

REACH 2018 – Get ready for the last registration deadline

Implementation of REACH and CLP and future challenges

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Luxembourg

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Outline

- Background
- Expectations for 2018
- Six phases towards successful submission
- Changes in the registration process

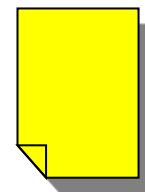
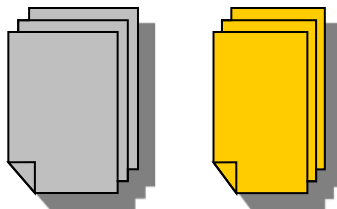




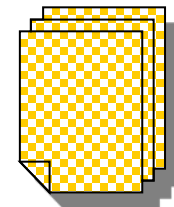
Registrants



+



+



Registration dossier

**Chemical Safety Report
Exposure Scenarios**

Safety Data Sheet

Exposure Scenarios



Information on uses



Safety advice



Customers (Downstream Users)

ECHA – EU Authorities



Public

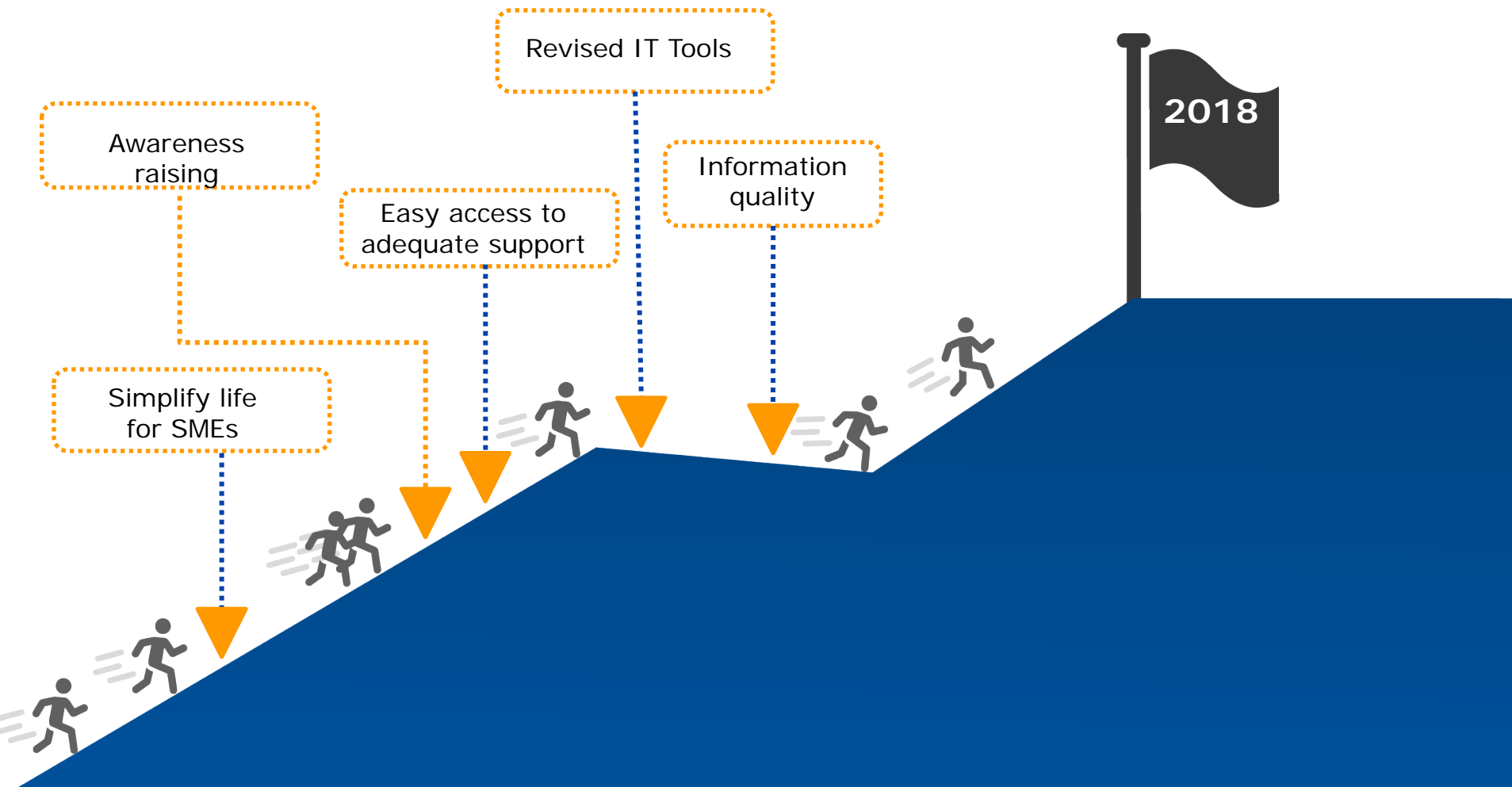


REACH 2018

- Third and last registration deadline for phase-in substances from 1 to 100 tonnes/year
- Experience proves: REACH is manageable!
 - Thousands of companies have already done it since 2008
- >4000 registrations for 1 to 100 tonnes/year received since 2014
 - 2014: 19% SMEs
 - 2015: 25% SMEs



What do we expect in 2018?





REACH 2018

- ECHA, national authorities and industry organisations join their forces to support companies

We are working to make it simpler

- Especially for substances between 1 to 10 tonnes
- Six registration phases towards a successful submission of your registration dossier by 31 May 2018

http://echa.europa.eu/reach-2018



The screenshot shows the ECHA website's REACH 2018 page. At the top, there is a navigation bar with the ECHA logo and a search box. Below the navigation bar, there are several menu items: About Us, Regulations, Addressing Chemicals of Concern, Information on Chemicals, Chemicals in our Life, and Support. The main content area is titled "REACH 2018" and features a section titled "Are you affected by the deadline?". This section includes an image of a hand pointing to a clock face and text explaining the registration obligations under REACH. Below this, there is a section for "Support to understand your tasks" with a list of links. On the right side, there is a "Support" section with a list of links, a "Related documents" section with a link to "ECHA's REACH 2018 Roadmap [PDF] [EN]", and a "Latest news on REACH 2018" section with a link to a press release. Several elements are circled in orange: the "Where do I start?" link in the bottom left, the "ECHA's REACH 2018 Roadmap [PDF] [EN]" link in the right sidebar, and the "Press release: REACH 2018 Roadmap published, 14 January 2015" link in the right sidebar.

