Registration post 2018 – Dossier updates

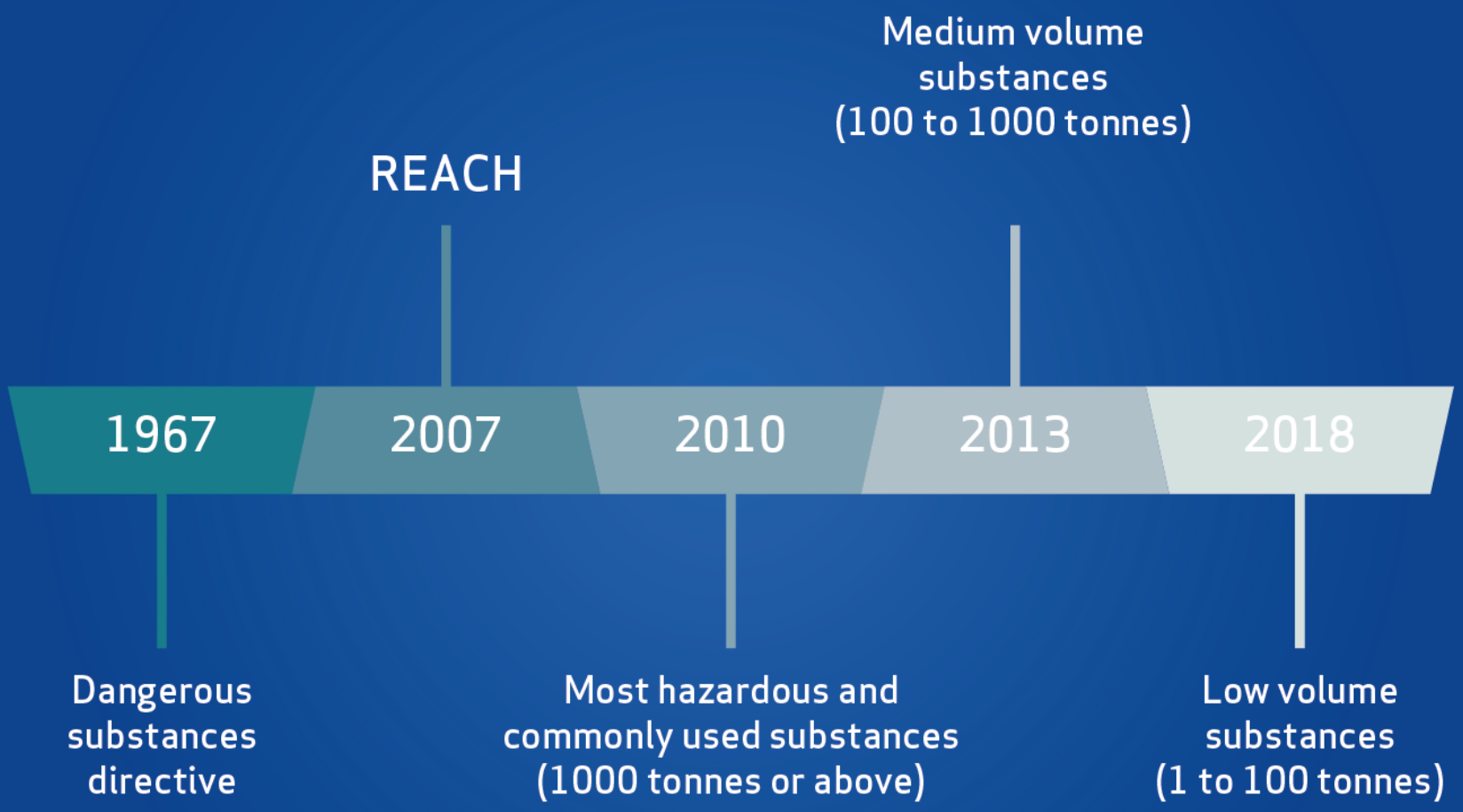
'REACH Compliance – A BfR-Workshop on data quality in registration dossiers'

23-24 August 2018

Hannu Braunschweiler
Senior Scientific Officer
Evaluation Unit II
ECHA

2018 deadline: what happened?

