REACH– RESTRICTED SUBSTANCES AND THEIR WIDE SPREAD IMPACTS

H2 Compliance

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March 19th, 2018

AGENDA

H2 COMPLIANCE

1. **INTRODUCTION OF RESTRICTED SUBSTANCES AND REACH**
2. **REGULATORY MANAGEMENT OPTIONS ANALYSIS – HOW DOES THE PROCESS WORK, TIMELINES & OUTCOMES**
3. **SUBSTANCE EVALUATION**
4. **CASE STUDY**
5. **OTHER SUBSTANCES TO WATCH AND IMPACT ON OTHER REGULATIONS**
6. **SUMMARY AND NEXT STEPS**

INTRODUCTION TO RESTRICTED SUBSTANCES AND REACH

REACH - OVERVIEW

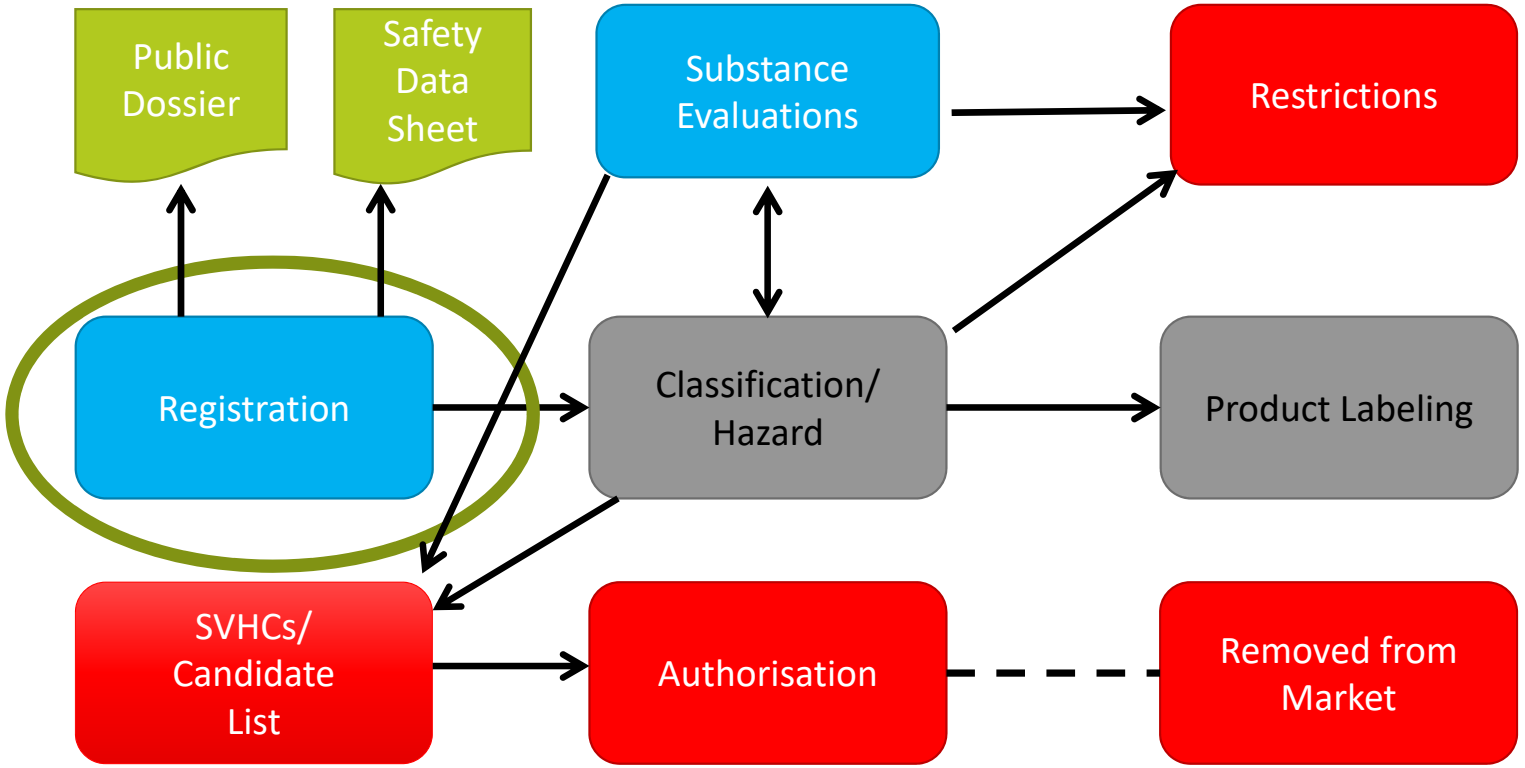
H2 COMPLIANCE

- Objective: "***to ensure the protection of Human Health & Environment"***

