REACHLAW
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MPTB Stakeholder Day| ESA, ESTEC – 16 May 2017

Joint Industrial Activities to Address REACH Challenges

Workshop on REACH obsolescence risk and supply chain management for space programs

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MPTB STAKEHOLDER DAY 2017

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REACH Challenges for the European Space Industry

A European Union Regulation: ”REACH”

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

Applies directly in entire EU/EEA (incl. French Guiana, excl. CH)

Managed by ECHA - key decisions with European Commission – Enforced by national authorities

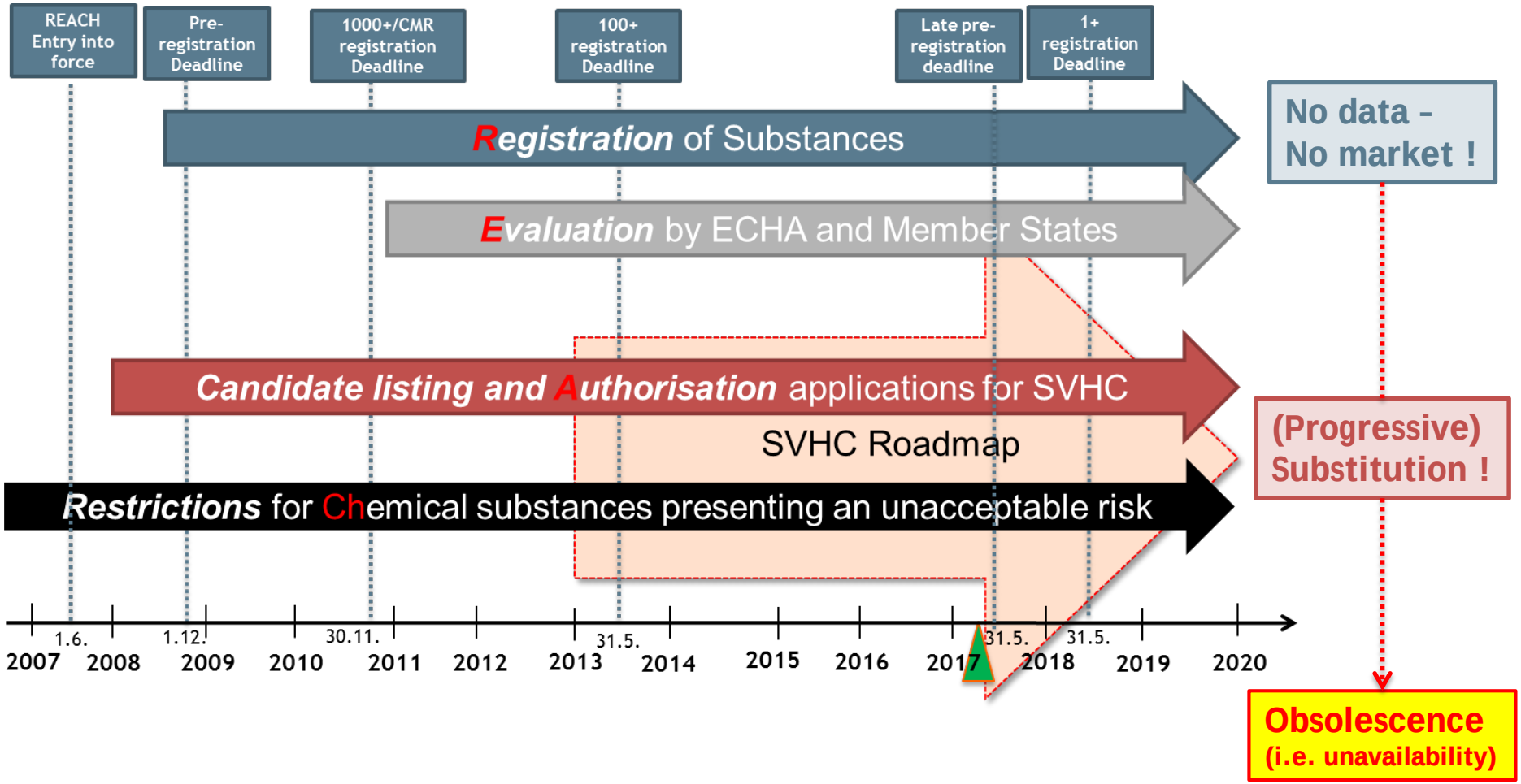
Main purpose: ensure a high level of protection of human health and the environment

In force since **1.6.2007**

Reverses the burden of proof for safe use from authorities to industry

REACH Challenges for the European Space Industry

REACH Processes and Obsolescence



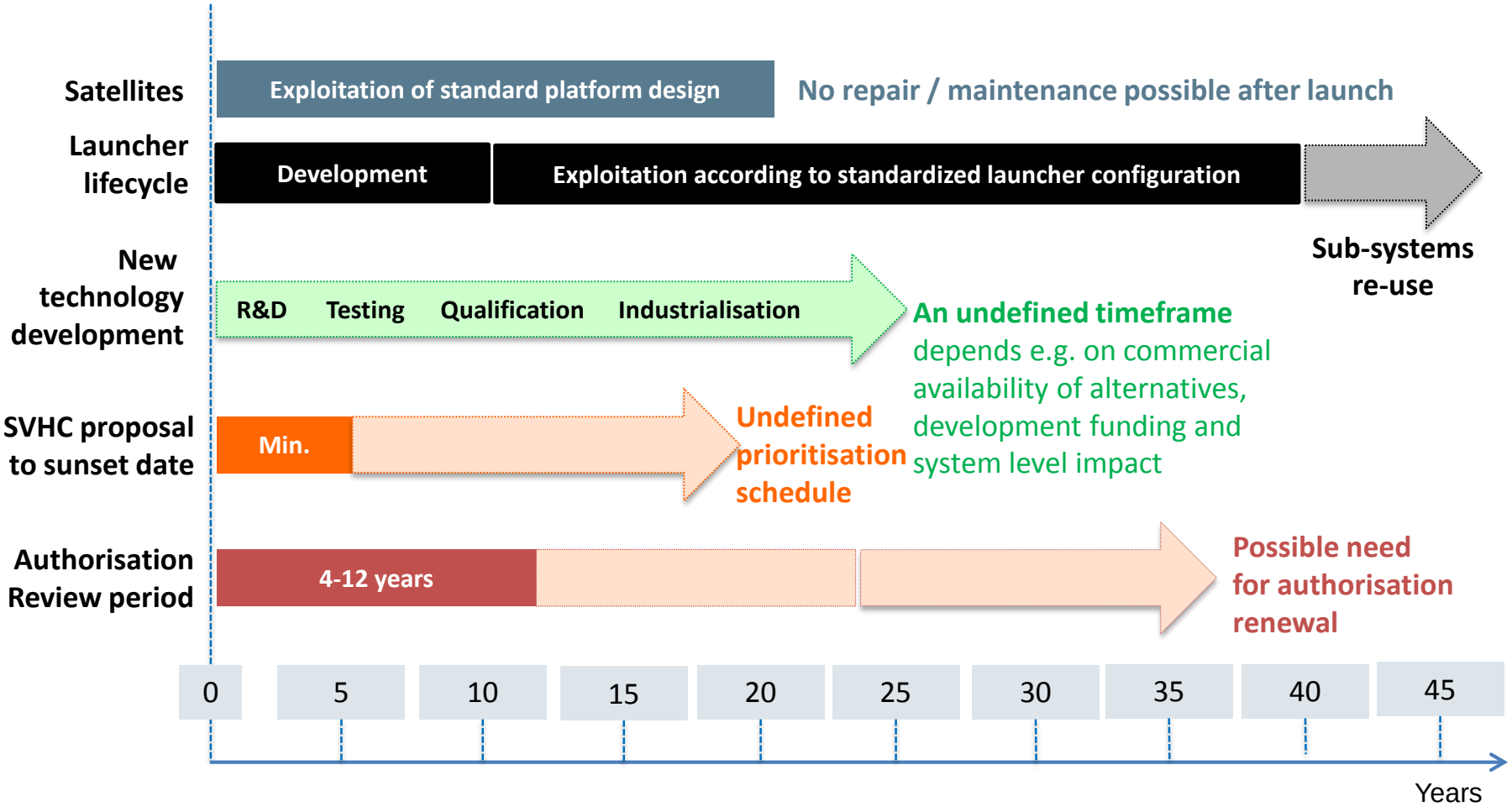
REACH Challenges for the European Space Industry

