

23.02.2017, 04:00PM (EET) | Webinar

**REACH 2017 Agenda:** Key deadlines and actions for industry



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# REACHLaw in brief

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
- ✓ Offices 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 2010 deadline, 5% /all OR
- ✓ Language support in 10+ different languages
- ✓ eSpheres investor
- ✓ More info about Us at: [www.reachlaw.fi](http://www.reachlaw.fi)

## SERVICE AREAS

- ✓ Global chemicals regulatory compliance, e.g.

REACH	CLP
Biocides	Turkish Compliance
K-REACH	China REACH

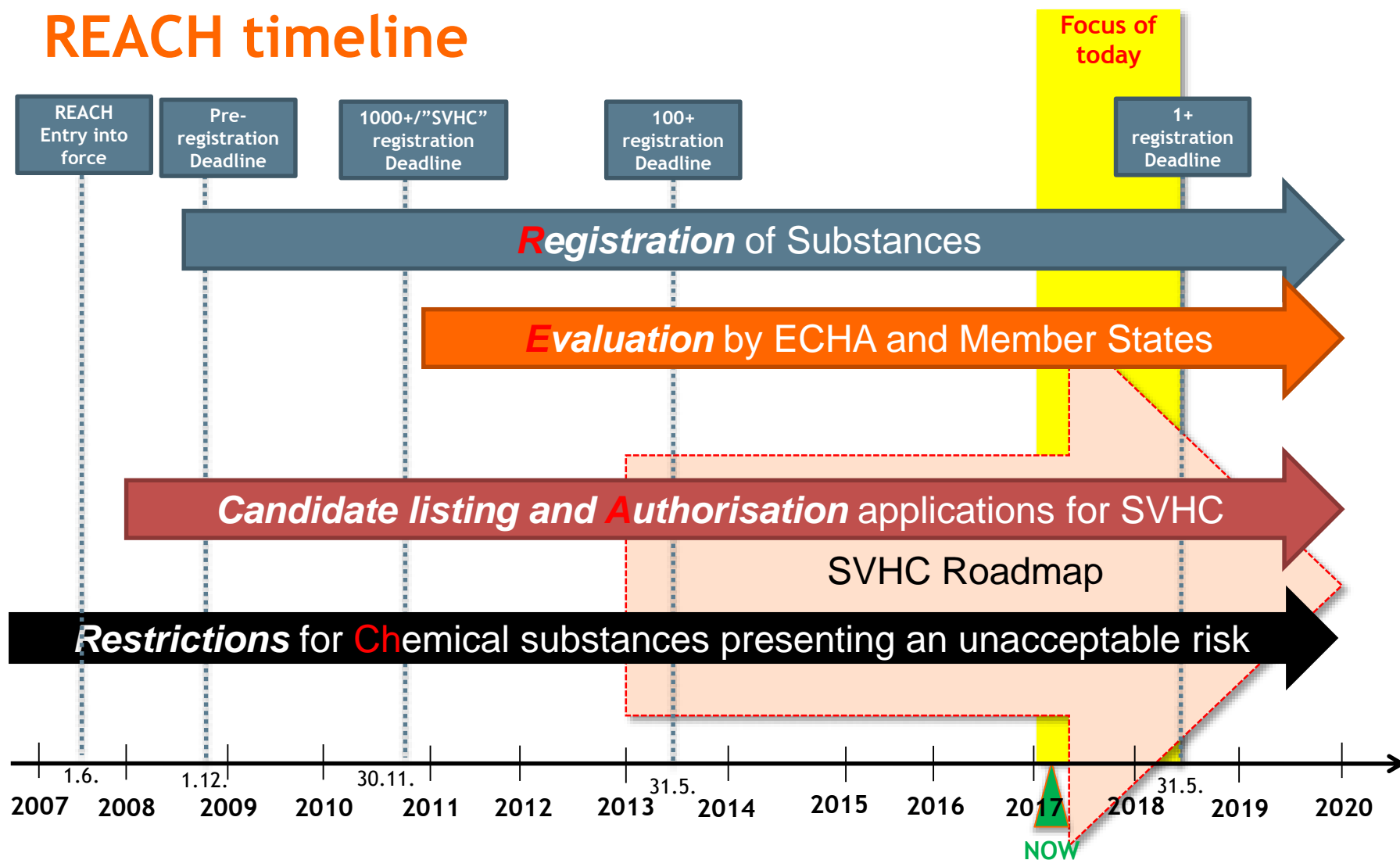
- ✓ We prepare the required dossiers to authorities, SDSs, labels and provide related business strategy, legal and monitoring support.
- ✓ Provide Outsourcing solutions for chemical compliance management
- ✓ Supply chain compliance management tools: [www.compliant suppliers.com](http://www.compliant suppliers.com)

## OUR CLIENTS

- ✓ More than 300 customers from 40+ countries, from Fortune 100 companies to SMEs.
- ✓ Major industries served: Oil, chemicals, specialty chemicals, metals, aerospace and defence sector
- ✓ Our customers are manufacturers, importers, traders, downstream users, industry associations and governmental organizations.

