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RESINSURF

RESINSURF WEBINARS

WEBINAR 1

An objective difficult to REACH.

A Guide to **REACH Compliance** for Surface Treatment Professionals.



Co-funded by
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- 1 REACH Regulation: What is it?
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PART 1: REACHing compliance

- 1 REACH Regulation: What is it?
- 2 How does REACH Regulation affect us?



RAMBOLL

Dr. Ana Isabel Sánchez

Senior Consultant
Health Sciences

Ramboll Iberia S.L.U.

asanchez@ramboll.com



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1. Introduction to Ramboll



Ramboll combines deep scientific expertise and technical acumen with a broad global footprint to deliver sustainable solutions that are protective of human health and the environment.

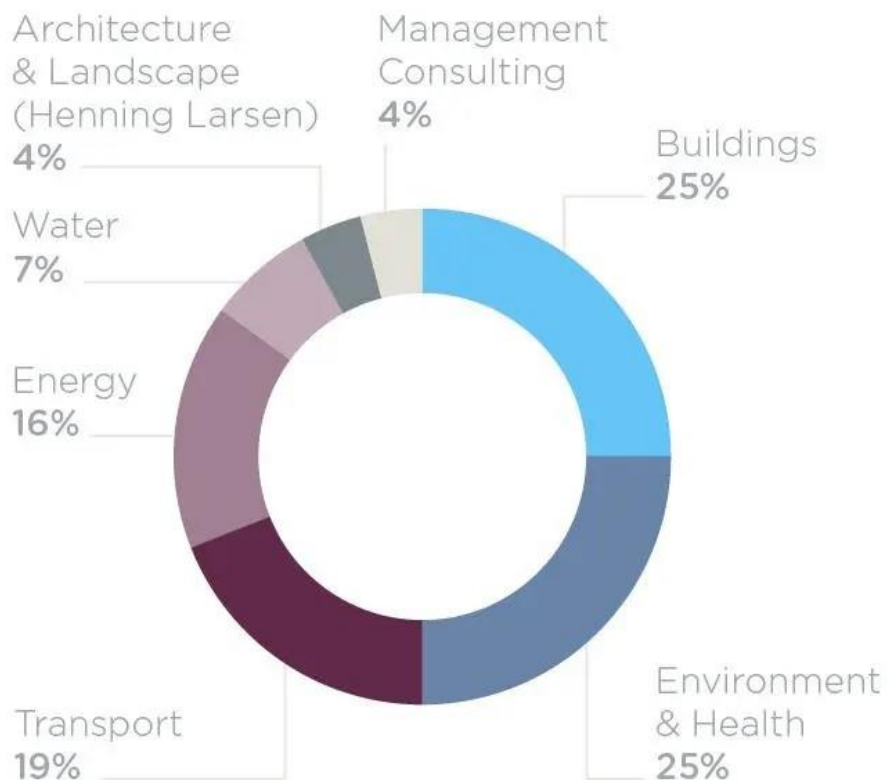




Ramboll's Global REH Service Offering

Revenue by market

share of total
2023



Independent engineering , architecture and management consultancy

1945

18,000

Experts

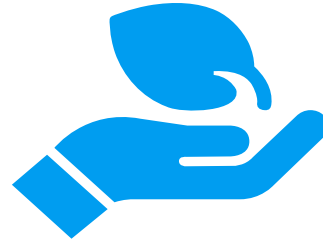
35

Countries

€2,2bn

Revenue

Owned by The
Ramboll
Foundation



Ramboll assists clients in regulatory compliance and environmental due diligence. A main legislation is REACH Regulation that includes product safety and stewardship.

