Obsolescence Management of Materials and Processes & risks associated with regulations

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Outline

Obsolescence Management of Materials and Processes & Regulatory constrains

- 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 (under development)
- Conclusions
- References and useful links

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

- 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 time line 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).

Theory: OM as per ECSS

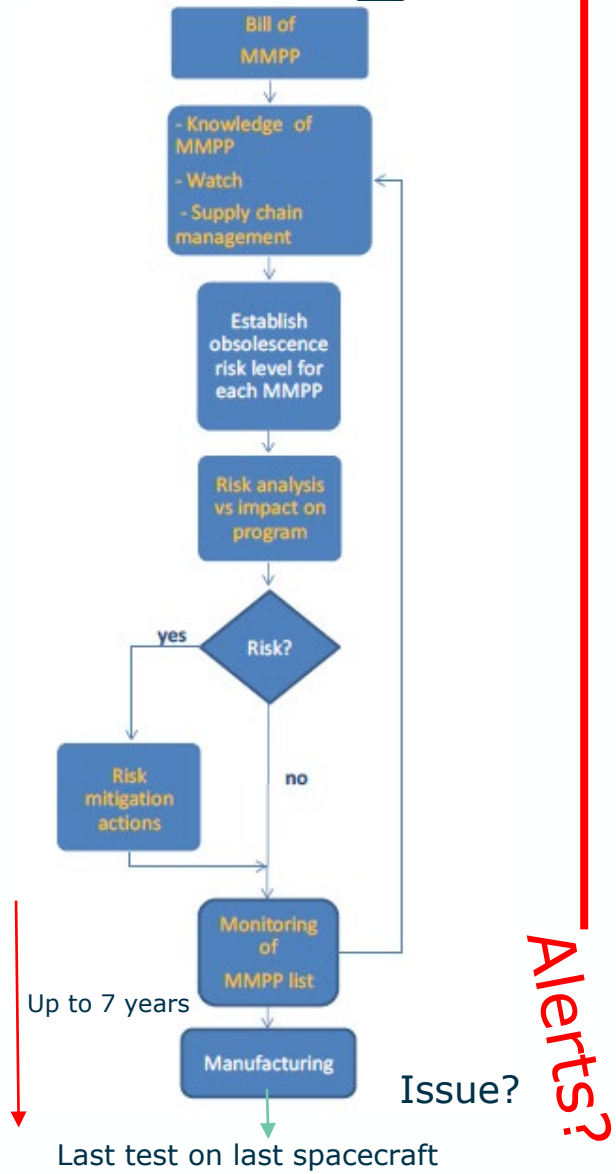
NEW REQUIREMENT!!!

Updated ECSS-Q-ST-70C rev2: 2019: ECSS-Q-ST-70_0490200, 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...*** (note refers to ECSS-Q-HB-70-23A), does not specify for how long nor how to do OM

-> check your PARD whether this requirement is applicable to your project!

ECSS-Q-HB-70-23A: OM Team composition:

- ECSS suggests to tackle obsolescence on project level:
- PM/TO + Procurement + M&P support + PA/QA + Design/Production + H&S + ... + REACH/Legal support (several people would need to meet regularly)
- HB-70-23A suggests to treat obsolescence management within MPCBs
- It may be advisable to use/develop specific obsolescence management tools which can tackle the link between material, procurement specs, manufacturing processes and space verification status of the related processes; it is most efficient to establish OM on company level to control full BoM
- If specific OM tools are designed, they should also reflect evolution in relevant regulations associated with material use (ROHS, REACH (EU & UK), Swiss ChemO,...)



KNOW YOUR MATERIALS!

Sources of Obsolescence in M&P: Examples

Market expansion and new production capabilities, (triggered by Commercial/Market factors)

- Expansion of production to embark on global markets, should bring higher production volume/capacity
- Example: New impregnation plant for pre-preg manufacturing, new processing lines, new raw material sourcing
- Issue: comparison between current and new production lines often brings risks; general test campaigns do not address all performance parameters, materials combinations, rely on assumptions => result in re-validation of materials and re-verification of processes (tests costs money and time)

Modification of Products/Processes (REACH or H&S policy, Green Deal, company commitments, technical ...)

- Huntsman: HV998 -> HV998-1 (BPA removal -> formulation change -> property change/name change)
- 3M: SW2216 -> Toluene-free hardener version (same reactive content = same product/ID number), as response on REACH restriction in use of Toluene in products intended for general public use,
- Modification of products by removal of CMR solvents from manufacturing processes (paints, silicones, ...)

Discontinuation of products (triggered by REACH/regulatory constrains, material unavailable, marketing decisions):

- Example: $SrCrO_4$ containing primer with absence of application for authorization = “no further use after sunset date” No equivalent alternatives proposed? -> substitution unavoidable! -> new products (less toxic)/BUT low TRL

