

REACH developments on SVHC scrutiny

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By WebEx from Helsinki, Finland

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"Increasing Space Mission Resiliency through Sustainability"

NASA's Kennedy Space Center, Florida - October 23, 2014

REACH DEVELOPMENTS ON SVHC SCRUTINY - AGENDA

1. Introduction
2. The REACH Authorisation process for SVHCs
 - a. Status
 - b. Overhaul
3. Conclusions for the Space sector

Introduction | 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.compliant suppliers.com

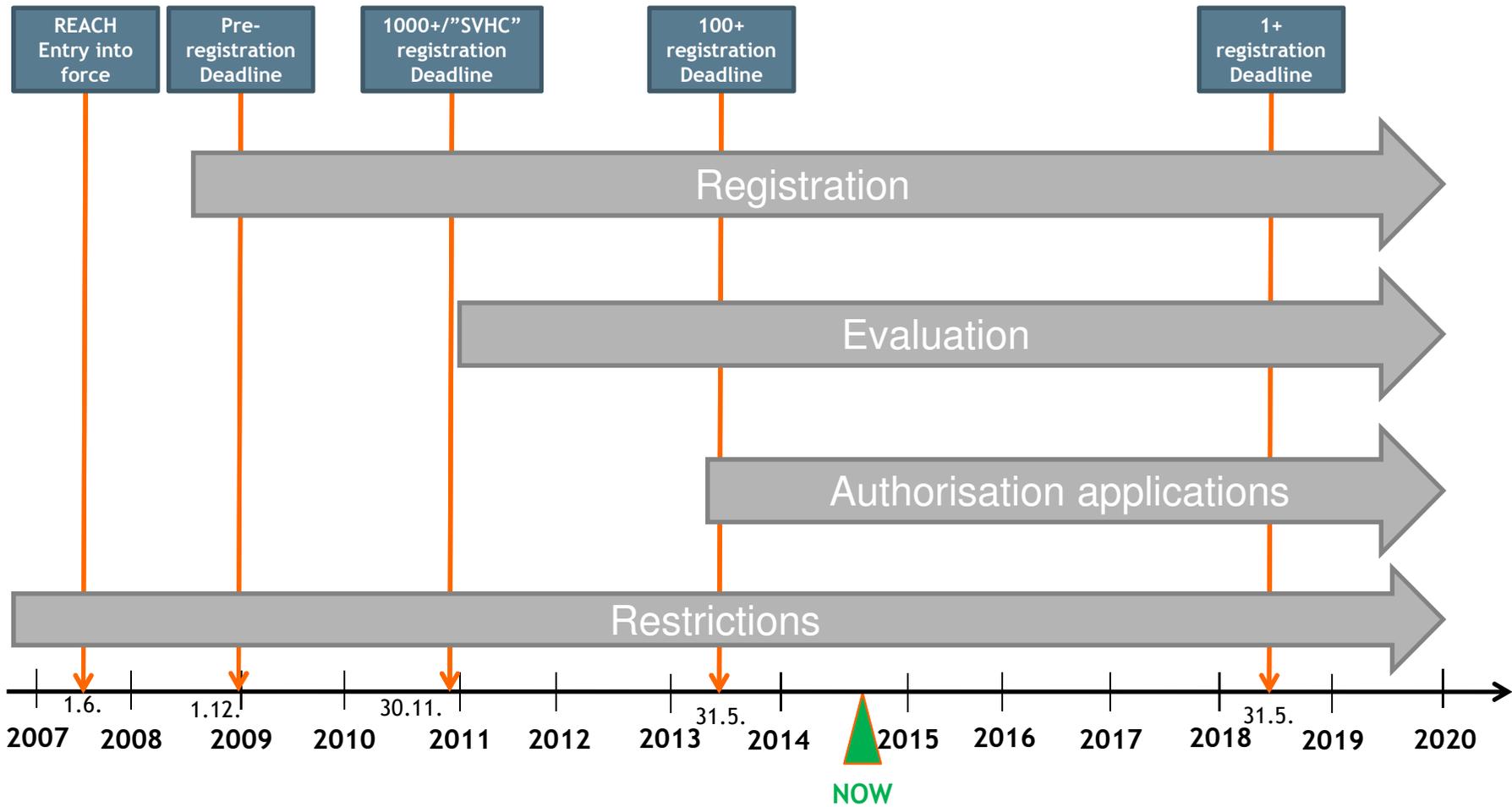
OUR CLIENTS

- ✓ 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 I REACH in brief

- *REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals (REACH); in force since 1.6.2007*
- **Applies directly in all 28 EU Member States, incl. French Guiana + Norway, Iceland and Liechtenstein; but not in Switzerland**
- **Managed by the European Chemical Agency (ECHA), Helsinki; enforced by national authorities**
- **Main aim is to reduce risks from use of chemicals to humans and the environment and to encourage / force substitution of the most hazardous substances**
- **REACH shifts responsibility for safe use of chemicals from authorities to industry: Manufacturers, Importers, Downstream users and Distributors of chemicals have to fulfil REACH related duties**
- **One of the most complex pieces of legislation in EU history**