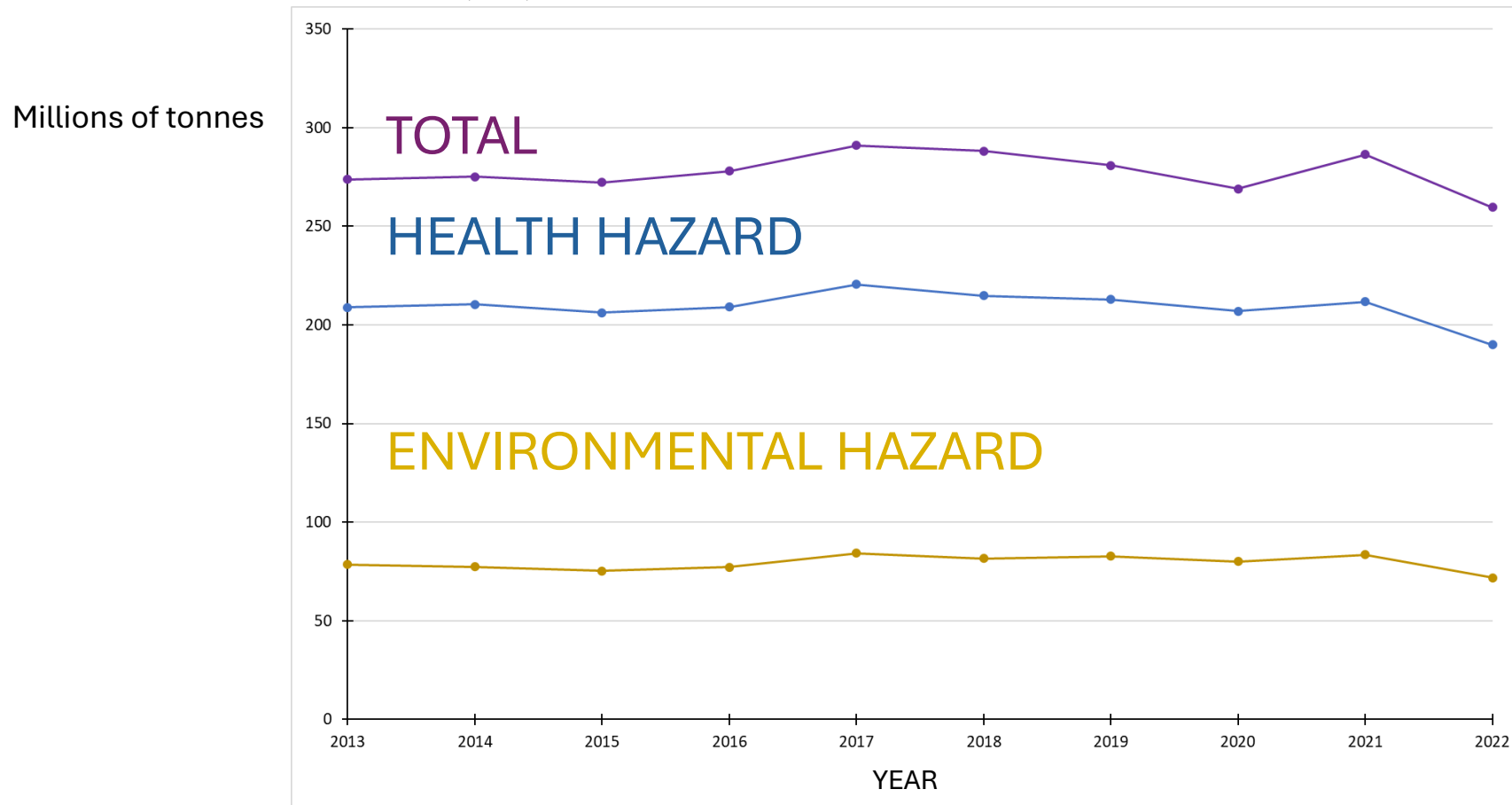


2. REACH Regulation



Chemicals in Europe

Production of Chemicals, EU, 2013-2022



If the drop in 2022 continued into 2023 and 2024, then it might be possible to say that there has been a downward trend since 2021.

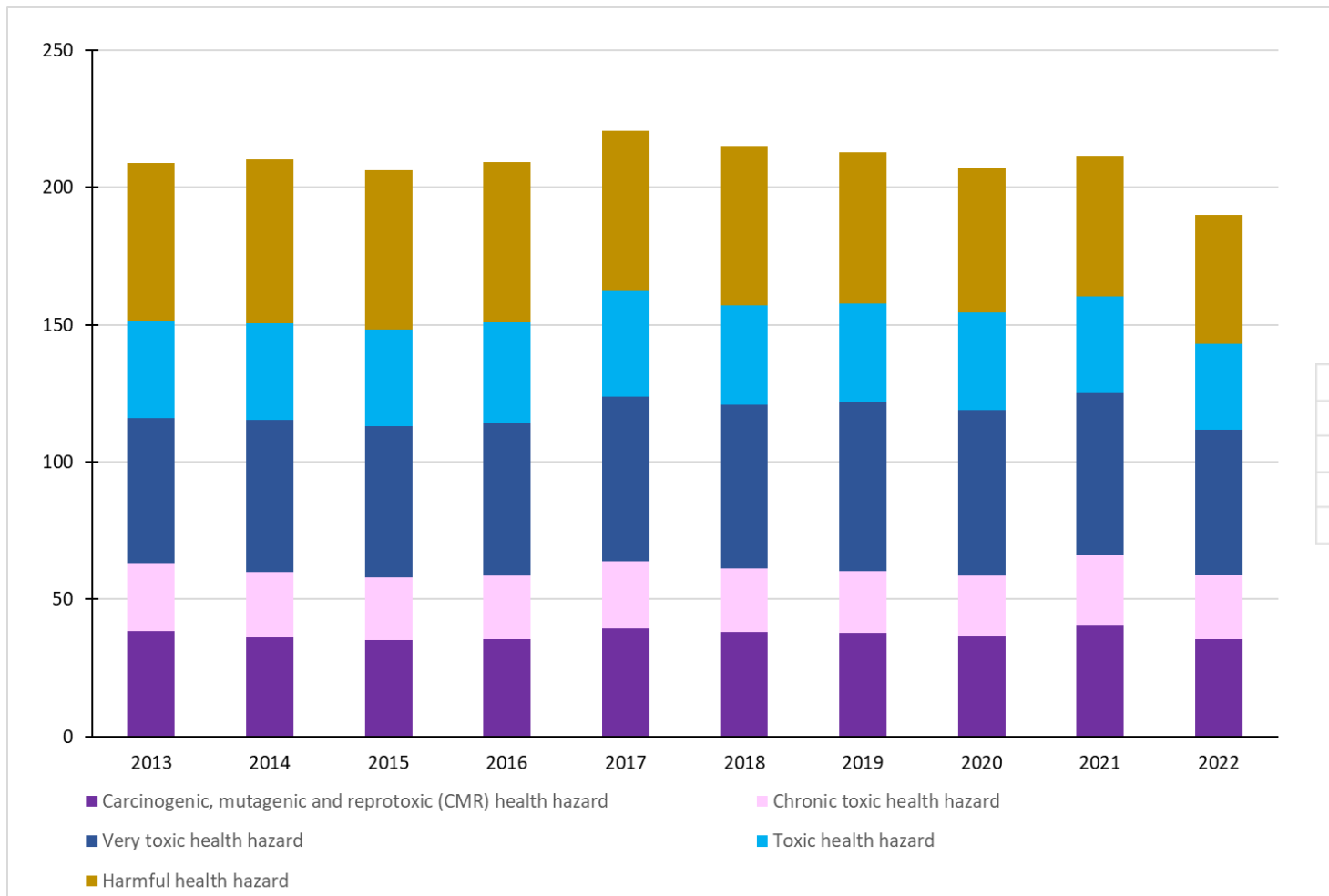
The production of chemicals hazardous to human health in the EU has been on a downward trend since 2013.

