

**13 November 2018**  
**ESA Headquarters, Paris**

# **REACH Regulation: Current status and focus on outlook**

2nd workshop on REACH regulation and its impact on space sector

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EU REACH & CLP

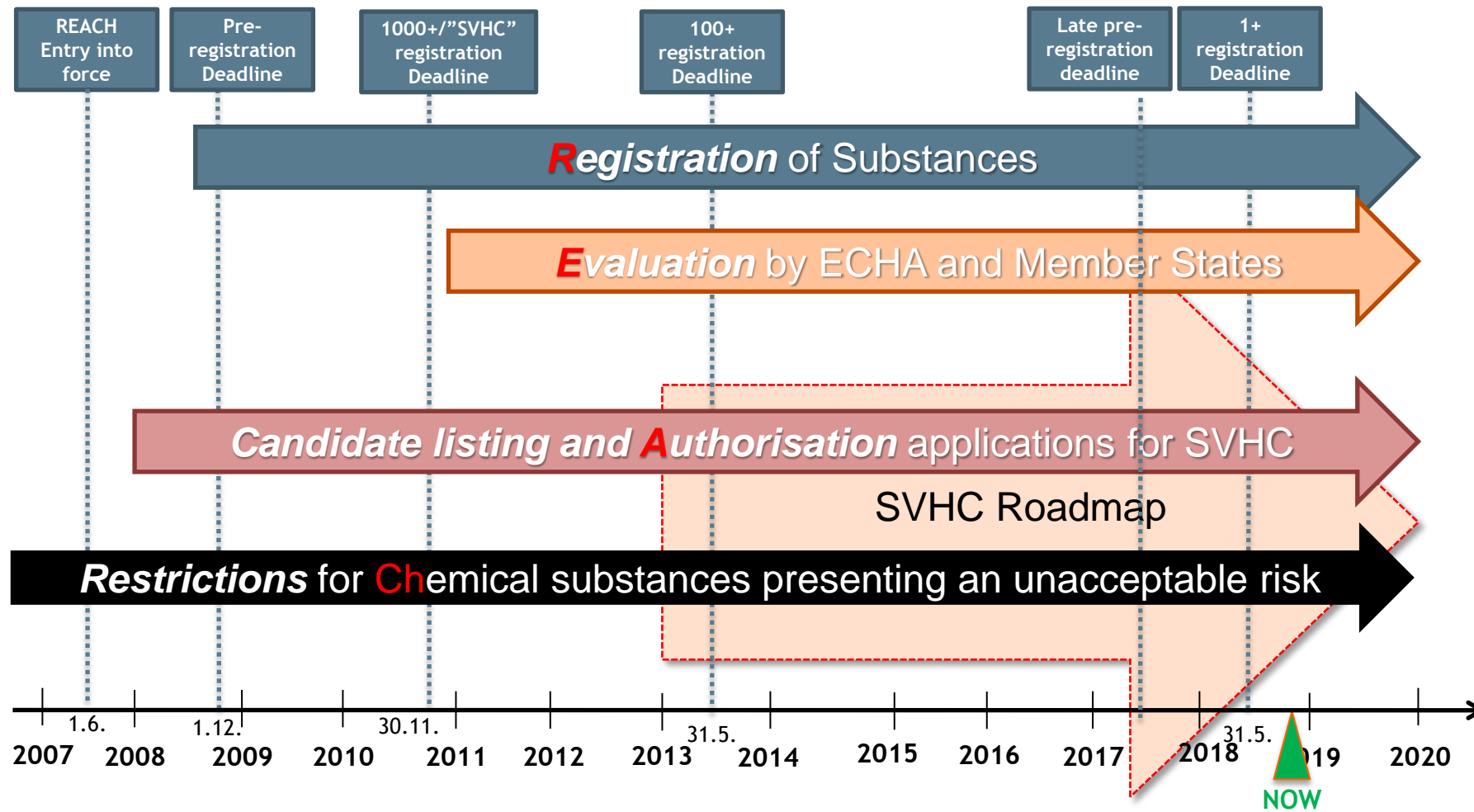
TURKEY KKDİK

CHINA REACH & GHS

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# Introduction

2018 marks the “end of the beginning”



Number of substances  
Status 24/10/2018

21 405  
registered

191 (candidate list)  
74 (prioritised)  
43 (Annex XIV)

