

# What happens next with your registration

REACH 2018 Stakeholders' Day

31 January 2018

Christel Musset  
Director of registration  
European Chemicals Agency



# What comes after registration...



# Dissemination

- Your dossier is published on ECHA's website
  - Aim: all dossiers published by end of 2018
  - Information claimed confidential removed until validity of the claim is assessed
- Tips
  - Use dissemination preview tool to verify what is published
  - Practical advice: Dissemination and confidentiality manual [echa.europa.eu/manuals](http://echa.europa.eu/manuals)
- Confidentiality claims
  - We will assess the claims – this will run over several years
  - Additional information may be requested by ECHA
  - You may ask ECHA to review a negative decision

# SME status

- If you are an SME, your status will be verified
  - Systematic check
  - This will run over several years
  - If you are an Only Representative: size of the non-EU company counts
  - Companies are contacted via REACH-IT
- Tips
  - Upload documentary evidence in REACH-IT before submitting your registration
  - Keep your contact details up-to-date in REACH-IT
  - Check your account regularly: you may have requests from ECHA



# Retrospective checks

- Your dossier may be checked retrospectively for completeness
  - Enhanced completeness check introduced in 2016
  - Dossiers rarely updated are targeted for retrospective checks to ensure level playing field
  - First campaigns focused on dossiers with 'on-going' studies not updated for a long time
  - Registrants were able to fulfil information requirements, e.g. provide a missing study
  - Some registration decisions were revoked (3 out of 39)



# Enforcement by national authorities

- Project in **2019** (reporting in 2020)
- All EU countries foreseen to participate
- Scope:
  - Registration obligations after the last deadline in cooperation with customs authorities
  - This includes verification of strictly controlled conditions applicable to substances registered as intermediates



# REACH is not over after May 2018



# The beginning of a journey

- Your registration dossier is proof of safe use
  - You know the properties of your substances
  - Your clients are informed about how to use them safely
- Authorities look at your registration

Convinced by the information provided and your assessment?



Dossier evaluation (compliance check) by ECHA

Further information to clarify a concern?



Substance evaluation by EU Member States

Further risk management at EU level?



