

Introduction to REACH and Obsolescence management of Materials and Processes



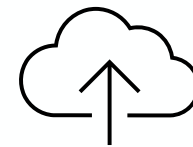
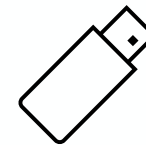
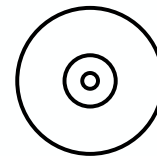
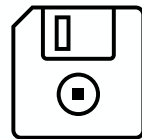
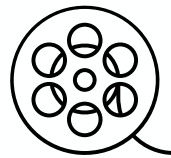
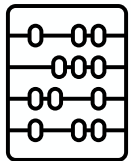
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ECSS M&P branch training

REFERENCE: ESA-TECQE-HO-2022-003642 v.2
ECSS M&P branch training webinar, 3-5th October 2023

Obsolescence Management of Materials and Processes & Regulatory constraints

- ❑ Definition of obsolescence as per ECSS
- ❑ Examples of obsolescence specific to M&P
- ❑ Obsolescence management of M&P, methodology, relevant ECSS standards & requirements
- ❑ Regulations as source of M&P obsolescence, EU REACH introduction
- ❑ Risk Metric using “REACH heat map” and OM methodology
- ❑ Examples of tools for obsolescence management: MATREX and ESA REACH Tool
- ❑ Conclusions
- ❑ References and useful links
- ❑ Acknowledgements

OBSOLESCENCE MANAGEMENT OF MATERIALS AND PROCESSES



Definition of obsolescence

ECSS-Q-HB-70-23A (2017), Materials, mechanical parts and processes obsolescence management handbook

Obsolesce =

... transition from availability to unavailability of a material, mechanical part or process from the manufacturer or supplier (ECSS-Q-HB-70-23A)

*...transition of an item from available to unavailable from the manufacturer **in accordance with the original specification.** (IEC 62402: 2019)*

BoM = Bill of Materials (Mechanical Parts and Processes),

... list of materials, processes or mechanical parts that are needed to manufacture or repair an end product

PCN = Product Change Notice: *...notification from a manufacturer announcing a change of process, properties, characteristics or specification of an item.*

PDN = Product Discontinuation Notice: *...notification of end of production of an item by the manufacturer*

- Obsolescence management (OM) is one of the key elements of successful manufacturing,
- OM may be governed centrally as well as on individual project/production level
- Modern, fully digital, end to end systems, are commercially available, help to monitor and maintain PCN/PDN across the supply chain – all can be automated and digitalised (including SDS essential information),
- Specifically for electronics components, commercially available notification systems/software services are linked to project/product manufacturing timeline to assure sufficient reaction time.

Prerequisites:

1. Traceability of materials and processes used for the manufacturing of the particular hardware,
2. Manpower and financial support needed, to enable going from **reactive** to **proactive approach**

Once Obsolescence Manager in place:

1. Define and maintain Obsolescence Management Plan within product life cycle,
2. Propagate down through supply chains (contractually binding, PO specific clauses on OM, assure change notifications during production, company/project specific requirements to protect supplies, after-sale support,... (beyond ECSS).



ECSS-Q-HB-70-23A (2017)

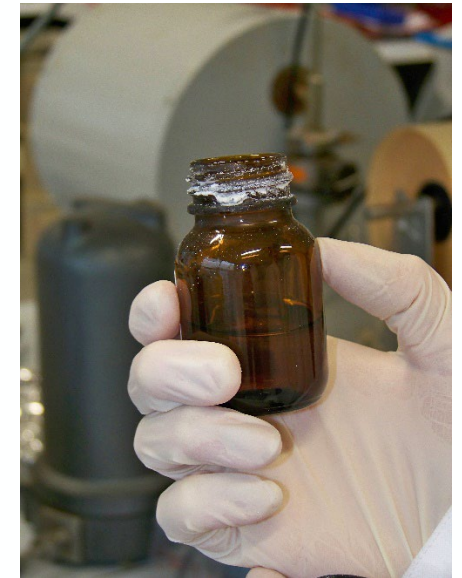
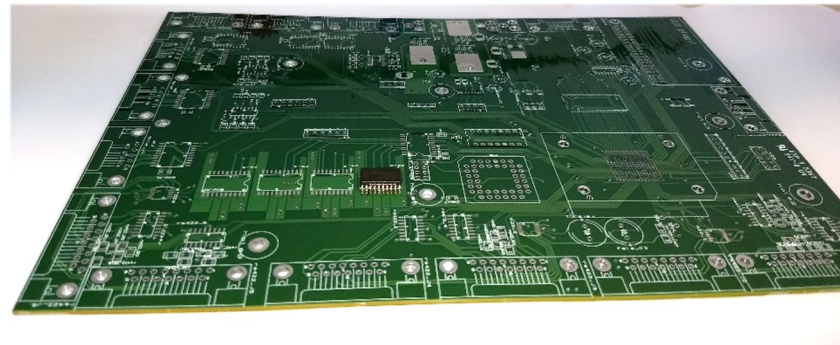
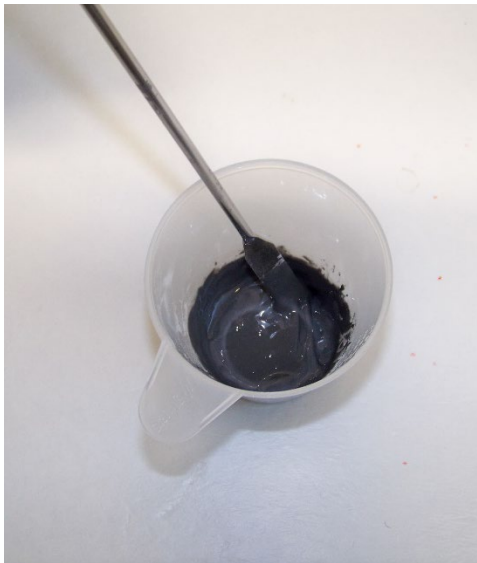
- Recommendations to tackle obsolescence at a project level
- OM team: PM/TO + Procurement + M&P support + PA/QA + Design/Production + H&S + REACH/Legal support
- Obsolescence management to be covered within MPCBs
- Clear examples of OM plans, templates, and REACH regulation process flow

Updated **ECSS-Q-ST-70C rev2** (in 2019) has new requirement

4.1.3.i.6, ...Identify and mitigate the risks linked to obsolescence of materials, processes, or mechanical parts at all levels of the customer-supplier chain...

and refers to ECSS-Q-HB-70-23A (recommendations)

KNOW YOUR MATERIALS!