68 substances/  
entries in  
Annex XVII

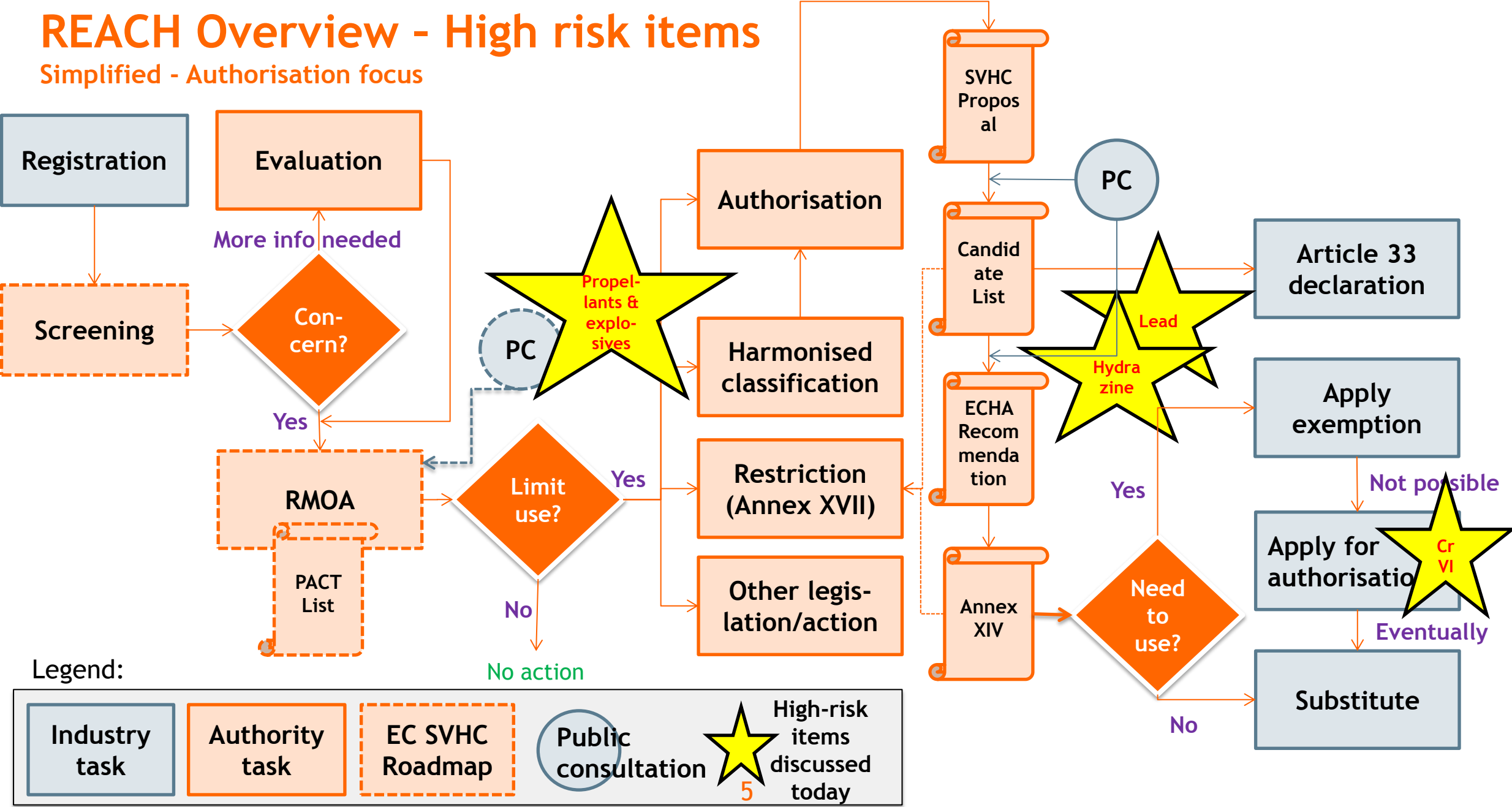
## REACH Regulation: Current status and focus on outlook

### Review of critical REACH action items for the Space Sector

- Authorisation and high-risk items
- Substances in articles: New requirements
- Obsolescence risk management
- Preparing for Brexit
- Commission priorities