Obsolescence

REGULATIONS & MATERIALS' OBSOLESCENCE

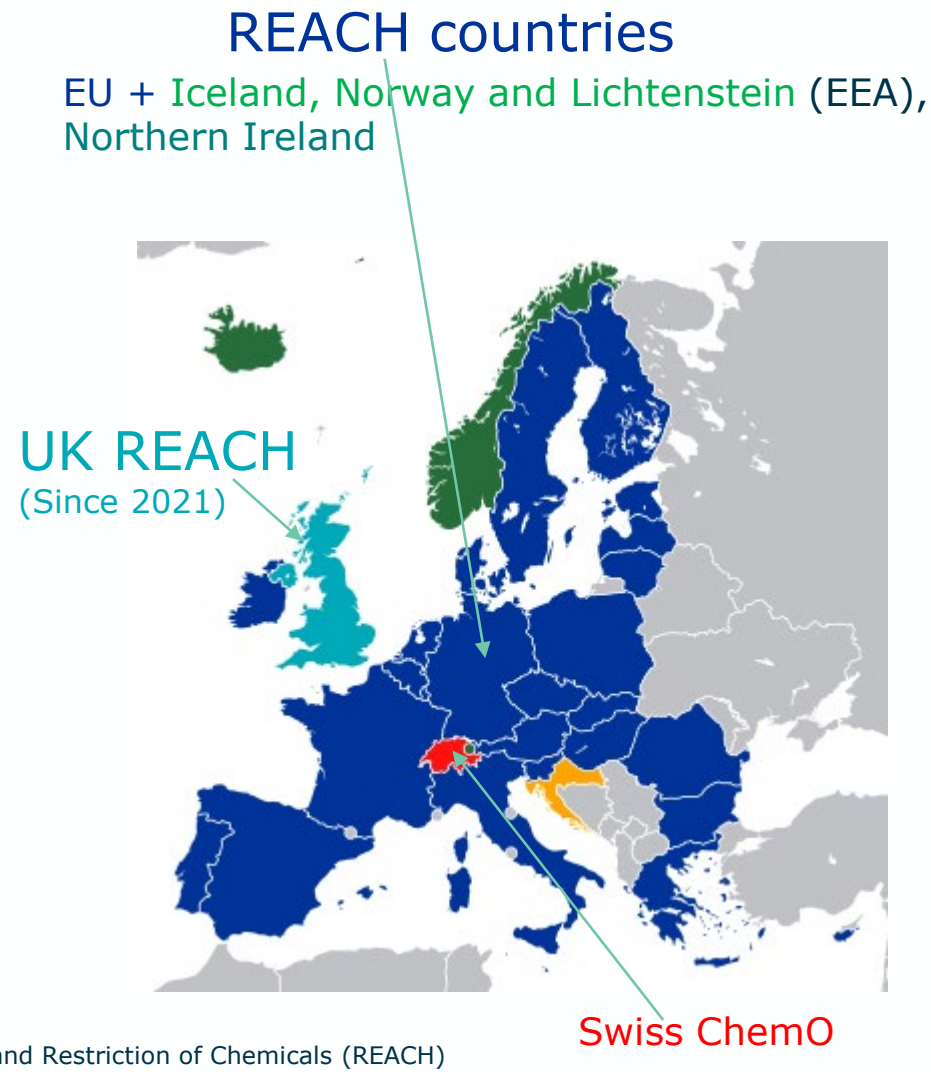
INTRODUCTION TO REACH

Introduction to REACH

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 will face 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

