:

- **WHO/IPCS definition**, requires the following:
  (1) an adverse effect (i.e. in laboratory animal studies)
  (2) endocrine mode of action (alters function of endocrine system)
  (3) biological plausible link between (1) and (2)
- **Criteria limited to hazard identification:** no potency, severity, irreversibility (hazard characterisation elements)
- Criteria included for human health and non-target species

Derogation:

- **Allows authorisation of identified substances have negligible risk**
- Proposed change from negligible exposure
- More aligned with WTO and similar EU legislation

Proposed Criteria
Overall Consistency

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- In its impact assessment, the Commission acknowledges:
  - Evidence linking ED diseases or environmental damages to man-made chemicals is lacking
  - Hazard characterisation is important to safety management, in particular potency
  - Option 4 (with hazard characterisation) fares better than others options

Why pursue a non-optimum option??

Timelines for adoption

- **Jul2016 - Present:** Discussion in Member States committee (SCoPAFF)
- **28 February 2017: ???**

Next steps

- SCoPAFF vote on proposal (February 28th; later?)
- **Q3 2017?:** Formal adoption of criteria for pesticides & biocides
- **Q4 2017?:** Entry into force of final ED criteria

Impacted sectors

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- The impact is different in different sectors
  - ***But increases costs and uncertainty for all…***

	Pesticides	Biocides	Chemicals	Cosmetics
	Reg 1107/2009	***Reg 528/2012***	***Reg 1907/2006***	***Reg 1223/2009***
Impact	**Hazard based non-approval** (at review)	**Hazard based non-approval** (at review)	Subject to authorisation - Annex XIV (SVHC) (risk assessment)	Review rules when agreed criteria in place
Derogation?	Yes: ➢ essential need ➢ negligible exposure ***Very limited!!***	Yes: ➢ essential need ➢ negligible risk ➢ Society benefit	Not necessary	Not relevant

Considerations and implications

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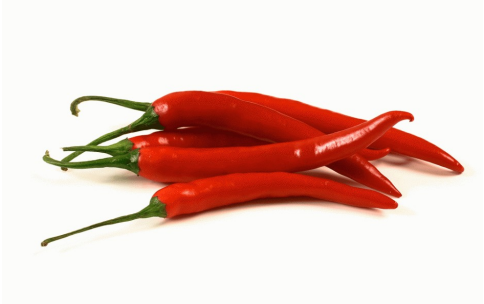
- Trade – WTO obligations
- Wider impact (data requirements for multiple sectors (esp.REACH)
- Animal testing
- Innovation
- Agriculture: Food security, productivity, resistance management …
- Mixing science, politics, vested interests …

- ***Will others follow EU and promote hazard-based Regulations??***

Where are these chemicals?????

Capsaicin
Eugenol
Cinnamaldehyde
Resveratrol
Curcumin
Cuminaldehyde
Naringine, obacunone
Quercitin









Concluding remarks

- **European Union will be the first to put ED criteria into legislation**
  - Scientific debate in a (very) political context
  - Legislation already very protective
  - Potential for substancial negative impact on innovation – and food production

- ***Full hazard characterisation and risk assessment provide a protective, proportionate and science-based decision making process***

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THANK YOU