# REACH Overview - High risk items

Simplified - Authorisation focus



# Authorisation and high-risk items

## Chromates - CTACSub upstream AfA: *Current status\**

Substance CAS number(s)	CLP Annex VI (SVHC class.)	SIN List (ChemSec)	Candidate List (inclusion date)	ECHA Recommendation	Annex XIV ( <b>sunset date</b> )	Comments
<b>Chromium trioxide</b> 1333-82-0	Carc. 1A Muta. 1B	YES	YES (15/12/2010)	YES (20/12/2011)	YES ( <b>21/09/2017</b> )	New binding OEL for CrVI (Directive 2017/2398 amending Directive 2004/37) - transpose by 17/01/2020

- Space sector relies on "CTACSub" upstream AfA (2015) by Lanxess et al. for required continued use
  - Space Chromates Task Force "STF" submitted a supportive AoA and SEA assessment to ECHA in October 2015
- ECHA RAC/SEAC opinions (2016) highlighted high uncertainties and recommend authorisation under strict conditions with **7 year review period** for space-relevant uses → *today not fully supported by EC and MS*
- EC decision delay: REACH Committee discussions on the AfA on September 27/28 and October 25 → *serious concern of adverse decision* & no final clarity → next meeting scheduled for Dec 11-12, 2018.
- **Main risks** for Space Sector:
  - **Not enough time** to fulfil the strict authorisation conditions and re-apply (e.g. March 2020 in case of 4 years only)
  - **Security of supply** and **no re-application** by CTACSub → "Replacement" DU authorisation to be applied for and granted by the end of the review period !

\*Similar situation for CCST Consortium AfAs covering **other chromates**, e.g. **strontium chromate** (sunset date 22/01/2019)

# Authorisation and high-risk items

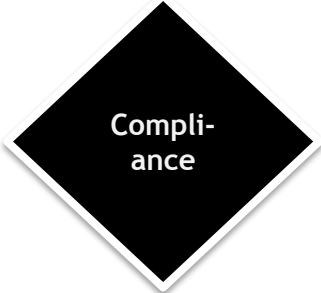
## Chromates - CTACSub upstream AfA: *Actions for Space Sector*



Aware-  
ness  
raising

Talk to [EC](#) and [Member States](#) to ensure viable CTACSub authorisation

- Awareness-raising on sector dependence and the impact of an adverse decision
- Commission decision requires the support of at least 16 Member States



Compli-  
ance

Compliance with CTACSub authorisation (*application, and future decision*)

- Apply CTACSub '*Good Practice Sheets*' and start addressing expected conditions
- Prepare for Article 66 downstream user notifications to ECHA (*per legal entity!!*)
- Prepare for upcoming REACH enforcement project for chromates (2019-)



AfA  
strategy  
adaptation  
for review

AfA strategy adaptation to be explored for the future

- End user level AfA is not suitable, because it cannot cover the complex supply chains
- Explore involvement of formulator level? (~ initial proposal to STF)

# Authorisation and high-risk items

## Lead metal: Current status and actions

Substance CAS number(s)	CLP Annex VI (SVHC class.)	SIN List (ChemSec)	Candidate List (inclusion date)	ECHA Recommendation	Annex XIV	Comments
Lead 7439-92-1	Repr. 1A	YES	YES (27/06/2018)	NO	NO - No sunset date today: <i>worst case could be in mid- late 2024</i>	RoHS/EEE: Space-related exclusion from scope but commercial threat of obsolescence due to the abandon of lead in some other sectors

- Lead metal is a substance **without alternatives in a wide range of space applications**, especially for tin-lead soldering of high reliability electronics → Impact of Article 33 duty
- A **Space Lead Task Force “LTF”** has been created (March 2018) in order to develop joint input for ECHA / EC (*Eurospace contribution of 20.4.2018*) and exchange with other industries (*cross-sector task force*) - Work to be continued to avoid disproportionate impact
- It is urgent to define a **Roadmap for lead-free transition** in the European Space Sector AND to allocate funding for the R&D tasks defined in that Roadmap.