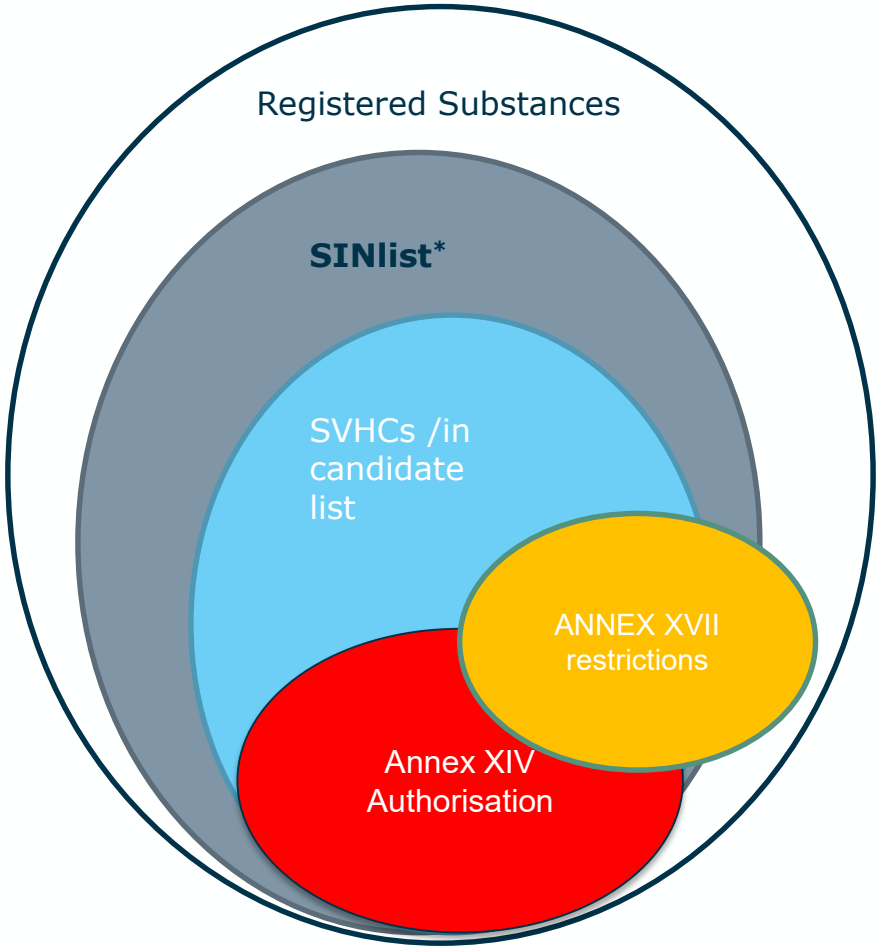


* Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Introduction to REACH 2/2

Chronology of regulatory timeline

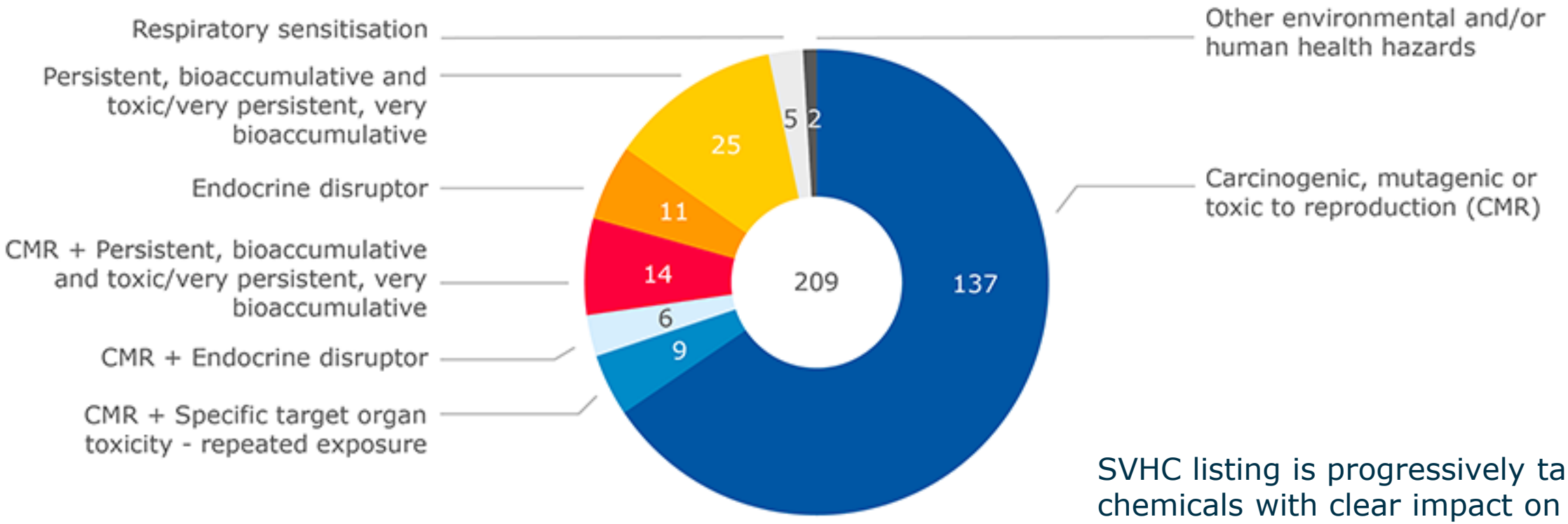
- Registration of Substance
- Placement on Substitute It Now (SIN*) list
- Memberstate/European Chemical Agency proposal for placement on candidate list (SVHC**)
- SVHC/Candidate for Annex XIV listing
- Annex XIV recommendation
- Annex XIV inclusion
- Authorisation for use (sunset date)



Note: Annex XVII restrictions follow different path

*) SIN list is non-Governmental organisation driven, using criteria from REACH to identify Substances of Very High Concern (SVHC**).

Candidate List Substances: Overview of Hazardous Properties

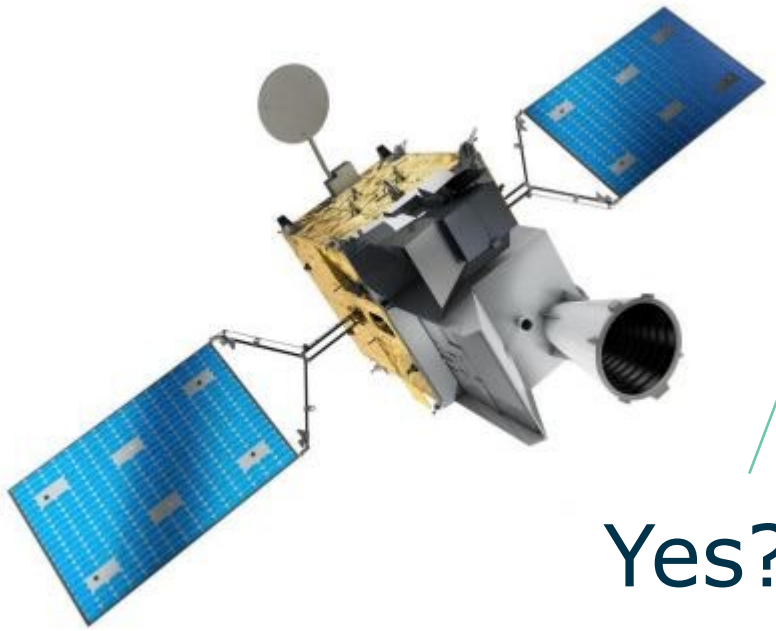


SVHC listing is progressively targeting chemicals with clear impact on health and safety

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

Example of REACH-affected Manufacturing Processes

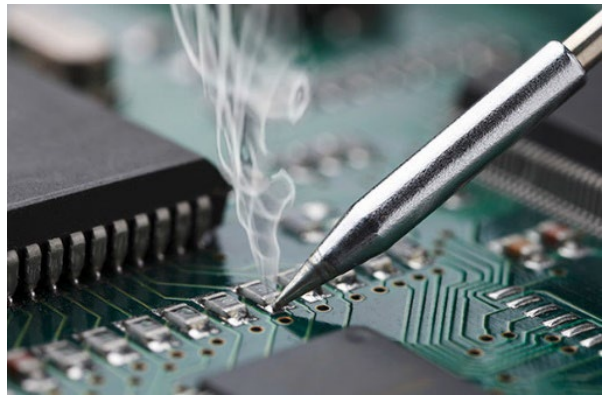
Are there any materials with SVHCs c>0.1%w/w?



Yes?

Arbitrary examples (Art. 33 declaration):

- Solar arrays – Cr^{6+} based primers
- Pyrovalves – phthalates
- PCDUs – B_2O_3 contained in insulators
- ...
- Electronic units – lead in solders



EXAMPLE: LEAD METAL (Pb)

Example of possible REACH Authorisation timeline for lead metal

2018 ... 2022 2023 2024 2025 2026 2027 2028

Candidate listing (SVHC)

Prioritisation* to Annex XIV

Worst Case Estimate

Inclusion to Annex XIV (authorisation)

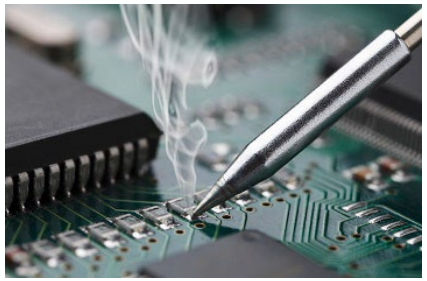
Default 3 years

Sunset date?

Deadline for application for authorisation

EC decision on inclusion to Annex XIV

Obligation for Article 33 declaration- list SVHCs to customer + info on safe use



*) ECHA drafts recommendation to include Lead metal to Annex XIV

No further use allowed after sunset date unless authorisation of use is granted by EC

Authorisation of use normally granted for 4-12 years (review period).

Regulation-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 trough 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, 2021)
- 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, etc...

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 constrains go beyond technical/contractual requirements.

