

Latest news on chemical regulations – REACH update

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Regulatory Update



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Agenda

- REACH
- Risk assessment under REACH
- Substances in the Focus of REACH
 - Chromium VI authorization
 - PFAS - Global regulatory activities
 - Lead and its compounds – New authorization?
- Revision in CLP

REACH



What is REACH?

Registration Evaluation Authorization and Restriction of Chemicals

Basic rule: No data, no market!

- **Registration**
 - Collection of information on substances on the market
- **Communication**
 - Improvement of communication in order to promote the safe use of chemicals
- **Authorization / Restriction**
 - Restriction and/or ban of the use of Substances of very high concern (SVHC)
- **REACH is about substances** → mixtures contain multiple substances that need to be considered under REACH individually

Exemptions under REACH

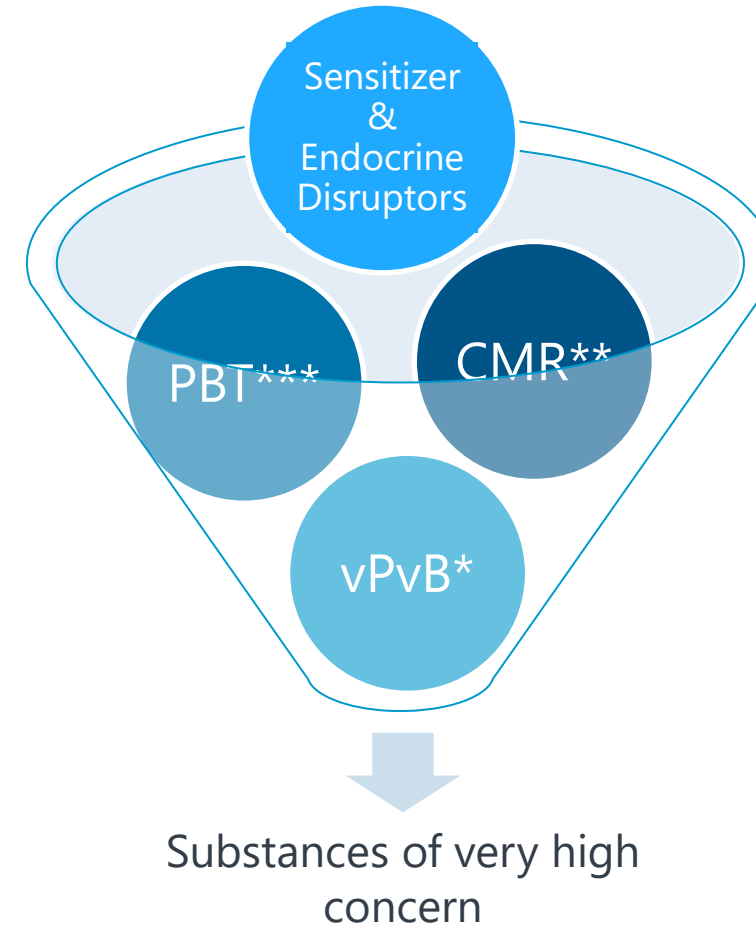
- Total exemptions
 - Radioactive substances
 - Substances in temporary storage under customs supervision, provided they are not being transformed or processed in any way
 - Non-isolated intermediates
 - Waste
- Partial exemptions
 - Scientific research
 - Food and feedstuffs
 - Medicinal products
 - Natural occurring substances