REACH Processes Comparison by Scope (*simplified*)

	REGISTRATION (EVALUATION)	AUTHORISATION	RESTRICTIONS	ARTICLE 33 COMMUNICATION
Activity triggering it	Manufacture / import	Use / placing on the market for it	Manufacture, use or placing on the market	Supply of articles
Substance scope	All substances (unless exempted)	SVHCs in Annex XIV	Hazardous substances in Annex XVII	SVHCs on Candidate list > 0.1% in article
Volume threshold	1+ t/y	No	No	No
Import/use of Articles in scope	No (*but EU article production is!*)	No (*but EU article production is!*)	Yes	Yes
Main relevant exemptions / derogations	Limited registration for transported intermediates under "strictly controlled conditions"	• Transported intermediates • Scientific R&D • In mixtures below certain concentrations limits • In certain fuels	• Scientific R&D • As defined in Annex XVII: e.g. concentration limits, derogations for certain critical applications	NONE (but to consumers the safe use information is only to be provided upon their request)

REACH Challenges for the European Space Industry

Typical timelines in the Space Industry vs. REACH



REACH Challenges for the European Space Industry
Role of SMEs

The space manufacturing sector in Europe is at the same time very concentrated and very fragmented

- Dominant role of prime contractors
  - The 30 largest space companies in Europe account for almost 80% of the sectors employment

- 100s of smaller players (SMEs) are mainly subcontractors to larger players.
  - E.g. surface treatment shops typically serve many businesses, in several industries; they have a critical role in the supply chain, especially as REACH Downstream Users of chemicals.

SMEs are still under-/non-represented in sector-level REACH activities

REACH Challenges for the European Space Industry

Complexity of the REACH Regulatory Processes

Picture: ECHA

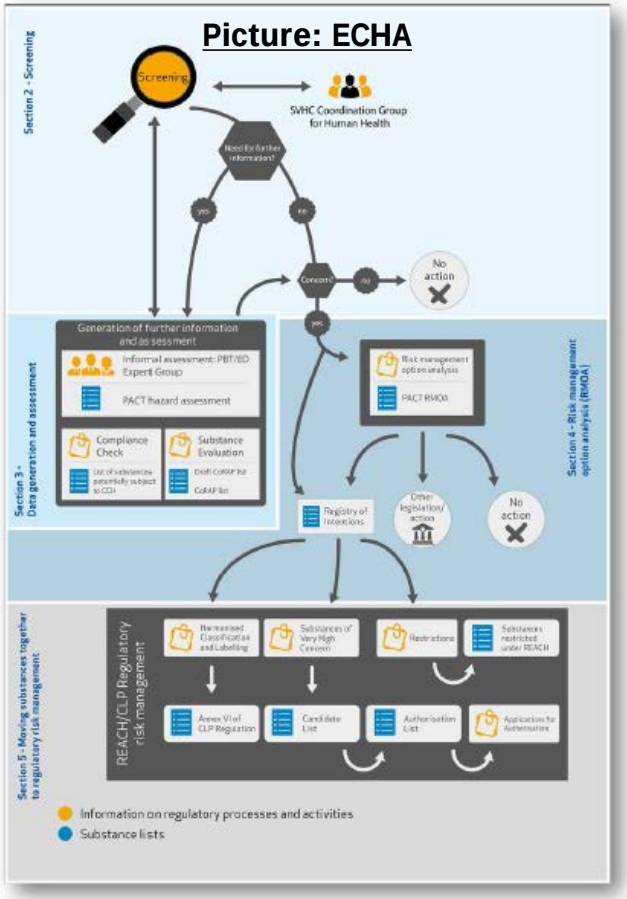
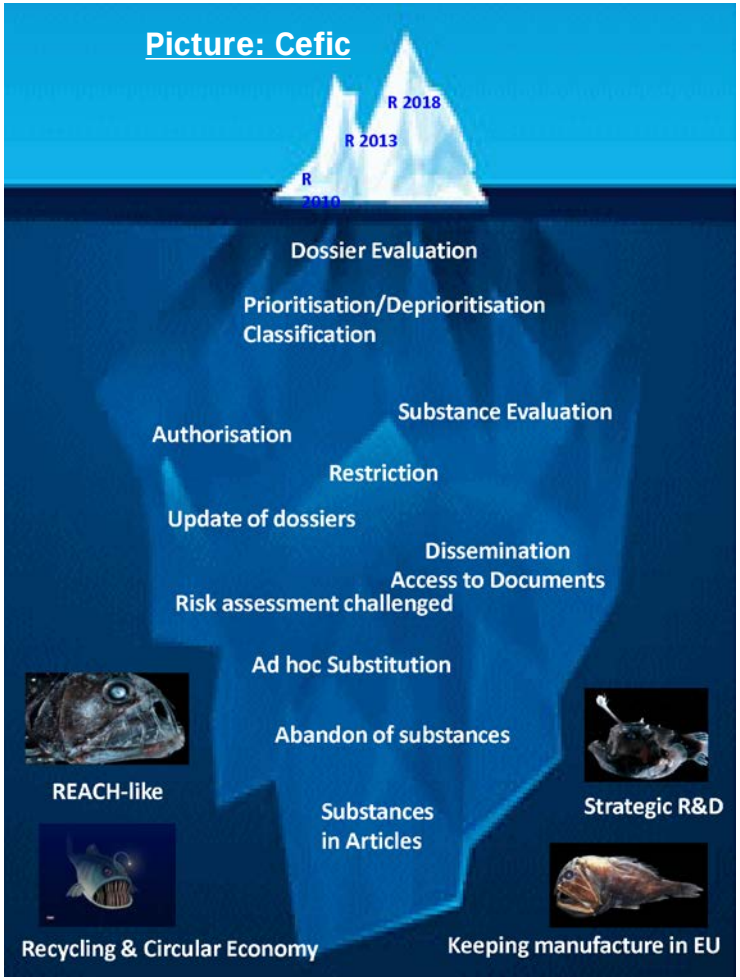


