ECHA
EUROPEAN CHEMICALS AGENCY

REACH 2018

Seven phases to successful registration

12th Stakeholders' Day

5 April 2017, Helsinki

Christel Musset

Registration at the core of REACH

What is at stake?

- ✓ Better knowledge of hazards, uses and risks
- ✓ Improved communication in the supply chain
- ✓ Better safety and control measures
- ✓ Reduce exposures and hence negative impacts
- ✓ Substitute (gradually) hazardous substances with less hazardous ones

➢ Registration and classification: starting point for pro-active product stewardship

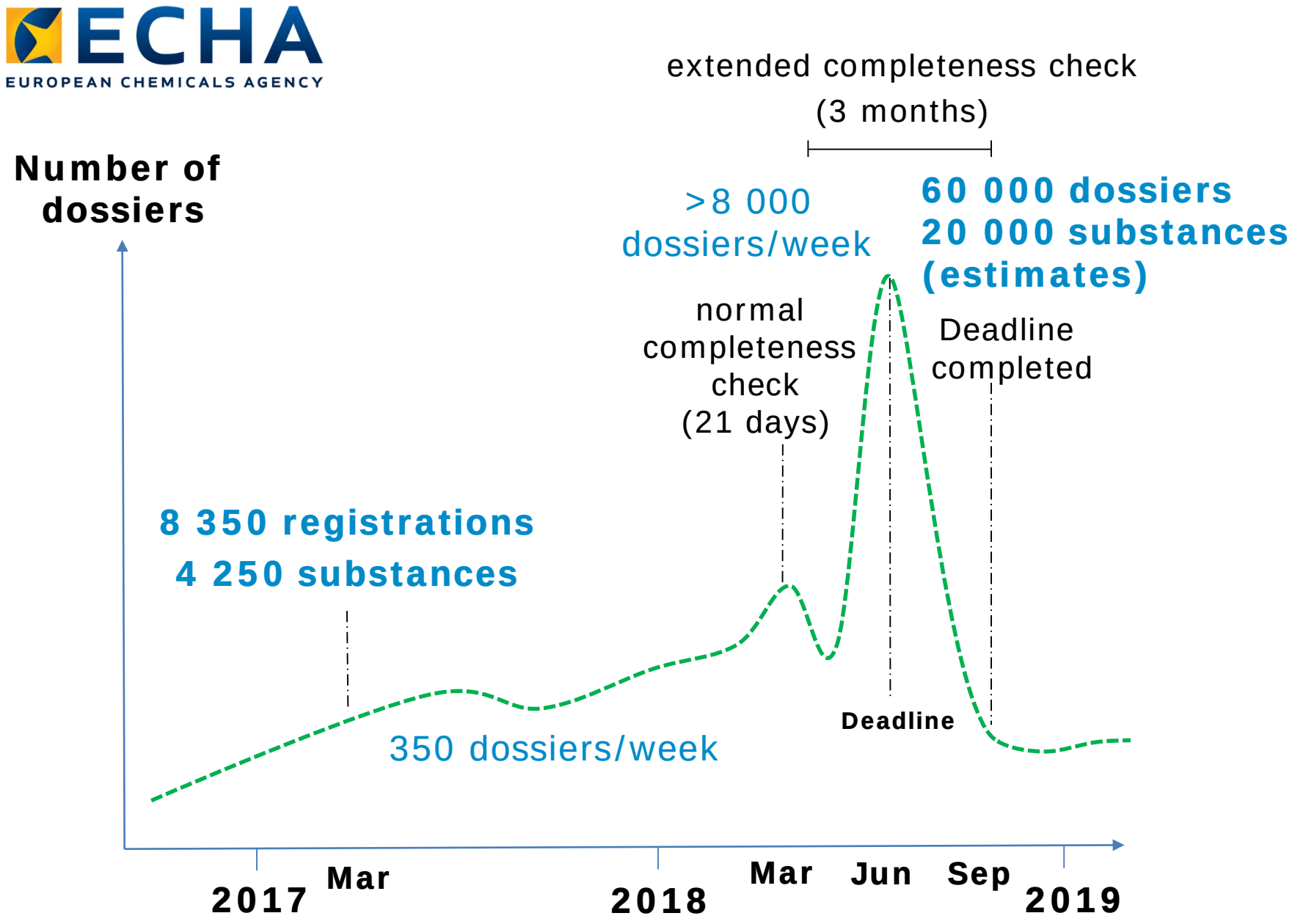
Registration dossier is vital

It demonstrates that:

- You know your portfolio
- All necessary information is available
- Your clients are informed adequately on how to safely use your substances

➢ Provides confidence to authorities, your investors and clients
➢ And are watched by the authorities!

