

Endocrine Disruptors



Peter Smith, Cefic Executive Director Product Stewardship
REACH Workshop, Sofia, 23 October 2018



Challenges

Public concern

- “ Not sufficiently controlled
- “ Major health issues (vulnerable populations)
- “ Hypothesis or proven causality?

Identification

- “ Mode of action
- “ Not toxicological/ecotoxicological end point
- “ Complex; case by case vs criteria/rules



A significant health/environmental concern

- “ Powerful substances (non-threshold)
 - Think hormones

- “ Disrupts the hormonal system
 - Think hormones

- “ Leads to serious health (environmental consequences)
 - Cancer, reproductive disease (C, R)

For established toxicological end-points: ED already severely regulated – How many ?

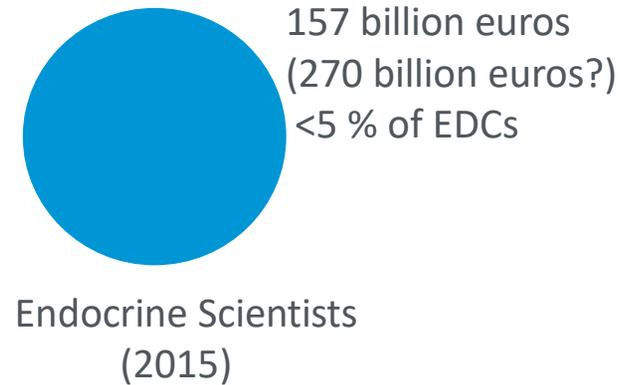
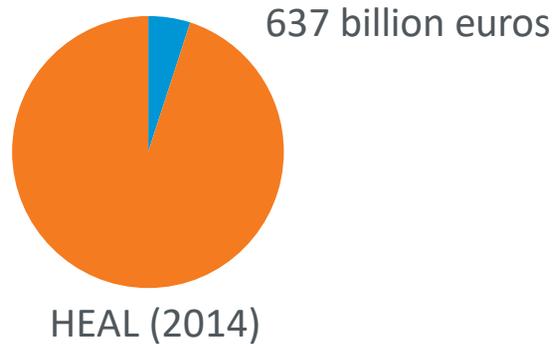


The Public Concern: What is the problem and how big is it?

The Politics

(unresolved scaling of the problem)

Scale of the health problem



What's the solution?

2-5% due to chemicals

All due to chemicals

Emotion



Disruptors: Scientific Input



What is an Endocrine Disruptor?

“ General scientific consensus

WHO/IPCS (2002) Definition

“An endocrine disruptor is an exogenous substance or mixture that alters the function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub)populations.”

3 elements

- alters endocrine system
- leads to an adverse effect
- plausible causal link between the two



EU Initiatives

1. Criteria (2012-2018)

- Horizontal vs. Sectoral

2. Union Strategy (1999-today)

- Lists vs. Stocktaking/Gap Analysis



EU Initiatives

1. Criteria (Scientific)

Intention
(Ambitious)

- Horizontally applied to EU legislation

Must do

- Scientific criteria for Biocides and Plant Protection Products

Outcomes
Plant

- To date, criteria only being implemented in Biocides and Protection products (2018)
- REACH review : scientific criteria not ELoC criteria (2016)
- Cosmetics... under review

(EU chemicals legislation fitness check 2018/19)



