REACH post 2018 - what happens next?

REACH - Notification for chemicals, mixtures and specific chemicals

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Overview

1. 2018 deadline: how did it go?
2. Life after the deadline
3. Dossier updates
4. Few take-home messages

Registration: at the core of REACH

- Registration process is vital
- Dossiers show what industry knows about their portfolio and if it can demonstrate safe use
- Basis for all other processes:
  - Informed decisions by authorities
  - Safety instructions in the supply chain
  - Information available to the general public

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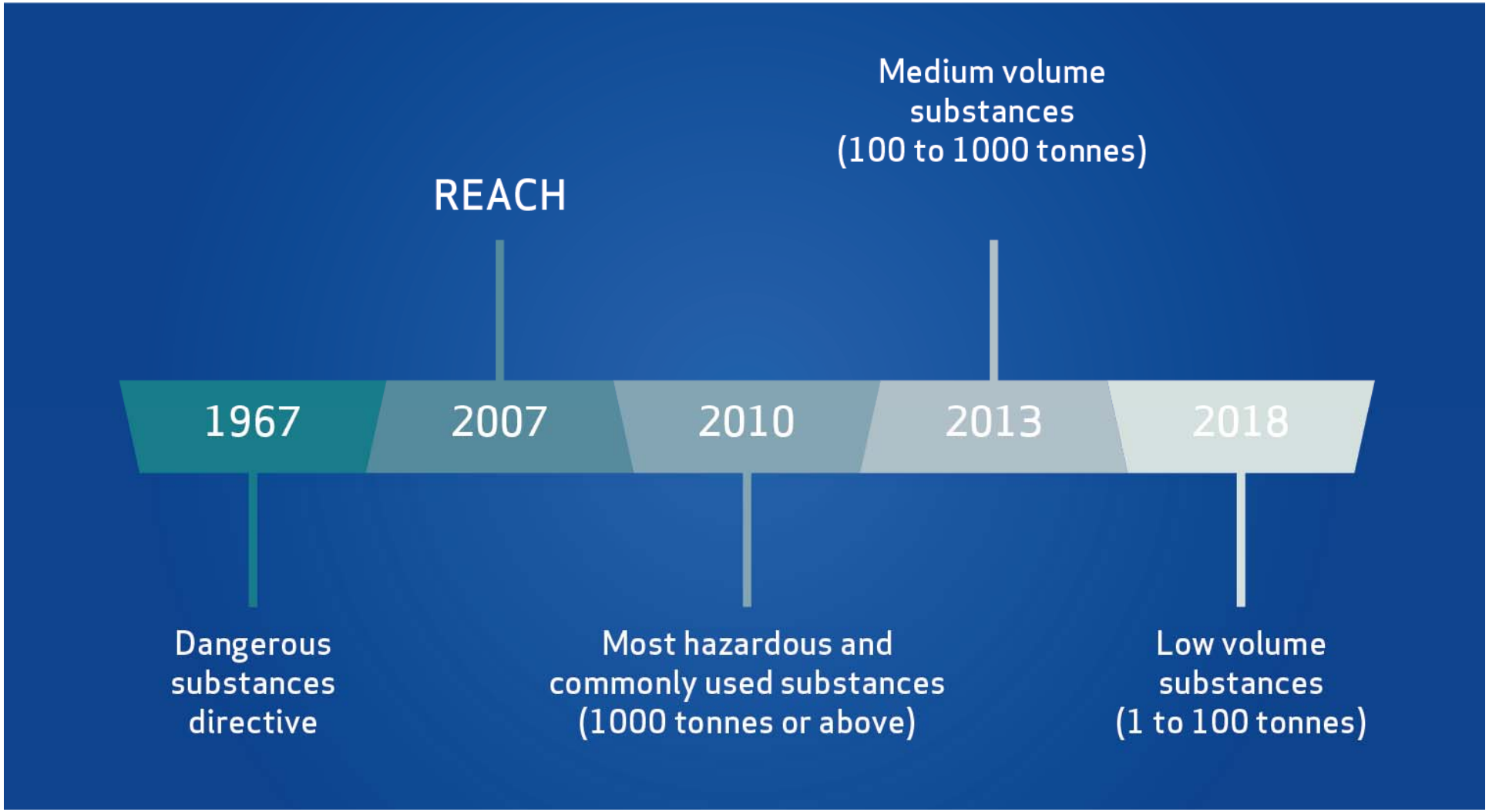
The REACH journey



2018 deadline: how did it go?