# REACH 2017 Webinar

## REACH timeline



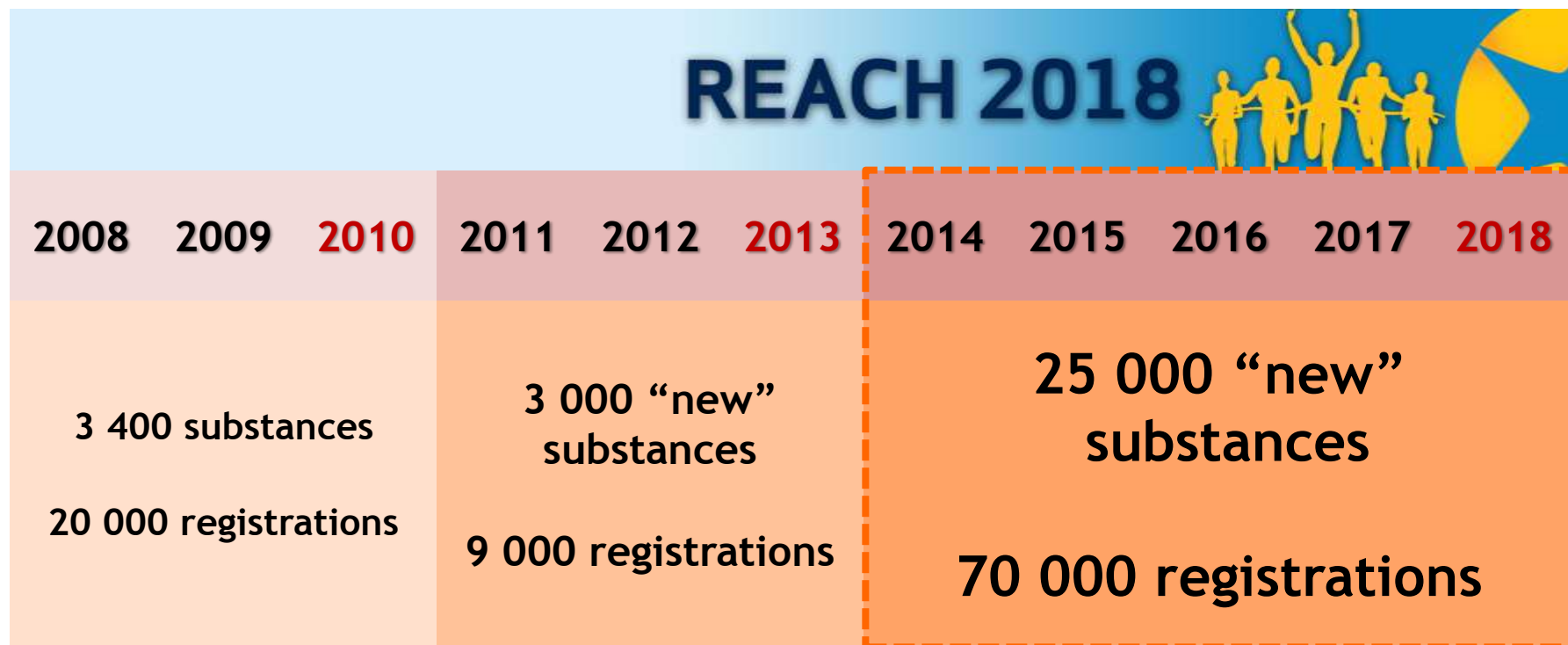
# AGENDA FOR PRESENTATION

1. Introductions
2. Late Pre-registration closes on 31 May 2017
3. Lead Registrant for 2018 and testing
4. Authorisation deadlines
5. Enforcement
6. 2<sup>nd</sup> REACH review (REFIT evaluation)
7. Brexit vote consequences
8. Conclusions

**Q&A after the presentation:**  
*Please send questions using the chat!*

# Introductions

## Registration 2018



- As of 11 January 2017 (*newest available data*):
  - Registrations: **48 318** (*this incl. smaller volumes of already registered substances*)
  - Unique substances: **10 557**

# Introductions

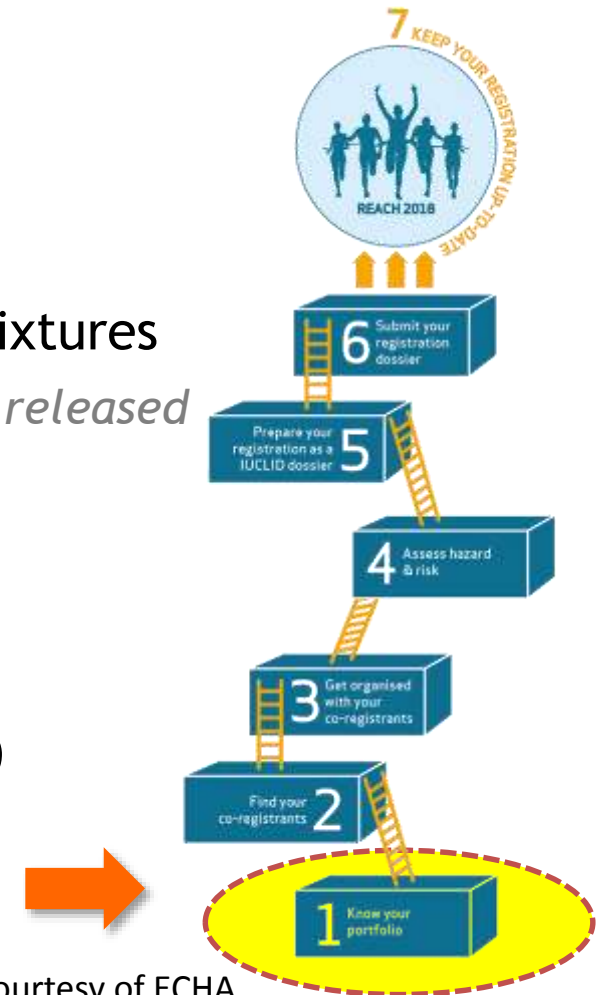
## Registration 2018: Know Your Substance Portfolio

### 1. Determine your chemical portfolio in terms of substances

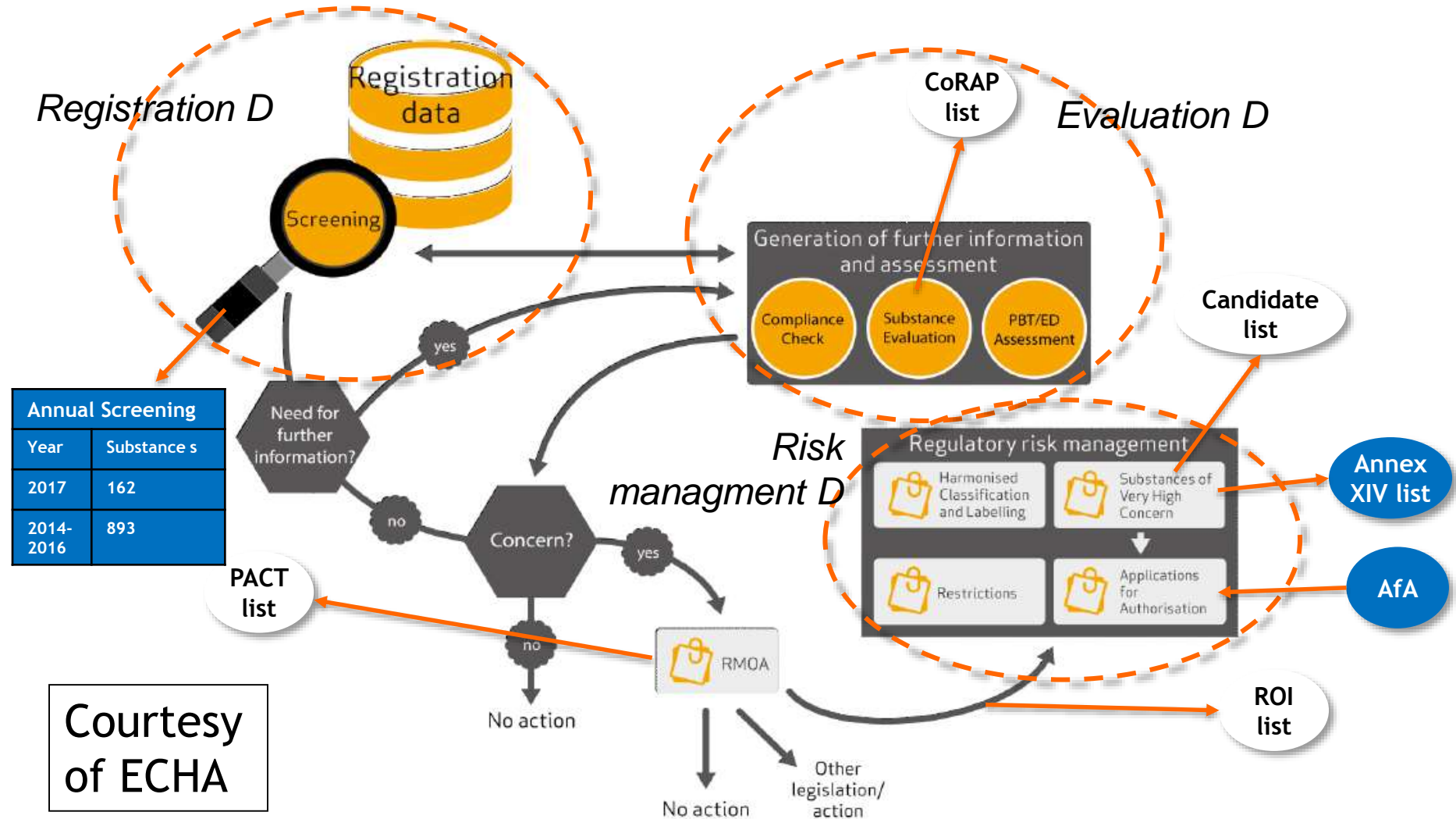
- Substances on their own
- Mixtures: which substances are in these mixtures
- *(Articles: which substances are intended to be released from them, not very common case)*

