

# REGULATORY ACTIONS UNDER REACH & CLP – FEEDBACK FROM ECHA'S RAC

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Annual Conference REACH&CLP

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# CONTENT

- ECHA and its Committees
- How substances of concern are regulated
- Tasks of the RAC
  - Harmonised classification and labelling - CLP
  - Application for Authorisation - REACH
  - Restriction - REACH
  - Art 95(3) REACH: Conflicts of opinions with other bodies

# ECHA AND ITS COMMITTEES

- **European Chemicals Agency:** regulatory authority for implementing the EU's chemicals legislation.
  - Member States Committee (MCS)
  - **Risk Assessment Committee (RAC)**
  - Committee for Socio-Economic Assessment (SEAC)
  - Biocidal Products Committee (BPC)
  - Forum



## REACH

Regulation (EC)  
No 1907/2006 on the  
Registration, Evaluation,  
Authorisation and  
Restriction of Chemicals

## CLP

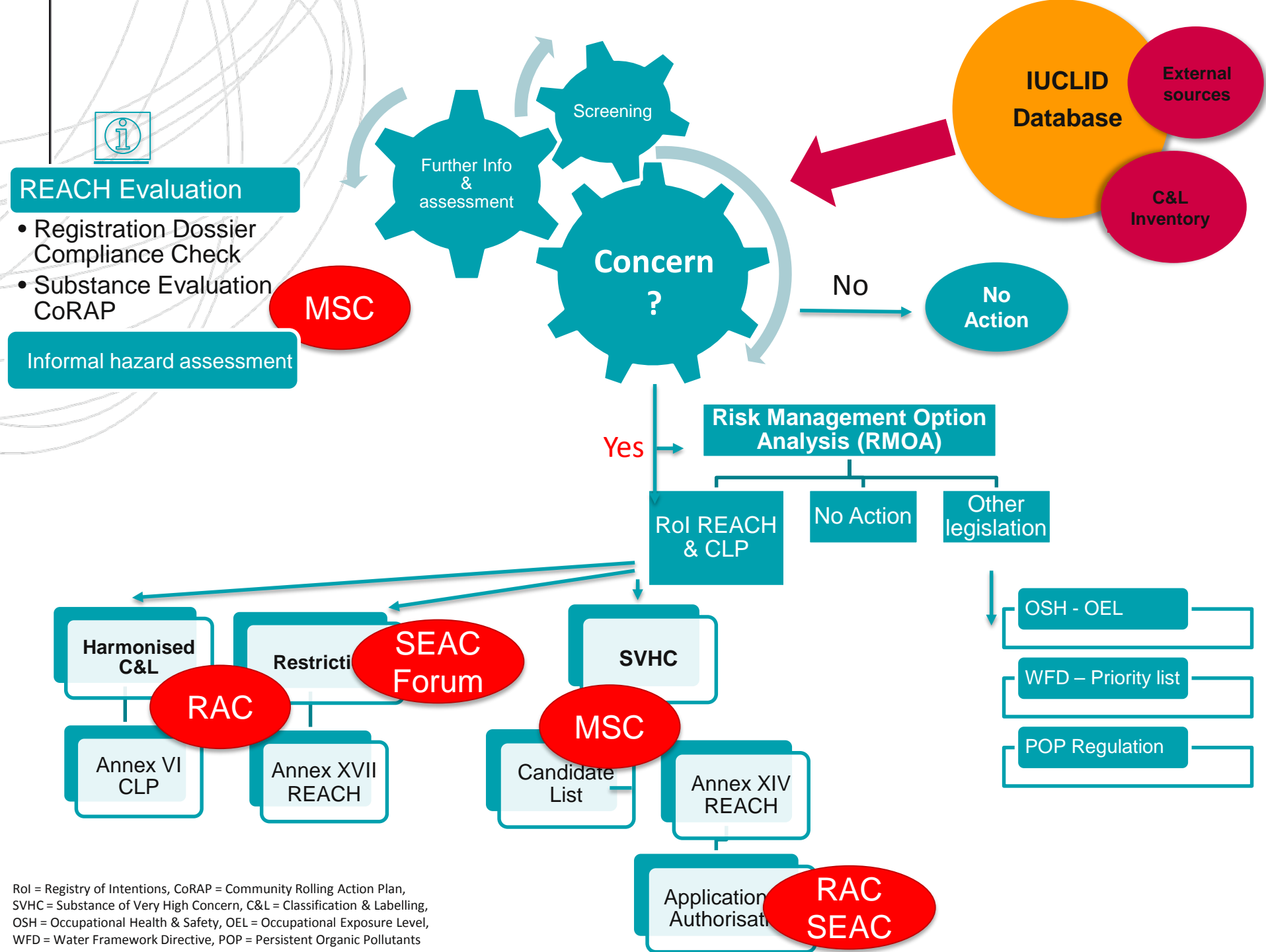
Regulation (EC) No  
1272/2008 on the  
classification, labelling and  
packaging of substances  
and mixtures

## BPR

Regulation (EU) No  
528/2012 concerning the  
making available on the  
market and use of biocidal  
products

## PIC

Regulation (EU) 649/2012  
concerning the export and  
import of hazardous  
chemicals