# Authorisation and high-risk items

## Hydrazine and other space propellants: Current status and actions

Substance CAS number(s)	CLP Annex VI (SVHC class.)	SIN List (ChemSec)	Candidate List (inclusion date)	ECHA Recommendation	Annex XIV	Comments
Hydrazine 302-01-2 7803-57-8	Carc. 1B	YES	YES (20/06/2011)	NO	NO - No sunset date today: <i>worst case could be in 2024</i>	New binding OEL for hydrazine (Dir. 2017/2398 amending Dir. 2004/37) - transpose by 17/01/2020

- The **Space Hydrazine Task Force "HTF"** has taken early action to respond to listing
  - **Exemption assessment** (2012-): Legal clarification by the **European Commission** pending
  - Further activities to map alternatives, highlight non-use impacts and exchange with other sectors
- A number of propellants and explosives are being addressed for SVHC properties, e.g.
  - *E.g. MonoMethyl Hydrazine "MMH"*: Harmonised classification as Carcinogenic 1B (like "*UDMH*"); *Dinitrogen Tetraoxide "NTO"*: Substance evaluation in 2019 as "suspected CMR"
  - Enhanced REACH obsolescence risk assessment in the frame of the MPTB
  - To be agreed: Inclusion of similar propellants in the scope of HTF?