The journey

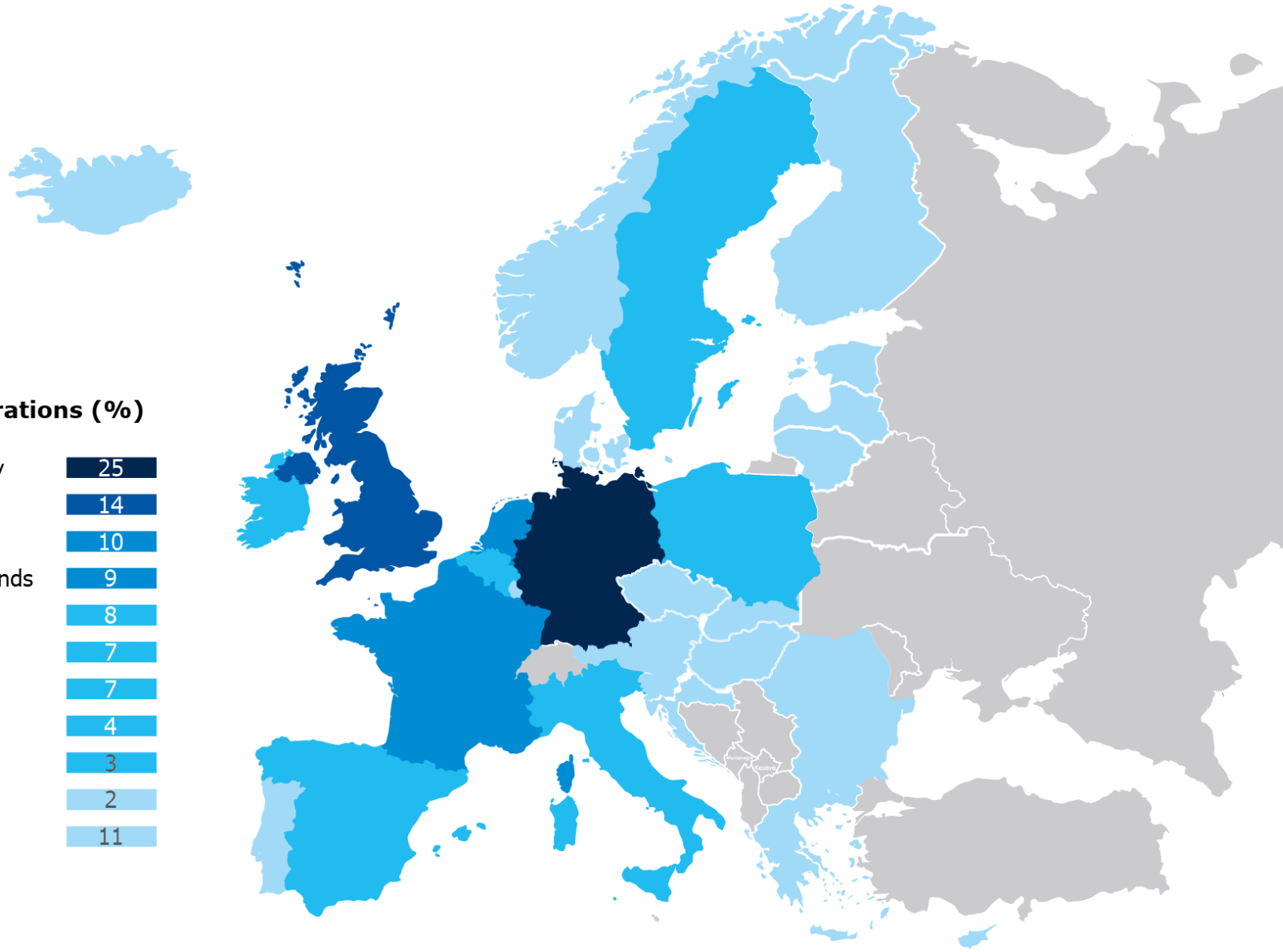

Medium volume substances (100 to 1000 tonnes)
REACH
1967
2007
2010
2013
2018
Dangerous substances directive
Most hazardous and commonly used substances (1000 tonnes or above)
Low volume substances (1 to 100 tonnes)

Main outcome

	All	DL 2018
Registrations	88 319	33 363
Substances	21 551	11 114

- Some registrations still being processed by ECHA (1300 additional submissions by 19/06)
- 18% of registrations from SMEs

