REACHLAW

Making global compliance your business benefit

EU REACH and other International Chemicals Regulations

Overview of current status of REACH and other International Environmental Regulations and how they are impacting the Space Sector including EEE parts

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EU REACH and other International Chemicals Regulations: Agenda

1. Introduction
2. EU: *REACH & RoHS*
3. Beyond EU: Other International Chemicals Regulations
4. The *Materials & Processes Technology Board (ESCC MPTB)*
5. Outlook

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.

EU REACH and other International Chemicals Regulations

Introduction: *Chemicals* legislation builds up globally

- The number and complexity of international environmental regulations has been increasing rapidly over the last ten years, with EU and UN-driven initiatives at the forefront.

- Most of those regulations address the manufacture, import, placing on the market and use of the smallest building blocks for various goods: *chemicals* (substances and formulations)

- Manufacturers and users of EEE components in space systems face both legal and commercial risks and challenges.

EU REACH and other International Chemicals Regulations

Introduction: Obsolescence risks for Space companies

- In the context of chemicals regulations an obsolescence risk in the space industry can be defined as any possibility of impairment of quality and reliability or even loss of critical technologies for qualified materials and processes, which is induced by a chemical's unavailability or substitution threat.
- There are two major forms of such obsolescence risks:

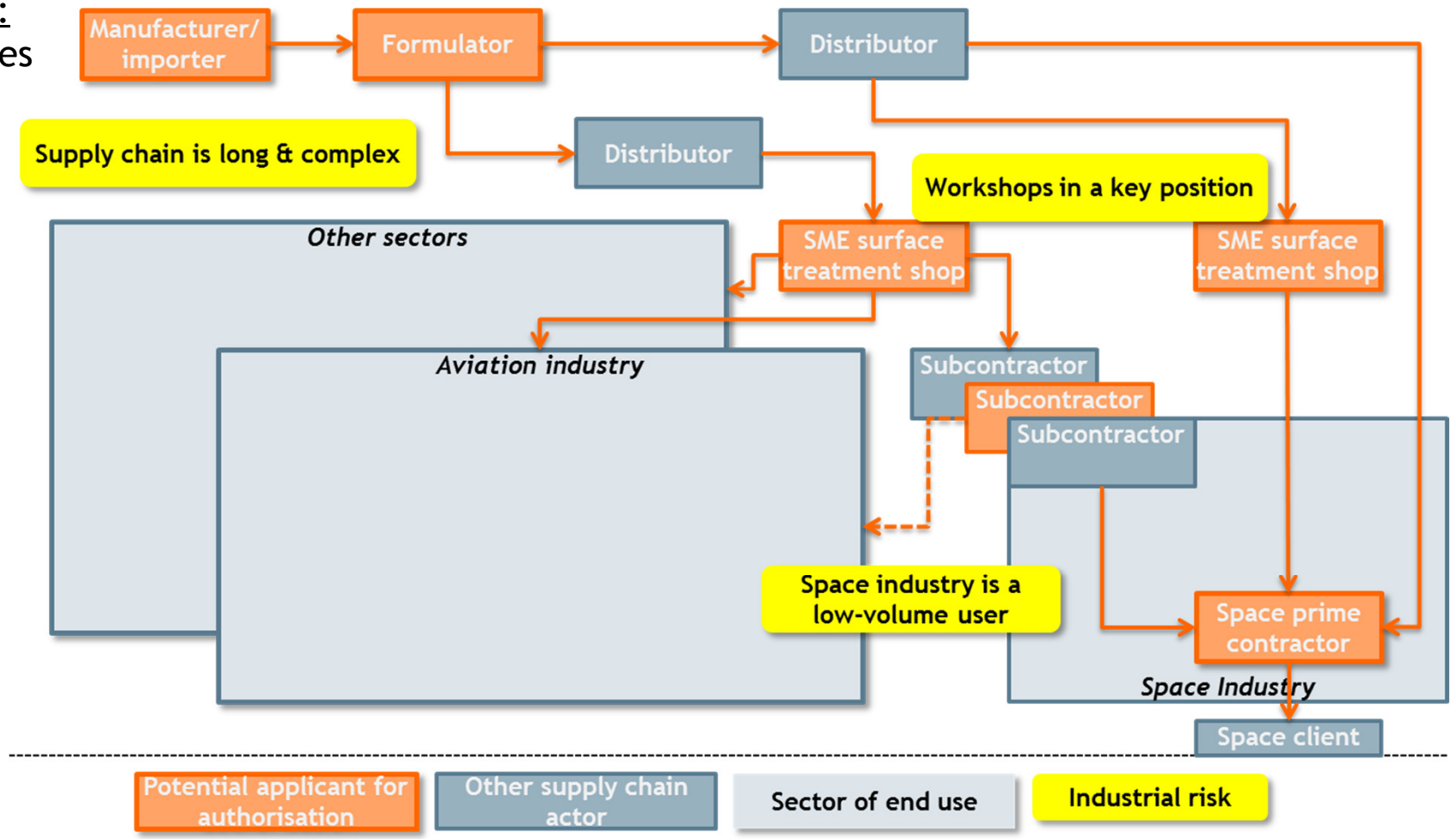
REGULATORY	COMMERCIAL
• Legal ban for certain chemicals • Non-compliance of duty holders • Enforcement by authorities	• Stop of product supply • Change of product composition • Space sector as niche market

