Future of Risk Management

Green Chemistry Change Manager

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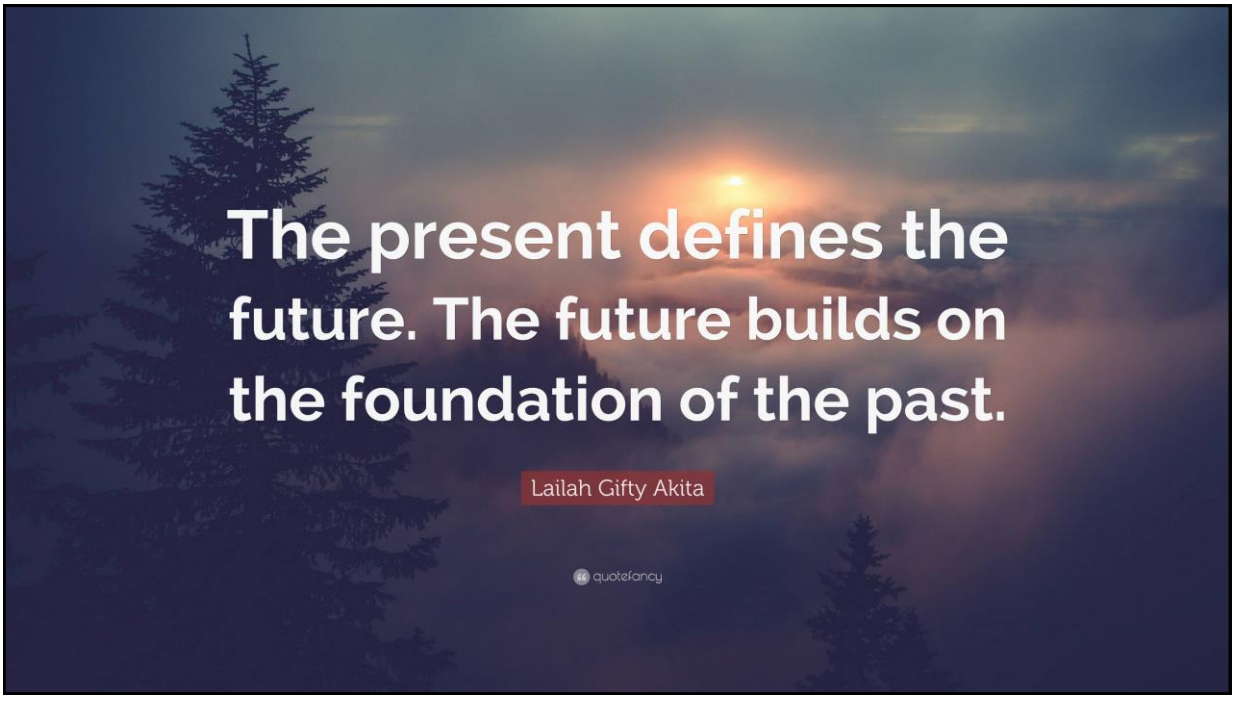

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https://echa.europa.eu/specific-reports-reach

Report on the operation of REACH and CLP 2021

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Company-level risk management

Data availability and supply chain communication

→ The final deadline in 2018 was a milestone – as we now have more data than ever before on 23 000 most-used chemicals in Europe.

→ The registration obligation motivated companies to **refocus, correct or strengthen their risk management**.

→ Companies need to improve the information in their registrations as well as in the main vehicles for communicating safe use – chemical safety reports, safety data sheets and exposure scenarios, and classification and labelling.

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Classification and labelling

- → CLP Regulation provides basis for hazard assessment and could play an important role in a 'one substance, one assessment' approach.
- → Through labels, CLP directly **drives risk management for workers, consumers and the environment**.
- → The Classification and Labelling Inventory contains information on around 180 000 substances self-classified by companies, but

- → Industry **compliance is insufficient** and there is still divergence in self-classifications for the same substance.

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Regulatory Risk Management
Authorisation

- → Authorisation has been **successful at reducing risk** to workers, consumers and the environment, and there are clear indications that **substitution has been achieved**.
- → See ECHA's report on Socio-economic impacts of REACH authorisations (2021)

- → However
  - it is **not efficient**, and
  - in general **information on available alternatives is lacking**.

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Applications for Authorisation under REACH

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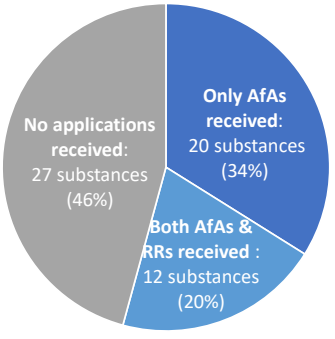
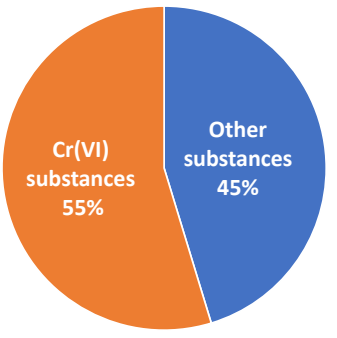
The example of chromates

