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Regulatory approaches under REACH and other regulations (cosmetics, medical devices, food contact materials) - An overview of experiences

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A TOPIC TO CONSIDER
ENDOCRINE DISRUPTORS

Outlook

- Background:
  - Chemicals: REACH Regulation (EC) No 1907/2006
  - Cosmetics: Regulation (EC) No 1223/2009
  - Food Contact Materials: Regulation (EC) No 1935/2004
  - Medical Devices: Regulation (EU) 2017/745
- Conclusions on ED assessment
- Experiences within knoell

Chemicals

REACH – Registration, Evaluation and Authorisation of Chemicals

ED assessment under REACH

▶B ▼C1

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

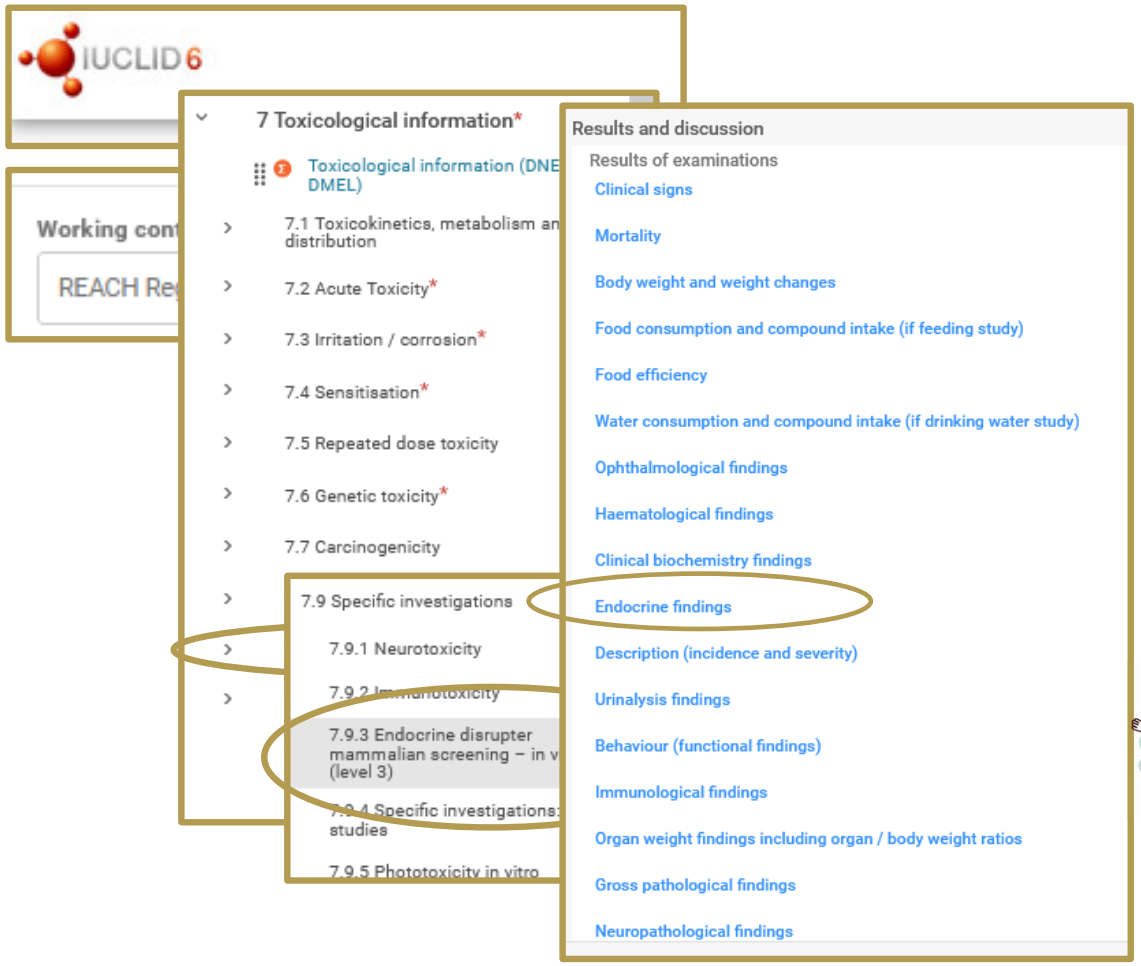
- **STANDARD INFORMATION REQUIREMENTS** (Annex VII – Annex X)

