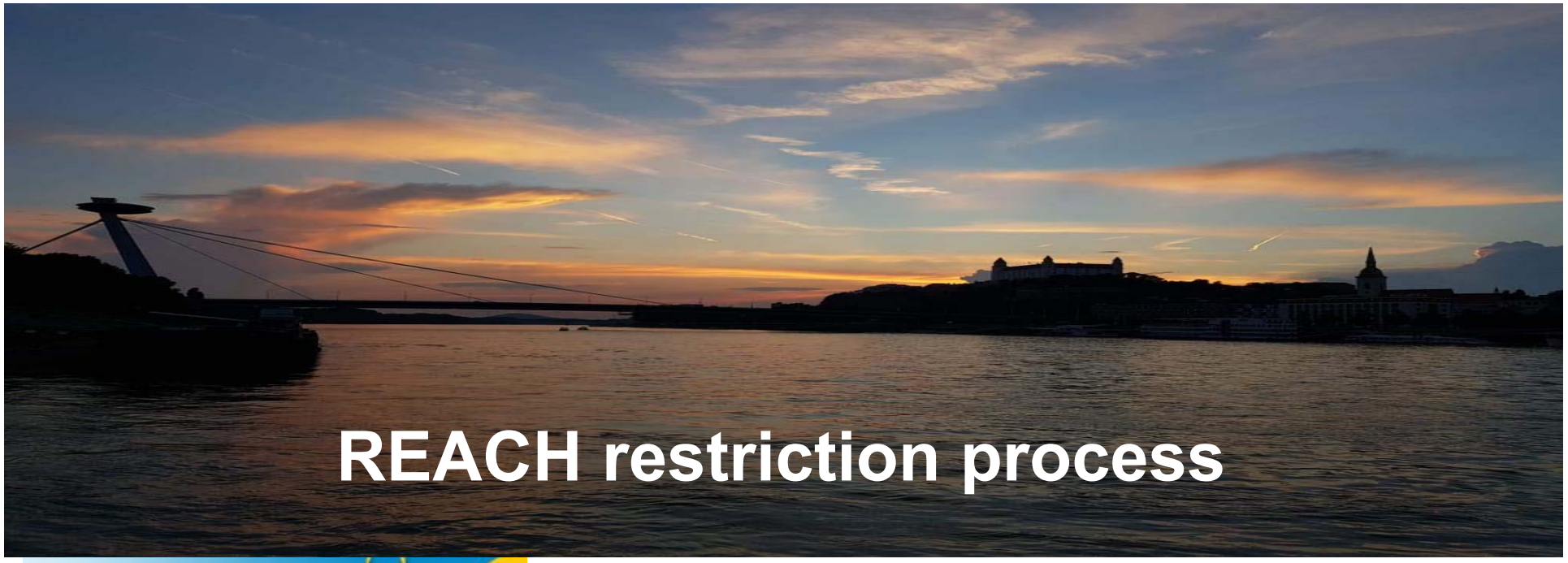

REACH restriction process

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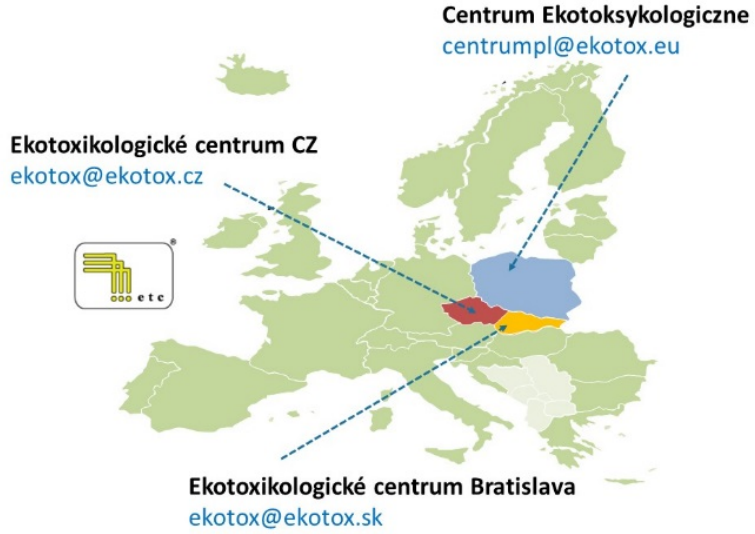


REACH Conference Bratislava

September 3-4, 2018

Overview

1. Restrictions under REACH
2. Overview of restrictions process
3. Actors affected by a restriction
4. Shortcomings and need for action
5. Interplay between Authorisation and Restriction
6. Conclusions

How do restrictions work in REACH?