EU Initiatives

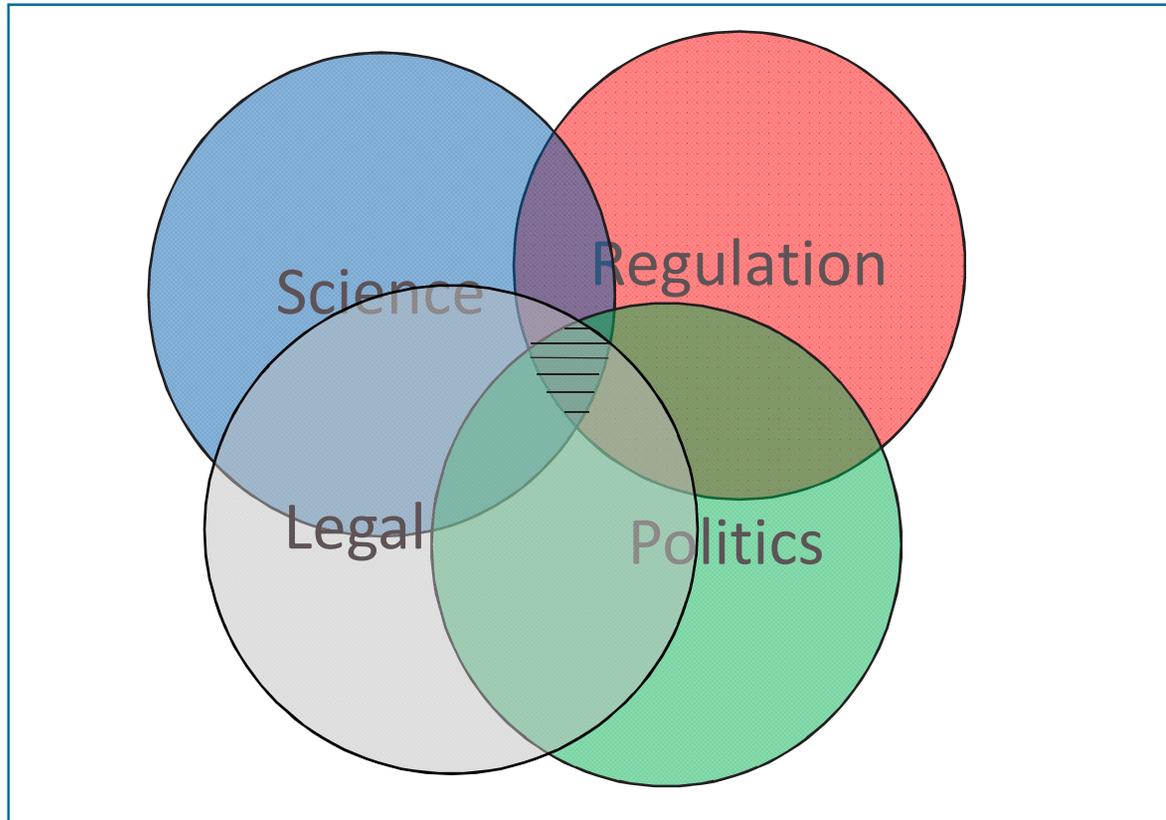
2. Union Strategy

- “ Published in 1999
 - Outdated/lists of substances

- “ Occasionally updated (1999-2011)
 - Amended lists

- “ Revision of Strategy planned for 2013
 - Overshadowed by the legal obligations for criteria (Biocides/Plant Protection Products)
 - Re-committed to Member States (2017)
 - Expect a Communication: “Towards a Comprehensive EU Regulatory Framework” (2018)

Disruptors: Where science meets politics and emotions run high



Area to work (large, expansive)

Convergent space for a solution pleasing everyone (limited)



Ideal (unconstraining)



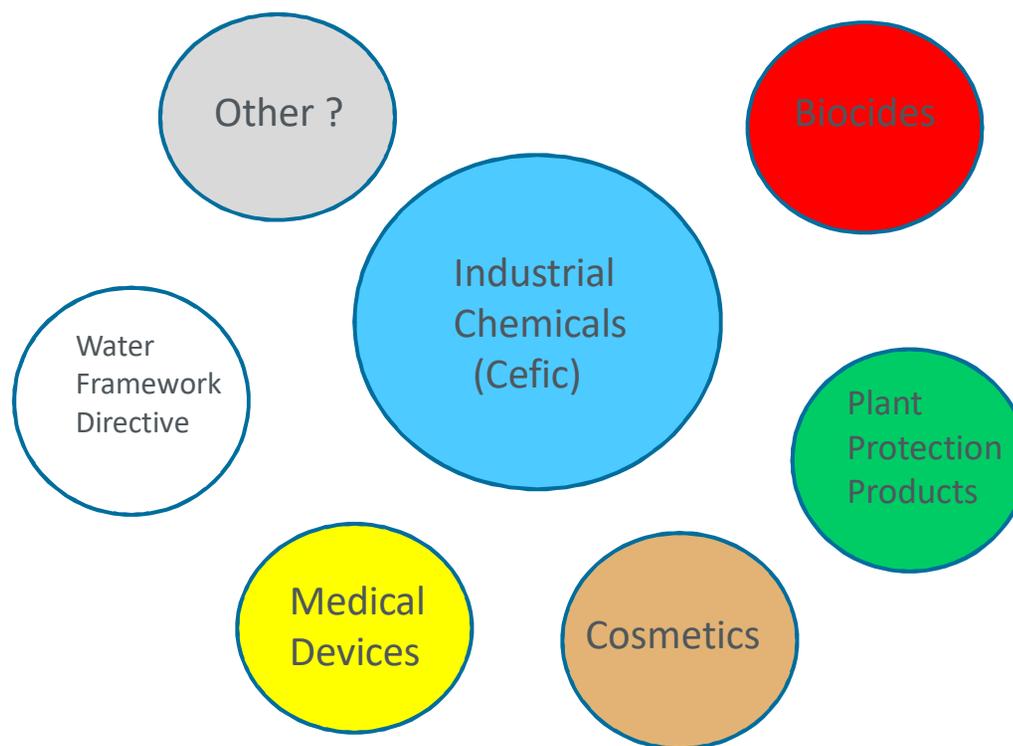
Reality (constrained)

REACH?