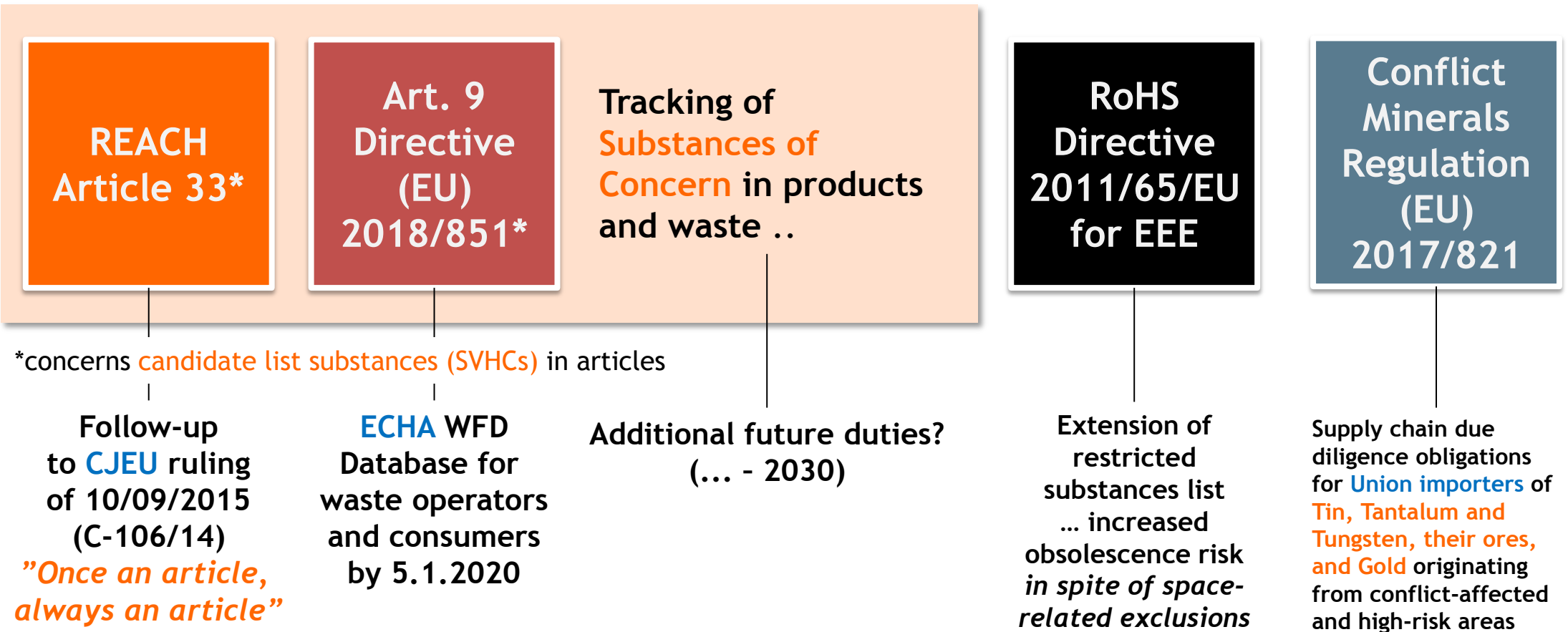
# Authorisation and high-risk items

## Other high-risk items for the Space Sector (*not exhaustive!*)

Substance CAS number(s)	CLP Annex VI (SVHC class.)	SIN List (ChemSec)	Candidate List (inclusion date)	ECHA Recommendation	Annex XIV	Comments
<b>Boric acid</b> 10043-35-3 11113-50-1	Repr. 1B	YES	YES (18/06/2010)	YES (01/07/2015)	No - postponed by EC in 2017	
<b>NMP</b> 872-50-4	Repr. 1B	YES	YES (20/06/2011)	YES (05/02/2018)	Not yet - possible in 2019	Restriction adopted COM Reg. (EU) 2018/588
<b>Gallium Arsenide</b> 1303-00-0	Carc. 1B + Repr. 1B (since 1.1.2017)	YES	NO	NO	NO	
<b>Indium Phosphide</b> 22398-80-7	Carc. 1B (ATP03 - 10/07/2012)	YES	NO	NO	NO	Priority substance currently assessed for addition to RoHS
Last update: 31.10.2018						

# Substances in articles

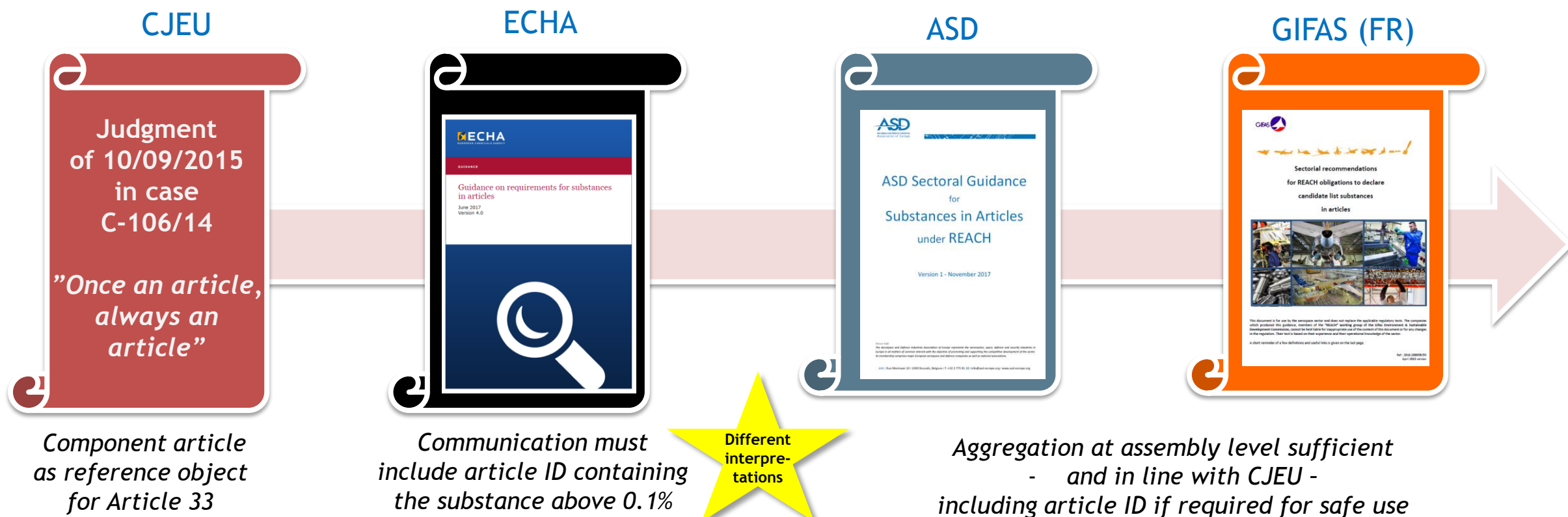
## Evolving regulations / implementation



# Substances in articles

## REACH Article 33 supply chain communication: New guidelines

**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.**



An EU coordinated **enforcement** pilot project addressing Article 33 compliance has been running since October 2017.

## Substances in articles

Taking it a step further: “Article 33” notification to ECHA database

**DIRECTIVE (EU) 2018/851 OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL of 30 May 2018**

**amending Directive 2008/98/EC on waste  
(Waste Framework Directive – “WFD”)**

In force since 5 July 2018. To be transposed into national laws by 5 July 2020.