Sources of Obsolescence in M&P: Examples

Modification of Products/Processes (REACH or H&S policy, Green Deal, specific directives, company commitments, local regulations, on-site procedures)

- Epoxy resins: Removal of **BPA** → Formulation change → Significant impact on mechanical property
- Epoxy resins: **toluene-free** hardener (reflecting on REACH Annex XVII, Res. entry 48), small impact
- Silicone purification processes: **CMR solvents removal** to follow Directive 2004/37/EC carcinogens or mutagens at work (CMD) → some impact on the product's mechanical properties
- Polyurethane-based potting compounds & conformal coatings – REACH Annex XVII Restriction Entry 74 on the **use of di-isocyanates**, → risk of discontinuation of import to EU
- Polyurethane-based paints – removal of **toluene and di-isocyanates** from formulations (discontinuation of products), impact on processes with space heritage → costs for requalification of new alternatives

Regulation-driven

Obsolescence

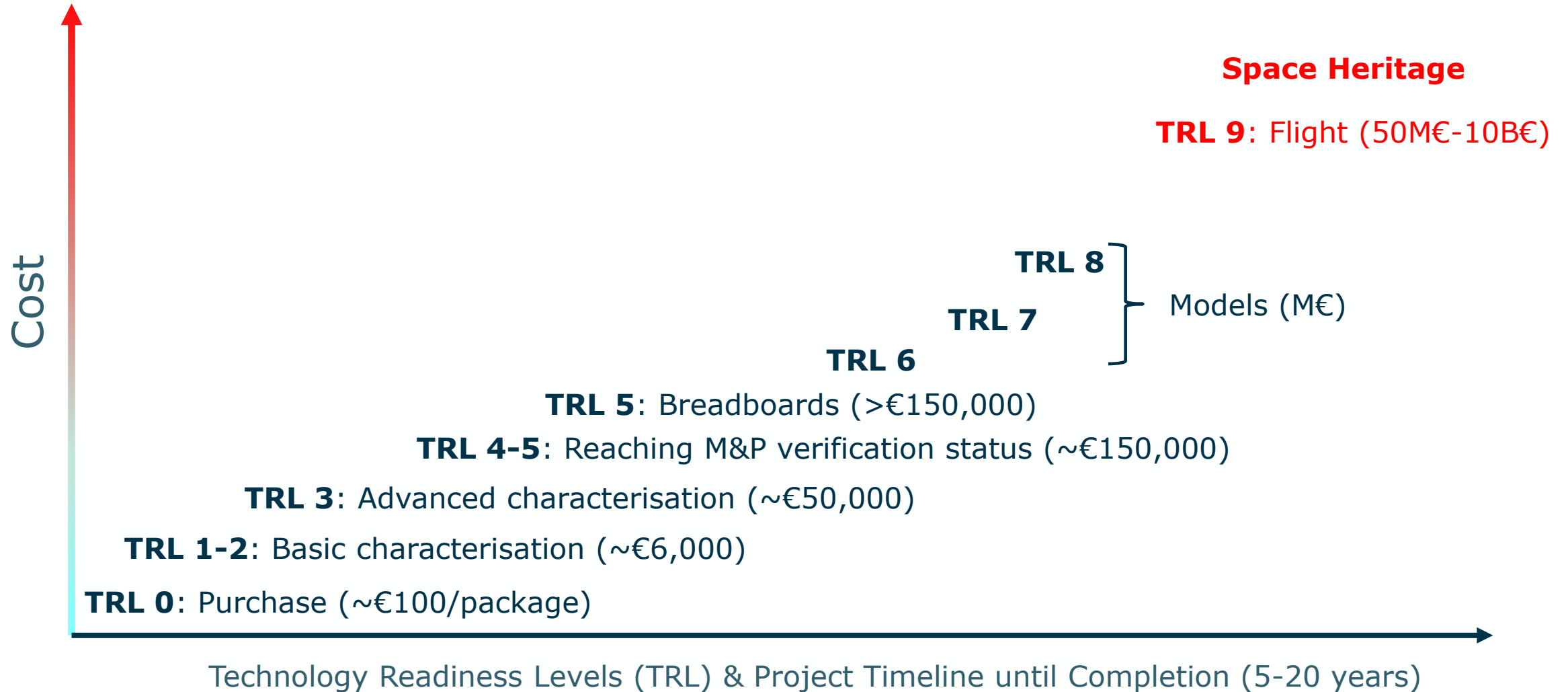
Discontinuation of products (triggered by REACH/regulatory constraints, material unavailable):

Epoxy resins: **NMP** – REACH Annex XVII Restriction Entry 71 on use of NMP, lead to discontinuation of high temp. hardener for epoxy, replacements available, significant impact on space heritage

- **SrCrO₄**-containing primer – Absence of Application for Authorisation by that specific manufacturer = “No use” → **Substitution unavoidable!**

New/Other: Sanctions, Import/export limitations, Restriction in procurement policy, User tracking (delays) etc...