Risk management under REACH



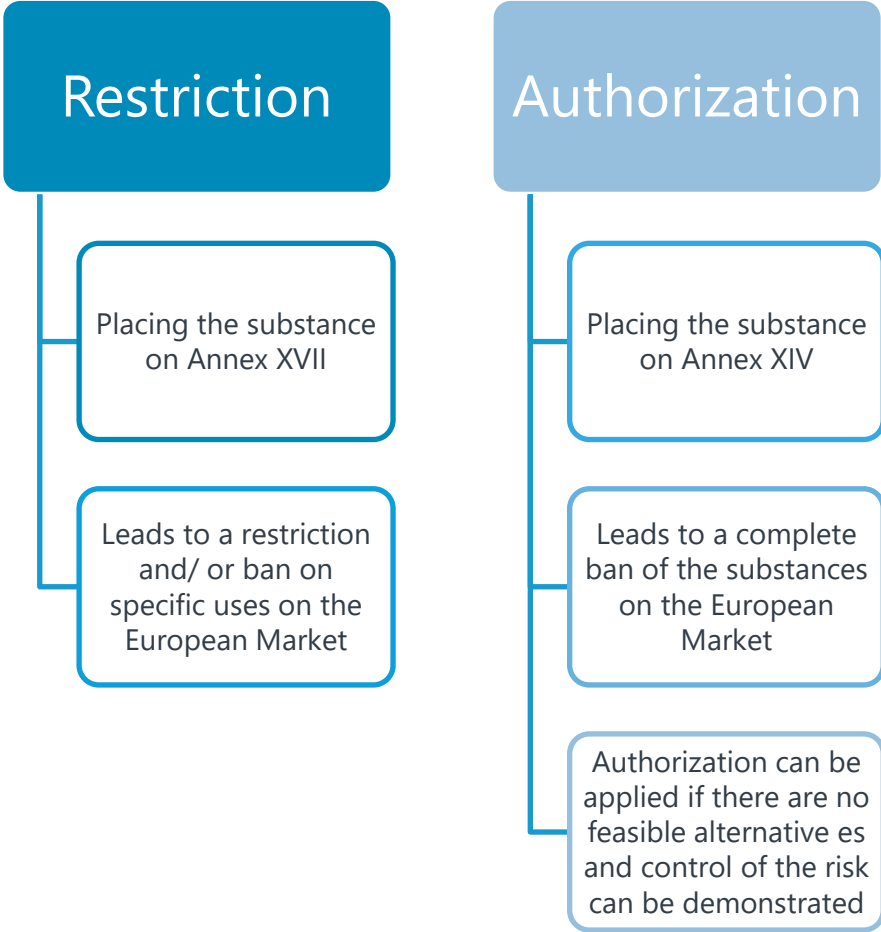
Substances of Very High Concern

- First step to determine and control hazardous substances posing an unreasonable risk to human health or the environment
- Focus on specific properties of the substances
- Further hazards will be added
- September 2023: 235 substances are on the SVHC candidate list
- [Liste der für eine Zulassung in Frage kommenden besonders besorgniserregenden Stoffe - ECHA \(europa.eu\)](https://echa.europa.eu)



*very persistent very bioaccumulative, **carcinogenic, mutagenic, toxic to reproduction, ***persistent, bioaccumulative, toxic

Substances of very high concern – the way forward

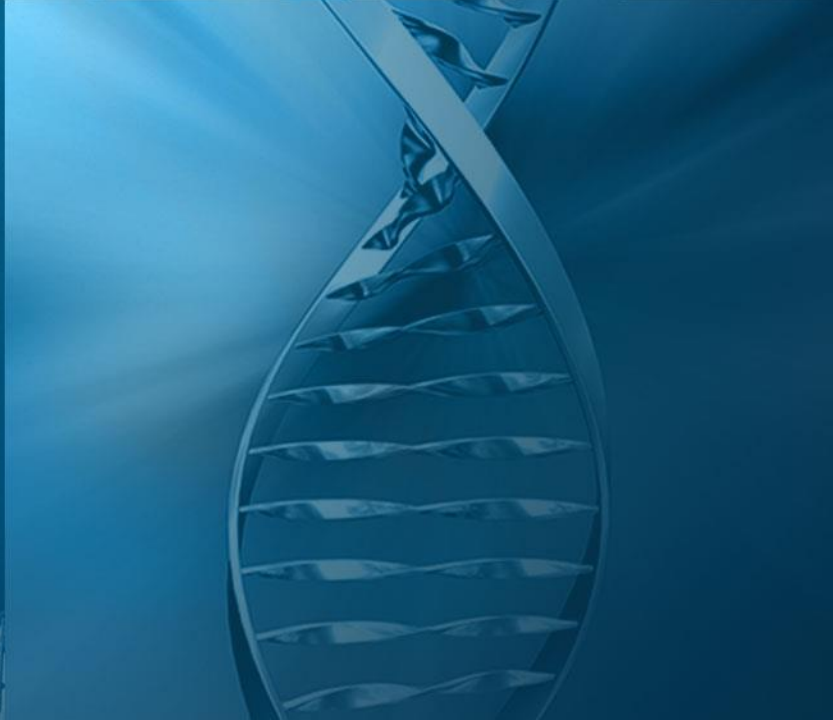


Our obligation under REACH



- Communication of substances of very high concern >0,1% along the supply chain
- Registration of substance manufactured or imported > 1 t/y in Europe
- Compliance with restriction conditions under Annex XVII
- Substitution and Phase-out of substances being placed on Annex XIV

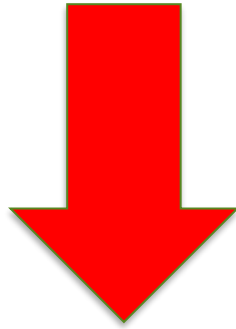
Substances currently in the Focus of REACH



Chromium trioxide authorization - Status

Hardchrome

- Atotech authorization was granted December 23rd 2020 and is valid until September 2024
- **Lawsuit European Parliament vs EU Commission to annul the authorization**