REACH is not the only regulation out there. There are other related regulations such as Waste Framework Directive, CLP,, Chemical Agents Directive, ... restrictions to specific chemicals complementary to REACH, focusing on safety of workers, 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.

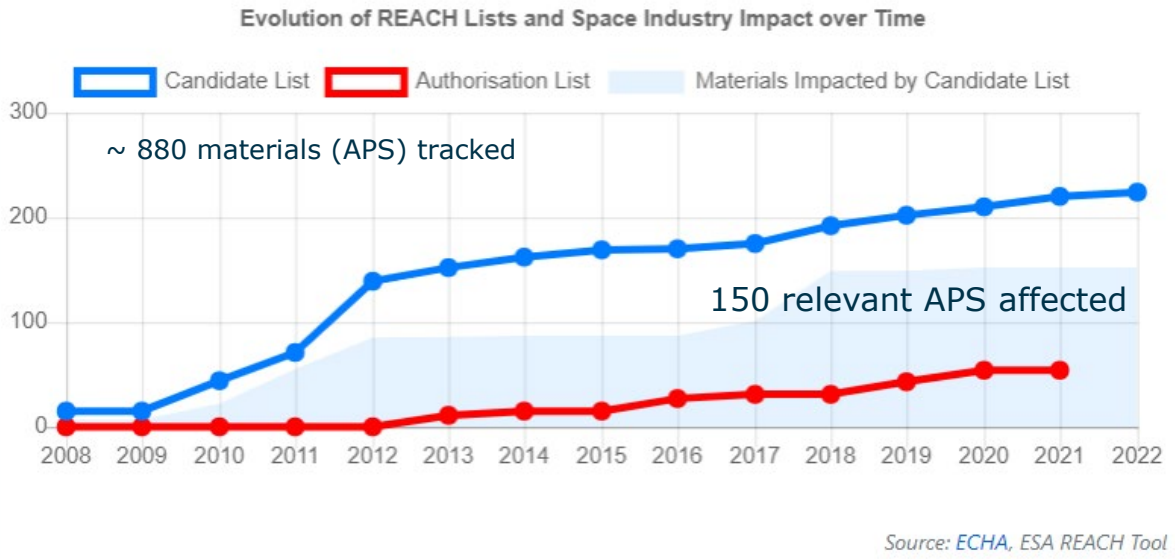
There may be specific derogations from individual restrictions for use of chemicals, but texts of each restricted use needs to be carefully analysed to find out whether could be applicable to the use of interest.

REACH Status: General update Numbers in 2021/4Q

- EU REACH Registered substances: **>22,796**
- EU REACH registrations: **~ 100,000**
- ECHA's Cand. List – **440*** Substances of Very High Concern (SVHCs), grouped in **219** entries

*Number of reference substances for SCIP notifications

- **109** SVHC substances are recommended for Annex XIV
- REACH Annex XIV –Authorization list: **54** XIV –**200+ applications** (AfAs) received for sub-set of substances
- REACH Annex XVII – Restriction entries: **71**



Source: ECHA, ESA REACH Tool

- OSG/REACH Tool analysis resp. points at
  - **14** REACH Annex XIV entries hit space-relevant materials,
  - **40** materials/mixtures with highest risk of obsolescence
- Analysis of impact of Annex XVII restrictions on space sector ongoing

OM METHODOLOGY USING REGULATORY EVOLUTION OF SUBSTANCE(S)

REACH/regulatory evolution used for OM

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

Identify materials (BoM) intended for the project, DML is good source of info but it is not enough,

Identify substances within materials/processes and crosscheck with regulatory lists (Figure D-2 in ECSS-Q-HB-70-23A),

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).

OM risk prioritisation in chronology:

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-authorised 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: indicate potential of becoming Annex XIV chemical (substances recommended for REACH Annex XIV)