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 > REACH 2018 

REACH 2018

Are you affected by the deadline?

If you manufacture chemical substances or import them from outside the EU above one tonne per year, you may have registration obligations under REACH. Additionally, if you manufacture or import a product (mixture, article), it may contain substances that need to be registered individually.

If you have pre-registered substances that you manufacture or import from outside the EU above one tonne but not more than 100 tonnes per year and have not already registered them, the REACH registration deadline of 31 May 2018 concerns you.

If you haven't yet pre-registered your substance, late pre-registration may still be an option until 31 May 2017.

[More information](#)

Support to understand your tasks

The following pages help you to understand what you need to do and take you through the process step-by-step.

 [Know your portfolio and start preparations for REACH 2018 now!](#)

Support

- [Contact your national REACH helpdesk or the ECHA helpdesk](#)
- [Contact ECHA's accredited stakeholder organisations for sector specific support](#)
- [Are you a small or medium-sized enterprise?](#)
- [Are you a non-EU company exporting chemicals to the EU?](#)

Related documents

- [ECHA's REACH 2018 Roadmap \[PDF\] \[EN\]](#)

Latest news on REACH 2018

- [Press release: REACH 2018 Roadmap published, 14 January 2015](#)

 [Where do I start?](#)

6 phases to REACH 2018

- 1 Know your portfolio
- 2 Find co-registrants
- 3 Share data
- 4 Assess hazards and risks
- 5 Prepare your dossier
- 6 Submit your registration





Know your portfolio

- Identify if **you** need to register (role in the supply chain) and if **substances** in your portfolio need to be registered
- Identify and name your substances → unambiguous identification essential for data sharing and joint registration
- Familiarize yourself with the information requirements
- Plan your work and inform your downstream users

① Support

- [‘Know your portfolio and start preparing now’](#) webinar
- [REACH2018](#) webpages / [‘Registration’](#) under ‘Support’ section on ECHA website
- Practical guide on chemical safety in your business targeted to SMEs
- Sector specific guidance on substance identification