Figure 1: REACH and CLP machinery serving ECHA's integrated regulatory strategy and the SVHC Roadmap[3].

Picture: Cefic



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Joint Industrial Activities to Address REACH

Overview: Compliance-Related Collaboration Areas

Area	Framework	Example(s)
REACH monitoring, incl. for SVHC-related obsolescence risks	MPTB	At least quarterly MPTB meetings incl. REACH and authorisation status updates (since 2011)
General REACH declarations and templates; small scale studies	MPTB	R&D exemption documentation for DOP (2015); REACH Article 33 "minimum" declaration (2017); Bisphenol-A intermediate study (2017)
Participation in public consultations / studies	MPTB-driven; submission through ASD-Eurospace	EC consultation on simplified authorisation (2015); EC consultation on REACH REFIT Review (2017); EC study on industry impact of authorisation (2017)
Space use mapping for REACH exposure / scoping studies and task force formation for high-risk items	MPTB-driven; facilitated by ASD-Eurospace	Hydrazine use mapping for exemption study and formation of Hydrazine Task Force "HTF" (2011); Chromates use mapping and scoping study for joint authorisation; formation of Space Chromates Task Force "STF" (2013)
Joint authorisation / exemption dossiers & related third party communication for high-risk items	Industry Task Forces facilitated by ASD-Eurospace; with space agencies' support	AoA & SEA for space use of Alodine 1200 - related STF comment to ECHA to support CTACSub upstream authorisation (2015); Hydrazine exemption position paper - presentation to EC for legal clarification (2012); Hydrazine report on Annex XIV consequences (2016)

General actions to benefit whole sector

Specific actions for industry compliance

Joint Industrial Activities to Address REACH

ESCC MPTB* (*see presentation by T. Rohr*)

Reason	Membership	Main REACH-related activities
European-wide coordination To optimise the utilization of the direct and indirect resources available in Europe and to enable all partners to co-operate and influence the formulation of a European Strategy and work plan in the area of Materials and Processes for space applications. The overall goal is cost reduction of space programs by consolidation of efforts, coordinated planning, and risk reduction. The MPTB shall formulate recommendations and strategic work plans in the field of Materials and Processes used in European space programs	• Space industry (Eurospace through its Members) AIRBUS DEFENCE AND SPACE AIRBUS SAFRAN LAUNCHERS AVIO MT Aerospace OHB RUAG TESAT THALES ALENIA SPACE (TAS) • Space agencies ASI, CNES, DLR, ESA • Suppliers MAP COATINGS • REACH consultancy REACHLaw	• **Legislation**: The MPTB maintains an intelligence of the legislative processes (e.g. REACH, RoHS) and of its consequences in order to coordinate preventive and corrective actions. It establishes the long-term obsolescence risk matrix for materials and processes for satellite and launcher applications, and proposes mitigating actions. Where necessary, dedicated task forces or industrial consortia are formed that deal with e.g. REACH authorisation or exemption. It also supports preparation of Space industry contributions to regulatory impact and review studies, e.g. on REACH. • **Obsolescence**: The MPTB identifies and proposes action plans to mitigate risks related to obsolescence in the field of Materials and Processes. • **R&D activities**: The MPTB coordinates the strategy definition of the Materials and Processes related work in Europe and propose the inputs to the SCSB for further endorsement. It supports the harmonisation of R&D studies aiming to meet the strategic objectives set by the SCSB. Further, the needs for in orbit materials testing are expressed through review of specifications and requirements if available. Results of in-orbit testing should be reviewed, monitored, and shared.

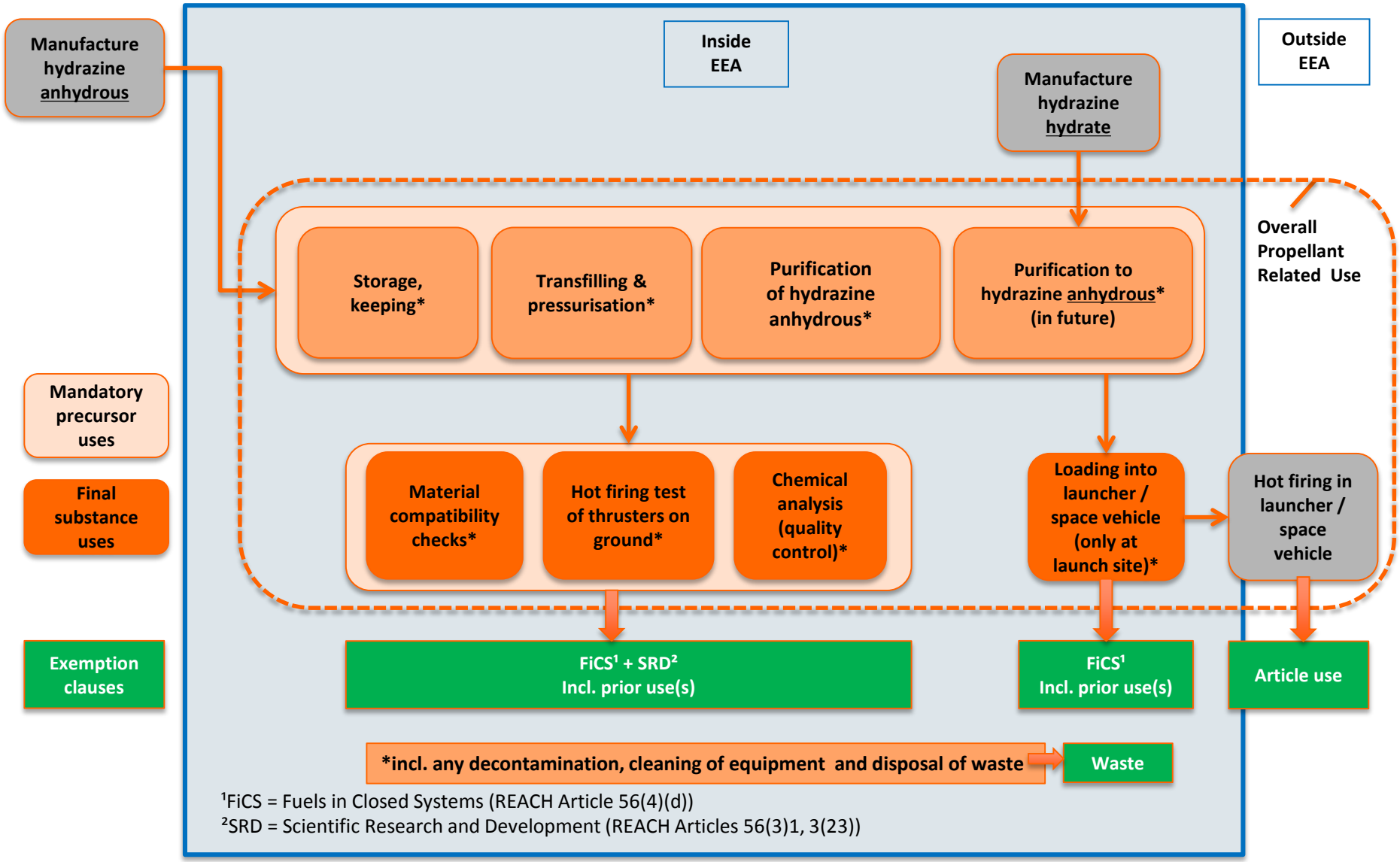
*Materials and Processes Technology Board of the European Space Components Coordination

