Endocrine Disruptors – Advocacy Update
Advocacy Network Call
Brussels, 18th May 2015
REPUTATION
Turn around general trend regarding the image of plastics vis a vis relevant target groups by increasing positive perception from 55% to 65% by 2020 and securing that no country scores below 50%

WASTE
Increase Recovery of Plastic waste from 60% to 100% by 2025

HEALTH
Increase confidence in the safe use of chemicals in Plastics

POOR KNOWLEDGE
Increase knowledge of target groups about benefits of plastics

FLAGSHIP INITIATIVES
Zero Plastics to Landfill by 2025
Marine Litter Solutions
Chemicals in Plastics
Plastics saves Energy
Plastics: The Wonder Material!
Strategic Objectives

Chemicals in plastics – Promote evidence based legislation for plastics

Avoid regulation of EDs in product and waste legislation

ED Criteria = secure criteria that includes hazard characterisation

Include safe threshold for EDs = secure threshold based regulations

Advocate for potency, severity, toxicity, irreversibility in ED criteria

Maintain cross-industry coordination with CEFIC, ECPA and cross-sector group. Engage with downstream sectors

Advocate for a toxicological approach to EDs
3 categories of EDs set by European Commission in ED strategy
- **Category 1** - evidence of endocrine disrupting activity in at least one species using intact animals;
- **Category 2** - at least some in vitro evidence of biological activity related to endocrine disruption;
- **Category 3** - no evidence of endocrine disrupting activity or no data available.

700 substances to be tested including **280 that are non-biocides or pesticides**: potentially substances used in plastics.

If DG SANTE will first work on the basis of the pesticides and biocides sectors, they have made clear that criteria will apply to other chemicals in the future.
## SWOT ANALYSIS

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<th><strong>STRENGTHS</strong></th>
<th><strong>WEAKNESSES</strong></th>
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| • Willingness to fund further research and position as responsible industry  
• Sound production base in Europe and network of contacts | • Scientific evidence showing endocrine disrupting properties of plastics  
• Availability of good alternatives?  
• Reputation management vs. political and NGO forces  
• ED strategy in DG ENVI |

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<tr>
<th><strong>OPPORTUNITIES</strong></th>
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| • Plastics properties for applications which alternatives do not have?  
• Scientific research that can show different results on endocrine disruptors  
• Difficult scientific discussion  
• Definition of ED criteria left DG ENVI for DG SANCO | • Big political pressure from Member States (France, Sweden and Denmark most vocal) and European Parliament  
• Issue is highly political leading to high probability of EU action  
• Consumer organizations and environmentalists’ pressure which could lead to lower demand and business reputation management issues  
• Campaigning scientists |
• Distinguish endocrine disruptors from endocrine active substances
  A substance should not be identified as an endocrine disruptor simply because it interacts with the hormonal system. This requires an adverse effect caused by the substance via the hormonal system.

• Regulation must consider the characteristics of adverse effects that may be observed during testing
  In order to identify endocrine disruptors of concern, regulation must also take into account the characteristic of the adverse effects that were observed during testing. Is the effect powerful, severe, or irreversible? If these characteristics are left out, it becomes difficult to differentiate substances for which regulation is needed from those similar to benign carrots.

• Allow thresholds to be set for endocrine disrupters
  Each substance must be considered on a case by case basis. Most conclusive scientific work shows that thresholds can be set for ED. Let’s not pre-empt the result of the scientific risk assessment about the possibility to set threshold.
NGO activities

- 5th March 2015: Studies published by the Endocrine Society
  - Neurobehavioral Deficits, Diseases and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union
  - Estimating Burden and Disease Costs of Exposure to Endocrine Disrupting Chemicals in the European Union
  - Male Reproductive Disorders, Diseases, and Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union
  - Obesity, Diabetes and Associated Costs of Exposure to Endocrine Disrupting Chemicals in the European Union
- Linked with ENDO 2015 event to present the studies
- Draw overall conclusion of cost on society of €150 Billion
- Extensive media coverage (France, Denmark, Sweden, EU press)
Events

- 11th November 2014: Endocrine Society event in the EP
- 6th January 2015: Screening of « Endoc(t)rination » in the EP
- 27th February 2015: HEAL event in Madrid
- 12th March 2015: HEAL event in Munich
- 20-25th March 2015: HEAL’s week on pesticides – Tour de France
Chemacademy event in Berlin

