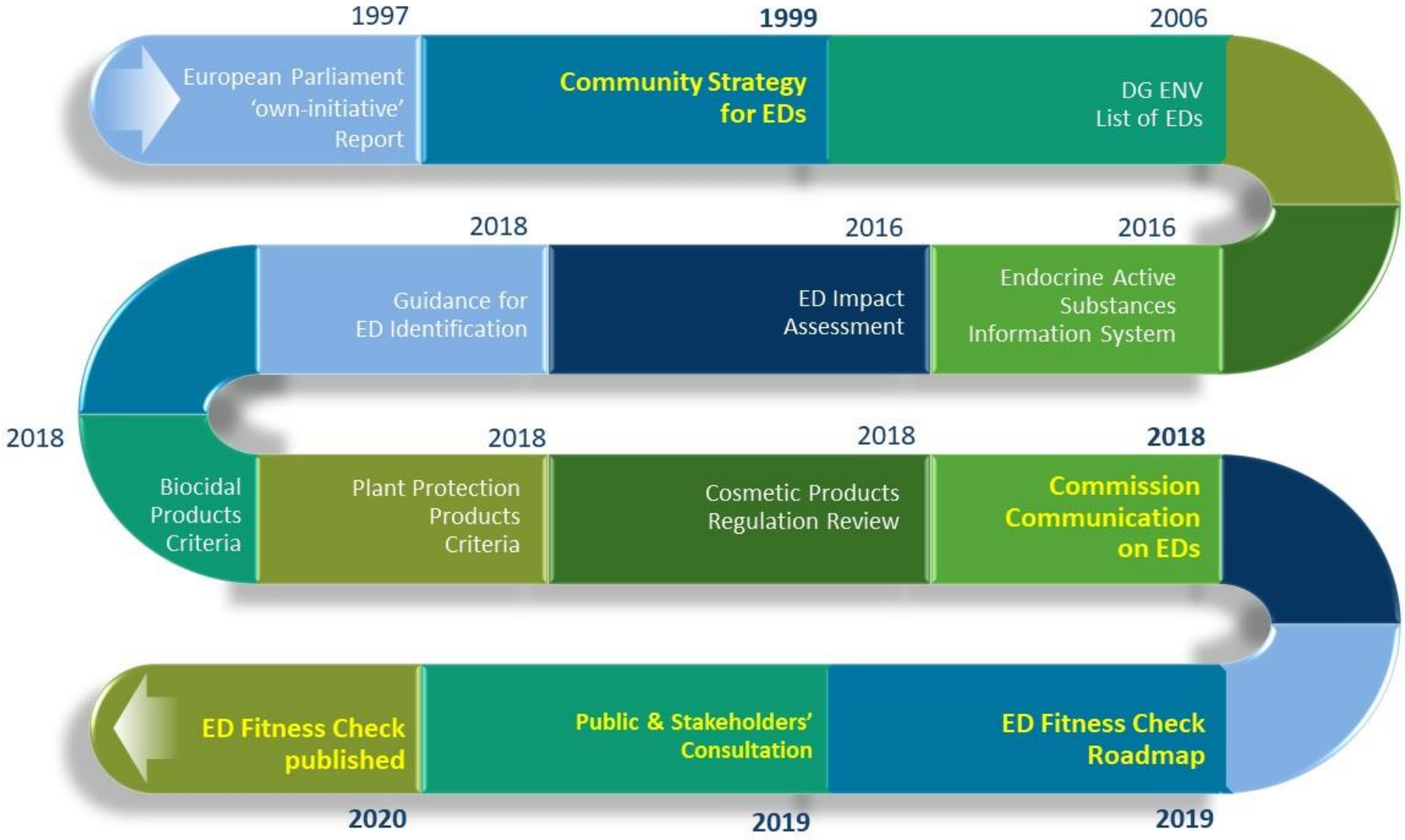
Fitness Check Endocrine Disruptors

Second Annual Forum on Endocrine Disruptors
Brussels, 17-18 December, 2020

INTRODUCTION

Introduction – historical background



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Introduction – Commission Communication 2018

Towards a comprehensive European Union framework on endocrine disruptors

"The Commission will launch a Fitness Check to assess whether relevant EU legislation on endocrine disruptors delivers its overall objective to ***protect human health and the environment*** *by minimising exposure to these substances.*

The Fitness Check will for the first time take a ***cross-cutting look at endocrine disruptors****…*

… It will allow an analysis of how the different provisions/approaches on endocrine disruptors interact, ***identify any possible gaps, inconsistencies or synergies****, and assess their* ***collective impact*** *….*