- REACH entered into force in 2007 across all EU Member States

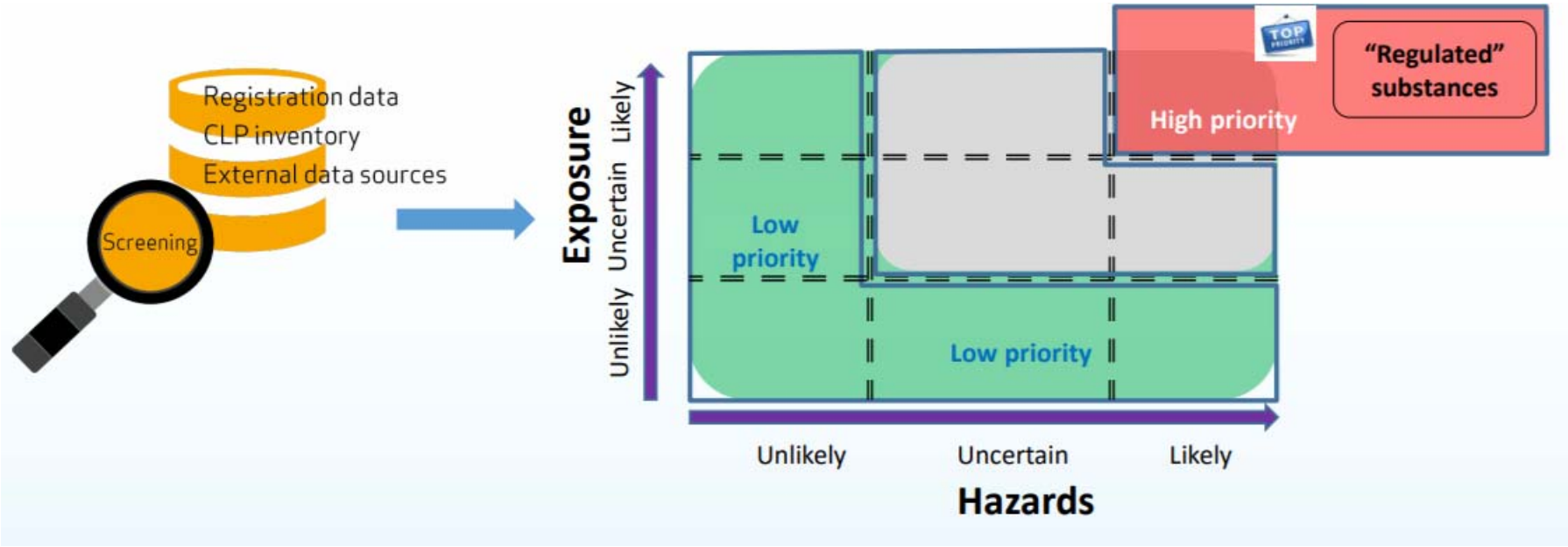
Registration	*all substances manufactured or imported above 1 tonne/yr.*
Evaluation	*targeted assessment of registered substances*
Authorisation	*process to phase out selected Substances of Very High Concern*
Restriction	*targeted limitation on uses of certain substances*
CHemicals	*all substances, manufactured, imported as such, in mixture or article*

REGISTRATION: THE "CORNERSTONE" OF REACH



Registration & Classification: Main starting point for pro-active product stewardship; statement from ECHA

CHEMICALS OF CONCERN



WHAT ARE THE MOST HAZARDOUS SUBSTANCES? "CHEMICALS OF CONCERN"