Can we make progress even without criteria?

A Cefic view of the landscape (human nature)



Hamonised regulatory approach

✓



Hamonised from industrial chemicals (REACH)

✓



Harmonised from a satellite legislation

X

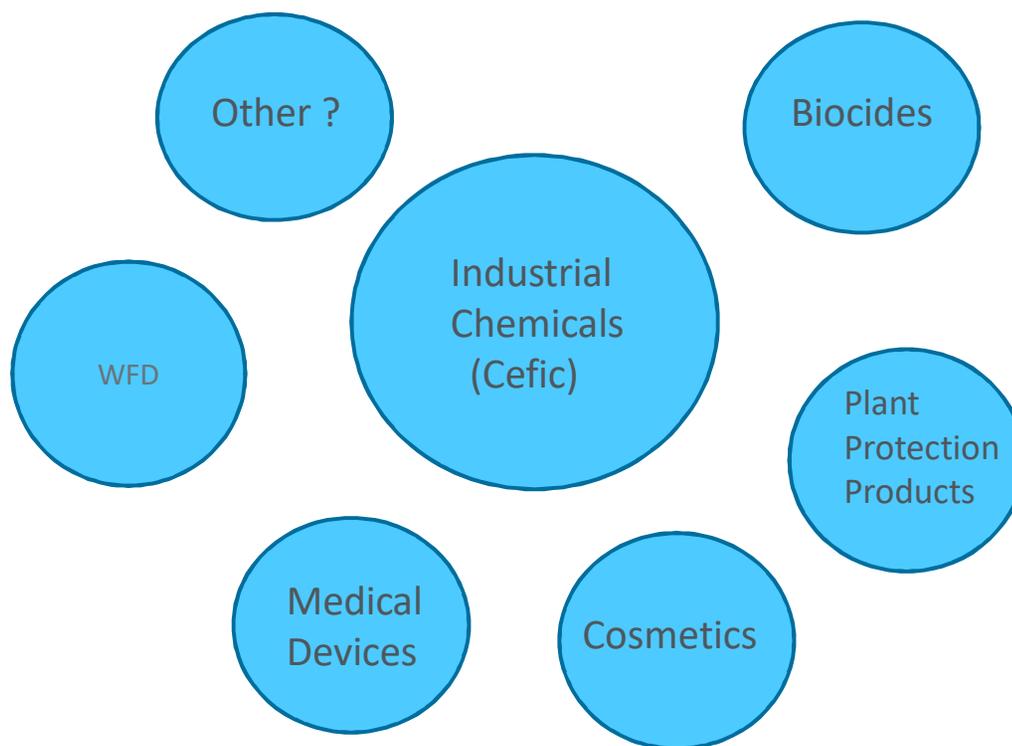


REACH?



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Hamonised regulatory approach

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✓



Harmonised from a satellite legislation

✓





REACH Processes

- PACT list (ECHA) - Register of Intent
- REACH Evaluation - CoRAP (Member States)
- ED Expert Group (ECHA) - Technical assessment; input to Member States
- SVHC Identification (ECHA) - SVHC Roadmap (Integrated Regulatory Approach);
RMOA
- Authorisation List
 - REACH Annex XIV
 - Sunset date
 - Authorisations (specific time)

REACH?



Can we make progress even without criteria?

Yes!

<u>REACH Results by Instrument</u>	<u>Status*</u>
PACT-RMOA List (potential EDs)	83
CoRAP List (suspected EDs)	29
Candidate List (identified EDs): Phthalates/BPA	10
Authorisation List (prohibited): Alkyl Phenols/APEs	2

— Assessment of alternatives

?

“ REACH is “working” (case by case)

“ ECHA has established an Endocrine Disruptors Expert Group (all stakeholders present)

“ EDs in the SVHC 2020 Roadmap/Integrated Regulatory Approach (*Status 2017)



Are we still missing anything?

Yes

- “ Impact assessments lead to various results
 - Up to 100s billions euros/years (EU)
 - Commission not resolved impact assessment discrepancy during development of ED criteria

- “ Non-traditional toxicological end-points considered
 - Diabetes/obesity
 - Neurodevelopment (reduced IQ)
 - More research needed on thyroid pathway (EU Strategy?)



Recent legislation (EU)

REACH (2006)

Equivalent Level of Concern (ELoC); Article 57f (SVHC): no criteria applied (yet); needs hazard characterisation?

