Get ready for 2018

Meeting your information requirements

11th Stakeholder's Day

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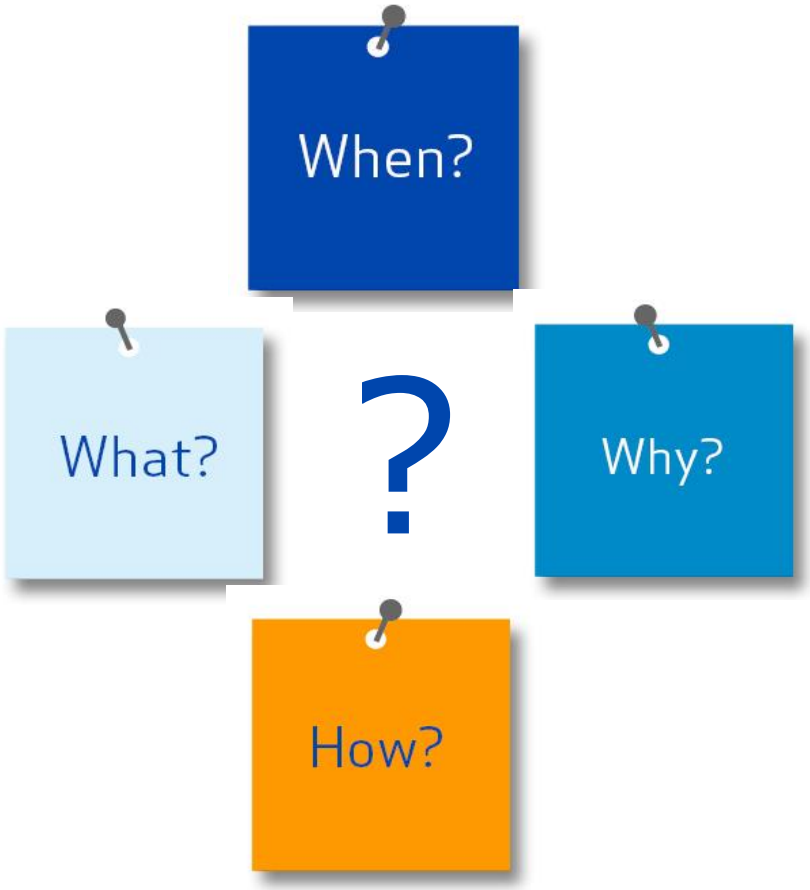
Key messages

- It takes time
- Get organised
- Know your requirements 2018
- Use help from ECHA
- Look for expertise and tips



