Evolution in Environmental Regulations - Update from ESA REACH Officer

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Outline

- REACH Introduction & Regulatory Challenges
- Sector-wide Initiatives, MPTB and its Task Forces/Working Groups
- Priority Actions: PFAS and Other Substances
- Introduction to ESA REACH tool
- Conclusions and outlook

REACH – INTRODUCTION
REGULATORY CHALLENGES

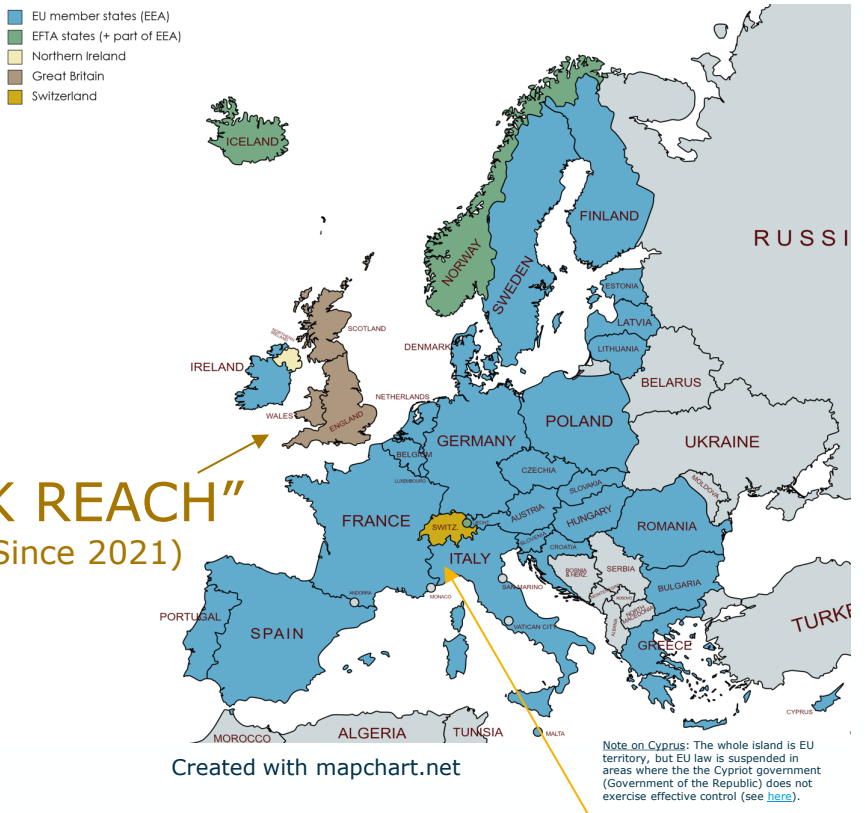
EU REACH is the main driver for change

Registration, **E**valuation, **A**uthorisation and **R**estriction of **Ch**emicals*

- Addresses potential **impacts of chemicals to human health** and on the environment, production & use of chemical substances.
- **Strictest law** to date regulating chemical substances.
- Very desirable and **ambitious** regulation to contribute to a safer and healthier environment, but
- Many chemical **substances facing** regulatory or commercial **obsolescence**, causing widespread impacts to downstream users.
- Causes wide-reaching **engineering and management challenges** for the space sector which is by nature driven by performance and applications' heritage
- REACH revision expected by ? ~~end of 2023 …~~ON HOLD

"EU REACH" territories

EU-27 + Iceland, Norway and Lichtenstein (= EEA) + Northern Ireland



Swiss chemicals regulation

* Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Evolution of Chemicals Regulatory Requirements*

*Important examples only, not exhaustive

esa ESCC / MPTB

Key EU policy drivers

European Green Deal (2019->)

Updated Circular Economy Action Plan (2020->)

Chemicals Strategy for Sustainability (CSS) 2020->

RoHS Directive(s) (2003-)
Restriction of hazardous substances in electrical and electronic equipment

ROHS review outcome publ. 7.12.2023

REACH Regulation (2007-)
Registration, Evaluation, Authorisation & Restrictions of chemicals

REACH Revision (for next Commission)

CLP Regulation (2008-)
Classification, labelling and packaging of substances and mixtures

CLP Revision final steps

Revised Waste Framework Directive (2018-)
incl. SCIP reporting on SVHCs in articles above 0.1% w/w to ECHA

Sustainable Products Initiative (2021-)
incl. ecodesign requirements and EU Digital Product Passport (ESPR)

+ outside EU/globally (e.g. UN GHS/TDG, Swiss chemicals regulation, UK REACH, U.S. PFAS, …): New similar requirements, often taking EU laws as example

Other regulations impacting compliance for M&P (2022-)
(European Chips Act, Conflict minerals, CRM Act, EU Sanctions, GCD (*draft*), CSRD, CSDDD, …)

Monitored by MPTB

Monitored by?

2005 2010 2015 2020 2025 2030

NOW

Complexity linked to overall regulatory compliance

Not exhaustive…

Supply chain resilience/ethics

Conflict Minerals, Critical Raw Material Act, Chips Act, multiple **EU sanctions,…**

ESA's additional requirements on suppliers, such as **ESA CSR Code of Conduct** (reflecting on Directive (EU) 2024/1760 on corporate sustainability due diligence),…

Legislation focused on Circularity, Sustainability (Environmental Footprint)

Waste Framework Directive/**WFD/SCIP**, **EEE Waste directive,** Reg. on **batteries and waste batteries**

NEW:

Ecodesign directive -> **ESP Reg.**; **Corporate Social Responsibility Reporting Directive** (CSRD), Directive on **Corporate Sustainability due diligence** (CSDDD), **Green Claims Directive (*draft*),…**

Future: EU Space Law/Earth sustainability part & application of PEFCR?