### 2. Identify your substances and determine REACH Scope

- Manufacture/Import  $\geq 1$  t/a (1-10, 10-100)
- No exemption from registration
- Intermediate only or Full dossier?
- Hazard classification?



# Introductions I Registration is only the start...





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# Late Pre-registration closes on 31 May 2017

## Can you still late pre-register?

### YES if cumulatively (REACH Art. 28(6)):

- + You manufacture or import
- + An existing "phase-in" substance (REACH Art. 3(20))
- + in quantities of  $\geq 1$  t/y -  $< 100$  t/y, with 31.5.2018 registration deadline
- + for the first time, after 1.12.2008
- + You pre-register within 6 months of first manufacturing/importing and no later than on 31 May 2017



You are allowed to continue manufacturing or import without registration until 31 May 2018

### Therefore excluded:

- Non-phase in substances (not fulfilling the definition in Art. 3(20))
- Substances subject to previous 2010 and 2013 deadlines, i.e. manufactured/imported  $\geq 100$  t/y or CMR Cat. 1/2  $\geq 1$  t/y (according to Directive 67/548/EEC)
- "First-time" Only Representative for substances already exported to EEA  $\geq 1$  t/y after 1 June 2008 (including to Importers with a pre-/registration)



You need to pass an ECHA inquiry and register before you may start manufacture/import

# Late Pre-registration closes on 31 May 2017

## Possibilities for "late" non-EU manufacturers

Strategy to avoid business disruptions for non-EU manufacturer wishing to appoint an Only Representative for the first time now while the late pre-registration conditions are not fulfilled:

- Only Representative (OR) inquiry and registration
- Until completed OR registration: Channel exports through validly pre-/registered EU customers (importers)
  - established importers may have already pre-/registered
  - "first-time" importers may still be eligible for late pre-registration
- OR registration relieves importers covered by it from (further) registration / update responsibilities.

# Late Pre-registration closes on 31 May 2017

## Possibilities for "late" non-EU manufacturers

Makes good business sense to appoint an OR

Why?

1. more control over the whole REACH process
2. centralised administration function
3. control of confidential and proprietary data/information
4. only one registration cost per substance
5. your importers become '*downstream users*' of the OR
6. updating of registration info is easier
7. competitive advantage

## EU Only Representatives

REACHLaw is one of the foremost  
*Only Representatives* in the EU,  
representing several hundred  
non-EU/EEA companies worldwide

( *North America, South America, non-EU/EEA  
Europe, Asia, Africa, Oceania, Middle East, ...* )

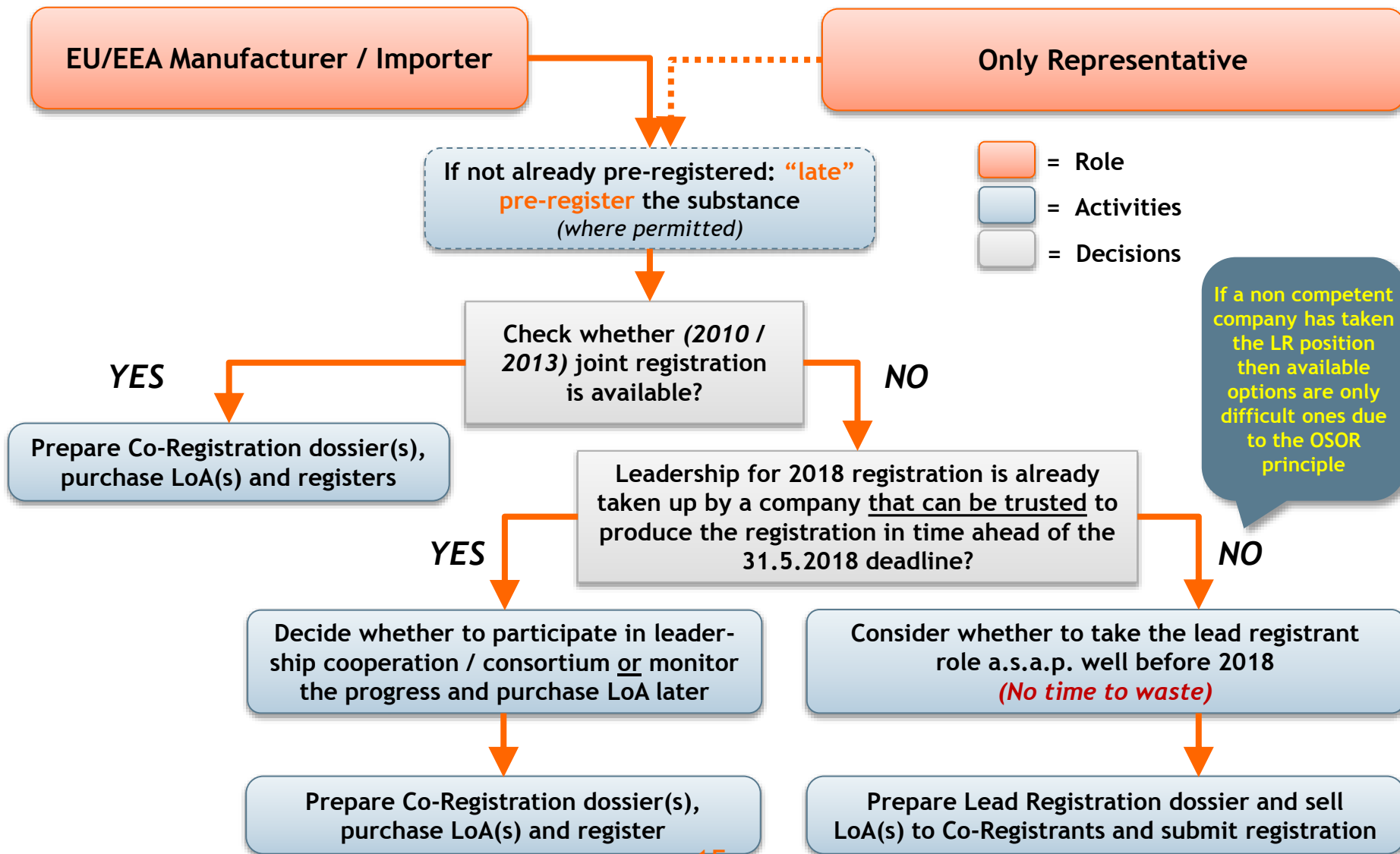
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# Lead Registrant for 2018