- **Regulation (EC) 1272/2008 Classification, Labelling and Packaging (CLP)**

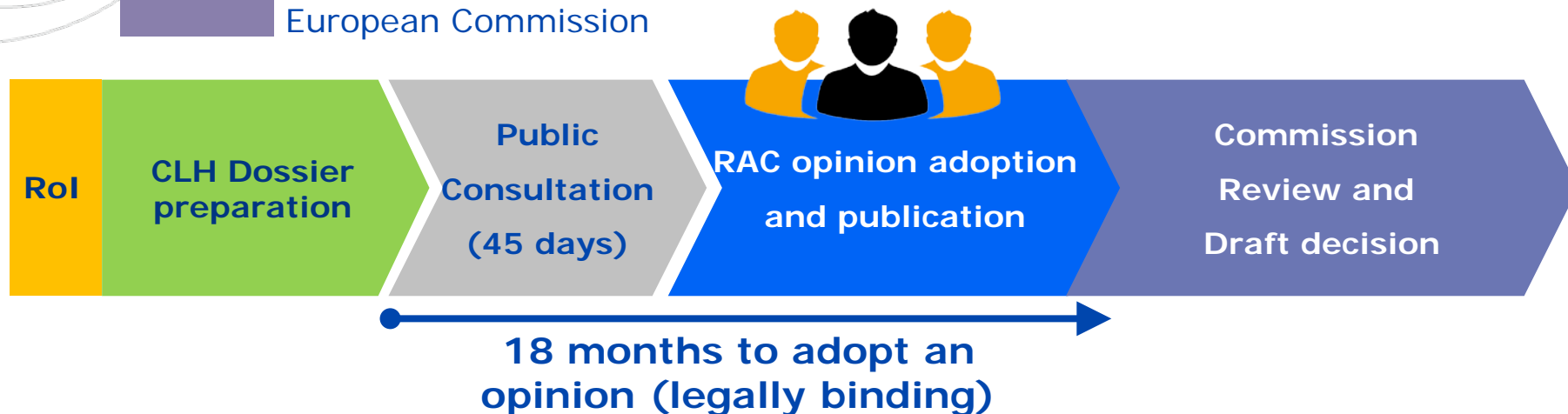
- Harmonisation of classification and labelling at an EU level (legally binding)
- Focus on substances which are of most concern to humans
  - Carcinogenic (C)
  - Mutagenic (M)
  - Reproductive toxicants (R)
  - Respiratory sensitisers (RS)
- Other hazard classes can be harmonised on a case-by-case basis – justification needed
- Active substances in plant protection products (PPP) and biocidal products (BP) shall normally be subject to harmonised classification and labelling – all hazard classes.
- Harmonised classified substances are included in Annex VI CLP



# HARMONISED CLASSIFICATION - PROCESS OVERVIEW

## Main actors:

-  Dossier submitter (Member states Competent Authority or industry)
-  ECHA / Committee for Risk Assessment
-  Parties Concerned including other MSCAs, individuals and NGOs
-  European Commission



**RAC and its Rapporteurs:** Examine the CLH proposals and prepare an **opinion** on the proposed harmonised classification for a substance

# CLP - HARMONISED CLASSIFICATION

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## RAC Opinion development



- **Commission (DG Enterprise & Environment)**
  - **Decision** on inclusion in Annex VI of CLP, based on opinion adopted by RAC
  - Commission acts as observer at RAC meetings
- **Manufacturer / Importer / DU:** Following the inclusion of the substance in Annex VI to the CLP, all manufacturers, importers and downstream users of the substance in the EU must classify the substance in accordance with the entry in Annex VI. Hazard classes not included in the Annex VI entry must be self-classified and labelled accordingly.

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
"009-016-00-2	trisodium hexafluoroaluminate [1] trisodium hexafluoroaluminate (cryolite) [2]	237-410-6 [1] 239-148-8 [2]	13775-53-6 [1] 15096-52-3 [2]	STOT RE 1 Acute Tox. 4 Aquatic Chronic 2	H372 H332 H411	GHS07 GHS08 GHS09 Dgr	H372 H332 H411			
603-012-00-X	2-ethoxyethanol; ethylene glycol monoethyl ether	203-804-1	110-80-5	Flam. Liq. 3 Repr. 1B Acute Tox. 3 Acute Tox. 4	H226 H360FD H331 H302	GHS02 GHS08 GHS06 Dgr	H226 H360FD H331 H302			
603-025-00-0	tetrahydrofuran	203-726-8	109-99-9	Flam. Liq. 2 Carc. 2 Eye Irrit. 2 STOT SE 3	H225 H351 H319 H335	GHS02 GHS07 GHS08 Dgr	H225 H351 H319 H335	EUH019	STOT SE 3; H335: C ≥ 25 % Eye Irrit.2; H319: C ≥ 25 %	

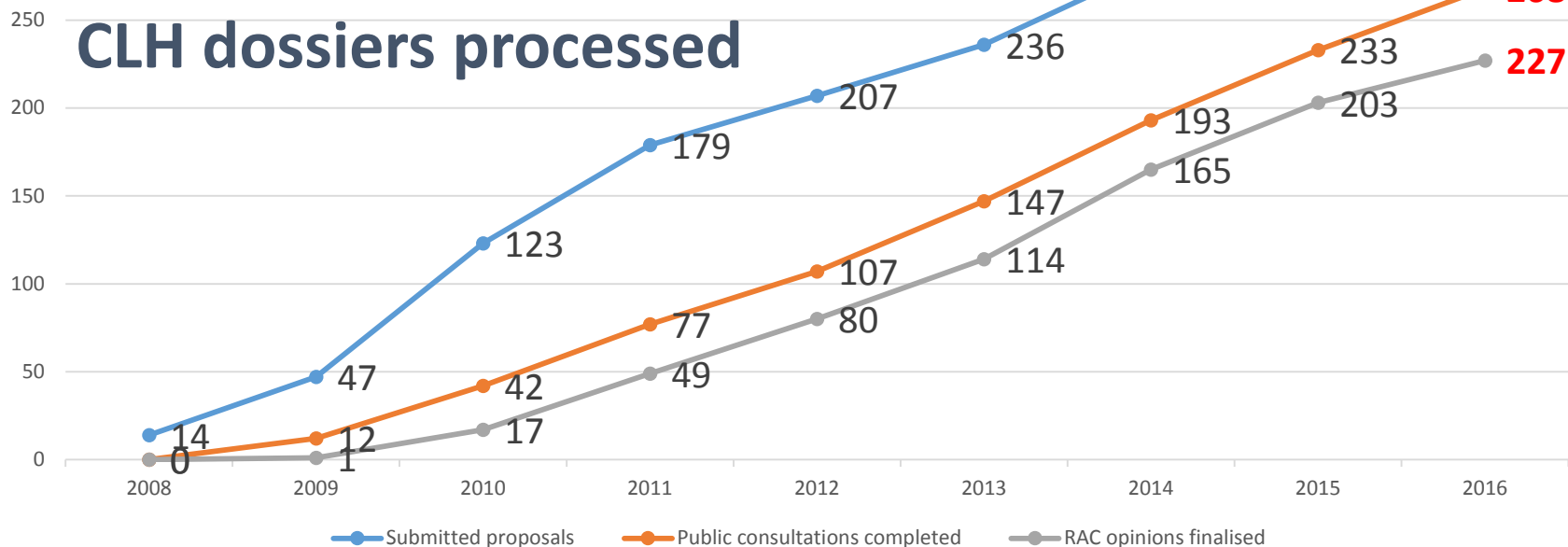
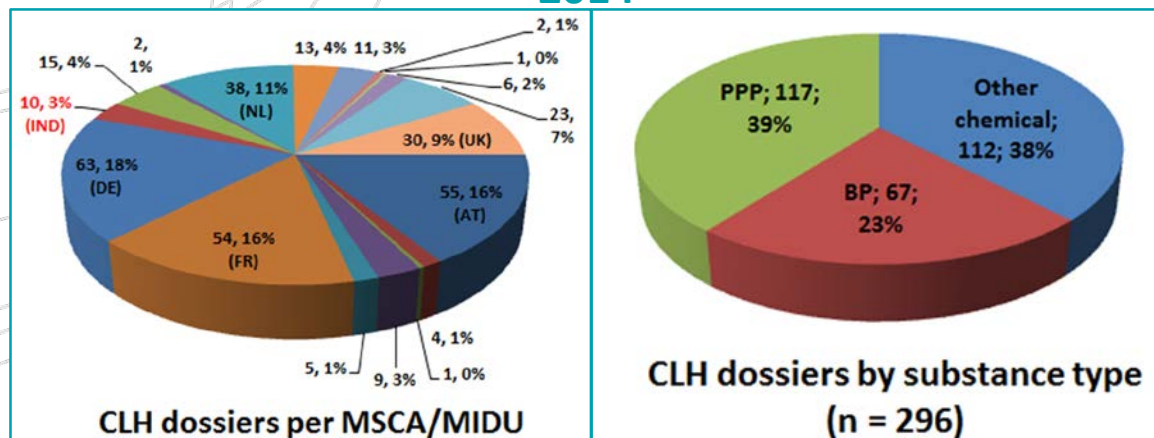
# CLP - HARMONISED CLASSIFICATION