Joint Industrial Activities to Address REACH
Space Hydrazine Task Force (HTF), 2011-

Reason	Membership	Activities	Results
• Hydrazine (EC 206-114-9) • Classified carcinogenic 1B • REACH candidate list inclusion 20.6.2011 • Worst case sunset date, if included in Annex XIV: 2022 • Strategic propellant for launchers and space vehicles – covering 90% of all monopropellant use • High degree of heritage and reliability • No alternative for complete thrust and mission range	Industrial HTF participants: • AIRBUS DEFENCE AND SPACE • AIRBUS SAFRAN LAUNCHERS • ARIANESPACE • AVIO • GHC Gerling, Holz & Co. Handels GmbH • MOOG UK Westcott Ltd • OHB • TAS Assisted by ESA, CNES and DLR. ASD-Eurospace as Secretariat, REACHLaw as consultant.	• Industry survey and use mapping (2011) • Exemption study, Position Paper and presentation to the EC for legal clarification (2012) • Information exchange with registration consortium and other sector task forces (2013-) • Analysis of substitution efforts and the possible socio-economic consequences of Annex XIV inclusion (2015/2016)	• Industry Position Paper documenting reasons for exemption from authorisation (2012) - EC clarification still pending today • (Draft) Report on substitution efforts and socio-economic consequences of Annex XIV inclusion (for possible future consultation) → **Joint framework and deliverables for REACH authorisation compliance; public awareness**

Joint Industrial Activities to Address REACH

HTF: Overview of Eurospace Exemption Position

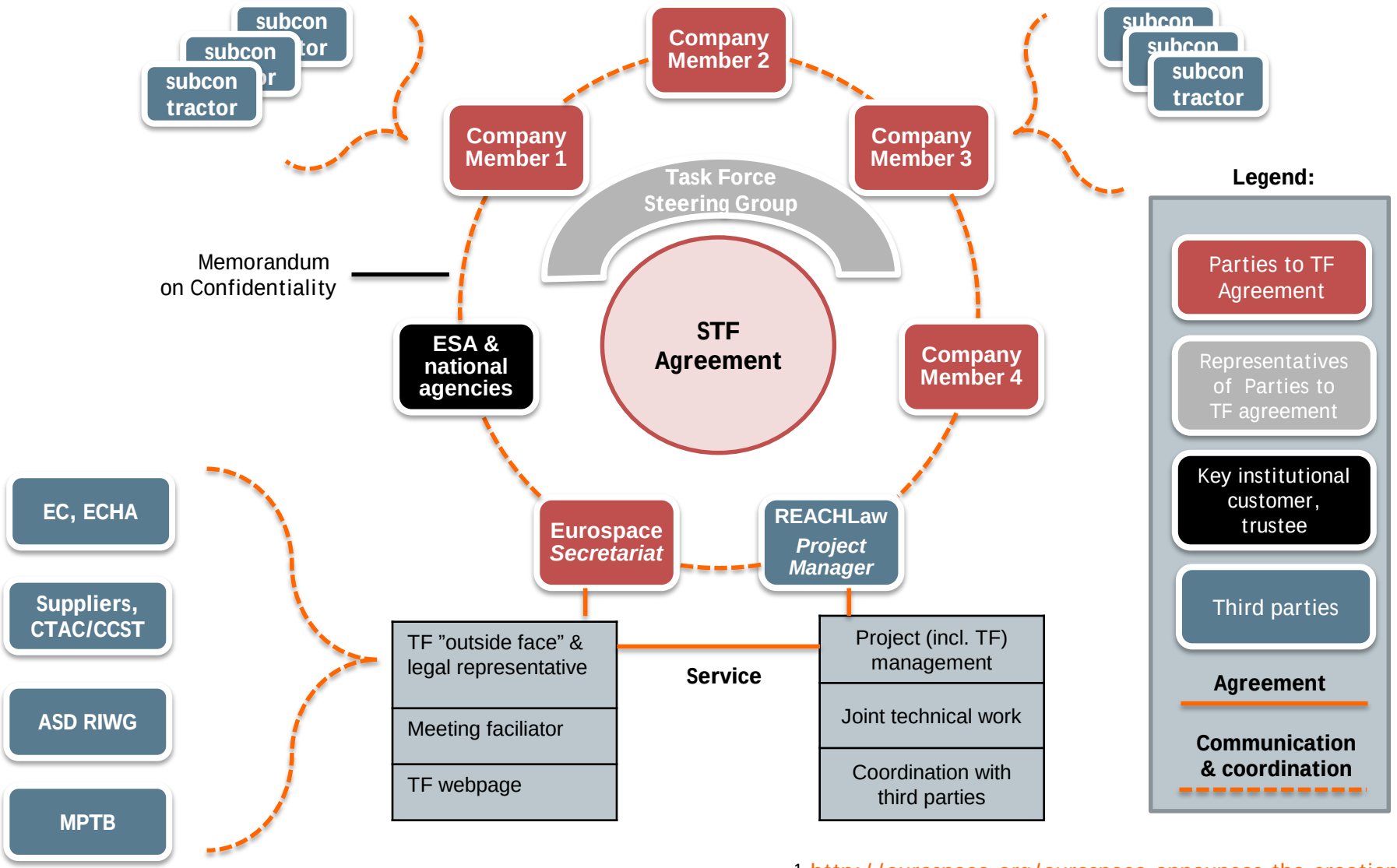


Joint Industrial Activities to Address REACH
Space Chromates Task Force (STF), 2013-