## Way Forward for 2018 Registrations for once you know your REACH substance portfolio



# Lead registrant for 2018

## Steps to be completed: A Big Responsibility

### Getting started

- Identification of critical substances for 2018 without lead registrant
- Estimate registration costs
- Selection of consultant
- Obtain lead registrant mandate from (pre-)SIEF and inform ECHA
- Leadership agreement (*less common for 2018*)
- Define and agree substance ID

### Prepare joint submission

- SIEF communication
- Data collection incl. uses
- Data gap analysis
- 2018 test program, incl. non-testing methods
- Data gap filling: Testing
- Prepare IUCLID dossier
- $\geq 10$  t/y: Chemical Safety Assessment and CSR, incl. Hazard assessment ( $\rightarrow$  C&L) and Exposure Assessment (if hazardous)
- Financial management, esp. cost calculations
- SIEF Agreement / LoA

### Submission and follow-up

- Lead dossier to ECHA
- Grant joint submission access to co-registrants
- Update (extended) Safety Data Sheet
- Keep dossier up-to-date (spontaneous updates)
- Respond to authority requests, e.g. ECHA compliance check
- Continuous financial management, e.g. reimbursement in case of new co-registrants

NOW

URGENT

Submit before April 2018



# Lead Registrant for 2018

## Duration of LR work (dossier preparation only!)

- The duration of Lead Registration work is typically:
  - ca. 6 - 9 months for 10-100 t/a full substances
  - ca. 2 - 3 months for 1-10 t/a full substances
  - ca. 1 - 2 months for 1-100 t/a t/a intermediates
- These include testing, where required to fill data gaps.
- **Testing capacity is already starting to clog up** so if you start now, expect some delays when testing can start
  - Will only get worse the closer we get to 2018 deadline

Cannot stress enough that **testing will be your bottleneck** in the whole process - Get it scheduled a.s.a.p.

# Lead Registrant for 2018

## Decision-criteria for lead registrant role

### BENEFITS: YOU ARE IN CONTROL

- Selection of consultants and testing laboratories
- Substance identification profile
- Dossier contents & quality
- Registration process
- Timing
- Coverage of uses (= markets)



Appropriate for  
Business-critical substances

### CHALLENGES: YOU ARE IN CHARGE

- *Technical*: Responsibility to lead the Joint Submission work
- *Legal*: Compliance with REACH, Data Sharing Regulation, etc.
- *Financial*: Cost tracking, LoA sales, reimbursements
- *"Lifetime commitment"*: e.g. post-registration updates, data sharing management



Need for multidisciplinary  
expertise

## Support Services for Lead Registrants

1. Substance ID verifications and SIP preparation
2. Data gap analysis
3. Data holder communications ( + *Read across* )
4. Testing planning and monitoring ( + *organising tests* )
5. Consortia / SIEF management and SIEF communication
6. CSR incl. Exposure scenarios
7. Classification & Labelling
8. Lead Registrant Dossier compilation and submission
9. Financial management (*for cost sharing purposes*)
10. LoA's (*fair and transparent*) and SIEF agreements
11. EU (e)SDSs (*Multilanguage*)
12. Continuous Lead Registrant dossier maintenance, data sharing management ...*etc.*

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# Authorisation deadlines

## Overview: Key authorisation dates & what they mean

	Latest submission window	Latest Application date	Sunset date	DU notification deadline	Review report
<b>When?</b>	ECHA website	Annex XIV	Annex XIV	REACH Art. 66 <i>"within 3 months of first supply"</i>	18 months before expiry of review period
<b>Why?</b>	Efficient ECHA Processing of AfAs; alignment with RAC/SEAC schedule	Safeguard continued use after Sunset Date in case of Pending EC decision	Continued use only within the frame of an EC authorisation	Information for enforcement purposes of the DUs that rely on upstream authorisation	Review authorisation decision based on latest Data on use and alternatives
<b>Consequences of late action:</b>	Likely delay in AfA decision making	Have to cease use from the Sunset Date, unless/until an EC decision granting the authorisation is granted	Use outside the frame of an EC authorisation is likely target of strict Member States' enforcement	Lack of timely notification is possible target of Member States' enforcement	Possible invalidity of authorisation decision at expiry of review period

# Authorisation deadlines

## Upcoming Sunset and Latest Application Dates

Ref	Nr	Substance name	EC	Latest application date	Sunset date (+ 18 m)	Exemptions
COM Reg (EU) 143/2011 of 17 February 2012	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
	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
COM Reg (EU) No 348/2013 of 17 April 2013	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
	23	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1	22 February 2016	22 August 2017	None
EC Regulation (EU) 895/2014 Of 14 August 2014	24	Arsenic Acid	231-901-9	22 February 2016	22 August 2017	None
	25	Bis(2-methoxyethyl)ether (Diglyme)	203-924-4	22 February 2016	22 August 2017	None
	26	1,2-Dichloroethane (EDC)	203-458-1	22 May 2016	22 November 2017	None
	27	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	22 May 2016	22 November 2017	None
	28	Dichromium tris(chromate)	246-356-2	22 July 2017	22 January 2019	None
	29	Strontium chromate	232-142-6	22 July 2017	22 January 2019	None
	30	Potassium hydroxyoctaoxodizincatedichromate	234-329-8	22 July 2017	22 January 2019	None
	31	Pentazinc chromate octahydroxide	256-418-0	22 July 2017	22 January 2019	None

