

Identification of HFPO-DA and PFBS as SVHC under Article 57(f) of REACH

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Third PMT Workshop:
Getting Control of PMT and vPvM
substances under REACH

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Outline

- General introduction of ECHA
- Identification of a Substance as a SVHC in REACH
- REACH Article 57(f) Case examples
- ECHA activities on PMT/vPvM
- Conclusion

European Chemicals Agency – ECHA



ECHA implements EU chemicals laws



REACH –
registration
of chemicals



Classification,
labelling &
packaging



Biocides



PIC –
import⁴
& export

Our other tasks under EU laws

- Chemicals in products
- Poison centres
- Nanomaterials
- Persistent organic pollutants
- Drinking water
- Exposure limits for workers
- Waste
- ...



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Chutima chaochaiya)

EU's approach to chemical safety



Industry

Provides
information proving
their chemicals are
safe



ECHA and national authorities

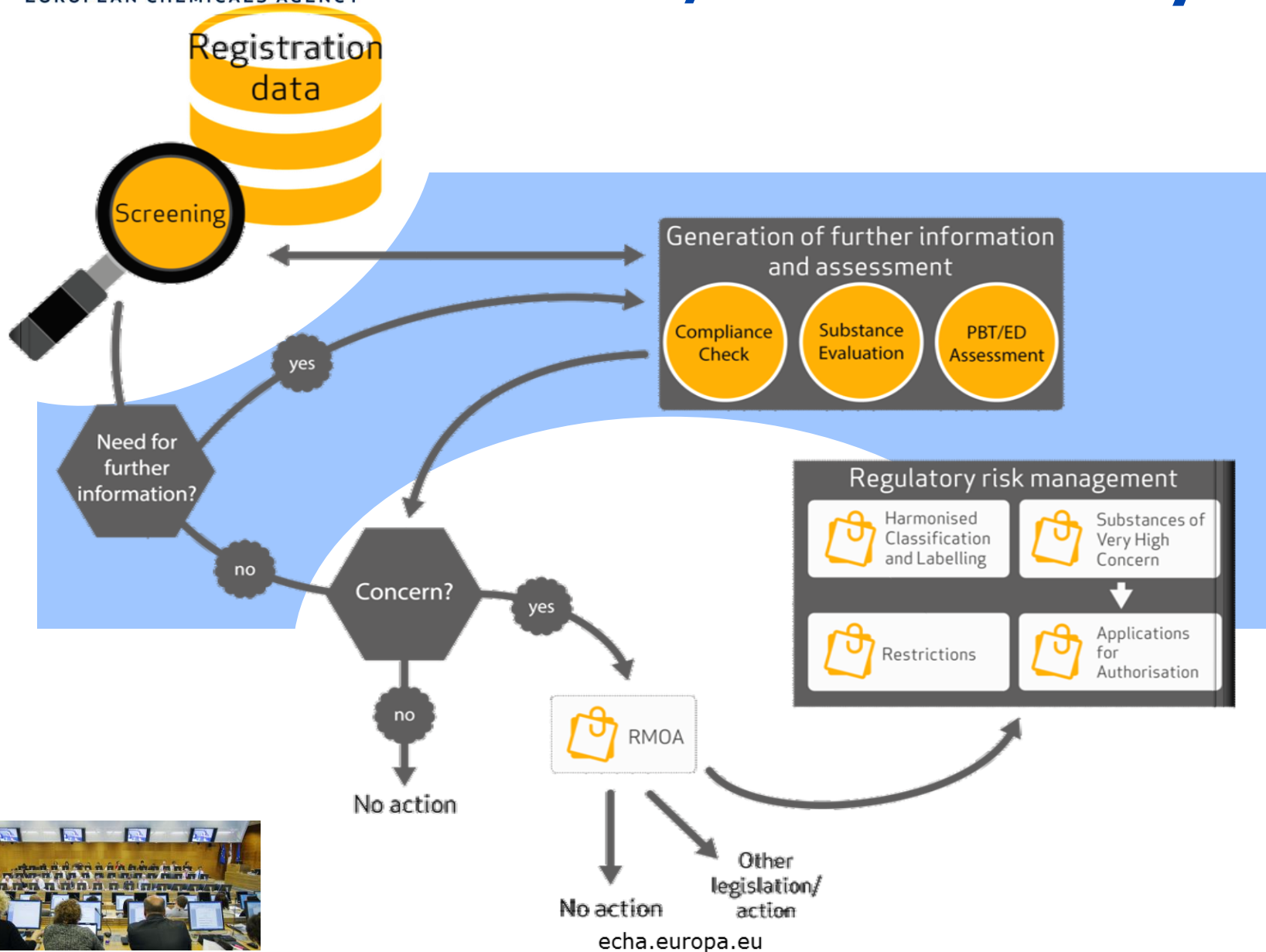
- ✓ Check the information
- ✓ Identify harmful chemicals
- ✓ Propose ways to regulate harmful chemicals
- ✓ Do checks (national inspectors)