Production in 2022 was 190 million tons.

Source: <https://ec.europa.eu/eurostat/databrowser/bookmark/3edac0c0-5d33-4dfc-b445-53b949680aa7?lang=en>



Consumption of chemicals hazardous to health, EU, 2013-2022



	Year 2013	Year 2022		
	(in <unidad>)			
HAZARDOUS TO HEALTH	205	190	7.3 %	
HAZARDOUS TO THE ENVIRONMENT	70	65	7.1 %	
TOTAL	275	255	7.3 %	

Note: The different classes of chemicals are classified according to their toxicity, from the most dangerous (lower class) to the least dangerous (upper class).

Source: <https://ec.europa.eu/eurostat/databrowser/bookmark/3edac0c0-5d33-4dfc-b445-53b949680aa7?lang=en>



REACH Regulation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&qid=1690877919203





Objectives & principles

OBJECTIVES

- Protection of human health and the environment.
- Encouraging and promoting the internal market in the EU.
- Transparency in information.
- Responsibility in the industry (producers).
- Alternative methods for assessing the hazardousness of substances (limiting animal testing).

PRINCIPLES

- **Precautionary principle**, identification of potentially dangerous effects on health and a scientific assessment of the risks which, due to lack of information, inconclusive or imprecision, does not allow the risk in question to be determined.
- **Principle of transparency of information**, the manufacturer, apart from compiling all the information on the substances, must evaluate the risks of the same for the intended uses.
- **Principle of action on a separate basis**, the manufacturer shall provide information including assessments based on tests and studies on the risks for the different uses of the substances.



REGISTRY

- Any substance manufactured or imported as such or in preparations in annual quantities ≥ 1 T (art. 6).
- Monomer substances or other unregistered substances that are present in polymers in a percentage $\geq 2\%$ w/w and in total annual quantity ≥ 1 T (art. 6.2 and 6.3).
- Substances contained in articles (special requirements art. 7.1).
- Intermediates isolated *in situ* (special requirements, art. 17).
- Transported isolated intermediates (special requirements, art. 18).

EVALUATION

- Competent authorities of the Member States and the dossier is evaluated by ECHA.
- Evaluation of substances produced or imported, quantity > 100 tonne.
- Evaluation of carcinogenic, mutagenic and toxic substances for reproduction (CMR).
- Evaluation of PBT, vPvB, quantity < 100 tonnes.

AUTHORISATION

- Risks of controlled substances of very high concern (SVHCs).
- Manufacturers or importers shall identify alternatives and consider the risks of these alternatives.
- CMR and PBT Specific Use Authorizations.
- In the case of substances in preparations (art. 56.6):
- Those PBT/vPvB or equivalent concern present therein at $> 0.1\%$ by weight or
- For other substances (mixtures) for those which exceed the concentration limits marked in such a way that the preparation is classified as hazardous.

RESTRICTIONS AND NOTIFICATIONS

Special procedures involving the submission of certain information to ECHA, relating to substances. These procedures are notifications, which are established in different articles. Submitting this information entails the payment of fees to ECHA.

It concerns the manufacture, placing on the market and/or use of dangerous substances, preparations or articles which pose an unacceptable risk to be addressed at Community level (Annex XVII). There are three types of notifications:

- Notifications of substances contained in article.
- IDOPP (Product and Process Oriented Research and Development) Substance Notifications.
- Classification and Labelling Notifications.



Registration dossier

REGISTRATION DOSSIER BASED ON TONNAGE

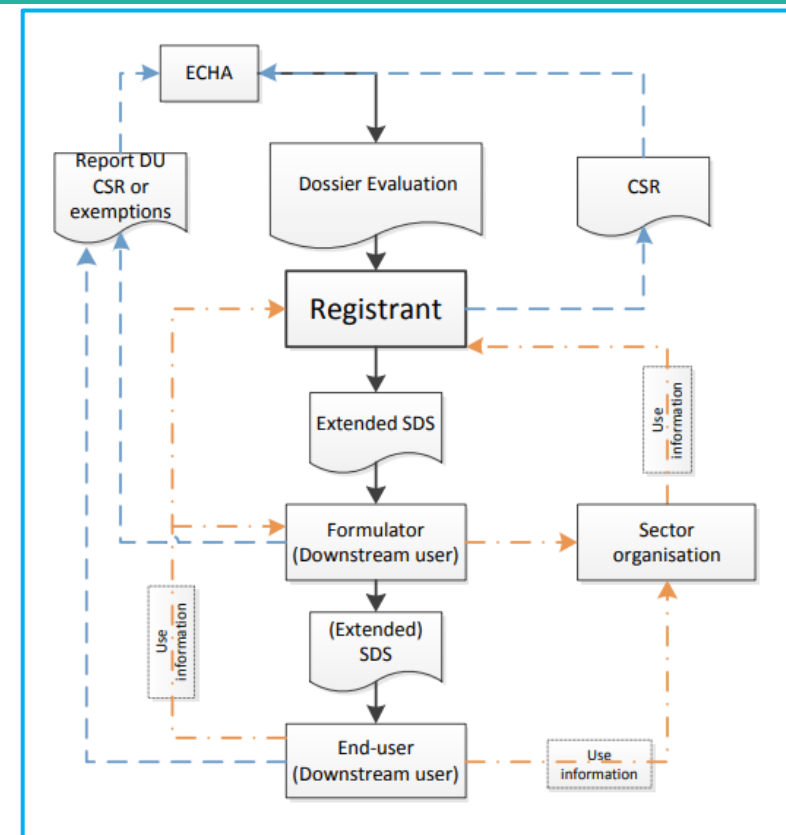
Sections VI and VII of the Registration Dossier request all available physicochemical, toxicological and ecotoxicological information, which varies according to volume or tonnage.