- If not properly identified, monitored and mitigated, obsolescence risks may result in costly supply chain and production disruptions

EU REACH and other International Chemicals Regulations

Challenges for space sector: Complex supply chains

Example:
Chromates



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EU: REACH

A European Union Regulation: ”REACH”

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the

***R**egistration* *”no data, no market”*

***E**valuation*

***A**uthorisation and Restriction of*

***Ch**emicals*

In force since 1.6.2007

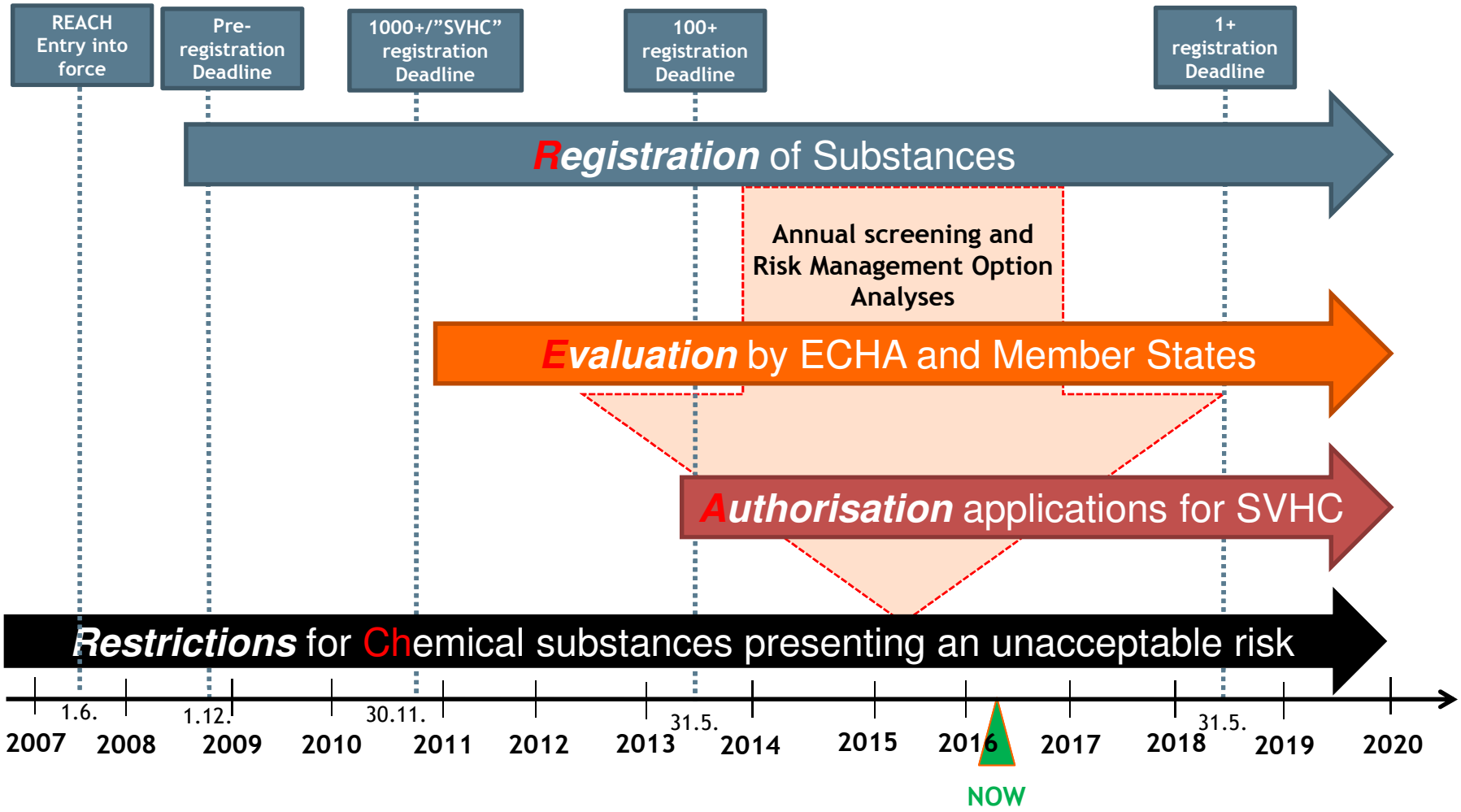
Applies directly in entire EU/EEA (incl. French Guiana, excl. CH)