H2 COMPLIANCE

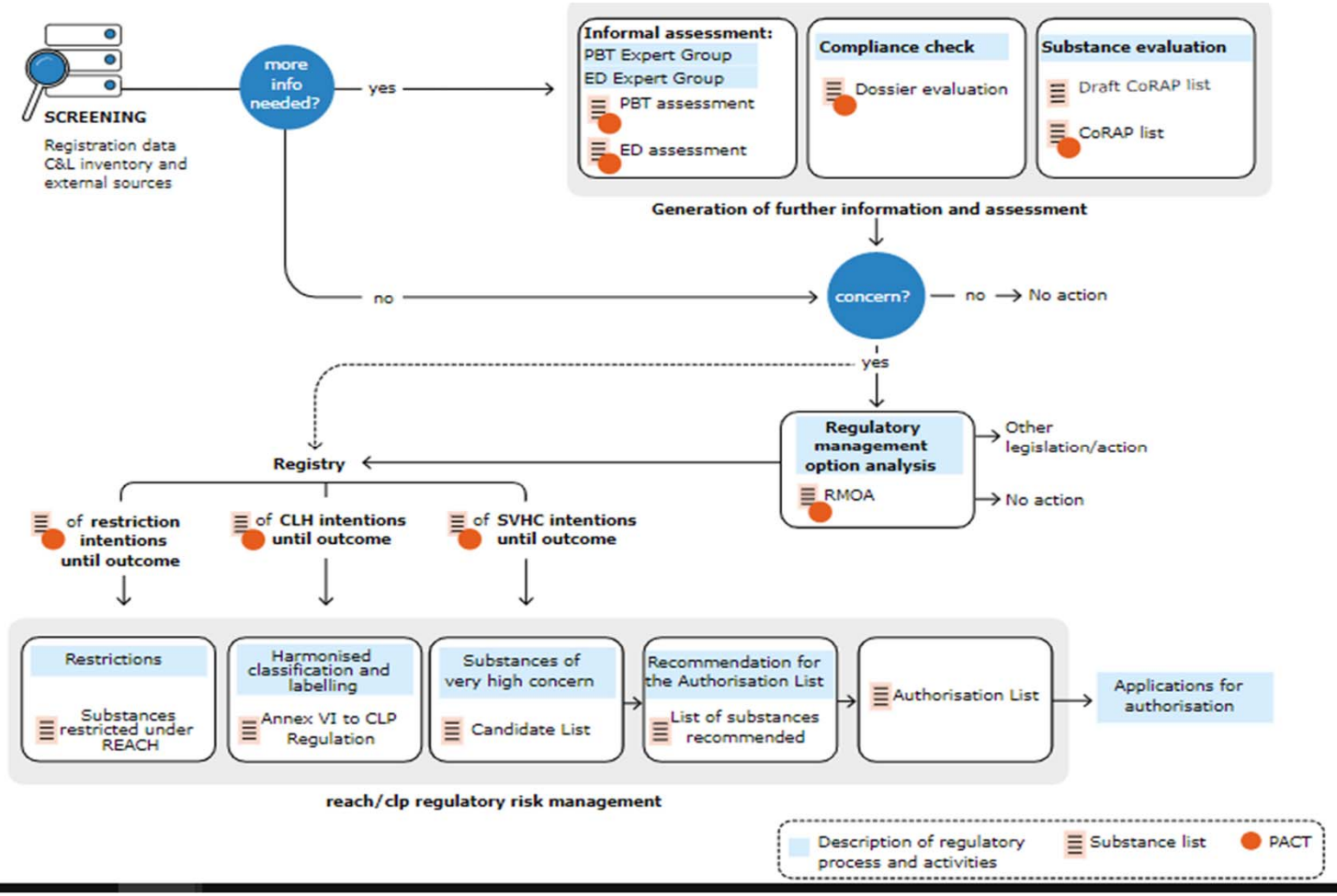
Article 57 of REACH: Substances of Very High Concern (SVHCs)

- A Carcinogen, Mutagen or Reprotoxin (Category IA & IB)
- A persistent bioaccumulative toxin (PBT),
- Very persistent very bioaccumulative toxin (vPvB),
- Substances of equivalent level of concern (ELoC), e.g. endocrine disruptors, respiratory sensitizers, case by case

The regulators left themselves some flexibility by providing for substances of "equivalent concern" under Clause 57(f).