Required endpoints on toxicological information (Column 1 of the respective Annex):

- 8.1 Skin corrosion/irritation
- 8.2 Serious eye damage/irritation
- 8.3 Skin sensitisation
- 8.4 Mutagenicity
- 8.5 Acute toxicity
- 8.6 Repeated dose toxicity (sub-acute, sub-chronic and chronic toxicity)
- 8.7 Reproductive toxicity (Screening studies, Developmental toxicity and EOGRTS)
- 8.8 Toxicokinetics

REACH Regulation has not yet been updated to establish data requirements for the identification of ED

ED and REACH dossiers



Technical features to submit relevant information on ED are implemented although ED is not yet specified as data requirement;

IUCLID quality warning on Repeated Dose Toxicity: *"You are expected to cover the following key investigations: [….] endocrine findings, […]". (*QLT229)

ED assessment under REACH

- Is the ED hazard assessed under REACH?
- Example 1: Propylparaben

https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.002.098

Propyl 4-hydroxybenzoate

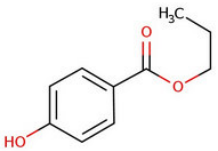
Regulatory process names 5 IUPAC names 14 Trade names 4 Other identifiers 3

Substance identity

EC / List no.: 202-307-7

CAS no.: 94-13-3

Mol. formula: C10H12O3



Hazard classification & labelling

According to the classification provided by companies to ECHA in **REACH registrations** this substance is harmful to aquatic life with long lasting effects.

Properties of concern

ED Under assessment as Endocrine Disrupting

More details

Important to know

- Substance included in the Community Rolling Action Plan (CoRAP).

How to use it safely

- Precautionary measures suggested by manufacturers and importers of this substance.

ED assessment under REACH

- Is the ED hazard assessed under REACH?
- Example 2: Bisphenol A
  - https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.001.133

4,4'-isopropylidenediphenol

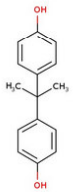
Regulatory process names 8 Translated names 23 IUPAC names 34 Trade names 20 Other names 2 Other identifiers 8

Substance identity

EC / List no.: 201-245-8

CAS no.: 80-05-7

Mol. formula: C15H16O2



Hazard classification & labelling

Danger! According to the **harmonised classification and labelling** (ATP18) approved by the European Union, this substance may damage fertility, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, causes serious eye damage, may cause an allergic skin reaction and may cause respiratory irritation.

Additionally, the classification provided by companies to ECHA in **REACH registrations** identifies that this substance may damage fertility or the unborn child.

Properties of concern

R Toxic to Reproduction

Ss Skin sensitising

ED Endocrine Disrupting

More details

Important to know

- Substance included in the Community Rolling Action Plan (CoRAP).
- Substance of very high concern (SVHC) and included in the candidate list for authorisation.
- Some uses of this substance are restricted under Annex XVII of REACH.

About this substance

This substance is registered under the REACH Regulation and is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 000 tonnes per annum.

This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

ED assessment under REACH is performed

ED assessment under REACH

- Evaluation of ED properties under REACH takes place, but how?

Reason for inclusion on REACH candidate list (REACH Article 57(f))

English
Carcinogenic (Article 57a)
Mutagenic (Article 57b)
Toxic for reproduction (Article 57c)
PBT (Article 57d)
vPvB (Article 57e)
Endocrine disrupting properties (Article 57(f) - environment)
Endocrine disrupting properties (Article 57(f) - human health)
Respiratory sensitising properties (Article 57(f) - human health)
Specific target organ toxicity after repeated exposure (Article 57(f) - human health)
Equivalent level of concern having probable serious effects to human health (and/or) the environment (Article 57f)

