



# The impact assessment for defining criteria on endocrine disruptors in the context of the plant protection products and the biocidal products regulations

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# Roadmap

*The starting point: a complex situation*

- *Divergent scientific views on some aspects*
- *Different regulatory frameworks*

*Implications:*

- *the scientific criteria will have regulatory consequences*
- *these regulatory consequences:*
  - are already defined in the sectorial legislation
  - differ among sectors

# Approach taken in the Roadmap

*Two aspects with some options each*

- **Aspect I: EU criteria to identify ED**
- **Aspect II: Regulatory decision making**

*Each aspect includes the "baseline" option:*

- **Interim criteria**
- **No change to regulatory framework**

# Aspect I – EU criteria to identify ED

## Option 1 (baseline)

- No policy change
- Interim criteria in the BPR and the PPPR apply

## Option 2:

- **WHO/IPCS definition** to identify ED

## Option 3:

- **WHO/IPCS definition** to identify ED
- **+ additional categories** based on the different strength of evidence

## Option 4:

- **WHO/IPCS definition** to identify ED
- **+ inclusion of potency**



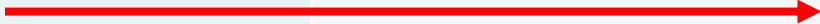
**All options  
are based on  
hazard**

## Aspect II - 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** into sectorial legislation.*

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

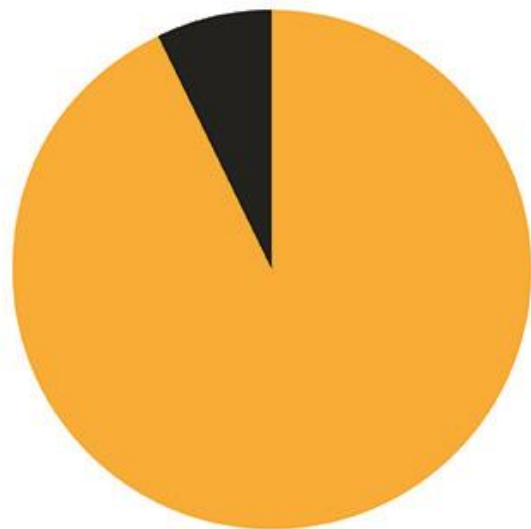


European  
Commission

# Public consultation

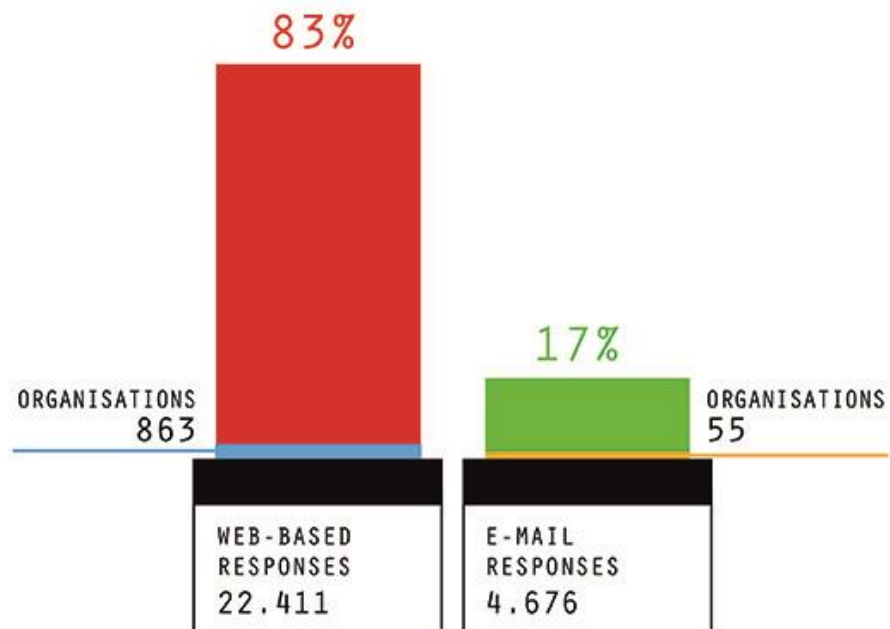


# 27.087 RESPONSES



93%

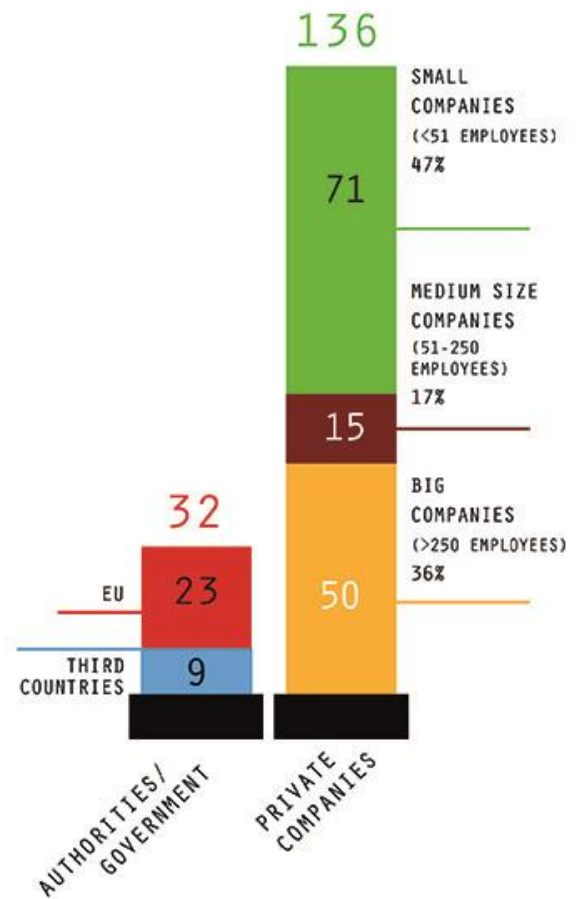
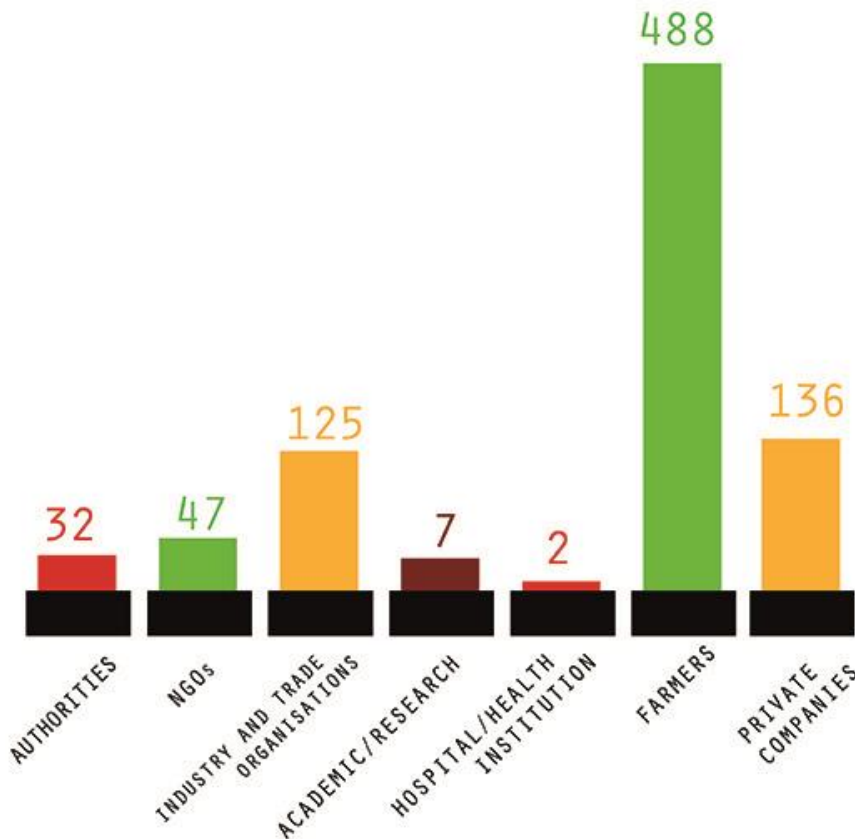
RESPONSES FROM TWO  
NGO-CAMPAIGNS







# WEB-BASED RESPONSES ON BEHALF OF ORGANISATIONS





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# Studies

## First study

### **JRC- method**

to define which chemicals  
fall under which option  
for the criteria

**Screening** of  
chemicals with JRC-  
method

## Second study

Assessment of potential impacts (pros/cons)  
on e.g. health, environment, trade,  
agriculture, ...

**We are here!**

- **1st study (on-going):**

- screening of 700 chemicals
- based on existing evidence → no new experimental studies
- estimate which chemicals would fall under which option
- can not replace assessments done for legislation requirements
- results will not be used for regulatory purposes
- event focused on the method is planned for autumn 2015

- **2nd study (planning phase)**

- Sequence: effective work can not start before screening is finalised



# Conclusions

*1 - The impact assessment is well on track*

*2- Important basic steps are done or initiated*

*3- ...and further work is ongoing...*

**We count on  
your support  
in the next  
months!**