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## Some statistics (status Sep 2016)

2014





# CLP - HARMONISED CLASSIFICATION

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## Registry of Intentions

https://www.echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions

ECHA EUROPEAN CHEMICALS AGENCY

Search the ECHA Website

Advanced search

About Us Regulations **Addressing Chemicals of Concern** Information on Chemicals Chemicals in our Life Support

ECHA > Addressing Chemicals of Concern > Registry of Intentions > Submitted CLH proposals

f t y e + 5

## Submitted CLH proposals

Registry of Intentions

Page 1 of 7

50 Items per Page

Showing 1 - 50 of 315 results.

← First

Previous

Next

Last →

Name	EC Number	CAS Number	Submission date	Regulatory programme	
imiprothrin (ISO); reaction mass of [2,5-dioxo-3-(prop-2-yn-1-yl)imidazolidin-1-yl]methyl (1R,3S)-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate and [2,5-dioxo-3-(prop-2-yn-1-yl)imidazolidin-1-yl]methyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	428-790-6	72963-72-5	05/09/2016	Exisiting active substance in Biocidal Products (in the meaning of Directive 98/8/EC)	<a href="#">Details</a>
paclobutrazol (ISO); (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol	-	76738-62-0	05/09/2016	Active substance in PPP	<a href="#">Details</a>
diisooctyl phthalate	248-523-5	27554-26-3	31/08/2016	Other substance	<a href="#">Details</a>
octamethylcyclotetrasiloxane	209-136-7	556-67-2	29/07/2016	Other substance	<a href="#">Details</a>
Dimethyl disulphide	210-871-0	624-92-0	14/06/2016	Other substance	<a href="#">Details</a>

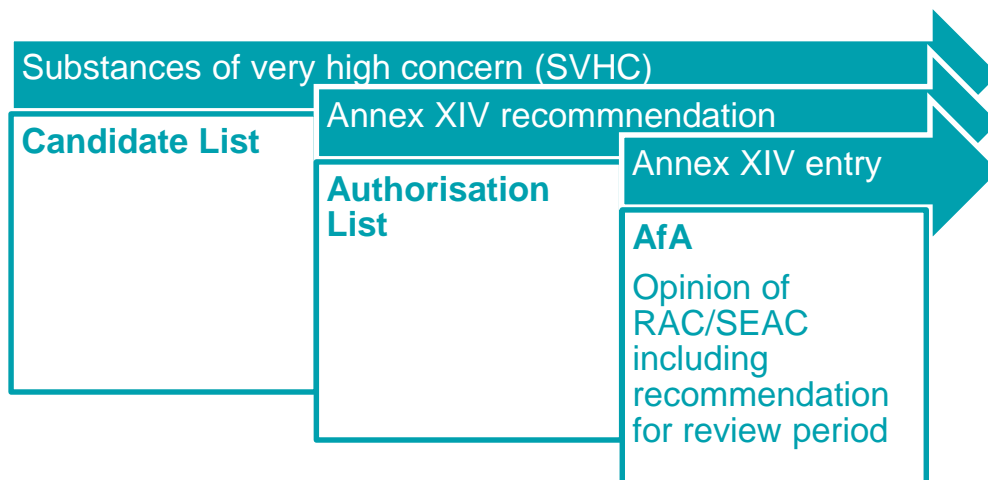
[quest/addressing-chemicals-of-concern/registry-of-intentions](#)