Reason	Membership	Activities	Results
Chromium trioxide: • Classified carcinogenic 1A, mutagenic 1B • REACH Annex XIV inclusion 21.4.2013 • Annex XIV sunset date: 21.9.2017 • Chromic Conversion Coating (CCC) Alodine 1200 used on essentially all Al-alloys Other chromates with space applications and included in Annex XIV, e.g. strontium chromate used in primers such as BR 127	Industrial STF participants: • AEROSPACE PROPULSION PRODUCTS • AIRBUS DEFENCE AND SPACE • AIRBUS SAFRAN LAUNCHERS • AVIO • EUROPROPULSION • HERAKLES • OHB SYSTEM AG • RUAG SPACE • TAS Assisted by ESA and CNES. ASD-Eurospace as Secretariat, REACHLaw as consultant.	• Industry survey and use mapping (2013) • Phase 1 – Scoping, incl. information exchange with third parties (2013) • Phase 2 – Industry-funded preparation of Authorisation Analysis (AoA) of Alternatives and Socio-Economic Analysis (SEA) for CrO3/CCC • Phase 3 - Support of cross-industry consortium "CTAC-Sub" in public consultation (2015)	• STF comment on the CTACSub upstream application for authorisation in public consultation (October 2015) • STF joint AoA and SEA for CrO3/CCC as basis of future space industry application(s) for authorisation → **Joint framework and deliverables for REACH authorisation compliance; public awareness**

Joint Industrial Activities to Address REACH

STF: A Sector-Level Authorisation Framework[1]

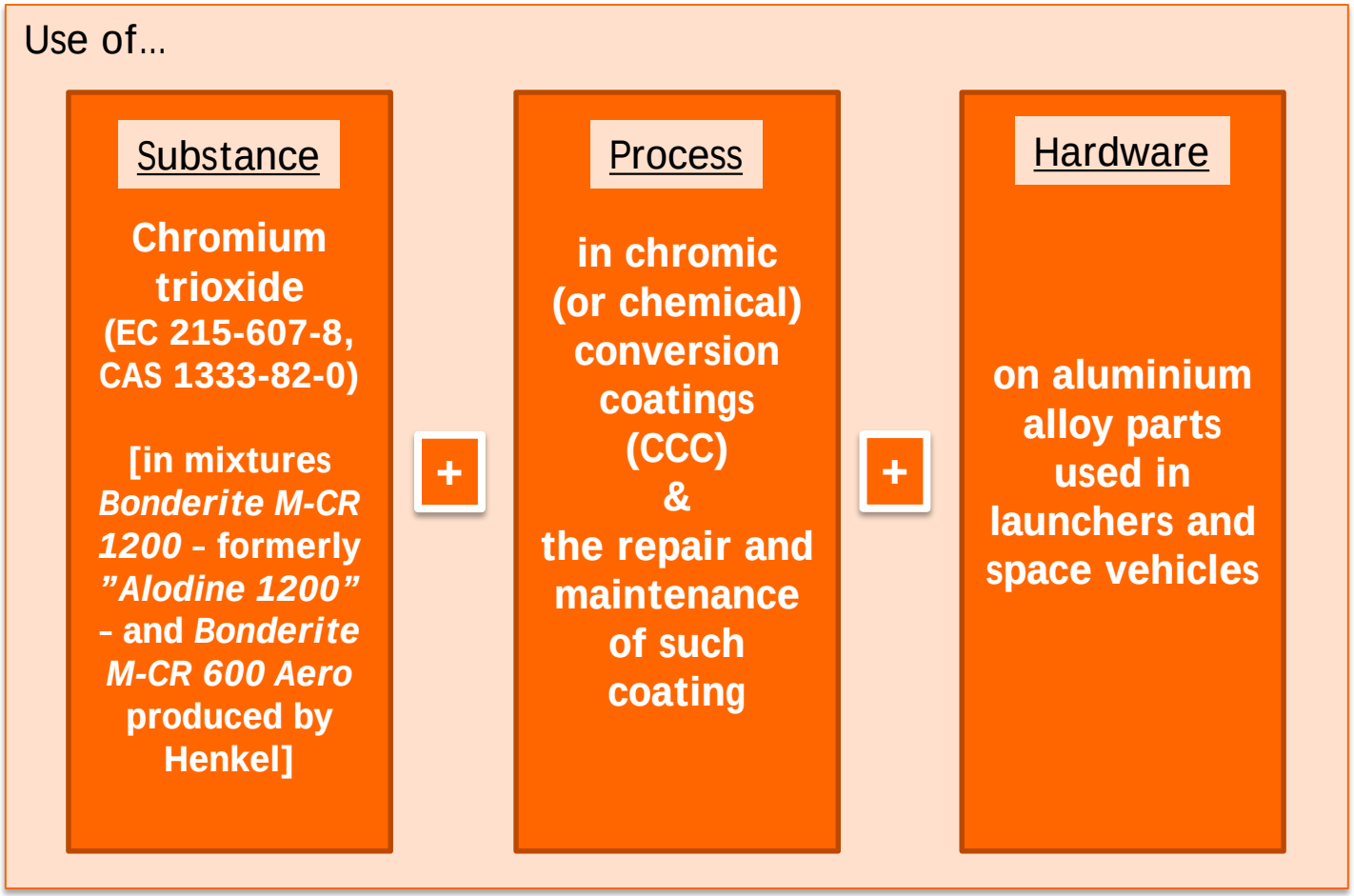


~ 20 counterparts…

[1] http://eurospace.org/eurospace-announces-the-creation-of-a-reach-chromates-space-industry-task-force.aspx