Legislation focused on Chemicals & Materials

ROHS, REACH, CLP, CMD, CAD, OELs

Mercury reg., POPs,…

REACH Update by Numbers in 2024 Q3

Registration, Evaluation, Authorisation and Restriction of Chemicals

https://reachtool.esa.int/

- EU REACH Registered substances: **>22,786**
- EU REACH registrations: **>107,372**
- ECHA's Cand. List -Substances of Very High Concern (SVHCs): **241** entries (**492** ref. substances)
- REACH Annex XIV –Authorization list: **59**
- REACH Annex XVII – chemical(s)-specific restrictions: **73** entries (~ 2,100 substances, excluding PFAS proposal)

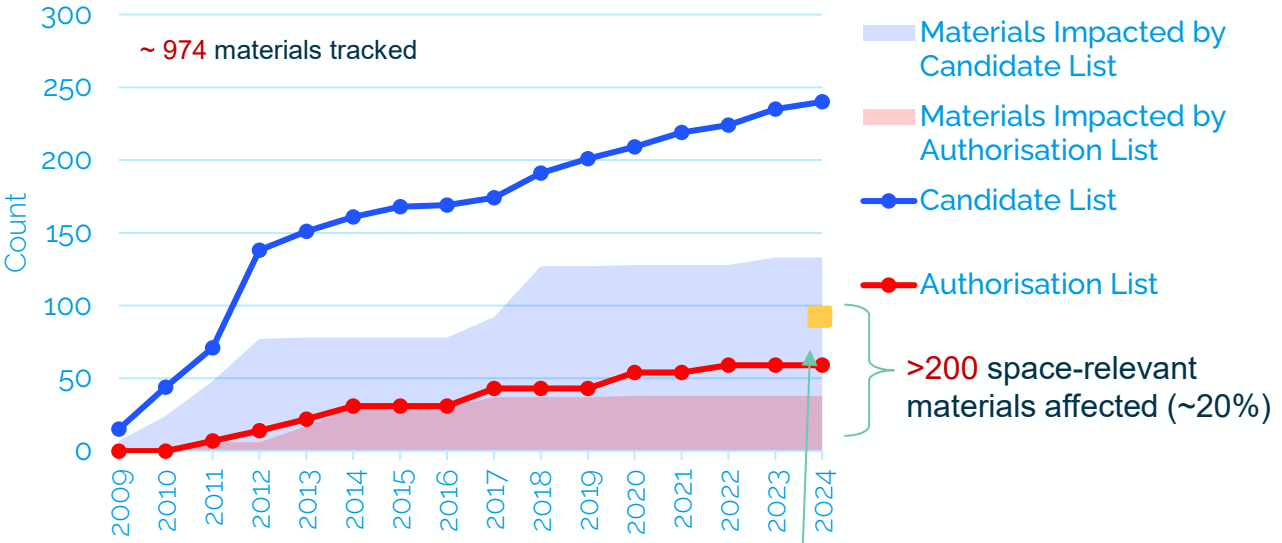


Figure 1. Evolution of entry count in relevant REACH lists and subsequent space relevant materials impact of over time, based on the bill of materials in the ESA REACH Tool.

- Obsolescence Splinter group /REACH Tool analysis by Q1 2024
  - **40** SVHC entries impact 133 (15%) of tracked materials
  - **13** REACH Annex XIV entries impact 38 (4%) of tracked materials
  - **13** Space-relevant Annex XVII entries impact 93 (~11%) of tracked materials
  - **55*** materials/mixtures in active use have very high risk of obsolescence!

(*last number space-relevant materials impacted by either Annex XVII or Annex XIV)

ESA REACH Office in a nutshell

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Key Objectives:

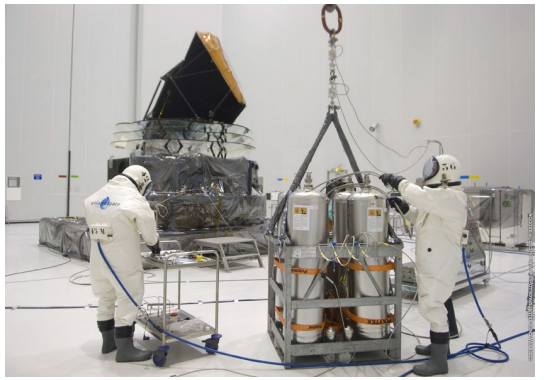
- support ESA projects in REACH compliance & managing obsolescence risks
- monitor future regulatory evolution with potential impact on space sector

Key Challenges:

- quickly evolving regulations causing materials' unavailability
- priorities: chromates, hydrazine, bisphenols, "forever chemicals" (PFAS), metallic lead,…
- EU initiatives: REACH revision process, broad group restriction proposals (PFAS, Cr(VI)), Cr(VI) re-authorisation (ADCR), …

Key Responsibilities:

- established and managed network of agencies, primes/LSIs with regular information exchange
- active contributions to public consultations, guidelines & ESA-internal reporting
- development of the ESA REACH tool and REACH awareness sessions
- organisation of REACH workshops for key stakeholders (positive feedback from industry)



Filling of Max Planck Probe
Photo: GHC

Participants on 5th ESA REACH workshop 2024
Photo: ESA

SECTOR-WIDE INITIATIVES

MPTB AND TASK FORCES

- European space sector groups addressing specific topics

Materials and Processes Technology Board (MPTB) Members

Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB). The ESCC MPTB is a partnership between the **European Space Agency (ESA)**, **national space agencies**, and the European space industry represented by ASD-EUROSPACE; it is chaired at present by ESA. The European Defence Agency (EDA), Leonardo Company and MAP SPACE COATINGS are invited as observers.