✓ No need to reinvent the wheel

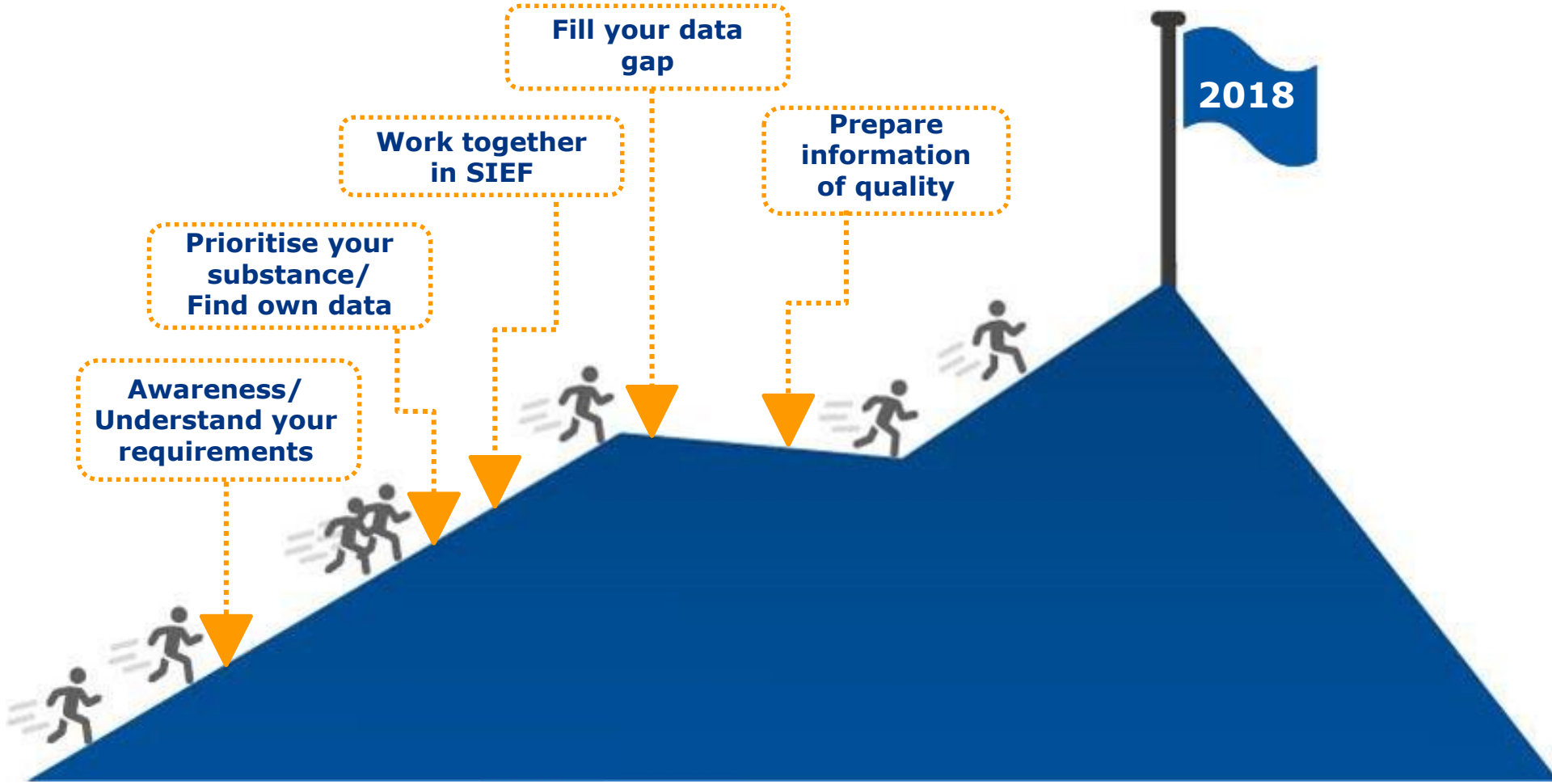
It takes time

- Know your portfolio
- Make business decisions for your substance(s)
- Understand how to gather information
  - Uses
  - Identity substance
  - Properties
- Get help

Get organised

- Ask the right questions
  - Is my substance already registered?
  - Are there other registrants for my substances?
  - What level of information do I need to submit?
    - Annex VII or Annex VII+VIII?
    - Can I benefit from some reduced requirements?
- Find the right help
  - Reserve resources: time/staff
  - Understand the information you need
    - ECHA Roadmap 2018 pages/Practical Guides
  - Find how to get information/support
    - Own lab/literature
    - External provider

… so you can achieve



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1-10 tonnes - requirements

Information on phys-chem, environmental and mammalian properties

- Not all are necessary in one dossier
- Testing on animals as last resort - one test
- Low risk substances
  - Possible reduced dataset
  - Fee waiver if all data submitted

http://echa.europa.eu/regulations/reach/registration/information-requirements

Information required for standard registration of 1-10 tonnes a year (Annex VII of REACH)	
Non-vertebrate animal endpoints	**Vertebrate animal endpoints**
Description of the state of the substance at 20°C / 101.3 kPa	
Melting/freezing point	Acute toxicity: oral
Boiling point (if applicable)	
Relative density	
Vapour pressure (if applicable)	
Surface tension (if applicable)	
Water solubility	
Partition coefficient	
Flash-point	
Flammability	
Explosive properties	
Self-ignition temperature	
Oxidising properties	
Granulometry (if applicable)	
In vitro skin irritation/corrosion	
In vitro eye irritation	
Skin sensitisation*	
In vitro gene mutation in bacteria	
Short-term toxicity on invertebrates	
Growth inhibition study aquatic plants	
Ready biodegradability (if applicable)	

