REACHLAW

Making global compliance your business benefit

REACH: How it works from a space sector perspective

Tim Becker, Chief EU Compliance Officer, REACHLaw Ltd.

REACH OVERVIEW - AGENDA

1. **Introduction**
2. REACH processes
   - How they work
   - Current status
   - Impact on space sector
3. High-risk items for ‘space’
4. Conclusions

Introduction I REACHLaw Ltd in a nutshell

What we do? We provide global regulatory compliance and environmental sustainability services to ensure market access and operational sustainability for global businesses

KEY FACTS ABOUT US

- ✓ Established in Helsinki
- ✓ subsidiaries in Brussels, New Delhi and Istanbul
- ✓ 30+ toxicologists, chemists, lawyers, socio-econ. analysts, business and environmental specialists
- ✓20+ local partners in Europe, Asia, Latin-America and the USA
- ✓ 350+ REACH registrations by the 2010 deadline
- ✓ Language support in 10+ different languages
- ✓ more info about Us: www.reachlaw.fi

SERVICE AREAS

✓ Global chemicals regulatory compliance, e.g.

REACH	CLP
Biocides	China REACH
TCCA-Korea	TSCA-USA

✓ We prepare the required dossiers to authorities, SDSs, labels and provide related business strategy, legal and monitoring support.

✓ **www.compliantsuppliers.com**

OUR CLIENTS

- ✓ More than 200 customers from 40+ countries, from Fortune 100 companies to SMEs.
- ✓Major industries served: Oil, chemicals, specialty chemicals, metals, space sector and other downstream users (DU) industries
- ✓ Our customers are manufacturers, importers, traders, DU´s, industry associations and governmental organizations.

Introduction

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

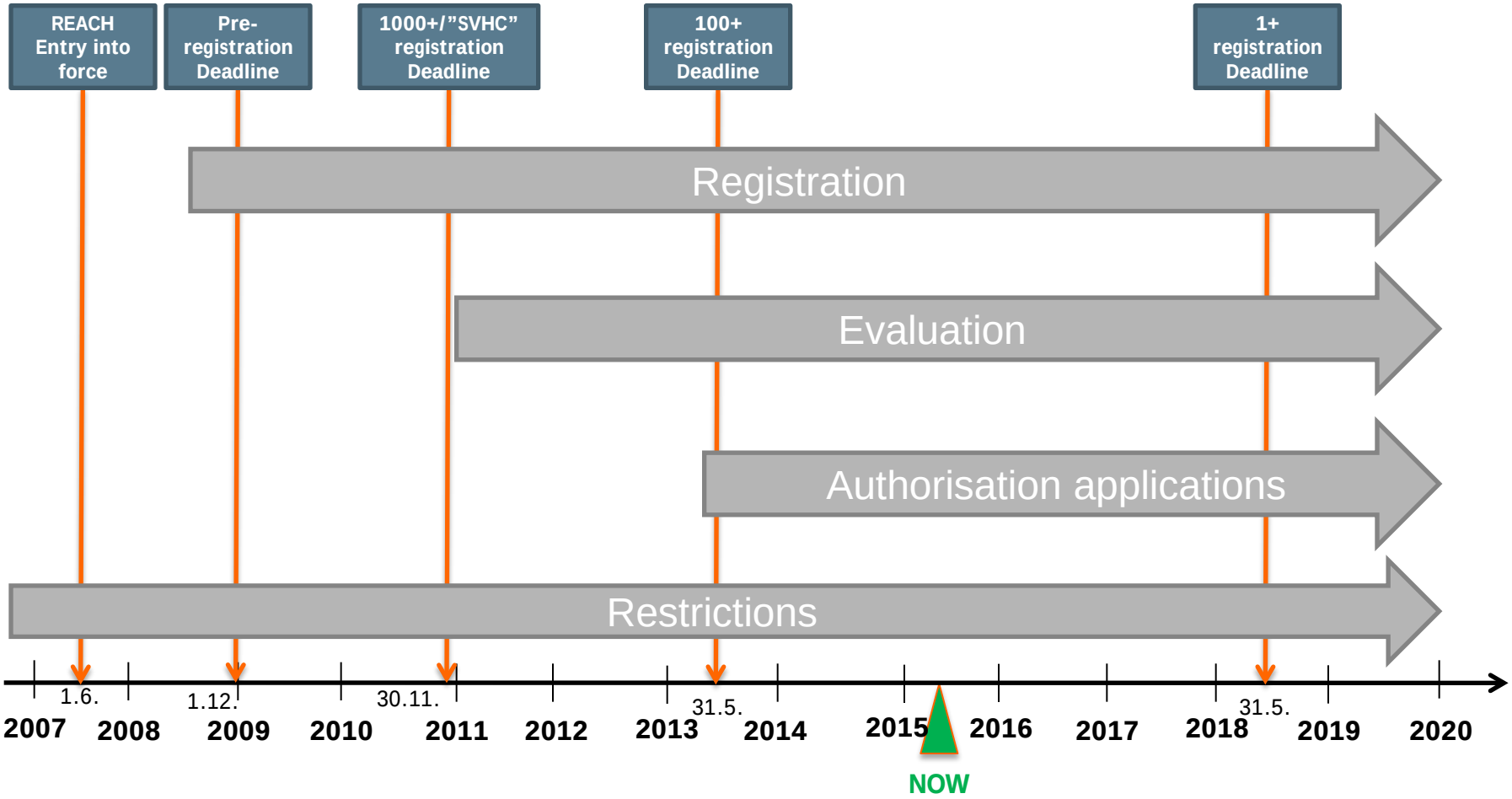
In force since 1.6.2007

Aims:

- Human health
- Environment
- Free circulation
- Competitiveness
- Innovation

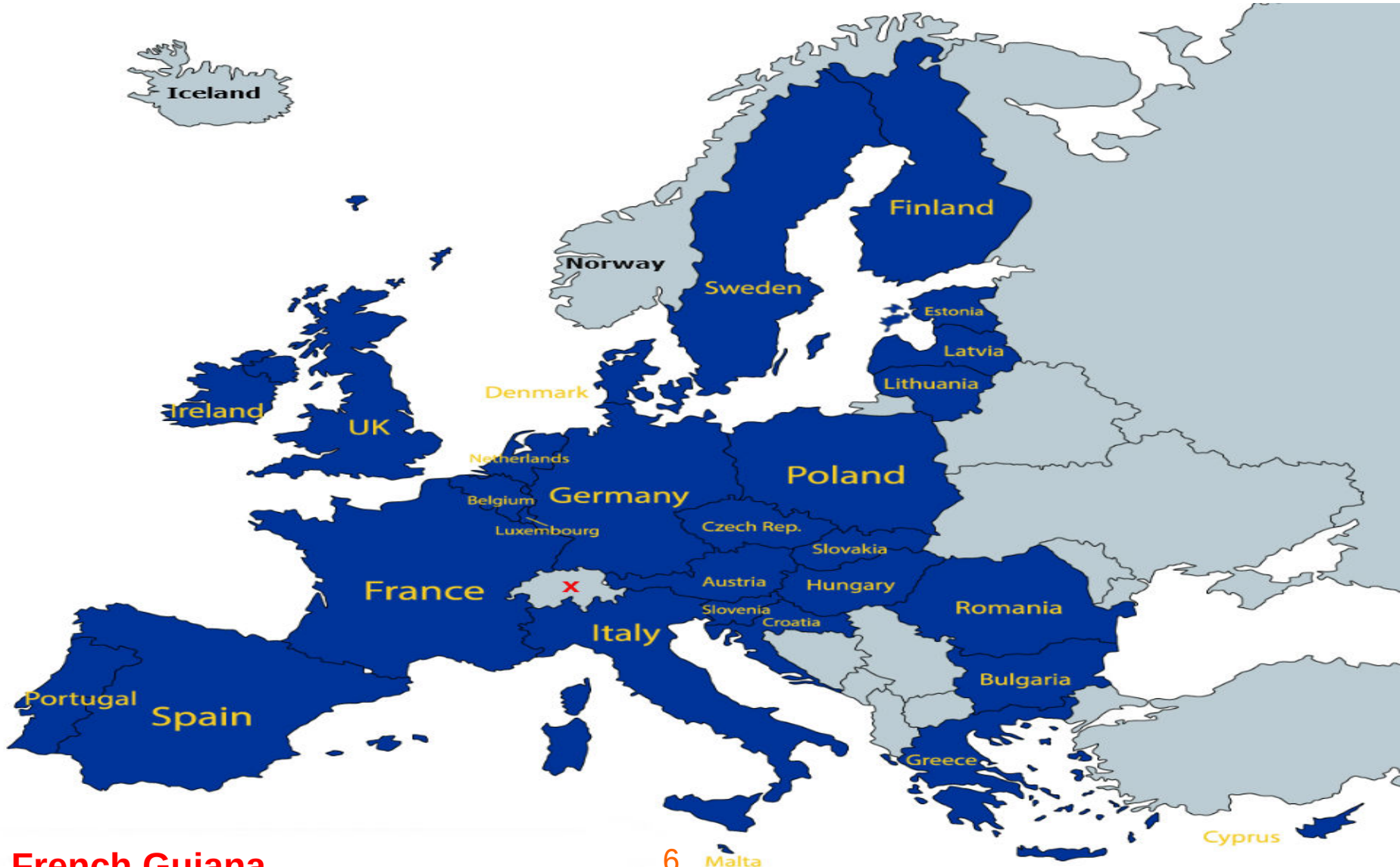
Introduction

Phase-in of REACH processes



Introduction

REACH applies in the entire EU/EEA



+ French Guiana

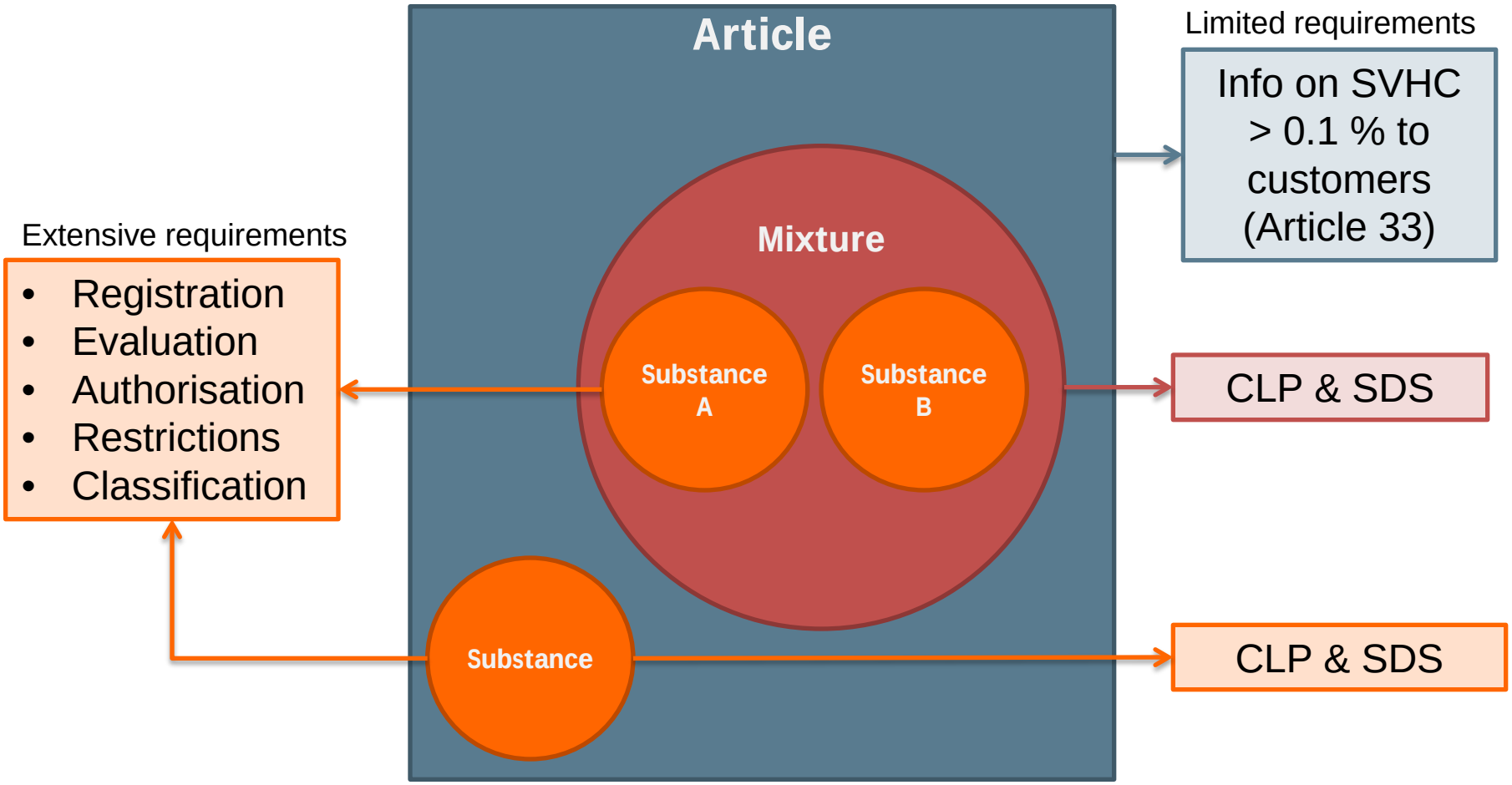
Introduction

Need to translate: Industry terms → REACH terms

- Need to translate terminology and identifiers used in the space / industrial domain into the proper REACH terminology

Space / industrial domain	REACH domain
Chemical	*Substance* • *Intermediate or non-Intermediate* *Mixture (previously called Preparation)*
Materials	*Substance* *Mixture* *Article*
CAS number	*EC number (EINECS, ELINCS, NLP)*
Processes	*Uses* *Manufacturing (of Substances)* *Production (of Articles)*

Introduction I REACH objects

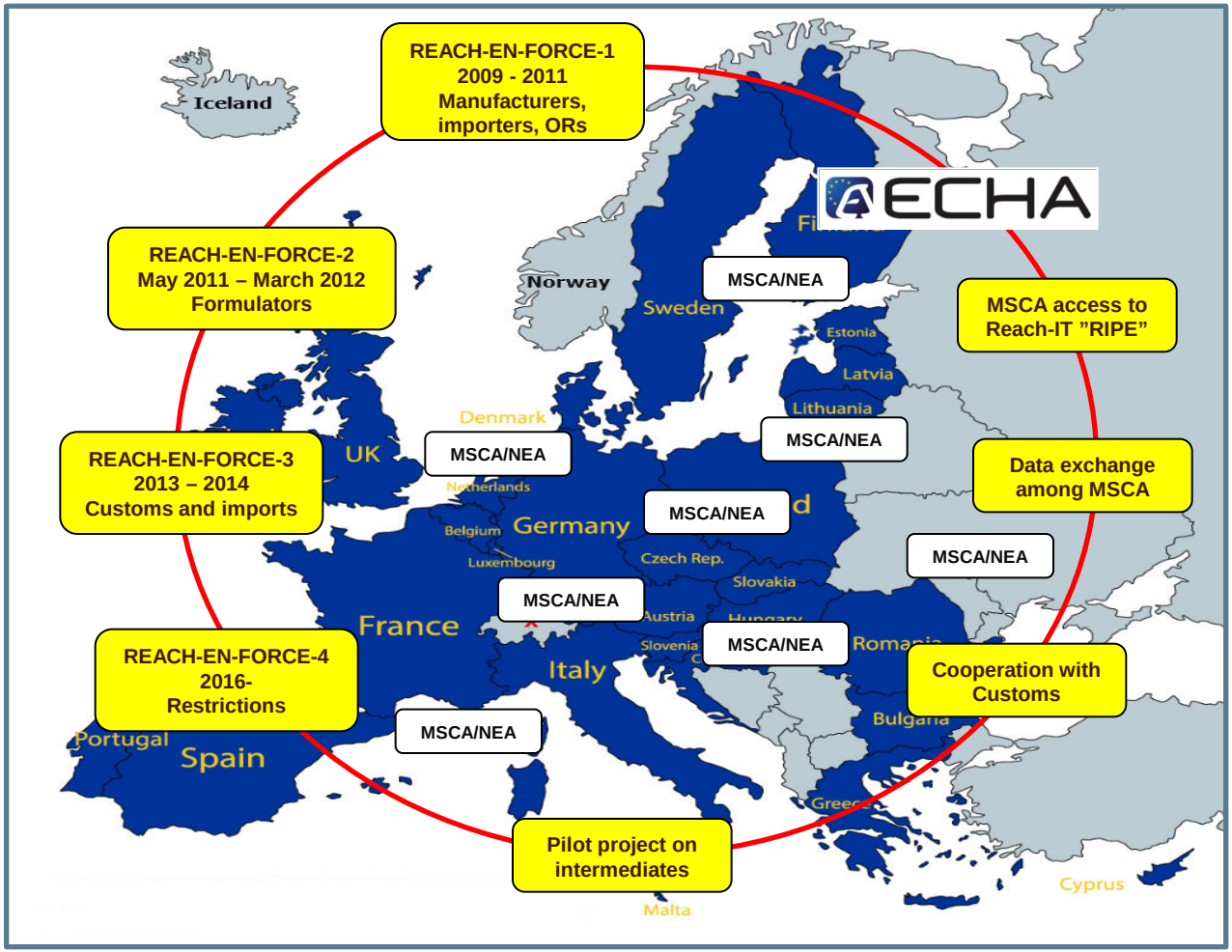


Introduction
REACH subjects (roles)

- Depends on product, origin and how you use it

Manufacturer of substances	**Importer of sub-stances/mixtures**	**Importer of articles**
Supplier of articles	**Distributor**	**Downstream user (incl. formulator)**
Supplier of hazardous sub-stances/mixtures	**Producer of articles**	**Only Representative of non-EEA company**

Introduction
Enforcement of REACH & CLP



- Member States are responsible for REACH & CLP enforcement; co-ordination through ECHA's Forum

- ECHA ensures quality of registration dossiers, may delete invalid pre-registrations and makes registration information available to MSCA for enforcement purposes

- Customs authorities may stop non-compliant goods at the border

Introduction
What REACH means for space companies in EU

- Space Industry has many REACH related **legal obligations** to fulfill towards:
  - Public authorities
  - Customers
  - Employees

- On the other hand REACH, because of its stated aim to eliminate the most hazardous substances from the EU, introduces major **direct and indirect risks to the business**:
  - Substances that space companies use may disappear from the market with or without warning ➔ Obsolescence Risks
  - Substances that they use may be affected by hefty price increases due to passing on of compliance costs