As from 5 January 2021 EU/EEA Article Suppliers have to **notify REACH Article 33-information on Candidate List substances in articles to ECHA**, for its database to be established by 5 January 2020 – Article 9 of the Directive.

The WFD revision is part of the EU’s waste legislation package, contributing to the EU's **Circular Economy (CE)** policy.

# Substances in articles

## “Article 33” notification to ECHA database: *Current status*

- ECHA has started planning the database
  - Call for stakeholder input and workshop in Helsinki on 22/23 October 2018
- Key elements of database draft proposal
  - Each article supplier (incl. assemblers) to notify REACH Article 33-information to ECHA
  - “Unique identifier” system for each item (article or complex object) is envisaged
  - Public access to all notified information, especially for **waste treatment operators**
  - ‘one-size-fits-all’ approach, ranging from simple articles to the most complex objects
- Herculean task ahead for both ECHA and Industry: *Mission impossible?*
  - Joint industry position paper regarding the WFD Database (October 2018) calling for solutions tailored to each sectors’ needs
- *Space Industry impact*
  - **Space Segment**: Eurospace Position Paper of 8 October 2018:\* **Out-of-scope argument** for launched hardware not resulting in “waste” on the EU territory
    - Pending clarification by the **Commission**
  - **Ground Segment**: Separate evaluation

\*<https://eurospace.org/wp-content/uploads/2018/10/eurospace-request-for-legal-clarification-final-08102018.pdf>

# Substances in articles

## Outlook: *Mandatory tracking of substances of concern by 2030?*

- As part of its **Circular Economy** initiative the **Commission** has suggested the **tracking of substances of concern in products and waste** by a set date, e.g. 2030, as a policy option.
  - This initiative is supported by the **European Parliament** and the **EU Council of Ministers**.
- On 29 October 2018 **Eurospace** has called for **sector-specific tracking solutions** (*if any*), given the limited scope of Circular Economy aspects for the Space Sector
  - Contribution to the EC *public consultation addressing the Interface between Chemical, Product and Waste Legislation*, see <https://eurospace.org/reach-waste-october2018>



# Obsolescence risk management

## Progress under way - major challenges remain

- Better tools to anticipate REACH obsolescence risks at an early stage
  - ECHA PACT list at <https://echa.europa.eu/pact> - extended in October 2018
  - ESA study to connect REACH and *Life Cycle Assessment* (being finalised)
  - Industry tools
- Major challenges remain
  - Limited predictability of Annex XIV entries
  - Risk of "regrettable substitution" (e.g. *chromium(III) oxide* = *substitute for CrO3 now on CoRAP*)
  - Complex supply chains imply: "hidden" obsolescence risks; critical dependence on upstream authorisation; commercial obsolescence
- To manage these challenges, both best possible transparency about regulatory intentions (positive and negative) and supply chain communication / collaboration are needed.

# Preparing for Brexit

## Planning for the event of a "hard BREXIT" on 29 March 2019

- If the UK is leaving the EU on 29 March 2019 without an agreement, UK companies will be regarded as **non-EU suppliers with regard to EU-REACH**. This means:
  - Registrations, notifications and (upstream) authorisations held by **UK suppliers of substances and mixtures to the EU** **will cease to be valid in the EU** (*UK has 2nd most registrations in EU! 10 000+*)
  - **UK suppliers of articles to the EU** are no longer obliged under REACH Article 33
  - **EU suppliers to the UK** have to follow the then UK rules for market access: **"UK REACH"**
- To prepare for this "hard BREXIT" scenario the following is required (***much simplified!***):
  - UK registrations / authorisations **to be transferred** to EU27 entities *as far as possible* for continued EU market access *with effect on the BREXIT date / earlier*, otherwise to be newly prepared...
  - REACH Article 33 duty to be **contractually agreed** with UK article supplier (*no automatism*)
  - EU suppliers to the UK to **familiarise themselves with the rules of UK REACH** and whether UK customers are getting ready too.