It will pay particular attention to those areas where ***legislation does not contain specific provisions for endocrine disruptors****, such as toys, cosmetics and food contact materials."*

Introduction – drivers and main objectives

DRIVERS

Stakeholder views that legislation in some areas is not adequate to protect human health and wildlife

Differences in legal provisions and regulatory approaches

MAIN OBJECTIVES

Assess if legislation delivers its objective to protect human health and the environment by minimising exposure to EDs

(Effectiveness question)

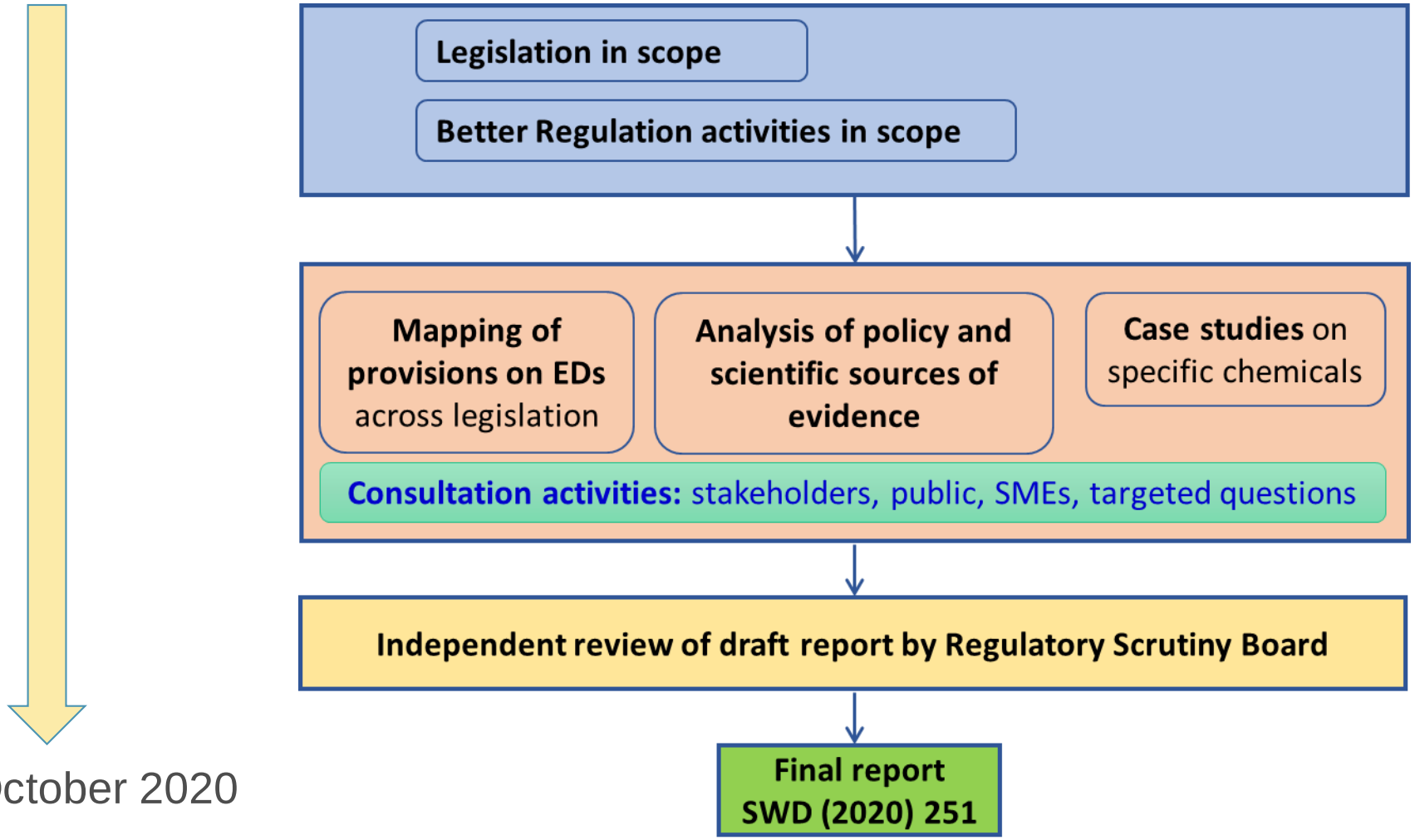
Assess whether legislation delivers its objective in a coherent way across regulatory sectors

(Coherence question)