Candidate list of SVHCs, harmonised classifications and restrictions



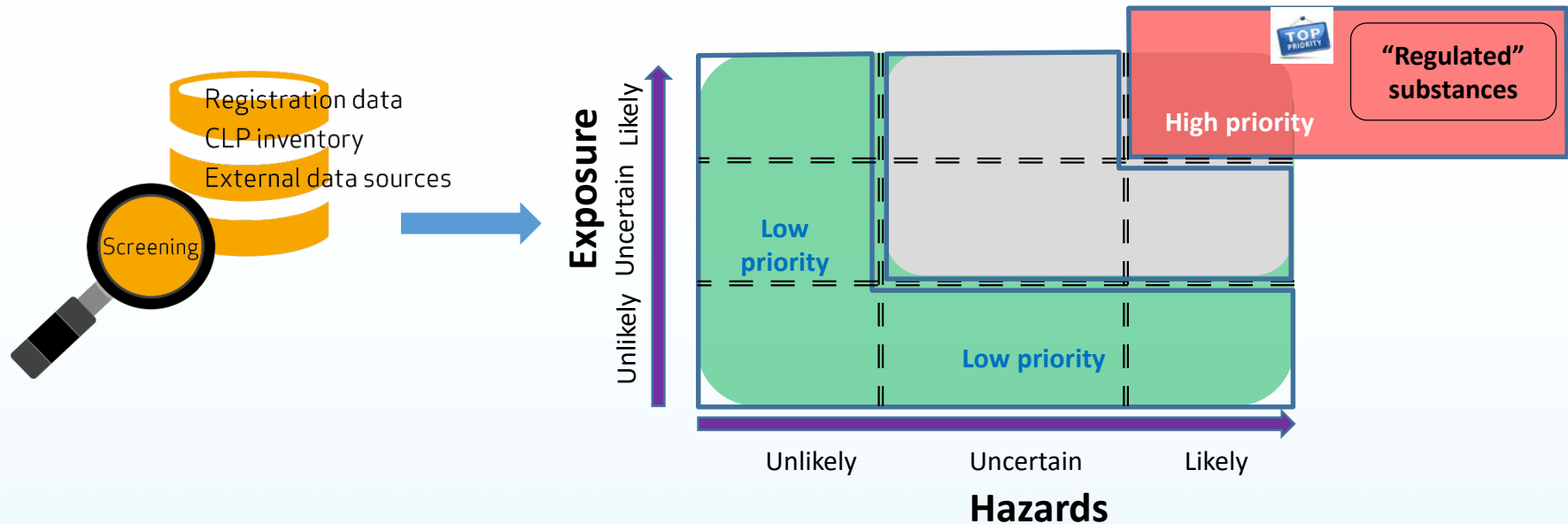
# Keep your dossier up-to-date

- Updating is a legal obligation
- Proof that you take your responsibilities seriously
- Ensure that you and the authorities assess safe use based on up-to-date and reliable data
- Obligation to all!
- The reality:
  - 67% of all dossiers have never been updated
  - Lead dossiers better off: over 50% updated
  - Dossiers submitted individually even more problematic: 80% never been updated



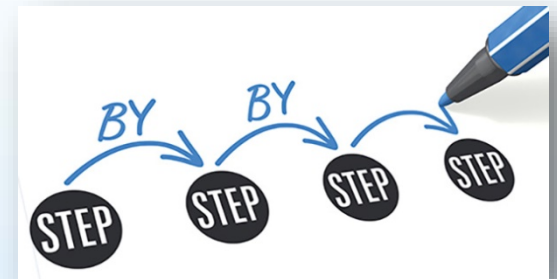
# Follow authorities' work

- All dossiers screened and prioritised for further assessment by authorities: evaluation or risk management



# Compliance check

- Your dossier may be prioritised if ECHA is not convinced by the information provided
- You normally get a chance to update your dossier before formal process starts
  - Substances potentially picked for compliance check published on our website:  
[echa.europa.eu/regulations/reach/evaluation/compliance-checks](https://echa.europa.eu/regulations/reach/evaluation/compliance-checks)
  - Stay informed through our Weekly news
- Recommendations in annual Evaluation reports:  
[echa.europa.eu/evaluation](https://echa.europa.eu/evaluation)



# Recommendations

- Update **new** information without undue delay
  - Changes in company status, substance composition, tonnages, uses and properties
- Make sure you **plan** for dossier updates
  - Keep the 'SIEF' alive: not a legal obligation after 2018 but needed for data and cost sharing
  - Ensure your SIEF agreements cover future costs:
    - New information may need to be generated, e.g. after a request from ECHA
    - Costs must be shared by all members of the joint registration – based on their data requirements obligations

# Compliance of your dossier is visible to all

- Compliance and quality give confidence to the public that substances can be used safely

Non confidential evaluation decisions published

Name	EC / List no.	CAS no.	Decision	Decision date	Further information
3-aminomethyl-3,5,5-trimethylcyclohexylamine	220-666-8	2855-13-2	CCH-D-2114356498-35-01/F	05/04/2017	
Trifluoroacetic acid	200-929-3	76-05-1	CCH-D-2114358335-47-01/F	30/03/2017	

Access to the registration data, registrants' names, frequency of dossier updates

# Substances on authorities' radar

- Substance evaluation and risk management
- Focus on substances that matter
  - Higher-tonnage registrations with important data gaps and with exposure potential
- Common screening in cooperation with Member States
  - Most suitable route to address concern is identified
- Short-listed substances
  - Letter sent to each registrant concerned, with advice and an update deadline before formal process starts
  - Webinar organised for more advice



REACH 2018

# Keep up-to-date: PACT

- Public activities coordination tool:  
[echa.europa.eu/pact](http://echa.europa.eu/pact)
- Find out: nature of our concern (CMR, PBT...), on-going activities, authority in charge and outcome