www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions

# REACH - AUTHORISATION

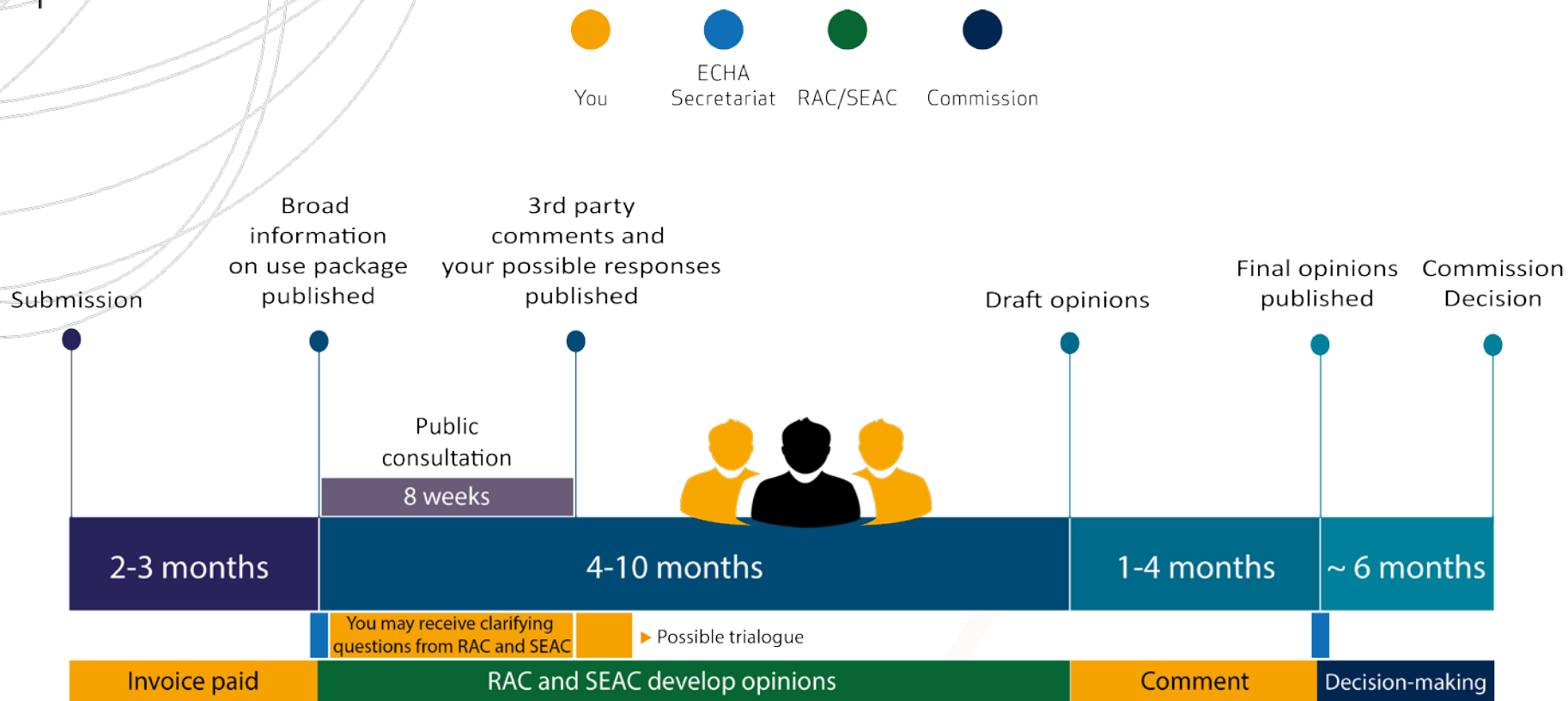
## RAC opinion development

- To ensure that the risks from **Substances of Very High Concern (SVHC)** are properly controlled and that these substances are **progressively replaced** by suitable alternatives while ensuring the good functioning of the EU internal market.
- Substances on the Authorisation List (Annex XIV of REACH) cannot be used or placed on the market for a use after a specific 'sunset date'
  - Unless an application for authorisation (AfA) is granted
  - Unless an application has been submitted before the latest application date (and a decision has not yet been made).



# APPLICATION FOR AUTHORISATION - PROCESS OVERVIEW

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- RAC: assessment of risk to human health and / or environment from the use applied for, including appropriateness and effectiveness of Risk Management Measures and, if relevant, risk from possible alternatives.

# REACH - AUTHORISATION

## Some statistics

	Received notifications to submit	Received <sup>1</sup> applications (applicants)	Number of uses	RAC-SEAC opinions per use	RAC-SEAC opinions per use and per applicant	Commission decisions per use and per applicant
2012	5	0 (0)	0	0	0	0
2013	11	8 (10)	17	1	1	0
2014	170	19 (33)	38	30	34	2
2015	72	7 (20)	13	25	51	10
2016*	14	77 (132)	112	33	74	47
<b>Total</b>	<b>272</b>	<b>111 (195)</b>	<b>180</b>	<b>89</b>	<b>160</b>	<b>59</b>

\*Indicative status on 17 November 2016, subject to rapid change; <sup>1</sup> Fee paid



## Joint RAC-SEAC Opinions per Use

Committee for Risk Assessment (RAC)  
Committee for Socio-economic Analysis (SEAC)

Opinion  
on an Application for Authorisation for  
Chromium trioxide use: Passivation of tin-plated steel (ETP)

ECHA/RAC/SEAC: AFA-O-0000006490-77-06/D

# REACH - AUTHORISATION

## Some statistics

Substance	Number of received* AfAs (Applicants)	Number of uses	RAC-SEAC opinions per use	RAC-SEAC opinions per use and applicant	Commission decision (per use and applicant)
Phthalates	8 (10)	17	17	21	14
Lead chromate pigments	1 (1)	12	12	12	12
HBCDD	1 (13)	2	2	26	26
Diarsenic trioxide	4 (4)	5	5	5	5
Trichloroethylene	13 (15)	19	19	21	2
Lead chromate	1 (1)	1	1	1	
EDC	10 (12)	12	1	1	
<b>Chromium VI substances</b>	<b>57 (123)</b>	<b>110</b>	<b>47</b>	<b>88</b>	
Diglyme	8 (8)	9	1	1	
Arsenic acid	1 (1)	1			
Technical MDA	1 (1)	2			
MOCA	1(1)	1			
<b>Total:</b>	<b>111 (195)</b>	<b>180</b>	<b>89</b>	<b>160</b>	<b>59</b>