Obsolescence Impact Cost and Delay – Example of a new Adhesive in Optics

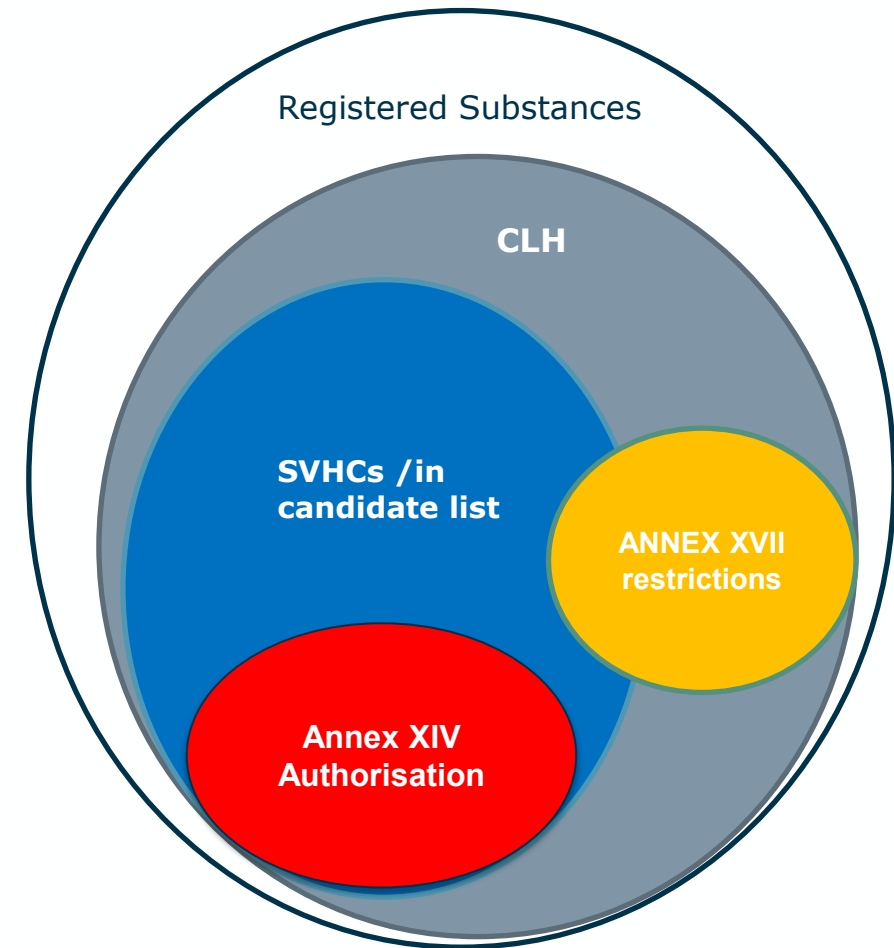


INTRODUCTION TO REACH

REACH in chronologic steps

Chronology of regulatory timeline

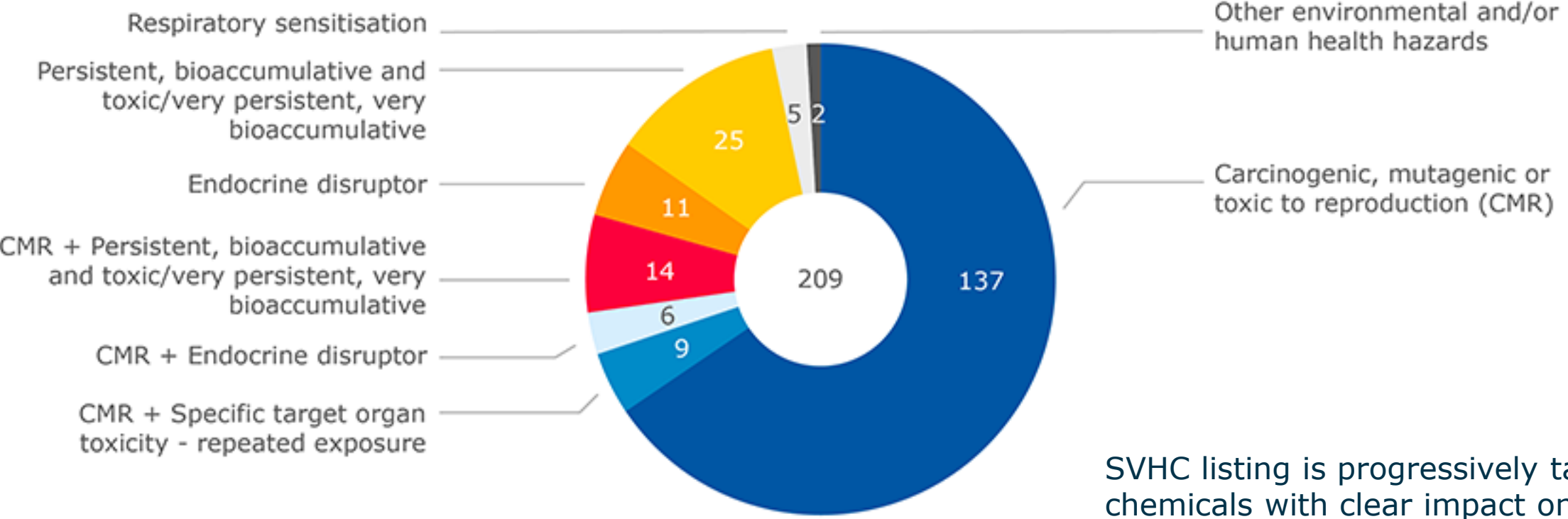
- Registration of Substance
- ...
- Harmonised classification and labelling (CLH)
- Member state/European Chemical Agency proposal for placement on candidate list (SVHC*)
- SVHC/Candidate for Annex XIV listing
- Annex XIV recommendation
- Annex XIV inclusion
- Authorisation for use (sunset date)



Note: **Annex XVII restrictions follow different path**

*SVHC = Substance of Very High Concern

Candidate List Substances: Overview of Hazardous Properties



SVHC listing is progressively targeting chemicals with clear impact on health and safety

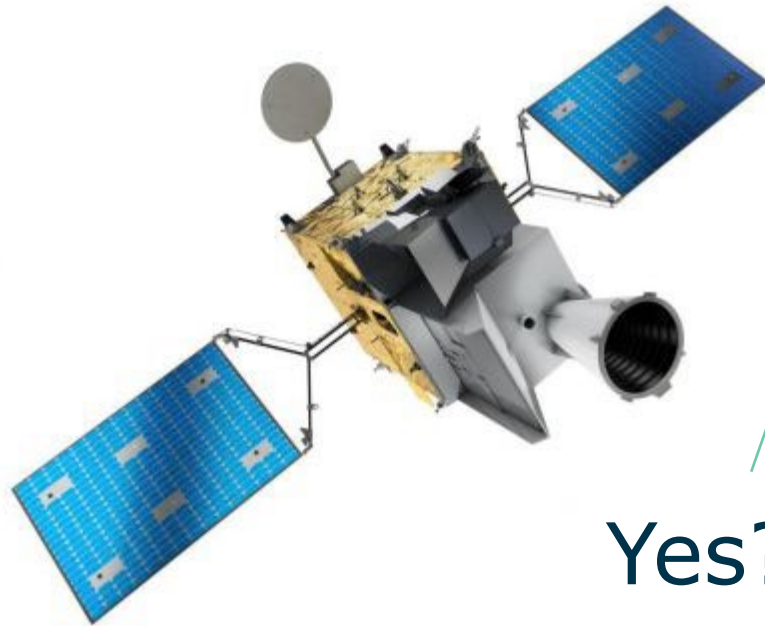
Source: <https://www.echa.europa.eu/-/candidate-list-update-four-new-hazardous-chemicals-to-be-phased-out>



Example of REACH-affected Manufacturing Processes

Are there any materials* with Candidate List SVHCs** c>0.1% w/w?