METHODOLOGY

Methodology: workflow and timeline

March 2019



October 2020

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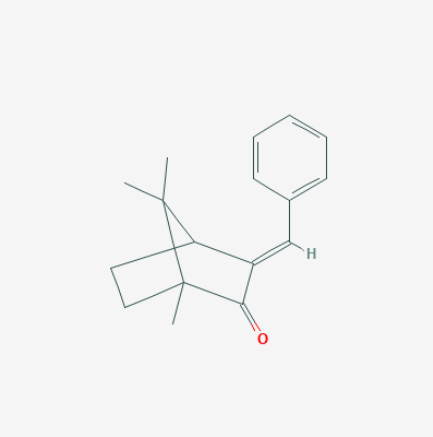
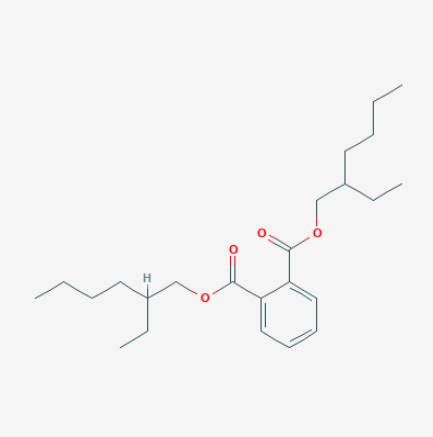
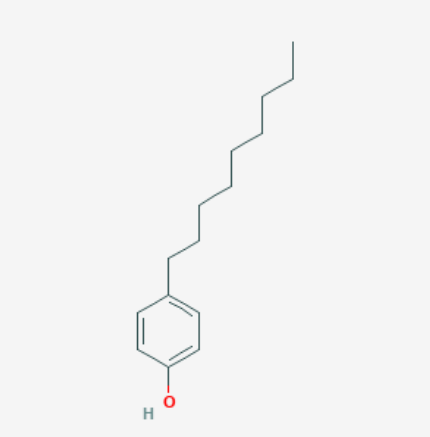
Methodology: case studies



3-Benzylidene camphor (3-BC)



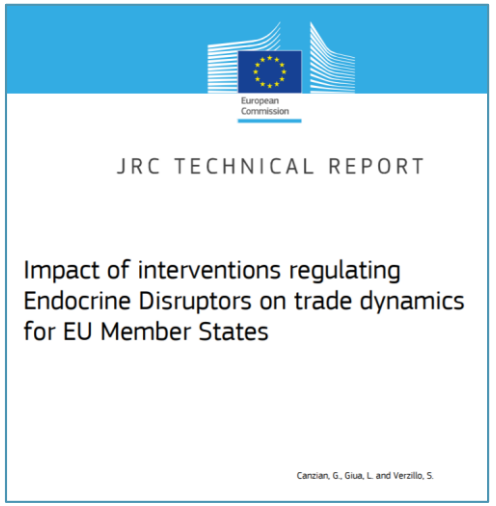
Diethylhexyl phthalate (DEHP)



Nonylphenol and its ethoxylates

Economic case studies (Canzian et al, 2020):

- Low molecular weight phthalates
- 3-Benzylidene Camphor (3-BC)



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Methodology: consultation activities

Consultation	Period	Respondents
Roadmap	12/06/19 to 10/07/19	66
Stakeholders	06/12/19 to 31/01/20	183
Public	16/12/19 to 09/03/20	474
SME	01/02/20 to 09/03/20	70

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FITNESS CHECK ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

TITLE OF THE FITNESS CHECK	Fitness Check on Endocrine Disruptors
LEAD DG – RESPONSIBLE UNIT	DG JRC – Directorate F – Health, Consumers and Reference Materials Unit F3 – Chemical Safety and Alternative Methods
INDICATIVE PLANNING	Planned start date: Q1 2019 – Planned end date: Q2 2020
ADDITIONAL INFORMATION	https://ec.europa.eu/health/endocrine_disruptors/overview_en

The Roadmap is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the document, including its timing, are subject to change.

