

Impact Assessment on criteria to identify EDs: options in the RM + public consultation + supporting studies

SANTE / E3, May 2015



Situation

- complex: scientific and regulatory aspects
- scientific criteria will have regulatory consequences
- the regulatory consequences:
 - are already defined in the sectorial legislation
 - differ among sectors



Analytical approach underlying the IA

- 2 aspects with some options each
 - Aspect I: EU criteria
 - Aspect II: Approach to regulatory decision making
- each set of options includes the "baseline" option



Aspect I – EU criteria to identify ED

<u>Option 1 (baseline):</u> No policy change. The interim criteria set in the BPR and the PPPR apply.

<u>Option 2:</u> WHO/IPCS definition to identify endocrine disruptors (hazard identification).

<u>Option 3:</u> WHO/IPCS definition to identify endocrine disruptors + introduction of additional categories based on the different strength of evidence (hazard identification).

<u>Option 4:</u> WHO/IPCS definition to identify endocrine disruptors + inclusion of potency (hazard identification and characterisation).



Aspect II- Approaches to regulatory decision making

Option A (Baseline): No policy change.

<u>Option B</u>: Introduction of further elements of risk assessment into sectorial legislation.

<u>**Option C:**</u> Introduction of further socio-economic considerations, including risk-benefit analysis, into sectorial legislation.



ASPECT I: Approaches for criteria to identify endocrine disruptors

ASPECT II:

Approaches to regulatory decision making (RDM)

A. No policy change (baseline)

В. elements of risk assessment considerations into sectorial legislation

Introduction of Introduction of socio-economic into sectorial legislation

Different decision making:

- 1) strong focus on hazard: PPP BP consumers
- 2) based on risk / socioeconomic assessment: BP professional use **REACH**

1. interim criteria (Baseline)	OPTION 1.A (BASELINE)
2. hazard identification based on WHO/IPCS definition	OPTION 2.A
3. hazard identification based on WHO/IPCS definition + categories	OPTION 3.A
4. hazard identification based on WHO/IPCS definition + inclusion of notency	OPTION 4.A



ASPECT I: Approaches for criteria to identify endocrine disruptors A. No policy change (baseline) Different decision making: 1) strong focus on hazard: ppp BP consumers 2) based on risk / socioeconomic assessment: BP professional use REACH 1. interim criteria (Baseline) OPTION 1.A (BASELINE) C. Introduction of elements of risk assessment into sectorial legislation Alignment of decision making: 1) hazard → risk 2) no changes 2) no changes OPTION 1.A (BASELINE) OPTION 2.A OPTION 2.B OPTION 2.C 3. hazard identification based on WHO/IPCS definition + categories 4. hazard identification based on WHO/IPCS definition + categories 4. hazard identification based on WHO/IPCS definition + inclusion of potency Legislative change		ASPECT II:			
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	WHO/IPCS definition + inclusion of	OPTION 4.A			



Public consultation 26 September 2014-16 January 2015

27087 responses

- 22411 on-line
- 4676 by email

- 863 on behalf of organisations
- 3 EU governments
- 6 governments of third countries
- About 20 EU agencies/authorities



First study

JRC method for defining if a chemical is falling under each of the options outlined in the RoadMap Screening of chemical substances to define if it is falling under each of the options outlined in the RM

Second study

Assessment of potential effects on health, environment, trade, agriculture, and socio-economy in general