Agencies

esa

cnes

DLR

asi agenzia spaziale italiana

Industry

ASD-EUROSPACE The Space group in ASD

AIRBUS DEFENCE & SPACE

ThalesAlenia Space

AVIO

ariane GROUP

OHB

beyond gravity

MT AEROSPACE

sener

TESAT

Observers

EUROPEAN DEFENCE AGENCY

MAP SPACE COATINGS

LEONARDO

REACH Task forces and Working group coordinator and expert

REACHLAW

REACH-related Regulatory Task Forces under the MPTB

MPTB

REACH obsolescence risk analysis. Regulatory monitoring. General studies and sector positions

initiates

report

ASD-Eurospace

communicate

- Member States
- EU Parliament
- EU Commission
- ECHA

coordinate

ASD

REACH & CHEM WG

exchange

Third party groups
(e.g. CEFICs group)
SMEs

Space Task Forces

Focus on chemicals

- Hydrazine Task Force* "HTF" (2011-)
- Chromates Task Force* "STF" (2013-)
- Lead Metal Task Force* "LTF" (2018-)
- WFD / SCIP Task Force (2019-)
- Energetic Materials WG* ("EMWG") (2020-)
- CSS Space Focus Group (SFG) (2021-)
- Restrictions Task Force* (RTF) (2023-)

*Includes also Non-MPTB members

PRIORITY ACTIONS
PFAS AND OTHER SUBSTANCES

- Focus of today's talk: EU REACH PFAS Group Restriction proposal, response and impact
- Other High priority substances (not discussed today):
  - CrO3 + Chromates
  - D4, D5 and D6 Cyclic siloxanes
  - Metallic Lead
  - Bisphenol A and its derivatives
  - …

Universal PFAS: Comments on Restriction Proposal


Paris, 22 September 2023

EUROPEAN SPACE SECTOR COMMENTS ON THE ANNEX XV RESTRICTION REPORT FOR PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

ECHA Public Consultation of 22 March 2023 on the proposed restriction on the manufacture, placing on the market and use of PFASs

- Assessed by space sector represented by MPTB (more here)
- Space Restrictions Task Force (RTF) between March – September 2023, in coordination with the Aerospace, Security and Defence Industries Association of Europe (ASD)
- **Investigations conducted:** ESA Internal PFAS Survey and REACH Tool Analysis; RTF survey ... 5 progress meetings
- **Elements:** Contribution paper (MPTB-ES-PO-0131) (link) and confidential Appendix (Table of PFAS uses) submitted to ECHA on 22.9.2023 - Eurospace News Alert of 25.9.2023 (link)

- **PFAS types in focus:** fluoropolymers: fluoroelastomers, non-polymeric liquids,...
- **Mapping has been performed to understand the use of PFAS, and wide-spread use in space applications,**
- **Severe impact on recurrent design, manufacturing and space heritage for launchers, spacecraft, etc.**
- Status update in RTF presentation (5 languages): link

PFAS use cases in launchers & spacecraft

Ariane 6

PFAS is in some form used in following:

- Lubricants,
- Coatings,
- Creep barriers,
- Functionalised polymer surfaces,
- Cleaning agents,
- Coolant fluids,
- Fluoro-elastomeric sealants,
- Pyrotechnic compositions,
- Blowing agents for thermal insulation,
- Adhesives,
- Fire suppressants,
- Cables insulation,
- Shrink sleeves,
- PCBs,
- Processes for electronic assembly
- …

Exemplar spacecraft: EarthCare

Where are PFAS used in spacecraft?: MLI, PCBs, lubricants, cables, connectors, insulation, gaskets, tubes, …

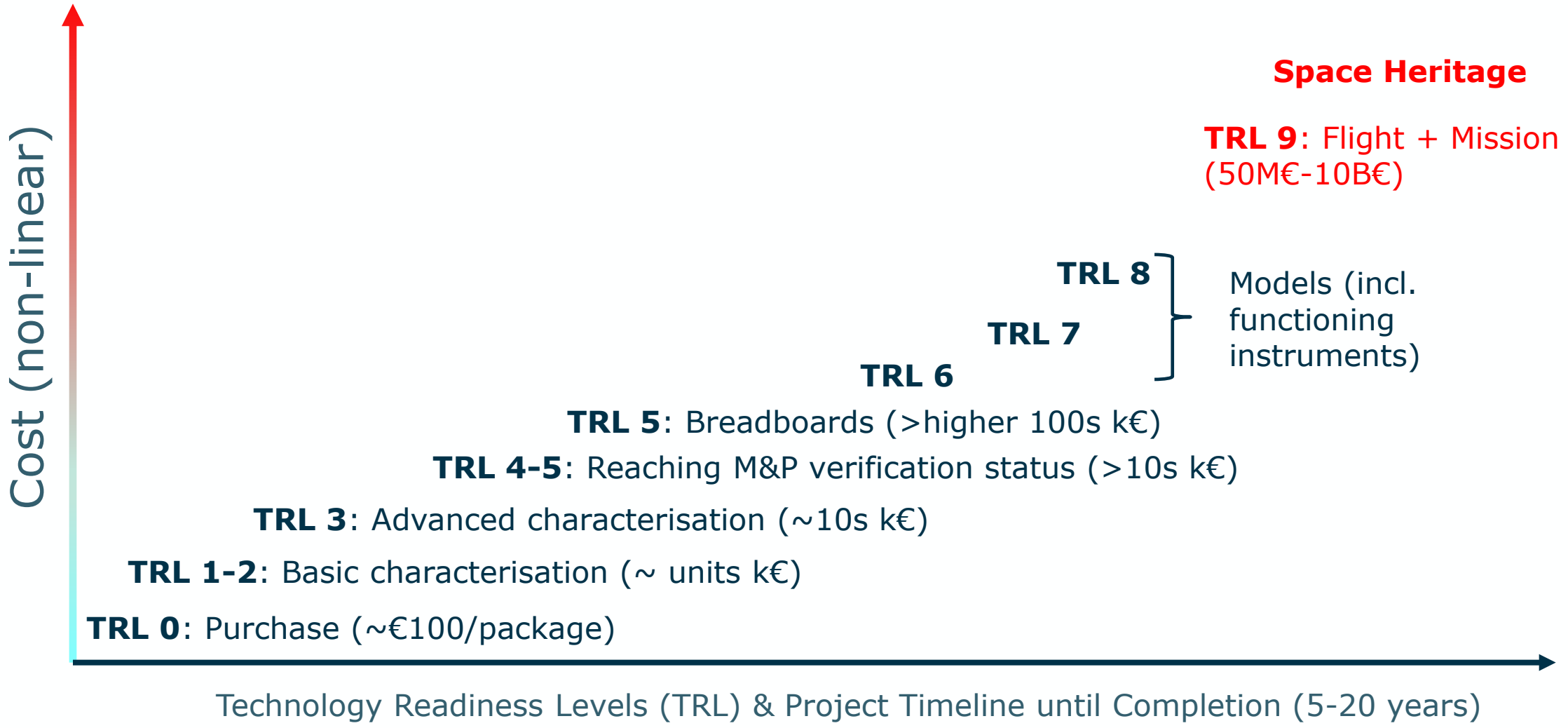
> 110 out of ~2700 DML items, mostly **PTFE**, **ETFE**, **FEP**, **PVDF**, **FKM***-based (5-10% of all declared material uses)