Joint Industrial Activities to Address REACH

STF: Scope of Joint AoA and SEA

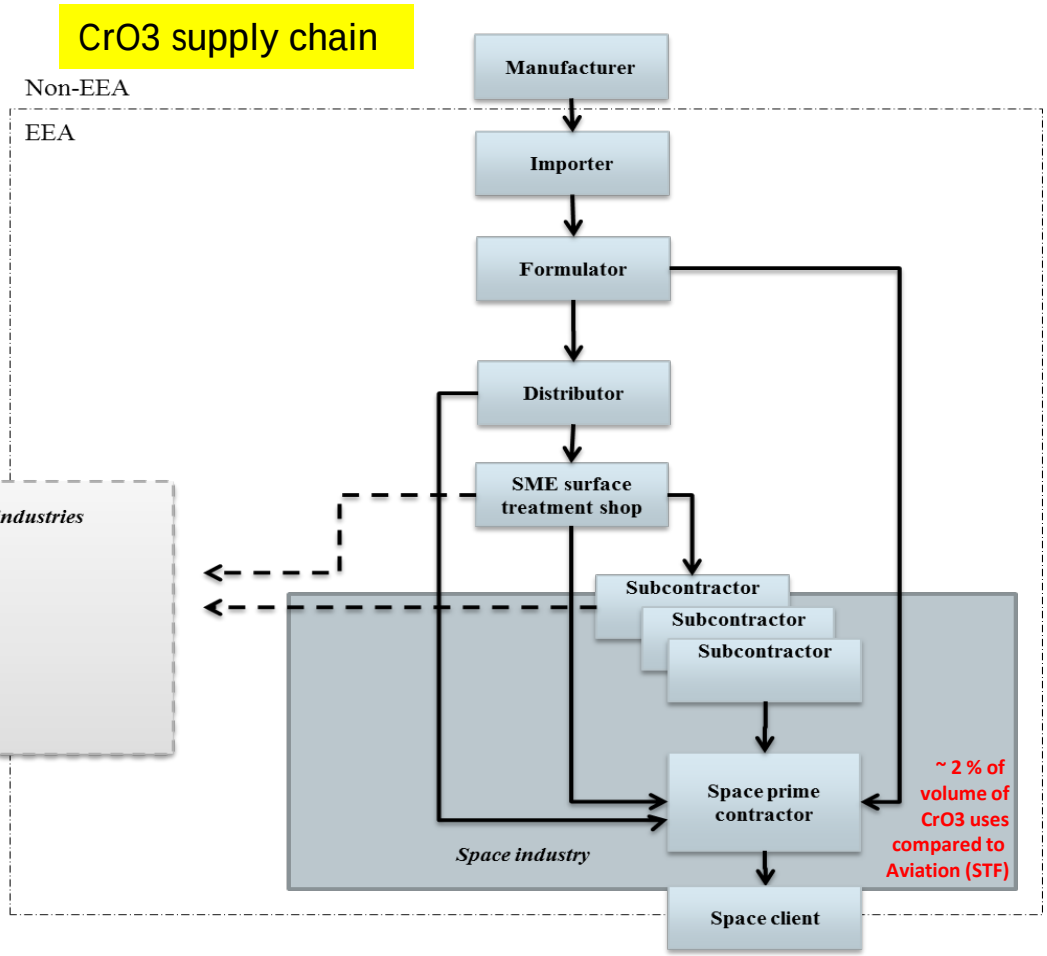


Joint Industrial Activities to Address REACH

STF: Dependence on Upstream Authorisation

- Due to supply chain complexity and number of actors involved an upstream application for authorisation (AfA) for the identified space use (CCC) by the formulator (here: Henkel) **or** the further upstream EU importer of CrO3 was mandatory.
- Eventually reliance on the AfA of the EU importers (CTACSub) was the only viable way forward.
- STF supported CTACSub AfA with a summary of its technical work (AoA and SEA) in the ECHA public consultation on the AfA.

Space Industry downstream users will have to comply with the future authorisation for CTACSub



Joint Industrial Activities to Address REACH

STF: Stakes for Continued Use of CrO3

What would happen if CrO3 was banned for use from the sunset date? (non-use scenario)

The supply chain member	Non-use scenario	Impacts on the space sector	Impacts on the EU, its space programmes and local business environments
Surface treatment processors/in-house plating units	Shutdown of their facilities in the EU	- Loss of the entire business and jobs	- The EU space industry's competitiveness in the global space market would suffer - The ability to ensure the political goal of Europe's independent access to the space would be jeopardized - Poor financial performance may lead to layoffs and skilled workforce could leave Europe ("brain drain") - The EU's ability to protect its citizen through space infrastructures may be jeopardized - Other players in the local business environment would have economic losses + Decreased human health risk from not having any chromium trioxide exposure
Launcher and space vehicle manufacturers and their component subcontractors	Interruption of the production of operational systems, either entirely or partly	- Loss of contracts and income (due to penalties because of non-respect of the contract or due to lose of future contracts)	
European launch service provider	Unable to provide launch services with European launchers	- Loss of contracts and income due to interruption in European launcher and space vehicle production, loss of experience etc.	

The possible total economic impact on the European economy - space sector manufacturers and the local business environments - together could be 2.6 Billion EUR annually until a solution is found for the industry.

Joint Industrial Activities to Address REACH
ASD-Eurospace REACH REFIT Position Paper*

Space sector contribution to the EC REACH Review 2017

REACH-relevant sector features	**REACH concerns & experience**	**Recommendations**
• HIGH-END NICHE SECTOR (very small production runs, qualification requirements, very long lifecycles, high strategic importance) • COMPLEX SUPPLY CHAINS • LOW VOLUME CHEMICALS USE • DEPENDENCE ON A PLETHORA OF SUBSTANCES – IN A PLETHORA OF SYSTEMS	• OBSOLESCENCE RISKS AND THEIR MAGNITUDE • PREDICTABILITY WITH REGARD TO SVHC REGULATION • REPLACEMENT OF SVHCS • SHORT ANNEX XIV SUNSET DATES • AfA CHALLENGES: CR(VI) CASE • EXEMPTIONS: CASE HYDRAZINE • ARTICLE 33 COMPLIANCE	• MORE TIME FOR INNOVATIVE SUBSTITUTION OF SVHCS • EU LEVEL FUNDING FOR SUBSTITUTION R&D • HARMONISED RMOA • REGULATORY PREDICTABILITY FOR CRITICAL SUBSTANCES • AfA SIMPLIFICATION • ARTICLE 33: WORKABLE APPROACH • MORE ATTENTION TO HIGH-END NICHE SECTORS
Annex: REACH STATUS OF GOVERNMENTAL AGENCIES		

* http://www.eurospace.org/position-paper-addresses-impacts-of-the-eu-chemicals-regulation-%E2%80%9Creach%E2%80%9D-on-space-activities-.aspx

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Planning Ahead: What's Next?
Key Topics To Be Addressed

- Compliance with the future CTACSub Authorisation
- REACH Article 33 Compliance for very complex objects
- REACH Enforcement
- EC REACH Review 2017
- Simplified / Streamlining of Authorisation

Planning Ahead: What's Next?
Compliance with the future CTACSub Authorisation

Confusion at Space Downstream User level (quotes from Q1/2017)

"Right now I feel there is a large confusion about what's going on regarding CrVI. It's very hard to know how to act under such uncertainty."

"Could you please briefly explain what the status on Cr(VI) is to date ? I am a bit confused, as we are painfully trying to replace Alodine in a space application of ours. Lately we've been hearing information from surface treatment suppliers that they will be able to continue to use CrVI at least for the rest or the year or even longer. Or that they "probably" will be able to continue. I'm not sure I can take this as a fact or not. There have also been indications from them that the reason is the sunset date for the chemical 21 Sep 2017 will be "removed" and that a new decision about a new sunset date will be made but not sure when and meanwhile it would be ok to continue using CrVI."