# Authorisation deadlines

## Upcoming Annex XIV update<sup>1</sup> (~ May 2017)

### List of 12 substances proposed by EC for 2017 Annex XIV inclusion

Ref	Entry no.	Substance name	EC	Concern
Draft Commission Regulation amending Annex XIV	32	1-bromopropane (n-propyl bromide)	203-445-0	Toxic for reproduction
	33	Diisopentylphthalate	210-088-4	Toxic for reproduction
	34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	Toxic for reproduction
	35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	Toxic for reproduction
	36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	284-032-2	Toxic for reproduction
	37	Bis(2-methoxyethyl) phthalate	204-212-6	Toxic for reproduction
	38	Dipentyl phthalate (DPP)	205-017-9	Toxic for reproduction
	39	N-pentyl-isopentylphthalate	-	Toxic for reproduction
	40	Anthracene oil	292-602-7	Carcinogenic, PBT, vPvB
	41	Pitch, coal tar, high temp. (CTPHT)	266-028-2	Carcinogenic, PBT, vPvB
	42	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	Endocrine disruptor (environment)
	43	4-Nonylphenol, branched and linear, ethoxylated	-	Endocrine disruptor (environment)

<sup>1</sup>Based on 5th (2014) and 6th (2015) ECHA Annex XIV recommendation. List according to positive REACH Committee vote of 08/12/2016. *Future rounds in the pipeline: 7th ECHA Annex XIV recommendation with 9 substances (10.11.2016), 8th ECHA Annex XIV Draft Recommendation (2017).*

- Proposed latest application dates range from 18-24 months post Annex XIV inclusion.
- Proposed sunset dates range from 36-42 months post Annex XIV inclusion.

# Authorisation deadlines

## DU Notification Deadline: REACH Article 66

- Instead of applying for authorisation themselves, a Downstream User may use an Annex XIV substance *"in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use"* (upstream AfA).\*
- Any such Downstream User shall *notify ECHA "within 3 months of the first supply of the substance."* \*\*
- The first major 'test' case for this provision is the **upstream AfA by the CTAC(Sub) Consortium**, covering uses of chromium trioxide in various industry sectors, with potentially 100s of DUs relying on it. ECHA RAC/SEAC opinions were given in September 2016. **The EC decision is expected during 2017.**
- It is expected that DU notifications to ECHA will start to be made as soon as the EC decision granting the authorisation has been published. **A major expected challenge is for those DUs to comply with the authorisation conditions.** ECHA RAC has recommended that DU's implement at least annual programmes of occupational exposure measurements and emissions of Cr(VI) to wastewater and air from local exhaust ventilation be measured at individual sites.

\*REACH Article 56(2)    \*\*REACH Article 66(1)

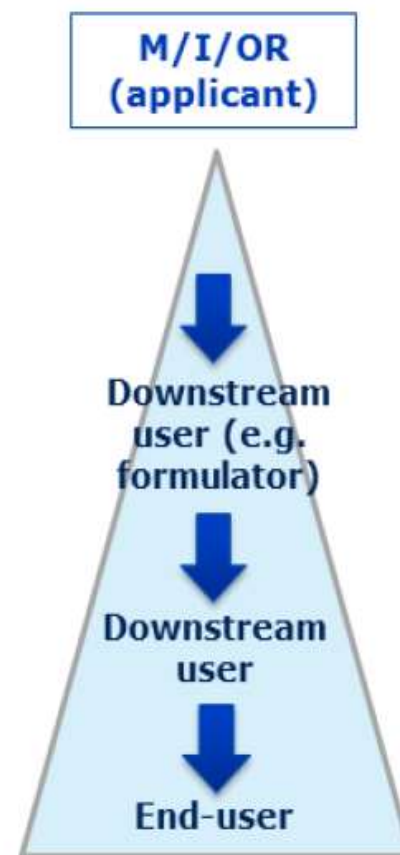


Image source: ECHA, 2016



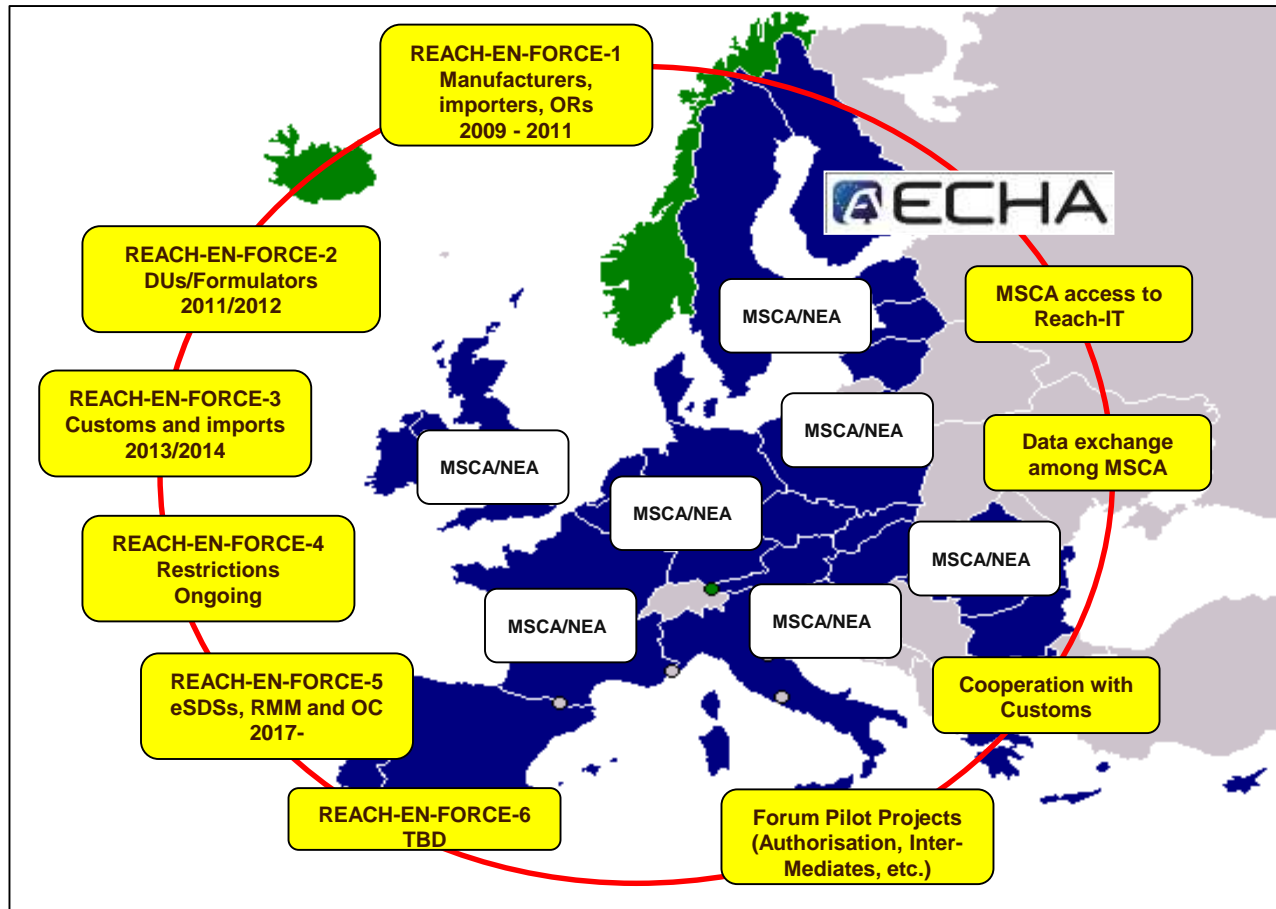
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# REACH enforcement