Introduction | Timeline of REACH processes



Introduction I REACH challenges for Space industry

- Space companies use chemicals in **small to minute volumes**
 - REACH authorisation process applies regardless of volume
 - Space industry is a minor market for many suppliers
- Limited control of **supply chain**
 - Have to rely on registration by upstream manufacturer/importer and authorisation for upstream uses (e.g. formulation)
 - Risk of sudden obsolescence of Space-qualified materials and processes due to REACH-induced alterations of materials and processes upstream
- Limited **visibility** of upcoming SVHC and envisaged Risk Management Options
 - hopes that EC 2020 SVHC Roadmap will improve this
- **Re-qualification and industrialisation** of alternative materials and processes is a long-term and cost intensive undertaking - need to decide as early as possible on the items to include in planning
- Space industry is a producer of **very complex articles**
 - REACH Article 33 (Duty to communicate information on SVHC in articles) implementation is challenging
 - Member States' disagreement on interpretation ("*Once an article, always an article*") adds to the complexity.

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1. Introduction

2. The REACH Authorisation process for SVHCs

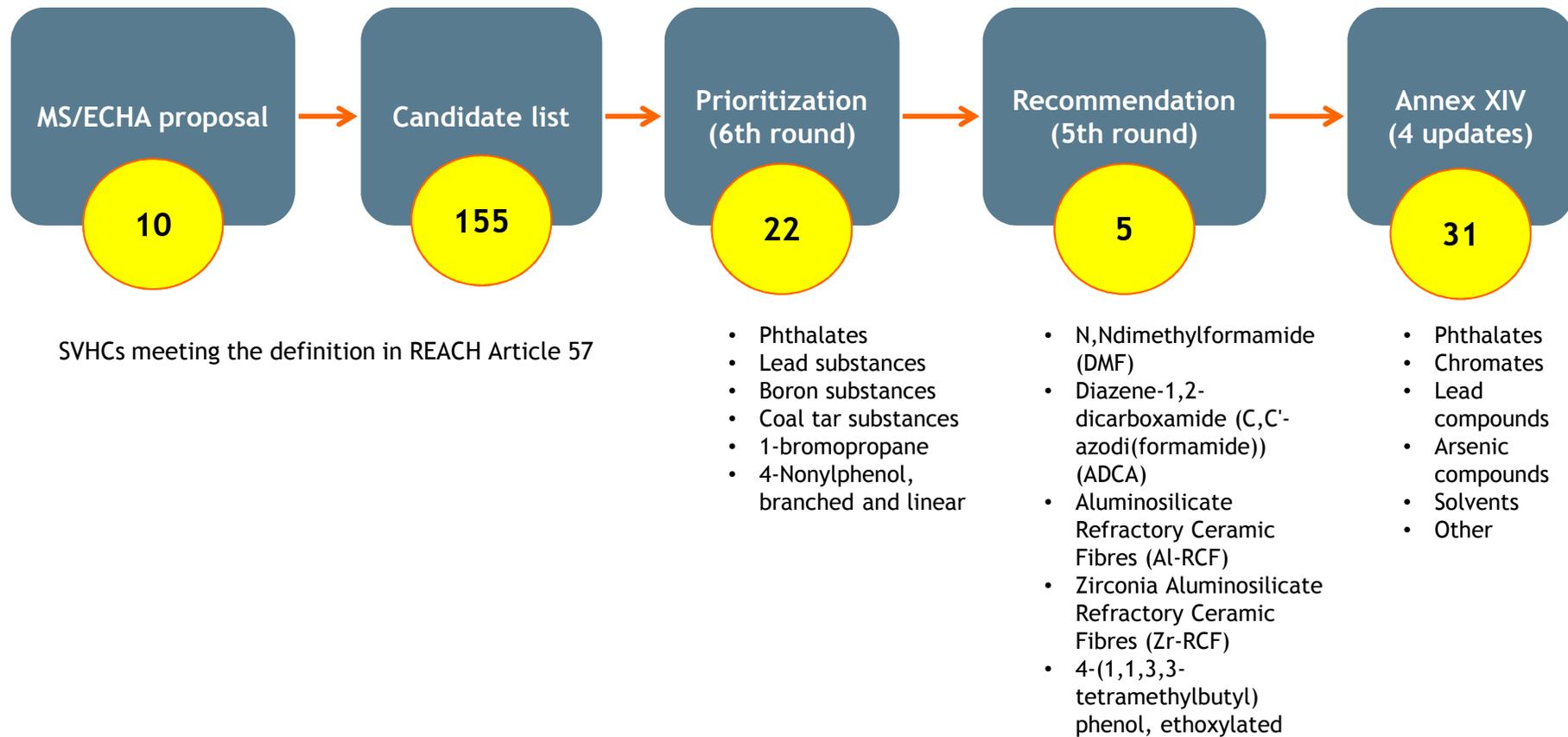
a. Status

b. Overhaul

3. Conclusions for the Space sector

Authorisation status

SVHCs currently in the listing pipeline



Authorisation status

1st EC decision available

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⁾)