1-10 tonnes:	Annex VII Information.
10-100 tonnes:	Information Annexes VII + VIII.
100-1000 tonnes:	Information Annexes VII + VIII (and test proposals).
≥1000 tonnes:	Annex VII + VIII + IX + X information (and test proposals)

- Identity of the substance
- Physicochemical properties
- Toxicological → **Exposure Scenarios From 10 tonnes**
- Ecotoxicological
- Uses
- Expected production volume
- Classification and labelling

Total exemptions

- Radioactive substances.
- Substances in temporary storage under customs supervision, provided they are not being transformed or processed in any way
- Substances used in the interest of defence when (these are) covered by specific national exemptions.
- The transport of hazardous substances on their own or in mixtures.
- Non-isolated intermediates.





Substances of Very High Concern (SVHC)

- Substances that meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, in accordance with Commission Regulation (EC) No 1272/2008 (**CMR substances**).
- Persistent, bioaccumulative and toxic substances (**PBTs**), or very persistent and very bioaccumulative substances (**vPvB**), in accordance with Annex XIII of the REACH Regulation.
- Substances that raise a degree of concern equivalent to that of CMR or PBT/mPvB substances, based on scientific evidence. They are identified on a **case-by-case basis**.

When the substance is identified as SVHC it is included in a list of candidate substances for authorisation (Annex XV).

The SCIP data base: requirement between REACH Regulation and the WFD

SCIP = **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts)

Suppliers of articles containing **SVHC** (Substances of **V**ery **H**igh **C**oncern) of the Candidate List, above **0.1% (w/w)** must notify them to the **SCIP** database (*managed by ECHA*)



Requirement established under the Article 9.1(i) of the **Waste Framework Directive (WFD)**

Objectives:

- ✓ Once the article is notified, a **SCIP number** (*random sequence of 36 hexadecimal characters*) will be obtained.
- ✓ The article will appear in the SCIP data base.
- ✓ The SCIP number has to be **transmitted through the supply chain**.

1. **Reduce** hazardous substances in waste.
e.g. **Pb, Cd,....**
2. Encourage **substitution** for safer alternatives.
3. Contributes to a better **circular economy** by giving information to the waste operators.



3. Surface treatment sector





Uses of SVHCs in the galvanizing industry

Chromic acid and its salts (chromium trioxide):

The main uses of chromium trioxide are:

- **metal finishing** (for electroplating, e.g. hard chrome plating, decorative or glossy chrome plating, conversion coatings, e.g. zinc, aluminium, cadmium and brass passivation, pickling [CrO_3 solution]).
- manufacture of wood preservation products (biocidal agent (not relevant to REACH); fixing agent in water-based wood preservatives).

Boric acid:

Flux agents for **welding, soldering and galvanizing**, coolants and lubricants (including lubricants for metal processing and for removing metal chips during milling), additive lubricants, welding metals, welding products, cutting oil, rolling oil, casting compounds, liquid grinding, metal hardeners, non-electrolytic metal coatings, metal surface treatment agents, electroplating agents, degreasing agents, corrosion inhibitors, antioxidant agents, rust removal agents.



Uses of SVHCs in the galvanizing industry

PFAS:

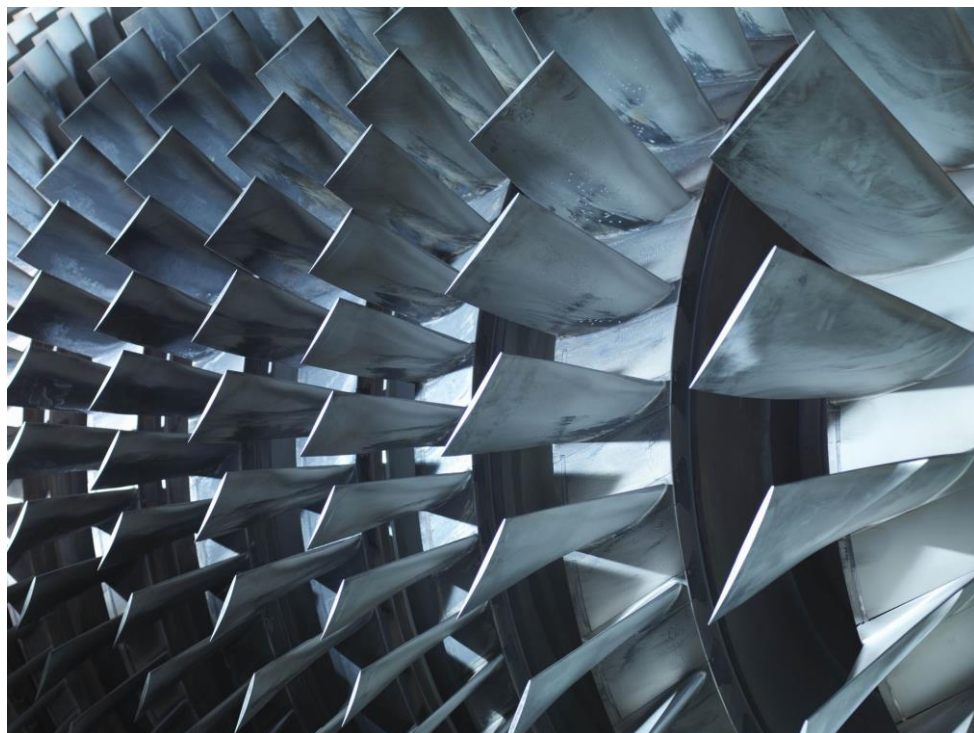
Per- and polyfluoroalkyl substances (PFAS) have been used across this industry sector as **wetting agents, fume suppressants**, dispersion products, coating additives, corrosion inhibitors, and more, due to their special properties of surface tension, temperature resistance, etc.

Cadmium:

High performing components in the aeronautic sector as fasteners and landing gear and hydraulic systems parts, marine equipment, such as salt-water settings, electronic applications, such as electrical connectors and contacts, military and defense equipment as steel components of military vehicles, aircrafts, submarines and ships which require **protection against harsh environmental conditions and corrosion**.



4. Cr(VI), PFAS, boric acid (H_3BO_3), Cd ...





Chrome plating: Process and chemicals used

Sulfuric Acid (H ₂ SO ₄)	Chromic Acid (H ₂ CrO ₄)	Sulfate Ions (SO ₄ ²⁻)	Organic Additives	Buffers and pH Adjusters	Anti-Pitting Agents	Passivation Solutions
Sulfuric acid is commonly used in the activation bath during hexavalent chromium plating.	Chromic acid is a key component in the chromium bath during hexavalent chromium plating	Sulfate ions are present in the trivalent chromium plating bath .	Various organic additives are used to modify the plating bath properties: wetting agents, brighteners, and suppressors .	Chemicals like ammonium sulfate or sodium acetate are used to maintain the desired pH level in the plating bath	To prevent pitting or roughness on the plated surface, anti-pitting agents are added to the bath	After plating, passivation solutions containing chromate compounds (such as sodium dichromate) are used to enhance corrosion resistance and improve the appearance of the chrome layer.
It helps prepare the surface of the workpiece by etching and removing impurities, allowing better adhesion of the chrome layer	It provides the source of hexavalent chromium ions (Cr ⁶⁺) necessary for depositing the chrome layer onto the workpiece	They help stabilize the trivalent chromium ions (Cr ³⁺) and facilitate the plating process.	These additives can influence the brightness, levelling, and distribution of the chrome layer	Proper pH control ensures consistent plating results.	These agents help maintain a smooth and uniform chrome layer.	

Cd, H₃BO₃ has very critical use in electrolytic deposition of metals such as Ni, anodizing, and it is also useful for metal working fluids and brazing fluxes.



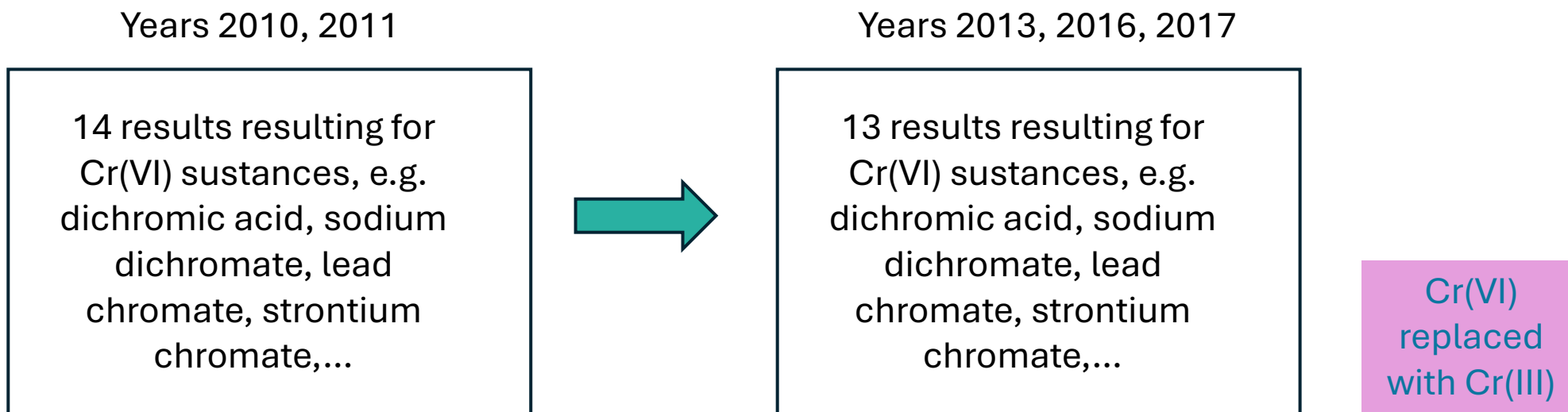
Environmental data on Europe and metals as wastes

- 8 million tons of wastewater / 40% are chemically treated.
- $\approx 2,000$ tons of heavy metals per year released in Europe from industrial wastewater (mainly As, Cd, Cr, Cu, Pb, Ni, Zn).
- 67% of this amount is released by Italy, Germany, Spain and France.
- $7,000 \text{ m}^3$ wastewater per year with up to 10% of metals produced by every SME in galvanic industry in Italy.