REGULATORY MANAGEMENT OPTION ANALYSIS– HOW DOES THE PROCESS WORK, TIMELINES & OUTCOMES

ADDRESSING CHEMICALS OF POTENTIAL CONCERN



Source: European Chemicals Agency, http://echa.europa.eu/

PUBLIC ACTIVITIES CO-ORDINATION TOOL (PACT)

PACT provides up-to-date information on the activities planned, ongoing or completed by ECHA and/or MSCAs for a given substance in the following areas:

- Data generation and assessment
  - dossier evaluation (DEv)
  - substance evaluation (SEv)
  - informal hazard assessment (PBT/vPvB/ED).
- Regulatory management option analysis (RMOA).
- Regulatory risk management
  - Harmonised classification and labelling (CLH)
  - SVHC identification
  - Restriction.

PACT ILLUSTRATION

H2 COMPLIANCE

Substance name	EC / List no	CAS no	Data generation and assessment				RMOA	Regulatory risk management			
			DEv	SEv	ED	PBT	RMOA	CLH	SVHC	Restriction	
(+)-tartaric acid	201-766-0	87-69-4	3	-	-	-	-	-	-	-	
(+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	119738-06-6	-	-	-	-	-	1	-	-	
(+/-) trans-3,3-dimethyl-5-(2,2,3-trimethyl-cyclopent-3-en-1-yl)pent-4-en-2-ol	411-580-3	107898-54-4; 244626-73-1; 1077898-54-4	1	-	-	-	-	-	-	-	
(-)-pin-2(10)-ene	242-060-2	18172-67-3; 127-91-3	-	1	-	-	1	-	-	-	
(1's,4'r)-4'-propyl-[1,1'-bi(cyclohexane)]-4-one	617-391-4	82832-73-3	1	-	-	-	-	-	-	-	
(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	214-619-0	1166-46-7	-	-	-	-	-	1	-	-	
(1-hydroxyethylidene)bisphosphonic acid, sodium salt	249-559-4	29329-71-3	3	-	-	-	-	-	-	-	