enterprise europe network

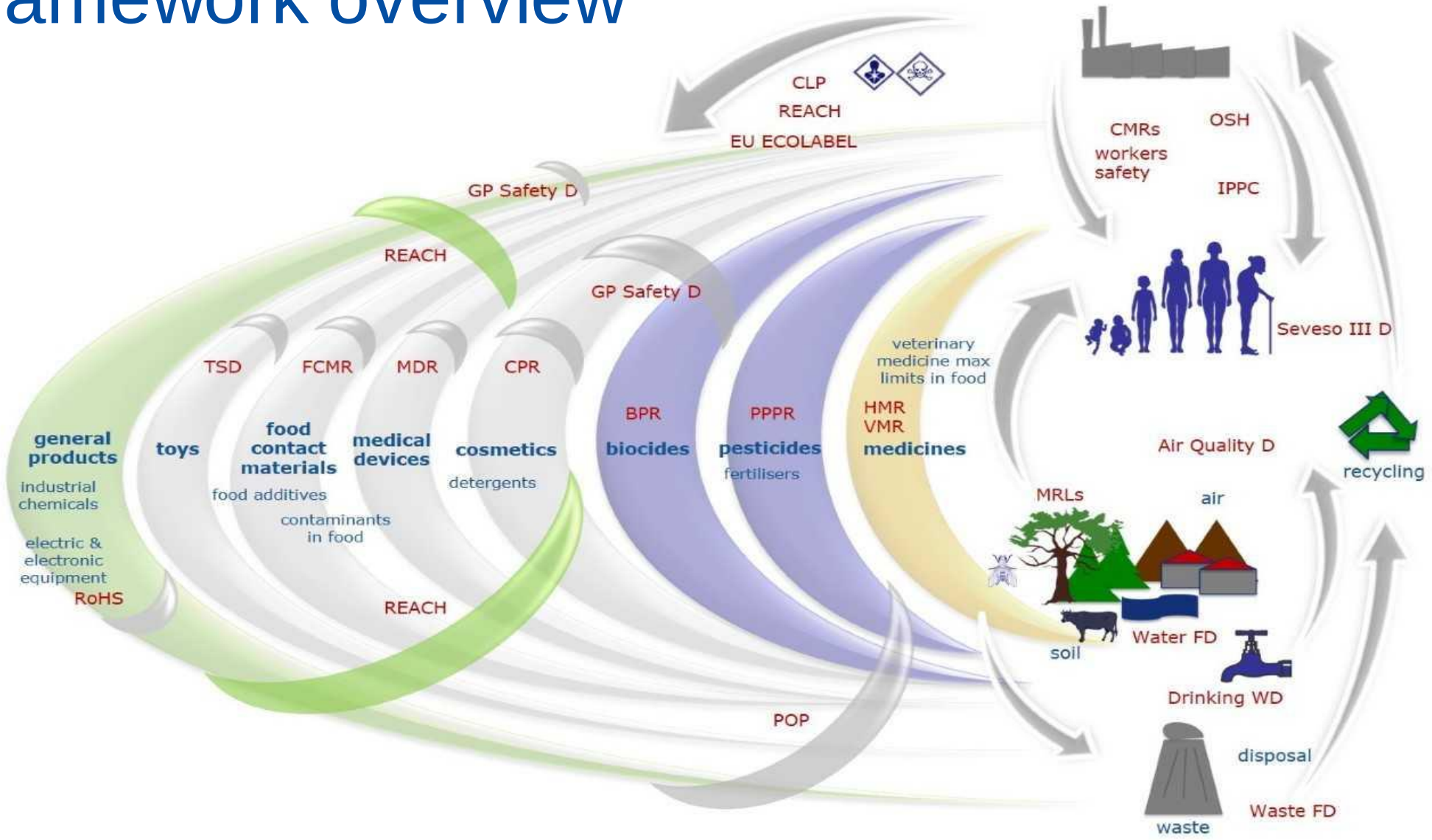
STATE OF PLAY

In scope legislation

- Biocidal products
- Plant protection products and residues
- REACH
- Classification, Labelling and Packaging (CLP)
- Persistent Organic Pollutants (POPs)
- **Toys**
- Food legislation (incl. **Food Contact Materials**)
- **Cosmetic Products**
- Medical devices and in vitro diagnostics
- Human and veterinary medicines
- Occupational Safety and Health legislation (OSH)
- Water legislation
- Waste (chemical-product-waste interface)
- Detergents
- Fertilising products
- Ecolabel
- General product safety
- Industrial emissions
- Air quality