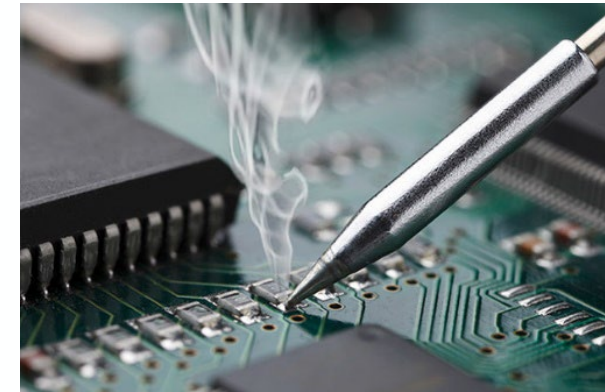
*"Articles" as defined in REACH Art. 3(3)



Yes?

Arbitrary examples (Art. 33 declaration & WFD/SCIP reporting):

- Solar arrays – Cr⁶⁺ based primers
- Pyro valves – phthalates
- PCDUs – B₂O₃ contained in insulators
- ...
- Electronic units – lead in solders



**SVHC- Substance of Very High Concern

REACH-associated obligations: summary

Legal obligations related to EU REACH which could be relevant to materials and article users:

- **For SVHC>0.1% w/w in article**, inform downstream users, **declaration as per Article 33 REACH**, to be flown through supply chain up to final customer; other specific obligation to notify ECHA under certain conditions,
- **For items with SVHC>0.1%, submission to ECHA SCIP database is required** (revised Waste Framework Directive)
- To comply with **EU REACH Annex XIV, if use of the substance** takes place in EEA territory -> **rely only on authorised use** (otherwise illegal), application for authorization (downstream user coverage?), **notification to ECHA Art 66, reporting obligations**

Important take-home summary on regulations:

Regulations relevant for particular materials and manufacturing processes are subject to local legislation; these are not ESA requirements! They are transposed in national law = legal requirements, not ESA technical requirements! So, legal constraints go beyond technical/contractual requirements.

REACH is not the only regulation out there. There are other related regulations such as Waste Framework Directive, CLP, Carcinogens and Mutagens at work (CMD), Chemical Agents Directive (CAD), ... restrictions to specific chemicals complementary to REACH, focusing on safety of workers, occupational exposure limits (OELs) and so on, which need to be considered too.

Unlike in RoHS, within EU REACH there is no specific exemption for *equipment designed to be sent into space*; therefore economic operators within EEA market area must comply with EU REACH.

There may be specific derogations from **individual restrictions (ANNEX XVII)** for use of chemicals, but texts of each restricted use needs to be carefully analysed to find out whether could be applicable to the use of interest.

“Space” in EU chemicals/product/safety legislation*



*Important examples tracked only, not exhaustive!

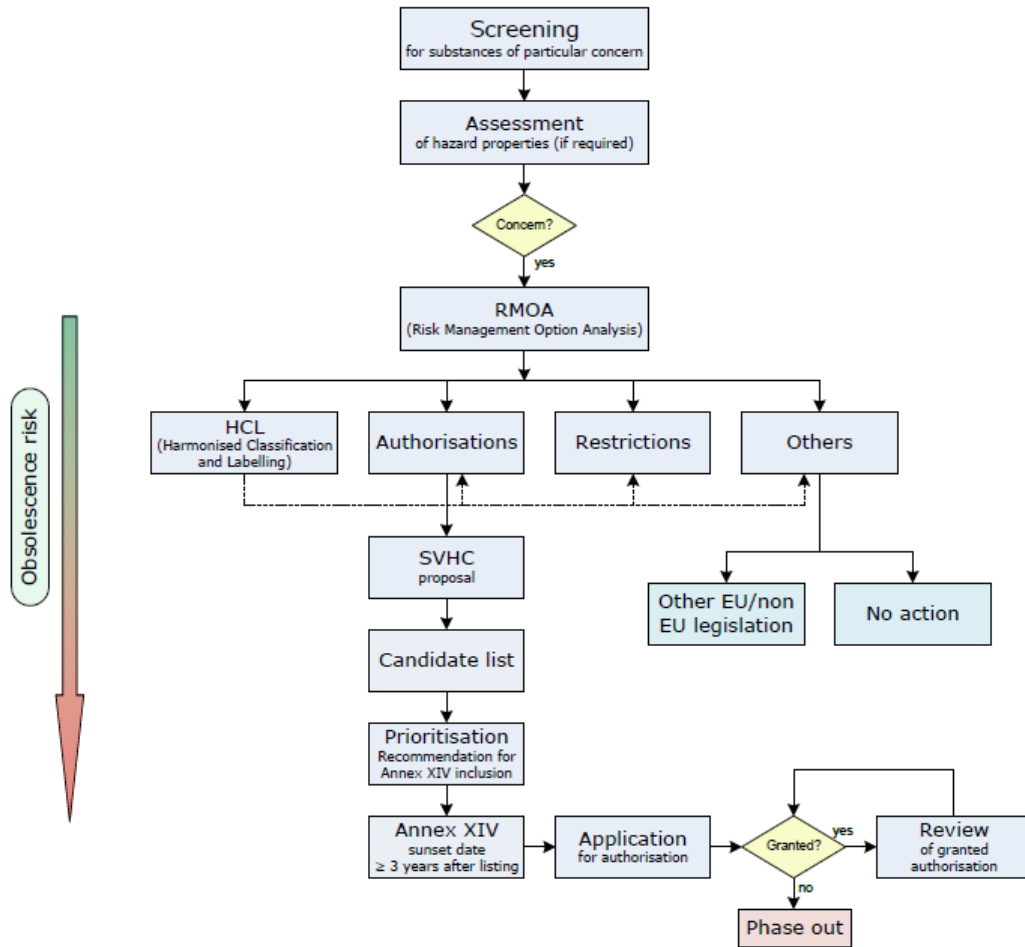
Exclusion from the scope for space applications	In scope – no exemption/exclusion	Product-specific requirements
<p>« <i>Shall not apply to ... equipment designed to be sent into space</i> »</p> <ul style="list-style-type: none"> ➤ Batteries Directive 2006/66/EC: <i>Batteries and accumulators</i> -> reg 2023/1020 ➤ RoHS Directive 2011/65/EU & since 15 August 2018 ➤ Waste EEE Directive 2012/19/EU: <i>Electrical and Electronic Equipment (EEE)</i> ➤ Mercury Regulation (EU) 2017/852: <i>New mercury-added products</i> 	<ul style="list-style-type: none"> ➤ REACH Regulation (EC) No 1907/2006: <i>Chemicals</i> registration, evaluation, authorisation and restriction; Article 33 reporting for Candidate List substances above 0.1% w/w in <i>articles supplied in EU</i> ➤ Revised Waste Framework Directive (WFD) 2008/98/EC: Reporting to ECHA SCIP Database for Candidate List substances above 0.1% w/w in <i>articles supplied in EU</i> ➤ CLP, CMD, CAD, Conflict Minerals Regulation, etc. 	<ul style="list-style-type: none"> ➤ Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC (ESPR) (COM(2022) 142 final), recital (16): - [...] “<i>Similarly, the space industry is strategic for Europe and for its technological non-dependence. As space technologies operate in extreme conditions, any ecodesign requirements for space products should balance sustainability considerations with resilience and expected performance.</i>” [...]