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Registration

Registration
No Registration – No Business in EU

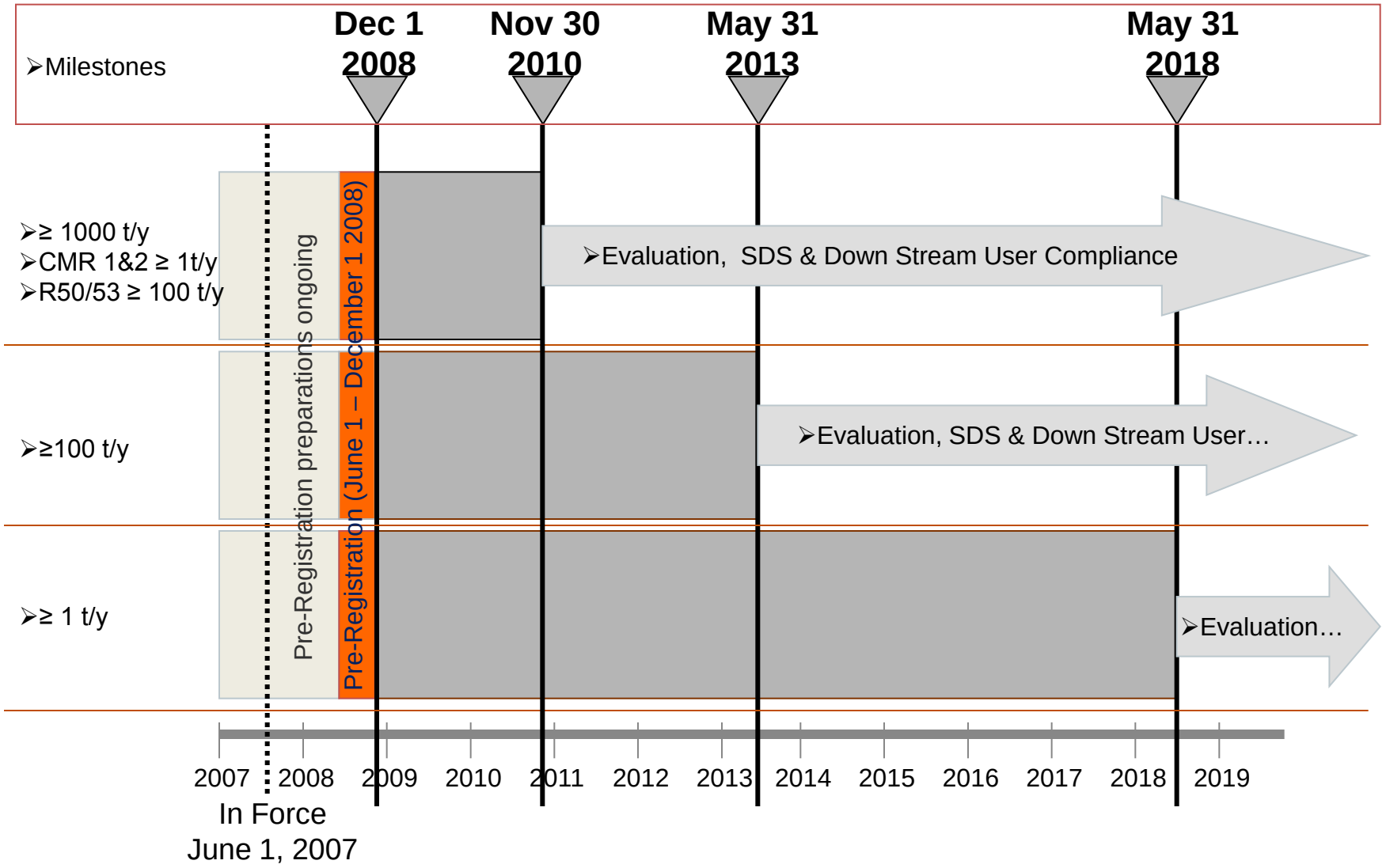
- REACH Article 5:

> **No data, no market**
>
> Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

Registration
Why? What? Who?

- The purpose of registration is to gather adequate information to ensure safe use of chemicals in EU/EEA
- It applies to all substances, on their own or in mixtures, manufactured or imported at 1 tonne or more per year
  - Certain exemptions from registration apply, e.g. to some naturally occuring substances (REACH Annex IV and V)
- Substance manufacturers and substance/mixture importers need to register; non-EEA manufacturers and formulators may appoint an Only Representative in EEA
- Registrations are submitted to the European Chemicals Agency (ECHA) via an online tool called REACH-IT
- Information requirements depend on the tonnage band and are reduced for ”intermediates” under ”strictly controlled conditions”

Registration I When? (existing chemicals)



Registration
Current status

- After passing of two registration deadlines (2010 and 2013) the registration process is fairly mature today
- As of 06/03/2015 a total of 41 223 registrations have been submitted for 8 269 substances
  - Intermediates: 8 675 registrations for 4 010 substances
  - Mostly by large manufacturers and importers
- Significant increase expected by the final registration deadline on 31/05/2018 for low volumes, between 1-100 tonnes per year.
  - ECHA expects up to 70 000 registrations
  - Challenge for SMEs, many of them not being part of chemical industry; large portfolios to be registered for large companies
- Latest statistics:
  - http://echa.europa.eu/regulations/reach/registration/registration-statistics

Evaluation
Why? What? Who?

Evaluation comprises authority-driven follow-up processes to registration to ensure that the information is sufficient to ensure safe use

Dossier evaluation by ECHA

- **Compliance check of dossiers**
- **Examination of testing proposals**

Substance evaluation by Member States

Community Rolling Action Plan (CoRAP)

- To clarify risks
- Annual update
- **May result in proposals for harmonized classification, authorisation, restriction, etc.**

Authorisation

Authorisation
Aim of authorisation

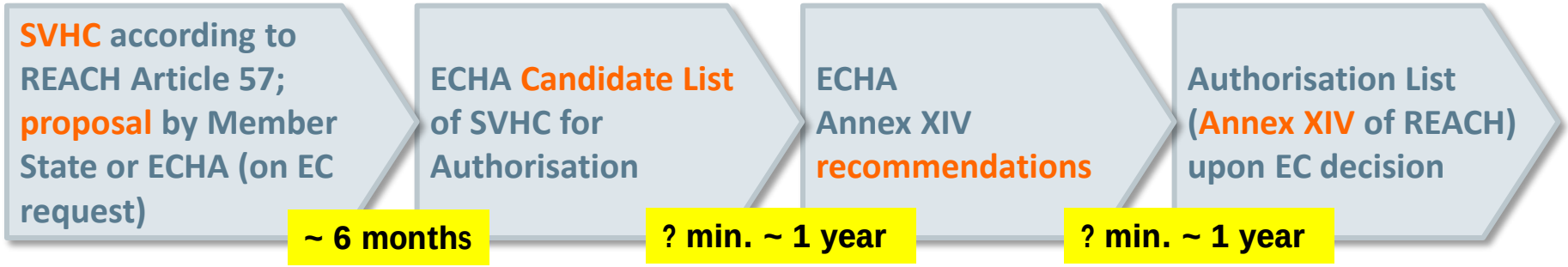
- REACH Article 55:

> *Article 55*
>
> **Aim of authorisation and considerations for substitution**
>
> The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

- No authorisation – no business / use

Authorisation – Listing process

Overview



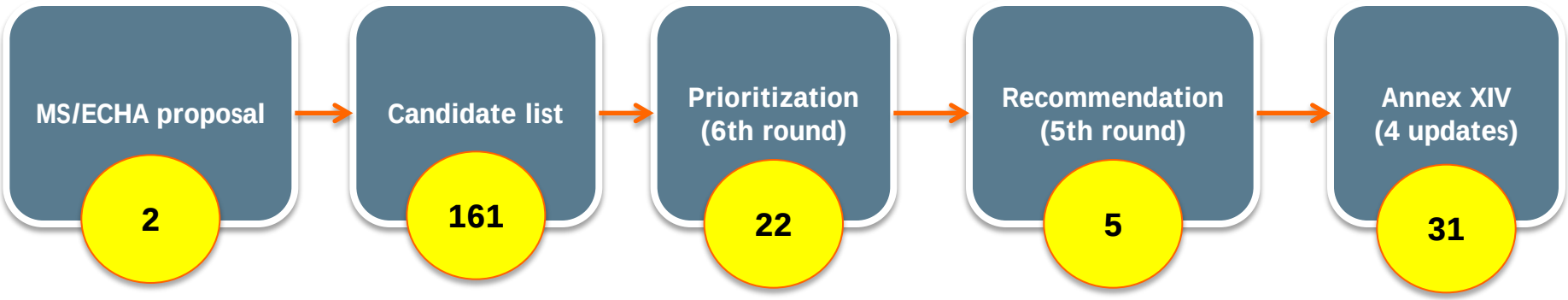
- SVHC identification is based on the substances' inherent properties causing concern for HH or Env
- The ECHA Registry of Intentions shows the imminent candidates selected by the Member States and ECHA (on EC request)
- Since September 2014 ECHA's PACT-RMOA list can be consulted as a pre-warning

- Once on the Candidate list, ECHA prioritises certain substances for authorisation. Priority shall normally given to substances with PBT or vPvB properties, wide dispersive use or high volumes
- During the prioritization process interested parties are invited to submit comments while ECHA builds the case.
- Once the prioritization process is complete ECHA recommends selected SVHC's to the EC for Annex XIV inclusion.
- The EC makes the final decision which substances are included in Annex XIV, taking into account socio-economic consequences

- Annex XIV foresees a latest application date and sunset date for each substance
- In principle, only authorised uses of the substance are permitted after the so-called sunset date, all other uses are prohibited.

Authorisation – Listing process

Current status



SVHCs meeting the definition in REACH Article 57

- Phthalates
- Lead substances
- Boron substances
- Coal tar substances
- 1-bromopropane
- 4-Nonylphenol, branched and linear

Final ECHA recommendation expected in July 2015

- N,Ndimethylformamide (DMF)
- Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA)
- Aluminosilicate Refractory Ceramic Fibres (Al-RCF)
- Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)
- 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated

Annex XIV inclusion postponed by EC

- Phthalates
- Chromates
- Lead compounds
- Arsenic compounds
- Solvents
- Other

Authorisation - Listing process

Annex XIV current status: after 3rd update

Ref	Nr	Substance name	EC	Latest application date	Sunset date (+ 18 m)	Exemptions in Annex XIV
COM Reg (EU) 143/2011 of 17 February 2011	1	musk xylene	201-329-4	21 Feb 2013	21 Aug 2014	None
	2	4,4'- Diaminodiphenylmethane (MDA)	202-974-4	21 Feb 2013	21 Aug 2014	None
	3	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified	247-148-4 and 221-695-9	21 Feb 2014	21 Aug 2015	None
	4	Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	21 Aug 2013	21 Feb 2015	uses in the immediate packaging of medicinal products
	5	Benzyl butyl phthalate (BBP)	201-622-7	21 Aug 2013	21 Feb 2015	
	6	Dibutyl phthalate (DBP)	201-557-4	21 Aug 2013	21 Feb 2015	
COM Reg (EU) 125/2012 of 14 February 2012	7	Diisobutyl phthalate (DIBP)	201-553-2	21 Aug 2013	21 Feb 2015	None
	8	Diarsenic trioxide	215-481-4	21 Nov 2013	21 May 2015	None
	9	Diarsenic pentaoxide	215-116-9	21 Nov 2013	21 May 2015	None
	10	Lead chromate	231-846-0	21 Nov 2013	21 May 2015	None
	11	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	21 Nov 2013	21 May 2015	None
	12	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	235-759-9	21 Nov 2013	21 May 2015	None
	13	Tris (2-chloroethyl) phosphate (TCEP)	204-118-5	21 Feb 2014	21 Aug 2015	None
	14	2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	21 Feb 2014	21 Aug 2015	None
COM Reg (EU) No 348/2013 of 17 April 2013	15	Trichloroethylene	201-167-4	21 Oct 2014	21 Apr 2016	None
	16	Chromium trioxide	215-607-8	21 March 2016	21 Sept 2017	None
	17	Acids generated from chromium trioxide and their oligomers	231-801-5 236-881-5	21 March 2016	21 Sept 2017	None
	18	Sodium dichromate	234-190-3	21 March 2016	21 Sept 2017	None
	19	Potassium dichromate	231-906-6	21 March 2016	21 Sept 2017	None
	20	Ammonium dichromate	232-143-1	21 March 2016	21 Sept 2017	None
	21	Potassium chromate	232-140-5	21 March 2016	21 Sept 2017	None
	22	Sodium chromate	231-889-5	21 March 2016	21 Sept 2017	None

Authorisation - Listing process

Annex XIV 4th update: EC Regulation (EU) 895/2014[1]

- In force since 22 August 2014

Ref	Nr	Substance name	Annex XIV property	EC	Latest application date	”Sunset date” (+18 months)
COM Reg (EU) 895/2014	23	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	Carc 1B	500-036-1	22 February 2016	22 August 2017
	24	Arsenic Acid	Carc 1A	231-901-9	22 February 2016	22 August 2017
	25	Bis(2-methoxyethyl)ether (Diglyme)	Repro 1B	203-924-4	22 February 2016	22 August 2017
	26	1,2-Dichloroethane (EDC)	Carc 1B	203-458-1	22 May 2016	22 November 2017
	27	2,2’-dichloro-4,4’-methylenedianiline (MOCA)	Carc 1B	202-918-9	22 May 2016	22 November 2017
	28	Dichromium tris(chromate)	Carc 1B	246-356-2	22 July 2017	22 January 2019
	29	Strontium chromate	Carc 1B	232-142-6	22 July 2017	22 January 2019
	30	Potassium hydroxyoctaoxodizincatedichromate	Carc 1A	234-329-8	22 July 2017	22 January 2019
	31	Pentazinc chromate octahydroxide	Carc 1A	256-418-0	22 July 2017	22 January 2019

- No exemptions or review periods set in Annex XIV entries

[1]http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_244_R_0003&from=EN

Authorisation – Listing process
The EC SVHC Roadmap to 2020 (05.02.2013)

- Aims to identify and include in the REACH candidate list all relevant currently known SVHCs by 2020 (no numerical goal)
- For the public the roadmap aims to improve predictability of SVHCs and risk management options (RMOs)
  - Publication of Substance-specific info by ECHA ("PACT")
  - Harmonization of SVHC identification and RMO Analysis

SVHC Roadmap 2020 Criteria	Yes	No
a) Art 57 criteria fulfilled	✓	
b) Full registrations (Art. 10)	✓	
c) Registration includes uses within scope of authorisation	✓	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	✓	

Authorisation – Listing process

Substances under scrutiny: The new PACT list

Public Activities Coordination Tool (PACT), first published by ECHA on 23.9.2014

Showing 1 - 20 of 80 results. Items per Page 20 Page 1 of 4 First Previous Next Last

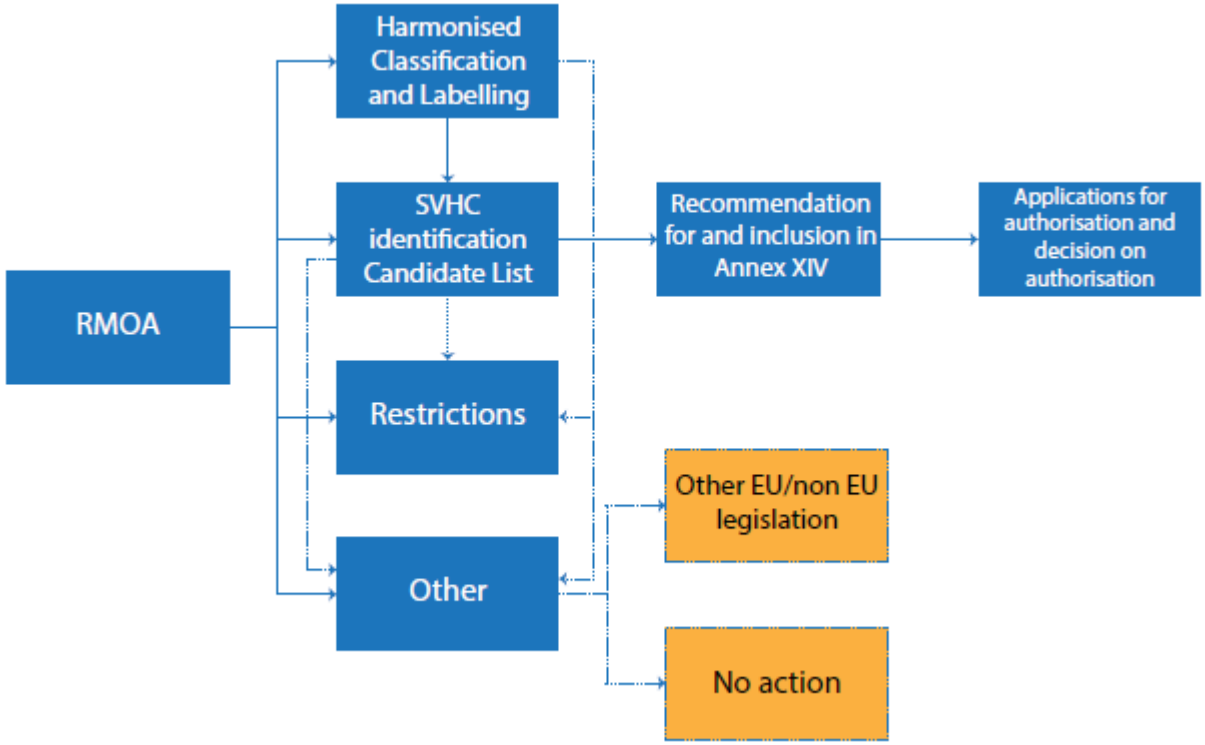
Substance Name	EC Number	CAS Number	Scope	Authority	RMOA Conclusion	Suggested follow up	
(±)-1,7,7-trimethyl-3-[(4-methylphenyl) methylene]bicyclo [2.2.1]heptan-2-one	253-242-6	36861-47-9	ED	Germany	Under development		Details
1,3-propanesultone	214-317-9	1120-71-4	CMR	ECHA	Under development		Details
2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine	426-040-2	25713-60-4	PBT	Netherlands	Under development		Details
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	239-622-4	15571-58-1	CMR	Austria	Appropriate to initiate regulatory risk management action.	SVHC	Details
DINCH	431-890-2	166412-78-8		France	Under development		Details

http://www.echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact

Authorisation – Listing process I PACT list extension to substances subject to a hazard assessment

Further info: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

Authorisation – Listing process
Risk Management Option Analysis (RMOA)



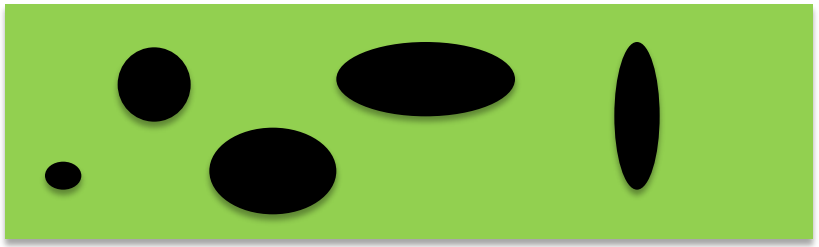
Source: ECHA, link to Annual Report dd. 23 March 2015:
http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf

An alternative RMO: Restriction
Why? What? Who?

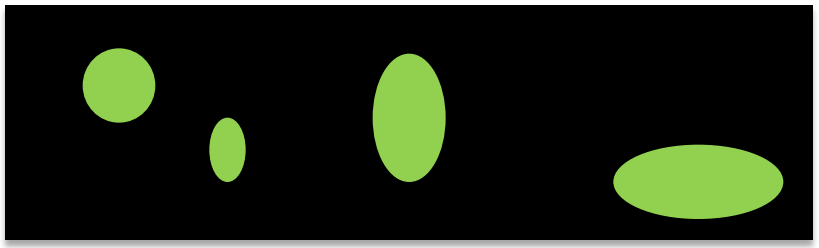
Restriction is a flexible instrument used as "safety net" to limit uses of substances posing an *unacceptable risk* to human health or the environment

- REACH Annex XVII on restrictions has replaced the Marketing and Use Directive (76/769/EEC) on 1.6.2009
- New process for adopting new restrictions: REACH Title VIII
  - Proposals by Member States or by ECHA (on EC request)
  - Stakeholder consultations
- Restrictions are increasingly considered as alternative to authorisation
  - Non-restricted uses can be continued without authorisation.