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

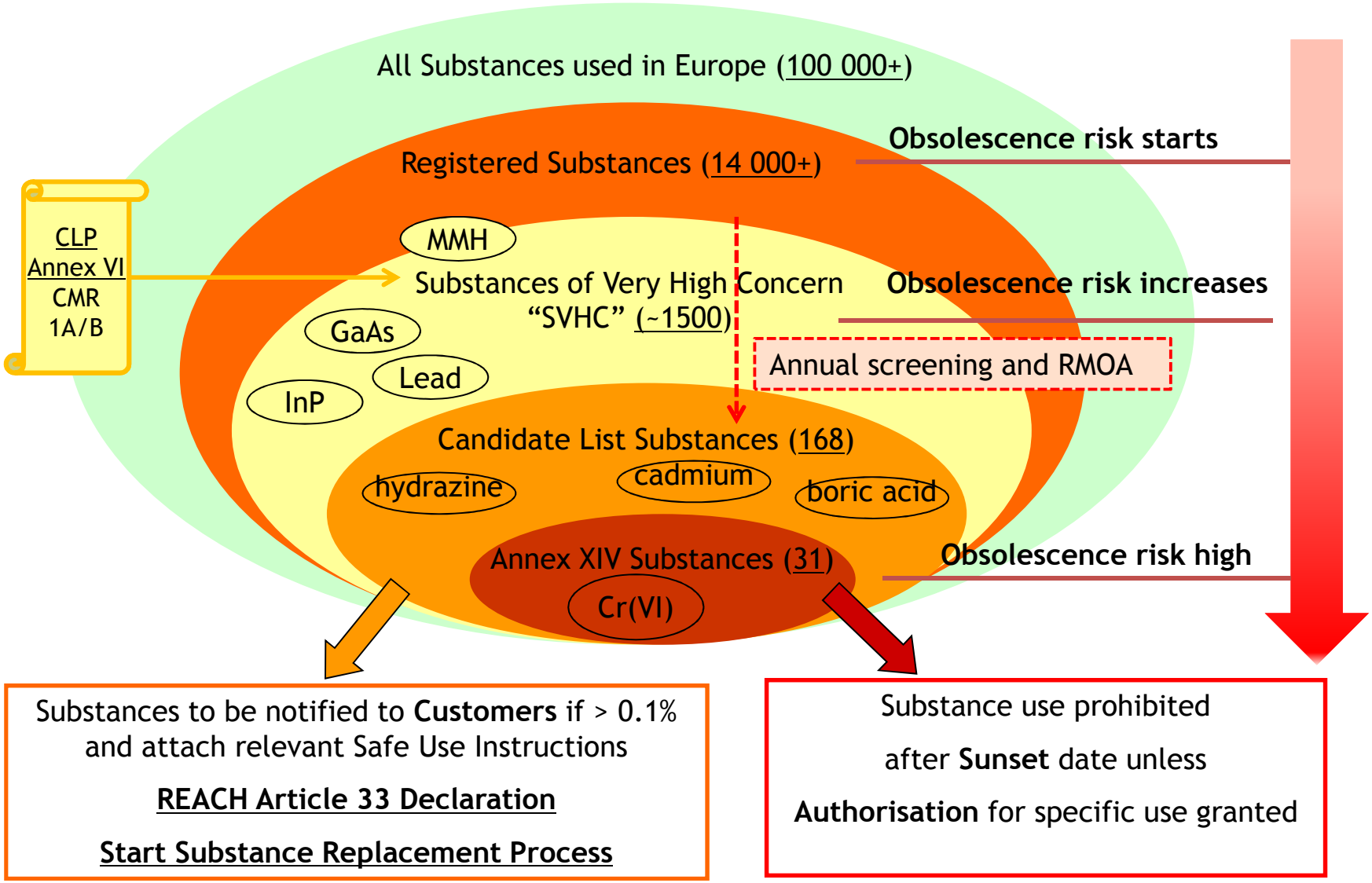
Main purpose: ensure a high level of protection of human health and the environment