*FKM= fluoro-rubber (Fluorine Kautchuk Material)

If EU REACH PFAS restriction is adopted without space-specific derogation, the European Space Sector would face serious issues!
(worst case scenario: to comply within 18 months period after PFAS restriction adoption)

IMPACT OF REGULATIONS ON SPACE SECTOR => OBSOLESCENCE

Obsolescence Impact: Cost and Delay – example of a new adhesive in optics



ESA REACH TOOL*

*Note: following slides are using some content and graphics from ESA REACH Tool Webinar, by REACHLaw 2024

Key objectives of the ESA REACH Tool

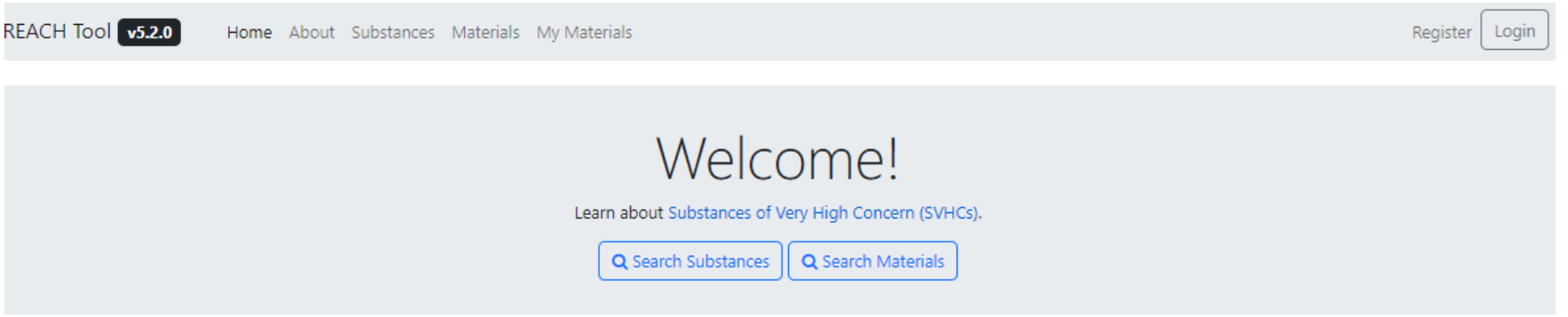
- Indicate regulatory threads from the substance crosschecked with M&P relevant entries (DMLs/materials)
- Rapid information at hand (shift from endless xls tables…)
- To be able to monitor “ideally” entire sector when it comes to dependency on substances = one common database of all materials/mixtures relevant to European space sector (very useful for impact assessments!)

Three main components of the Tool’s:

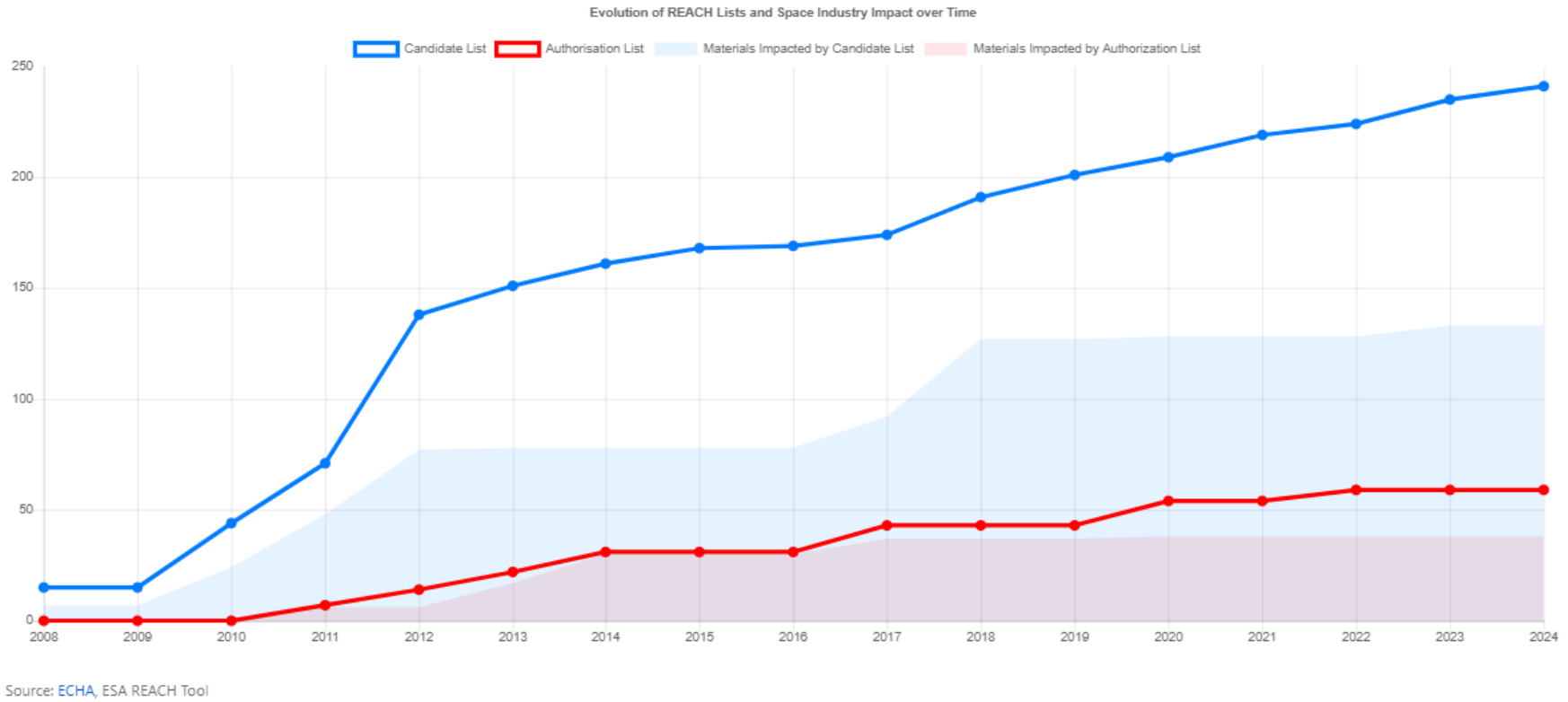
- Material information (substances contained within)
- Substance regulatory information (ECHA’s REACH lists)
- User-subjective information (data filtering relevant for user’s interest)

- Targeted user groups:

  M&P, PAs, Procurement/Compliance & Supply chain, Sustainability engineers.