(2014/C 260/10)

Decisions granting an authorisation

Date of decision	Substance name	Holder of the authorisation	Authorisation number	Authorized use	Date of expiry of review period	Reasons for the decision
7 August 2014	Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	Rolls-Royce plc PO Box 31, Derby Derbyshire DE24 0BJ UNITED KINGDOM	REACH/14/1/0	Processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades	21 February 2022	<ul style="list-style-type: none"> — 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 5-10 year research programme.

See: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2014.260.01.0010.01.ENG

Authorisation status

Application for authorisation (AfA) status

- 25 applications / ~ 40 applicants
- 1st AfA (Rolls-Royce) has reached end of pipeline in August 2014
- RAC/SEAC opinions so far only published for “Adequate Control Route” (first “Socio-Economic Route” opinions to come shortly)
- Detailed scrutiny of AfAs by RAC and SEAC, incl. assumptions used, calculations of exposure and economic values, overall scientific quality of the reports
- DU applications are easier to process, supplier applications (esp. if covering various sectors) are more challenging
- Short review periods (e.g. 4 years) or rejection of AfA for deficient 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 status

Status of Space-sector REACH Task Forces

- **Chromates** Space Task Force (STF)
 - Authorisation route: sign-up until 31 October 2014 for Phase 2 ('space' application dossier development for Alodine 1200 and application strategies), see <http://www.eurospace.org/call-for-participation-in-space-chromate-task-force-for-reach-authorisation-development.aspx>
- **Hydrazine** Space Task Force (HTF)
 - Exemption route: waiting for EC clarification; HTF reconvened in summer 2014 in response to ECHA prioritisation to determine further actions and discuss with other sectors
- Further information:
 - http://www.reachlaw.fi/images/uploads/files/REACHLaw_Eurospace_Li onnet_29_September_2014.pdf

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Authorisation challenges | Complex process

<u>AUTHORITY IN CHARGE</u>	<u>PROCESS STEP</u>	<u>MONTHS</u>	<u>RELEVANT ISSUES</u>
Member States (MS) ECHA on request of EC	MS or Agency prepares Annex XV SVHC dossier (Art. 59 (2) and 59 (3))	~ 6-12	SVHC identification and properties
	↓	~ 6	Public consultation: SVHC identity & properties (uses & alternatives)
ECHA [+ its MSC + EC]	Candidate list inclusion (Art. 59 (1))	>6	Public consultation ECHA: Priority setting, exemptions, proposed Annex XIV entry
	↓	~ 12	
ECHA + its MSC's opinion	Prioritisation procedure (Art. 58 (3))	~ 12	
	↓	~ 12-15	NEW (2014): Call for information by EC: Socio-economic impact
EC	Annex XIV inclusion (Art. 58 (1))	~ 12-15	
	↓	~ 18-24	Control of risks ? Suitable alternatives available? (incl. through Public Consultation)
ECHA + its RAC and SEAC	Application for authorisation (Art. 62)	~ 18-24	
	↓	<24	Socio-economic benefits of the continued use?
EC	Authorisation granted/not granted (Art. 60)	<24	
	↓	~ 84-144	
	Review of granted authorisations (Art. 61)	~ 84-144	