- a tool to protect human health and the environment from unacceptable risks posed by chemicals
- may limit or ban the manufacture, placing on the market or use of a substance
  - on its own,
  - in a mixture or
  - in an article
  - including those that do not require registration
  - also apply to imports
  - ECHA can also propose a restriction on articles containing substances that are on the Authorisation List (Annex XIV)

Restrictions procedure

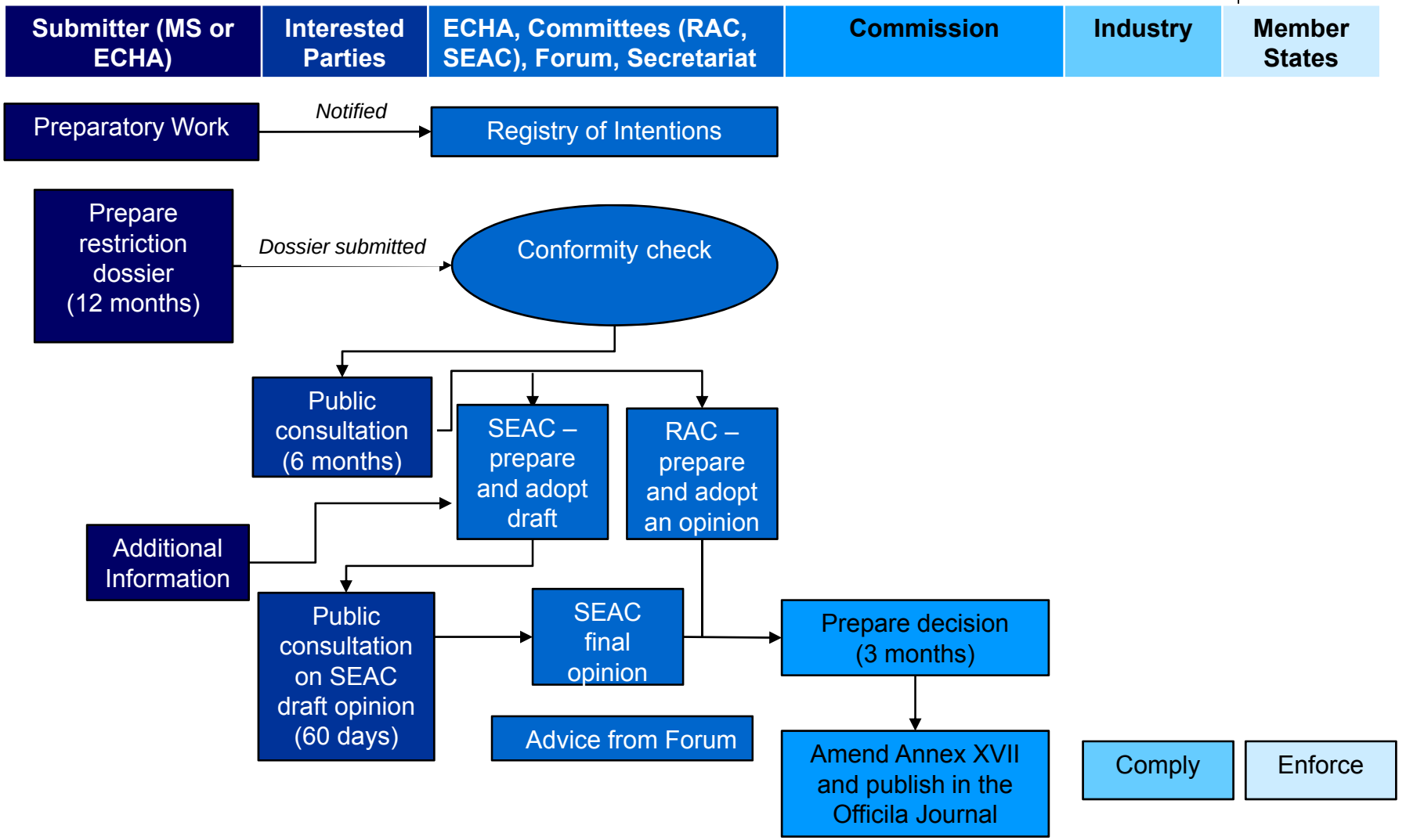
- form of the restriction process is similar to Directive 76/769/EEC - Marketing and Use Directive
- process of restriction is described by Articles 69-73 of REACH
- take many forms:
  - general bans on all uses;
  - bans on specific uses (e.g., as a flame retardant);
  - a ban for products available to the general public; or limits on the concentration of the substance in consumer products such as tyres, clothing or jewellery