10-100 tonnes - requirements

Information on environmental and mammalian properties

- In addition to previous information
- Animal testing as last resort
  - Recent changes in requirements
  - Less tests on animals
  - Consider alternatives first
  - Smart testing strategies
- Ensure completeness and quality
- Relevance, adequacy and reliability

Information required for standard registration of 10-100 tonnes a year (Annex VIII of REACH)

Non-vertebrate animal endpoints	Vertebrate animal endpoints
In vitro mutagenicity study in mammalian cells or *In vitro* micronucleus study	*In vivo* skin irritation*
In vitro gene mutation in mammalian cells	*In vivo* eye irritation*
Activated sludge respiration inhibition test	Testing proposal for *in vivo* genotoxicity (if applicable)
Degradation	Acute toxicity: inhalation/ dermal**
Hydrolysis	Short-term repeated dose toxicity (28-day)
Adsorption/desorption screening	Screening for reproductive/ developmental toxicity
	Short-term toxicity on fish or testing proposal for long-term toxicity on fish (if applicable)

Help from ECHA

- Guidance
  - Pathfinder to Guidance on information requirements and chemical safety assessment
  - Updated use description guidance, framework for exposure assessment, worker, consumer and environmental exposure assessment
- Tools to find and organise information
  - IUCLID 6 and REACH-IT
  - OECD QSAR Toolbox
  - Chesar for chemical safety assessment and reporting
- Dedicated pages on ECHA's website
  - Testing methods to be used
  - Alternatives

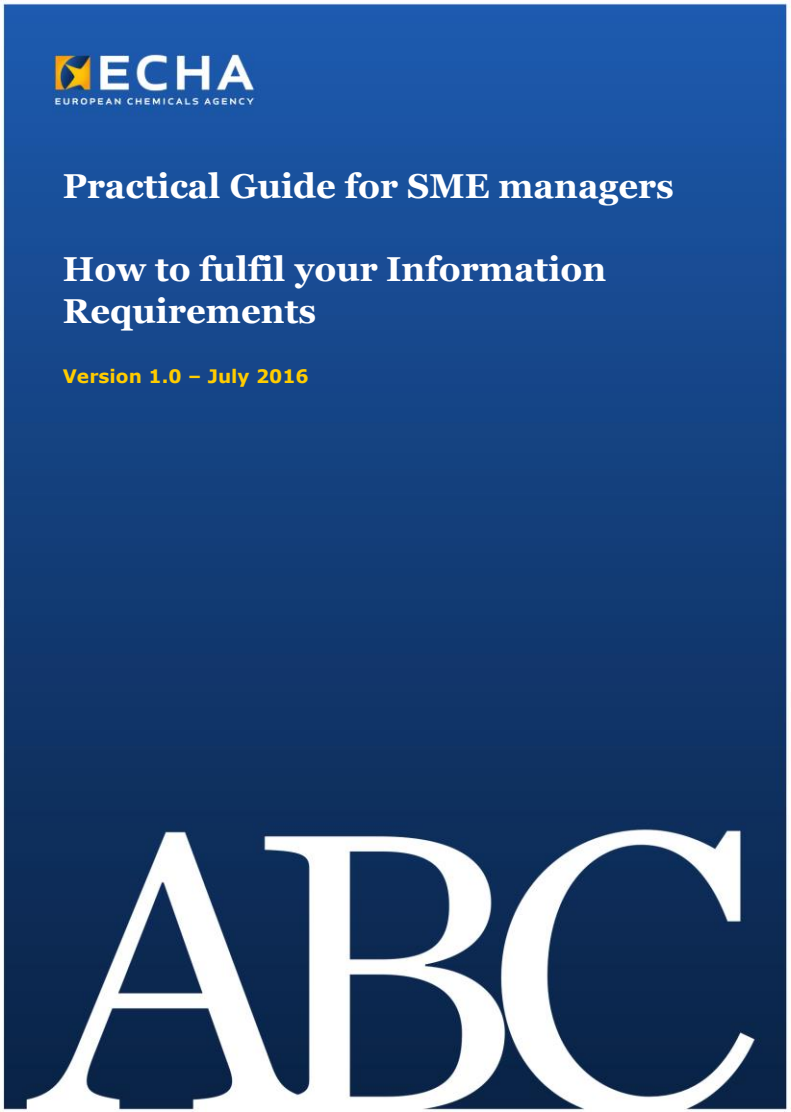
Look for appropriate expertise

- Consider use of expert services
  - National helpdesks
  - Industry associations
  - Existing registrants
  - Service providers
- Expertise needed
  - Chemistry + process substance
  - (Eco)toxicology
  - Regulatory + IT
- No need to reinvent the wheel
  - Investigate and find what you jointly need in SIEF
  - Remain critical, and business-realist