Source: European Chemicals Agency, http://echa.europa.eu/

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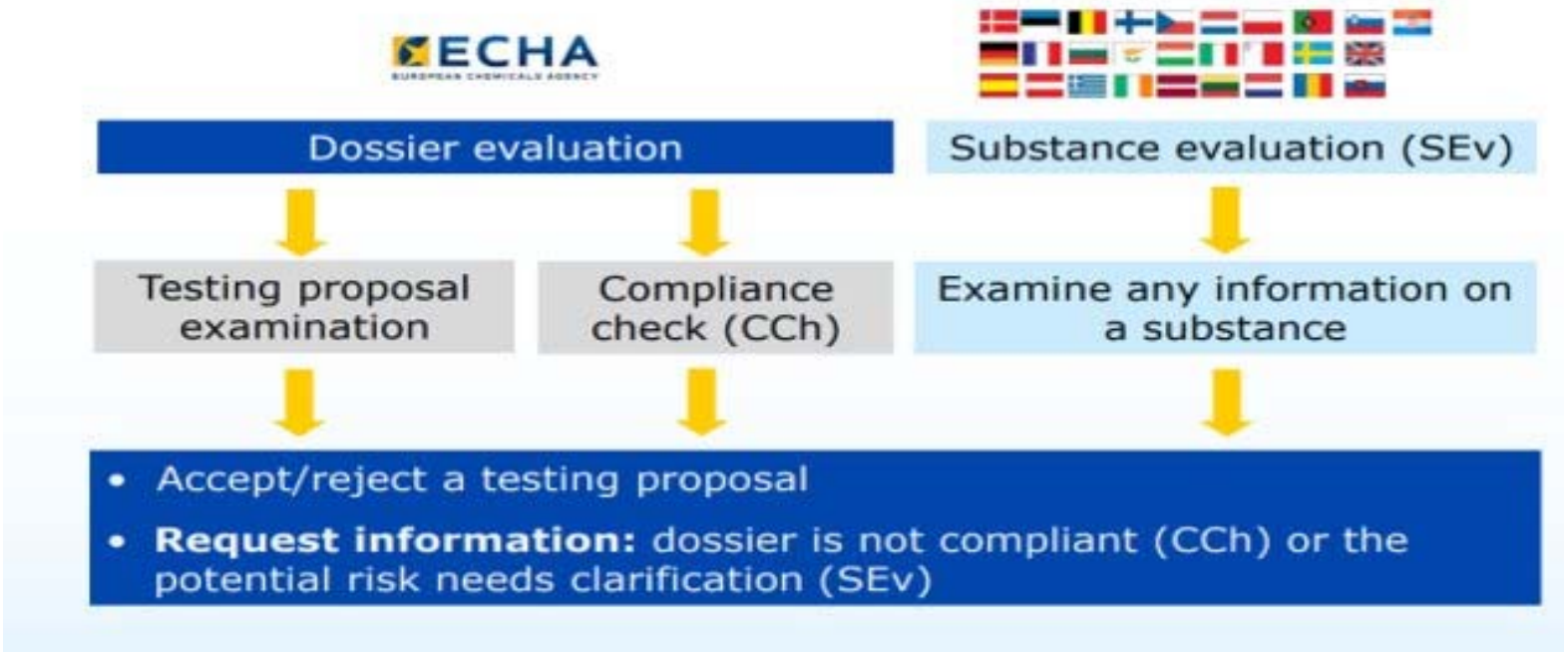
ECHA
EUROPEAN CHEMICALS AGENCY

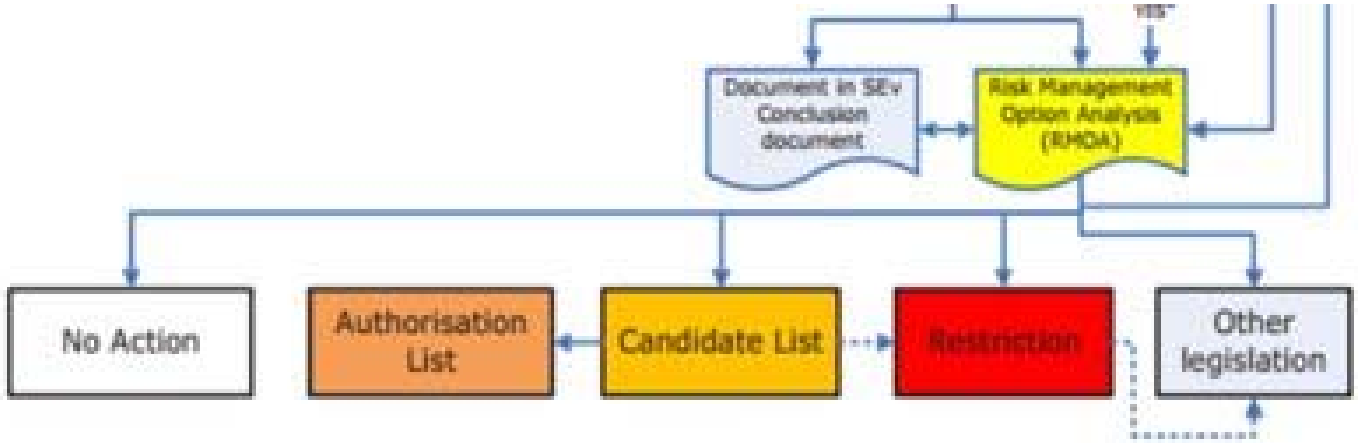
Evaluation processes

REACH 2018



REGULATORY MANAGEMENT OPTION ANALYSIS (RMOA)

Clarify whether risk management activities are required and identify the **most appropriate instrument to address a concern**.