Half of Annex XIV substances applied for…

Applications received for Annex XIV substances

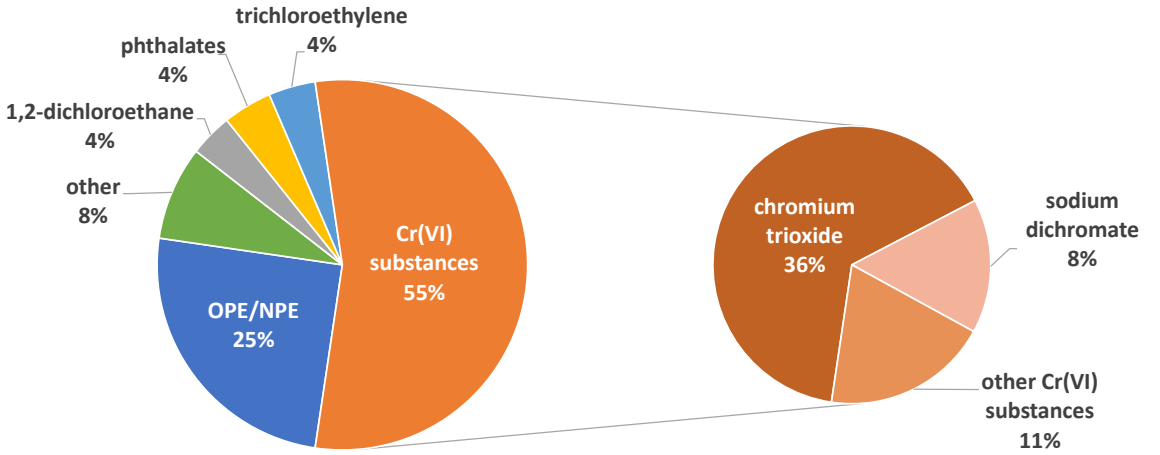


Uses applied for (585 uses)
AfAs & RRs



… Cr(VI) substances in majority

Distribution of uses applied for per Annex XIV substance



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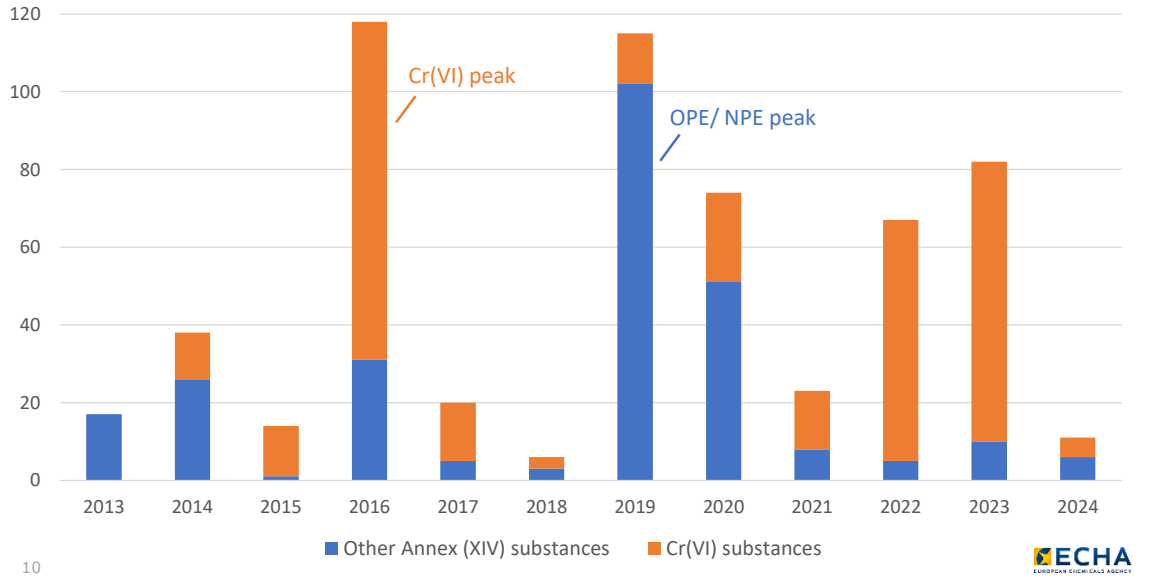
Waves of applications since 2013