ED assessment under REACH: REACH candidate list

- REACH candidate list (*Update of Candidate list on 17 Jan 2023):*

  https://echa.europa.eu/de/candidate-listtable?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_ disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

- 22 substances have been identified as SVHC based on ED properties
- Human Health: 6 substances
- Environment: 16 substances

- **Examples of agreed cases:**

  Diethylhexyl phthalate (DEHP)

  Bisphenol A

  Dicyclohexyl phthalate (DCHP)

ED assessment under REACH: Regulatory Consequences

- Substances identified as ED undergo authorisation under REACH (hazard-based approach)
  - uses of the substance need to be approved on the authorisation list (Annex XVI)
  - after the Sunset date, ED may only be used if authorisation has been granted

- Substances can be authorised when
  - the risk for a specifc use is adequately controlled („adequate control route“)
  - socio-economic benefits outweigh the risk (SEA route)

Cosmetics

Cosmetics

ED in the Regulation on Cosmetic Products (EC) No 1223/2009

▶B REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 November 2009

on cosmetic products

- Article 15:

4. When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.

- Annex I: Cosmetic Product Safety report
  - "the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints". A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made.

***Cosmetic Product Regulation** does not explicitly define ED as relevant toxicological endpoint, BUT ...*

ED: Safety Assessment for Cosmetic Products

Scientific Committee on Consumer Safety
SCCS
THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION
12TH REVISION

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- Relevant toxicological endpoints for safety evaluation are established in the SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation *(12th revision, 2023)*

Assessment of "EAS" is included in the safety assessment of cosmetics

Data obtained from in vivo testing should only be provided if the data were already available before the animal testing ban or obtained for the purpose of demonstrating compliance with other (non-cosmetic) legislations (e.g. REACH).

Safety assessment of ED for Cosmetic Products

Scientific Committee on Consumer Safety
SCCS
THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF
COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION
12TH REVISION

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- ED properties can be assessed only in a stepwise approach due to the animal test ban under the Cosmetic Regulation using data generated outside the cosmetic field or using NAMs
- For a new cosmetic ingredient, characterisation will be limited to level 1 and level 2 studies defined in OECD´s conceptual framework 150

Level 1	Existing data and non-test information *eg* : Physical and chemical properties / QSARs
Level 2	*In vitro* assays providing data about selected endocrine mechanism(s) / pathways(s) *eg* : Estrogen receptor transactivation (OECD TG 455) / Estrogen or androgen receptor binding affinity
	In vivo assays providing data about selected endocrine

„While the results from levels 1 and 2 approaches can be indicative of endocrine activity of a cosmetic ingredient, they will not definitively inform whether the substance will cause adverse effect(s) in the intact organism to be regarded an ED.“

“Due to the ban of animal testing, the available data on cosmetic ingredients usually cannot comply with the criteria laid down in the OECD conceptual framework.”

ED assessment under Cosmetic Product Regulation

https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-products-specific-topics/endocrine-disruptors_en

Scientific Committee on Consumer Safety
SCCS
THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION
12TH REVISION

- The Cosmetic Product Regulation includes a system of restrictions on and bans of certain substances in cosmetics.
- The restrictions are based on a risk assessment performed by the SCCS

- Based on the SCCS opinion, the Commission takes action to prohibit or restrict the use of ED substances in cosmetics.
- SCCS Notes from December 2023: 14 substances have been assessed for ED properties by the SCCS
  - Examples: Resorcinol, Propylparaben, Triclosan, Benzyl salicylate

ED assessment under Cosmetic Product Regulation

European Commission

CosIng - Cosmetics Ingredients

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►B REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 30 November 2009
on cosmetic products

- List of Annexes (Regulation (EC) 1223/2009):
  - Annex II: List of substances prohibited in cosmetic products
  - Annex III: List of substances which cosmetic products must not contain except subject to the restriction laid down

  - Annex IV: List of colourants allowed in cosmetic products
  - Annex V: List of preservatives allowed in cosmetic products
  - Annex VI: List of UV filters allowed in cosmetic products

ED assessment under Cosmetic Product Regulation

Scientific Committee on Consumer Safety

SCCS

OPINION ON
Propylparaben (PP)

- Example: Propylparaben
- REACH: Under assessment for ED; already concluded for environment
- Cosmetics: SCCS Opinion

Conclusion SCCS:
On the basis of the safety assessment of Propylparaben, and considering the concerns related to potential endocrine disrupting properties, the SCCS has concluded that Propylparaben is safe when used as a preservative in cosmetic products up to a maximum concentration of 0.14 %.