Change of paradigm: Chemicals manufacturers, importers and downstream users to proof safe use

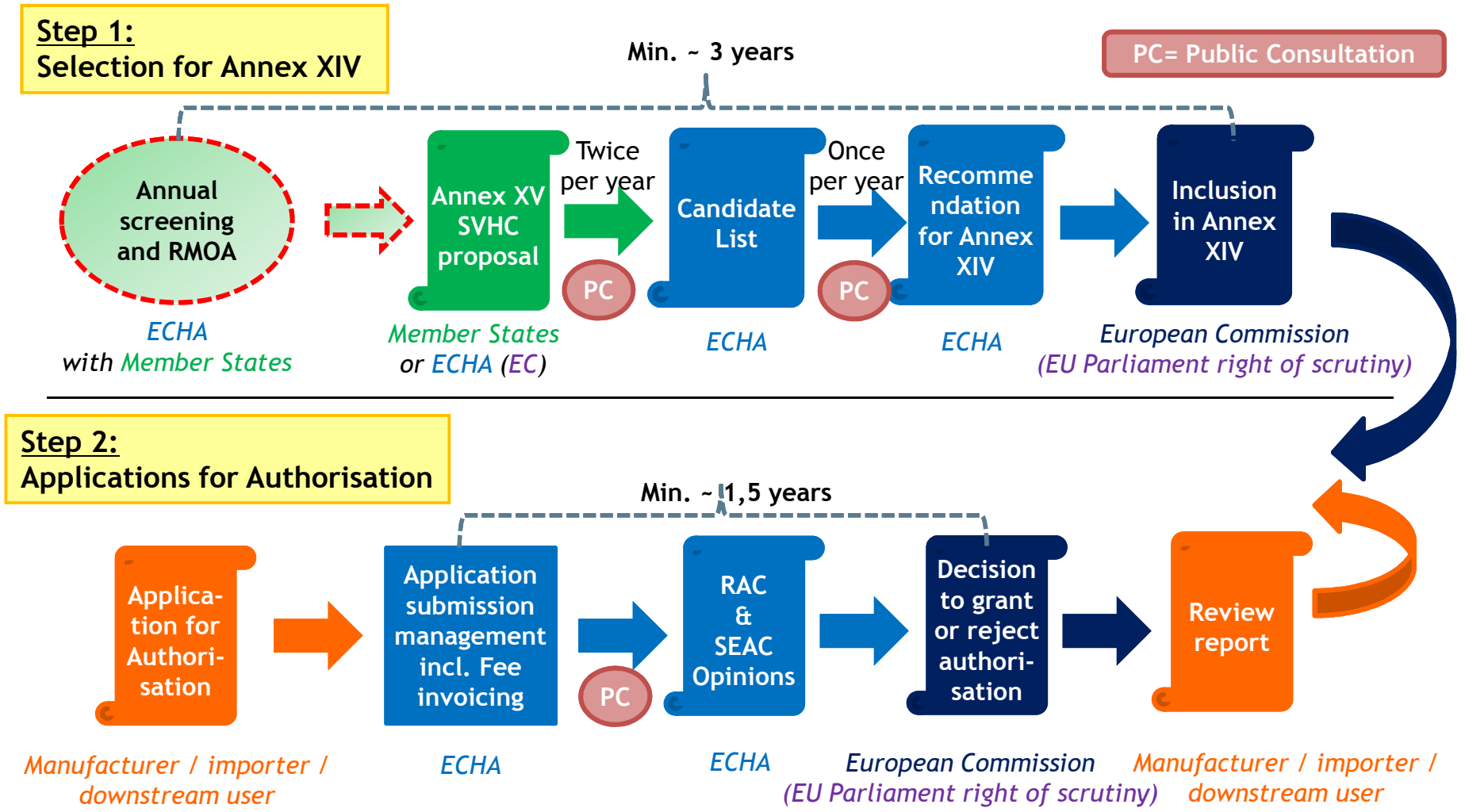
EU: REACH
Phase-in of REACH processes



EU: REACH I Elimination of Hazardous Chemicals



EU: REACH I The Autorisation Process



EU: RoHS Directive(s)

Hazardous substance restrictions specific to EEE

Lead (0.1 %) | **Mercury (0.1 %)** | **Cadmium (0.01 %)** | **Hexavalent chromium (0.1 %)** | **Polybrominated biphenyls (PBB) (0.1 %)** | **Polybrominated diphenyl ethers (0.1 %)**