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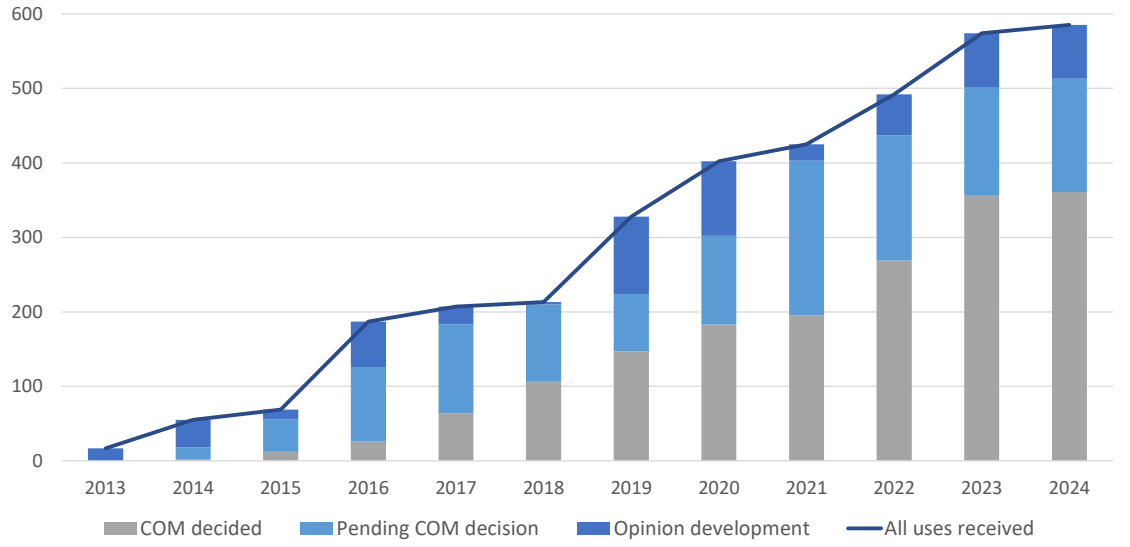
Status of applications in the process



Learnings (+)

→ A well-oiled opinion-making process…
- solid, consistent and transparent
- deliver within legal timeline
- quality / fit-for-purpose
- good understanding and level of acceptance by stakeholders

→ … which proved to be able to adapt to:
- 3 court cases
- emerging challenges, expectations from stakeholders and evolving needs of decision-makers

Learnings (–)

→ Challenges with substances with **widespread uses**
- (too) high number of applications *vs.* capacity of the process

→ Concept of **upstream applications**
- different approaches taken by applicants
- challenges re. level of granularity required *vs.* supply chains communication's reality

Typical Cr(VI) uses:
Formulation, Electroplating, Etching, Passivation, Chemical conversion coating, Anodising/Anodise sealing, Slurry coating, Stripping

ECHA

Regulatory Risk Management
Restriction

→ EU restrictions are **working well**, resulting in greater protection for workers, consumers and the environment. Thanks to the **grouping approach**, more substances – covering more uses – have been proposed to be restricted than in earlier years.

→ See ECHA's report on Costs and benefits of REACH restrictions proposed between 2016-2020

→ Industry also generally complies with restrictions – more than 80 % of consumer products inspected by Member State inspectors comply with restriction obligations, with most incompliance in **imported products**.

ECHA

Restriction
-
Generic **R**isk management **A**pproach

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What is GRA?

→ Based on generic risk considerations (not only hazard based)

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ECHA EUROPEAN CHEMICALS AGENCY

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What is GRA?

→ GRA exists already today under REACH Restriction Title
- Article 68(2) for **CMRs** Cat. 1A or 1B as such, in mixtures or in articles that **could be used by consumers**

→ Standard restriction process (Articles 69 to 73) does not apply ("fast track")
- COM right of initiative to propose a restriction
- adopted through comitology

Implementation of the existing GRA

→ CMR substances **on their own or in mixtures**
- existing generic entries 28-30 of Annex XVII to REACH semi-automatic: when newly classified CMR Cat. 1A or 1B: COM proposes amendment through

→ **Articles**
- Empowerment used twice so far
  - Certain **CMR substances in textiles** (entry 72) (could be expanded in the future)
  - **PAHs in rubber and plastic** (entry 50)
- **CMRs in childcare articles**: COM asked ECHA to prepare an investigation report in preparation of a COM proposal (31/10/2023)

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Integrated Regulatory Strategy / Grouping	One Substance One Assessment (1S1A)	ECHA's new tasks	GRA	REACH Authorisation	Substitution

• IRS aims to:
  • identify and prioritise substances of concern for regulatory risk management
  • address issues of compliance with the registration information requirements
  • use the REACH and CLP instruments in a coordinated manner to enable regulatory risk management where needed
• Grouping has accelerated the screening of registered substances and has sped up the assessment of whether more data generation or risk management measures are needed.
	Pilots on prioritising actions on common substances across different legislations, incl. considering the synergies between the existing and new tasks within ECHA's mandate	• Water legislation
		• Batteries
		• Packaging and packaging waste
		• *RoHS*
		• *End-of-life vehicles*
		• *POPs in waste*
		• *Toys*
		• *Medical devices*
		• Support to Industrial Emissions Directive
		
		→ Some synergies with ECHA's current tasks (e.g. REACH Authorisation / Restriction procedures)
		→ Some new, specific focus (article life stage, waste,…)
			• Other hazards?
			• Other categories of uses?
			• Changes in procedure?
				• Revised scope/procedure/…?
				• Reviewed interplay with Restriction
					Ongoing Commission studies on:
					• "Strengthening the role of substitution planning in the context of REACH and other chemicals legislation"
					• "EU Substitution Centre(s) - Providing support to businesses to substitute their use of hazardous chemicals through collaboration, innovation, research and direct assistance"

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Thank you

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