Look for our tips

- ✓ ECHA to help - practical support
- Targeted practical Guides and Manuals
- Low risk substances: reduced data requirements
  - Inventory of substances not suitable
- Sector use maps
  - Indicate typical uses and conditions of use in the sector
- Mainstream messages + Q&As

- ✓ Improved access to information

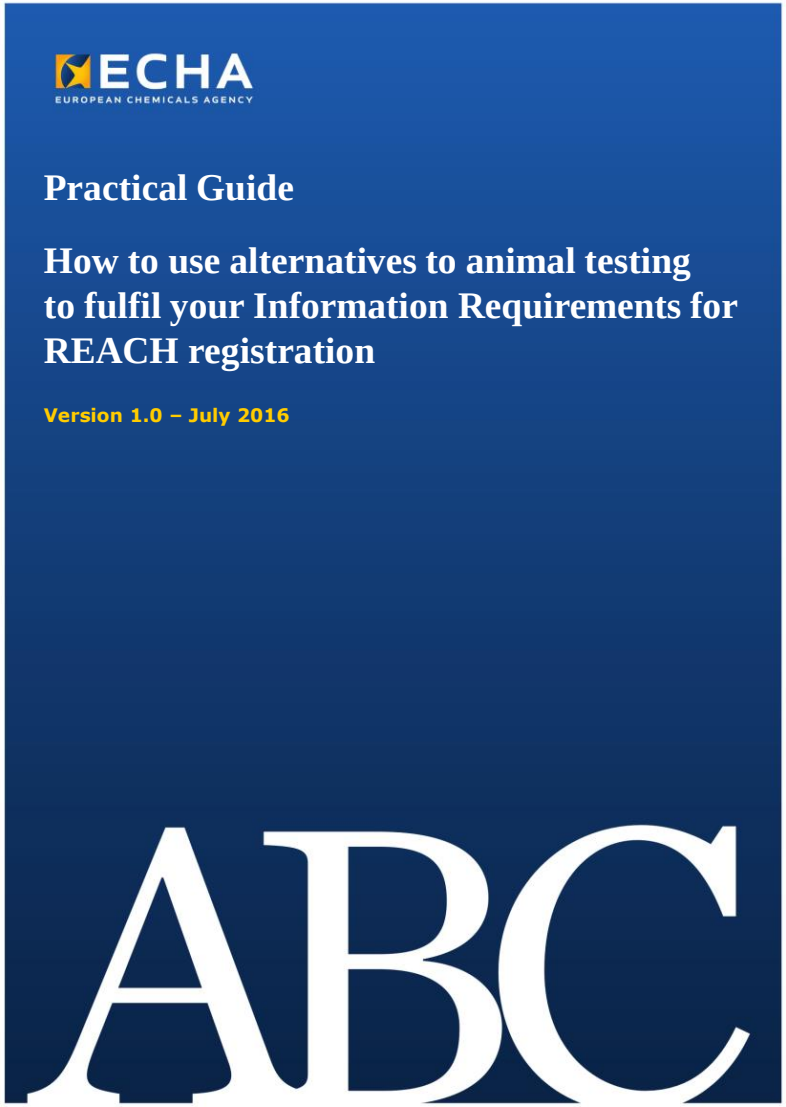


Guide for SME managers

- Advice tailored to business managers
- Simple-term explanations of the information requirements for 1 to 10 tonnes/year and for 10 to 100 tonnes/year registrations
- Reference document for future business decisions

Guide on how to use alternatives to animal testing

- All-in-one advice tailored to registrants
- Make best use of the opportunities REACH offers
- Key messages on obligations and supporting business decisions