"When and how can we know for sure that we can use yellow chromate in our products produced also after 21 September 2017?"

"The question came up – what if we use a surface treatment supplier outside the EU for surface treatment of our products, would that mean no obligation whatsoever to ECHA/REACH? (authorization, notification etc) Does the total amount of "surface treatment" weight % in product influence considering we will deliver these items both inside and to outside of EU?"

"If and under which circumstances our supplier could benefit from the upstream authorization and continue producing mixture XYZ after the sunset date? Consider that we do not know at which level of the supply chain the applicants stay."

- Continued use post 21.9.2017?
- Imported articles?
- Coverage by upstream AfA?
- ...

Planning Ahead: What's Next?
Compliance with the future CTACSub Authorisation

PRESS RELEASE[1]
JANUARY 18, 2017

The **CTACSub Consortium** (CTAC Submission Consortium) is pleased to announce that ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) have recommended in September 2016 that the European Commission ('Commission') grant the authorizations for continuation of the 6 uses of chromium trioxide (EC 215-607-8; CAS 1333-82-01)[2] applied for by the members of the CTACSub Consortium, on the basis that the socio economic benefits of continued use outweigh the health and environmental risks thereof.[3]

The Commission is now actively working on the draft authorization Decisions, which will have to be agreed with the EU Member States. As no legal deadline is provided for the Commission to issue its final Decisions, and given previous experience on other authorization files, it is possible that the authorization Decisions may not be issued before the Sunset Date of September 21, 2017.

However, in case of delay, Art. 58(1)(c)(ii) REACH provides that downstream users supplied directly or indirectly by the 7 applicants may continue their uses beyond the Sunset Date until the Commission will have decided on the authorizations. Please note though that such continued use is only permitted in as far as the uses are within the remit of the authorization applied for. The CTACSub Consortium therefore encourages its downstream users to thoroughly review the scope of the applications for authorization on the ECHA website.

http://www.jonesdayreach.com/SubstancesDocuments/Press%20Release%20CTACSub%20Consortium%20(combined)%20January%202017.pdf

Planning Ahead: What's Next?
Compliance with the future CTACSub Authorisation

Actions for Downstream Users to be covered:

Use in scope of the authorisation

"Surface treatment for applications in the aeronautics and aerospace industries" (ECHA consultation number 0032-04)

CTACSub supply chain

The DU notifies ECHA of its use under the CTACSub authorisation

REACH Art.66 *"within 3 months of first supply"*

DU identifiers and authorisation number have to be notified

Use complies with the authorisation conditions

As set out in the EC decision. RAC and SEAC opinions provide proposals.

DU to check the updated eSDS, once available

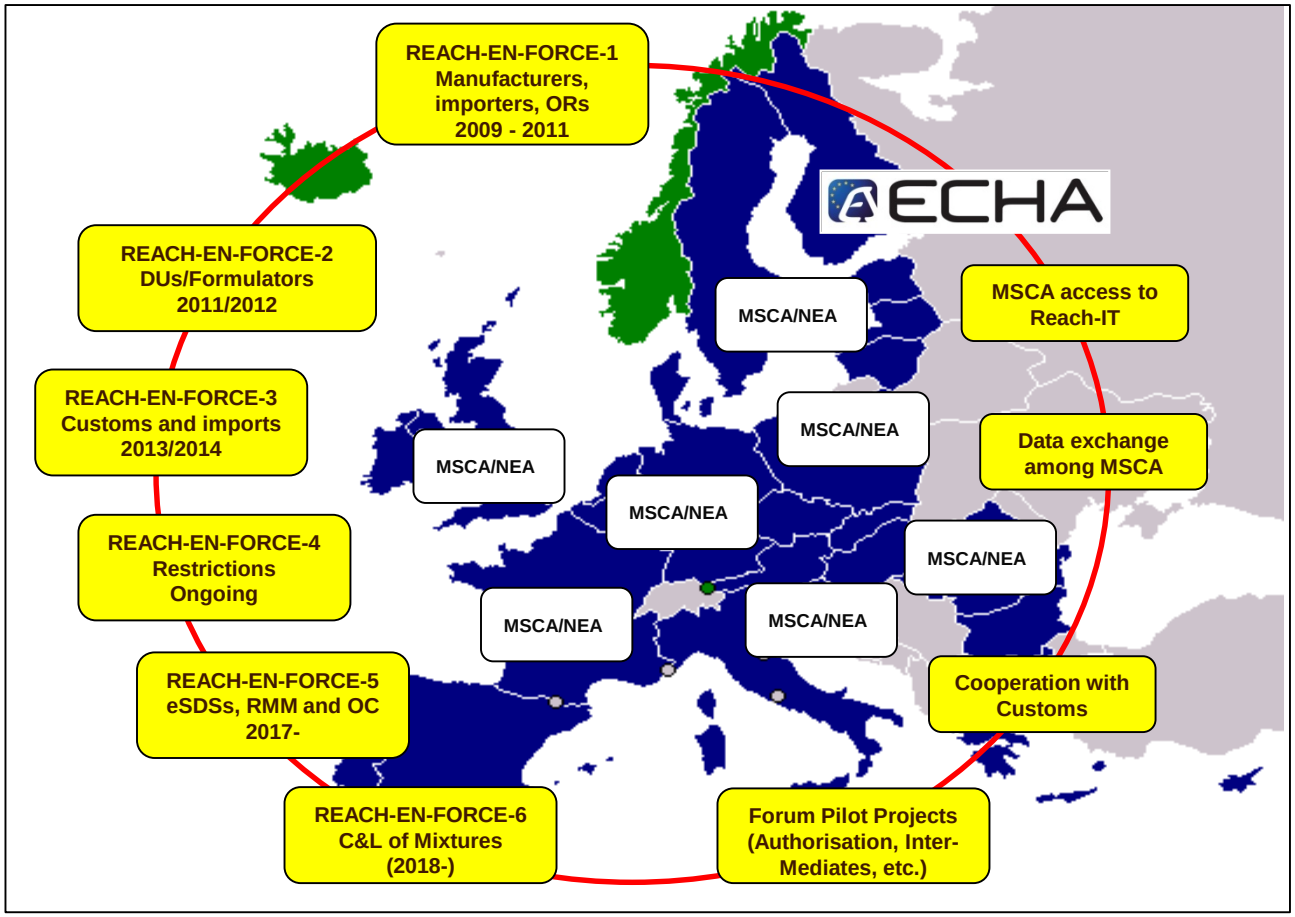
Planning Ahead: What's Next?
REACH Article 33 Compliance

Legal text: *Any supplier of an article containing a substance on the candidate list in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article (or the consumer upon his request) with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*

- ✓ Calculation for each component article separately (CJEU judgment of 10.9.2015 in case C-106/14)
  - *What?* Identify and differentiate each article joined or assembled together
  - *How?* E.g. supply chain tracking, contract clauses
- ✓ Relevant "safe use" information
  - Assess and decide on a case-by-case basis, considering all life-cycle stages of article use and exposure/risk potential
  - E.g. use conditions, risk management measures

Enforcement: The ECHA *Guidance on requirements for substances in articles* is currently under revision to align with the CJEU judgment (*update possibly by July/Aug 2017*). It should further elaborate on the calculation and relevant information required. An EU coordinated enforcement pilot project addressing Article 33 compliance is scheduled to start in Q4/2017.