The result is a huge loss of valuable resources and a dramatic release of harmful pollutants.



Cr(VI) from the Candidate List for Authorisation to Annex XIV



Regulatory future

ECHA is deciding on the regulatory future of chromium trioxide based on data submitted by the industry.

Authorization

Restriction



ECHAS' s current activities on restrictions on Cr(VI) substances

27 September 2023

This implies to include these substances in Annex XV of REACH

Substance Name	EC number	CAS number	Type of the task	Scope of the task	Entry in Annex XVII	Other remarks
Certain chromium (VI) substances	-	-	Prepare an Annex XV restriction dossier	The Commission is requesting ECHA to prepare a restriction dossier in line with the requirements of Annex XV in view of a possible restriction certain Cr(VI) substances. The number of applications for authorisation for the use of certain Cr(VI) substances has far exceeded the predictions at the time of inclusion of the substances in REACH Annex XIV, and the approach envisaged for regulating Cr(VI) substances (authorisation) is no longer appropriate to control the risk to human health posed by these substances.		Commission's request to ECHA [PDF] Commission's Q&A Commission's amendment to the request to ECHA [PDF] [EN]

“The potential restriction of those substances would enter into force at the same time of their de-listing from Annex XIV, replacing the current authorisation requirements”.



PROCEDURE RELATED TO Cr (VI) SUBSTANCES

27 September 2023 – Request to the ECHA to prepare an Annex XV restriction dossier on certain chromium (Cr) substances



“within 12 months from entering the relevant intention and initiate the restriction process, should the dossier demonstrate that the restriction is the most appropriate EU wide measure in the light of the considerations made above”.

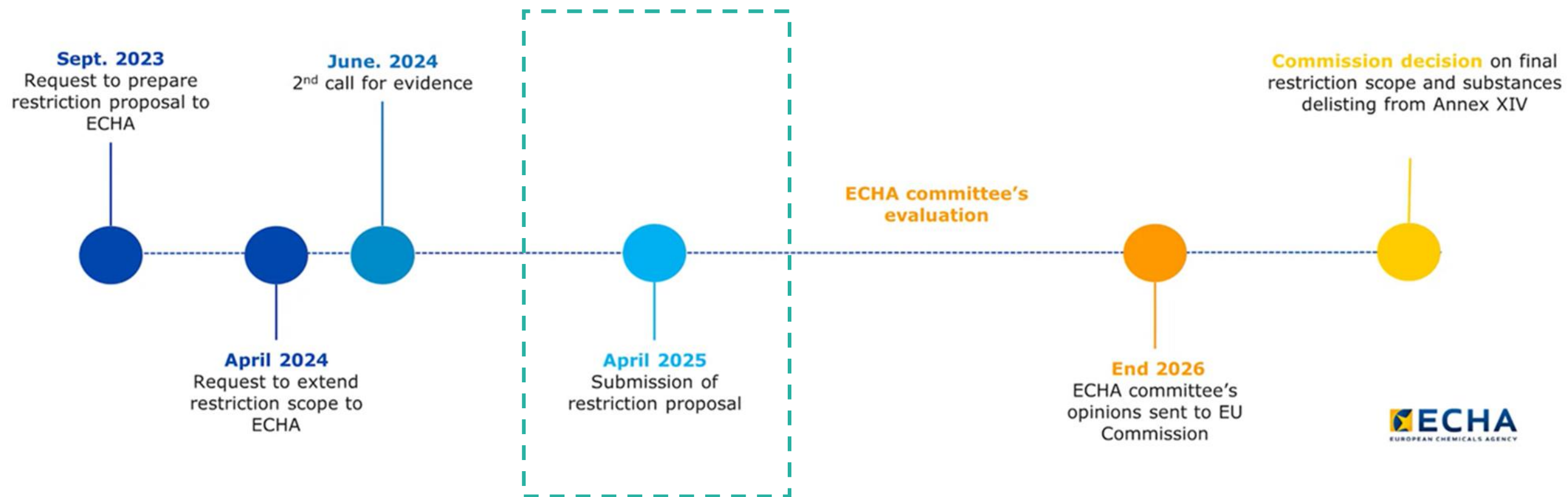


“the Commission hereby considers justified to extend the time for completing the Annex XV restriction dossier from 12 to 18 months. The Commission therefore expects **ECHA to submit the Annex XV** dossier on **11 April 2025**”.

Information on this intention to restrict Cr(VI) along with other substances can be found on the following ECHA page: [ECHA's current activities on restrictions - ECHA \(europa.eu\)](https://echa.europa.eu/restrictions)



TIMING – RESTRICTION OF Cr(VI) SUBSTANCES





Boric Acid

Year 2021

9 results resulting for
boric acid substances,
e.g. sodium perborate,
borate, perboric acid,
sodium
peroxometaborate ,...

No restriction process in boric acid. But Authorisation process ([27/05/2023](#)).