EU and Member States

Take final decisions to
regulate chemicals

6



Identification of a Substance as Substance of Very High Concern (SVHC) in REACH



Article 57 of REACH

- Article 57 of REACH sets out criteria to identify a substance of very high concern (SVHC).
 - Carcinogenic (C), category 1A or 1B (*Art. 57. a*)
 - Germ cell mutagenic (M), category 1A or 1B (*Art. 57. b*)
 - Toxic for reproduction (R), category 1A or 1B (*Art. 57. c*)
 - Persistent (P), Bioaccumulative (B), Toxic (T)(*Art. 57. d*)
 - Very P very B (vPvB) (*Art. 57. e*)
 - Of Equivalent Level of concern (ELoC) (*Art. 57. f*)

Provides the legal boundaries within which regulators can operate

Role	Responsibility
Dossier submitter (Member States or ECHA)	Compiles all the evidence on the substance that meets the Art.57 criteria in a dossier and submits it to ECHA
ECHA	Initiates consultation on the dossier
Interested parties	Submits comments on the dossier
ECHA	<p>If no comments received – ECHA includes substance on the candidate list</p> <p>If comments received – ECHA refers dossier to MSC</p>
Dossier submitter	Revises dossier/support document based on comments received
Member State Committee (MSC)	Resolves potential divergence of opinion on proposals for identification of SVHC
Commission	Decides on the identification of the substance if MSC fails to reach unanimous agreement

Member State Committee (MSC)

Responsibilities (among others)



- One of the four committees of ECHA

Article 76(1)(e) of REACH:

- Resolving potential divergences of opinions (i.e. agreement seeking) on:
 - Draft evaluation decisions
 - Proposals by ECHA or Member States (Dossier Submitter; DS) for **identification of substances of very high concern** (SVHC)
- *Unanimous agreement required (Art. 59(8) of REACH).*
- If no unanimous agreement is reached, the majority view becomes the opinion of MSC and is sent to the Commission for their further decision making.

Identification of Substances of Very High Concern – SVHC

- SVHC become candidates for prioritising their inclusion in the Authorisation List (Annex XIV of REACH).
- All SVHC identified so far, are listed on the Candidate List on the ECHA website (Article 59 of REACH).

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Substance name	EC No.	CAS No.	Date of inclusion	Reason for inclusion	Decision	IUCLID dataset	
Diocetyl tin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety diocetyl tin dilaurate; stannane, dioctyl-, bis(coco acyloxy) derivs. EC No.: - CAS No.: - Stannane, dioctyl-, bis(coco acyloxy) derivs. EC No.: 293-901-5 CAS No.: 91648-39-4 Diocetyl tin dilaurate EC No.: 222-883-3 CAS No.: 3648-18-8	-	-	19/01/2021	Toxic for reproduction (Article 57c)	D(2020)9139-DC		
Bis(2-(2-methoxyethoxy)ethyl)ether	205-594-7	143-24-8	19/01/2021	Toxic for reproduction (Article 57c)	D(2020)9139-DC		

Article 57 (f)

*'Substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is **scientific evidence** of **probable serious effects** to human health or the environment which give rise to an **equivalent** level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59'*

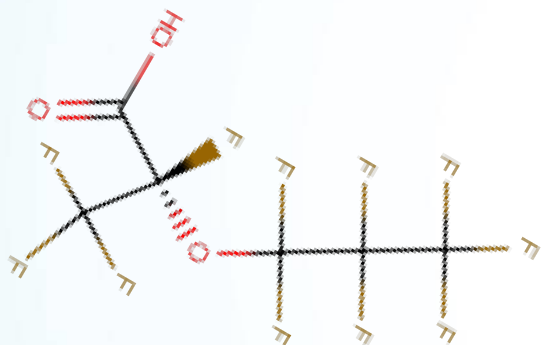
According to the European Court of Justice, two cumulative conditions need to be satisfied in order to identify a substance as an SVHC under Article 57(f):

- the effects of the substance on human health or the environment are probable and capable of being regarded as '**serious**';
- there must be scientific evidence that those effects '**give rise to an equivalent level of concern**' to those of CMR, PBT or vPvB substances.

