Endocrine Disruptors: EU Perspective

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About EPPA

- A specialist management consultancy in Brussels helping clients to develop alignment between business, institutions and governments, technology developments and social-cultural shifts
- Areas:
    - envi/health/agri/trade, with particular expertise in agrochemicals
- Focal point:
    - Advocacy
    - Regulatory
    - Compliance
- Celebrating 30th anniversary in 2017!
- Office in Moscow since 1993

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Outline

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- Why EDs matter?
- Background of EU discussions

II - Legal Situation & Case Studies

III – Future outlook

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Why EDs matter?

Why EDs matter?

Impact through via downstream legislation:

- Industrial chemicals (Regulation 1907/2006)
- Cosmetics (Regulation 1223/2009)
- Plant Protection Products (Regulation 1107/2009)
- Biocidal Products (Regulation 528/2012)

Yet there is no definition…

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Where to find ED criteria?

- **REACH**
  - no reference, just apply directly once become available
- **Cosmetics**
  - COM to review regulation after 2015…
- **BPR & PPR**
  - Supposed to come back with criteria by 2013
  - yet as of Oct 2017 no criteria are in force!
  - interim criteria (C2R2) still valid…

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Background of EU discussions

Who is interested in EDs?

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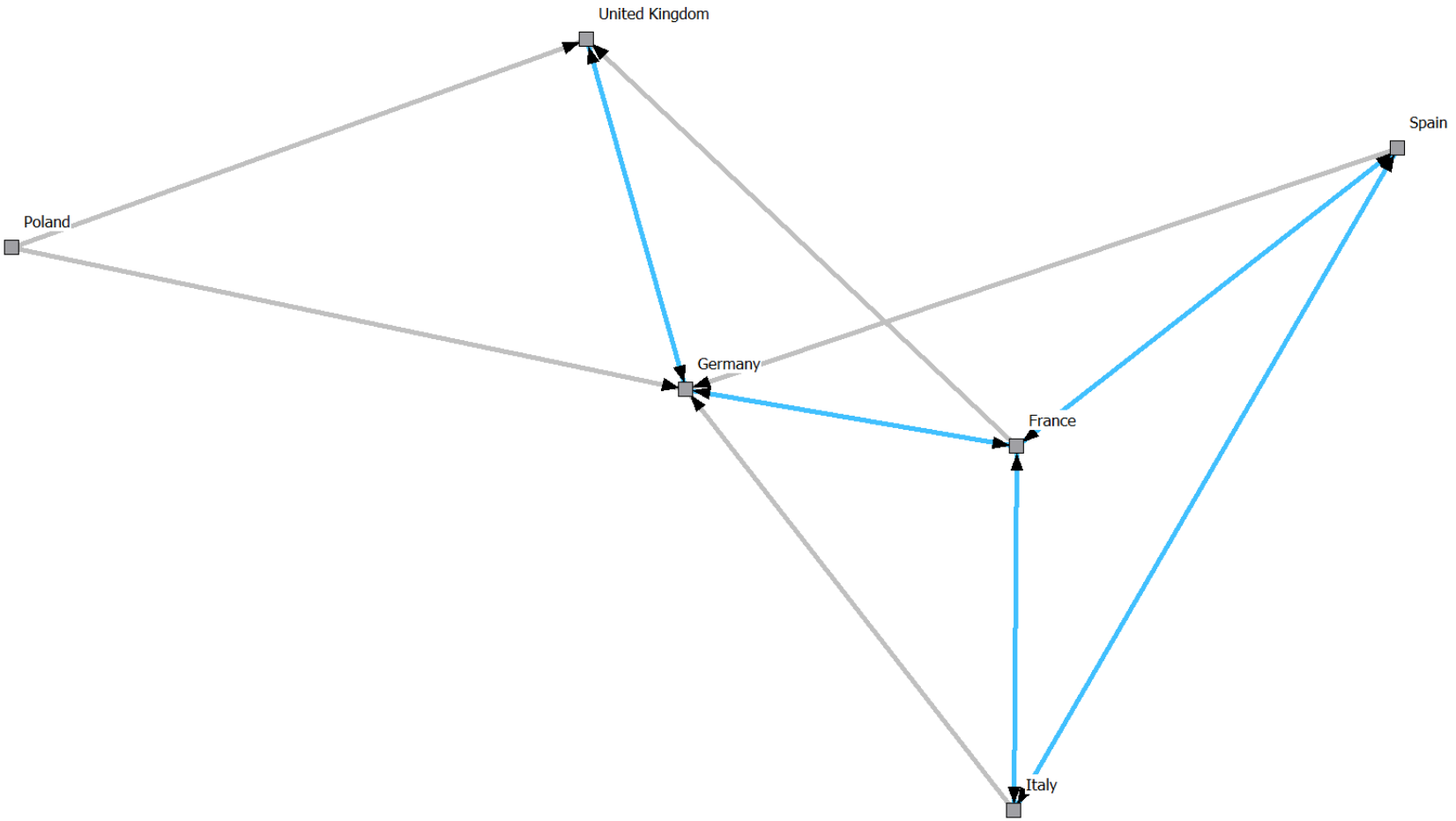
Impact of Brexit on the ED debate