The available data on Propylparaben provide some indications for potential endocrine effects. However, the current level of evidence is not sufficient to regard it as an endocrine disrupting substance, or to derive a toxicological point of departure based on endocrine disrupting properties for use in human health risk assessment.

ED under Cosmetic Product Regulation: Regulatory consequences

- Substances identified or suspected as ED for human health are assessed by the SCCS
  - Risk assessment is performed
  - The safety in individual products is judged based on MoS
  - Substances are included in the respective Annex of the Cosmetic Regulation
    - EDs can be prohibited (Annex II) or allowed/restricted (Annex III – VI) in specific cosmetic products
    - Maximum concentrations are defined if EDs are allowed to be used in cosmetic products

Food Contact Materials

Food Contact Materials

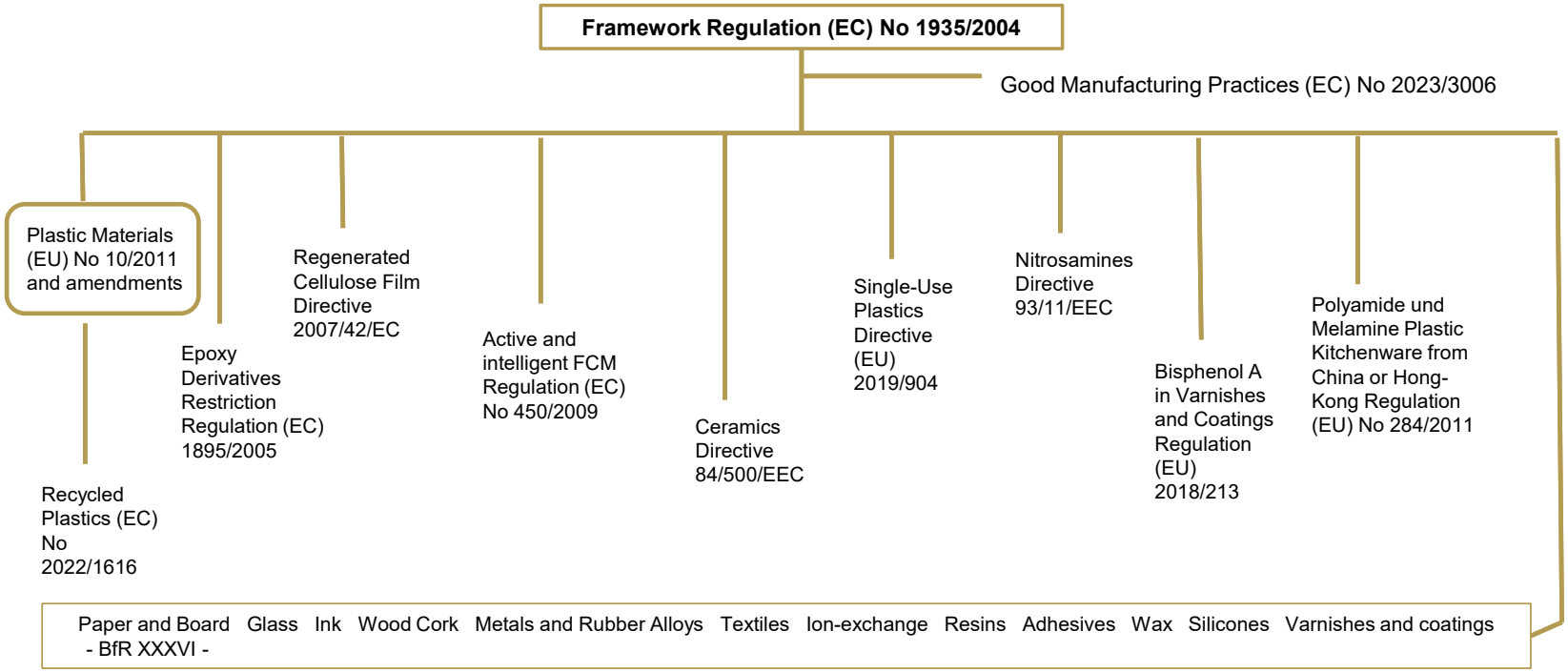
ED in the Regulation of Food Contact Materials