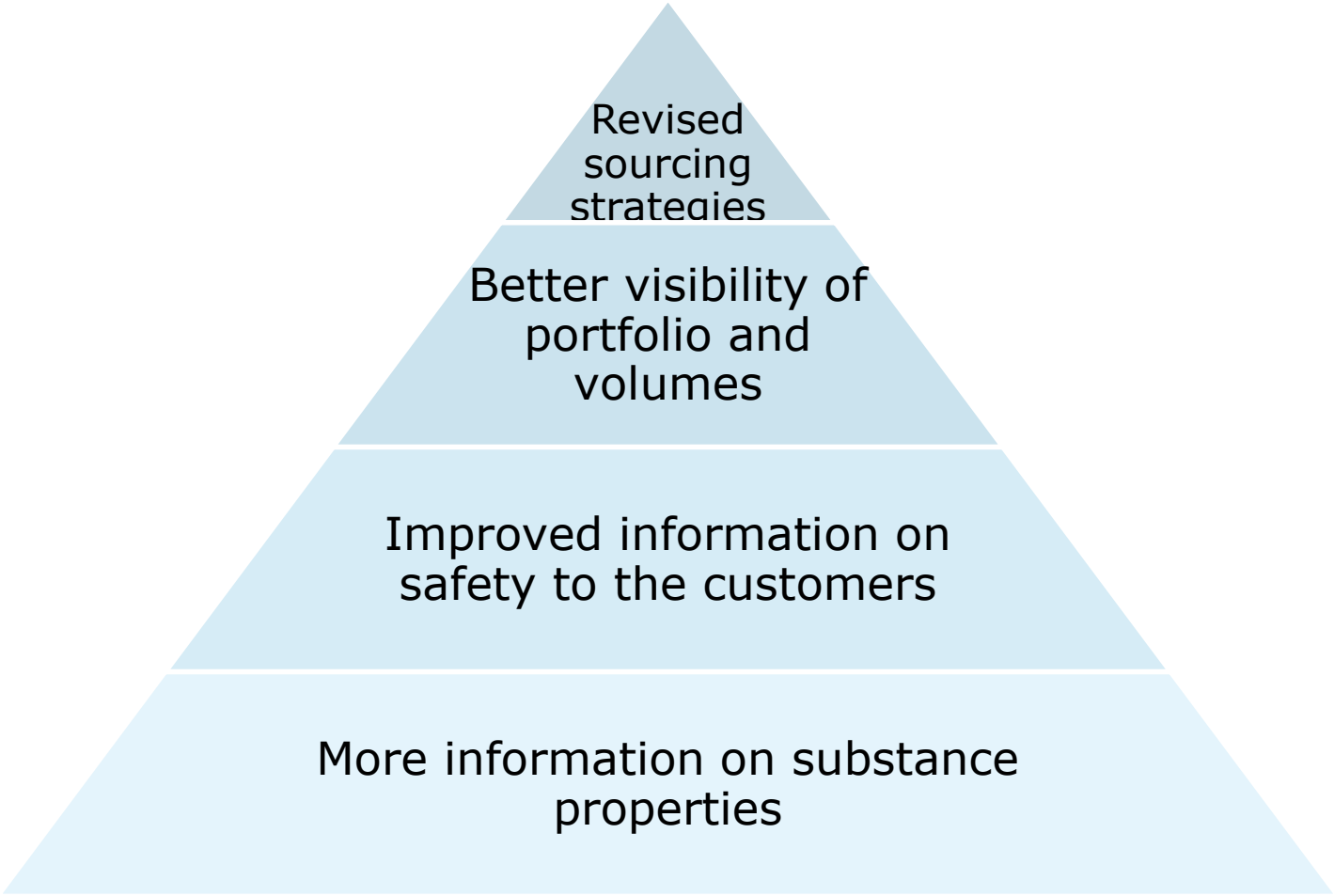
EU/EEA countries (all)



Was the outcome as expected?

- **Fewer** registrations and substances than forecasted for the 2018 deadline
- Overall, **closer** to the forecast for all tonnages
- Registrations **still** coming in
- **Number of substances similar** to the US market

Benefits for companies?



Summary

- 21 550 chemicals registered - we know more than ever about the chemicals used in the EU
- Registrants have done their part for the initial registration - information flows in the supply chain improving workers' safety and resulting in safer products
- EU has established clear and harmonised rules for all EU manufacturers and importers of chemicals
- Registration is only the start

What comes after the registration deadline

Late comers / new players

- No manufacturing or importing in EU over 1 tonne without registration
- Those concerned should bring themselves to compliance asap
- Need to submit an inquiry
- It is also recommended to document all efforts for enforcement activities
- Late comers / new players advised to contact ECHA if need help

- New substances/uses for research: **PPORD**

In the coming months

Publication of dossiers on ECHA's website

- Aim: all dossiers published by end of 2018
- Assessment of confidentiality claims (may lead to request for information

SME verification

- All dossiers from SMEs
- For Only representative, it is the size of non-EU entity
- Registrant to upload evidence in REACH-IT

Manual checks as part of completeness check

Manual checks ensure that registrants who deviate from standard requirements provide a justification that is relevant within the REACH context.