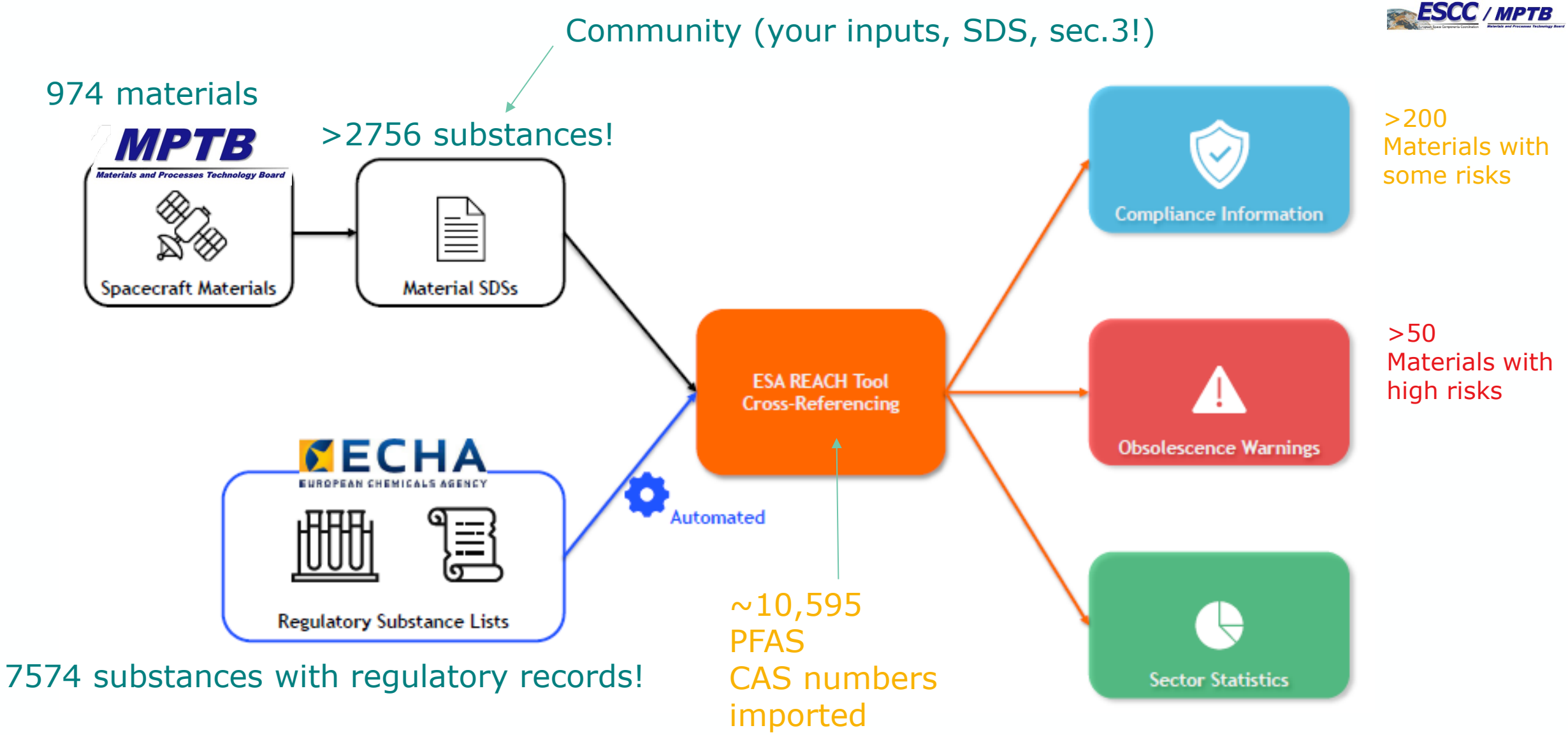
https://reachtool.esa.int/



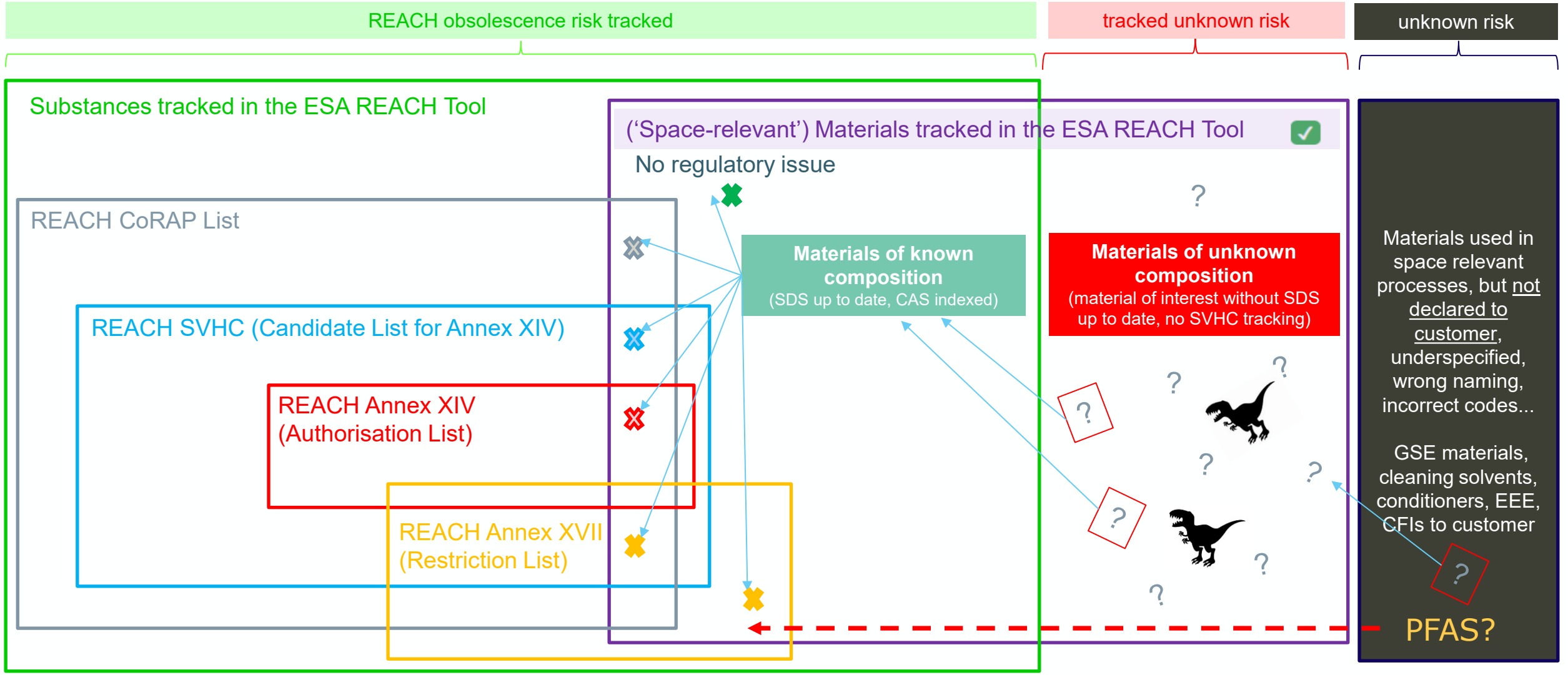
Source: ECHA, ESA REACH Tool

QR code to the Tool

Basic principle of the data flow in the Tool

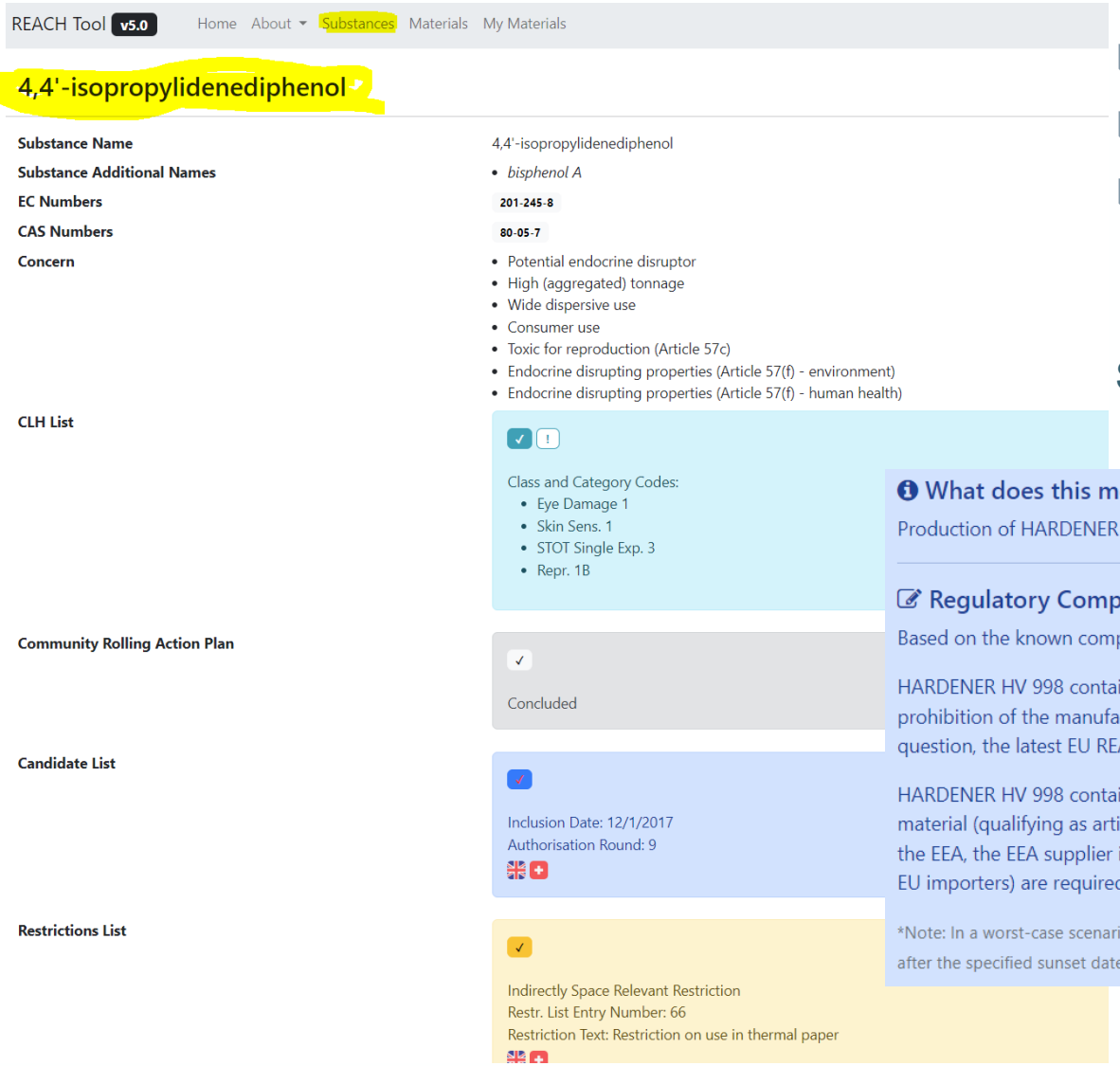


Substances vs. REACH lists – overview of “intersections”



Note: It is impossible to perform any REACH cross-check/regulatory risk assessment if the substances present in materials & process are not traced/identified

EXAMPLE: 4,4'-isopropylidenediphenol, (BPA)



- Authorisation list? -> no
- SVHC? -> yes, recommended for Annex XIV?: yes
- Relevant restriction(s)? Yes and no, Entry 66 no (thermal paper), Entry 30, on group entry for 1B class potentially relevant (public use, nevertheless derogations may be applicable!)

Short risk assessment of e.g. **Hardener HV 998 of Huntsman:**

What does this mean?

Production of HARDENER HV 998 may now be **obsolete**

Regulatory Compliance

Based on the known composition, indexed from the SDS with the above revision date, the REACH Tool has identified that HARDENER HV 998 contains a SVHC.

HARDENER HV 998 contains a substance found in the **Restrictions List** (REACH Annex XVII), therefore **action may be required**. Restrictions may be any condition for or prohibition of the manufacture, use or placing on the EEA market. Please consult the ECHA website for further details on the specific entry that covers the substance(s) in question, the latest EU REACH Safety Data Sheet provided by the substance/mixture supplier and – if in doubt – regulatory experts.

HARDENER HV 998 contains a substance found in the **Candidate List** of Substances of Very High Concern for Authorisation*, therefore **action may be required.** If the material (qualifying as article as such or assembly of articles) containing this substance above 0.1 % weight by weight in the article is being supplied to another entity in the EEA, the EEA supplier is required to provide a REACH Article 33 Declaration. Furthermore, as from 5 January 2021 EU suppliers of such articles/assemblies (including EU importers) are required to submit a SCIP notification based on Article 9 of the EU Waste Framework Directive in association with the applicable national law.