National body

REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 2004

on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC



ED in the Regulation of Food Contact Materials

Plastic Regulation (EU) No 10/2011 - Union list of authorized substances

- Plastic materials must be manufactured with authorized substances included within the **Union list** (EU) No 10/2011 Annex 1 and its amendments.
  - The data requirements for hazard assessment to include a substance into the Union list depend on the migration of a substance (according to EFSA Note for guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials, 2020)

Migration < 0.05 mg/kg food / food simulant:	2 genotoxicity tests (OECD 471 / 487)
Migration 0.05 – 5 mg/kg food / food simulant:	genotoxicity testing + 90-day oral toxicity study (OECD 408)

ED testing as such is not included in the data requirements (plastic food contact materials)

Migration 5 – 60 mg/kg food / food simulant:	genotoxicity testing / 90-day oral toxicity study + Studies on ADME Studies on reproduction and developmental toxicity Studies on long-term toxicity / carcinogenicity

ED in the Regulation of Food Contact Materials

- EFSA Scientific Opinion 'Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials (2016))

Tier number and specifications	Toxicity data required	Additional considerations
Tier 1: Human exposure up to 1.5 µg/kg bw per day **or if** **The substance is classified as Cramer class I and exposure is less than 30 µg/kg bw per day**	– Genotoxicity studies – Available information including an appropriate literature search	In general, no other toxicity studies are required below this threshold. Exceptions are: (1) if there are existing data indicating the potential to affect endocrine or neural systems; (2) for substances with a high potential to accumulate in humans; (3) for nanomaterials, even if the non-nanoform material has been evaluated and approved for FCM.
Tier 2: Human exposure from 1.5 to 80 µg/kg bw per day	As above, plus: – Extended 90-day oral toxicity study in rodents	A study on absorption, distribution, metabolism and excretion (ADME) should be used to assess the potential for accumulation in humans of substances for which such a potential could be anticipated. If there are existing data indicating endocrine activity suggesting potential effects from prenatal exposure, a 90-day study with a prenatal treatment period or an extended one-generation reproduction toxicity study (EOGRTS) should be considered.
Tier 3: Human exposure higher than 80 µg/kg bw per day	As above[(a)], plus: – Study on ADME – Studies on reproduction and developmental toxicity – Studies on long-term toxicitv/carcinogenicity	If there are existing data indicating endocrine activity suggesting potential effects from prenatal exposure, a chronic study with a prenatal treatment period or an EOGRTS should be considered.

(a): The extended 90-day oral toxicity study required in tier 2 might not be necessary as it is covered by the long-term testing.

ED testing as such is not included in the data requirements, but the EFSA recommends to consider endocrine potential as additional consideration which requires further testing.

ED assessment for Food Contact Materials

- Example: Bisphenol A
- REACH: identified as ED for human health (and environment)
- Food Contact Materials: Regulation (EU) 2018/213 (consolidated version)

COMMISSION REGULATION (EU) 2018/213

of 12 February 2018

on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

(1) FCM substance No	(2) Ref. No	(3) CAS No	(4) Substance name	(5) Use as additive or polymer production aid (yes/no)	(6) Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	(7) FRF applicable (yes/no)	(8) SML [mg/kg]	(9) SML(T) [mg/kg] (Group restriction No)	(10) Restrictions and specifications	(11) Notes on verification of compliance
'151	13480 13607	0000080-05-7	2,2-bis(4-hydroxyphenyl) propane	no	yes	no	0,05		Not to be used for the manufacture of polycarbonate infant (1) feeding bottles (2). Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants (3) and young children (4).	