Planning Ahead: What's Next?
REACH Enforcement



- Member States (not ECHA!) are responsible for REACH & CLP enforcement; co-ordination through ECHA's Enforcement Forum
- ECHA ensures quality of registration dossiers, may delete invalid pre-registrations and makes registration information available to MSCAs for enforcement purposes
- Customs authorities may stop non-compliant goods at the border

Planning Ahead: What's Next?

REACH Enforcement

Year	EU Coordinated (REACH-EN-FORCE/REF) Projects		
	ID	**Scope**	**Main Results**
2009	**REF-1**	**Obligations for Manufacturers and Importers of substances on their own or in mixtures with regards to Registration, Pre-registration and Safety Data Sheets**	2,400 inspected companies in 26 Member States 22% of the companies were found to be non-compliant, esp. with regard to SDSs → higher than expected ORs not always Article 8-compliant
2011	**REF-2**	**Compliance with the legal requirements imposed by REACH and CLP on those Downstream Users who are Formulators of mixtures**	1,181 inspections in 29 MSs Two thirds of the inspected enterprises were failing to comply Every second SDS (52%) deficient
2013	**REF-3**	**Registration obligations by Manufacturers, Importers and Only Representatives in close cooperation with Customs ("No Data - No Market"); emphasis on imported substances (71%)**	1,169 companies inspected in 28 MSs, covering 3 065 substances in total (till 8/2013) 13% of companies non-compliant with registration obligations → "very high" Only representatives show the highest non-compliance rate (34%) compared to importers (15%) and manufacturers (6%).
2016	**REF-4**	**Restrictions (REACH Annex XVII)**	Pending (Forum meeting on 7-9 November, 2017)
2017	**REF-5**	**Extended SDSs, Risk Management Measures and Operational Conditions**	Pending
2018	**REF-6**	**Classification and labelling of mixtures**	Project under development

+ Pilot projects on e.g. authorisation, intermediates, substances in articles (Article 33 – *to start in Q4/2017*)

Planning Ahead: What's Next?
EC REACH Review 2017

Topical Issues (*EC Report expected in October 2017*)

Quality of Registration dossiers / Data gaps	Complexity of post-Registration processes	Enforcement not sufficient across EU? (level playing field)
SVHC Roadmap to 2020 and its pace	Substances of potential concern /unknown priority	Does REACH promote innovation?
Addressing groups of substances	Imported Articles – Authorisation loophole	Consistency with non-REACH laws and policies (e.g. OSH)
Extended safety data sheets	Substances in Articles (Article 33)	Challenges for SMEs

Planning Ahead: What's Next?
Simplified / Streamlining of Authorisation

The EC, ECHA and a number of Member States Competent Authorities have been working on the simplification and streamlining of the Application for Authorisation (AfA) process – AfA Task Force since August 2014

- Low quantities – A European Commission implementing act to simplify the authorisation dossier for uses up to 100kg is still pending adoption.

- Legacy spare parts (*for articles no longer produced*) – Extension of Annex XIV dates for a number of Annex XIV substances incl. chromates is pending.
  - Limited relevance for the space industry

- Discussions on other special cases are ongoing, e.g. (relevant for space) industrial process chemicals and upstream AfAs.

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Joint Industrial Activities to Address REACH
Conclusions / Key Messages

- REACH registration and authorisation processes pose major obsolescence risks for the space industry.
- Joint sector-level solutions are necessary to manage REACH-related obsolescence risks and compliance challenges efficiently.
- The current collaboration model (MPTB + Industry task forces for high-risk items) works well.
- Stakeholder communication (supply chain incl. SMEs, authorities) are pivotal for the success of sustainable supply.
- For broadly used chemicals there is a critical dependence of space industry on upstream applications for authorisation in order to cover the entire supply chain(s).
- Compliance with future CTACSub Authorisation will be a key priority
- Art. 33 compliance remains challenging, more support is underway

Joint Industrial Activities to Address REACH
Links for further Information

- ASD-Eurospace REACH REFIT 2017 Position Paper

  http://www.eurospace.org/Data/Sites/1/pdf/reach/spacesectorcontributiontotheecreachreview2017.pdf

- STF Comment on the CTACSub Application for Authorisation

  https://echa.europa.eu/documents/10162/18074545/a4a_comment_665_1_attachment_en.pdf

- Hydrazine Authorisation Exemption Position Paper

  http://www.eurospace.org/Data/Sites/1/pdf/positionpapers/Hydrazinereachpositionpaper_final_14june2012.pdf

Thank you for your attention

List of Acronyms (1/2)

Abbreviation	Explanation
AfA	Application for Authorisation
CLH	Harmonized Classification & Labelling
CJEU	Court of Justice of the European Union
CLP	Classification, Labelling and Packaging (Reg. (EC) 1272/2008)
CMR	Carcinogenic, Mutagenic, toxic to Reproduction
CoRAP	Community Rolling Action Plan (for REACH Substance Evaluation)
DU	Downstream User (of substances on their own/in mixtures)
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area (EU MS + Norway, Iceland, Liechtenstein)
HTF	Hydrazine Space Task Force for REACH
MPTB	Materials & Processes Technology Board (previously M&P WG)
MS	Member State
MSCA	Member State Competent Authority
OEL	Occupational Exposure Limit
PACT	Public Activities Coordination Tool

List of Acronyms (2/2)

Abbreviation	Explanation
PBT	Persistent, Bioaccumulative and Toxic
RAC	Risk Assessment Committee (ECHA)
RMO(A)	Risk Management Option (Analysis)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Reg. (EC) 1907/2006)
RoI	Registry of intentions
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SEAC	Socio-Economic Analysis Committee (ECHA)
SIN	Substitute It Now list of the NGO ChemSec
SME	Small and Medium-sized Enterprises
STF	Chromates Space Task Force for REACH
SVHC	Substances of Very High Concern (as defined in REACH Article 57)
vPvB	very Persistent and very Bioaccumulative
WPL	Worker Protection Legislation

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COMPLIANCE. SUSTAINED.

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