RMOA is **voluntary**: it is not part of the processes defined in the EU chemicals legislation. Further actions are proposed through the Registry of Intentions

REGISTRY OF INTENTIONS (ROI)

Exist for 3 Regulatory Outcomes:

- SVHC Identification
- Restriction
- Harmonised Classification and Labelling

The ROI gives the status of the Regulatory Proposal against the stage gates in the process:

- Notification of Intention
- Submission and Scope of justification dossier
- Public Consultation and Response to Comments
- Committee Opinions and Reports
- Legal Instruments

ROI EXAMPLE- 11 JANUARY 2019

formaldehyde and formaldehyde releasers	-	-	Submitted	11/01/2019	ECHA	Restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses	30/01/2019	
microplastics	-	-	Submitted	11/01/2019	ECHA	Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.	30/01/2019	
Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6) **Dodecamethylcyclohexasiloxane** D6 EC / List no: 208-762-8 | CAS no: 540-97-6 **Octamethylcyclotetrasiloxane** D4 EC / List no: 209-136-7 | CAS no: 556-67-2 **Decamethylcyclopentasiloxane** D5 EC / List no: 208-764-9 | CAS no: 541-02-6	-	-	Submitted	11/01/2019	ECHA	Leave on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D4/D5/D6 in concentrations > 0.1% shall not be placed on the market. In addition, wash off and rinse off cosmetic products containing D6 in concentrations > 0.1% shall not be placed on the market.	30/01/2019	

SUBSTANCE EVALUATION AND CASE STUDY

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DICYCLOPENTADIENE (DCPD)- A CAUTIONARY TALE

H2 COMPLIANCE

- Manufactured and/or imported in the European Economic Area in 100 000 - 1 000 000 tonnes per year.
- This substance is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.
- The substance is already subject to a Harmonised C&L (non-CMR)
- An 8-hour TWA of 5 ppm (27 mg/m^3) has been assigned in several jurisdictions
- The REACH Registration dossier was submitted in 2010
- Change in supplier C&L on SDS prompted client to seek mitigation

DCPD- DOSSIER EVALUATION

Initial Targeted Compliance Check (TCC) initiated in May 2013

- Based on high tonnage and widespread/dispersive use

TCC Decision issued October 2014

- The Technical Dossier was missing a mandatory mutagenicity test
- Dossier update requested by October 2015

RED FLAG

Comprehensive Compliance Check (CCC) initiated August 2015

- initial step in Substance Evaluation

CCC decision issued December 2015

- Insufficient detail included in Reprotoxic Robust Study Summaries (RSS)
- Higher tier Environmental studies missing
- Dossier RSS update required by March 2016 to feed into Substance Evaluation

DCPD SUBSTANCE EVALUATION

DCPD selected for Evaluation by the French Competent Authority (ANSES) using the following selection Criteria

- Suspected CMR
- High aggregated tonnage

Grounds for Concern

- Suspected Reprotoxin – effects at high doses
- Worker exposure
- High Risk Characterisation Ratio (RCR) in the Chemical Risk Assessment
- High Tonnage

Potential Follow-up actions

- Harmonised C&L for Reproductive Toxicity
- Restriction

DCPD FURTHER ACTIONS

The Registrant updated the Reproductive Toxicity RSS in the Registration Dossier

- OECD 422 conducted in Japan- English summary
- 3-generation Reproductive Toxicity study (1978)

Following evaluation of the above data, a testing decision has been issued (April 2017)

- Prenatal Development Study
- Extended One Generation Reproductive Test (EOGRT) with Cohorts 1A&B, 2A&B and 3

The Registrant proposed (June 2017):

- Self-classification as ReproTox category 2
- Testing Prenatal Development and waiving EOGRT if Category 1 is warranted.
- The Testing proposal for the Prenatal Development Study was published for public comment on 28th February 2019…. Still have several years before the results are available, evaluated and the RMOA is completed.