- **RoHS 1: Directive 2002/95/EC** on the Restriction of the Use of certain hazardous substances in Electrical and Electronic Equipment (EEE)
- **RoHS 2: Directive 2011/65/EU ("recast")** entered into force on 21 July 2011: incl. process for assessing inclusion of new substances of concern mainly based on waste-related criteria

Legal exclusion relating to space systems (et. al.), RoHS 2 Article 2(4)(b) & (f):

- *Equipment designed to be sent into space*, e.g. satellites, space probes
- *Means of transport for persons or goods*, e.g. commercial vehicles, aircraft

However, commercial obsolescence risk due to tin-lead solders being phased out by suppliers (tin whisker issue)

Evolution of RoHS:

- EC(2014): RoHS 2 is preferred legal instrument for tackling substance-related issues in EEE
- Study 2014 by Austria, incl. a priority list of 56 substances (see p41): http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/0_RoHS_AnnexII_Final_Report.pdf
- Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II, to be applied from 22.7.2019

DEHP (0.1 %) | **BBP (0.1 %)** | **DBP (0.1 %)** | **DIBP (0.1 %)**

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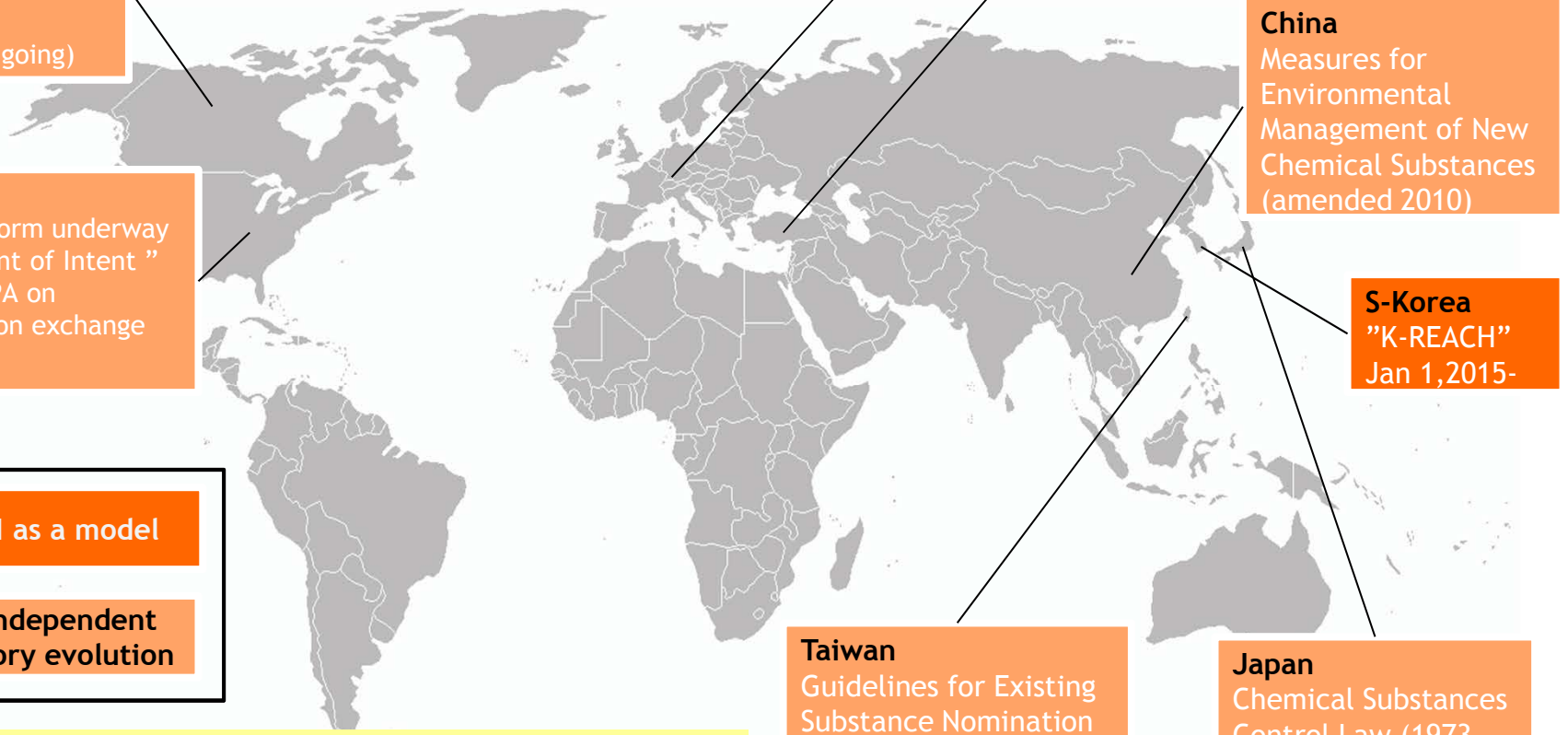
Beyond EU: International Chemicals Regulations