Name	EC / List no.	CAS no.	Association
Boric acid	233-139-2	10043-35-3	Expert judgement (ECHA)
Boric acid, crude natural	234-343-4	11113-50-1	Expert judgement (ECHA)



Restriction process for PFAS (Annex XV of REACH)

Substance Name	EC number	CAS number	Type of the task	Scope of the task	Entry in Annex XVII	Other remarks
Per- and polyfluoroalkyl substances (PFAS)	-	-	Prepare an Annex XV restriction dossier for uses in firefighting foams Commissions request to ECHA [PDF][EN]	Report [PDF][EN] Annex [PDF][EN] Appendix [PDF][EN]	14/01/2022	

Submitted restrictions under consideration

Name ↕	EC Number ↕	CAS Number ↕	Start of consultation on Annex XV report ↕	1st deadline for comments on Annex XV report ↕	End of consultation on Annex XV report ↕	Start of consultation on SEAC draft opinion ↕	End of consultation on SEAC draft opinion ↕	
Per- and polyfluoroalkyl substances (PFAS)	-	-	22/03/2023		25/09/2023			Details



SUMMARY FOR PFAS AND BORIC ACID in REACH REGULATION

- PFAS are not in the Authorisation List
- Some PFAS already restricted and a global process to restrict more than a 10,000 PFAS substances is on the way ([07/02/2023](#), last versión [22/03/2024](#)).



Cadmium

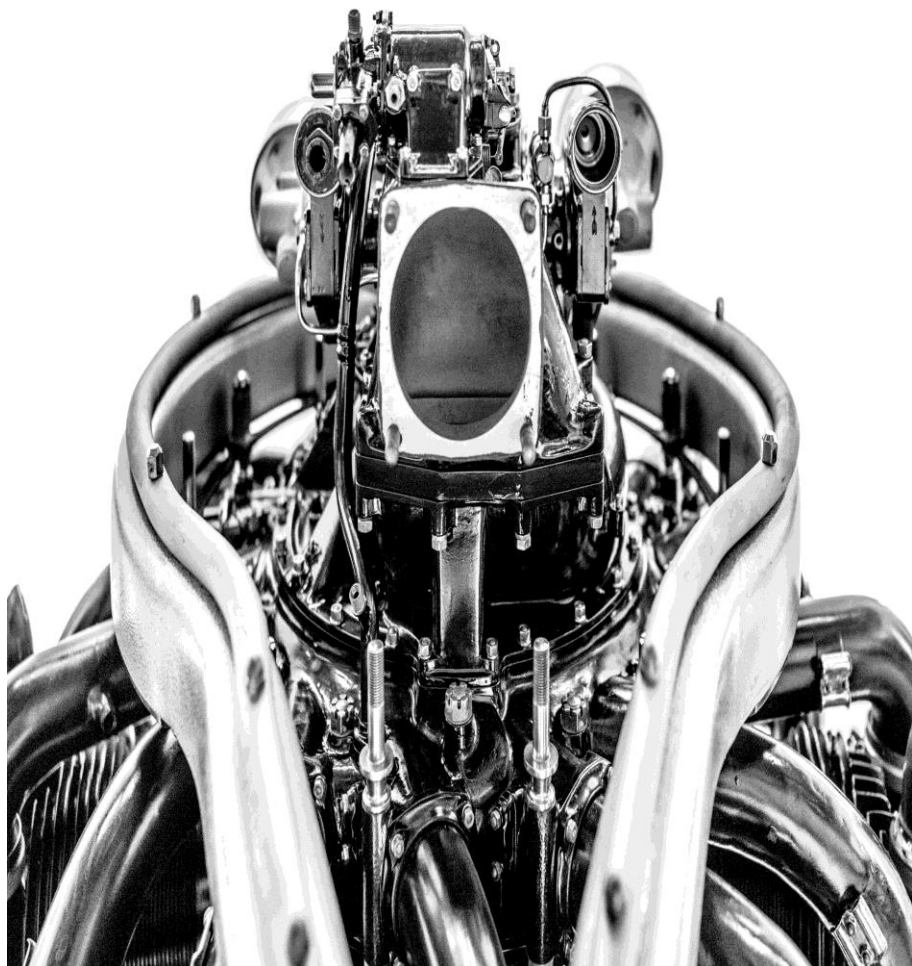
Some uses of this substance are restricted under [Annex XVII of REACH](#).

Substance name 	EC No. 	CAS No. 	Entry no. 	Conditions	Appendices
expand / collapse Cadmium and its compounds Process related name: Cadmium Cadmium di(acetate), dihydrate EC No.: 611-525-5  CAS No.: 5743-04-4 Sulfuric acid, cadmium salt, hydrate (3:3:8) EC No.: 616-572-5 CAS No.: 7790-84-3 cadmium chloride (CdCl₂), hydrate (2:5) EC No.: 640-998-0 CAS No.: 7790-78-5 Cadmium compounds EC No.: - CAS No.: -	-	-	23		