## National responsibility, EU-wide co-ordination



- **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

# REACH enforcement

## REACH-EN-FORCE-5 on eSDSs since January 2017

- The first joint EU enforcement project that aims to improve communication, through safety data sheets, throughout the supply chain
- Objective: inspect how safety information on hazardous chemicals is compiled, communicated in the supply chain and followed at workplaces → safety for workers
- Focus: Check compliance of extended Safety Data Sheets (eSDSs) with manufacturers' Chemical Safety Report (CSR); check Exposure Scenarios
- Effective communication of eSDSs through the supply chain will also be mapped
- Workers compliance with the safety information at their workplaces will also be checked
- Authority collaboration of inspectors from national REACH enforcement authorities with labour inspectors
- Timeframe: From January 2017, throughout the year



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# 2nd REACH Review 2017 (REFIT evaluation)

## Overview

- **5-year General Report on the Functioning of REACH**
- Managed by the European Commission (EC)
- Follow-up of the 1st EC REACH review in 2012 (published in 2013)
- Carried out in the frame of **"REFIT": Regulatory Fitness and Performance Programme of the EC**, covering five compulsory evaluation criteria: **Effectiveness, Efficiency, Relevance, Coherence and EU Added Value**, including examining the **potential to improve** the way in which REACH delivers on its objectives and the potential for **burden reduction and simplification**.
- The related public consultation of stakeholders closed on 28 January 2017
- The review results will provide useful insights for industry on possible REACH evolutions beyond 2018.

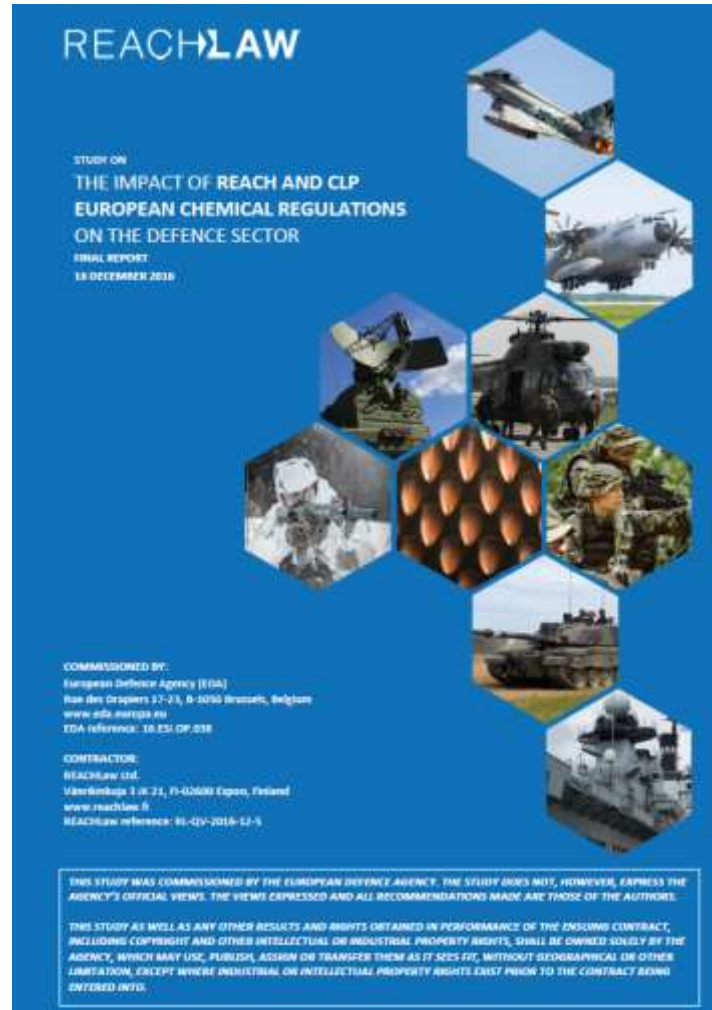
# 2nd REACH Review 2017 (REFIT evaluation)

## 17 Thematic Studies

Study on registration requirements for low tonnage (1 - 10Tn/y)	Technical assistance on extension of the registration requirements for substances 1 - 10 tonnes	Technical assistance related to the extension of the obligation of a CSA /CSR for CMR 1A/1B substances < 1-10 tonnes per year	Technical assistance related to the review of REACH with regard to the registration requirements on polymers
Study to develop EU enforcement indicators for REACH and CLP	Study on the impact of REACH on innovation, competitiveness and SMEs	Study formulating recommendations based on statistical analysis of Member State reporting according to Article 117(1) (operation of REACH in the Member States)	Study on impact of REACH and corresponding legislation in third countries on the international competitiveness of the EU chemicals industry and selected downstream user
Cumulative Cost Assessment for the chemicals industry	Substance Identity (SID) in REACH: analysis of SID and substance sameness of complex substances	Calculation of the indicators of benefits of chemical legislation on human health and the environment	Cumulative human health and environmental benefits of chemical legislation
Cumulative socio-economic benefits of chemical legislation	Study on the costs and benefits of authorisation	REACH baseline study - 10 years update	Evaluation of ECHA
Eurobarometer survey on the perception of chemical safety			

# 2nd REACH review 2017 (REFIT evaluation)

## Stakeholder input prepared by REACHLaw



<https://www.eda.europa.eu/docs/default-source/documents/eda-reach-study-final-report-2016-december-16-p.pdf>

REACH REFIT 2017 Position Paper  
27 January 2017

ASD-EUROSPACE

**ASD-EUROSPACE**  
The Space group in ASD

### SPACE SECTOR CONTRIBUTION TO THE EC REACH REVIEW 2017 – POSITION PAPER

This is the joint contribution to the European Commission (EC) REACH review 2017 (REFIT<sup>1</sup> evaluation) of the European Space industry – represented by ASD-Eurospace – with the support of European and national space agencies.<sup>2</sup> Furthermore, reference is made to the contribution by ASD of 24 January 2017 to the same consultation; it is fully supported by the space industry.