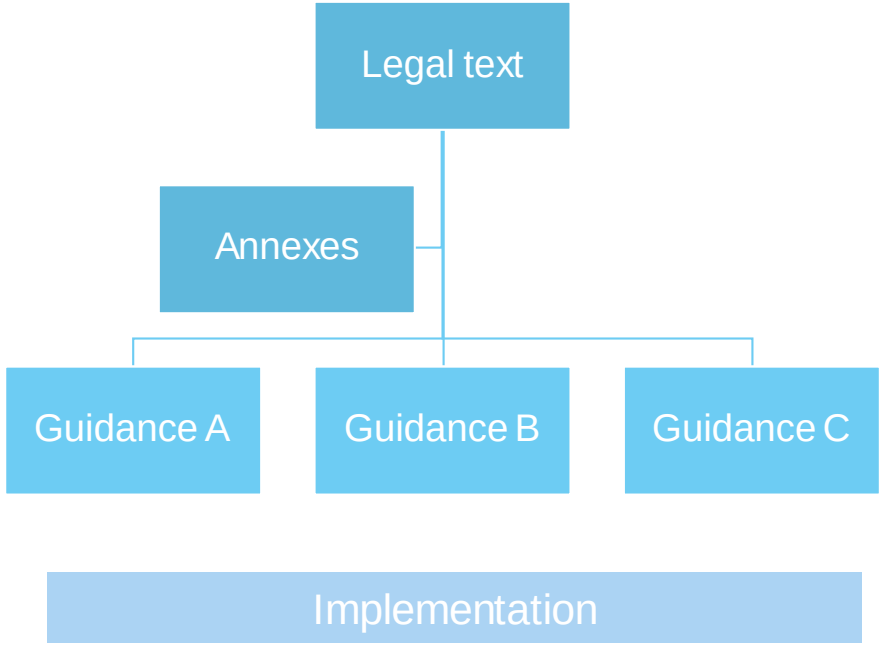
Protection of human health and the environment by minimizing overall exposure (COM(2018) 734)

Framework overview



Mapping of provisions

Assessment (incl. ED identification)	Risk management	Links with other legislation



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Identification

Assessment (incl. ED identification)	Risk management	Links with other legislation

Identification	Examples	Needs
Requiring identification (meeting the criteria for ED or not)	PPPR, BPR	Criteria Data requirements
Requiring identification of substances of concern (SVHC, PS) with explicit reference to EDs	REACH, WFD	
Refer to one of the above	MDR, Ecolabel, DWD	Clear regulatory connections
Does not explicitly require (directly or indirectly) identification of EDs	CLP, CPR, FCMR, TSD, OSH	

Risk management principles

Assessment (incl. ED identification)	**Risk management**	Links with other legislation

RISK MANAGEMENT PRINCIPLE	EXAMPLES	NEEDS
Generic risk (hazard based) → exposure minimisation	PPPR, BPR, REACH, many others*	
Specific risk (risk based) → safe uses	CPR, FCMR, REACH, many others	Derivation of safe threshold
Risk – benefit	MDR, REACH, PPPR, BPR, many others	

* to the extent EDs are also CMRs

Regulatory interplay

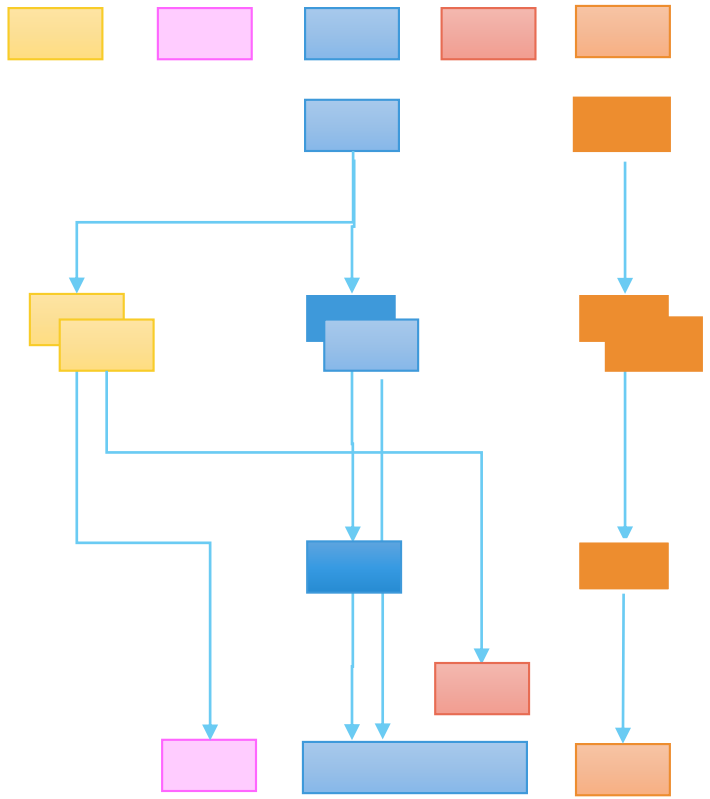
Assessment (incl. ED identification)	Risk management	Links with other legislation