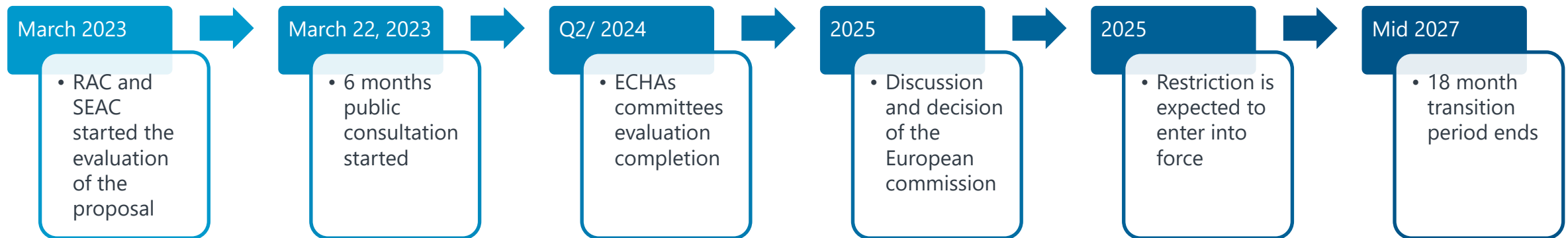
- April 20th, 2023 press release was published that the **granted authorization for CTACSub will be annulled**
- Application back in pending status -> Use of Chromium trioxide is still allowed
- **EU Commission has to take a new decision within 1 year**

Decorative


- Not Decided - pending
- Substitution plan was rated as “non-credible”
- EU Commission could propose a refusal for decorative use authorization
- Refusal:
 - **Acceptance:** Stop of use of Chromium trioxide for Decorative applications
 - **Rejection:** New discussions on how to proceed

Per- and polyfluoroalkyl sulfonates – REACH restriction

- February 7, 2023: Restriction proposal on PFAS published by ECHA
 1. Shall not be manufactured, used or placed on the market as substance on their own,
 2. Shall not be placed on the market in
 - a. Another substance, as a constituent,
 - b. A mixture
 - c. An articleIn a concentration of or above:
 - I. 25 ppb for any PFAS (polymeric PFAS excluded)
 - II. 250 ppb for the sum PFAS
 - III. 50 ppm for PFAS (including polymeric PFAS)
 3. Paragraphs 1 and 2 shall apply 18 months after entry into force of the restriction.
- Exemptions:
 - Biocidal products
 - Plant protection products
 - Human and veterinary medicinal products
- Potential Derogations:
 - Hardchrome plating until 6,5 years after entering into force
 - Semiconductor manufacturing process 13,5 years after entering into force



Lead and its compounds

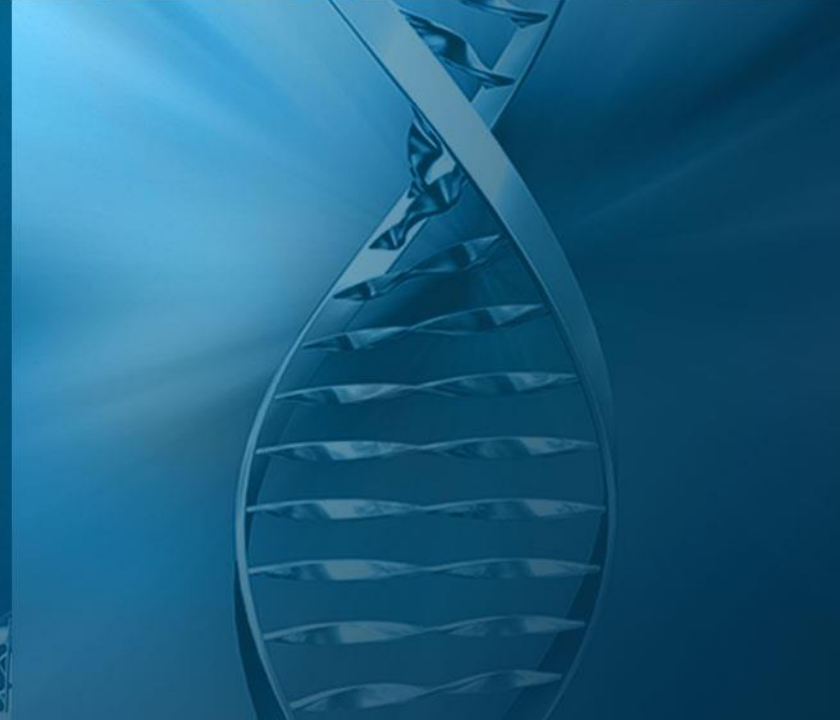
- February 2022: Lead as part of 11th recommendation for inclusion in the authorization list 
- **February 2023: Member states committee vote to include Lead in Annex XIV (proposed Latest application date: 36 months and sunset date = LAD + 18 months)**
- **Proposed timeline:**



Revision of ANNEX XVII REACH on Lead

- May 8, 2023: announcement of an amendment of ANNEX XVII of REACH that should enter into force on May 28, 2023
- Restrict the placing on the market or use of **lead and its compounds in polymers or copolymers of vinyl chloride (PVC) exceeding a concentration of 0,1%**
- Prohibition will enter into force on **November 29,2024**

Revision of the CLP regulation



Revision of the CLP regulation

- **April 20, 2023: amendment to CLP regulation entered into force**
- **New hazard classes:**
 - Endocrine disruption for human health in Category 1 and Category 2;
 - Endocrine disruption for the environment in Category 1 and Category 2;
 - PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative);
 - PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile).
- Transition period:
 - **May 1, 2025** for new substances on the market;
 - **November 1, 2026** for substances already on the market;
 - **May 1, 2026** for new mixtures on the market;
 - **May 1, 2028** for mixtures already on the market.



THANK YOU

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