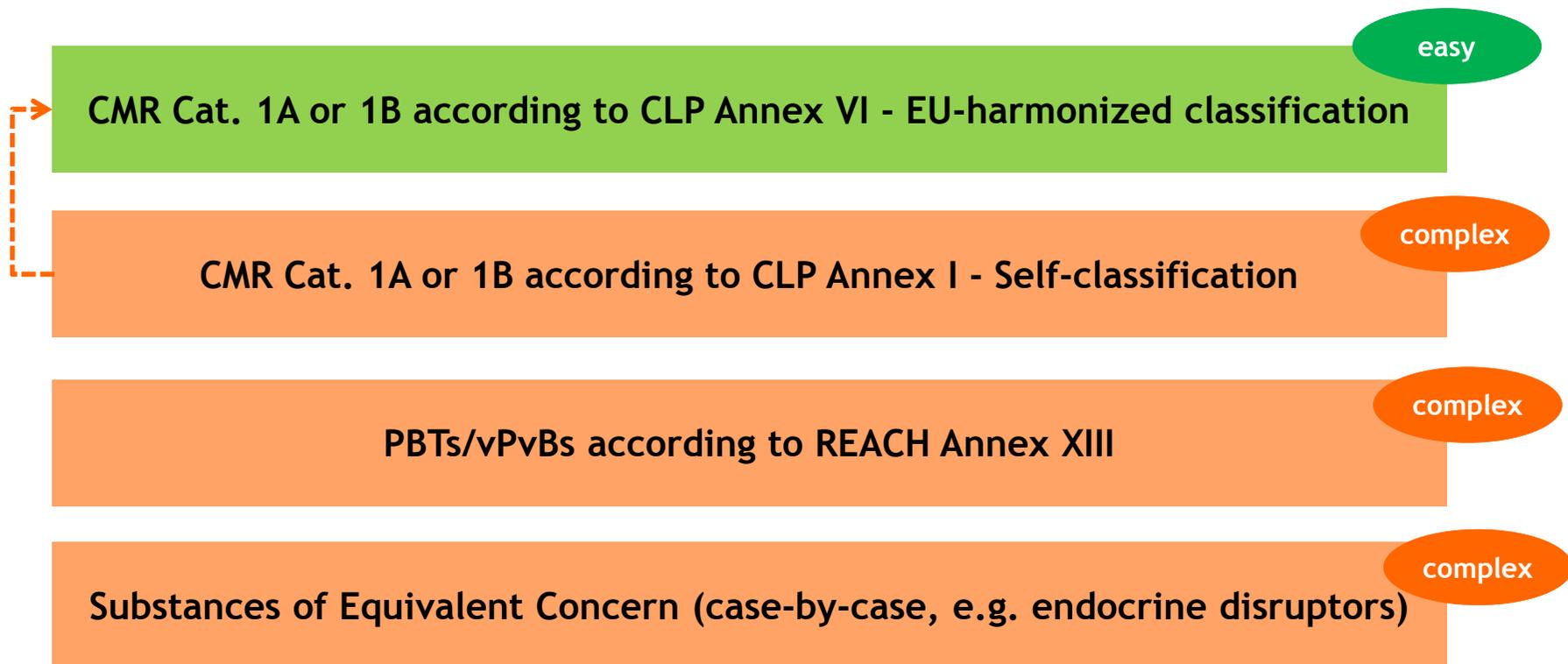
! Each authorisation has a time-limited review period

Authorisation challenges | Anticipation of SVHCs

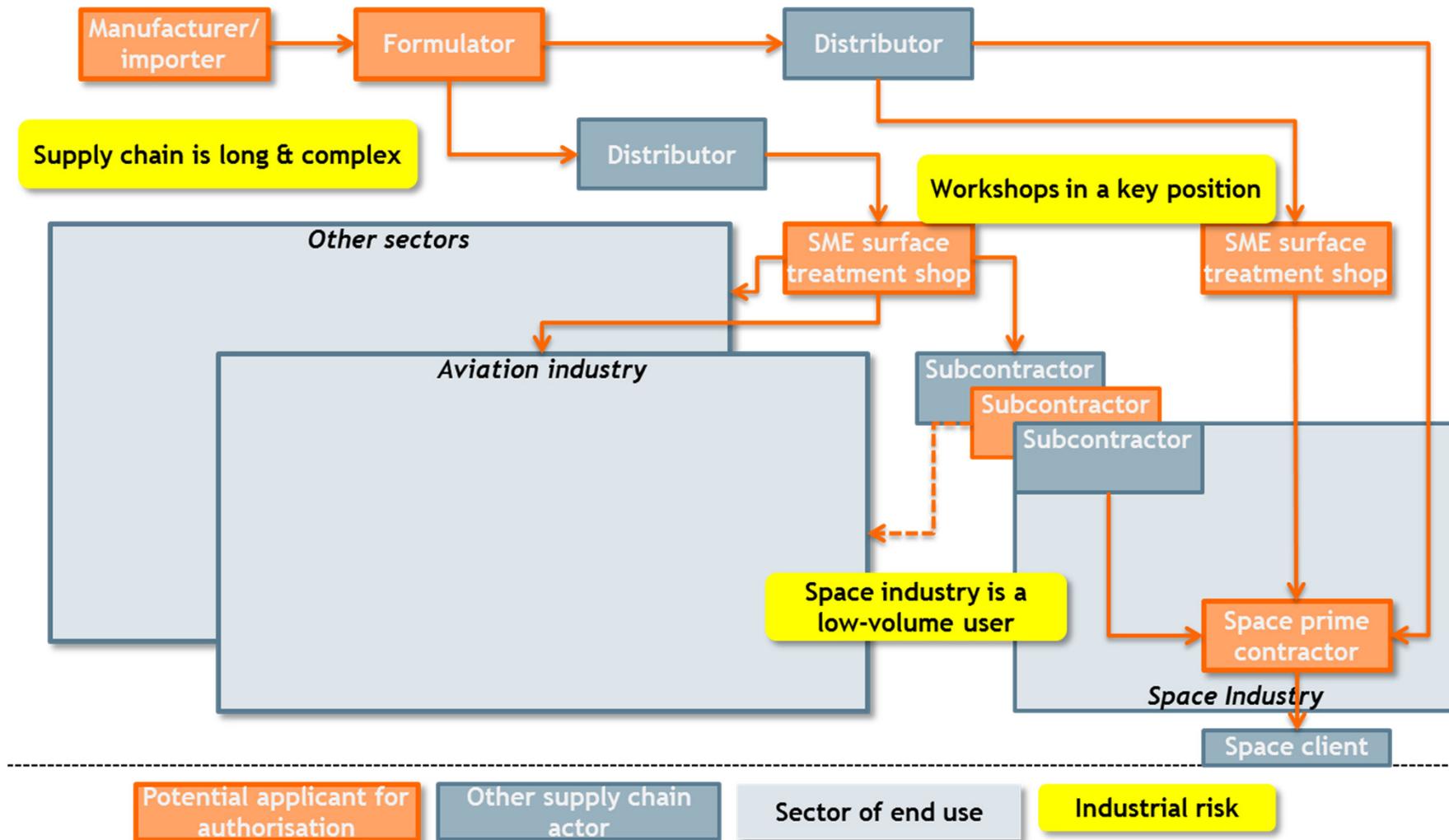
- New substances are currently proposed every 6 months for the Candidate List for eventual inclusion in Annex XIV
 - <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions>
- Only rough idea which substances are proposed next, e.g.
 - <http://www.chemsec.org/what-we-do/sin-list>
 - <http://www.subsport.eu/list-of-lists-database>