A draft Commission Regulation (EU) on the restriction/prohibition of BPA and BPA-derivatives in (plastic) FCM has been released in 2024

ED under the Framework for Food Contact Materials: Consequences

- Substances identified or suspected as ED can be used in Food Contact Materials (FCM)
  - Specific migration limits (SML) and restrictions are defined for individual FCM applications
  - The SML must not be exceeded

Medical Devices

Medical Devices

ED in the Regulation of Medical Devices

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Notified bodies

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REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

10.4.1. Design and manufacture of devices

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

Devices, or those parts thereof or those materials used therein that:

— are invasive and come into direct contact with the human body,

— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

(a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]), or

(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council ([3]), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

The Regulation on Medical Devices refers to the REACH and Biocidal Product Regulation (BPR)

ED assessment in Medical Devices

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Notified bodies

knoell worldwide registration

- EDs can be used in Medical Devices in concentrations above 0.1% (w/w) when a proper justification can be provided (Annex I, Chapter II Section 10.4.2 of Regulation (EU) 2017/745)

10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances

The justification for the presence of such substances shall be based upon:

(a) an analysis and estimation of potential patient or user exposure to the substance;

(b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;

(c) argumentation as to why possible substance and/ or material substitutes if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and

(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.

ED assessment in Medical Devices

- For Medical Devices, the exposure of patients and users towards EDs has to be considered to justify their presence
  - A risk assessment is required based on a step-wise approach

Step 1

Worst-case chemical release „“It all comes out“

Acceptable Risk

Step 2

Estimate chemical release in extractables

Acceptable Risk

Step 3

Estimate chemical release in leachables

ED assessment in Medical Devices: Examples

- Example: Phthalates
  - Di-(2-(ethylhexyl) phthalate (DEHP) is widely used in Medical Devices (such as blood bags, nutrition pockets, tubing, catheters and respiratory masks)
  - The use of DEHP is restricted under REACH (Annex XIV):
    https://www.echa.europa.eu/web/guest/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2d0d

Properties of concern

R Toxic to Reproduction

ED Endocrine Disrupting

More details

Important to know

- Substance of very high concern (SVHC) and included in the candidate list for authorisation.
- Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH).
- Some uses of this substance are restricted under Annex XVII of REACH.

DEHP can still be used in Medical Devices, the EU has postponed the ban in Medical Devices in November 2023

Latest application date is January 2029; Sunset date is July 2030

ED assessment in Medical Devices

- Substances identified or suspected as ED can be used in Medical Devices
  - At concentrations > 0.1%, a justification has to be provided
  - The risk assessment has to prove a controlled risk
  - REACH - Authorisation: The *Latest application date* and *Sunset date* do not apply for Medical Devices

Conclusion/Experiences

Wrap-up (I): REACH and ED

- ED assessment of chemicals registered under REACH takes place, although the REACH Regulation and its Annexes have not been updated to establish the data requirements to specifically test for ED properties (mechanistic data)
- Regulation of EDs is based on the identification as Substance of Very High Concern (SVHC) alongside with CMR substances. This results initially in a hazard-based approach
- Several substances have been identified as SVHC based on ED properties and are inlcuded on the candidate list for authorisation
- Autorisation/Restriction is the regulatory consequence for chemicals identified as EDs

Wrap-up (II): Cosmetic Products and ED

- ED assessment is included in the safety assessment of cosmetics as “specific investigation”
- ED properties can be assessed only in a stepwise approach due to the animal test ban under the Cosmetic regulation using data generated outside the cosmetic field or using NAMs
- For a new cosmetic ingredient, characterisation will be limited to level 1 and level 2 studies defined in OECD´s conceptual framework 150
  - Due to the ban of animal testing, the available data on cosmetical ingredients usually cannot comply with the criteria laid down in the OECD conceptual framework.
- Safety assessment: SCCS treat ED like other substances of concern for human health and therefore carry out risk assessment

