



Reference:

M. Vainio, *REACH activities -update from ECHA*, 4th ESA REACH Workshop, ESA HQ Daumesnil, Paris, 18th October 2022

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REACH activities - update from ECHA

ESA REACH Workshop

18 October 2022

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Key elements of REACH

Registration

- Substances manufactured and imported into EEA are registered with ECHA
- Information for safe use is communicated in the supply chain

Evaluation

- Examination of registrant testing proposals
- Compliance check of registration dossiers
- Evaluation of selected substances

Regulatory Risk Management

- Authorisation
- Restriction
- Harmonised classification and labelling

Chemicals Strategy for Sustainability

Key milestones relevant to ECHA



How to take into account interests of space industry

- Commission & Member States need to work together to balance the need to maintain space capability & protect human health the environment
- Space industry is an important catalyst for innovation/R&D
- Space industry works in very extreme climatic and operational conditions:
 - If there is a need for exemptions, the regulator needs to know this

What's new for risk management

- Authorisation is not a BAN. It gives an opportunity to apply for continued use.
- The substitution effect is becoming clear
 - 45% reduction of substances subject to authorisation from 2010 to 2021
- The system is heavy – it needs to be addressed
- In particular improve how to use restrictions and authorisation better in combination

Information on substances of specific interest

Diisocyanates, Lead, Hydrazine, NMP &
Chromium trioxide

Diisocyanates: see RAC 2020 Opinion

OEL as 8-hour time weighted average exposure

- Based on the 'NCO group' can be obtained from the exposure - excess risk relationships for hyperresponsiveness or diisocyanate asthma.
- Excess risk over a working life period
- Exposure in $\mu\text{g}/\text{m}^3$ NCO in air
 - 0.1% <0.025
 - 0.5% 0.027-0.040
 - 1% 0.055-0.070
 - 2% 0.12-0.19
 - 3% 0.22-0.33
 - 4% 0.40-0.48
 - 5% >0.67

Short Term Exposure Limit

- Value which is maximally a factor 2 higher than a derived OEL based on the exposure - excess risk relation. This STEL value should not exceed $6 \mu\text{g}/\text{m}^3$ NCO.
- No Biological Limit Value
- BGV: Set at the limits of quantification for relevant diisocyanate metabolites in urine
- Notations: skin sensitisation, respiratory sensitisation, 'skin'

Lead: see RAC 2020 Opinion

OEEL as 8-hour time weighted average exposure

- 4 $\mu\text{g lead}/\text{m}^3$ (inhalable) for lead and its inorganic compounds
 - None for organic lead compounds
- No Short Term Exposure Limit
- **Biological Limit Value: 150 $\mu\text{g lead}/\text{L}$ blood for lead and its inorganic compounds**
 - None for organic lead compounds
- Biological Guidance Value: 45 $\mu\text{g lead}/\text{L}$ blood
- Notations: None

Hydrazine

- Candidate List 20 June 2011
- OEL
 - Long-term Exposure Limit Value 0.013 mg/m³
 - Skin Designation