Companies to prepare BREXIT Impact assessment and Action Plan

# Commission priorities

## EC 2nd REACH Review: Identified key issues and actions (5.3.2018)

Knowledge and management of chemicals throughout the supply chain

Action 1: *Encourage updating of registration dossiers*

Action 2: *Improve evaluation procedures*

Action 3: *Improving the workability and quality of extended Safety Data Sheets*

Action 4: *Tracking substances of concern in the supply chain*

Enhanced risk management

Action 5: *Promote substitution of SVHCs*

Action 6: *Simplification for a more workable authorisation process*

Action 7: *Early socio-economic information for possible regulatory measures*

Action 8: *Improve Restriction Procedure*

Action 9: *Further enhance Member State involvement in the restriction procedure*

Action 10: *Frame the application of the precautionary principle*

Action 11: *Interplay between authorisation and restriction*

Coherence, enforcement and SMEs

Action 12: *Interface REACH and OSH legislation*

Action 13: *Enhance enforcement ... including controls on imported goods*

Action 14: *Support compliance by SMEs*

Fees and future of ECHA

Action 15: *Fees and the future of ECHA*

Need for further assessment

Action 16: *Review of registration requirements for low tonnage substances and polymers*

# REACH Regulation: Current status and focus on outlook

## Conclusions

- REACH is now fully operational
  - ECHA and Member States work to ensure that safe use becomes a reality. This is reflected in the focus on good quality dossiers and enforcement in safety critical areas
- Authorisation
  - Follow up of *upstream* applications (case CTACSub) likely to trigger major workload for industry, including space
  - A number of high-risk items are on the candidate list or have SVHC properties that require attention / preemptive action
- Substances in articles: Ever tightening requirements at unprecedented speed
  - Important to ensure recognition of the specificities of high-end sectors such as space.
- New tools to anticipate obsolescence risks emerge, but major challenges remain
- BREXIT outcome still to be seen - but prepare (also) for “hard Brexit” scenario

# REACH Regulation: Current status and focus on outlook

## References for further information

- Eurospace "REACH" section at <https://eurospace.org/working-groups>
- ECHA <https://echa.europa.eu>
- European Commission REACH websites
  - DG GROWTH [https://ec.europa.eu/growth/sectors/chemicals/reach\\_en](https://ec.europa.eu/growth/sectors/chemicals/reach_en)
  - DG ENVIRONMENT [http://ec.europa.eu/environment/chemicals/reach/reach\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/reach_en.htm)
- Cefic / CIA advice *Brexit : Preparing for a future "UK out of REACH scenario"*
  - [http://www.cefic.org/Documents/RESOURCES/PositionPapers/Brexit\\_Preparing\\_for\\_UK\\_out\\_of\\_REACH\\_Scenario.pdf](http://www.cefic.org/Documents/RESOURCES/PositionPapers/Brexit_Preparing_for_UK_out_of_REACH_Scenario.pdf)

*Questions ?*

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# **Appendix:** ***List of acronyms***

## List of acronyms (1/2)

Abbreviation	Explanation
AfA	Application for Authorisation
CE	Circular Economy
CLP	Classification, Labelling and Packaging (Reg. (EC) 1272/2008)
CMR	Carcinogenic, Mutagenic, toxic to Reproduction
CoRAP	Community Rolling Action Plan (for REACH Substance Evaluation)
CTAC	Chromium Trioxide Authorisation Consortium
CTACSub	CTAC Submission Consortium (incl. Lanxess Deutschland GmbH and six other companies)
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)
EEE	Electrical and Electronic Equipment
MPTB	Materials and Processes Technology Board (currently chaired by ESA)
MS (MSCA)	Member State (Member State Competent Authority)
OEL	Occupational Exposure Limit
PACT	Public Activities Coordination Tool

## List of acronyms (2/2)

Abbreviation	Explanation
PC	Public Consultation
RAC	Committee for Risk Assessment (ECHA)
RMO(A)	Regulatory Management Option (Analysis)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Reg. (EC) 1907/2006)
RoHS	Restriction of certain Hazardous Substances (Directive 2011/65/EU)
RoI	Registry of intentions
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis (ECHA)
SIN	Substitute It Now list of the NGO ChemSec
SME	Small and Medium-sized Enterprises
SVHC	Substances of Very High Concern (as defined in REACH Article 57)
WFD	Waste Framework Directive (Directive 2008/98/EC, last amended by Directive (EU) 2018/851)

***REACH is a journey,  
not a destination!***

***END OF FILE***