Wrap-up (III): Food Contact Materials and Medical Devices

Food Contact Materials and ED

- EDs can be allowed as Food Contact Material when the SML is not exceeded by the migration of the ED substance (risk-based approach)

Medical Devices and ED

- The Regulation on Medical Devices directly refers to REACH and BPR for the endpoint ED

- EDs can be contained in Medical Devices when their use is justified. Exposure shall be considered (risk-based approach)

ED under the Chemical Strategy for Sustainability (CSS)

- ED assessment relevant across all regulations

  - Example: DEHP
  - Identified as SVHC based on Reproductive and ED properties under REACH
    Included in Annex XIV (Authorisation list)

Chemicals

Latest application date:
21 August 2013

Sunset date:
21 February 2015

Cosmetics

Listed on Annex II
(CMR properties)

Prohibited in
cosmetics

Food Contact Materials

Latest application date:
14 June 2023

Sunset date:
14 December 2024

Medical Devices

Latest application date:
01 January 2029

Sunset date:
1 July 2030

All regulatory areas are affected on EU level, although ways of derogation apply to Food Contact Materials and Medical Devices

ED under the Chemical Strategy for Sustainability (CSS)

- ED assessment relevant across regulations

- „One substance, one assessment“
  - The assessment of ED properties is mostly based on the data available under REACH, BUT
    - Different Committees may be involved in the assessment
      - REACH: eMember State; ED expert group, RAC and SEAC
      - Cosmetics: SCCS
  - Different approaches may be followed
    - REACH: Hazard-based approach
    - Cosmetics/FCM and MD: Risk-based approach

ED under the Chemical Strategy for Sustainability (CSS)

- ED assessment relevant across regulations

- „One substance, one assessment“

- The Commission will ensure that EDs are banned in consumer products as soon as they are identifed, allowing their use only where it is proven to be essential for society

  - EDs can be banned under REACH and other Regulations, but their use may also be authorised/restricted/allowed in Cosmetics, Food Contact Materials and Medical Devices and under REACH

ED under the Chemical Strategy for Sustainability (CSS)

- ED assessment relevant across regulations

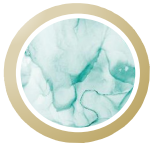
- „One substance, one assessment“

- The Commission will ensure that EDs are banned in consumer products as soon as they are identifed, allowing their use only where it is proven to be essential for society

- The Commission will ensure that sufficient and appropriate information is made available to authorities

Assessment approach

Level 1	Level 2	Level 3	Level 4	Level 5
Existing and new non-testing data	*In vitro* studies – mechanistic data	*In vivo* studies – mechanistic data	*In vivo* studies – RDT and Devtox studies	*In vivo* studies – EOGRTS and OECD 416



Chemicals

Level 1
Level 4
Level 5
Mechanistic data missing

Cosmetics

Level 1
Level 2, reference to other regulations
Data on adversity missing

Food Contact Materials

Reference to REACH dossier

Medical Devices

Reference to REACH dossier

The data basis for ED assessment is not harmonised among the different regulatory areas. The data packages do not comply with the criteria laid down in the OECD conceptual framework."

ED under the Chemical Strategy for Sustainability (CSS)

- ED assessment relevant across regulations
- „One substance, one assessment“

- The Commission will ensure that EDs are banned in consumer products as soon as they are identifed, allowing their use only where it is proven to be essential for society

- The Commission will ensure that sufficient and appropriate information is made available to authorities

REACH (planned updates NOT included in the current European commission work programme!):

- **Update data requirements** for screening of ED activity?