DATA GENERATION

HAZARD ASSESSMENT

RISK ASSESSMENT

RISK MANAGEMENT



Regulatory interconnections

ED specific

non ED specific

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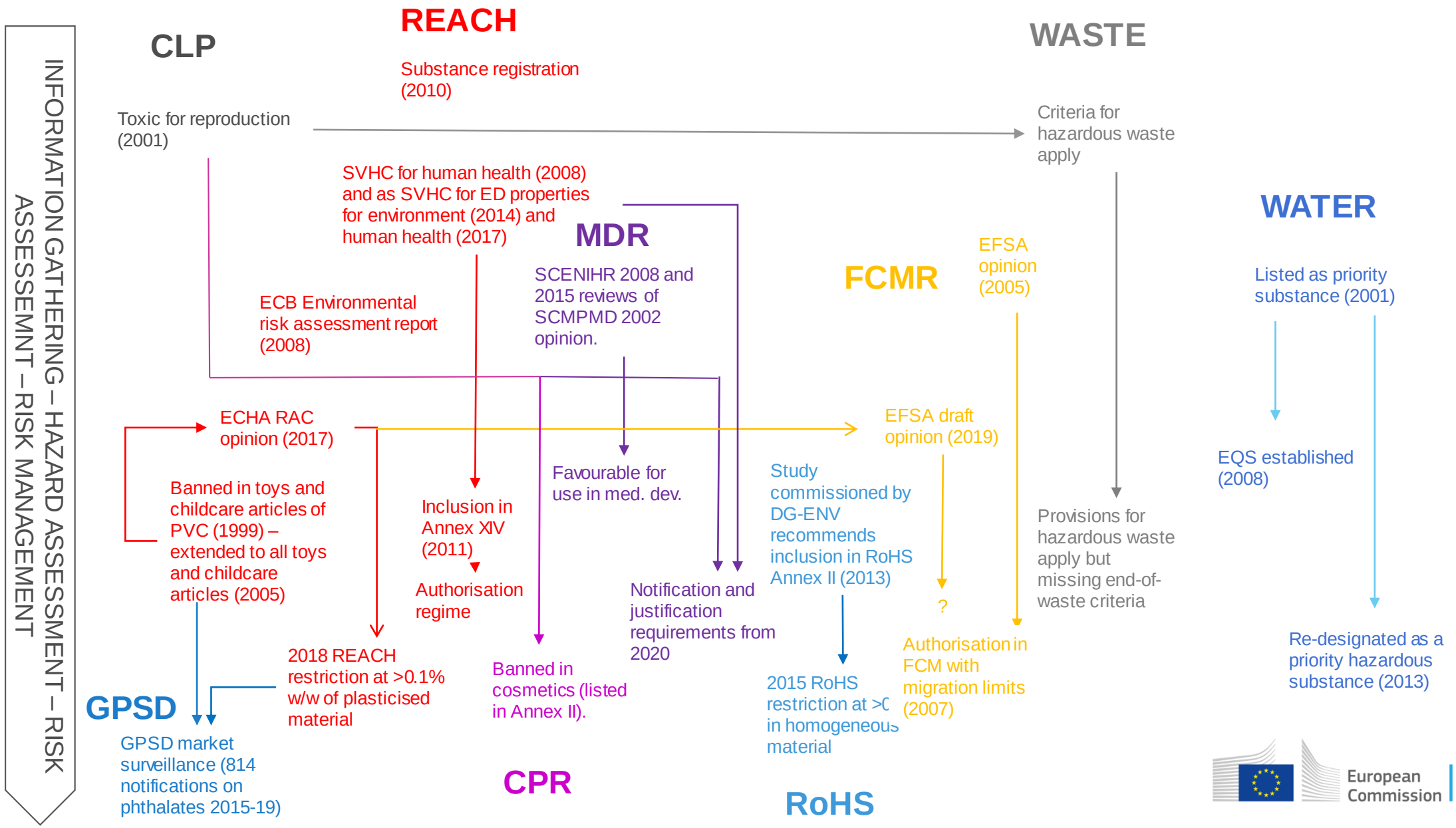
Regulatory interplay with REACH

Assessment (incl. ED identification)	Risk management	Links with other legislation

	Registration	Chemical Safety Report		Authorisation		Restriction	
		Human health	Env	Human health	Env.	Human health	Env.
Cosmetics	✓		✓		✓		✓
Toys	✓	✓	✓	✓	✓	✓	✓
Food contact materials	✓		✓		✓	✓	✓

Case study - DEHP



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FINDINGS

Findings – effectiveness and coherence

- Identification (criteria, data requirements, sufficiency of test methods)
- Risk management principles (coherence across legislation)
- Effectiveness (minimising exposure, including vulnerable groups)

Identification - criteria

- REACH has applied the IPCS/WHO 2002 definition in practice since 2013
- The criteria for identifying endocrine disruptors were adopted in 2018 under the Plant Protection Products Regulation and Biocidal Products Regulation, which build on the IPCS/WHO definition
- No explicit provisions for ED identification in other legislation
- The fitness check could find no evidence of inconsistent identification of EDs across the legislation.