Authorisation challenges I **Complex SVHCs**

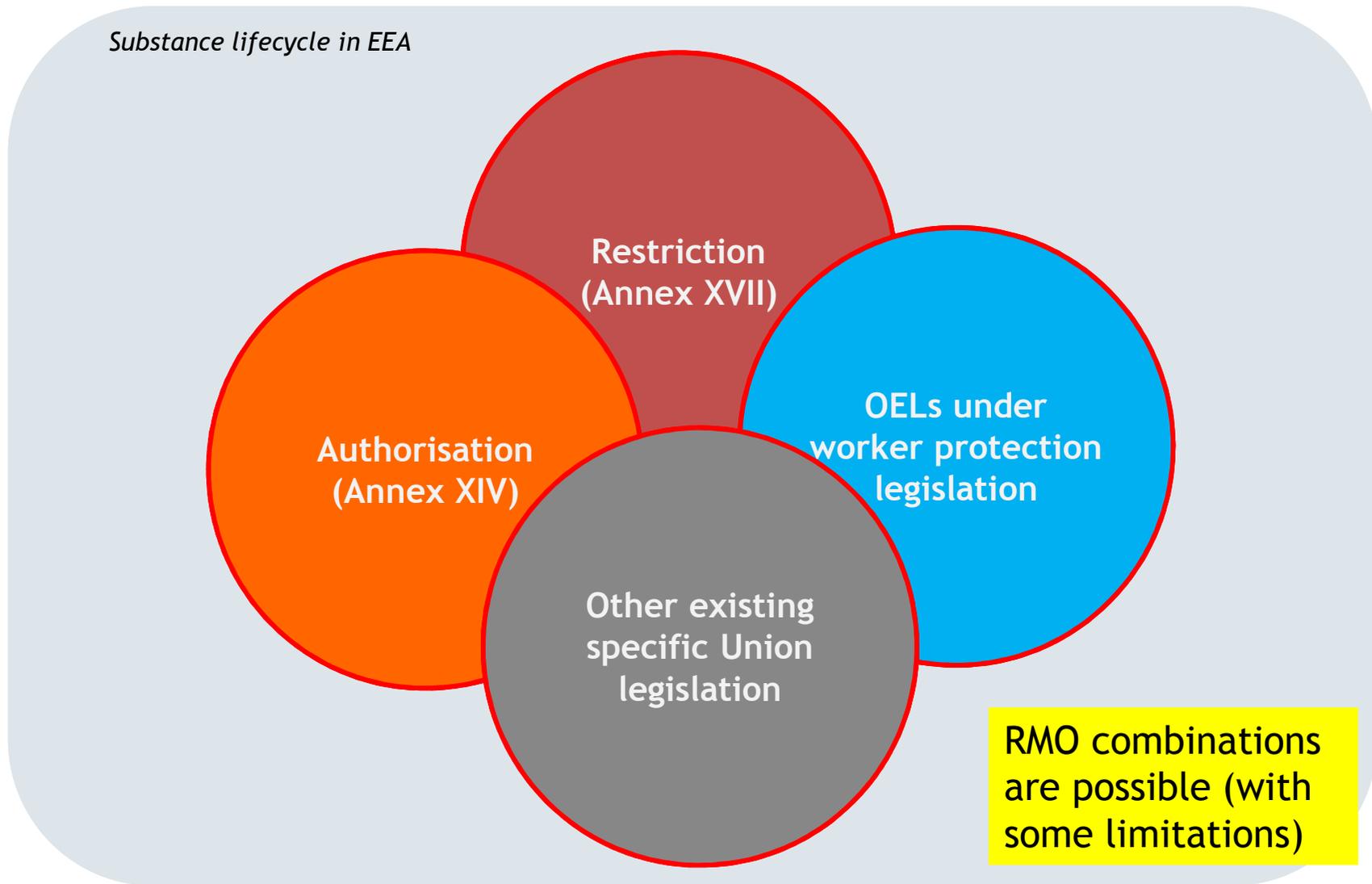
- SVHC criteria are defined in REACH Art. 57 (“Substances to be included in Annex XIV”)