#### 1. INTRODUCTION

The REACH requirements impact the European space sector to a great extent, both from a regulatory compliance and commercial perspective. The processes for registration and in particular Authorisation of Substances of Very High Concern (SVHC), which aim at their substitution with suitable alternatives, pose continuous challenges or even risks that have to be actively monitored and mitigated by the space industry to avoid costly production and supply chain disruptions in order to secure the reliable continuation of space activities and the EU's independent access to space as a key element of the EU's space policy<sup>3</sup> in an increasingly competitive environment globally. The strict communication requirements of REACH Article 35<sup>4</sup> pose a further specific challenge for the space industry as manufacturers of highly complex launcher and space systems (space vehicles).

The objective of the document is to

- Outline key REACH relevant features of the space sector (Section 2);
- Highlight key sector concerns with regard to REACH and return on experience (Section 3);
- Provide recommendations for REACH implementation improvement (Section 4).

<sup>1</sup> Regulatory Fit and Performance Programme of the EC, covering five compulsory evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value, including examining the potential to improve the way in which REACH delivers on its objectives and the potential for burden reduction and simplification.

<sup>2</sup> This contribution has been prepared in the frame of the Materials and Processes Technology Board of the European Space Components Coordination (ESCC-MPTB). The ESCC-MPTB is a partnership between the European Space Agency (ESA), national space agencies, and space industry represented by Eurospace, initiated and presided by ESA. Current participants from Eurospace include: Airbus Defence & Space, Airbus Defence Launchers, Aéro, OHB, RUAG, RUAG and Thales Alenia Space. Participating national space agencies are: Agence spatiale Belge (ASB), Centro Nacional de Estudios Espaciales (CNES) and Deutsche Zentrum für Luft- und Raumfahrt e.V. (DLR). Other participants are ESA, a manufacturer of satellites, and Reachlaw, a consultancy supporting the group on REACH and other chemical regulations.

<sup>3</sup> [http://ec.europa.eu/space/docs/Space\\_2016.pdf](http://ec.europa.eu/space/docs/Space_2016.pdf), in its "Space Strategy for Europe" of 24 October 2016 the European Commission proposes a number of actions to maintain Europe's autonomous access to space.

<sup>4</sup> As recently confirmed by the judgment of the Court of Justice of the European Union (Case C-626/14), see <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62014J0147&id=1&aspe=html&fulltext=true&cid=1&lang=fr>.

For the purpose of this Position Paper the term 'space vehicle' refers to space launch vehicles (launchers) and spacecraft (e.g., satellite systems, probes). Space vehicles are produced by governments, public institutions (military and civil) and commercial entities in Europe and worldwide.

<http://www.eurospace.org/position-paper-addresses-impacts-of-the-eu-chemicals-regulation-impacts-of-the-eu-chemicals-regulation-%E2%80%9C9Creach%E2%80%9D-on-space-activities-.aspx>

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# Brexit vote consequences

## Current status of Brexit vs. REACH and the UK

### BREXIT plans

- UK referendum on 23 June 2016 to **leave the EU**
- UK government intention to leave the EU Single Market and the jurisdiction of the Court of Justice of the EU (CJEU), but **preserve EU law where it stands at the moment before the UK leave the EU and ensuring free trade with the EU\***
- UK 'leave' notification under Article 50 of the TEU expected in March 2017 (parliamentary mandate pending), followed by UK-EU negotiations

### REACH and the UK today\*\*

- UK registrations: 5 836 (12% of EEA) for 2 414 substances (~23% of EEA)
  - By UK Only Representatives: 2 523 (~23% of EEA) for 1 219 substances (39% of EEA)
- UK Lead Registrants: 723 (~9% of EEA)
- UK authorisation applicants / downstream users

\*[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/588948/The\\_United\\_Kingdoms\\_exit\\_from\\_and\\_partnership\\_with\\_the\\_EU\\_Web.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/588948/The_United_Kingdoms_exit_from_and_partnership_with_the_EU_Web.pdf)

## REACH registration roles - % of EEA: (ECHA – January 2017)

Country	M	I	M/I	OR
Germany	26%	27%	38%	16%
United Kingdom	6%	13%	7%	23%
France	11%	8%	9%	6%
Netherlands	4%	13%	7%	12%
Italy	11%	8%	8%	1%