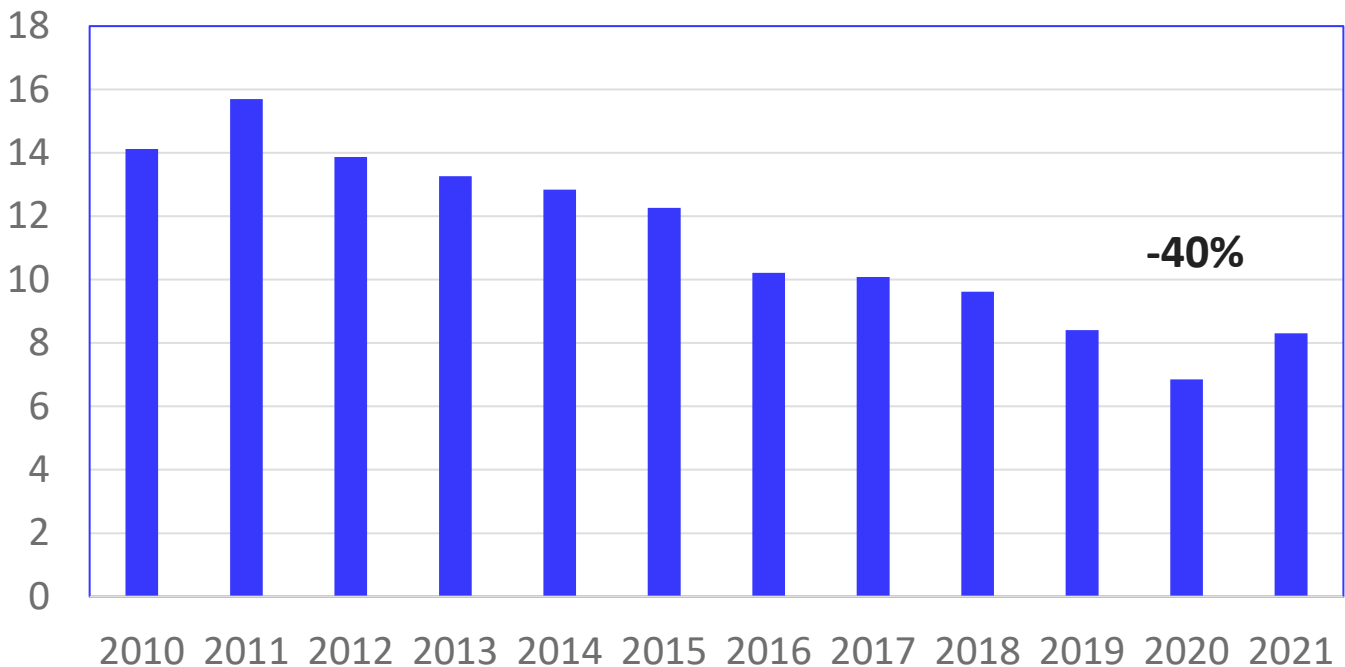
1-Methyl-2-pyrrolidone (NMP)

- Candidate list 20 June 2011
- Recommended to be added to Annex XIV (8th) on 5 February 2018
- Restricted 9 May 2020 (Entry 71 of Annex XVII)
 - DNELs workers 14.4 mg/m³ (inhalation) 4.8 mg/kg/day (dermal)
 - Derogation for coating wires till 9 May 2024
- OEL
 - Long-term Exposure Limit Value 40 mg/m³
 - Short Term Exposure Limit: 80 mg/m³

Chromium trioxide

- Candidate list 15 December 2010
- Recommended to Authorisation list 20 December 2011
- Added to Authorisation list on 17 April 2013
- 108 applications for 153 uses received
 - Typical exposure under $1 \mu\text{g} / \text{m}^3$
- OEL Long-term Exposure Limit Values
 - $10 \mu\text{g} / \text{m}^3$ until 17 January 2025
 - $5 \mu\text{g} / \text{m}^3$ after 17 January 2025

Net imports of Chromium trioxide to EU-27, 2010-21 (kilotons)



Source: Eurostat (Comext)

Further information

- [Information on Chemicals](#)
- [PACT - Public Activities Coordination Tool](#)
- [Registry of CLH intentions until outcome](#)
- [Registry of restriction intentions until outcome](#)
- [Candidate List of substances of very high concern for Authorisation](#)
- [Authorisation List \(Annex XIV\)](#)
- [Substances restricted under REACH \(Annex XVII\)](#)

SCIP

Substances of **C**oncern **I**n articles as such or in complex objects (**P**roducts) established under the Waste Framework Directive (WFD).

Duty

- Companies that produce, import or supply articles containing Substances of Very High Concern have to submit information on these articles placed on EU market to the SCIP database.