Cd
replaced
with Zi-Ni



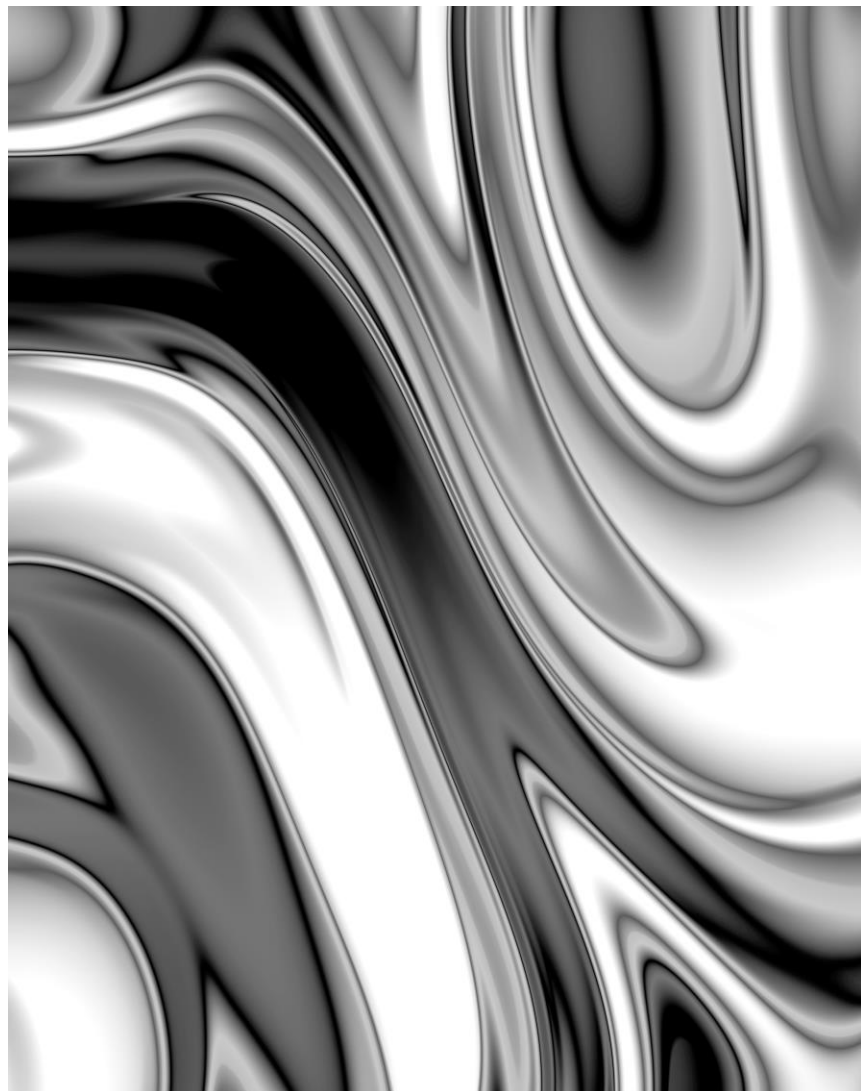
5. Surface projects in Ramboll





Ramboll key projects on Authorisation and Restriction

- Applications for Authorisation – about 80% of the AfA sent to ECHA have been prepared by Ramboll for a number of clients (over 120 AfAs).
- In the first and second “Call for Evidence” related to chromium substances on restriction, Ramboll has supported several companies to send their comments and Information to ECHA.
- Ramboll has supported numerous companies in the “Call for Evidence” for the restriction of PFAS.
- Ramboll is helping to inform companies on different news affecting the sector through AIAS (articles, Technical Notes and short communications).



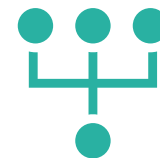
5. Conclusions



Messages for business to take home



The galvanising sector must be fully informed and updated on the different decisions taken by ECHA's Committees (RAC and SEAC) and which affect its future business development.



Companies must carry out the appropriate processes to comply with the REACH Regulation, according to the options presented and as decided which is the most appropriate by the EC.



Failure to comply with the regulation can lead to sanctions by the relevant administrative authorities and potentially insatisfied clients.



RAMBOLL IBERIA HEALTH SCIENCES TEAM



Dr. Rosa Cirera

Senior Managing Consultant

Barcelona



Dr. Ana Isabel Sánchez

Senior Consultant

Madrid



Antoni Guiu

Consultant

Barcelona



Marga Estrany

Consultant

Barcelona



Alejandro Calle

Junior Consultant

Madrid



Adriné Ganimian

Junior Consultant

Barcelona

Ramboll Madrid Office

Calle de Orense 34 - 7th floor.
28020 Madrid

Contact: **Dr. Ana Isabel Sánchez**

E-mail: asanchez@ramboll.com

Ramboll Barcelona Office

Carrer de la Diputació, 211.
08011 Barcelona

Contact: **Dr. Rosa Cirera**

E-mail: rcirera@ramboll.com



+34 910 874 500



[Environmental and Nature-Based Services -
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Other Ramboll support)



Regulations

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals and Mixtures)

CLP (Classification, Labelling and Packaging)

BPR (Biocidal Products)

POPs (Persistent Organic Pollutants)

PIC (Prior Informed Consent)

ADR (Transport of Dangerous Goods)



Safety policies

Waste Framework (SCIP, RoHS)

Carcinogenic and Mutagenic Chemical Agents Directive, Exposure of Workers

Toxicology

Risk assessment



Emerging regulations

Nanocomposites and nanomaterials

Emerging Contaminants: PFAS

Endocrine Disruptors



How can Ramboll help you?



Diagnosis of REACH obligations

- Determination of exempt products: natural/synthetic, polymers/monomers
- Diagnosis of obligations for the various UK-EU-Third Country exports



REACH Procedures

- Substance Registration
- Authorization
- Procedures related to other procedures: Evaluation



CLP Support

- Classification of substances
- Preparation/Review of Safety Data Sheets (SDS)
- Hazardous Mixtures Notification