OM METHODOLOGY USING REGULATORY EVOLUTION OF SUBSTANCE(S)

REACH/regulatory evolution used for OM

As per handbook ECSS-Q-HB-70-23A:



1. Identify materials (BoM) intended for the project, DML is good source of info but it is not enough,
2. Identify substances within materials/processes and crosscheck with regulatory lists (Figure D-2 in ECSS-Q-HB-70-23A),
3. How? analyse Safety datasheets (SDSs) of chemicals/mixtures or Article 33 declarations for articles and safe use instructions from suppliers, (SDS may be mandatory as per 1907/2006/EC, Article 31).

Risk ranking:

1. The highest obsolescence risk is associated with the use of material under **specific REACH Annex XVII restriction, which bans** specific type of use (e.g. Toluene in adhesives intended for general public market)
2. High risk of obsolescence is associated with chemicals with **Substance on Annex XIV** (only EC-authorized use is allowed!) + other obligations
3. **Process-unspecific REACH Annex XVII restrictions** affecting the material of interest but not necessarily the use of interest
4. **SVHC (candidate list) substance**: indicates potential of becoming Annex XIV chemical (**after ECHA Annex XIV recommendation**)

Figure D-2: Simplified REACH substances regulatory risk management process

Obsolescence Risks Metric

- How to define **Risk** in case of obsolescence management?
- Risk [R] = Likelihood [L] * Severity [S] (standard definition)
- Likelihood is a function of time, represented by the status of a substance in REACH process (Annex XIV, Prioritized, Candidate list, SINlist, ...)
- Severity has two components: Volume of Use [V] and Ease of Replacement [E].

$$[S] = [V] / [E]$$

- Note: Restrictions under Annex XVII can have very variable effects depending on specific type of use

Likelihood
(worst case sunset date)