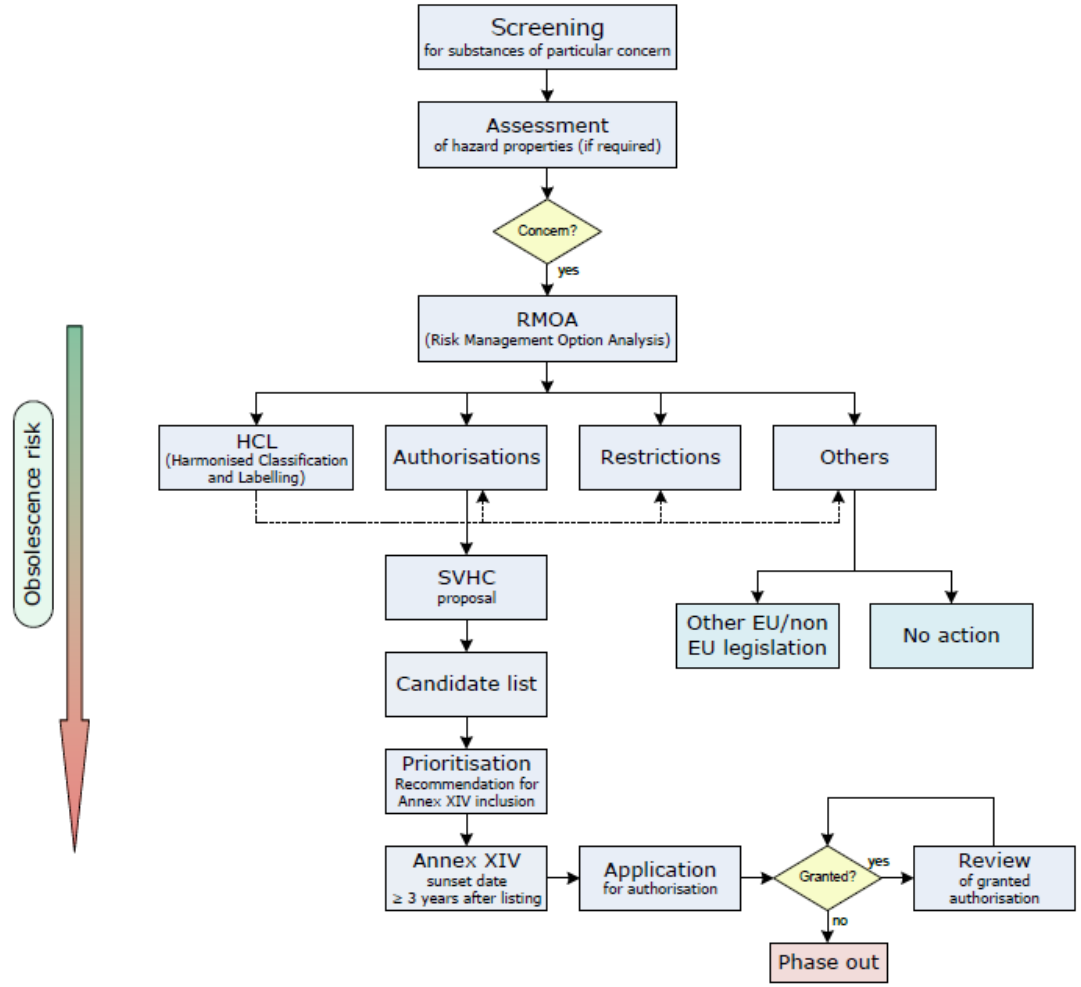


Figure D-2: Simplified REACH substances regulatory risk management process

Obsolescence Risks Metric

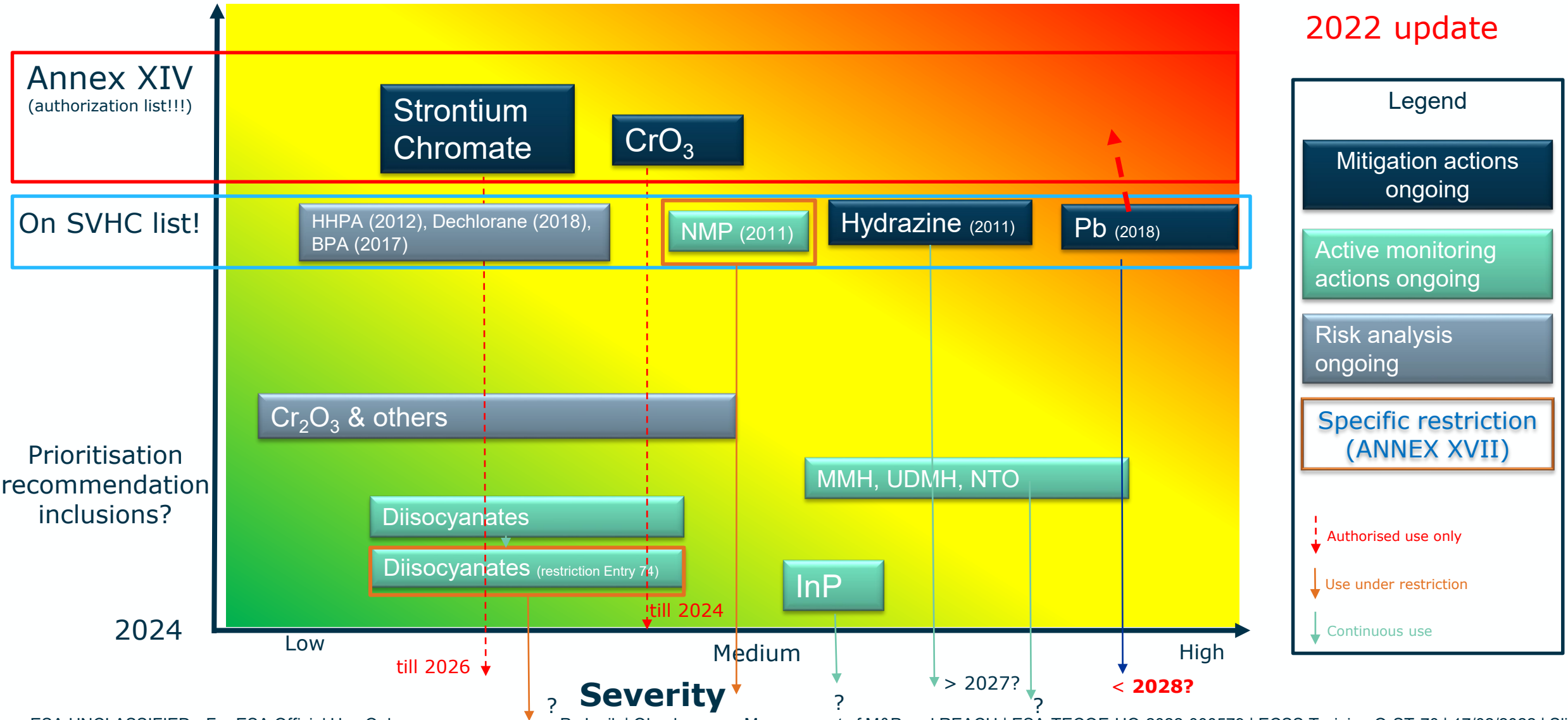
- How to define **Risk** in case of obsolescence management?
- Risk [R] = Likelihood [L] * Severity [S] (standard definition)
- Likelihood is a function of time, represented by the status of a substance in REACH process (Annex XIV, Prioritized, Candidate list, SINlist, …)
- Severity has two components: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