One year to go!


extended completeness check
(3 months)
Number of dossiers
>8 000 dossiers/week
60 000 dossiers
20 000 substances
(estimates)
normal completeness check (21 days)
Deadline completed
8 350 registrations
4 250 substances
350 dossiers/week
Deadline
2017
Mar
2018
Mar
Jun
Sep
2019

7 phases to get prepared

1. Know your portfolio
2. Find co-registrants
3. Share data
4. Assess hazards and risks
5. Prepare your dossier
6. Submit your registration
7. Keep your registration up-to-date

1 Know your portfolio

- Identify if you need to register and if the substances in your portfolio need to be registered
- Unambiguous substance identification
  - Essential for data sharing and joint submission
  - Letter of access: helps you verify that data from lead registrant is suitable for your substance
  - Sector specific guidance on ECHA's website
- Plan your work and inform your downstream users

Substance identification

- Substance identity information is company-specific
  - Detailed composition and analytical data
  - More advice on specific cases: Q&As - Substance identity
- Improved format in IUCLID 6
  - More transparent reporting
  - Scope of joint submission in the substance identity profile (SIP)
  - Specific fields for reporting information on nano forms
- May be checked manually during completeness check
  - Inconsistencies e.g. between name and composition
  - Manufacturing process for UVCB substances

Nanos: updated guidance

- Existing guidance updated based on:
  - Developments in regulatory science
  - Increased knowledge at OECD level
  - Experience gained in doing evaluations
- To be available by May 2017:
  - Identification of nanoforms (new how to guide)
  - Read across and grouping between nanoforms of the same substance (new guidance)
  - Nano specific advice for human health and environmental endpoints (guidance update)

2 Find your co-registrants

- Check your pre-registration
- Discuss substance sameness
- Joint submission for the same substance is mandatory - even in case of opt-out
- Opt-out
  - Duly justified – this may trigger a compliance check
- Lead registrant
  - You need the consent of the SIEF members
  - Inform ECHA in case of difficulties and bring evidence

List of lead registrants

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List of lead registrants
Data as of 2 Feb 2017

Public

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu
https://echa.europa.eu/support/helpdesks/

Number of Joint Submissions 9821

* ECHA's preferred substance name or non-confidential name that has been notified to ECHA, or of which ECHA is aware.

*** "Available in REACH-IT" means you can access this info in REACH-IT if you have registered, pre-registered or inquired for this substance.

Number of Joint Submissions with publication acceptance 3126

** Registered "No" means that no submission exists yet (only the JS), or that the Lead submission is pending in the system.

Creation Date	Substance*	EC Number	CAS Number	Registration Type	Lead Dossier Submitted	Lead Dossier Registered**	Lead Name***
02/02/2017	4-(p-chlorophenyl)piperidin-4-ol	254-479-8	39512-49-7	Intermediate	No	No	OLON Spa
02/02/2017	(dihydro-3,3-diphenyl-3H-furan-2-ylidene)dimethylammonium bromide	253-649-9	37743-18-3	Intermediate	No	No	OLON Spa
02/02/2017	Melperone	609-173-2	3575-80-2	Intermediate	No	No	OLON Spa
01/02/2017	Copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, aminosulfonyl sulfo derivs., ammonium sodium salts	290-998-6	90295-08-2	Full	No	No	ARCHROMA IBÉRICA, S.L.U.
01/02/2017	Benzenesulfonic acid, 4-C15-16-sec-alkyl derivs.	941-154-7	-	Full	No	No	Sasol Italy S.p.A.
01/02/2017	Isopropylcyclohexane	211-792-4	696-29-7	Full	No	No	Available in REACH-IT
01/02/2017	(R)-quinuclidin-3-ol	246-857-6	25333-42-0	Intermediate	No	No	synkem
01/02/2017	3,4-dimethoxyphenethylamine	204-376-9	120-20-7	Intermediate	Yes	No	RECORDATI SPA
01/02/2017	2,3-Dichlorobenzonitrile	-	6574-97-6	Intermediate	No	No	AlzChem AG
31/01/2017	3,3'-dioctadecyl-1,1'-methylenebis(4,1-phenylene)diurea	406-690-3	43136-14-7	Full	Yes	No	IMPERATOR
31/01/2017	1-benzyl-5-phenylbarbituric acid	276-940-2	72846-00-5	Intermediate	No	No	Chemische Fabrik Berg GmbH
31/01/2017	Diethyl diethylmalonate	201-016-2	77-25-8	Intermediate	No	No	Chemische Fabrik Berg GmbH
31/01/2017	Diethyl phenylmalonate	201-456-5	83-13-6	Intermediate	No	No	Chemische Fabrik Berg GmbH
31/01/2017	Trimethyl-3-[(1-oxoallyl)amino]propylammonium chloride	256-181-3	45021-77-0	Full	No	No	Available in REACH-IT
31/01/2017	Trisodium nitrilotrimethanesulphinate	245-839-5	23714-12-7	Full	No	No	Available in REACH-IT
31/01/2017	Poly[oxy(methyl-1,2-ethanediyl)], a-hydro-w-hydroxy-, ether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol (3:1), 2-propenoate	676-712-6	68890-85-7	Full	No	No	Available in REACH-IT
30/01/2017	Alkenes, C>8	270-095-3	68411-00-7	Full	Yes	No	Available in REACH-IT
30/01/2017	Undecyl glucoside	308-766-0	98283-67-1	Full	No	No	Available in REACH-IT
30/01/2017	Pentyl valerate	218-528-7	2173-56-0	Intermediate	No	No	Available in REACH-IT
30/01/2017	Isopropyl myristate	203-751-4	110-27-0	Intermediate	No	No	Available in REACH-IT

[List of substances with lead registrants]

Newcomer to the market?