Exemptions from restrictions

do not apply to:

- the manufacture, placing on the market and use of a substance for scientific research and development (PPORD);
- the use of a substance as an on-site isolated intermediate;
- the use of substances in cosmetic products as defined in Directive 76/768/EEC, with regards to restrictions addressing the risks to human health within the scope of that Directive
- entries 1–58 of Annex XVII, the restrictions do not apply to the *storage, keeping, treatment, filling into containers, or transfer from one container to another* of the substances *for export* (unless the manufacture of the substance is prohibited).

Overview of restrictions process



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Who is affected by a restriction?

anyone who **manufactures, imports, uses or supplies** substances (on their own, in a mixture, or in an article) could potentially be affected by a restriction

1. Manufacturers and importers of substances
2. Producers and importers of articles
3. Substance/mixture suppliers
4. Downstream users of chemicals

1. Manufacturers and importers of substances

- on its own or in a mixture should check whether this is permitted under the conditions of the restriction
- registered substances – ECHA will inform you if a notification is submitted to RoI (https://echa.europa.eu/sk/registry-of-restriction-intentions)
- to plan for and contribute to the public consultation process if you wish to do so,
- to communicate with others in your supply chain to coordinate your contributions

2. Producers and importers of articles

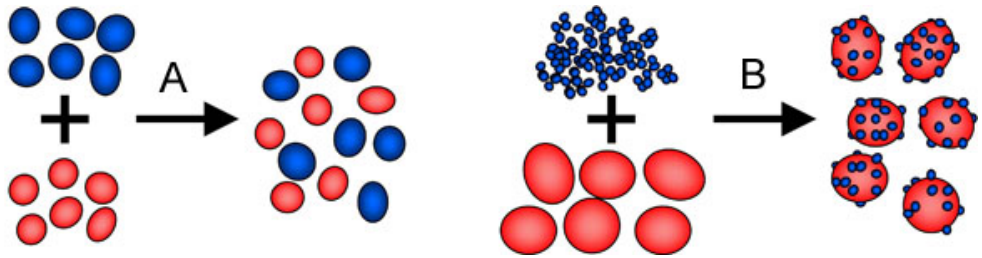
- articles containing a restricted substance - need to check whether this is allowed or whether the article complies with any limits set
- importers may have limited knowledge of the chemical substances used to produce the products
- Column 2 of Annex XVII gives information on the types of product to which the restriction applies

3. Substance/mixture suppliers

- to check that the supply is still permitted under the restriction
- need to communicate information about the restriction down the supply chain
- if a SDS required - information about the restriction should be included in Section 15
- if a SDS is not required - need to provide the information in a separate communication

4. Downstream users

- supplier should advise you whether the substances they supply are subject to a restriction (in Section 15 of the SDS or in a separate communication if a SDS is not required)
- compare the conditions of the restriction with your conditions of use, your risk management measures and the mixtures or articles you produce
- a formulator – a mixture component is a subject to a restriction, include information on the restriction in the SDS, or in a separate communication if a SDS is not required



Status of received restrictions per year

	Received intentions	Restriction dossiers submitted by Member States	Restrictions prepared by ECHA	RAC-SEAC opinions	Commission decisions
2009	4	0	0	0	0
2010	1	3	1	0	0
2011	2	1	0	4	0
2012	2	1	1	1	4
2013	7	3	1	2	0
2014	4	4	2	4	3
2015	4	3	0	6	2
2016	2	2	2	2	5
2017	5	1	2	2	2
Total	**31**	**18**	**9**	**21**	**16**