Find your co-registrants

- Check your pre-registration
- Identify the lead registrant, or
- Find your co-registrants
- Discuss the sameness of your substance to share data and submit jointly



Support

- Guidance on identification and naming of substances
- REACH-IT:
 - (Sign-up and) Manage your REACH-IT account
 - The pre-SIEF helps you to identify other potential registrants of the same substance
- ['Search for Chemicals'](#) on ECHA's web:
 - Registrants are displayed under 'administrative data'

Support

- Webinar held on 18 November
- New support web pages published on 18 November
 - How to join an existing SIEF
 - How to get organised for a new SIEF
- The new generation of REACH-IT (2016)
 - Improved means to find existing lead registrants
 - Enhanced user interface and online help



Data sharing

- Organise your SIEF cooperation, or get active in the existing SIEF
- Share data to meet your information requirements
- Negotiate costs in a fair, transparent and non-discriminatory manner
- Share the costs of common data



Support

- Implementing act on data sharing by the European Commission (expected)
- On the ECHA website
 - Guidance on data sharing
 - Data sharing dispute procedure and ECHA's decisions on the disputes
 - Recommendations on sound SIEF management and considerations when joining an existing by the Directors' Contact Group

Support

- Practical advice on the ECHA website
 - Ten steps for data sharing negotiations
 - What you can do in case of disagreement
 - Typical cost elements in data sharing negotiations
 - Coming: Advise on how to establish a new SIEFs



4

Assess hazard and risk

- Information required depends on tonnage and uses
- 1-10 tonnes: Possible reduced data requirements for less hazardous substances
- > 10 tonnes: chemical safety report needed
- Pay attention to data quality: relevance, adequacy and reliability
- Some long-term studies require a testing proposal
- Animal testing is the last resort - Consider alternatives



4 Assess hazard and risk – alternative methods

- Dedicated pages on the ECHA website on testing methods and alternatives
- OECD QSAR (quantitative structure-activity relationship) Toolbox
 - Freely available platform for filling data gaps by grouping chemicals, read-across, trend analysis and (Q)SARs
 - Help in reducing the cost and the testing on animals
 - Videos and tutorials available online
- Coming: Skin sensitisation: *in vitro* methods to be used in an integrated approach



Support

- Guidance: Pathfinder on information requirements and chemical safety assessment; updated use description guidance, framework for exposure assessment, worker, consumer and environmental exposure assessment
- Annual evaluation reports
- Practical advice (to come)
 - Advice on information requirements for 1 to 10 tonnes/year and 10 to 100 tonnes/year substances
 - Checklist for reduced data requirements
 - Inventory of substances with indication that they require a full data set



Support

- If you need to prepare a chemical safety report
 - Chesar, ECHA's IT tool for chemical safety assessment – new version available in 2016
 - Use our templates for chemical safety reports and exposure scenarios



Prepare your dossier

- Prepare your technical IUCLID dossier
 - Identity of the registrant
 - Identity of the substance
 - Information on the substance's intrinsic properties
 - Information on use and exposure
- Chemical safety report annexed above 10 tonnes/year
- ECHA provides IUCLID free of charge