Experiences within knoell

- ED assessment is conducted under REACH and other Regulations by the authorities
  - although no clear assessment approaches are defined under REACH and the other regulations
  - assessment is performed based on the existing data packages

- ED assessment is carried out on voluntary basis by registrant(s)
  - although the approach are not clearly defined under REACH and the other regulations
  - assessment is based on the existing data
    - level 4 and level 5 studies

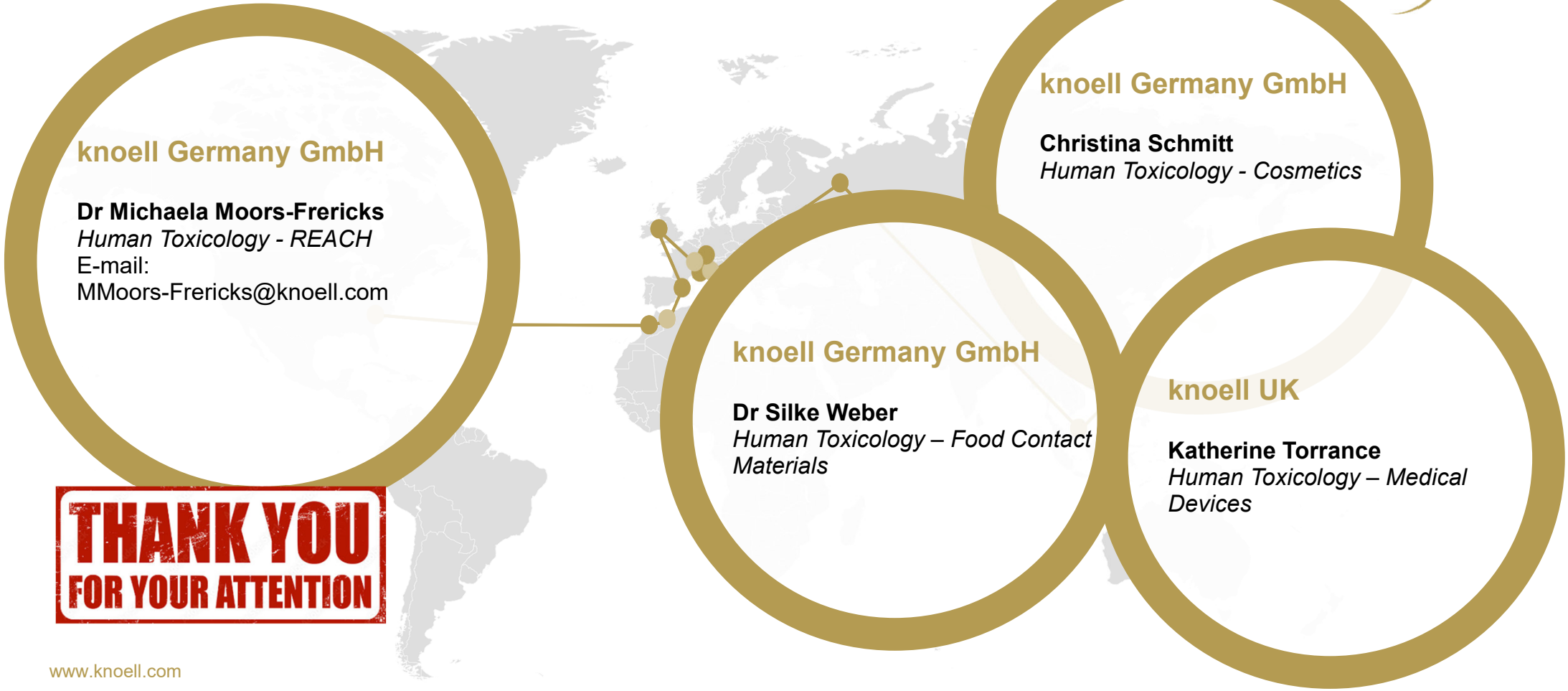
Experiences within knoell

- Companies start to screen the REACH dossier(s) in regard to ED
  - *We develop screening approaches to identify „red-flags“*

- ED assessment performed by knoell for Chemicals:
  - *We draw on our experience with active substances and combine the different regulations*
    - For ED assessment, we follow the ECHA/EFSA Guidance
    - We „use“ the existing templates for Biocides/PPP for ED assessment of Chemicals

Think globally, act locally - your local contact

knoell worldwide registration



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