Current focus of manual checks:

- Justification for waiving of standard information requirements (physicochemical, environmental fate and hazard information)
- Substance identification (justification for deviations from naming and identification of substances, and waiving of analytical information; identification of UVCB substances)
- Justification for waiving of chemical safety report
- Testing proposal on vertebrate animals (presence of considerations for adaptation possibilities)

Retrospective checks

- An older dossiers may be checked retrospectively for completeness and fulfilling OSOR

- Enhanced completeness check introduced in 2016
- Dossiers not updated are targeted for retrospective checks to ensure level playing field
- First campaigns showed that registrants were able to fulfil information requirements, e.g. provide a missing study
- Some registration decisions were revoked

- One substance, one registration (OSOR): Implementing Regulation from 2016 tasked ECHA to ensure joint submission

- Registrants will be informed of a retrospective check via REACH-IT

REACH is not over after May 2018

The beginning of a journey

- The registration dossier is proof of safe use
  - The registrant knows best the properties of the substances
  - Clients are informed about how to use them safely
- Authorities now look at the registration:

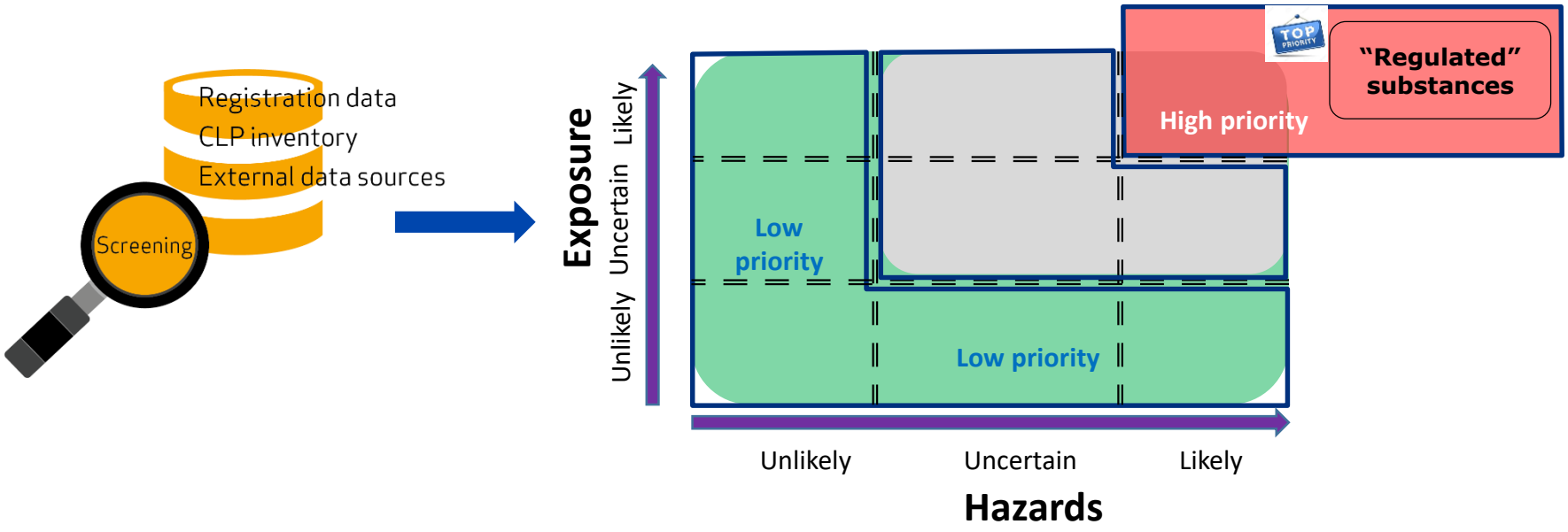
Convinced by the information provided and the assessment?	→ Dossier evaluation (compliance check) by ECHA
Further information to clarify a concern?	→ Substance evaluation by EU Member States
Further risk management at EU level?	→ Candidate list of SVHCs, harmonised classifications and restrictions