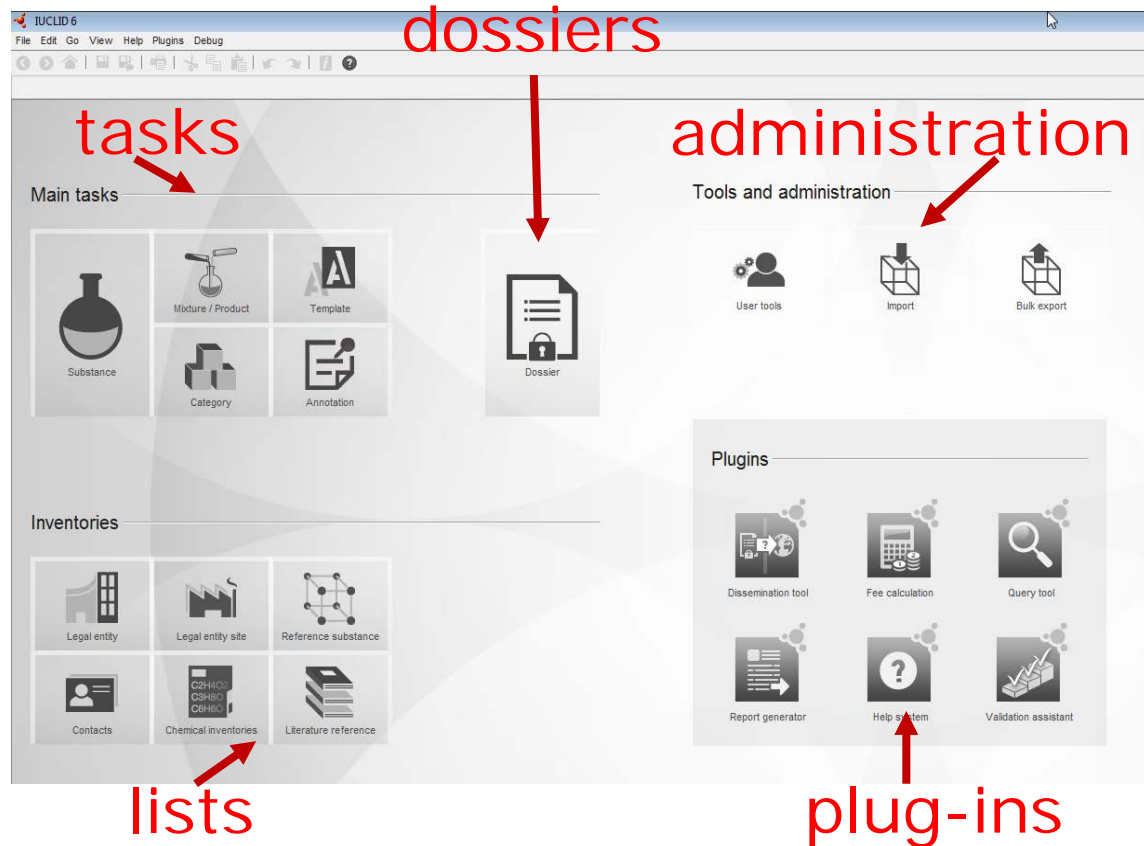


Support

- Currently IUCLID and its plug-ins:
 - e.g. the Validation Assistant supports you filling in the IUCLID data fields
- Manuals for data submission and practical advice
- Webinars provide tips and hints on how to bring your registration dossier in compliance with REACH

5  **IUCLID 6 in 2016**

- One-click installation
- Integrated help system
- New user interface
- Improved user management
- Improved substance identification



dossiers

tasks

administration

lists

plug-ins



Submit your registration

- Check and update the information in REACH-IT which is relevant for registration
- Carefully assess your SME status
- Set up or join the joint submission in REACH-IT
- Submit your registration dossier: first the lead registrant, then all co-registrants
- Follow up on the communication in the REACH-IT message box