- Restriction: *Permitted unless banned*



- Authorisation: *Banned unless authorised*



An alternative RMO: Restrictions I E.g. Solvents

Name	EC number	Candidate List	Prioritized	Annex XIV Inclusion	Latest appl. date	Sunset date	Comments
Trichloroethylene	201-167-4	Carc.	20/12/2011	21/04/2013	21/10/2014	21/04/2016	
1,2-Dichloroethane (EDC)	203-458-1	Carc.	17/01/2013	22/08/2014	22/05/2016	22/11/2017	
Bis(2-methoxyethyl) ether (Diglyme)	203-924-4	Reprotox.	17/01/2013	22/08/2014	22/02/2016	22/08/2017	
N,N-dimethylacetamide (DMAC)	204-826-4	Reprotox.	17/01/2013	EC: Put on hold to await RAC / SEAC opinions on NMP restriction	TBC	TBC	
N,N-dimethylformamide (DMF)	200-679-5	Reprotox.	06/02/2014	TBC	TBC	TBC	PACT list: RMOA by Italy concluded: restriction process launched
1-methyl-2-pyrrolidone (NMP)	212-828-1	Reprotox.	*Priority (28) high, but->*				Restriction proposed by RAC&SEAC
2-Methoxyethanol	203-713-7	Reprotox.	*Priority (18) moderate*				
2-Ethoxyethanol	203-804-1	Reprotox.	*Priority (16) moderate*				
Formamide	200-842-0	Reprotox.	*Priority (14) moderate*				

Authorisation – Application process
Who? What? When?

- Applications for authorisation have to be made for a specific use of a substance included in Annex XIV, unless an exemption applies.
- Unlike for registration, there is no minimum tonnage threshold.
- The application should be made by the "latest application date", in order to ensure continued use after the "sunset date" **~ min. 3 years after listing**
- Potential applicants include manufacturers, importers and downstream users of the substance, incl. as part of mixtures.
- To be successful, the application must include a chemical safety report, analysis of alternatives and socio-economic analysis for the use.
- Applications are submitted to ECHA and reviewed by its Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC); the EC decides whether or not to grant the authorisation.
- Re-application required after a review period set by the EC: short – 4 years; normal – 7 years; long – 12 years; other – case-specific.

Authorisation – Application process
Resources required

PARAMETERS

Resources for authorisation applications are very case-specific. They may depend on e.g.

- Number of companies to be covered (supplier vs. DU AfA)
- Availability of relevant information / analyses; non-use scenario
- Workload during ECHA/EC decision-making process

TIME

- Preparation of application: e.g. ~ 3 months – 2 years
- ECHA/EC decision making process: ~ 12 – 24 months

FINANCIAL

- Expert support for full dossier preparation and project management: Approximate range: EUR 50 000 – EUR 500 000 per use
- ECHA application fee: min. EUR 53 300 for non-SMEs (one use)
- Possible third party fees, e.g. ”letter of access”
- Use of own manpower within the company

+ actual testing and substitution costs !!! (millions…)
+ any costs for preparatory sector surveys / analyses
+ any costs for participation in ECHA/EC consultations prior to Annex XIV listing
Note: Companies may collaborate and share costs (task forces/consortia)

PERSONNEL

- Specialists within the company: their working time and travel expenses
- External specialists: consultants for CSR, AoA and SEA

Authorisation – Application process
Status of Applications for Authorisation (AfA)

- AfA process has passed the starting phase
- 28 applications / 44 applicants
- 3 AfAs have reached end of pipeline: granted
  - No rejections proposed so far, but conditions
- Main types of AfAs submitted:
  - Downstream user applications for specific uses
  - Supplier applications for broad(er) uses
- Review periods proposed by ECHA RAC/SEAC range from 22 months to 12 years.
- In some cases additional risk management conditions are imposed by ECHA RAC/SEAC
- Simplification of authorisation for special uses under development by EC and ECHA:
  - Uses in low volumes
  - Uses in legacy spare parts
  - Other cases discussed

Space sector response being finalized

- Upcoming chromates applications (from ECHA Newsletter, October 2014):

UPCOMING CHROMATES APPLICATIONS

March 2016 is the latest application deadline for a group of chromium VI substances that are listed on the Authorisation List (Annex XIV of REACH). These substances are used by many companies in Europe. So far, ECHA has received over 150 notifications of potential applications for 2015. These relate mainly to different uses of chromates, ranging from plating for corrosion prevention in the automotive industry, to very niche uses in the health care sector. ECHA has collaborated with aviation, space and metals industries from 2013 onwards to make sure that the applicants are fully aware of what is needed for their application.

In November, ECHA will participate in a Eurometaux/Cefic seminar for potential applicants for chromates and share the lessons learnt from applications received so far. The chromate applications will start to go through ECHA's opinion-making system in 2015. Companies who want to request a pre-submission information session are requested to do so well in advance of their application.

Authorisation – Application process
Latest (3rd) EC decision

Summary of Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Published pursuant to Article 64(9) of Regulation (EC) No 1907/2006 (1))

(Text with EEA relevance)

(2015/C 91/02)

Decisions granting an authorisation

Reference of the decision (1)	Date of decision	Substance name	Holder of the authorisation	Authorisation number	Authorised use	Date of expiry of review period	Reasons for the decision
C(2015) 1619	17 March 2015	Bis(2-ethylhexyl) phthalate (DEHP) EC No 204-211-0 CAS No 117-81-7 Dibutyl phthalate (DBP) EC No 201-557-4 CAS No 84-74-2	Roxel (UK Rocket Motors) Ltd, Summerfield, Kidderminster, DY11 7RZ, Worcestershire, UNITED KINGDOM	REACH/14/3/0 REACH/14/3/1 REACH/14/3/2	The industrial use of DEHP in the manufacture of solid propellants and motor charges for rockets and tactical missiles The industrial use of DBP in the manufacture of solid propellants and motor charges for rockets and tactical missiles The industrial use of DBP within a specialty paint in the manufacture of motors for rockets and tactical missiles	21 February 2019	— Risk is adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006. — There are no suitable alternatives at present and search for technically feasible alternatives is ongoing under a replacement programme with requalification requirements for defence industry products.

(1) The decision is available on the European Commission website at: http://ec.europa.eu/enterprise/sectors/chemicals/reach/authorisation/index_en.htm

Authorisation – Application process

How to construct a good case for authorisation

Objective: Get an authorisation granted by the European Commission with a sufficiently long review period and without limiting conditions and monitoring arrangements.

Means to ensure this: Focus on decision-critical items:

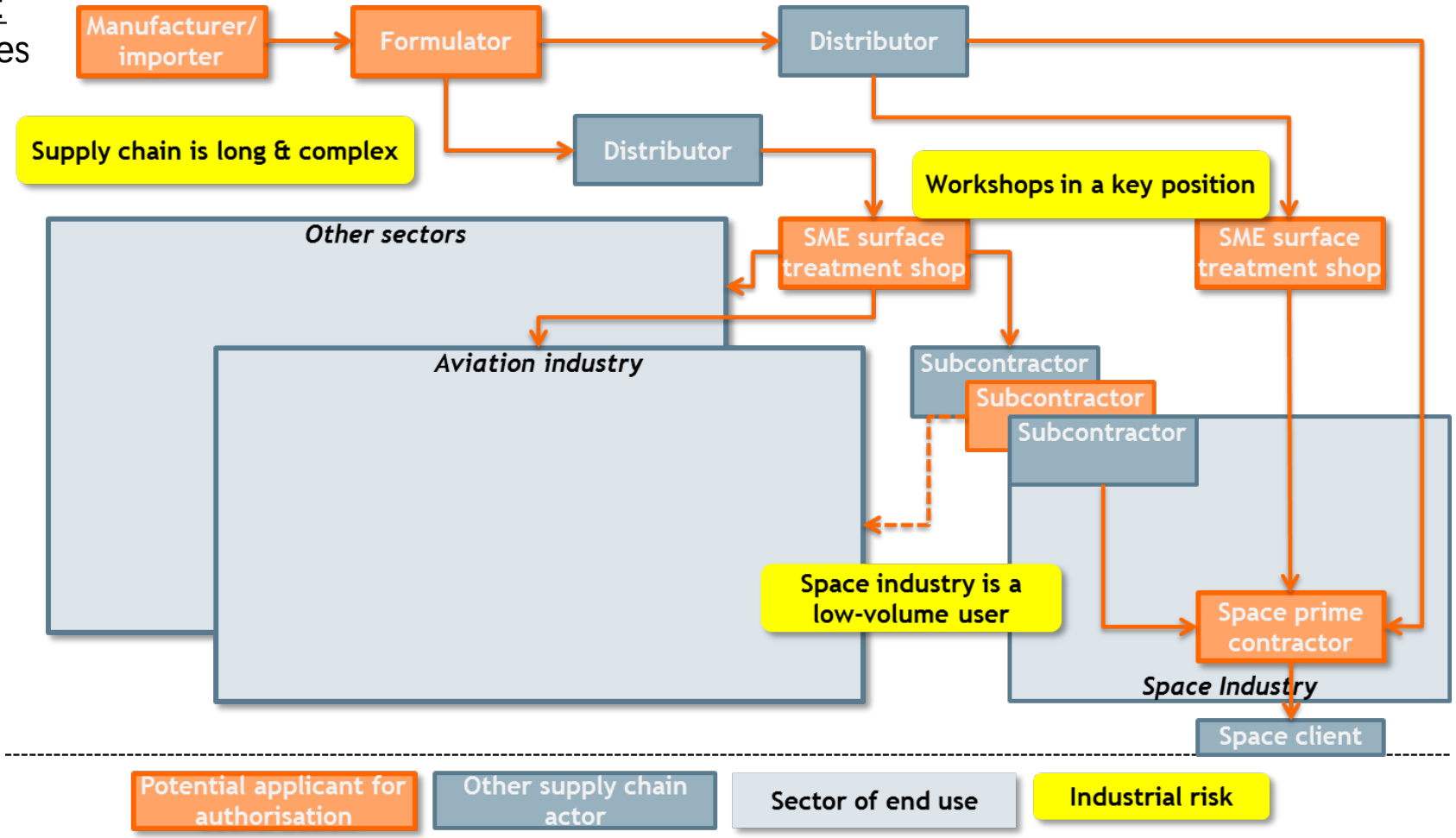
- CSR: Minimization of risks, low volumes
- AoA: Thorough review of alternatives and outline of substitution schedule as basis for setting of review period
- SEA: Socio-economic consequences of non-use/authorisation

The more realistic and credible (i.e. based on facts) the application, the better the chances to get the desired outcome.