The lack of a unified approach to identification renders decision-making less transparent and more complex.

Criteria set under PPPR and BPR may provide a starting point for a future cross-sectorial definition in EU legislation.

Identification - criteria

- REACH has applied the IPCS/WHO 2002 definition in identification of EDs across the legislation.

Box 4.1

Stakeholders support horizontal identification

ED hazard class under CLP – mixed responses

! Industry view - not necessary, can be done under REACH

! Public authorities view – support, common basis for identification and risk management (UN GHS - coherent identification worldwide).

! Suspected category – Industry against, public authorities & NGOs in support

The lack of a unified
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Identification - Information requirements

- Legal obligations on Manufacturer & Importer
- There are differences in data requirements (not ED-specific) across different sectors. Proportionality – balance costs and animal welfare against exposure potential
- Main legal instruments with data requirements are PPPR, BPR and REACH
- Substances used in toys, cosmetics, FCM have obligations to register under REACH, additional requirements in some cases

Data generation not necessary in each regulation so long as ready access to the data

Sufficiency of information requirements

- PPPs, BPs and REACH (>1000t/yr) substances- comprehensive dataset for adverse effects but 'mechanistic' or 'endocrine activity' data not required.
- Deficiency recognised and revisions ongoing based on relevant OECD Test Guidelines.
- Assessments based on all available data (e.g. scientific literature).
- Decisions have been made on ED properties under PPPR, BPR and REACH.

Need to strengthen information requirements to aid the identification of EDs

Active substance assessments for endocrine disrupting properties under the PPPR & BPR

	Assessed for ED properties	Meeting the ED criteria	Not meeting the ED criteria	No conclusion possible (further data may be required)	Assessment waived
PPPs Human Health	57	7	17	20	12
PPPs Environment	55	3	5	39	8
BPs Human Health & Environment	17	3	3	11	

Extract from SWD(2020) 251 – Tables 5.1 & 5.2

Assessment of endocrine disrupting properties under REACH

- REACH registered substances screened for endocrine activity as far as possible based on structural alerts, grouping and existing data.
- Around 90 substances (or groups of substances) brought to ED EG for discussion based on concern (e.g. through substance evaluation) (many still in process)
- 17 substances identified as SVHC due to ED properties
  - Human Health 5 (phthalates, butyl paraben)
  - Environment 10 (alkylphenols, 3-BC)
  - Both HH & ENV 2 (DEHP, BPA)

Identification - sufficiency of test methods

- Available OECD TGs can detect certain EDs which interfere with estrogen, androgen pathways, production of steroid hormones (EAS) and some aspects of interference with thyroid (T) system
- OECD TGs are not sufficient for addressing all the different ways in which the endocrine system might be disrupted
- Screening and testing methods under development (e.g. EURION thyroid system, metabolic disruption, female reproduction, developmental neurotoxicity),
- EURL ECVAM coordinated validation study on *in vitro* thyroid assays with support from EU NETVAL

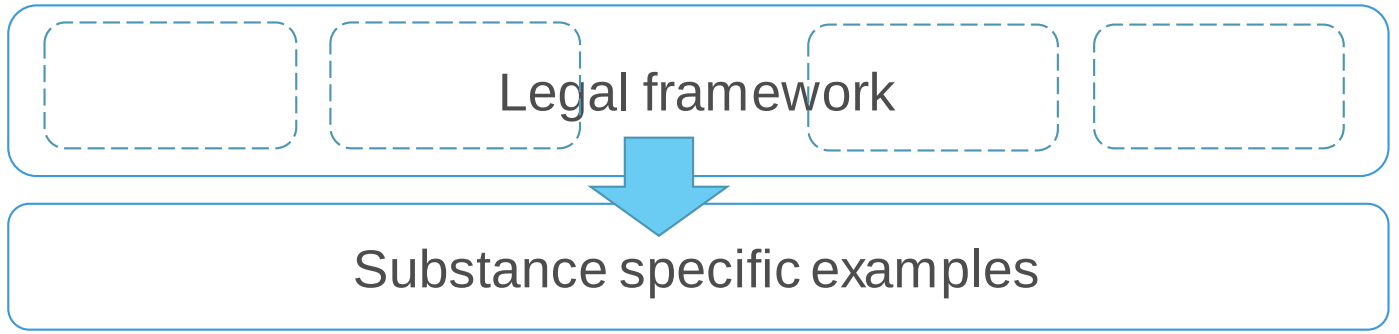
Need to further develop methods for identifying EDs (e.g. *in vitro* and *in silico* approaches)