OTHER SUBSTANCES TO WATCH AND IMPACT ON OTHER REGULATIONS

PROPOSED RESTRICTIONS 11 JANUARY 2019

H2 COMPLIANCE

formaldehyde and formaldehyde releasers	-	-	Submitted	11/01/2019	ECHA	Restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses	30/01/2019	
microplastics	-	-	Submitted	11/01/2019	ECHA	Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.	30/01/2019	
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SELECTED RESTRICTED MATERIALS LEGISLATIONS – UNIQUE DRIVERS

Legislation	Target groups	# of Restricted substances	Growth	Obligations Concentration based	Exposure – Risk based	Alternatives Substitution Requirements	Socio-economic Requirement	Requirements
Reach SVHC – Candidate List (CL)	**Industrial, professional & consumers**	**197**	**Growing**	**0.1% w/w**	**Screening only**	**Indirect**	**No**	**Communication**
Reach Authorisation	**Defined users**	**43**	**Subset of CL-Growing**	**0.1% w/w**	**Yes**	**Direct**	**Yes**	**Approval for continued use; requires renewal, or banned**
California Proposition 65	**Consumers and workers**	**~1000**	**Growing**	**Safe harbor limits**	**Yes**	**Indirect**	**No**	**Labeling and communication**
EU RoHS+ (Restriction of Hazardous Substances Directive)	**Waste operators**	**<20**	**Growing-very slowly**	**0.1% w/w**	**No**	**Indirect**	**No**	**Labeling and communication**
Waste Framework Article 9	**Waste & consumers**	**197 (CL)**	**Linked to CL-Growing**	**0.1% w/w**	**No**	**Indirect**	**No**	**Reporting in database; safe handling guidance**
EU MDR	**Patients**	**Approx. 800 CMR 1 < 20 EDC**	**Growing**	**0.1% w/w**	**Yes**	**Direct**	**Benefit-risk Mixed approach**	**Justification for use; labelling & information for Use**

REVISED WASTE FRAMEWORK DIRECTIVE (WFD):
ARTICLE 9: NOTIFICATION OF SUBSTANCES IN ARTICLES

H2 COMPLIANCE

EU's Circular Economy Policy – to promote non-toxic material cycles

Facilitates recycling of materials and allow consumers to make more informed choices

Existing REACH Obligations on Candidate List still in place (Article 7(2); Article 33(1))

Additional requirements for notification of substances in articles

- Jan 5, 2021 - requires **notifications for articles that contain SVHC > 0.1%**
- Requires ECHA to establish database to receive notifications (by 5th Jan 2020)
  - But lack of funding has scaled back ECHA's database to a "scaled-down prototype"
- Applies to every article incorporated in a complex object (article-centric approach)
- Impacts all Actors in Supply Chain: producers, importers, assemblers, distributors & retailers
- Information on safe use of articles at all life cycle stages
- ECHA proposed all the data received on articles to be publicly available on ECHA's website
- But Questions remain …..

WHAT ARE EU MEDICAL DEVICE DIRECTIVE (MDR) RESTRICTED MATERIALS

H2 COMPLIANCE

Category 1 CMRs or Endocrine disrupting chemicals

- 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 - CLP regulation,
- Or
- 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

- Article 59 of Regulation (EC) No 1907/2006 - Reach Regulation or,
- Article 5(3) of Regulation (EU) No 528/2012 - Biocidal Product Regulation

Specific criteria from EC 1272/2008 (CLP) and EC 1907/2006 (REACH) that will trigger label declaration and justification under EU MDR.

SUMMARY AND NEXT STEPS

SUMMARY & NEXT STEPS

H2 COMPLIANCE

- Regulatory actions based upon REACH dossier submissions are now underway
- Evaluation of the submitted Hazard information and Chemical Safety Reports can result in request for further testing and updating of dossiers and the CSR
- Regulatory Management Option Analysis informs the further steps taken:
  - No Action
  - SVHC Identification (Candidate List)
  - Authorisation proposal
  - Restriction proposal
  - Harmonised C&L proposal

- Each of these Regulatory actions can take several years after the RMOA has been completed.