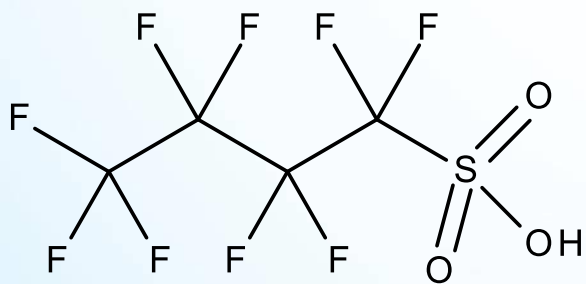
Case examples

(Art. 57(f) REACH)

HFPO-DA

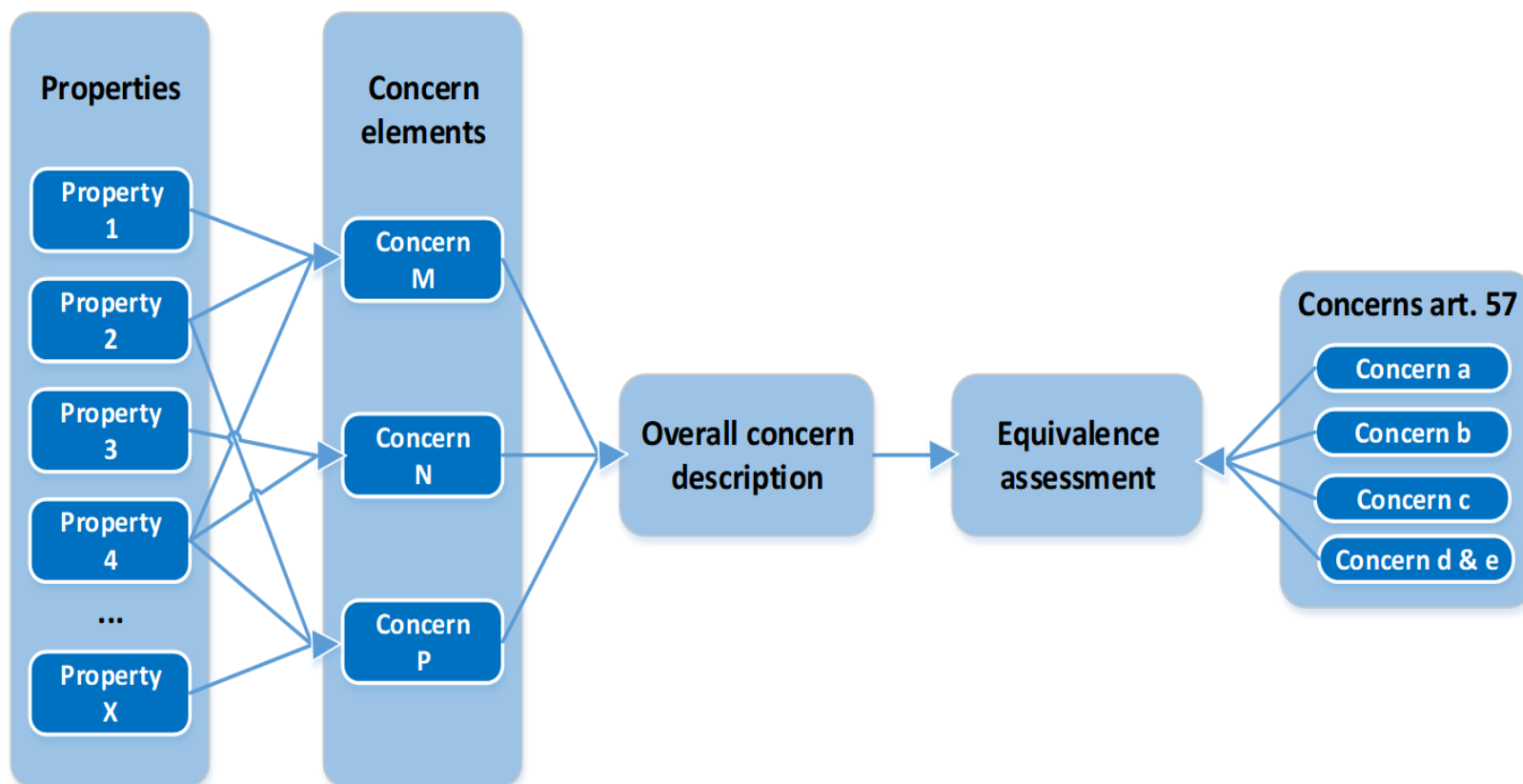


PFBS



	2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy) propionic acid, (HFPO-DA), its salts and its acyl halides (<i>covering any of their individual isomers and combinations thereof</i>)	Perfluorobutane sulfonic acid (PFBS) and its salts
Molecular Formula	C ₆ HF ₁₁ O ₃	C ₄ HF ₉ O ₃ S
EC No.	236-236-8	206-793-1
Water solubility at 20 °C	>756 g/L	Fully miscible
Log K _{oc}	1.1	1.2 - 2.7
Characteristic Travel Distance (CTD) (km)	5728	17616
Dossier Submitter	The Netherlands	Norway
MSC meeting	MSC-65	MSC-67
Inclusion in Candidate List	16-07-2019	16-01-2020

ELoC argumentation for HFPO-DA and PFBS



Properties of the substance driving the concern

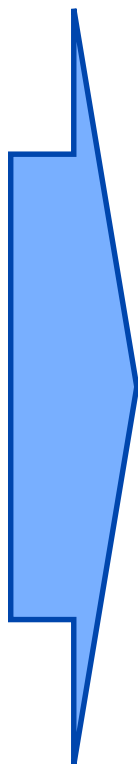
- Very high persistence
(*very stable highly fluorinated alkyl chains*)
- High mobility
- High LRTP
- Low adsorption (*Difficult removal*)
- Moderate (bio)accumulation in humans/plants
- Adverse effects HH & ENV

Probable serious effects from intrinsic properties of the substance

- Adverse effects for HH & ENV seen in the studies considered serious
 - HFPO-DA
 - effects in rodents on liver, kidney, haematological system, immune system, development
 - secondary poisoning of herbivores and fish-eating wildlife
 - PFBS
 - effects in rats and mice on thyroid hormone disturbances, liver, kidney, haematological system,
 - reproductive development deficiencies in mice
 - disturbed oestrus cyclicity in rodents
 - effects on reproduction in marine medaka fish (fulfils T criteria in Annex XIII of REACH)
 - thyroid hormonal disturbances in marine medaka

Properties

- Very high persistence
- High mobility
- High LRTP
- Low adsorption
(*Difficult removal*)
- Moderate
(bio)accumulation
in humans/ plants
- Adverse effects
HH & ENV



Concern Elements

(arising from the substance properties)

- Potential for irreversible and increasing presence in the environment
- Continuous presence in water results in continuous bioavailability
- Potential for causing serious effects although those would not be observed in standard tests