Responses to REACH and RoHs



Canada
Chemical Management Plan "CMP" (2006-ongoing)

Switzerland
Autonomous align-ment with REACH

Turkey
KKDIK, GBF, SEA
Harmonization with REACH

China
Measures for Environmental Management of New Chemical Substances (amended 2010)

US
TSCA, reform underway "Statement of Intent " ECHA - EPA on information exchange (11/2010)

S-Korea
"K-REACH" Jan 1,2015-

REACH as a model

More independent Regulatory evolution

Taiwan
Guidelines for Existing Substance Nomination and New Chemical Notification (2009)

Japan
Chemical Substances Control Law (1973, amended 2009)

RoHS: Model for similar laws introduced in min. 15 non-EEA jurisdiction, e.g. China, Japan, Korea, US

Beyond EU: International Chemicals Regulations
Canada: Chemical Management Plan (CMP)

- Objective: meet goals set by the World Summit on Sustainable Development for the sound management of chemicals by 2020.
- Baseline: *Domestic Substances List (DSL)*: chemicals on the market
- Results under CMP to date
  - 2,740 of 4,300 priority chemicals assessed
  - 363 chemicals classified as harmful to the environment and/or health
  - 76 risk management actions addressing 325 of those chemicals
  - Approx. 4,500 chemicals assessed prior to their introduction on the market
- 2015: published a proposed pollution prevention plan for *hydrazine*
- 2016-2020: The last federal budget committed Canadian $491.8m.
  - This will be used to complete remaining chemicals assessments, under the plan (Phase 3), and manage the risks of chemicals found to be harmful
- CMP is seen as an alternative approach to REACH in some jurisdictions (e.g. USA TSCA, Brazil)

Beyond EU: International Chemicals Regulations
USA: The Toxic Substances Control Act (TSCA)

- The fundamental federal chemicals law enacted in 1976
- Controlling body: Environmental Protection Agency (EPA)
  - *TSCA Inventory* of initially 62,000 *existing* chemicals
  - Regulatory control over the introduction of *new* chemicals
  - Wide reaching recordkeeping and reporting requirements
  - Regulation of toxic substances (’Section 6’)
- TSCA reform underway
  - Systematic safety review for all commercially used chemicals
  - More efficient prioritization and chemicals risk evaluations
  - Public on-line database of chemical information & EPA decisions
  - Promotion & development of incentives for safer alternatives

”*House Bill 2576*” and ”*Senate Bill 847*” in 2015 - Congress to converge

Beyond EU: International Chemicals Regulations
Switzerland: A non-REACH island in Europe

- Current policy is to modernise the Swiss chemicals law autonomously, taking into account foreign schemes
- Alignment with REACH key provisions, especially for SVHC:
  - Swiss authorisation list (Annex 1.17 ChemRRV)
    - Unilateral recognition of EU (EC) authorisations
  - Swiss candidate list of SVHC (Annex 3 ChemV)
    - REACH Article 33-communication for SVHC
- Further updates are being prepared, e.g.
  - Notification of hazardous intermediates
  - Extended authority information requests for risky chemicals
  - Co-operation with ECHA on the evaluation of chemicals and knowledge exchange

Beyond EU: International Chemicals Regulations
Turkey: Close to its EU neighbours

Turkey pursues full harmonization with EU REACH and CLP

- Key authority: Ministry of Environment and Urbanization
- Chemicals Inventory and Control Regulation (CICR)
  - 2011: Notification requirement to create a Turkish national chemicals inventory (a Turkish version of the EU EINECS)
- "SEA" ~ Regulation on classification, labelling and packaging of dangerous substances and mixtures ("Turkish CLP")
  - Deadline 1.6.2015 for Substances, 1.6.2016 for Mixtures
- "GBF" ~ Regulation on safety data sheets
- "KKDIK" ~ Chemicals Registration, Evaluation, Authorisation and Restriction ("Turkish REACH"): to replace CICR
  - Provisionally registration from 31.12.2015 – 31.12.2018

Beyond EU: International Chemicals Regulations
China: Focus on New and Hazardous chemicals

China has a differentiated complex own chemicals regulatory framework, which is evolving, also taking into account international developments (e.g. UN GHS); key acts:

"China REACH"
Measures for Environmental Management of of New Chemical Substances
(amended 2010)