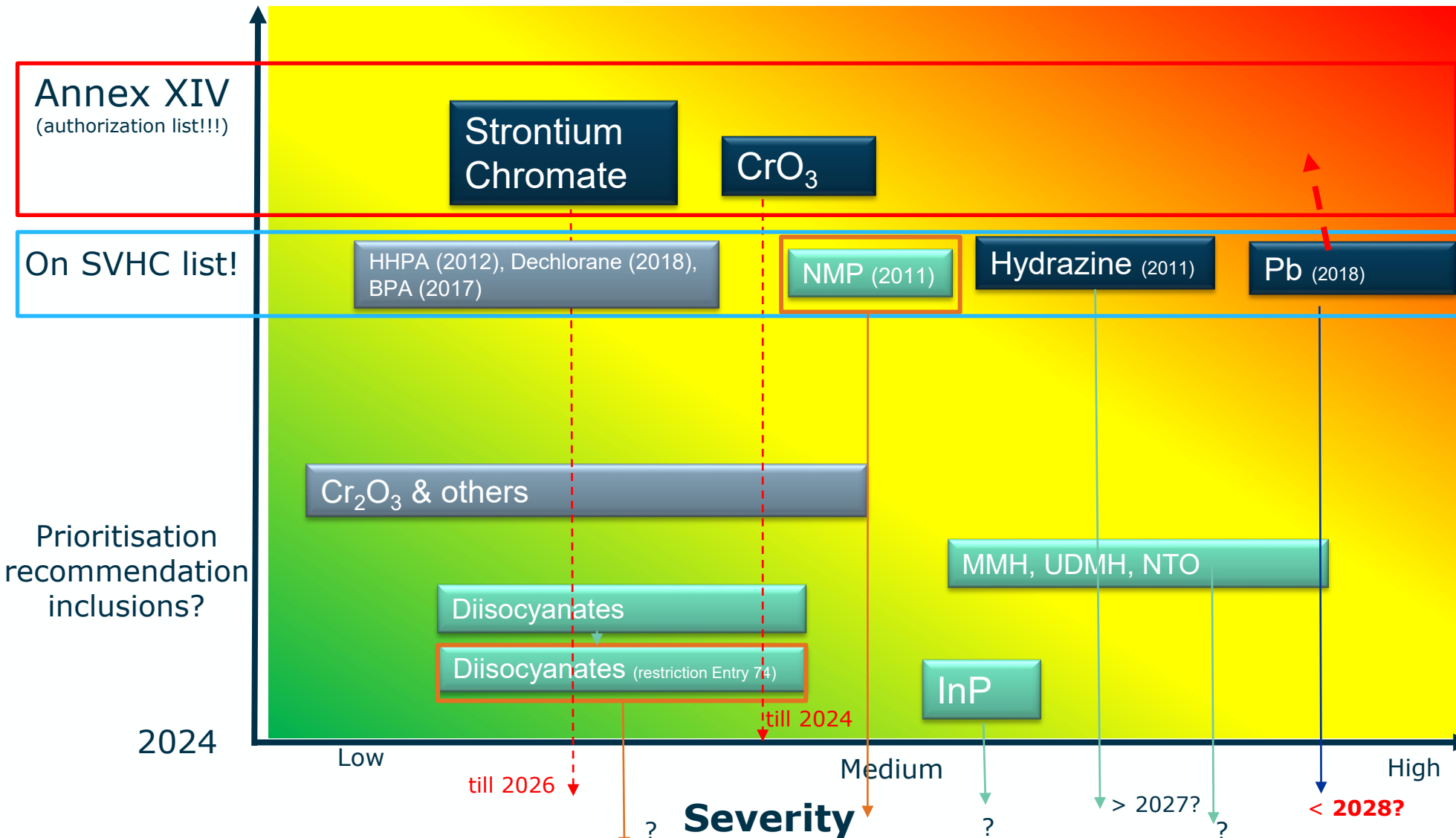
Severity

Green – Tolerate, investigate
Yellow – Monitor, plan
Red – Mitigate, control

Risk Assessment for Selected Substances

Likelihood
(worst case sunset date)

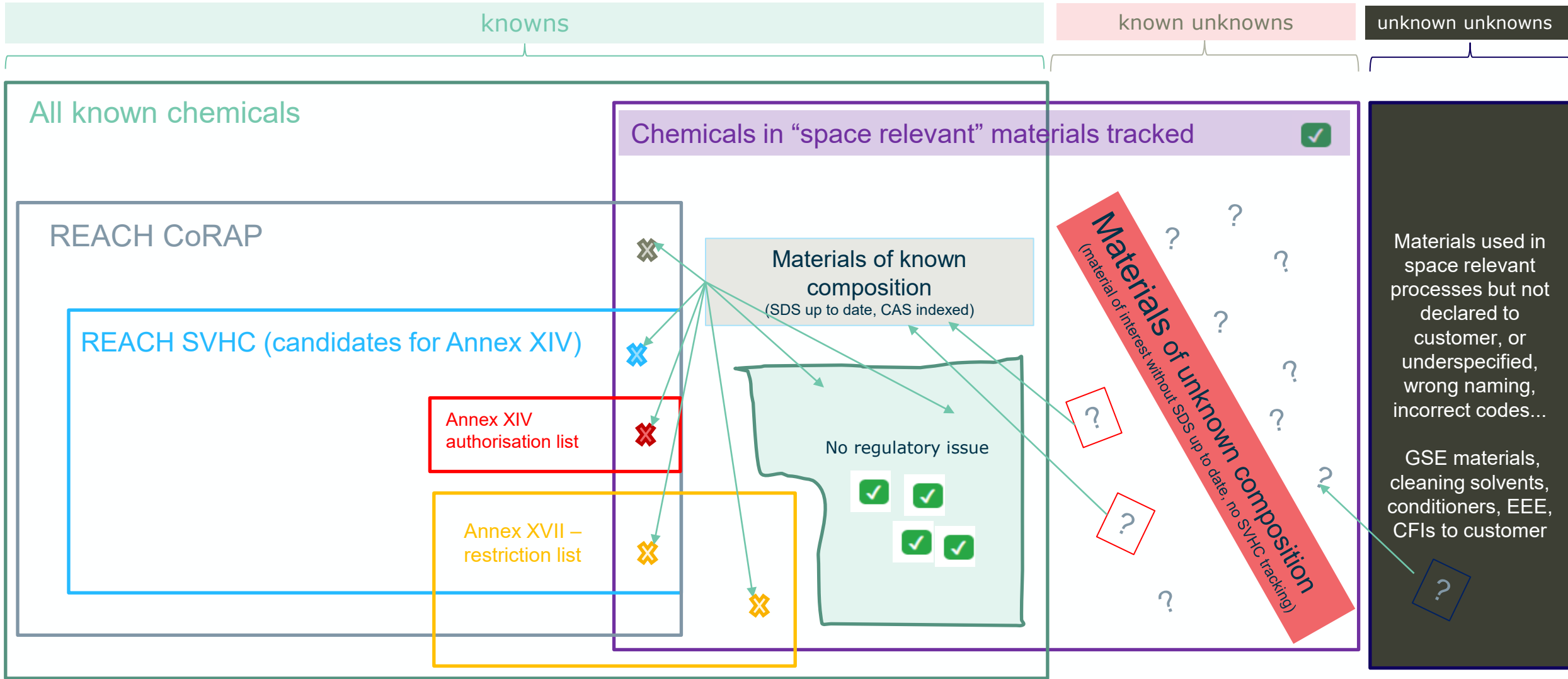
2022 update



Legend

- Mitigation actions ongoing
- Active monitoring actions ongoing
- Risk analysis ongoing
- Specific restriction (ANNEX XVII)
- Authorised use only (red dashed arrow)
- Use under restriction (orange arrow)
- Continuous use (green arrow)

OM logic using REACH lists – overview of “intersections”



material with unknown content (outside of the green box)? -> impossible to perform crosscheck and regulatory obsolescence risk assessment