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

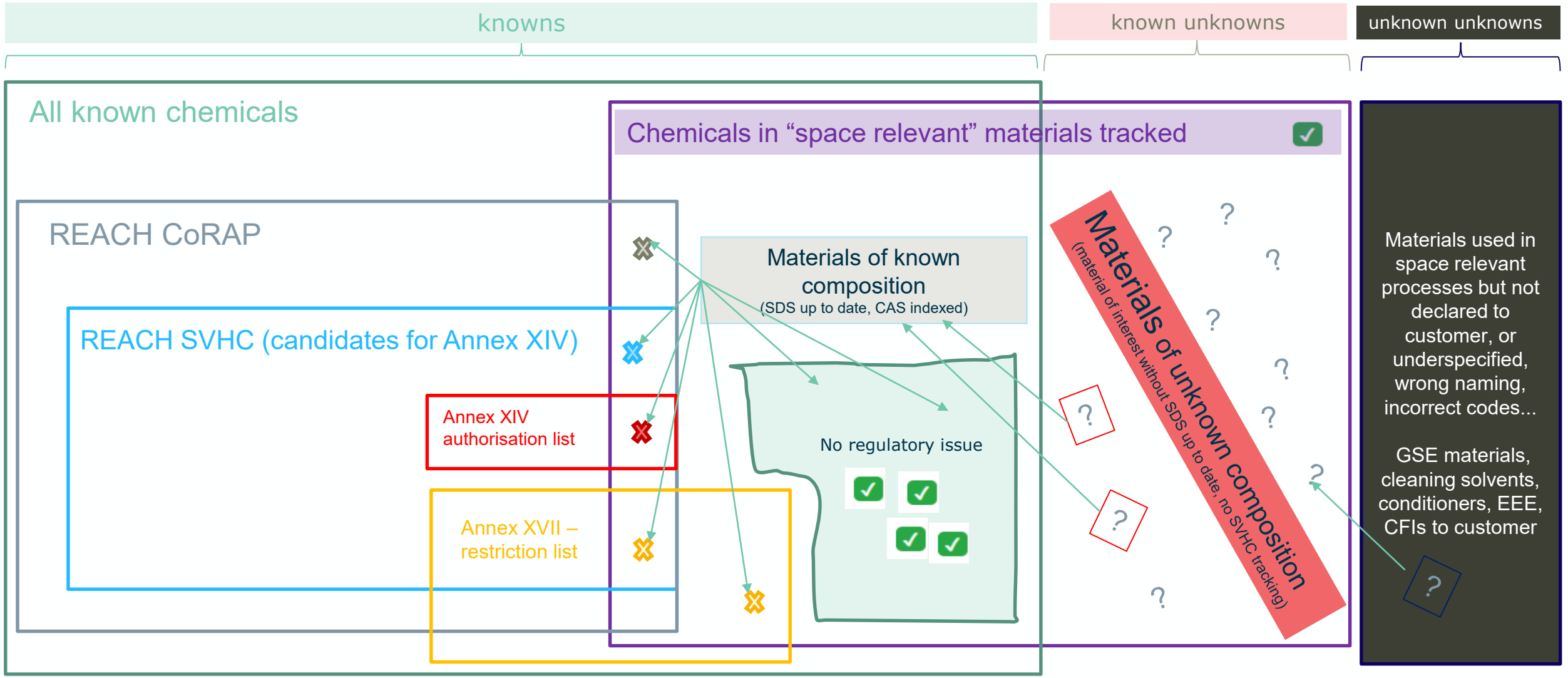
- Note: Restrictions under Annex XVII can have very variable effects depending on specific type of use

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

Risk Assessment for Selected Substances

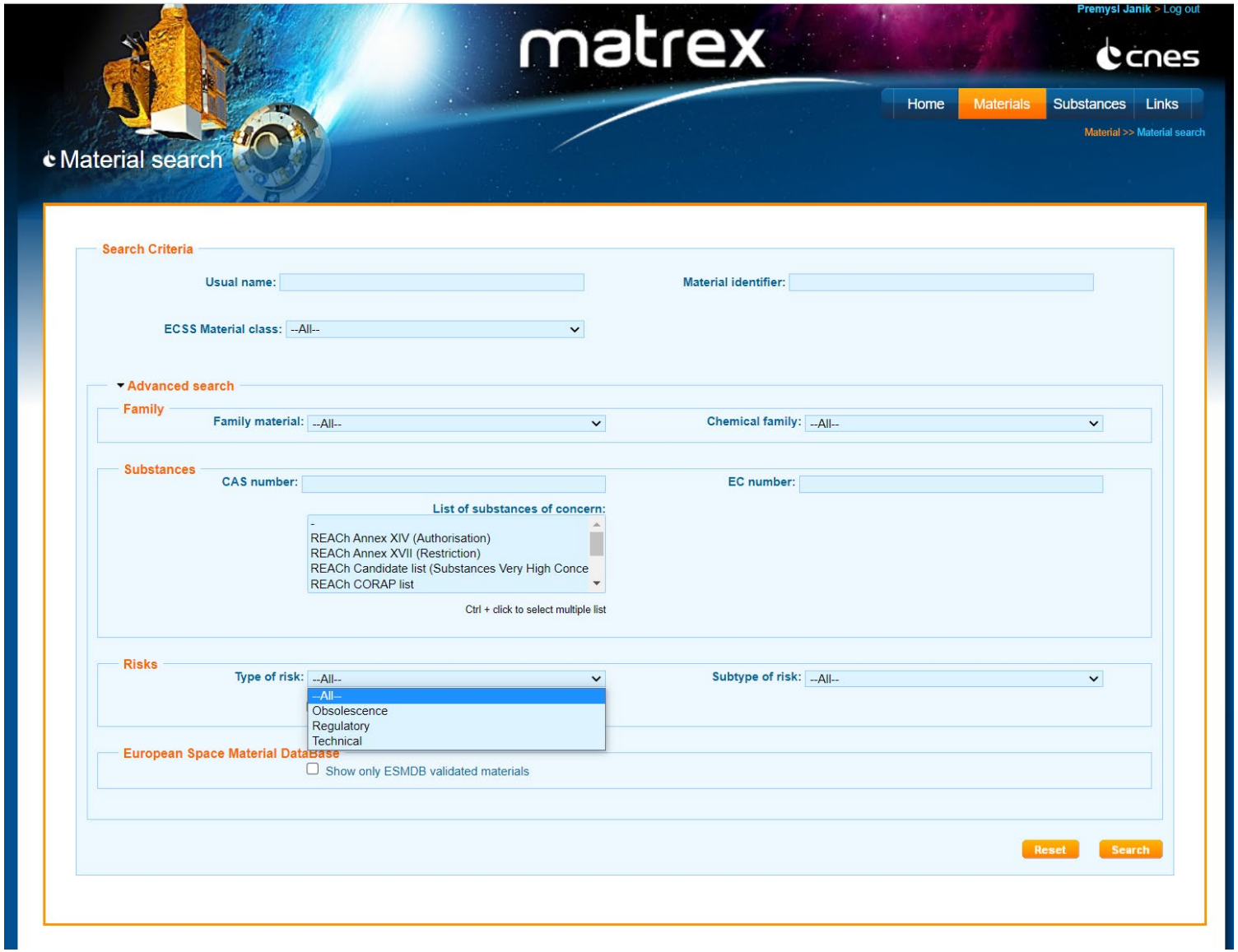


OM logic using REACH lists – overview of “intersections”