*Note: In a worst-case scenario, the substance may enter the Authorisation List within about 2 years from the Candidate List inclusion date, banning its use within the EEA without authorisation after the specified sunset date.

BPA removed -> Hardener HV998-1 (= new formulation)

Any hits? 16 materials

Proposed levels of obsolescence risks (under development)*

#	REACH Risk Categorisation for Chemical Substances	Annex XVII related	Annex XIV related
0	Substance has no known regulatory risks		
1	Substance has a hazard code in CLH		
2	Substance meets SVHC hazard threshold but not is not in the Candidate List		
3	Substance is an SVHC and has entered the Candidate List		
4	Substance has been prioritised for Authorisation List (Annex XIV) inclusion or contains PFAS which does not have yet higher regulatory limitation	Contains PFAS	Prioritised for An. XIV
5	Substance is in the Authorisation List (Annex XIV) but pre-sunset date or targets space-irrelevant use in the Restriction List (Annex XVII); both with high commercial obsolescence risk potential.	Space irrelevant restriction	An. XIV but sunset date not passed
6	Substance is in the Authorisation List (Annex XIV) but there are some Applications for Authorisation (AfAs) for specific use of the substance, or the substance has an indirectly space relevant entry in the Restriction List (Annex XVII).	Indirectly relevant restriction	An. XIV but has AfAs
7	Substance is in the Authorisation List (Annex XIV) but **NO** Applications for Authorisation (AfAs) have been received for use of the substance, or the substance has an entry in the Restriction List (Annex XVII) that **bans** its use relevant to space industry.	Directly relevant restriction	An. XIV but no AfAs