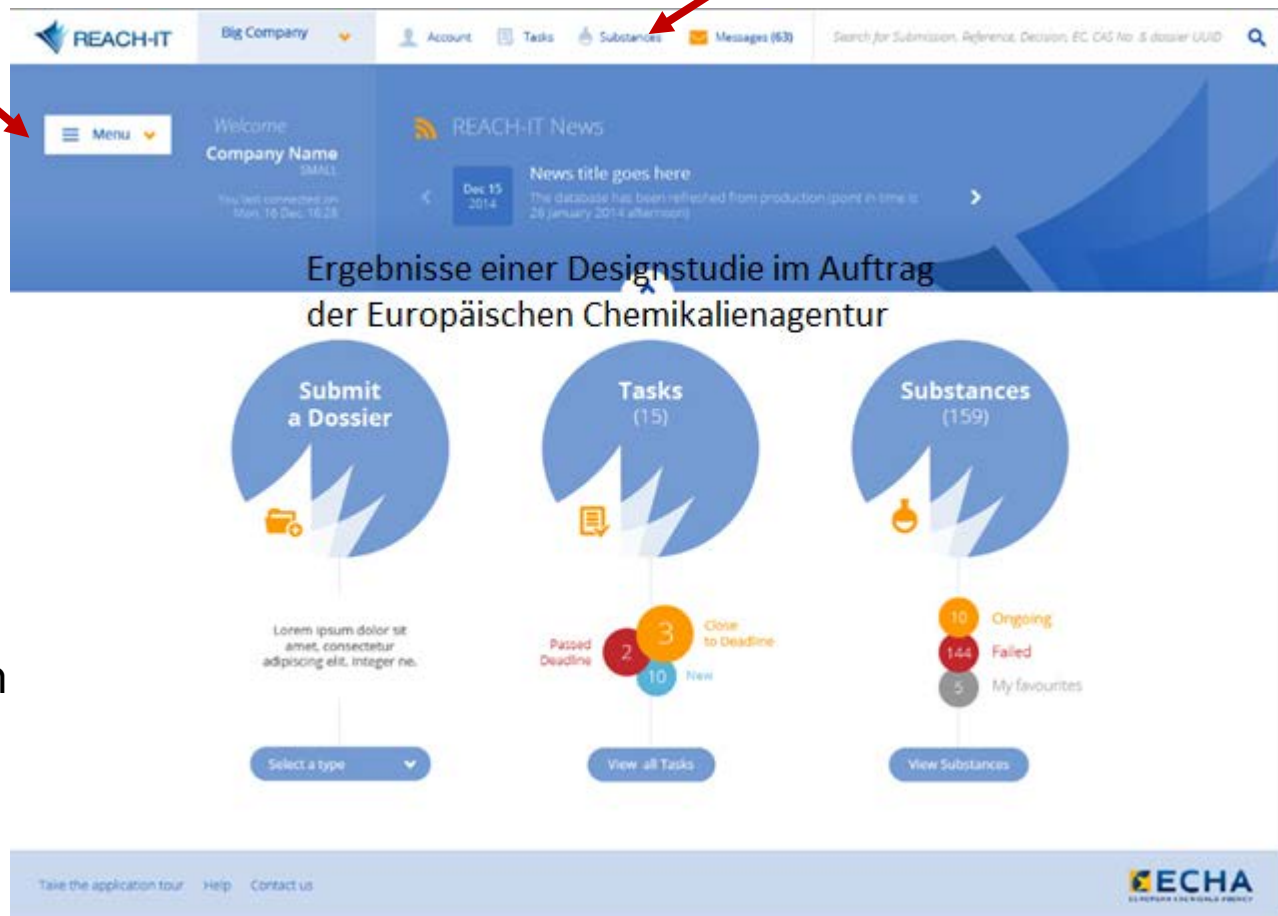
Support

- Currently you submit your registration dossiers via REACH-IT 2
- REACH-IT industry user manuals and FAQs
- Webinars on dossier submission (prepared for registration deadline 2013)

6 REACH-IT 3 in 2016

menu

navigation



- Intuitive operation
- Improved identification of co-registrants and existing joint submissions
- Online help system

6 REACH-IT 3 in 2016

bread crumbs

page title

- Wizards improve steps
- Aim to include online registration without IUCLID installation for member registrants

Submit a Dossier Ergebnisse einer Designstudie im Auftrag der Europäischen Chemikalienagentur

1 Registrant type 2 Upload Dossier 3 Dossier details 4 Confirmation

Submission type: Registration Change

Registrant type: Member of a Joint Submission Change

Find a Joint submission Search again

d Results

Joint Submission	Lead registrant	Substance Identity	Contact	
Joint Submission Name	Big Company	subathzone EC: 242-161-1 CAS: 18283-82-4 IUPAC: 15236/4564	Tester, John 00302101258647 ohntest@domain.com	Tester, John 00302101258647 ohntest@domain.com <input checked="" type="checkbox"/> Selected Deselect
Joint Submission Name	Big Company	subathzone EC: 242-161-1 CAS: 18283-82-4 IUPAC: 15236/4564	Tester, John 00302101258647 ohntest@domain.com	Tester, John 00302101258647 ohntest@domain.com <input type="checkbox"/> Select

Continue to Upload Dossier >

Take the application tour Help Contact us

ECHA
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check lists
and help text

Changes in the registration process

- Additional verification in REACH-IT to prevent duplicate joint registrations
 - Joint registration is mandatory to ensure sharing of data and no unnecessary testing on animals
- Revised technical completeness check
 - ECHA's experience in REACH implementation allows better targeted completeness check rules
 - Manual verification at completeness check starting in 2016 to ensure that justifications are plausible