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

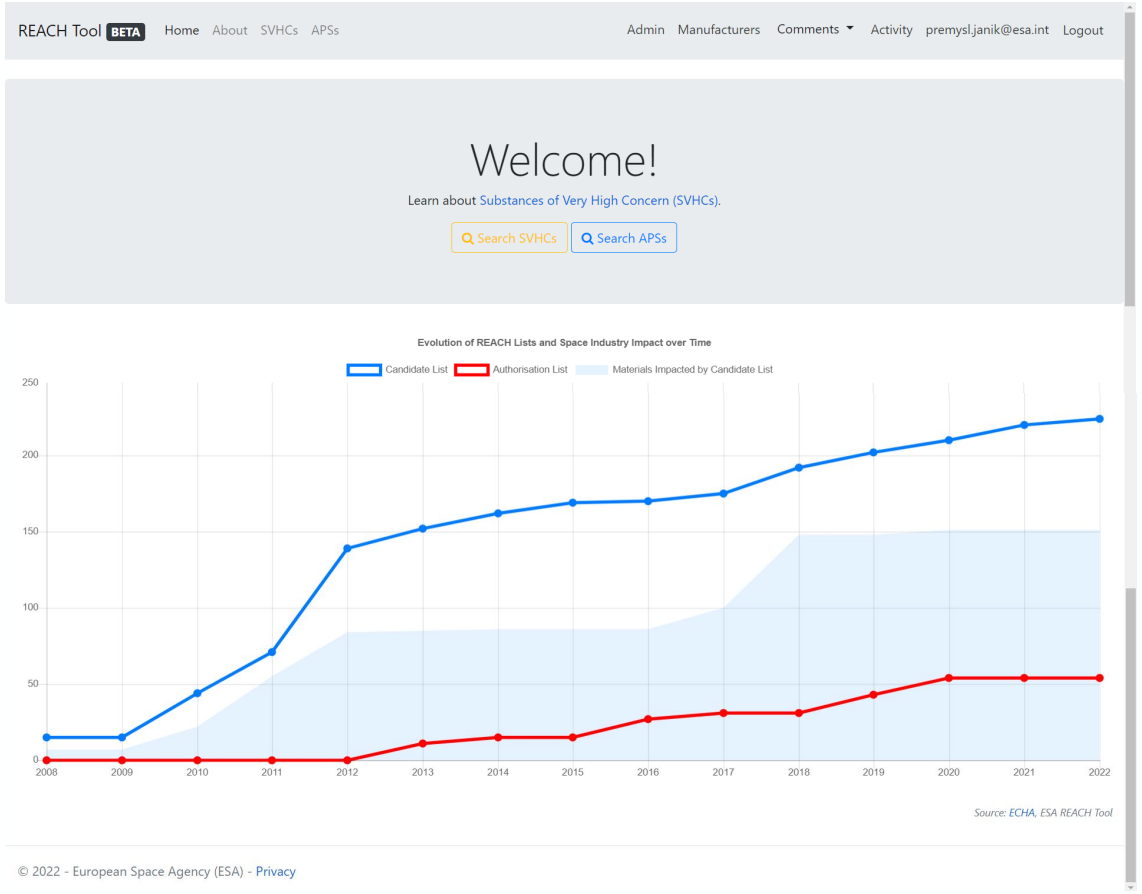
- 622 materials
- 65 materials with risks
- 78 users

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 from our REACH consultant
- Crude REACH obsolescence risk predictions based on current REACH lists
- Active markers to keep materials data relevant



Statistics:

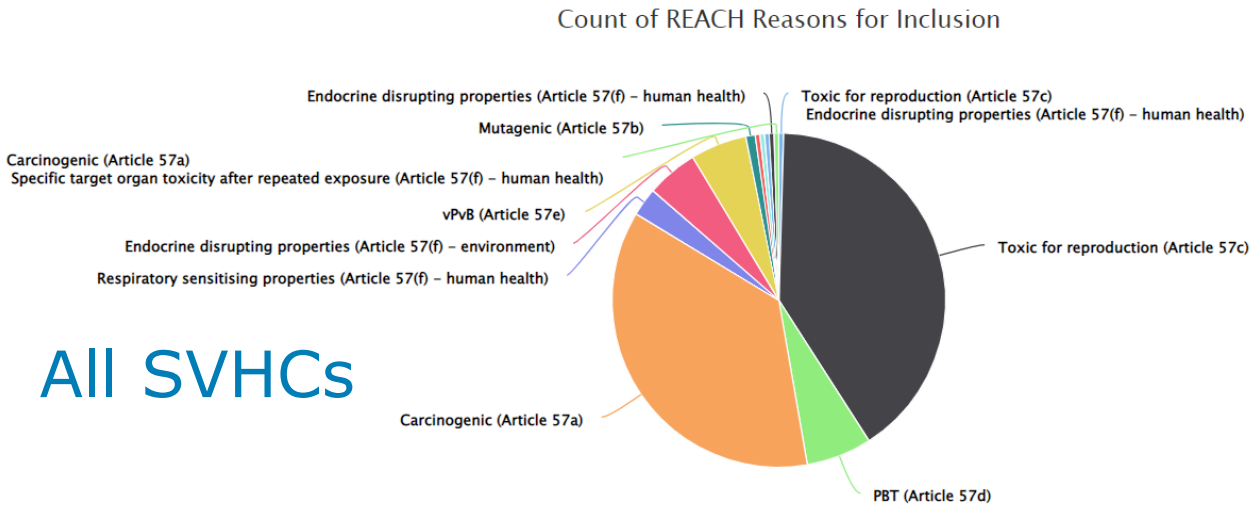
- > 880 Materials (>263 Active, further validation ongoing)
- > 695 Substances from EU REACH lists
- So far users community restricted to ESA engineers and MPTB/OSG members, potential expansion under discussion