- October 12th and 13th (+ workshop on 14th)
- Agenda:
  - Regulatory update
  - Report from competent authorities
  - ECETOC approach to identify EDs
  - Current state of the science on EDs
  - REACH in the context of EDs
  - State of the Science for testing methods
  - Use of weight of evidence for decision making
  - Risk assessment
  - Case study: Bisphenol A
  - Threshold, low dose effects and NMDR
  - ED in ecotoxicology
  - Workshop: EDs and the interaction of different pieces of regulation
## Timing

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<tr>
<th>Process steps</th>
<th>Q1 2015</th>
<th>Q2 2015</th>
<th>Q3 2015</th>
<th>Q4 2015</th>
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<tr>
<td>PlasticsEurope submits its answer to the consultation</td>
<td>JAN 15th</td>
<td>FEB</td>
<td>MAR 15th</td>
<td>JUN 15th</td>
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<td>Publication of the results of the consultation</td>
<td>JAN 15th</td>
<td>FEB 15th</td>
<td>MAR 15th</td>
<td>JUN 15th</td>
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<td>Plenary debate on ED</td>
<td>JAN 9th</td>
<td>FEB 9th</td>
<td>MAR 9th</td>
<td>JUN 9th</td>
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<td>Stakeholder roundtables/conference on ED</td>
<td>JAN 25th</td>
<td>FEB 24th</td>
<td>MAR 24th</td>
<td>JUN 24th</td>
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<td>JRC drafts methodology for impact assessment</td>
<td>JAN 12th</td>
<td>FEB 11th</td>
<td>MAR 11th</td>
<td>JUN 11th</td>
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<td>First impact assessment on substances</td>
<td>JAN 1st</td>
<td>FEB 1st</td>
<td>MAR 1st</td>
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<td>Second socio-economic impact assessment (+ agronomic IA for PPPs)</td>
<td>JAN 1st</td>
<td>FEB 1st</td>
<td>MAR 1st</td>
<td>JUN 1st</td>
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<td>Drafting of criteria by DG SANTE</td>
<td>JAN 1st</td>
<td>FEB 1st</td>
<td>MAR 1st</td>
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Recent developments

- DG SANTE has decided to engage more transparently and actively on the issue through public discussions:
  - 1st roundtable with NGOs, scientists and industry
  - 2nd roundtable with representatives from the Member States
  - 3rd roundtable with Members of the European Parliament
  - Stakeholder conference « Endocrine disruptors: criteria for identification and related impacts »
Results of the 1st roundtable

- Explanation of the impact assessment process
  - A public consultation and stakeholder meetings are part of the IA process in order to gather views and appropriate data
  - The benefits and costs of the options specified in the roadmap will be analysed
  - It also assesses the impact on health and the environment
  - The IA report summarises the outcome of the analysis of data gathered through the public consultation and supporting studies
  - The IA board will review the supporting studies and check the quality of the report
Results of the 1st roundtable

• Study on the substances
  • JRC developed a screening methodology
  • External contractor will screen the evidence available for about 700 chemicals and determine if they fall under each of the 4 options outlined in the roadmap
  • The substances to be screened include:
    • Most substances approved under plant protection products and biocides legislation
    • A group of additional chemicals falling under REACH regulation, cosmetic products regulations and water framework directive

• Study on the socio-economic impact that will look at the benefits and drawbacks of each option
Impact assessment

- JRC developed the methodology, which is currently being discussed within the Commission. Possibility for the contractor to suggest minor changes for any deficiencies/difficulties found in the JRC methodology.
- Choice of substances for chemicals is still on-going, with an attempt to be made to ensure random selection.
- Screening and socio-economic assessment will be done in stages, starting with PPPs and ending with chemicals from REACH and cosmetics.
Coordination with industry actors

• CEFIC in the lead developing advocacy and communication plan on ED
• Media briefings organised by CEFIC together with ECPA: PlasticsEurope provided input and key messages on plastics related issues
• ED Cross sector group: Member companies to coordinate in order to attend 1st June Conference. J. Ragot will be going as representative of the CiP group of PlasticsEurope and P. Vangheluwe will go representing PlasticsEurope.
• ECPA advocating proactively with www.reasonabledebate.eu
Coordination with industry actors

- 1st June conference: coordination of industry approach:
  - List of people attending for the industry communicated by CEFIC to DG SANTE
  - PlasticsEurope will be represented at the conference by JR, PV and AM
Key action in 2015

- **Support** actions of CEFIC and ECPA in advocating for risk-based approach to ED criteria
- **Ensure** PlasticsEurope’s specificities are being considered
- **Develop** common communication tools for cross-sector group on ED (Q&A together with CEFIC)
- **Monitor** NGO actions to level the debate on EDs