- If not in **Existing chemicals inventory "IECSC"**[1] (incl. ~ 46,000 substances)
- Notification and evaluation prior to manufacture or import, incl. safety info
- Key authority: Chemical Registration Centre of the Ministry of Environmental Protection (MEP-CRC)

[1]Inventory of Existing Chemical Substances Produced or Imported in China

Regulation on Safety Management of Hazardous Chemicals - "China HazChem"
(1994, as amended)

- Catalogue of hazardous chemicals (~ 3,000 in 2015; further expanding)
- Covers production, import, storage, transport and use
- Registration of hazardous chemicals (incl. safety info) and license for operation
- use of Chinese GHS compliant SDS & labels

Provision on the First Import of Chemicals and the Import and Export of Toxic Chemicals
(1994)

- "License to operate with toxic chemicals on Chinese market"
- Certification/notification by exporter/importer
- The latest list of toxic chemicals severely restricted to be imported into or exported from China contains 162 substances (2014)

PROHIBITED CHEMICALS

Beyond EU: International Chemicals Regulations

South Korea: ”K-REACH”

Act on Registration and Evaluation, etc. of Chemicals (”K-REACH”), in force since 1.1.2015, targets a broad alignment with EU REACH; key aspects:

- Key authority: Ministry of Environment (MoE)
- Registration of New (before import) and 510 Priority Existing Chemicals Subject to Registration on ”PEC List 2015” ≥ 1 t/y (by 30.6.2018; list to be extended in future with similar 3-year period)
  - EU SVHC list was also used when building the PEC List 2015
- Hazard and risk assessment by authorities to identify toxic substances and substances of concern
- Authorisation to obtain approval for the manufacture, import and/or use of SVHC
- Annual reporting of use and volume info: next by 30.6.2016

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Materials & Processes Technology Board (MPTB)
Overview of purpose, membership & activities

- The magnitude of the risks requires European-wide coordination, realised through the Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB), a partnership between ESA, national space agencies, and space industry, chaired at present by ESA.
- A large part of resources are dedicated to obsolescence risk management in relation to REACH.
- The MPTB allows early identification and proactive coordination of proper mitigation of obsolescence risks.
- For most critical chemicals and related space applications presenting a high obsolescence risk with a specific need for joint mitigating action, the ESCC MPTB has initiated dedicated industry task forces under co-ordination of Eurospace.

REACH Task Forces initiated by the ESCC MPTB

Space Hydrazine Task Force (HTF)

Reason	Membership	Activities	Results
• Classified carcinogenic 1B • REACH candidate list inclusion 20.6.2011 • Worst case sunset date, if included in Annex XIV: Q1/2021 • Propellant for attitude control of launch vehicles and spacecrafts • Strategic for satellite and launcher programs, no viable alternative is available yet	Industrial HTF participants: • Airbus DS GmbH: • Airbus Defence and Space Ltd • Arianespace • AVIO SpA • GHC Gerling, Holz & Co. Handels GmbH • MOOG UK Westcott Ltd • OHB System AG • Thales Alenia Space France Assisted by ESA, CNES and DLR. ASD-Eurospace as co-ordinator, 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 socio-economic consequences of Annex XIV inclusion (2015-)	• Industry Position Paper documenting reasons for exemption from authorisation (2012) - EC clarification still awaited today • Report for EC on socio-economic consequences of Annex XIV inclusion (Q 1 2016) → **Joint framework and deliverables for REACH authorisation compliance; public awareness**

REACH Task Forces initiated by the ESCC MPTB

Space Chromate Task Force (STF)

Reason	Membership	Activities	Results
Chromium trioxide: • Classified carcinogenic 1A, mutagenic 1B • REACH Annex XIV inclusion 21.4.2013 • Annex XIV sunset date: 21.3.2016 • Conversion coating 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: • AIRBUS DEFENCE AND SPACE • AEROSPACE PROPULSION PRODUCTS • AVIO • EUROPROPULSION • HERAKLES • OHB SYSTEM AG • RUAG SPACE • TAS Assisted by ESA and CNES. ASD-Eurospace as co-ordinator & 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; support of cross-industry consortium "CTAC-Sub" in public consultation (2015)	• STF comment on the CTACSub application for authorisation in public consultation (October 2015) • STF joint AoA and SEA for CrO3/CCC (to be finalized shortly) as basis of future space industry application(s) for authorisation → **Joint framework and deliverables for REACH authorisation compliance; public awareness**

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EU REACH and other International Chemicals Regulations
Outlook

- The EU and rest of the world are becoming increasingly regulated, EU REACH and CLP are prompting similar changes globally. The REACH candidate list is being populated with new SVHC (*SVHC Roadmap to 2020*).

