



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

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

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

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

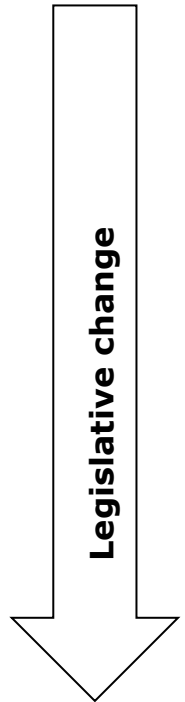
Option 4: WHO/IPCS definition to identify endocrine disruptors + inclusion of **potency** (**hazard identification and characterisation**).

Aspect II- Approaches to regulatory decision making


Option A (Baseline): *No policy change.*

Option B: *Introduction of further elements of risk assessment into sectorial legislation.*

Option C: *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) 	B. Introduction of elements of risk assessment into sectorial legislation	C. Introduction of socio-economic considerations into sectorial legislation	
1. interim criteria (Baseline)	<i>Different decision making:</i> <div style="border: 1px solid red; padding: 5px; margin: 5px 0;"> 1) <i>strong focus on hazard:</i> <i>PPP</i> <i>BP consumers</i> 2) <i>based on risk / socio-economic assessment:</i> <i>BP professional use</i> <i>REACH</i> </div>			
2. hazard identification based on WHO/IPCS definition				OPTION 1.A (BASELINE)
3. hazard identification based on WHO/IPCS definition + categories				OPTION 2.A
4. hazard identification based on WHO/IPCS definition + inclusion of potency				OPTION 3.A OPTION 4.A



ASPECT I: Approaches for criteria to identify endocrine disruptors	ASPECT II: Approaches to regulatory decision making (RDM)		
	A. No policy change (baseline)	B. Introduction of elements of risk assessment into sectorial legislation	C. Introduction of socio-economic considerations into sectorial legislation
	<i>Different decision making:</i> 1) <i>strong focus on hazard: PPP BP consumers</i> 2) <i>based on risk / socio- economic assessment: BP professional use REACH</i>	<i>Alignment of decision making:</i> 1) <i>hazard → risk</i> 2) <i>no changes</i>	
1. interim criteria (Baseline)	OPTION 1.A (BASELINE)	<u>Not applicable</u>	
2. hazard identification based on WHO/IPCS definition	OPTION 2.A	OPTION 2.B	OPTION 2.C
3. hazard identification based on WHO/IPCS definition + categories	OPTION 3.A	OPTION 3.B	OPTION 3.C
4. hazard identification based on WHO/IPCS definition + inclusion of potency	OPTION 4.A	<u>Discarded as similar to 2.B and 2.C, respectively</u>	



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