- Pre-registration still possible until **31 May 2017** for substances with registration deadline on 31 May 2018
- After that, the substance needs to be registered before it can be manufactured/imported
  - First step: inquiry to ECHA
  - You will be in contact with existing registrants
- R&D substance or process in development?
  - You can get a 5-year registration exemption (PPORD)
  - Only to listed customers

3 Data sharing

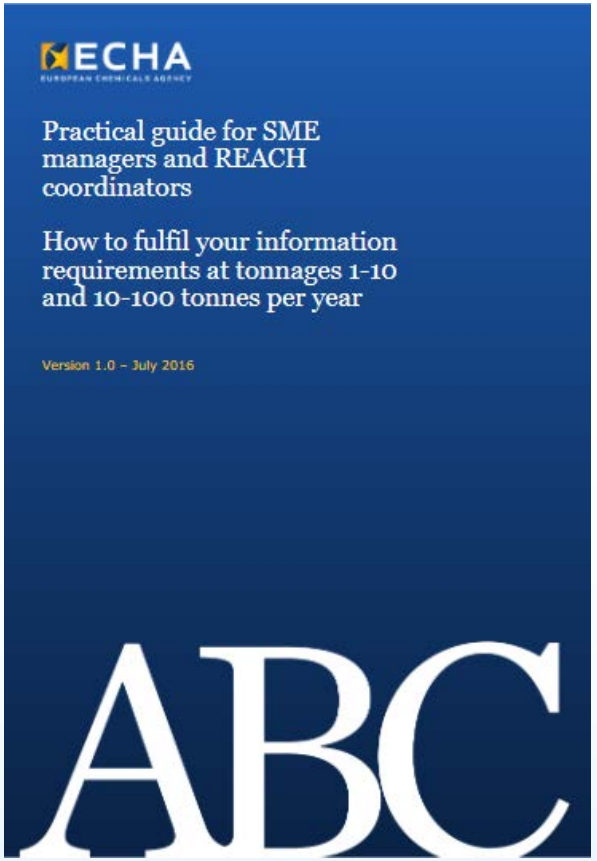
- Get organised and active in the SIEF
- Model data sharing agreements available with your sector organisations
  - Make sure to cover future costs
- Negotiate costs in a fair, transparent and non-discriminatory manner
- But… there is a price to pay for quality dossiers
- Data sharing dispute can be submitted to ECHA

4 Assess hazard and risk

- Information required depends on tonnage and uses
- 1-10 tonnes: possible reduced data requirements for less hazardous substances
  - Verify Annex III inventory – ECHA
  - Justification needed in IUCLID 6
- Get quality right: relevant, transparent, reliable
- Animal testing is a last resort
  - Consider alternatives
  - Use the QSAR Toolbox

Guide for SME managers

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



4 Chemical safety report

Needed for substances > 10 tonnes

chesar

- Step by step chemical safety assessment
- Comprehensive help text
- Synchronise with your IUCLID dossier
- Import use maps, standard phrases
- Generate automatic chemical safety report
- Prepare exposure scenarios for safety data sheets
- Facilitate updates

Prepare your dossier

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

5 Prepare your dossier

- One-click installation
- Integrated help
- More structure for reporting substance identification, uses and hazard data and improving data quality

- Members who fully rely on lead registrant's dossier can prepare their dossier in REACH-IT

New in 2017!

Service for SMEs:
IUCLID online

6 Submit your registration

- Check and update the information in REACH-IT
- 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
- Manual step introduced in completeness check
- Follow up on the communication in the REACH-IT message box

6 Submit your registration

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REACH-IT

- More intuitive user interface
- Extensive help within the tool
- Help available in all EU languages
- Improved means to find existing joint submissions and lead registrants

Step-wise support available

- Introduction to the topic
- Three levels of information
- Collection of links to more material
- Explanatory webinar

REACH 2018 Spring School

- Intensive REACH 2018 week
- Live Q&A tied to re-runs of our webinars
- Practical examples for each of the phases
- Animated videos
- **Save the date**: 15-19 May

More help?

- National helpdesks central in supporting SMEs
  - In your own language
- Contact ECHA if
  - questions on your submission, e.g.
    - your dossier is blocked or
    - you don't understand ECHA's instructions for re-submission
  - need technical support with the IT tools for registration
- Sector organisations
  - For practical knowledge
  - Can help harmonise information (exposure scenarios)
  - Some have working groups or mentoring programmes

Take home messages

- Registration is challenging but manageable
- Have a solid plan for managing your registrations by the 2018 deadline
- Support is available from ECHA, national authorities and industry organisations

Remember to keep your registration up-to-date!

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Thank you

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