



ENDOCRINE DISRUPTORS: THE EU REGULATORY FRAMEWORK

**Ladislav Miko, SANTE
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Outline

- EU legislation on endocrine disruptors (EDs)
- Regulation on Plant Protection Products and Biocidal products + criteria to identify EDs
- The Impact Assessment

Specific provisions on EDs

- Water Framework Directive (2000)
- REACH Regulation (2006)
- Regulation on Plant Protection Products (2009)
- Regulation on Cosmetics (2009)
- Regulation on Biocidal Products (2012)





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Adverse effects caused by EDs already covered by "standard" risk assessments

- Chemicals (REACH)
- Plant protection products
- Biocidal products
- Cosmetics
- Workers legislation
- Food Contact Materials
- Toys
- Medical Devices
-



➔ Outside EU: no criteria to identify EDs for regulatory purposes

EU legislation: already high protection from EDs to human health & environment





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Regulations on Plant Protection Products & on Biocidal Products



- Regulatory consequences for EDs already defined
- Interim criteria to identify EDs set
- New criteria required by end 2013

Regulatory consequences for EDs

- **PPP**
 - ED is "approval criterion" (strong hazard component)
 - Art. 4.7 derogation in case of serious danger to plant health
- **BP**
 - Professional use: (strong risk component + Art 5.2 derogation for disproportionate negative impact on society)
 - Consumer use: hazard-based non-approval

High political attention on criteria to identify EDs

- Council Conclusions (2012)
- European Parliament Resolution (2013)
- 7th EAP (2013)
 - Horizontal criteria
 - Impact assessment



2009-2013: COM work for developing criteria



➤ Studies/Opinions requested

- Kortenkamp Report (2011)
- EFSA Opinion (2013)
- JRC Expert Advisory Group Report (2013)



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2009-2013: COM work for developing criteria

➤ Activities

- Ad-hoc WG (lead by DG ENV)
- ED Expert Advisory Group (lead by JRC)
- COM Conference 2012
- 1st draft for criteria:
 - discussed in the Ad-hoc WG
 - consensus not reached
 - formal COM Inter-Service Consultation did not start





Complexity



- Science divergences
- Criteria to identify EDs likely to impact other sectors
- Regulatory consequences vary across sectors (decision making based on hazard/risk/risk-benefit)
- Significant impacts expected depending on criteria and sectors
- Different legal procedures to implement criteria



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2013  start of an
Impact Assessment



Impact Assessment well on track

..more details in next
presentations





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