Authorisation – Application process

Challenges for space sector

Example:
Chromates



Authorisation enforcement
Authorisation pilot project

- Agreed by ECHA Enforcement Forum
- Targeting the use of Annex XIV substances with a sunset date before 2016
- Targeting whole supply chain, i.e. manufacturers, importers, other suppliers and downstream users
- Inspectors will check for example:
  - that Annex XIV substances with expired sunset date are not on the market without an authorisation
  - if SDS includes the authorisation number
  - Compliance with the conditions of the granted authorisation

- Results of the project are expected at the end of 2016.

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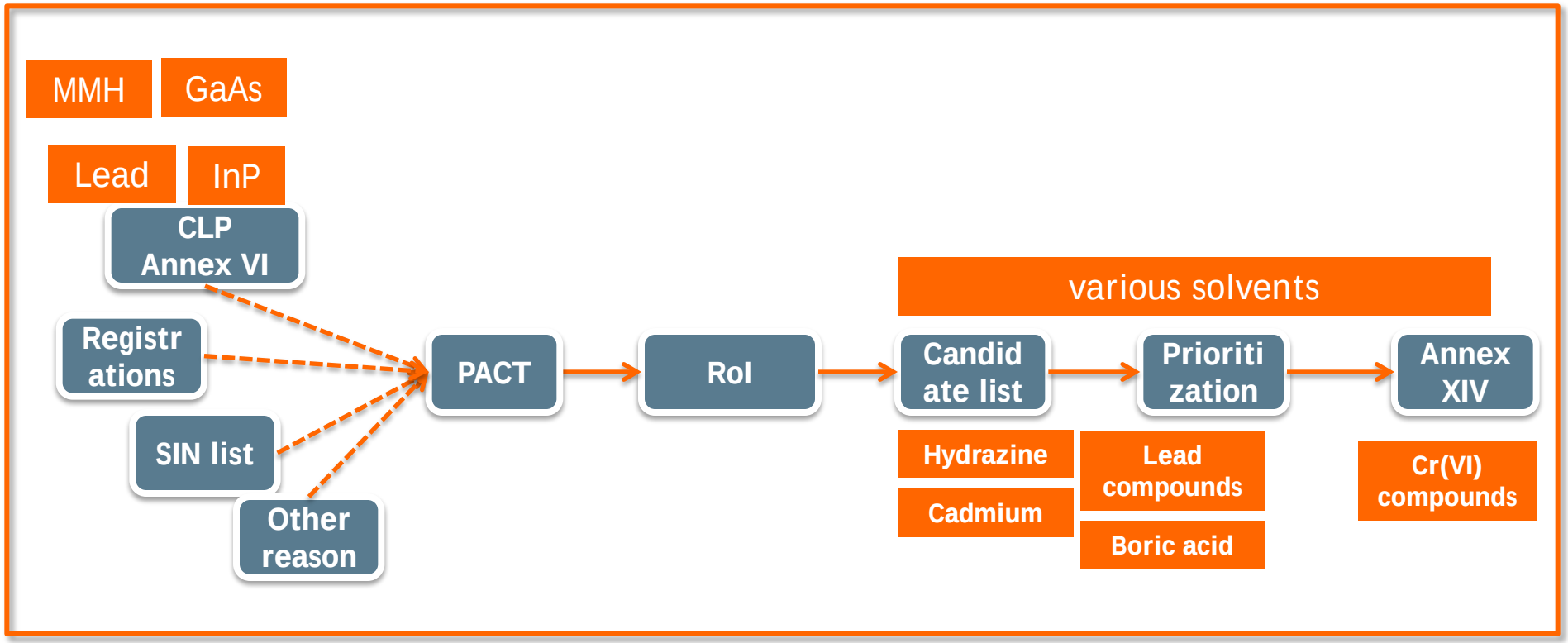
High-risk items for ’space’

Status in CLP and REACH Annex XIV listing process



SVHC of special concern for European space industry

3. High-risk items for ‘space’ – Task Force activities

- **Hydrazine**
- **Chromium trioxide (and other Cr(VI) compunds)**

High-risk items for 'space'
Hydrazine I Status in REACH authorisation process

Main criterion	Sub criterion	Value
Space use	In t/a	*< 10*
	Applications	*Satellite constellations, ESA missions, Auxiliary Power Units, A5 G version, Soyuz Upper stage, VEGA, Lunar/Mars landers*
Classification	SVHC properties	*Carc. 1B (CLP Annex VI)*
Registration	Registered (Y/N, type, number)	*Yes (Full dossier), 6 co-registrants*
	Volume (in t/a)	*> 10,000*
	Uses (main)	*Intermediate, corrosion inhibitor (incl. by professional workers), reducing agent, stabilising reagent, propellant*
Official lists	Candidate list and AXIV	***Candidate List: score 2014: 23 (~ high)***
	Other (e.g. PACT, CoRAP, AXVII)	*No specific listing*
Non-official lists	SIN list (Y/N)	*YES*
	Other lists (cf. www.subsport.eu)	*Not further analysed*
Other comments	Affecting obsolescence risk	*Space exemption from authorisation TBC by the EC*
Conclusion	Level of obsolescence risk	*Probably mid-term: earliest A XIV SSD in Q1/2020; followed up in frame of Hydrazine Space Task Force*

High-risk items for 'space'
Hydrazine I Task Force Creation (since 10/2011)

- Task Force participants (Industry)
  - AIRBUS DEFENCE & SPACE
  - ARIANESPACE
  - ELV S.p.A. / AVIO
  - GHC Gerling, Holz & Co. Handels GmbH
  - HERAKLES
  - MOOG UK Westscott Ltd
  - OHB System AG
  - Surrey Satellite Technology Ltd (SSTL)
  - THALES ALENIA SPACE (TAS)
- Administration
  - Eurospace as Secretariat
  - REACHLaw Ltd as Consultant
- Task Force support (space agencies):
  - European Space Agency (ESA)
  - Centre National d'Etudes Spatiales (CNES)
  - Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR)
- Task Force sector-wide coordination activities
  - REACH/Hydrazine activities monitored by Eurospace WGs:
    - EEE Components
    - Standardization
    - Research and Technology
  - Information exchange with
    - ASD REACH WG (Aerospace)

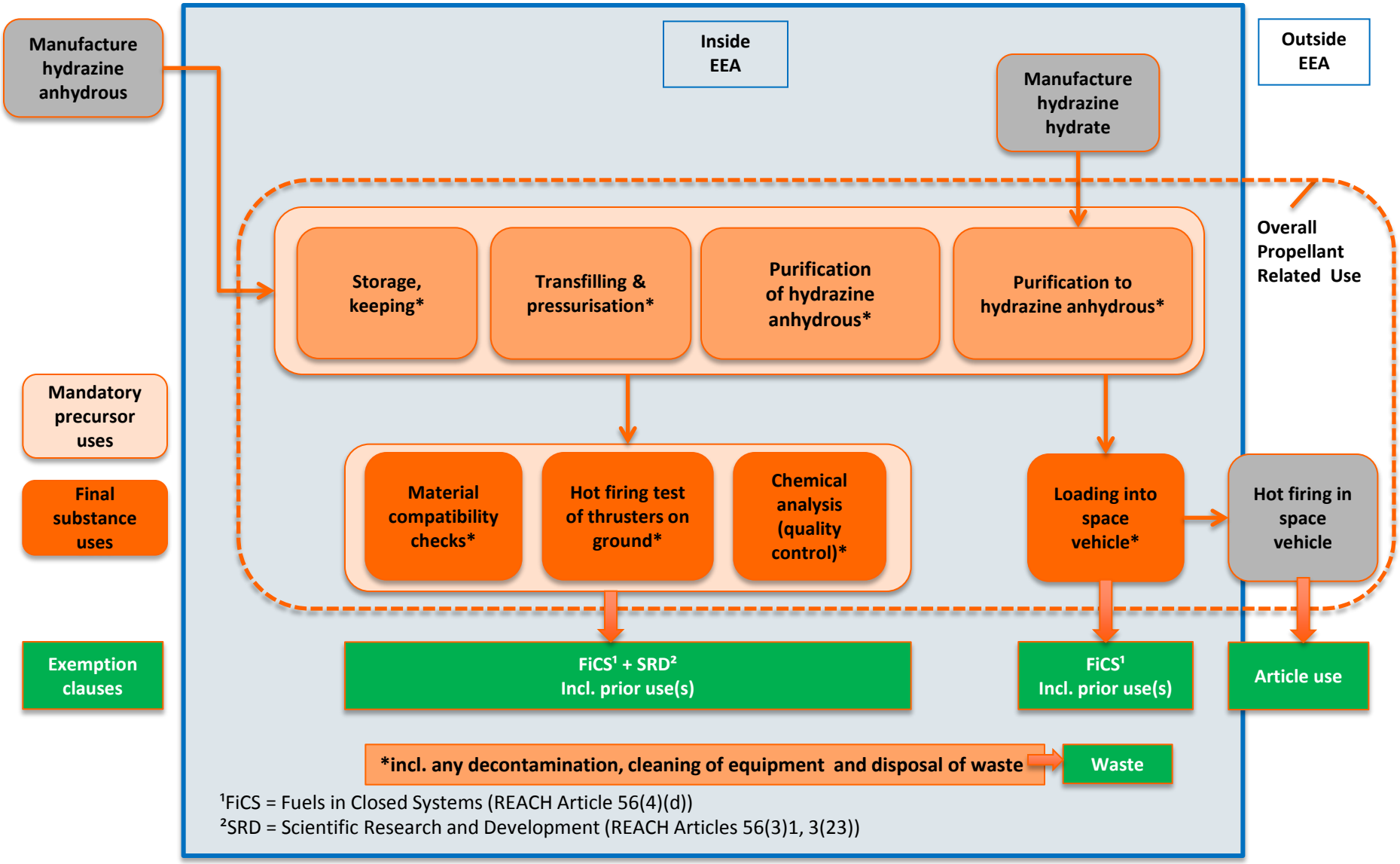
High-risk items for 'space'
Hydrazine I REACH authorisation strategy

- A legal exemption from authorisation was investigated:
  - *"use as fuels in closed systems"*, REACH Art. 56(4)(d) (et al.)
  - If the exemption applies: no need to apply for authorisation