*Note: these risk level formulations proposed by ESA are still due to be reviewed and endorsed by MPTB/OSG community

NEW feature: Risk thermometer (testing phase)

1/7	Substance has no known regulatory risks
2/7	Substance has a hazard code in CLH
3/7	Substance has an SVHC level hazard code but is not in the Candidate List
4/7	Substance is an SVHC and has entered the Candidate List
5/7	Substance has been prioritised for Authorisation List (Annex XIV) inclusion or has a space irrelevant entry in the Restriction List (Annex XVII)
6/7	Substance is in the Authorisation List (Annex XIV) but >0 Applications for Authorisation (AfAs) have been granted for specific use of the substance, or the substance has an indirectly space relevant entry in the Restriction List (Annex XVII)
7/7	Substance is in the Authorisation List (Annex XIV) but 0 Applications for Authorisation (AfAs) have been granted for use of the substance, or the substance has a directly space relevant entry in the Restriction List (Annex XVII) that bans its use

Substance example: **toluene** (CAS nr. 108-88-3)
Concerns: **CMR**, consumer use, large quantity, dispersive use, others…
Regulated? **Annex XVII restriction Entry 48** – subject to **space-relevant use**
Space specific materials hits? **Yes**,
How many materials impacted? **48!**
➔ Risk level is second highest, 6/7

Consequence: manufacturers frequently removing toluene from their formulations!

Substance Name		EC Numbers	CAS Numbers	Reasons	CLH	CoRAP	CL	Restr	Auth	Hits
Toluene	6/7	203-625-9	108-88-3	• High (aggregated) tonnage • Wide dispersive use • Other hazard based concern • Consumer use • CMR	✓	✓	×	✓	×	48

CONCLUSIONS AND OUTLOOK

Conclusions

- Regulatory constraints in Europe lead to significant number of obsolescence cases in M&P domain negatively impacting space industry,
- EU REACH PFAS restriction as proposed would represent unmanageable burden to space sector,
- Proactive M&P obsolescence management is a key for successful businesses, regulatory monitoring is one of its essential elements,
- ESA REACH Tool is useful, provides platform to collect information about chemical content of space relevant materials and visualises obsolescence risks caused by chem. Regulations,
- The ESA REACH Tool may be used to spot changes in regulatory risks of certain substances and to see trends in material compositions from European space sector point of view,
- ESA REACH Tool page: https://reachtool.esa.int/
- MPTB webpage: https://escies.org/webdocument/showArticle?id=1045&groupid=6

Thank you for your attention!

Questions?

Contact: reach.officer@esa.int

List of important contributions with references

in reverse chronological order

- Continued use of chromium trioxide under EU REACH while new authorisation decisions are pending, 22 August 2024, (here)
- Lead metal vs. EU REACH: Brief note to projects, v1.2, 11 July 2024 (here)
- 5th ESA REACH Workshop on regulations, 19th June 2024, ESA/ESTEC, the Netherlands, summary + all presentations available (here)
- Comments on new special packing provision “PP5” to UN2029 for hydrazine anhydrous, 12 June 2024 (here)
- Environmental Regulations and Their Impact on European Space Sector, 16-19th October 2023, CSID 2023, (link)
- European Space Sector comments on the Annex XV restriction report for per- and polyfluoroalkyl substances (PFAS) of 22 September 2023 (here)
- European Space Sector comments on the REACH restriction proposal for certain bisphenols, 22-05-2023 (here)
- European Space Sector feedback on New Product Priorities for Ecodesign for Sustainable Products, 23-5-2023,(here)
- Materials and Process Technology Board (MPTB): presentation on ESCCON 2023, available here
- Reporting on SVHCs in articles: SCIP Guidelines 2022 (here) and REACH Article 33 declaration template v1.1 2024 (here)
- European Space Sector comments on REACH Revision, 13 April 2022 (here)

A list of further contributions is available at https://eurospace.org/working-bodies/reach/. In addition, a number of contributions have been submitted by ASD, with the support of MPTB/its task forces and working groups.

Important references and links

EUROSPACE, trade association of the European Space Industry: https://eurospace.org/

HEISKANEN P. et al., Regulatory and Commercial Obsolescence Risks of Materials and Processes (International Chemical Regulatory and Law Review, Volume 3 (2020), Issue 1): https://doi.org/10.21552/icrl/2020/1/4

MATREX, CNES space materials and regulatory risk tracking database: https://matrex.cnes.fr

MAPTIS, Materials And Processes Technical Information System of NASA: https://maptis.nasa.gov/

REACH-Related:

ECHA list of Annex XIV substances (authorisation list): https://echa.europa.eu/authorisation-list

ECHA list of Annex VXII restrictions (restriction list): https://echa.europa.eu/substances-restricted-under-reach

ECHA's SVHC list (Candidate list for Annex XIV): https://echa.europa.eu/candidate-list-table

ECHA SCIP database: https://echa.europa.eu/scip-database

REACH & Obsolescence management relevant ECSS (https://ecss.nl/)

- ECSS-Q-ST-70C rev2 - Materials, mechanical parts and processes
- ECSS-Q-HB-70-23A – Materials, mechanical parts and processes obsolescence management HB

Databases M&P & EEE component relevant info:

- ESA REACH Tool: https://reachtool.esa.int (for European entities active in space-relevant activities)
- MODESA, outgassing database: https://modesa.esa.int/
- ESCIES: European Space Component Information Exchange System: https://escies.org/ -> MPTB web (link)