Biocides (2017)

Criteria for identification of EDs implemented; limited risk derogation (negligible); Insect Growth Regulator exemption; criteria applied to products; technical guidance document available (ECHA/EFSA); implementation guidance available.

Plant Protection Products (2018)

Criteria for identification being implemented; no risk derogation (“negligible exposure”); no exception for intentional insect growth regulators; technical guidance document available (ECHA/EFSA).

Cosmetic Regulation

Under review (criteria/risk assessment): Late? (January 2015 target?)

Medical Devices

Cross references REACH

Substances or Active substances: What has all the fuss been about?



(William Shakespeare: “Much ado about nothing?”)

Original Commission proposal for Biocides - Active Substances

— Guided by impact assessment

- “Substances”

“Substances” unclear (co-formulants; substances of concerns, impurities, *etc.*)

“Substances” overlap with REACH (where criteria are not a legal requirement)

Industry preference

Treat substances under REACH (ELoC) first – then consider Biocidal Products

Do the Biocides scientific criteria fit with the regulatory needs of REACH (ELoC)? Probably not.

Guidance for Criteria (BPR/PPPR)



- “ 2018 – Guidance completed (ECHA-EFSA-DG JRC).
 - Industry believes an early review of guidance is needed

- “ Positives (industry view)
 - Logical progression; WoE approach; applicable to data “poor” and data “rich” situations.
 - Conclude “not an ED” at the first “fall” (not only at the end)

- “ Challenges (industry view)
 - EOGRTS requests (WoE to use all available data); criteria not designed to identify non-EDs but EDs; Thyroid (Annex A) not reflecting state of science; population relevance necessary (for environmental impact).



Outside - EU (Examples)

- “ US EPA Drinking Water Screening test programme
 - Phased data gathering programme (tiering)
- “ OECD conceptual framework (test methods)
- “ UN Environment/SAICM (reports)

EU: What is the rest of the world doing?



- “ EU tends to lead the regulatory work on ED (others follow)
 - National initiatives/strategies (France/Belgium/Denmark)

- “ Internationally, UN (*e.g.* SAICM programme) recognises ED as an emerging policy issue
 - WHO/UNEP Report (2012): ICCM-3
 - IPCP: 3 reports commissioned by UNEP (now available): ICCM-4
 - Ongoing work with UNEP + other IOMC organisations up to ICCM-5

- “ Regional activities
 - China (environmental hormone substance): Integrated risk assessment
 - Australia: EDs to be included in hazard categorisation of substances (NICNAS update)
 - Brazil: New chemicals control law
 - Japan: Extend + Speed (includes 67 suspected EDs)
 - US: EPA (EDSP); tiering approach to testing



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	<u>EU</u>	<u>US</u>
Objective	Protect Health/Environment	Same
Focus (pathways)	EATS	EAST
Basic definition	WHO/IPCS	Same
Approach (conceptually)	Hazard/risk (derogation)	Risk-based assessment
Approach (technically)	Assess available data against criteria (interim \Rightarrow scientific)	Data creation <ul style="list-style-type: none"> - Fast throughout screening (tier 1) - Dose-response adverse effects (tier 2)
Regulatory consequences	EDs incorporated into several existing chemicals regulations (Commission Roadmap 2014)	To be clarified (?)

Industry view: “Jury is out” on which is better (if either); results from US EPA work not sufficiently incorporated into the recent IPCP reports.



User/Worker Protection

Thresholds

“ No scientific consensus on the existence of safe thresholds for EDs (generically)

But

“ No specific consensus on there being no safe threshold

So

“ Under REACH, no change to Art 60(3) deemed relevant

- thresholds may exist; industry to provide evidence (dose-response); environmental thresholds expected to be difficult.



User/Worker Protection

Treat as with any other hazardous substance

- “ Apply a logical hierarchy
- “ EFSA conclusion (on EDs); apply risk assessment



User/Worker Protection

Logical Hierarchy (to control exposure)

1. Avoid use

- substitute or eliminate (where possible)

If not possible,

2. Avoid exposure through technical means (e.g. closed system)

- Threshold: limit exposure below safe level (OEL)
- Non-threshold: technically maintain lowest exposure possible

Process design (build in lowest possible exposure) first

Personal protection (PPE) last resort

Management measures

- minimise number of workers
- minimise duration of exposure



Other recent legislation

- “ Nanomaterials
 - Annex changes in REACH (waiting for publication)
 - Technical guidance needed to update dossiers (January 2020)
 - Revised definition (on-hold with Commission)

- “ POPs
 - Recast of POPs in EU (Lisbon Treaty)
 - To be completed under Austrian Presidency (end 2018)

- “ Plant Protection Products
 - REFIT exercise complete 2019
 - Pesticides Committee (European Parliament) 2018/19



Thank-you

Any Questions?

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