Coherency - risk management principles

Legislation combines elements of generic risk, specific risk and risk-benefit approaches.
Differences in risk management do not imply incoherence if:

1. **Assumptions** underpinning assessments are **scientifically consistent**

2. **Clear rationale** for different risk management approaches and decisions



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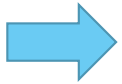
Risk management - scientific coherence

*It may be difficult (albeit not impossible) to determine a safe threshold with reasonable certainty for EDs. (*COM(2016) 814)

- Choose an approach that does not require that discussion (e.g. generic approach **PPPR**, **BP**)
- Case by case feasibility of derived safe (or acceptable) thresholds to base decisions (e.g. **REACH authorisation**).

Legal provisions and guidance

Stakeholder inputs



Some sectorial regulations (cosmetics, FCM) have not clarified how to deal with EDs, for which it is not possible to quantify a safe (or acceptable) threshold.

Risk management – scientific coherence (substance specific evidence)

- **DEHP**: SVHC for ED properties. In Annex XIV for reproductive toxicity. ECHA and EFSA risk assessments focused on reproductive toxicity (safe threshold).
- **BPA**: SVHC for ED properties. EFSA risk assessment established TDI based on kidney toxicity + uncertainty factor of 6 (safe threshold).
- **Nonylphenol** SVHC for ED properties for environment. No safe threshold established → authorisations based on socio economic route.
- **CPR**: no SCCS opinion issued after ED identification by other legislation.

No evidence of scientific incoherence due to lack of horizontal approach or any other ED related issues.

Few examples, framework not fully implemented

Risk management – rationale for differences

Policy specific considerations explain differences in RM:

- ✓ Risk benefit considerations (MDR)
- ✓ Risk benefits between policy objectives (REACH-Waste interface)

Several stakeholders argue they are not justified:

- ! Generic (PPPR, BPR) vs specific risk approach (CPR, FCMR)
- ! DEHP, BPA, triclosan, butylated hydroxytoluene, propyl- and butylparaben, Cd, Pb

DEHP

REACH broad restriction with specific authorisations

FCMR allowed below migration limit

MDR allowed based on risk-benefit

WFD measures aimed at cessation of exposure (PHS)

The rationale for some of the differences not always clear and transparent

Effectiveness in minimising exposure to EDs

- Limited number of substances identified as EDs and restricted due to ED properties
- Many substances with ED properties already restricted due to other hazardous properties.
- Some evidence from monitoring that restriction measures have reduced exposures and/or recovery of population
- Increase in endocrine-related non-communicable diseases in humans suspected to be associated with chemical exposures
- Contribution of manufactured chemicals to disease incidence unclear

Need better health and ecosystem indicators to evaluate the effectiveness of EU laws (e.g. biomonitoring).

Effectiveness – vulnerable groups

- Vulnerable groups - higher exposure and/or higher sensitivity
- EDs can cause effects during development of foetus or early life with effects only evident later in life (delayed effects)

It is important that data requirements for ED assessment cover sensitive life stages

CONCLUSIONS

Conclusions - identification

- The lack of a unified approach renders decision-making less transparent and more complex
- A cross-sector approach could build on the PPPR and BPR criteria
- Effective regulatory interplay will depend on ready access to data
- Information requirements need to be strengthened
- Need to further develop and apply test methods, focusing on non-animal approaches

Conclusions – assessment and management

- Certain sectors need to clarify how to deal with EDs for which safe thresholds cannot be established
- No evidence of incoherent management based on ED-related scientific inconsistencies
- Need for consolidation, simplification and better communication of risk management principles

Conclusions – protecting people and the environment

- Identification and management of EDs is contributing to decreasing exposure
- No conclusions on effectiveness of legislation in reducing adverse health and environmental impacts
- Future actions should focus on improving our ability to:
  - Identify and assess EDs
  - Monitor effectiveness of regulatory interventions

Q&As