NEXT STEPS

Initiate Substance tracking for key substances using:

PACT list for

- Dossier Evaluation
- Substance Evaluation

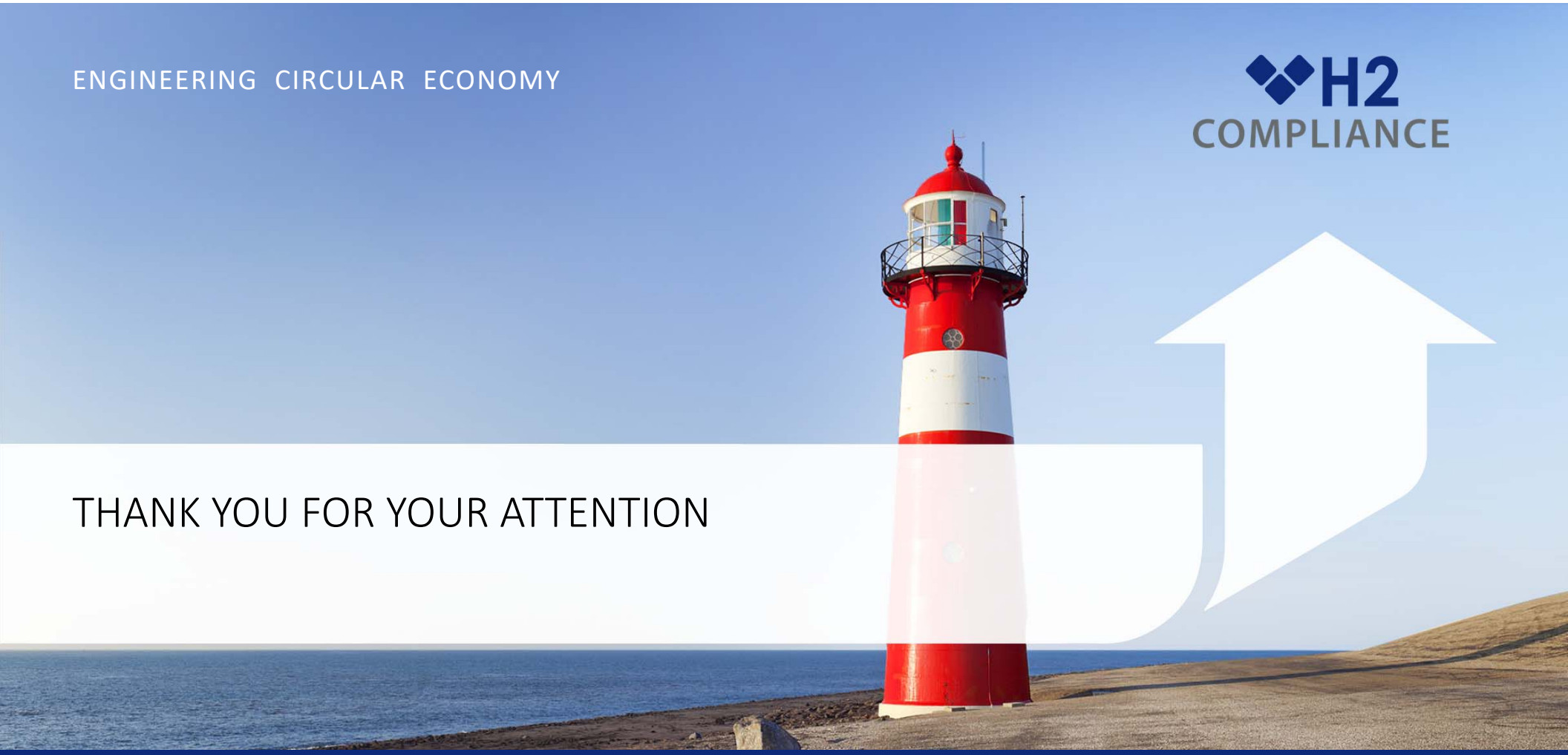
Identify concerns for further action using:

- RMOA list
- Registry(s) of Intentions

Be pro-active and prepare to :

- Revise hazard communication tools (labels, SDS and CSR)
- Replace/remove/reduce substances identified for Restriction or Authorisation.

ENGINEERING CIRCULAR ECONOMY



THANK YOU FOR YOUR ATTENTION

European Recycling Platform · H2 COMPLIANCE · prodigentia · LANDBELL · DS Entsorgungs- und Dienstleistungs-GmbH · GREEN ALLEY AWARD