Authorisation challenges | Complex supply chains



Authorisation challenges | Complex interfaces



Authorisation challenges

Industry fears



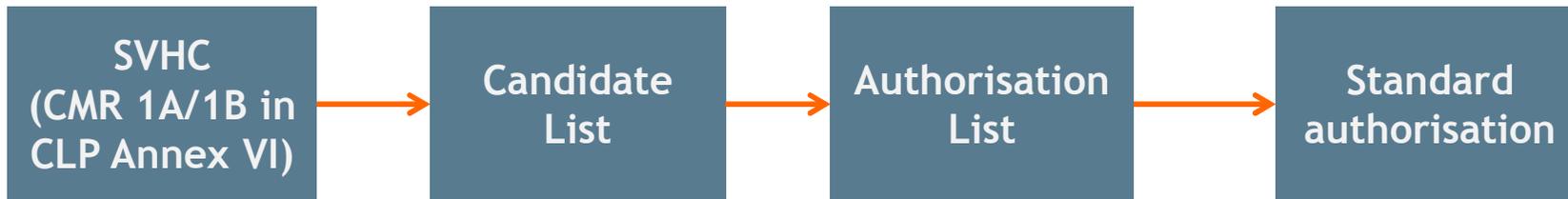
Brussels, 25 November 2013

The 2020 roadmap for substances of very high concern: Industry fears for unequal treatment of the European industry

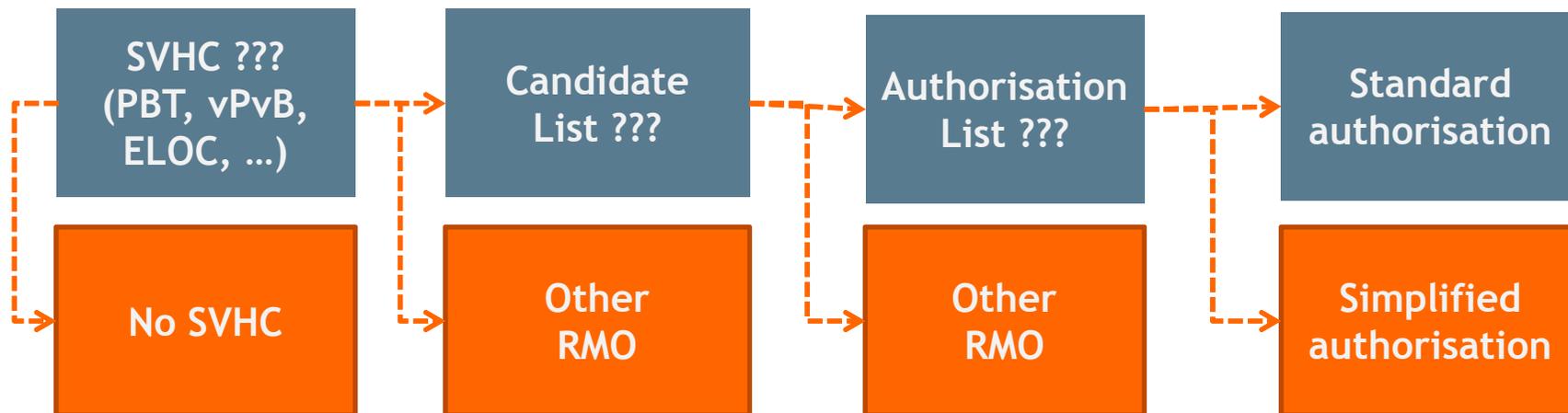
Industry strongly believes that a Risk Management Option (RMO) analysis should be the standard procedure to be followed by all Member States, respecting the outcome of this RMO. This RMO analysis should not be limited to REACH authorisation or restriction but should consider as well other EU legislation that is covering human health protection for workers or consumers or environmental protection. This should always take place before any initiative, regulatory or communication of intention, is started, even at national level, indicating the route to be followed for all substances. Industry sees that the principle is indeed accepted on paper, but finds this should be communicated clearly as being the standard procedure to be followed.