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

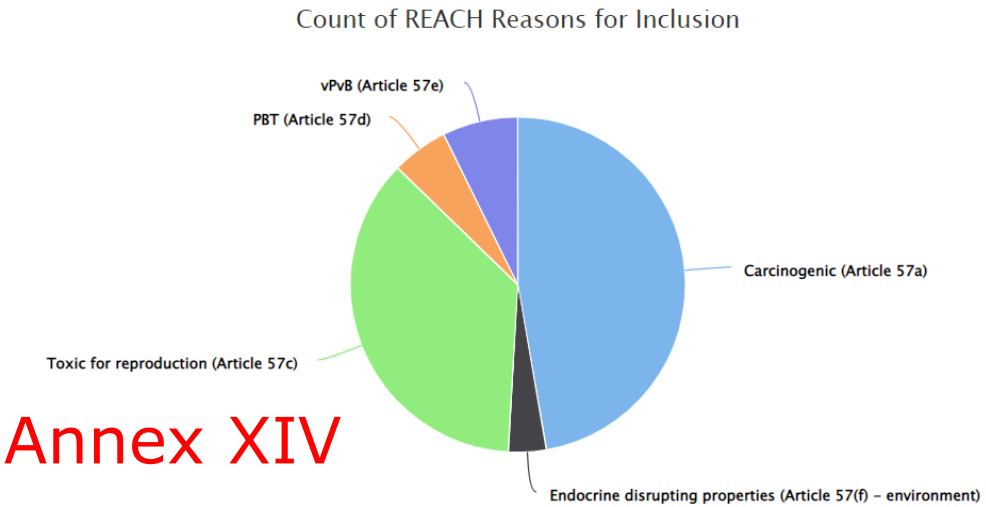
- connected to ECHA's API real time,
- allows quick screening the of the highest risks, filters with dynamic graphs

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

Substance Name	EC Numbers	CAS Numbers	Reasons	CoRAP	CL	Restr.	Auth.	APS Hits	
							✓	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



All SVHCs



Annex XIV

Obsolescence Management in the REACH Tool

REACH Obsolescence

- REACH List markers
- Estimation of potential REACH risk
- Automated based on REACH updates

REACH Tool view of Pattex FT101

SVHC Name	CAS Numbers	Reasons	Regulatory Status
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol	25973-55-1	PBT (Article 57d)	Candidate List | Inclusion Date: 17/12/2014 Authorisation List | Sunset Date: 27/11/2023
Trimethoxyvinylsilane	2768-02-7	Suspected Sensitiser	CoRAP | Concluded

Showing 1 to 2 of 2 entries

Previous 1 Next

What does this mean?

Production of Pattex FT101 All Colours has a **very high risk** of becoming **obsolete** due to REACH.

Regulatory Compliance

Based on the known composition, indexed from the SDS with the above revision date, the REACH Tool has identified that Pattex FT101 All Colours contains a SVHC.

Pattex FT101 All Colours contains a substance found in the **Authorisation List** (REACH Annex XIV), therefore **action is required**. This material (if qualifying as a substance/mixture) cannot be used within the EEA market without authorisation after the sunset date stated above*. Users relying on an authorisation granted to the supplier have to notify the European Chemicals Agency (ECHA) within 3 months of the first supply of the substance/mixture (REACH Article 66).

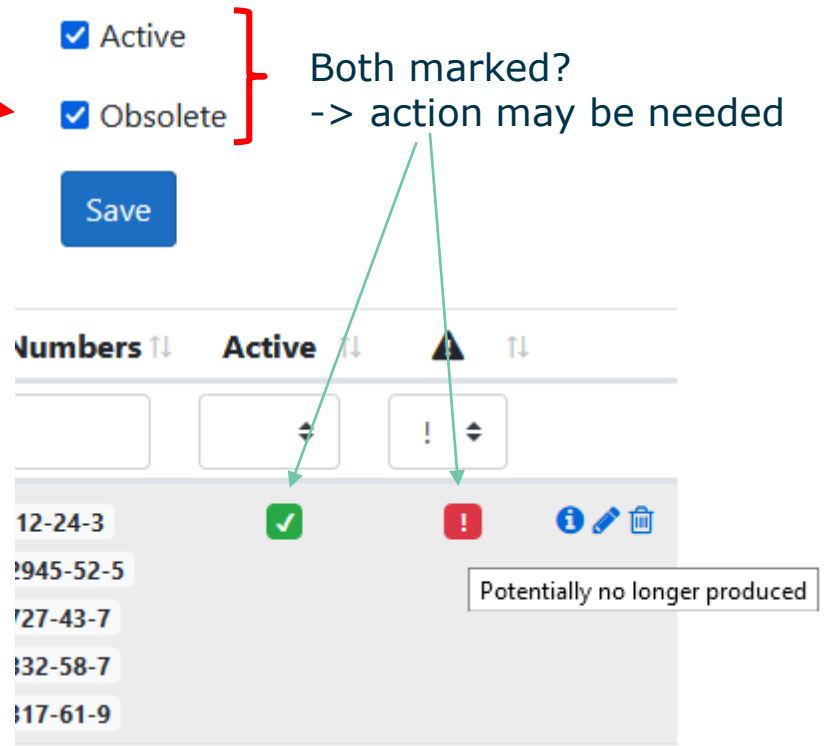
*Note: Some chromates may be allowed for continued use, e.g. until 21 September 2024, despite their elapsed sunset date. For details on authorised uses, authorisation timelines and conditions, the user should consult the latest EU REACH Safety Data Sheet provided by the supplier, the applicable authorisation decision and – if in doubt – regulatory experts.

Pattex FT101 All Colours 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.

Production Obsolescence

- Obsolescence marker
- Ability to comment on a material entry
- User input



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),
- Full traceability/identification of materials and processes is a key to assess the risks associated with obsolescence (if no corporate database available = 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!

Important references and links

ECSS OM relevant (source: 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 handbook,

Databases M&P & EEE component relevant:

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

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

External links:

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

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

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

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

Q&A

Thanks a lot for your attention

Any questions?

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