Indicative status on 17 November 2016, subject to rapid change; \*Fee paid

# REACH - AUTHORISATION

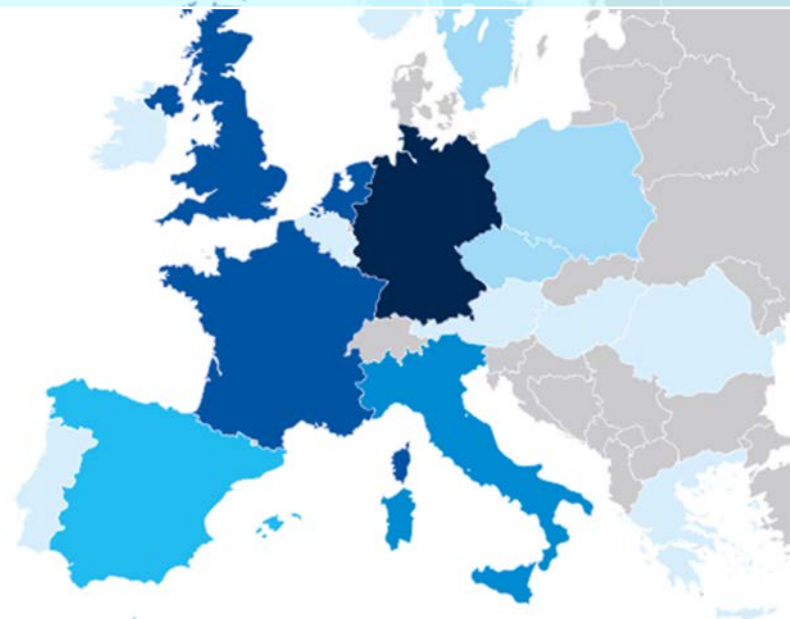
## Some statistics

Companies	Uses and sites
<b>Single applicant</b> One or more own uses on own site(s)	Typical, compact <b>downstream</b> applications from SME's to large multi-nationals
<b>Consortium:</b> single or multiple own uses on multiple (named) sites	Larger, more complex <b>downstream</b> applications – representativeness of OC, RMM and exposure data comes into play
<b>Single applicant or consortium:</b> single or multiple uses on multiple (mostly un-named) sites covering part of a supply chain	Very large <b>upstream</b> applications, where representative 'standards' on OC, RMM and exposure data are proposed

OC = Operational Conditions, RMM = Risk Management Measures

### NUMBER OF APPLICANTS PER COUNTRY

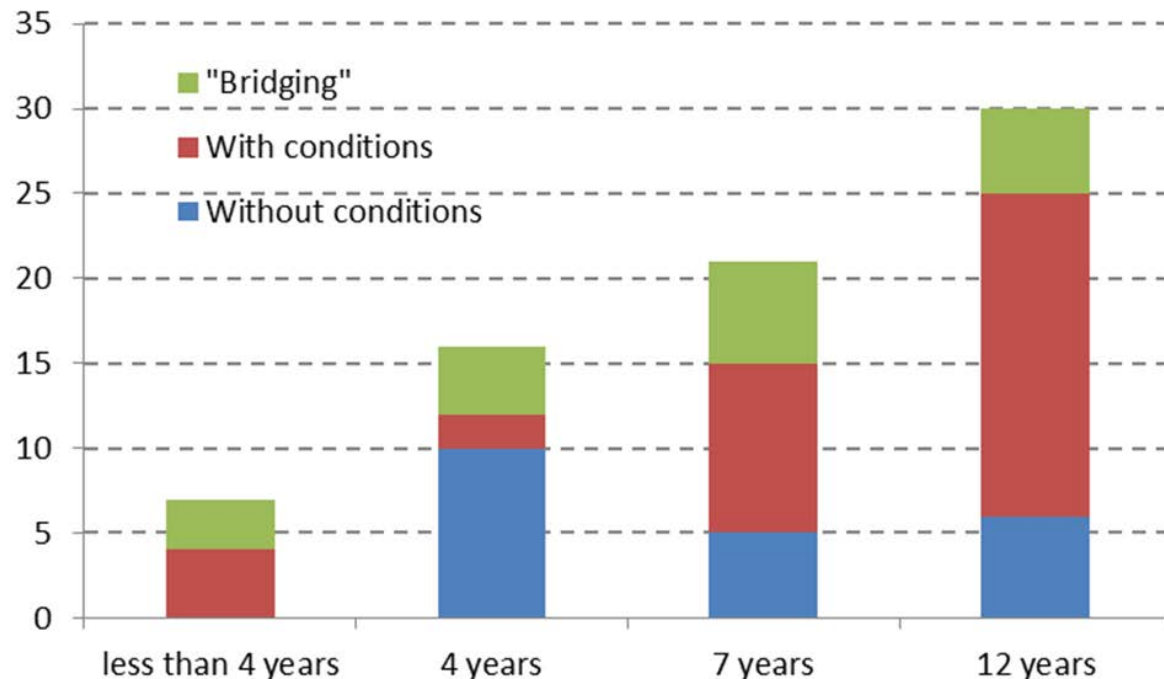
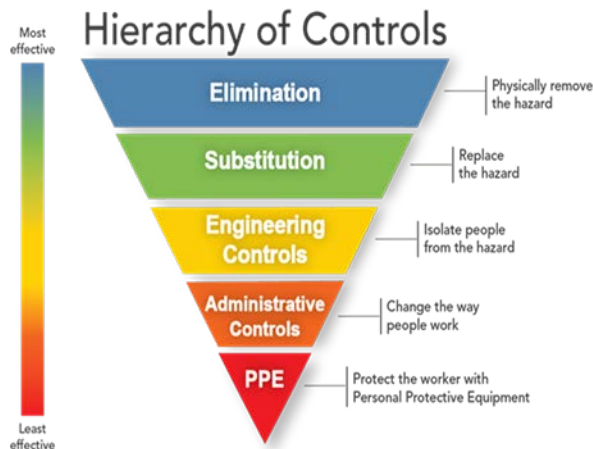
Germany	56	Austria	3
France	27	Ireland	3
UK	24	Belgium	2
Netherlands	21	Hungary	2
Finland	13	Luxembourg	2
Italy	12	Portugal	2
Spain	7	Greece	1
Poland	5	Norway	1
Czech Republic	4	Romania	1
Sweden	4		



# REACH - AUTHORISATION

## Some statistics

- RAC and SEAC have recommended a variety of review periods – both with and without conditions for the authorisation and/or the review report
  - RAC: Exposure monitoring, review / introduce / strengthen Risk Management Measures, maintain records for inspection by enforcement authorities.
  - SEAC: quantities used, timeline, scope of alternative assessment