Authorisation overhaul | The response (simplified)

- So far: An automatism



- Now/future: Holistic approach + more transparency



Authorisation overhaul

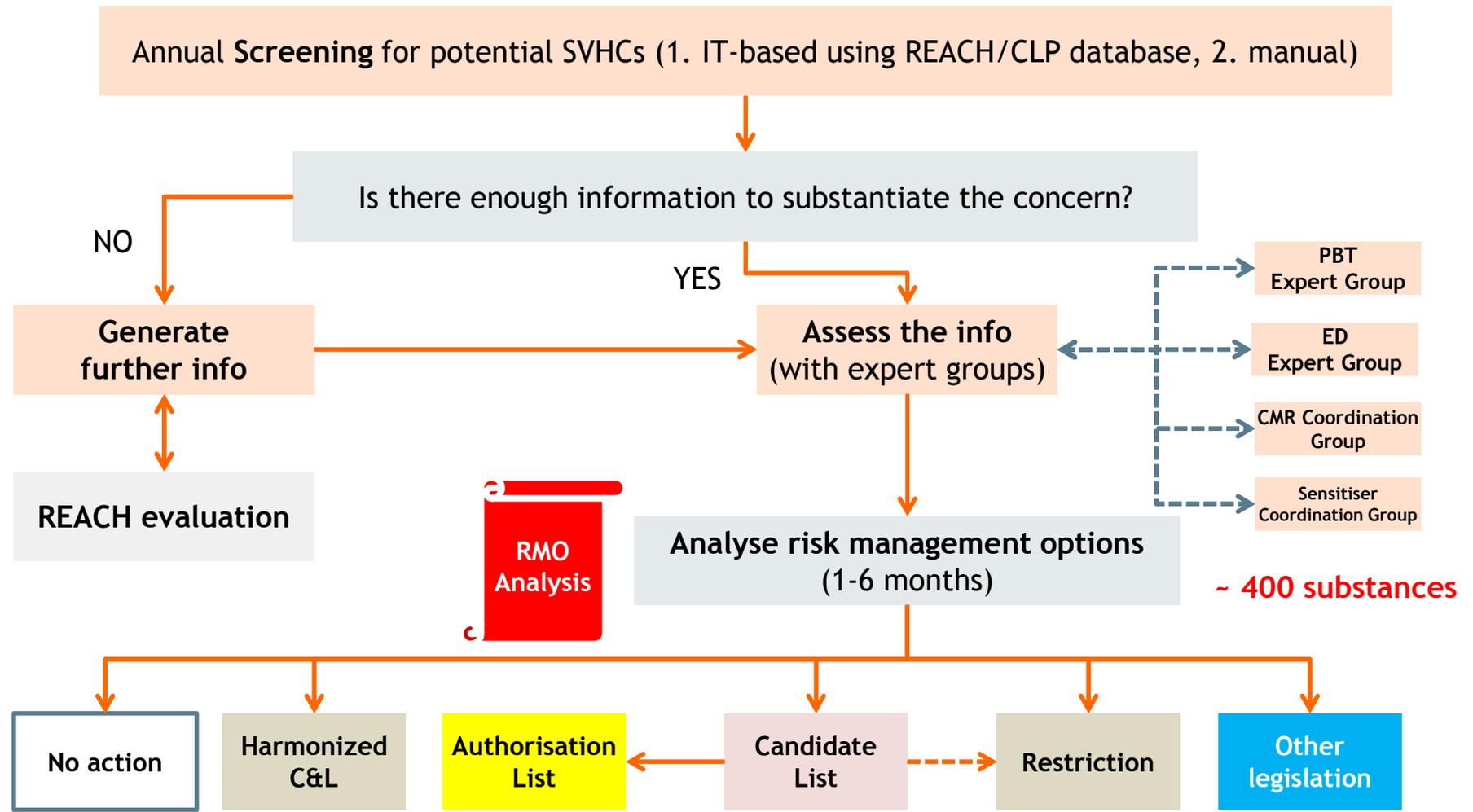
The EC SVHC Roadmap to 2020 (05.02.2013)

- 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)
 - Harmonization of SVHC identification and RMO Analysis
 - Publication of Substance-specific info by ECHA ("PACT")

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?	✓	

EC SVHC Roadmap to 2020

ECHA/MS implementation plan



EC SVHC Roadmap to 2020

Focusing on five substance groups

Grouping by Effect*	Estimated # RMOAs
1. CMR [Cat. 1A or 1B in CLP Annex VI]	50
2. Allergic (Sensitizing) [Cat. 1A or 1B in CLP Annex VI]	30
3. Endocrine disruption	40
4. PBT/vPvB	82
5. Petroleum streams	200

Source: National Institute for Public Health and the Environment, The Netherlands, September 2014, cf. http://www.reachlaw.fi/images/uploads/files/REACHLaw_RIVM_Fleur_van_Broekhuizen_29_September_2014.pdf

*incl. substances containing an impurity, constituent or additive with a harmonized classification under CLP: CMR or Sens Cat 1A or Cat 1B

New since 23.09.2014

EC SVHC Roadmap to 2020

Substances under scrutiny: The new PACT list

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

Showing 1 - 20 of 80 results.