- Potential for delay of effects
- Potential for rapid and wide geographic scale distribution
- Intergenerational effects, mother-to-offspring transfer
- Difficulty to derive safe concentration levels
- Societal concern - drinking water contamination

Equivalence

- Means that the overall concern of the substance is equivalent to the overall concern of 57(a) to (e).
- Individual concern elements in a Weight of Evidence (WoE) do not need to include clear fulfilment of the criteria for P or B or T.
- Art 57 (f) captures concerns other than CMR or PBT/vPvB.

HFPO-DA and PFBS ELoC conclusion:

Dossier submitters concluded that:

- Taking together, the concerns arising from the substance properties,
- in a WoE approach,
- there is scientific evidence of probable serious adverse effects of these substances to the environment and humans, which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of the REACH Regulation,
- MSC supported the conclusion of dossier submitters
- MSC unanimously agreed to identify HFPO-DA and PFBS as SVHC
- Substances are on the Candidate List.

ECHA activities related to PMT/vPvM:

- Case specific discussions at the PBT Expert Group
- SVHC identification by MSC based on Art 57 (f)
- Envisaged scientific and technical support to the Commission on the PMT/vPvM criteria

Integrated Regulatory Strategy - If a substance is already on the candidate list or regulated by other means, authorities need to consider the added regulatory value of submitting an SVHC dossier for concern arising from its PMT/vPvM properties:

- Will the identification of the additional concern of a substance under Art. 57 (f) likely lead to e.g.:
 - Improvements in company level risk management?
 - Implications for customer?
 - Considering the substance as non-threshold, when it had been considered as having a threshold previously?
 - Significant improvements in the regulatory risk management driving substitution and preventing regrettable substitution?

References

- [HFPO-DA Support Document](#)
- [PFBS Support Document](#)
- [MSC-65 minutes](#)
- [MSC-67 minutes](#)

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