Name	EC/List No	CAS Number	Authority	Activity	Latest update	Scope	Outcome	
1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	244-617-5	21850-44-2	Germany	Hazard assessment	05/01/2018	PBT	Substance evaluation under development	<a href="#">Details</a>
Disodium octaborate	234-541-0	12008-41-2 12280-03-4	Sweden	RMOA	05/01/2018	CMR	Appropriate to initiate regulatory risk management action	<a href="#">Details</a>
Methylcyclohexane	203-624-3	108-87-2	Finland	Hazard assessment	09/11/2017	PBT	According to authority's assessment NOT PBT/vPvB	<a href="#">Details</a>

# What else to expect?





# REACH review

- Report expected by March 2018
- ECHA's input to the Commission on registration
  - Dossier quality is a concern
    - Consider means for ensuring dossier updates
    - Compliance checks of high tonnage dossiers must continue to ensure that objectives of safe use are met
  - Dissemination
    - Effective and powerful tool
    - We will continue to improve and make information available
    - Reward for good dossiers: confidence to the public



# Nanoforms: review of REACH Annexes

- Ongoing review will clarify existing REACH requirements for nanoforms of substances
- Commission proposal currently being discussed by Member States in REACH Committee
- Changes not expected to enter into application until January 2020
- We will develop guidance to ensure sufficient support for industry in fulfilling the requirements

# 1-10 tonnes information requirements and polymers

- Studies done by the Commission:
  - Chemical safety report requested for CMR substances in the 1-10 tonnes range
  - Increasing information requirements for substances in the 1-10 tonnes range
  - Registering polymers of concern
- Studies show benefits are higher than costs
- Further assessment needed on economic impact on industry, especially SMEs



REACH 2018

# UK withdrawal from the EU

- Prepare for withdrawal date: **30 March 2019**
- UK-based registrants obliged to register under REACH, subsequently subject to UK law
- All registrants (within EU-27/EEA and UK) will be affected in various ways
- See details and follow developments on ECHA's website:  
[echa.europa.eu/uk-withdrawal-from-the-eu](http://echa.europa.eu/uk-withdrawal-from-the-eu)



Impact on ECHA - Background information



Advice to companies / Q&As



Cooperating with UK authorities



UK participation in ECHA's bodies and networks



Impact on ECHA's regulatory decisions



Inform yourself on the EU-UK withdrawal negotiations



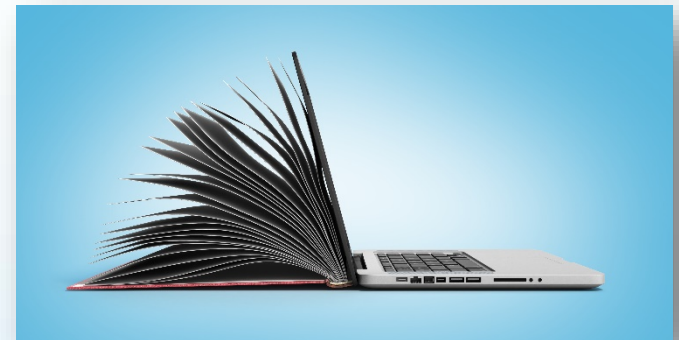
Recruitment of staff



Procurement and contracts

## Take home

- Registration is not over by May 2018
- You need to update your dossier – this is the law, and also the proof that you take safe use of chemicals seriously
- Make sure you have a structure in place to handle updates
- Legislation evolves: outcome of the REACH review is around the corner



# Thank you

christel.musset (at) echa.europa.eu

## Follow our news

News: [echa.europa.eu/subscribe](http://echa.europa.eu/subscribe)

Twitter: [EU\\_ECHA](https://twitter.com/EU_ECHA)

Facebook: [EUECHA](https://www.facebook.com/EUECHA)

YouTube: [EUchemicals](https://www.youtube.com/EUchemicals)

LinkedIn: [European Chemicals Agency](https://www.linkedin.com/company/european-chemicals-agency)