- Actions taken on space sector level:
  1. Eurospace use mapping survey of space industry (Q4/2011)
  2. Technico-legal exemption study by REACHLaw (Q1/2012)
     - Conclusion: exemption based on REACH Art. 56(4)(d) is possible
  3. Eurospace Exemption Position Paper (Q2/2012)
     - Presentation to EC to obtain legal clarification (Q4/2012) – Today, this clarification is still pending. Therefore as additional measure:
  4. Sector-level Socio-Economic and Alternatives Analysis (ongoing)
     - Report to be submitted to the EC in case of Annex XIV prioritisation

High-risk items for 'space'

Hydrazine I Exemption position paper (6/2012)



3. High-risk items for ‘space’ - Task Force activities

- Hydrazine
- Chromium trioxide (and other Cr(VI) compunds)

High-risk items for ’space’
Cr(VI) I Status in REACH authorisation process

Substance name	Description of use	Latest application date	”Sunset date” (+18 months)
Chromium trioxide	Surface treatment of aluminium alloy parts (incl. repair) (chemical conversion coating, sulfochromic pickling and anodization)	21 March 2016	21 Sept 2017
Sodium dichromate	Surface treatment of aluminium alloys and cadmium-plated parts (anodization sealing, chromic finishing of cadmium-plated parts)	21 March 2016	21 Sept 2017
Potassium dichromate	Surface treatment of stainless steel and cadmium-plated parts (chromic finishing of cadmium-plated parts, stainless steel passivation)	21 March 2016	21 Sept 2017
Dichromium tris(chromate)	Repair of surface-treated aluminium alloy parts (chemical conversion coating)	22 July 2017	22 January 2019
Strontium chromate	Primers and jointing compounds (incl. for repair purpose) on aluminium alloy, titanium alloy, steel and composite parts	22 July 2017	22 January 2019
Potassium hydroxyoctaoxodizincatedichromate	Primers on alloy parts	22 July 2017	22 January 2019
Pentazinc chromate octahydroxide	Primers on alloy parts	22 July 2017	22 January 2019

High-risk items for 'space'
Cr(VI) I REACH authorisation strategy

Preparation for REACH authorisation applications is required for certain surface treatment uses of Cr(VI) containing formulations, for which replacement by the sunset date is not possible/sure

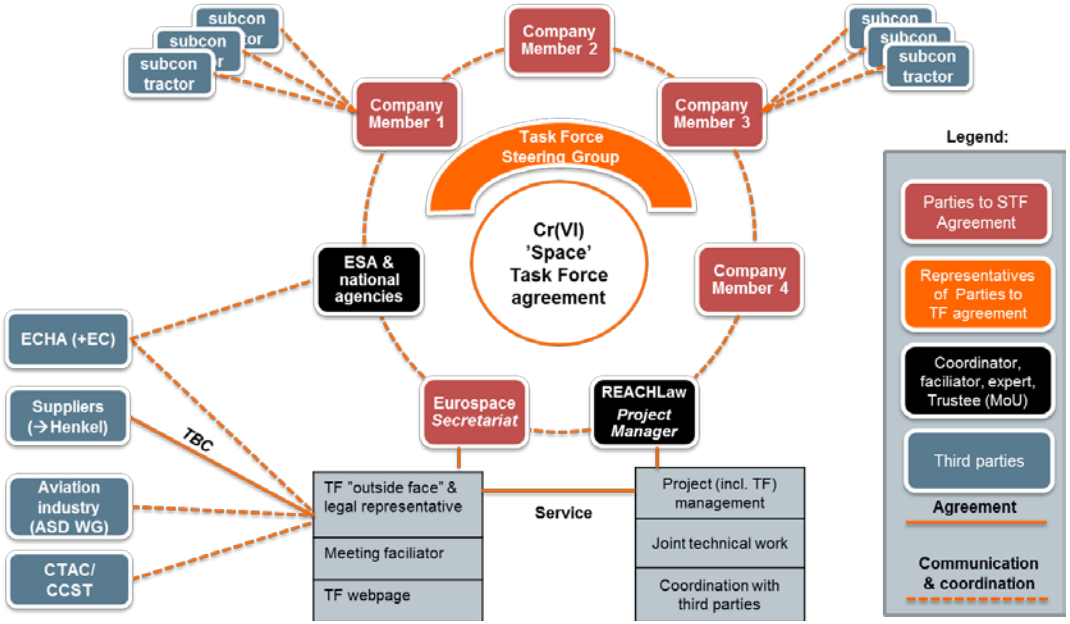
- Chromium trioxide (CrO3) as part of Alodine 1200 (formulator: Henkel) is of key concern to various actors in the European space industry
- Space companies and agencies (ESA, CNES) have the required information to prepare a focused joint Analysis of Alternatives and Socio-Economic Analysis for REACH authorisation
- Because the supply chain for Alodine 1200 is very complex, with many downstream users on different supply chain levels, an upstream supplier (e.g. formulator) is needed to apply for the "space" authorisation
- Other cross-sectoral consortia involving space companies have been created to pursue more generic authorisations for uses of CrO3 ("CTAC") and other CR(VI) substances ("CCST") – need for alignment with space sector activities

High-risk items for 'space'

Cr(VI) I Task Force Creation (6/2013) - Participants

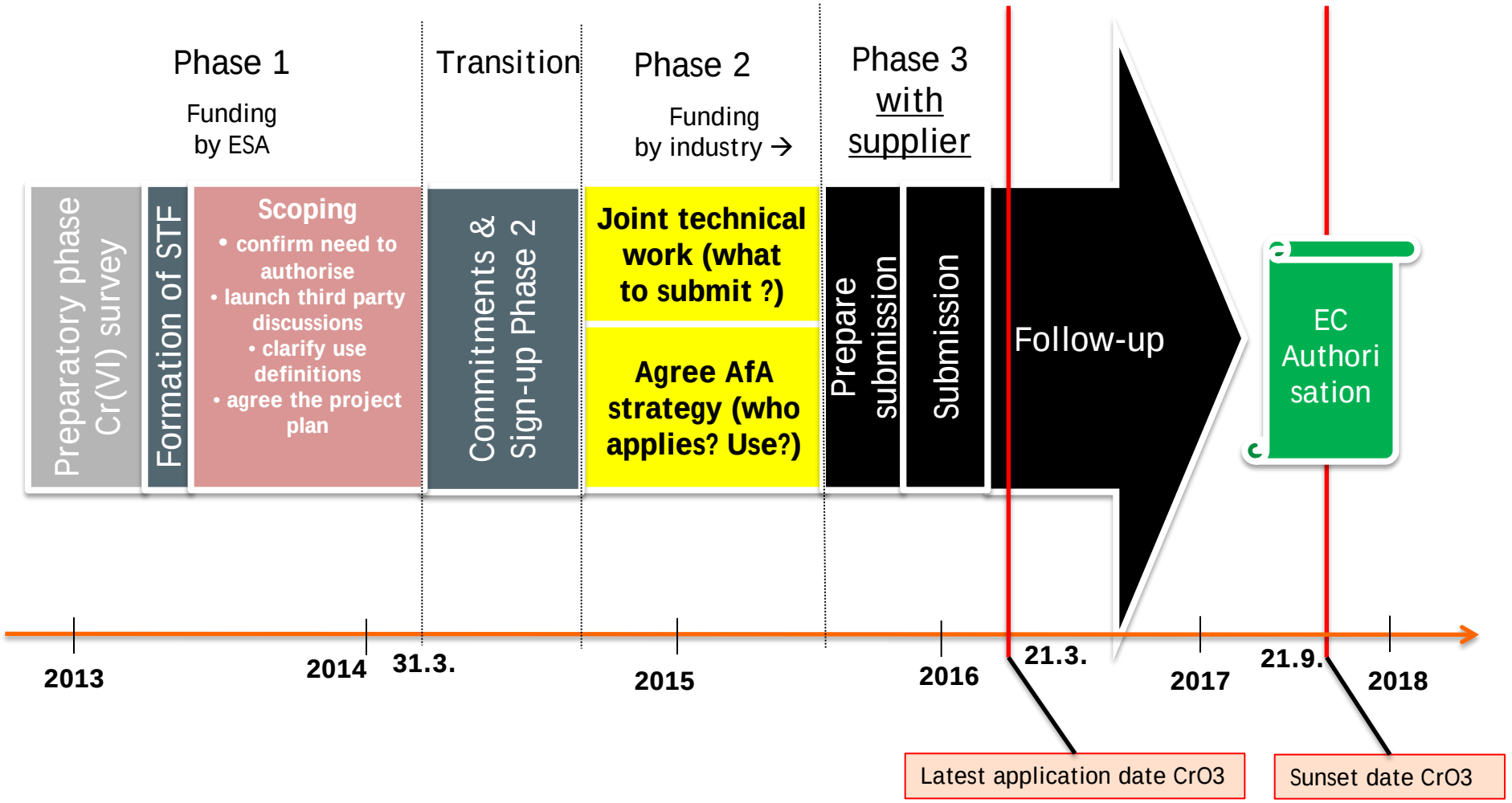
- Task Force participants (Industry)
  - AIRBUS DEFENCE & SPACE
  - AEROSPACE PROPULSION PRODUCTS
  - AVIO
  - EUROPROPULSION
  - HERAKLES
  - OHB SYSTEM AG
  - RUAG SPACE
  - THALES ALENIA SPACE (TAS)
- Administration
  - Eurospace as Secretariat
  - REACHLaw Ltd as Consultant
- Information exchange with
  - ASD REACH WG (Aerospace)

- Task Force support (space agencies):
  - European Space Agency (ESA)
  - Centre National d'Etudes Spatiales (CNES)



High-risk items for 'space'