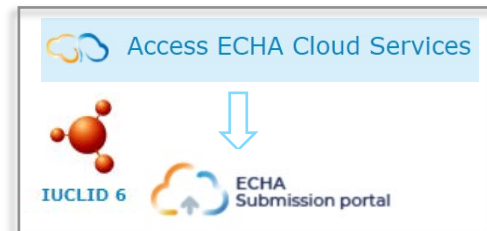
Our advice for submitters

- Make use of IT tools developed (Simplified SCIP Notifications (SSN), referencing, grouping)
- Use SSN if your company belongs to the same corporate group
- Provide clear identifiers (descriptive name, brand/model in 'Other names', accurate 'Article category')
- Simplify the hierarchy
- Look at the submitted data before you refer to it (search by SCIP number)
- Ensure that your notification does not include potentially sensitive commercial information (of your client) in published fields
- Keep data updated, submit an update when required and meaningful for the users of SCIP
- [SCIP support material](#)

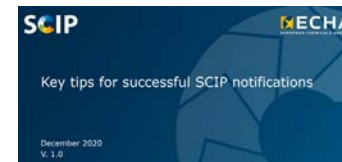
Support

SCIP webpage (echa.europa.eu/scip):

- News
- Supporting materials
- IT submission tools



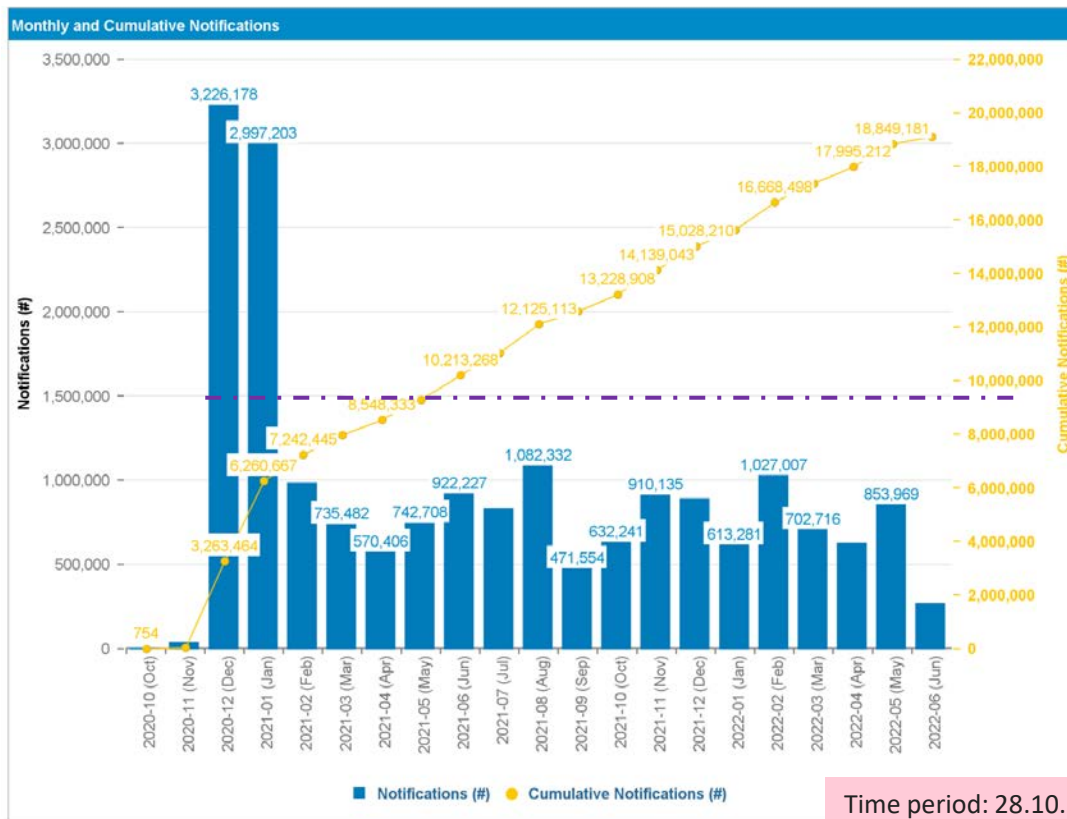
Questions and answers



Contact ECHA

Companies are delivering

Some 19 million SCIP notifications received



Monthly average:
approx. 800k



by > 8000
companies

Number of
entries/factsheets in
the SCIP database:
>8 million

Time period: 28.10.2020 – 10.06.2022

Thank you

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