- For the European space industry as a small volume user and thus typical niche customer for the chemicals industry, the market realities may lead to significant commercial obsolescence risks over and above the complex REACH regulatory demands.
- Stakeholder communication (supply chain, authorities, associations, etc.) is pivotal for the success of sustainable supply.
- European Space Industry, together with ESA and national space agencies have built and operated joint platforms to collaborate efficiently for obsolescence risk identification and mitigation (mainly due to REACH).
- The space sector relies on predictability and legal certainty with regards to regulatory requirements affecting its materials & processes.

THANK YOU
FOR YOUR ATTENTION !

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Additional slides

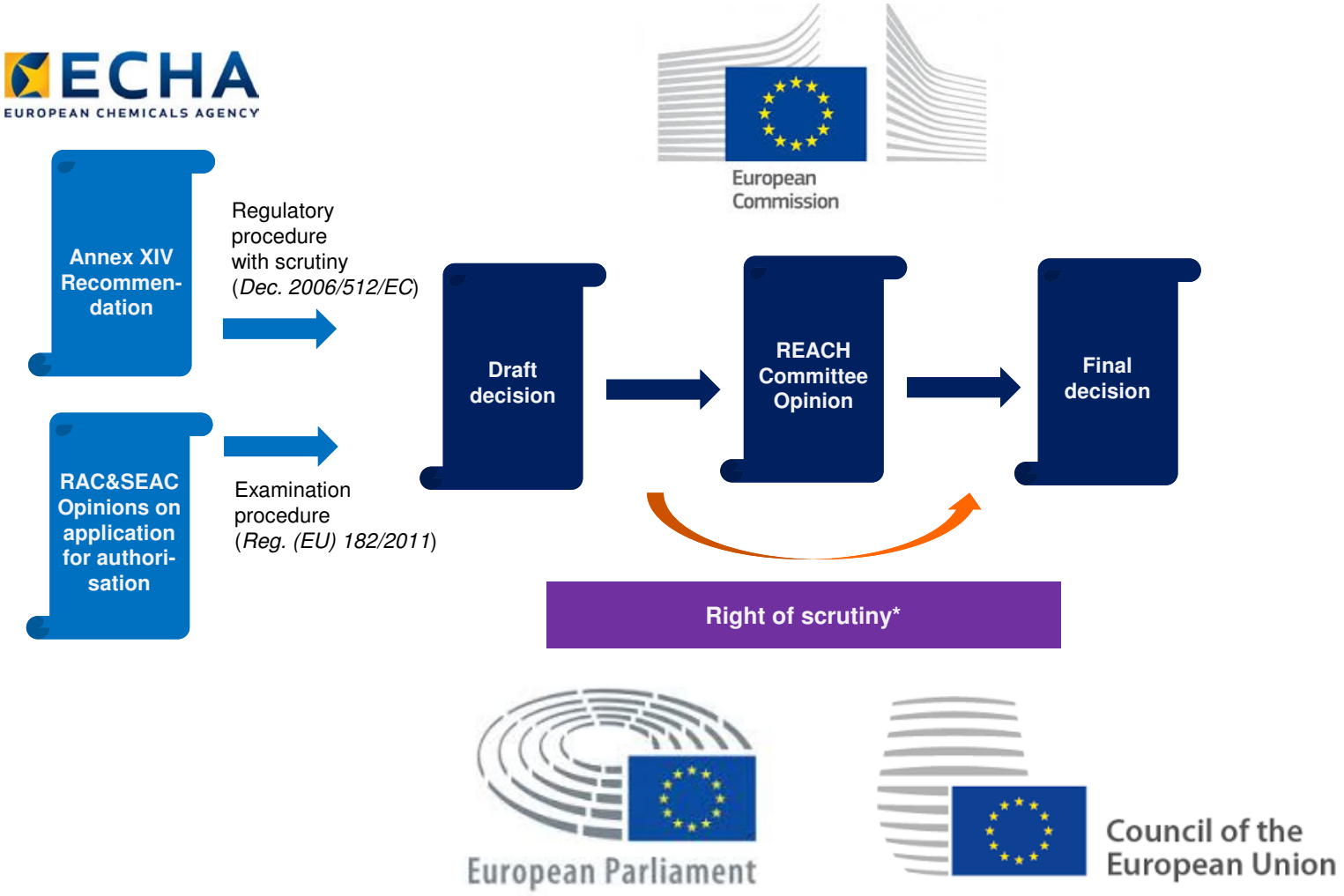
List of acronyms (1/2)

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

EU: REACH I Commission decision on authorisation



*Blocking right for Annex XIV only