# REACH - AUTHORISATION

## Positive effects for the protection of workers

- No applications, or only very few were received for some Annex XIV substances.
- About 25% of applications request shorter review periods as a 'bridge' to alternative substances.
- Authorisation has stimulated fresh workplace exposure investigations
  - Nearly all downstream applications indicate new (2013-2015) campaigns to measure exposure or, to show the intensification of existing monitoring programmes
- Many applications already show improvements to operational conditions and risk management measures as a result of monitoring and reassessment in the preparing the application
  - Improvement in specific RMMs during the preparation of the application
  - Implementation of plans to reduce overall exposure to SVHC



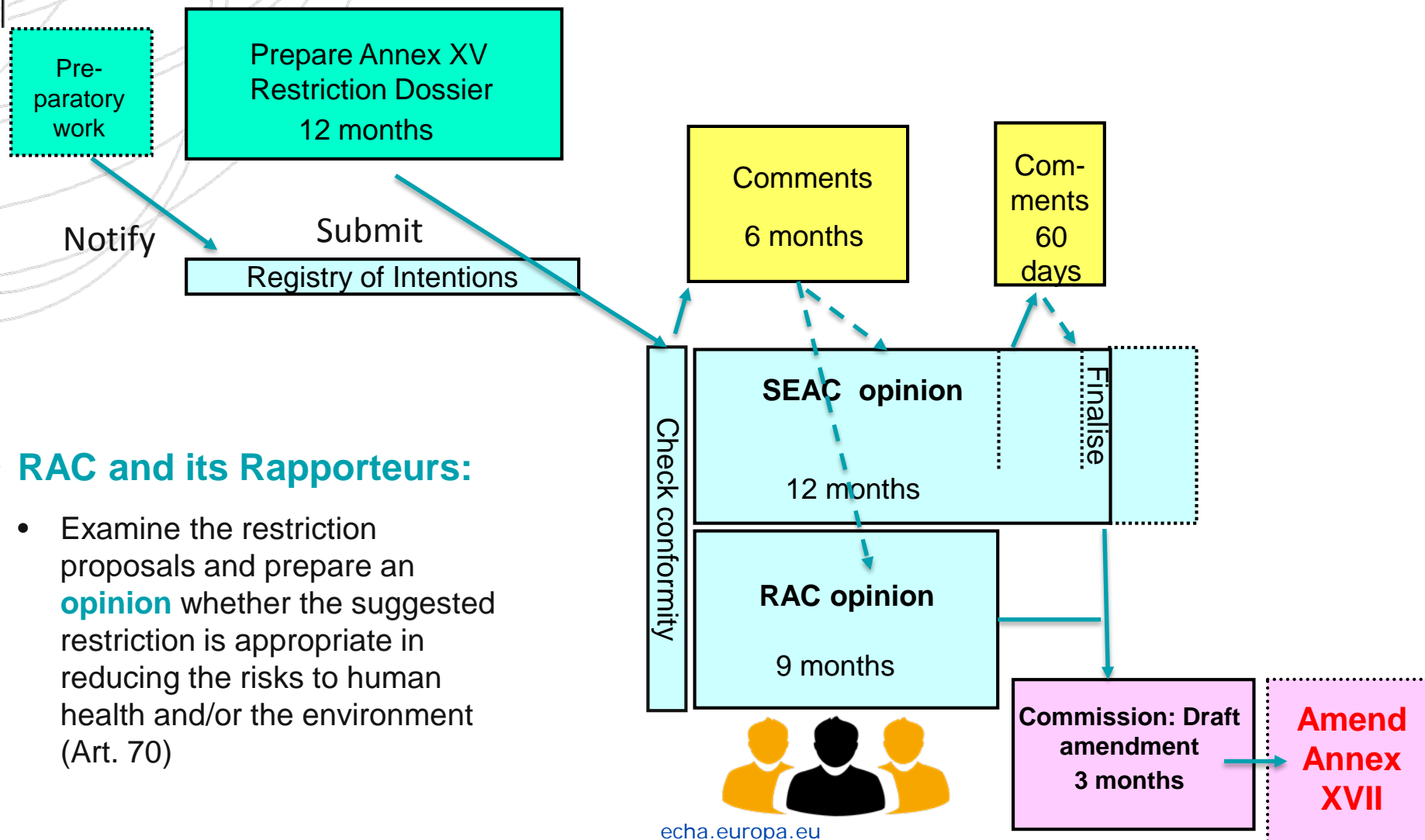


# REACH - RESTRICTION

- Continues the work done under Directive 76/769/EEC
- **A safety net:**
  - Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment
  - Authorisation or other Community actions are not more appropriate
  - Other REACH processes do not ensure adequate control of risks
  - **Community-wide action:** the same requirements apply to whole EU from entry into force
- Restrictions may be imposed on:
  - Manufacture, use and/or placing on the market
  - A substance on its own, in preparation or in an article, when...



# REACH - RESTRICTION



# REACH - RESTRICTION

- **Specific restriction cases:**
  - **Carcinogenic, mutagenic and toxic to reproduction** (CMR category 1A/1B):
    - Used by consumers (substance as such, in mixture or in articles):
    - Entry 28-30 REACH Annex XVII
  - **Annex XIV substances (authorisation list) – A69(2):**
    - After sunset date, ECHA considers if the use of the substance in articles causes risk that is not adequately controlled and prepares a restriction proposal
- **Article 129 cases – Safeguard clause**
  - MSs take appropriate provisional measures if urgent actions are needed, e.g. ammonium salts in cellulose
  - Commission decision - if authorising provisional measures: Annex XV dossier submission to ECHA by the Member State

28. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogen category 1A or 1B (Table 3.1) or carcinogen category 1 or 2 (Table 3.2) and listed as follows:

- Carcinogen category 1A (Table 3.1)/carcinogen category 1 (Table 3.2) listed in Appendix 1
- Carcinogen category 1B (Table 3.1)/carcinogen category 2 (Table 3.2) listed in Appendix 2

29. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as germ cell mutagen category 1A or 1B (Table 3.1) or

Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:

1. Shall not be placed on the market, or used,
  - as substances,
  - as constituents of other substances, or,
  - in mixtures,

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

- either the relevant specific concentration limit

# REACH - RESTRICTION

## Ongoing opinion making and proposal preparation

TABLE 11: KEY DATA ON RESTRICTIONS FOR 2009-15

	Received intentions	Restriction dossiers submitted by Member States	Restrictions prepared by ECHA	RAC-SEAC opinions*	Commission decisions
2009	4				
2010	1	3	1		
2011	2	1		4	
2012	2	1	1	1	4
2013	7	3	1	2	
2014	4	4	2	5	3
2015	4	3	0	6	3
Total	24	15	5	18	10**

\*)A RAC-SEAC opinion means formally three opinions: one RAC opinion, one SEAC draft opinion and one SEAC opinion

\*\*) In addition, Commission decisions on 2 further restriction proposals were made in January/February 2016

- PL: Methanol in windshield washing fluids (finished Dec 2015)
- UK: D4/D5 in personal care products (finished June 2016)
- DK: TDFA in spray products (conformity)
- ECHA/DK: Phthalates - DEHP, DBP, DIBP, and BBP in articles (conformity)
- IT: DMF (submission in 7/2016)
- DE: Isocyanates (submission in 10/2016)
- ECHA: Lead stabilisers in PVC (submission in late 2016)
- ECHA: Lead shot in wetlands (submission in mid 2017)
- ECHA: CMRs/sensitisers in Tattoo inks and permeant make up (submission in late 2017)

# REACH - RESTRICTION

## Ongoing proposals

Proposed restriction

Column 1. Designation of substance	Column 2. Conditions of restriction
(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives, including among others:  (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)trimethoxysilane CAS No. 85857-16-5 EC No. 288-657-1  (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triethoxysilane CAS No. 51851-37-7 EC No. 257-473-3  (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triisopropoxysilane CAS No. 1240203-07-9	<ol style="list-style-type: none"><li>1. Shall not be used in formulation of mixtures with organic solvents in spray products intended for supply to the general public</li><li>2. Shall not be placed on the market, in a concentration equal to or greater than 2 ppb by weight, in spray products containing organic solvents for supply to the general public.</li><li>3. Spray products should in this context be understood as aerosol dispensers, pump and trigger sprays and mixtures marketed for spray application by any means.</li><li>4. Organic solvents mentioned in paragraph 1 and 2 include organic solvent used as aerosol propellants.</li></ol>

### Brief title:

The restriction is a ban on the use of TDFA's in mixtures containing organic solvents placed on the market or used in spray products for consumers (aerosol dispensers, pump and trigger sprays and mixtures marketed for spray application)



# REACH - RESTRICTION

## Ongoing proposals

Table 1. Proposed restriction

<p>Bis(2-ethylhexyl) phthalate (DEHP) EC number: 204-211-0 CAS number: 117-81-7</p>	<ol style="list-style-type: none"> <li>Articles containing DEHP, DBP, DIBP, and BBP in a concentration, individually or in combination, greater than or equal to 0.1% by weight of the plasticised material shall not be placed on the market.</li> <li>Paragraph 1 shall apply three years from the entry into force of the restriction.</li> </ol> <p>Paragraphs 1 and 2 shall not apply to:</p> <ol style="list-style-type: none"> <li>articles only for outdoor use where the phthalate-containing material is not in prolonged contact with human skin or any contact with human mucous membranes  <p>"Prolonged contact with human skin" should in this context be understood as covering a daily overall contact with skin of more than 10 minutes continuously or 30 minutes discontinuously.</p> <p>"Only for outdoor use" should in this context be understood as articles which are not used or stored in the interior of dwellings where humans are present under normal and reasonably foreseeable conditions.</p> </li> <li>articles only for use in industrial or agricultural workplaces. This derogation does not apply to articles where the phthalate-containing material is in prolonged contact with human skin by workers.</li> <li>measuring devices for laboratory use</li> <li>articles placed on the market in the European Union prior to the date in paragraph 2.</li> </ol>
<p>Benzyl butyl phthalate (BBP) EC number: 201-622-7 CAS number: 85-68-7</p>	
<p>Dibutyl phthalate (DBP) EC number: 201-557-4 CAS number: 84-74-2</p>	
<p>Diisobutyl phthalate (DIBP) EC number: 201-553-2 CAS number: 84-69-5</p>	<p>Paragraph 1 and 2 shall not apply to articles covered under existing legislation:</p> <ol style="list-style-type: none"> <li>Food contact materials covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials.</li> <li>Immediate packaging of medicinal products covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC, or to medical devices covered by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC.</li> <li>Toys and childcare articles containing DEHP, DBP and BBP covered by existing restriction entry 51 in Annex XVII of REACH 'Childcare article' is defined as in the existing restriction entry 51 in Annex XVII.</li> </ol>

### Brief title:

Restriction on articles containing the four phthalates for:

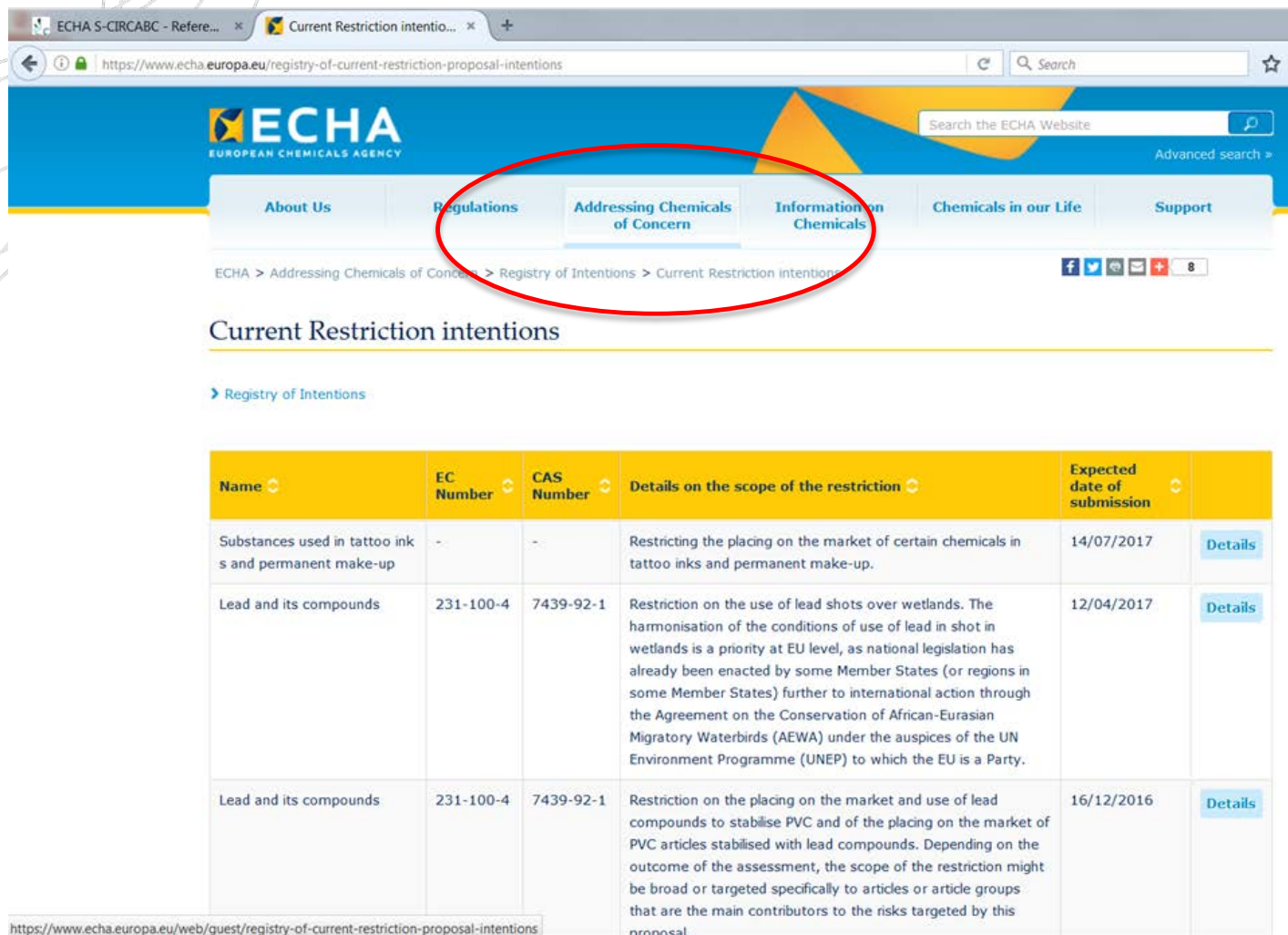
- indoor use
- outdoor use, if in contact with human skin or mucous membranes





# REACH - RESTRICTION

## Registry of Intentions



The screenshot shows the ECHA website with the URL <https://www.echa.europa.eu/registry-of-current-restriction-proposal-intentions>. The navigation menu includes 'About Us', 'Regulations', 'Addressing Chemicals of Concern' (highlighted with a red circle), 'Information on Chemicals', 'Chemicals in our Life', and 'Support'. The breadcrumb trail is 'ECHA > Addressing Chemicals of Concern > Registry of Intentions > Current Restriction Intentions'. The page title is 'Current Restriction intentions'. Below the title is a link to 'Registry of Intentions'. The main content is a table with the following data:

Name	EC Number	CAS Number	Details on the scope of the restriction	Expected date of submission	
Substances used in tattoo inks and permanent make-up	-	-	Restricting the placing on the market of certain chemicals in tattoo inks and permanent make-up.	14/07/2017	<a href="#">Details</a>
Lead and its compounds	231-100-4	7439-92-1	Restriction on the use of lead shots over wetlands. The harmonisation of the conditions of use of lead in shot in wetlands is a priority at EU level, as national legislation has already been enacted by some Member States (or regions in some Member States) further to international action through the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of the UN Environment Programme (UNEP) to which the EU is a Party.	12/04/2017	<a href="#">Details</a>
Lead and its compounds	231-100-4	7439-92-1	Restriction on the placing on the market and use of lead compounds to stabilise PVC and of the placing on the market of PVC articles stabilised with lead compounds. Depending on the outcome of the assessment, the scope of the restriction might be broad or targeted specifically to articles or article groups that are the main contributors to the risks targeted by this proposal.	16/12/2016	<a href="#">Details</a>

<https://www.echa.europa.eu/web/guest/registry-of-current-restriction-proposal-intentions>

# ART 95(3) REACH: CONFLICTS OF OPINIONS WITH OTHER BODIES

- **Art. 95(3):** “Where there is fundamental conflict over scientific or technical points and the body concerned is a community agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and /or technical points of conflict.”

ECHA and SCOEL are therefore requested to establish a joint Task Force for the comparative critical assessment of REACH DNEL and OEL methodologies

- a) for the inhalation route and
- b) for dermal route, including ‘skin notation’ and dermal DNEL



Internal

I(2015)0377 1 (3)

16-12-2015

## Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment

**Ref: Request to the Committee for Risk Assessment to create a joint task force with the Scientific Committee on Occupational Exposure Limits (SCOEL) on scientific aspects and methodologies related to the exposure of chemicals at the workplace and to prepare a report on their scientific evaluation**

Based on the request from the European Commission to ECHA of 6 July 2015, the purpose of this note is to give a mandate to RAC to create a joint task force with the Scientific Committee on Occupational Exposure Limits (SCOEL) for the comparative critical assessment of REACH DNEL and OEL methodologies a) for the inhalation route and b) for dermal route, including ‘skin notation’ and dermal DNEL.

### 1. Background

The processes for deriving REACH ‘derived no effect levels’ (DNELs) and occupational safety and health (OSH) ‘occupational exposure limits’ (OELs) are carried out separately and often result in different numerical values for exposure limit values and derived effect threshold levels for the same chemical, principally as a result of the different use of expert judgement and methodologies, which in turn reflect the different contexts in which each concept has been developed.



# Thank you for your attention!



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**REACH & CLP**

Un service du Luxembourg Institute of Science and Technology  
En partenariat avec le Ministère du Développement durable et des Infrastructures  
et le Ministère de l'Economie

Thanks to



for support