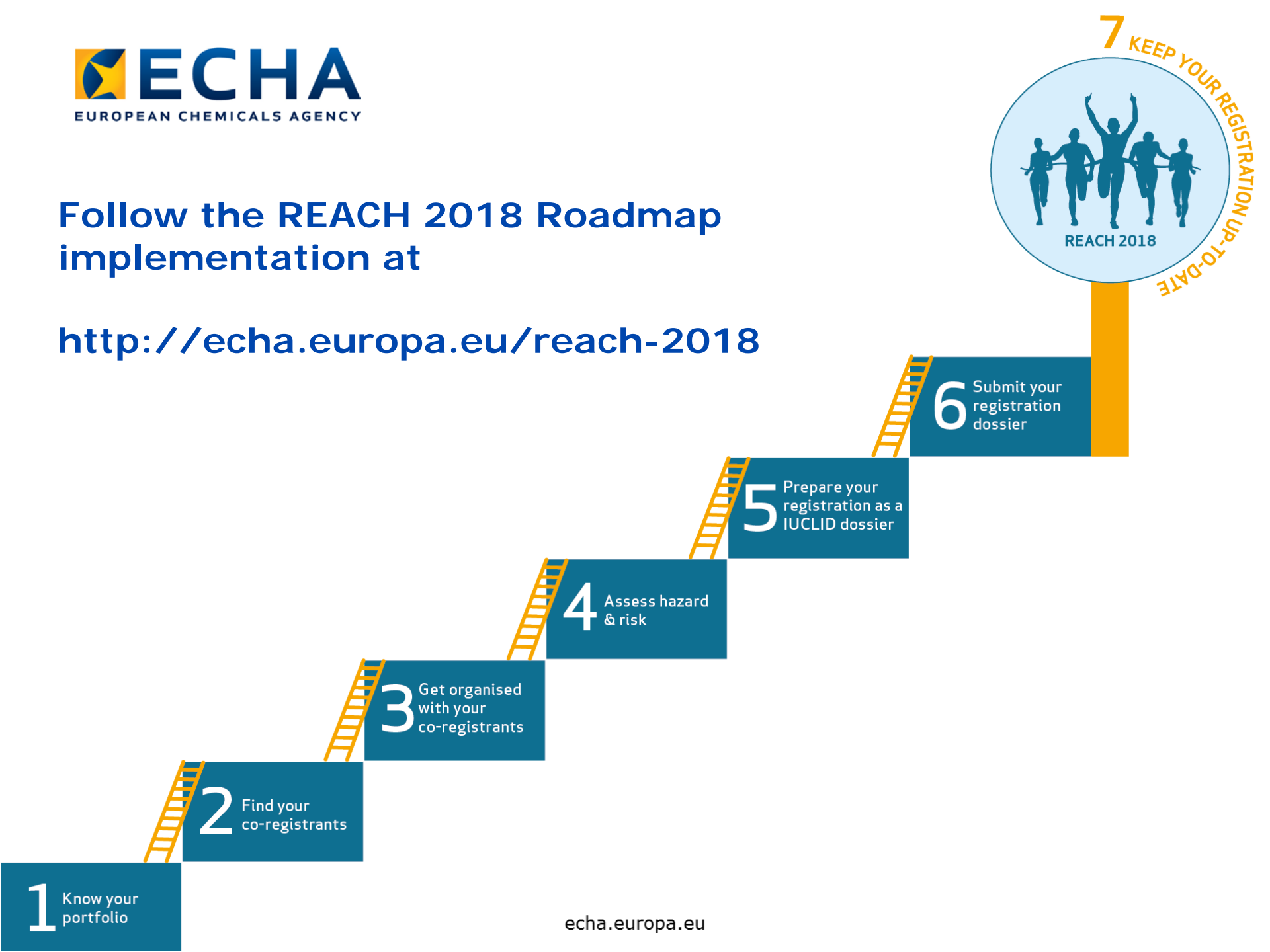
Key messages

- Registration is challenging but manageable
- Start preparing now, even for registering in 2018
- If you are newcomer, better to wait the new IT tools in 2016 before submitting your registration

7 ...and remember to keep your registration
up-to-date!

Follow the REACH 2018 Roadmap implementation at

<http://echa.europa.eu/reach-2018>



Thank you!

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