Example of OM tools: MATREX



bienvenue

My Actions

- ▶ 0 materials being modified
- ▶ 0 materials being validated

Matrex figures

- ▶ 622 materials
- ▶ **65 materials with risks**
- ▶ 78 users

<https://matrex.cnes.fr>

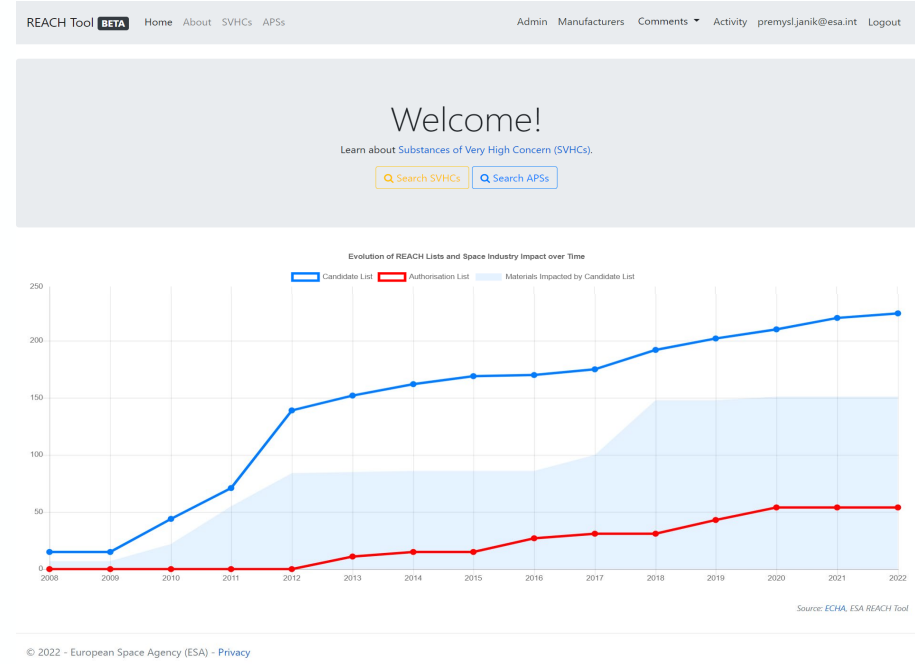


Example of OM tools: ESA REACH Tool development



Functionalities include:

- Improved sorting and dynamic filtering
- Dynamic statistics introduced
- Commenting functionality
- Legal compliance notes
- risk predictions based on current EU REACH lists
- Active markers to keep materials data relevant



REACH Tool in numbers:

- > 970 Materials (>330 Active, further validation ongoing)
- > 695 Substances from EU REACH lists (+ CLH added, >7300 substances)
- So far users community restricted to ESA engineers and MPTB/OSG members, potential expansion under discussion (SMEs observers to MPTB, ESA entity codes for identification)



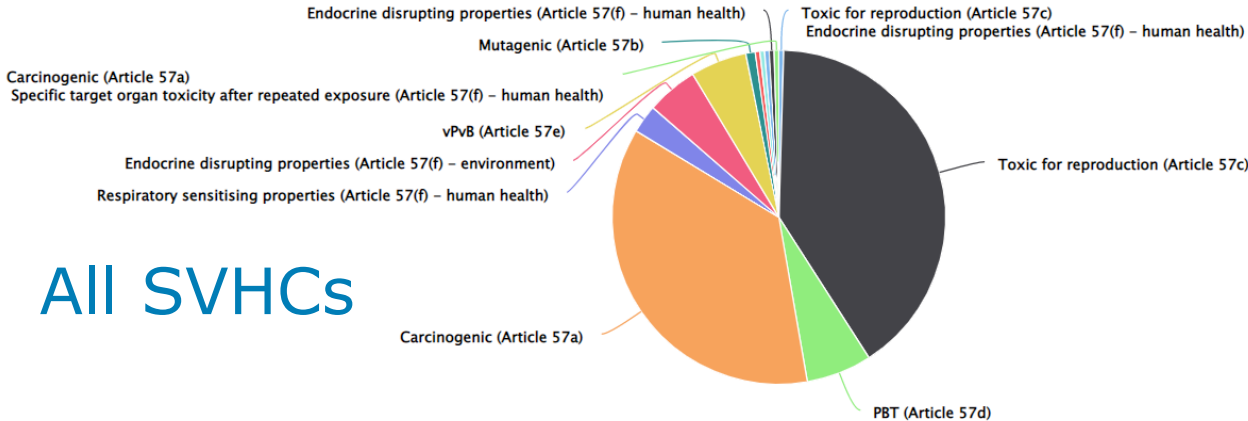
SVHC (Substance of High Concern, candidates for Annex XIV)

- Works with data from ECHA
- allows quick screening the of the highest risks, filters with dynamic graphs

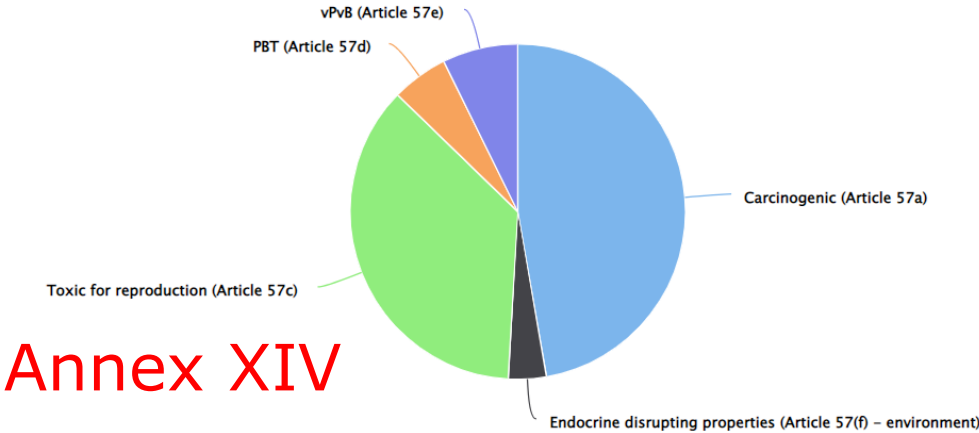
NEW Feature: manual entry of SVHC (to allow specific group entries)

Substance Name	EC Numbers	CAS Numbers	Reasons	CoRAP	CL	Restr.	Auth.	APS Hits
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	⌵	⌵	⌵	✓ ⌵	Min.
Strontium chromate	232-142-6	7789-06-2	Carcinogenic (Article 57a)	×	✓	×	✓	7 Details
Formaldehyde, oligomeric reaction products with aniline	500-036-1	25214-70-4	Carcinogenic (Article 57a)	×	✓	×	✓	7 Details
Chromium trioxide	215-607-8	1333-82-0	Carcinogenic (Article 57a)	×	✓	×	✓	6 Details