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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>

EC SVHC Roadmap to 2020

Public Consultations on RMOAs: German example

[Homepage](#) [REACH-Regulation](#) [SVHC-Roadmap-to 2020](#) [German RMOA-List](#)

German RMOA-List

Structure of the following table:

The substances are listed by their chemical name and sometimes also their common name.

The gathered information in the category "known uses" are abstracts from registration dossiers and therefore may not be complete.

The status shows whether a risk management option analysis (RMOA) is in progress or has already been concluded.

The "consultation" category gives companies or associations from the affected industries the possibility to submit relevant information via the web form provided (only active during consultation period).

name of the substance	CAS no.	EC no.	(suspected) concern	known uses	status	suggested follow up	consultation
beryllium	7440-41-7	231 - 150-7	carcinogen	component of alloys; construction of scientific equipment; nuclear technology and aerospace industry; mechanic equipment; electronic devices; metal articles	RMOA under development		Till 22.11.2014 online survey
1,7,7-trimethyl-3-(phenylmethylene)bicyclo [2.2.1] heptan-2-one (or trivial: 3-benzylidene camphor)	15087-24-8	239 - 139-9	endocrine disruptor	UV filter in sunscreens and other cosmetics	RMOA under development		Till 08.12.2014 online survey

Public Activities Coordination Tool

RMOA-List of substances of all member states

http://www.reach-clp-biozid-helpdesk.de/en/REACH-en/SVHC-Roadmap-en/DE_RMOA-Liste-en/DE_Stoffliste-en.html

Authorisation overhaul

Updated ECHA prioritization approach

- Legal basis (as before): REACH Article 58(3): "Priority shall normally be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes."
- Overview of scoring for each criterion:

Key reference: REACH registration info

Inherent properties		Volume		Wide dispersive use	
57(a) or/and 57(b) or/and 57(c) or/and 57(f) ^{13,14}	1	no volume	0	no use	0
57(f) (ED)	7	< 10 t/y	3	IND	5
57(d) or 57(e)	13	10 - <100 t/y	6	PROF	10
57(d) and (at least) one other SVHC property or 57(e) and (at least) one other SVHC property	15	100 - <1,000 t/y	9	CONS	15
		1,000 - <10,000 t/y	12		
		≥ 10,000 t/y	15		

- Hence: highest score for PBT/vPvB, Endocrine Disruptors, Consumer and Professional Uses
- **Grouping** considerations to avoid unwanted substitution
- Further info: ECHA document dd. 10 February 2014 available at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

Authorisation overhaul

Grouping considerations for SVHC management

New grouping of SIN List chemicals based on structure and toxic properties:

Alkylphenols	Amino carbonyl compounds	Antimony compounds	Aromatic amines	Arsenic compounds	Azo compounds
Beryllium compounds	Bisphenols	Boron compounds	Cadmium compounds	Chromium compounds	Cobalt compounds
Electrophiles	Glycol ethers	Hydrazines	Lead compounds	Mercury compounds	Mineral fibres
Nickel compounds	Nitro compounds	Nitrosamines	Parabens	Perfluorinated compounds	Petroleum
Phthalates	Polyaromatics	Polyhalogenated aromatics	Polyhalogenated alkanes	Polyhalogenated alkenes	Thioamino carbonyl compounds
Tin compounds	<i>[Non-grouped substances]</i>				

Source: http://chemsec.org/images/stories/2014/Grouping_SINimilarity_factsheet.pdf,
http://www.chemsec.org/images/stories/2014/SIN_launch_presentations/Lars_Swanson_ChemSec.pdf

Authorisation overhaul

Commission initiatives to reduce the burden

- Before Annex XIV listing: Stronger consideration of **socio-economic impacts**
 - ECHA does not consider such impacts during prioritisation
 - Current parallel call for information on socio-economic consequences of the authorisation requirement
<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list>
- After Annex XIV listing: simplifying the authorisation process for some special cases, such as
 - uses in very low-volume
 - uses essential from a Socio-Economic point of view

EC is working on an Implementing Regulation to REACH.

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2. Status of the REACH Authorisation process
3. EU-level activities towards a more adequate risk management
4. Conclusions for the Space sector

REACH developments on SVHC scrutiny

Conclusions

- Positive
 - More systematic approach of SVHC identification
 - Consideration of other regulatory options than authorisation
 - More influence for industry on the process
 - More transparency
- The challenges
 - Complexity of obsolescence risk assessment
 - Need to monitor closely on a substance level
 - Include *similar* substances in the risk assessment
 - Do not miss consultation windows (member state level)

Questions ?

**THANK YOU
FOR YOUR ATTENTION !**

Compliance. Sustained.

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Additional slides

List of acronyms (1/2)

Abbreviation	Explanation
AfA	Application for Authorisation
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)
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
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