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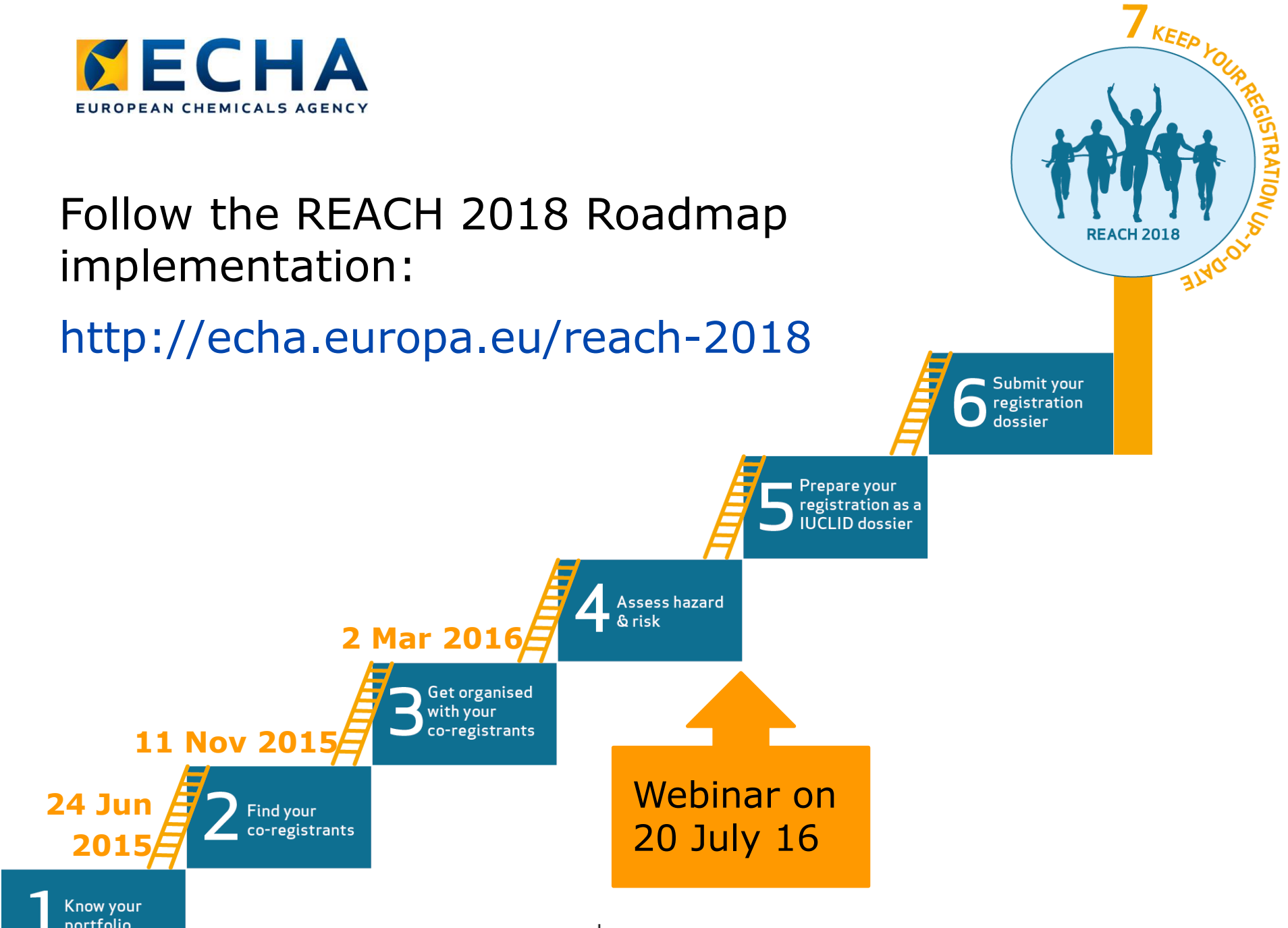
Follow the REACH 2018 Roadmap implementation:

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



To take home

- Registration is challenging but manageable
- It takes time to be ready by 2018
- Animal testing is the last resort
- ECHA can support you

Thank you

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