Enforcement by national authorities

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

Follow authorities' work

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



Compliance checks and testing proposal examination

- Compliance checks needs to be opened for at least 5 % of the new registrations submitted
  - This is 1 668 compliance checks for 33 363 registrations on 11 114 substances

- Testing proposals were submitted in 120 new registrations by 1 June 2018
  - ECHA needs to issue draft decisions on these by 1 June 2022

Compliance of a 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

Keep up-to-date: PACT

- Public activities coordination tool: 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	Details
Disodium octaborate	234-541-0	12008-41-2 12280-03-4	Sweden	RMOA	05/01/2018	CMR	Appropriate to initiate regulatory risk management action	Details
Methylcyclohexane	203-624-3	108-87-2	Finland	Hazard assessment	09/11/2017	PBT	According to authority's assessment NOT PBT/vPvB	Details

Changes in regulatory requirements

Nanoforms:

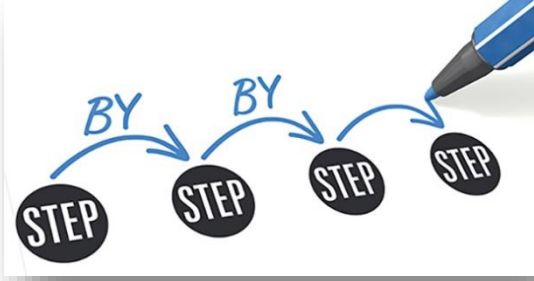
- Clarification of requirements voted in April
- Changes not expected to enter into application until January 2020
- Guidance and support under preparation

1-10 tonnes and polymers:

- Part of REACH Review
- Chemical safety report requested for CMR & increasing information requirements for 1-10?
- Registering polymers of concern?

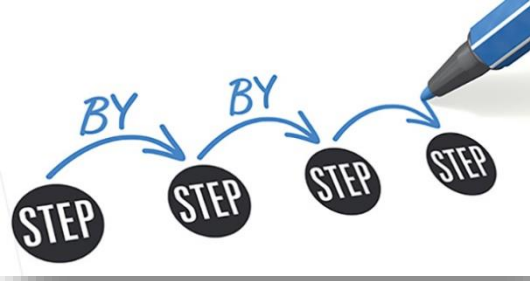
UK withdrawal from the EU

- Advised to 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



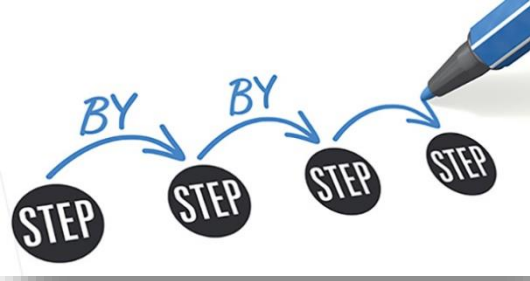
Keep dossiers up-to-date -1

- The reality:
  - 67% of all dossiers have never been updated
  - Lead dossiers better off: over 50% updated
  - Registrants survey: 85% of the companies are familiar with the update process, but only 55% have already discussed how to handle future updates
- Updating is a legal obligation!
- The registrant need to ensure that he and the authorities assess safe use based on up-to-date and reliable data
- Registrants need to set-up a process within the joint submission to keep dossier up-to-date!



Keep dossiers up-to-date -2

- Update **new** information without undue delay
  - Changes in company status, substance composition, tonnages, uses and properties
- Registrants to make sure to **plan** for dossier updates
  - To keep the 'SIEF' alive: not a legal obligation after 2018 but needed for data and cost sharing
  - To ensure the 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



Keep dossiers up-to-date -3

- Recommendations how registrant could improve their dossiers are given in the annual Evaluation reports: echa.europa.eu/evaluation
- Hence registrants also to check their dossiers against the Evaluation reports to identify if a dossier is compliant and to submit testing proposals as necessary
- Registrants to also check regularly ECHA website to see if their dossier is under scrutiny and get prepared for the formal process(es)

Take-home messages

- ✓ Registration is not over by May 2018
- ✓ Registrants need to update their dossiers – this is the law, and also the proof that registrants take safe use of chemicals seriously
- ✓ Registrants should ensure they have a structure in place to handle updates
- ✓ Legislation evolves: follow the developments

Thank you!

hannu.braunschweiler(at)echa.europa.eu

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
@EU_ECHA

Follow us on Facebook
Facebook.com/EUECHA