Source: ECHA General Report 2017

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Current status

- Annex XVII – 68 entries
- RoI – 47 entries – intentions or submitted (5 withdrawns)
  - PAHs limit – in plastic or rubber garnules used for sport pitches and playgrounds (Netherlands)
  - Oxo-degradable plastics and microplastics in products for proffessional and consumer use (ECHA)
  - Tattoo inks and permanent make-up (ECHA)



Benefits outweigh the costs

Challenging to estimate

Benefits

- annual human health related benefits from restrictions processed under REACH since 2009, were estimated at over EUR 700 million per annum
- adopted restrictions were estimated to reduce emissions of PBTs, vPvBs and other substances of concern by about 190 tonnes per annum
- furthermore, there were other positive impacts from the restrictions for at least 81 000 consumers and workers, the value of which could not be estimated

Costs

- estimated annual cost of all restrictions for which ECHA's committees gave favourable opinions during 2011-15 was about EUR 300 million
- five most expensive restrictions represent around 88 % of the total costs

Source: ECHA 2016. Report on The Operation of REACH and CLP. ECHA-16-R-08-EN.
https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

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Procedure improvement

- two distinct EU risk management approaches:

  a) **Restrictions** enable the EU to impose conditions on the manufacturing, placing on the market or use of substances

  b) **Authorisation** is designed to ensure that substances of very high concern (SVHCs) are used safely while promoting substitution by suitable alternatives

- recent evaluation has identified a number of shortcomings and need for action:
  - simplification of the process;
  - quicker decision making;
  - improvements in efficiency.

Source: Commission General Report on the operation of REACH and review of certain elements, Brussels, 5.3.2018 COM(2018) 116 final, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

Interplay between Authorisation / Restriction (1)

Practical Considerations Industry	Authorisation	Restriction
Costs	• *Fee: 50,000 € + Expenses from authorisation application*	• *Less expenses for industry (participation in public consultation)*
Involvement	• *Direct involvement/active role*	• *Reaction to public consultation*
Different effects	• *Legal requirements start from inclusion in Candidate List* • *If granted, Authorisation allows continue use but only for some time*	• *No legal requirements during the restriction process* • *If adopted, restriction or ban may no longer allow continued use*
Existence of Alternatives	• *Industry to provide information on alternatives* • *Existence of alternatives (or not) has more direct legal consequences*	• *Information provided by authorities* • *Industry can comment on this is during consultation process*
Enforcement	• *Difficult to enforce: applicant -specific (and its supply-chain)*	• *Easier to enforce: all actors at the same time*

Interplay between Authorisation / Restriction (2)

- restrictions/authorisations – powerfull policy measures aimed at limiting human exposure to the chemical concerned

- but somtimes a substance might be a subject of both
  - LMW (lower molecular weight) phthalates case – DIBP, BBP, DBP and DEHP
    - Placing on the market of articles containing BBP, DEHP, DBP and DiBP for indoor environments and direct exposure (submitted, DK 2011)
    - Restriction under Article 69(2) on the four classified phthalates in articles. Depending on the outcome of the assessment, the scope of the restriction might be broad or targeted specifically to articles or article groups that are the main contributors to exposure of the general population. (submitted, DK 2016)

Background information on the current regulatory status:

- DIBP and BBP are no longer used in Europe as there was no Authorisation dossier submitted for these substances by the sunset date of February 2015.
- DBP is authorised in very limited specific industrial applications.
- DEHP : Authorisation for use in producing original PVC compounds and articles has been recommended by ECHA and while official confirmation by the European Commission is still pending – the substances can currently be safely used in those applications for which an Authorisation request was submitted.The recycling of flexible vinyl containing DEHP has also been Authorised for several companies and recently ECHA has recommended re-Authorisation of such recycling.

Conclusions

- The REACH Restriction process, as such, represent significant challenges and may cause delisting of chemicals in key industrial applications.
- The number of new restrictions has so far not met the original expectations.
- Although the process has improved as a result of the actions initiated after the 2013 REACH review, there is room for further improvement.
- In the meantime, companies must roll up their sleaves to face the complex challenges ahead!