Impact of Brexit on EU debate

- Stronger Fr-DE axis impact on EU policy
- Expected revived Weimar triangle not in sight given tight relationship FR-PL
- DE in search for new alliance given close ties to UK (both ways). Idem for PL
- FR benefits strategically from Brexit given the no-reciprocity with UK but strong ties with SP-Italy
- Spain-Italy to become more pivotal
- Scandinavian MS views risk being more influential
- Change in voting behaviour & loss of “pro-science” votes
- The continental model, if any, as regards science will grow. Reinforcement of the hazard-based likely
- A more prescriptive EU is a ‘risk’

Latest discussions

- ED Roadmap (June 2016)
  - ✓*Potency*
  - ✓*Socio-economic derogations*
  - ✓*Categories "suspected ED"*
  - …
- Commission adopts criteria through a *regulatory procedure with scrutiny* (July 2017)…

Derogations:
Negligible exposure vs. Negligible risk

- COM wanted to uniform derogations in different legislations through derogations
  - ✓test EP/MS attitude on PPR within the framework of the Refit program
- Yet EP sensitive to replacing NE with NR
- Lastly, NE GD document blocked pending the adoption of ED criteria.

Legal Situation & Case Studies

Unclear situation

- Interim criteria (C2R2) in force
- ED criteria almost ready
- CLP vs. PPR/BPR
  - C2R2 -> ECHA responsibility
  - ED -> EFSA responsibility
- What about endogenous EDs?

How should Commission handle situation?

To be ED or not to be ED?

Case 1	**C2R2**	**Not ED**
Case 2	Not C2R2	ED

Case Studies

Case studies

Substance	What ECHA thinks (CLP)	What EFSA thinks (PPPR)	Regulatory outcome under relevant law	
			Interim criteria	New ED criteria
Biocide X	R2 but not C2	/	Authorized	Banned*
Pesticide X	C2R2	Not ED	Banned	Authorized
Pesticide Y	Not C2R2	C2R2	Authorized	Banned

* derogation possible, yet consumer use still banned

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Future outlook

Timeline

- **Commission adopts criteria (Jul 2017)**
  - 3 month scrutiny period for EP and Council:
    - ✓Council supported;
    - ✓Yet EP ENVI blocked with 36 votes against 26… (Sep 2017)
    - ✓Plenary vote to take place… tomorrow (4 Oct)

EP ENVI reasoning

"The criteria in the draft regulation are however not fit for horizontal application in all relevant Union legislation due to at least two failures:

*a. failure to include a category of **suspected endocrine disrupters**,*

*b. failure to include **read-across** in the operative part of the data to be considered"*

Will EP Plenary reject the criteria?

Changes in comitology rules

The issue

- The glyphosate case triggered strong disagreements between MS and the Commission. Glyphosate inclusion prolongation was decided by the Commission only in Appeal Committee
- The Commission wishes to avoid that a MS such as France blame the Commission while not proposing any policy or regulatory option

Way Forward

- Quorum: simple majority, only those present count. No opinion does not count
- Transparency of all discussions in the Appeal Committee
- Appeal Committee at Ministerial level or Discussion at Member State level or Ministerial opinion within 3 months of the Appeal Committee
- Rules to be adopted by Co-decision

The Consequences

- Higher pressure on the Member States to take a position
- Increased importance of engaging MS at SCOPAFF
- While new rules are adopted, fewer decisions to be taken by Commission when no majority at Appeals Committee

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Conclusion & Considerations

Conclusion & Considerations

- **Gear up for uncertainty:**
  - EDs will be always political with media involvement
  - Risk of “glyphosatisation” of ED debate
  - So gear up for upstream advocacy

- **Big battle on derogations ahead:**
  - more important EP role (incl. with new comitology)
  - what about NR derogation under BPR?

- **Defend yourself:**
  - Fight against C2R2 with ECHA
  - Justify non-ED under the new criteria

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Thank you!

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