**M** manufacturer



**I** importer

**M/I** manufacturer and importer

**OR** only representative of non-EU manufacturer

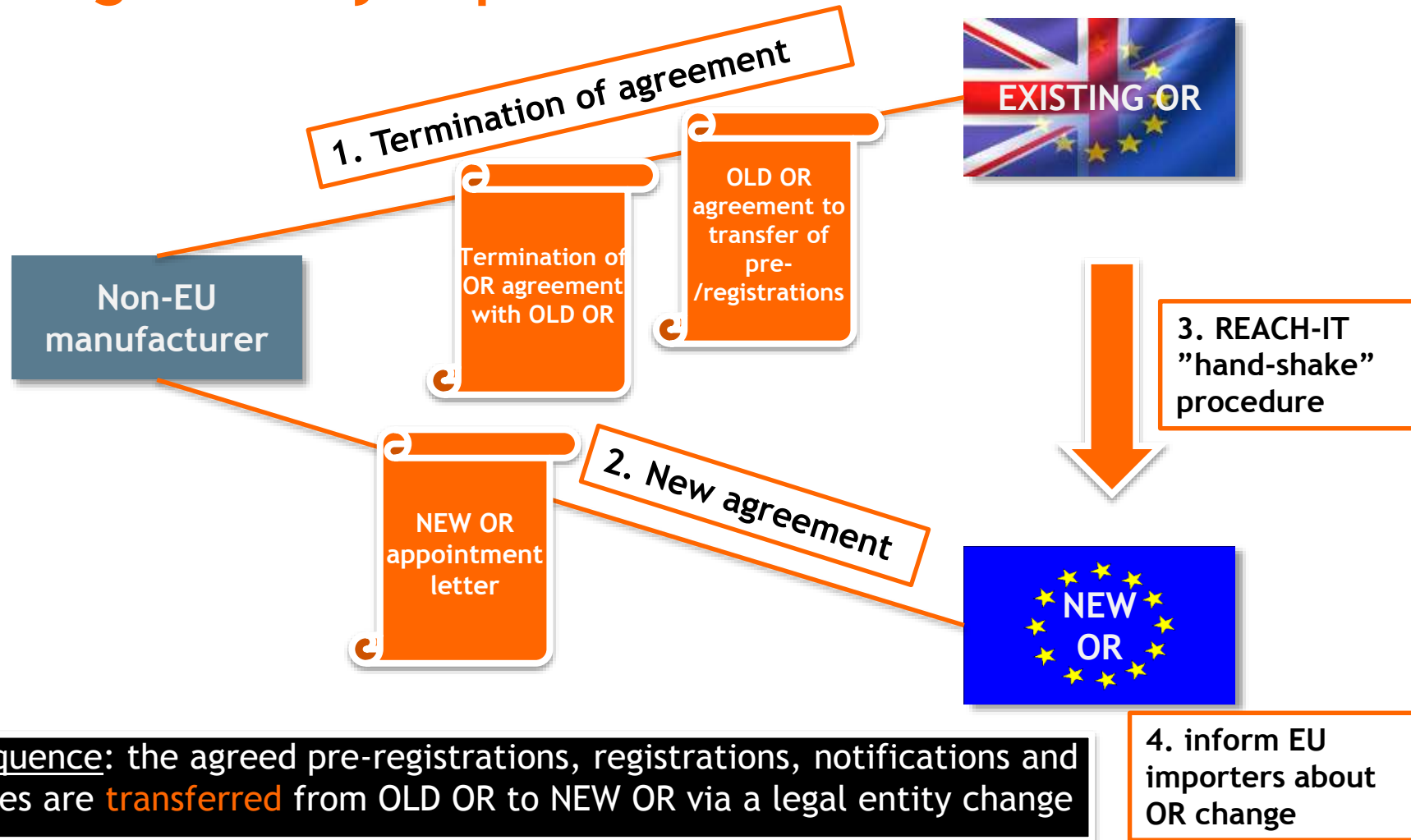
# Brexit vote consequences

## Planning ahead (*based on current knowledge*)

 2017	2018	2019 
<p><b>UK-EU negotiations on Brexit expected to start after March 2017 ("Article 50 'leave' Notification")</b></p> <ul style="list-style-type: none"><li>• REACH fully applies in UK</li><li>• <b>But: Strategic company decisions for REACH to consider the future exit from the EU <u>now</u>, e.g.</b><ul style="list-style-type: none"><li>• <u>New lead registrant nominations</u> for 2018</li><li>• <u>New EU REACH Only Representative appointments</u> by non-EU manufacturers</li><li>• <u>Revision of existing OR/Lead Registrant/Importer nomination</u></li></ul></li></ul>	<p><b>UK-EU negotiations on Brexit expected to continue</b></p> <p>See column to the left: Finalise work / decision-making / impact assessment</p> <p>i.e. <b>registration 2018 also applies to UK industry</b></p>	<p><b>UK-EU negotiations on Brexit expected to end, UK will leave the EU</b> max. 2 years after Art. 50-notice</p> <p><b>"Post Brexit" REACH - as interpreted by the CJEU - <i>could</i> initially become part of the UK domestic law.</b></p> <p><b><u>To be agreed (among others):</u></b></p> <ul style="list-style-type: none"><li>• Status of existing UK REACH registrations?</li><li>• Use of REACH data in UK?</li><li>• Change of UK lead registrants and ORs to EU?</li><li>• Handover from ECHA/EC to UK authorities?</li><li>• Transition regime?</li><li>• Update of REACH Annexes?</li></ul>

# Brexit vote consequences

## Change of Only Representative



# AGENDA FOR PRESENTATION

1. Introductions
2. Late Pre-registration closes on 31 May 2017
3. Lead Registrant for 2018 and testing
4. Authorisation deadlines
5. Enforcement
6. 2<sup>nd</sup> REACH review (REFIT evaluation)
7. Brexit vote consequences

8. Conclusions

Q&A after the presentation:  
*Please send questions using the chat!*

# REACH 2017

## Conclusions: Key Messages for Companies

- **Manufacturers and importers** to ensure **2018 registration**
  - Identify your critical substances that still need registration
  - If no **lead registrant** today, get ready **now** to step up yourself
  - If no pre-registration, **late pre-registration** by 31 May 2017?
- **Downstream users** to ensure that
  - Your uses will be covered in the **2018 registration** dossier
  - Substances subject to **authorisation** may be used beyond sunset dates
- **Strategic planning** ahead, e.g.
  - **EU Only Representative** Appointments by non-EU manufacturers
  - Anticipate **Brexit** consequences (e.g. for UK ORs and Lead Registrants)
  - Maintain **up-to-date Registrations** and **REACH Safety Data Sheets**

# REACH 2017

## Conclusions: Key Deadlines and Activities

2017												2018				
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
UK Brexit law			UK-EU Brexit negotiations: Assess implications for your business and plan strategy accordingly													
Late preregistration 1-100					Inquiry process before registration. 2018 deadline does not apply.											
Use identification for 2018																
Lead registrant nomination - Data gap analysis - Testing - Dossier preparation												Joint submission				
Co-registration - Analytical data - Purchase LoA - Complete other non-lead tasks (e.g. SME check)														Co-register		
Chromate authorisation							1	2	DU notifications (within 3 months of first supply)							
2nd EC REACH REFIT Review					Reporting on the Operation of REACH							Implementation phase				
REACH-EN-FORCE 5: Extended Safety Data Sheets												Possible extension?				
SVHC Roadmap Implementation																

### Deadline

<sup>1</sup> 22 July 2017: Latest application date for strontium chromate et al.

<sup>2</sup> 21 September 2017: Sunset date for chromium trioxide et al.

# REACH 2017

## Conclusions: Deadline Relevance

Deadline	Action/event	Main relevance for industry
<b>Without delay</b>	Lead registrant nomination and testing for registration by 31.05.2018	Risk of missing the 2018 deadline, if testing cannot be done in time
<b>31.05.</b>	Late pre-registration for registration by 31.05.2018	New EEA market entrants. After 31.05. only inquiry route before registration
<b>31.05.</b>	Downstream user right to make use known for registration by 31.05.2018	Risk of use not covered in registration dossier and need for own DU CSR
<b>01.06.</b>	Commission REACH Review Report	Informatory, planning beyond 2018
<b>21.09.</b>	Authorisation sunset date for critical Cr(VI) substances, e.g. chromium trioxide for surface treatment uses	Non-applicant DUs have to be covered by an upstream authorisation and need to notify ECHA (REACH Article 66(1))
<b>All year</b>	Joint EU enforcement project on (e)SDS quality & compliance (REF-5)	Concerns all supply chain actors and workers handling hazardous chemicals



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***Thank you for your attention!***

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# REACH and Chemical Regulations

Seminar in Baltimore, Maryland (USA)

5th and 6th of April, 2017

REACH 2018 | SVHCs & Authorisation | BREXIT | Toll Manufacturing | Only Representation |  
Global Chemical Regulations | Case Examples

Sign-up here: [http://www.reachlaw.fi/event/reach\\_baltimore/](http://www.reachlaw.fi/event/reach_baltimore/)