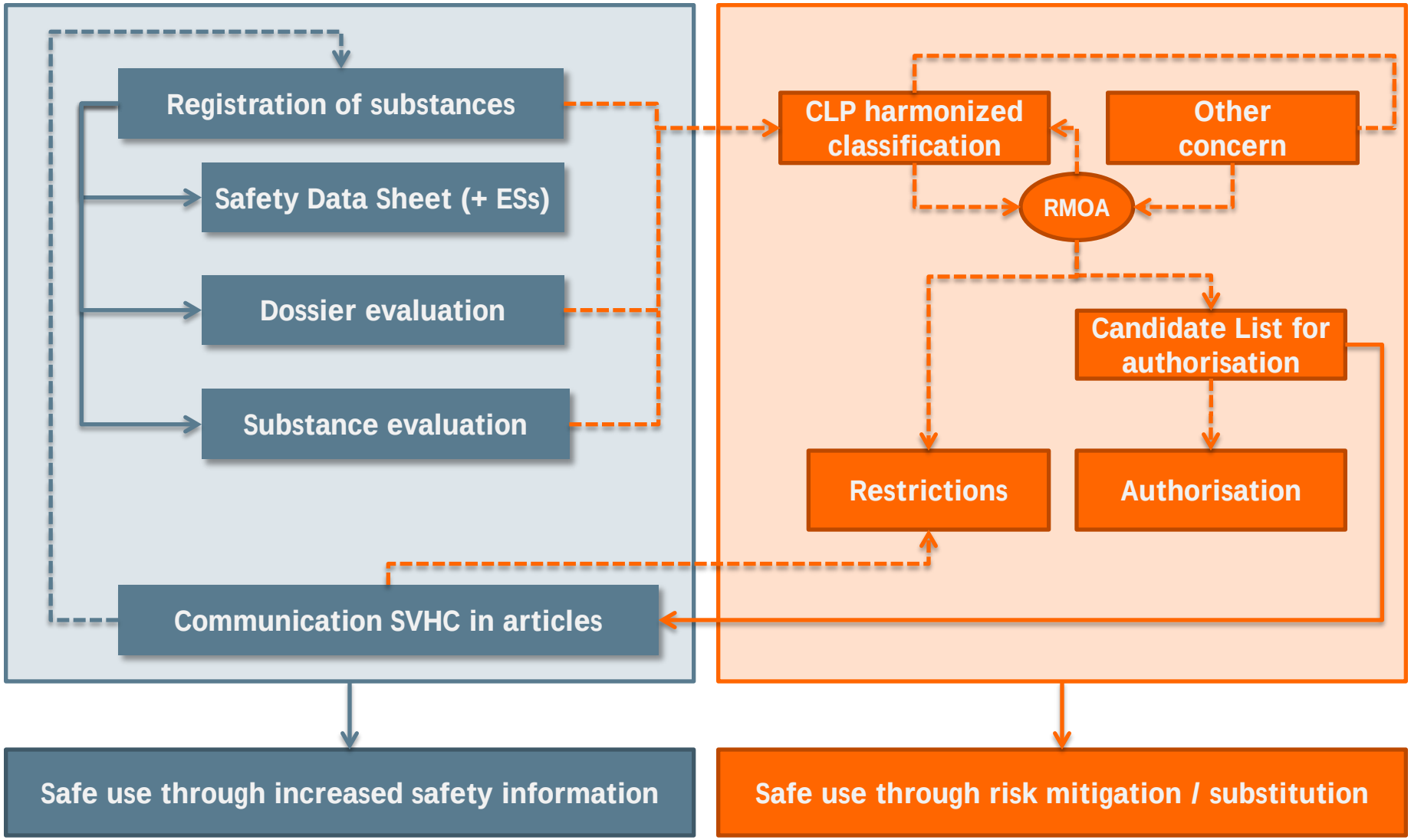
Cr(VI) I Overview of project



REACH OVERVIEW - AGENDA

1. Introduction
2. REACH processes
   - How they work
   - Current status
   - Impact on space sector
3. High-risk items for ‘space’
4. Conclusions

Conclusion I REACH elements



Conclusion
Risk of ”unknowns”

- Non-registered substances, non-authorised uses
- Supplier decisions affecting availability of chemicals
- Predictability of authority decisions (e.g. authorisation, enforcement)
- Limited visibility
  - Upstream supply chain
  - Substances used in processes
- Substitution schedule
  - testing, qualification, industrialisation

Conclusion
Addressing REACH and related risks

Regulatory:	Anticipation of SVHC, Candidate list and authorisation	Registration and safety data sheets
Business:	Substitution of SVHC without impact on space programmes	Stability and control of supply chains to space industry
Solutions:	Collaboration and shared responsibility of space agencies and industry to proactively identify, monitor and mitigate REACH obsolescence risks	

Questions ?

THANK YOU
FOR YOUR ATTENTION !

Compliance. Sustained.

Contact:
Tim Becker
Chief EU Compliance Officer
Tim.becker@reachlaw.fi
+358 40 773 8143

REACHLaw Ltd.
Vänrikinkuja 3 JK 21
02600 Espoo
Finland
www.reachlaw.fi

Additional slides

List of acronyms (1/2)

Abbreviation	Explanation
AfA	Application for Authorisation
AoA	Analysis of Alternatives
CLH	Harmonized Classification & Labelling
CLP	Classification, Labelling and Packaging (Reg. (EC) 1272/2008)
CMR	Carcinogenic, Mutagenic, toxic to Reproduction
CoRAP	Community Rolling Action Plan (for REACH Substance Evaluation)
CSR	Chemical Safety Report
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)
ES	Exposure Scenario annexed to the safety data sheet under REACH
HTF	Hydrazine Space Task Force for REACH
M&P WG	Materials & Processes Working Group facilitated by ESA
MPTB	Materials & Processes Technology Board (previously M&P WG)
MS	Member State
MSCA	Member State Competent Authority
OEL	Occupational Exposure Limit

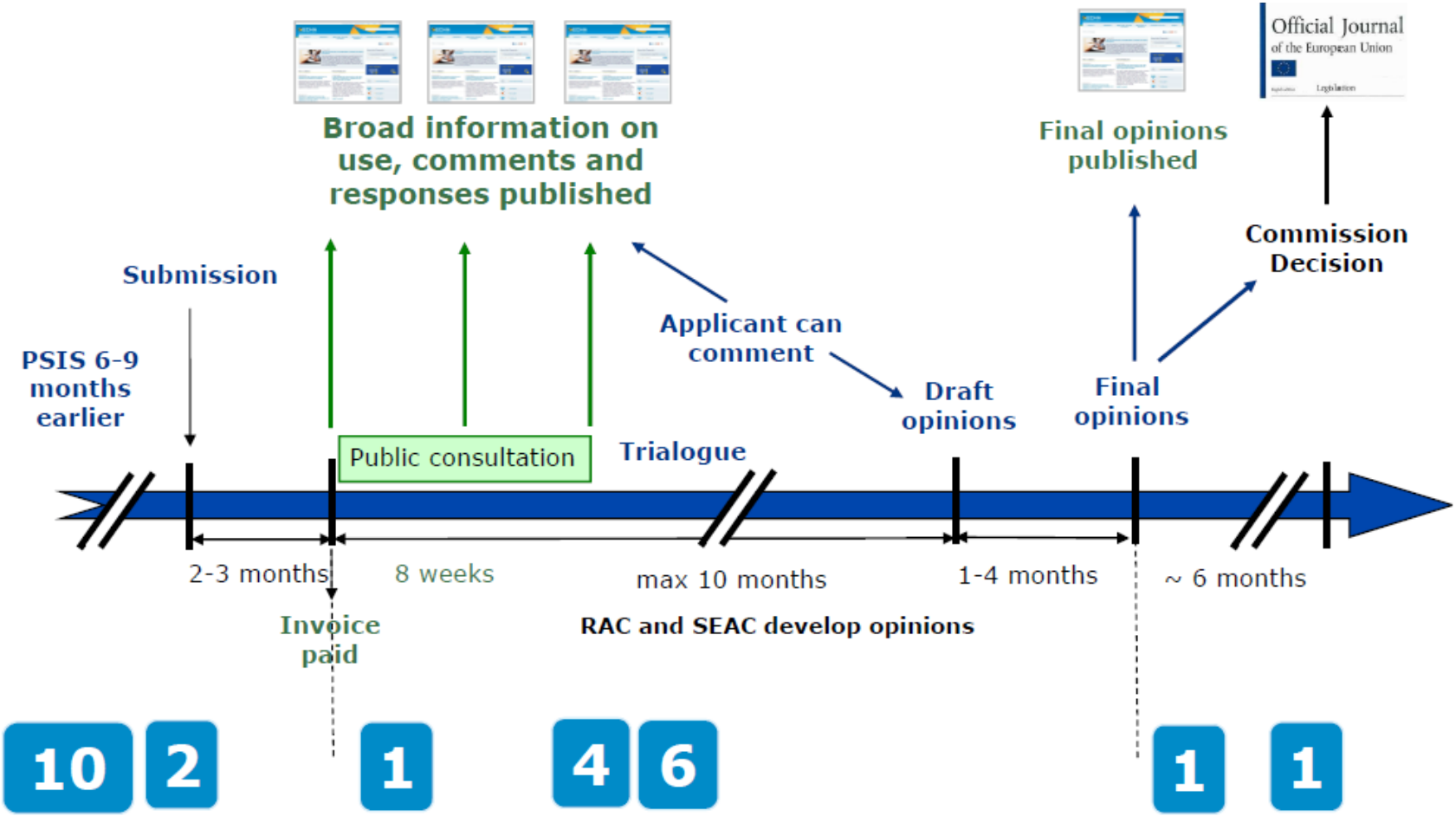
List of acronyms (2/2)

Abbreviation	Explanation
PACT	Public Activities Coordination Tool
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

Simplified authorisation
Special cases under EC consultation or discussion

- Low volumes – EC consultation ongoing (separate MPTB action), implementing act under preparation
- Legacy spare parts – EC consultation ongoing (separate MPTB action), implementing act under preparation
- Type-approval cases (aviation, automotive) – CARACAL discussing alignment of review period with recertification schedule
- Process chemicals and recycling materials – Stakeholder claim (Eurometaux)
- Uses like ”packaging and reformulation” – Stakeholder claim (Eurometaux)
- Uses with high socio-economic values, or substances considered “biologically essential”, such as pharmaceuticals

Application for authorisation process
Overview



Source: ECHA, May 2014