Count of REACH Reasons for Inclusion



Count of REACH Reasons for Inclusion



REACH Update by Numbers in 2023 (as of January)

Registration, Evaluation, Authorisation and Restriction of Chemicals

- ❑ EU REACH Registered substances: **>20,000**
- ❑ EU REACH registrations: **>100,000**
- ❑ ECHA's Cand. List -Substances of Very High Concern (SVHCs): **233 (479 ref. substances)**
- ❑ REACH Annex XIV –Authorization list: **59**
- ❑ REACH Annex XVII – chemical(s)-specific restrictions: **71 (multiple substance entries)**

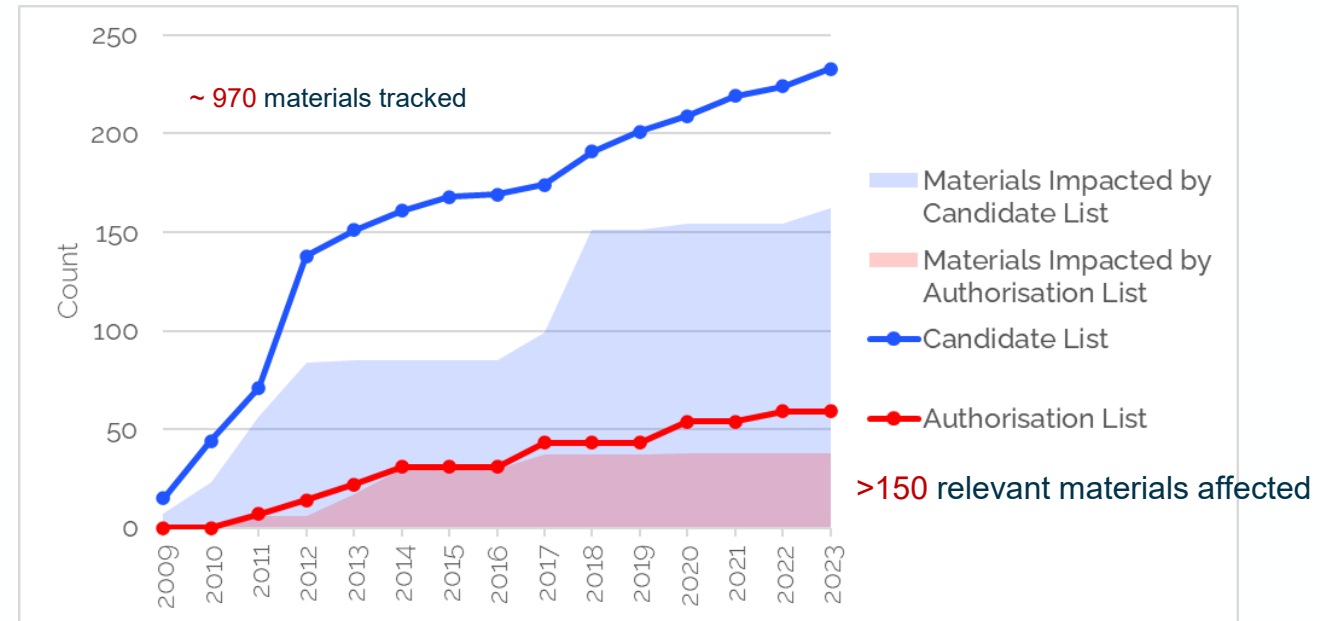


Figure 1. Evolution of entry count in relevant REACH lists and subsequent space relevant materials impact of over time, based on the bill of materials in the ESA REACH Tool.



- ❑ OSG/REACH Tool analysis resp. points at
 - ❑ **15%** of active materials impacted by Candidate List
 - ❑ **13** REACH Annex XIV entries hit space-relevant materials,
 - ❑ **45** materials/mixtures with highest risk of obsolescence
- ❑ Analysis of Annex XVII impact on space sector ongoing

Conclusions

- ❑ The latest revision of ECSS-Q-ST-70C rev.2, brought the first requirement on obsolescence management in M&P domain, 4.1.3.i.6, to be addressed within MPCBs,
- ❑ Basic principles of Obsolescence Management of M&P are mentioned in ECSS-Q-HB-70-23A, but we don't have any detailed requirements on OM (project's responsibility), upon projects to set this up!
- ❑ Full traceability/identification of substances in materials, parts and processes is a key to assess the risks associated with obsolescence (if no screening/proactive approach = impact/perimeter is unpredictable)
- ❑ EU REACH and associated regulations are applicable for entities within European Economic Area,
- ❑ REACH/regulatory constrains are only subset of all sources for obsolescence in M&P, but could be used in advantage for anticipation of future material obsolescence, allowing pro-active approach and timely substitution strategies,
- ❑ Tools for Obsolescence management exist (examples ESA REACH Tool, CNES MATREX),
- ❑ Don't hesitate to ask your customers about their OM strategy -> to be clear on the topic right from the beginning of the project (key inputs for material selection)!

Important references and links

Openly accessible information relevant to REACH and other regulations:

EUROSPACE, trade association of the European Space Industry: <https://euospace.org/> (-> position papers, useful guidelines, clarifications)

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>

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, Tools for M&P & EEE component relevant info:

ESA REACH Tool: <https://reachtool.esa.int> (relevant for MPTB/OSG members and SMEs as observers, on conditions...)

MODESA, outgassing database: <https://modesa.esa.int/>

DMPL Tool: <https://dmpl-web.esa.int/>

TRL Calculator: <https://trlcalculator.esa.int/>

ESCIES: European Space Component Information Exchange System: <https://escies.org/>

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/>

Thanks a lot for your attention

Any questions?

Reach.officer@esa.int

Acknowledgement



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Special thanks to Tim Becker & Oliver Musgrove from REACHLaw for their contributions in frame of contract with ESA, 4000112903/14/NL/GLC (CCN1),

Note: Some slides are using references from 4th ESAs REACH Workshop 18th October 2022, specifically from presentations of T. Becker., P. Janik and O. Musgrove,

(link: <https://atpi.eventsair.com/esa-4th-reach-workshop/>)