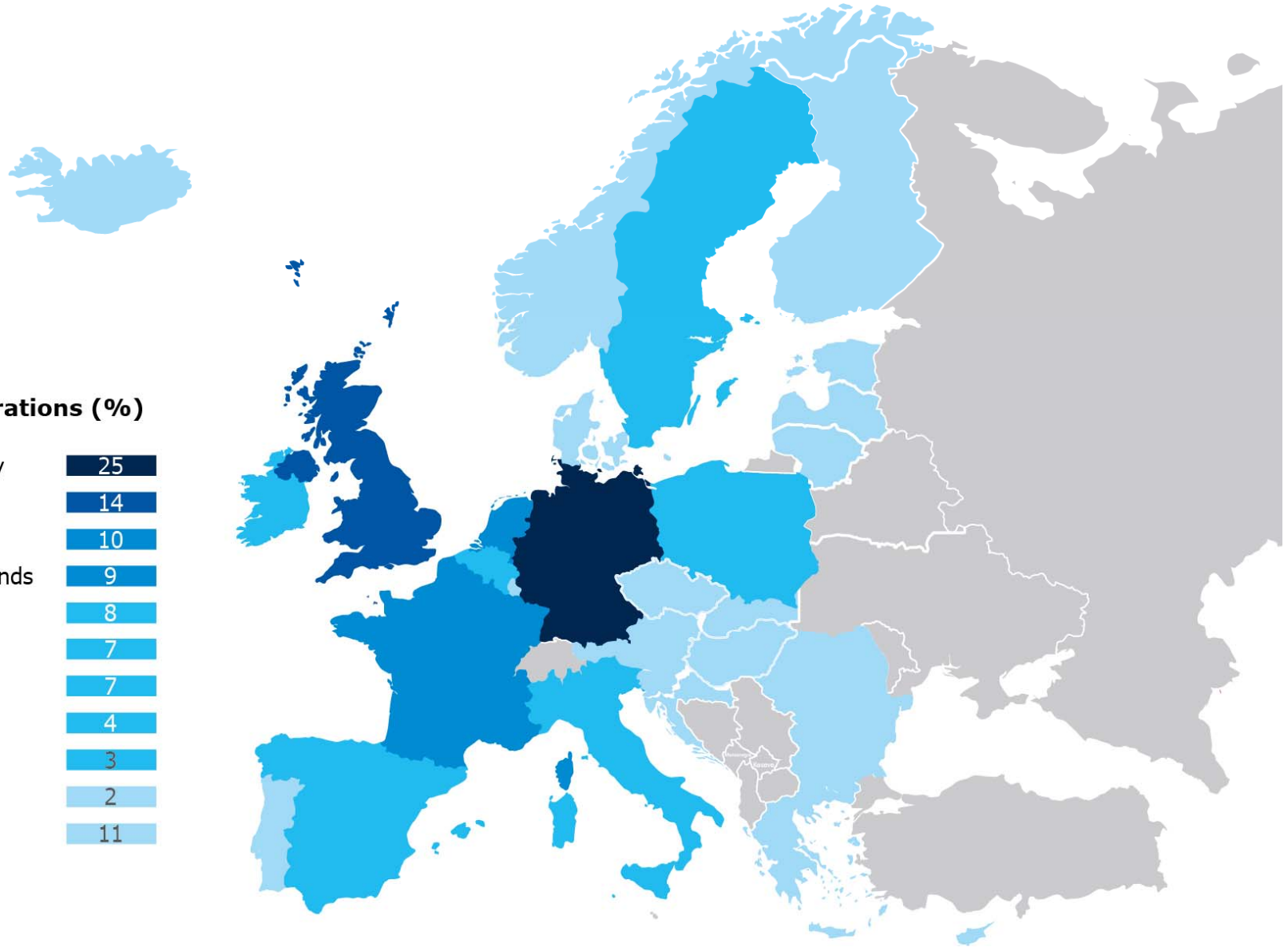
Main outcome of the 2018 deadline

	All	DL 2018	Bulgaria All	Bulgaria DL 2018
Registrations	90 627	33 363	525	121
Substances	21 601	10 708	235	56

- All registrations processed
- 18% of registrations from SMEs
- Registrations from outside of EU: 43% from importers and 29% from OR

echa.europa.eu/-/registration-numbers-granted-to-32-515-reach-2018-registrations

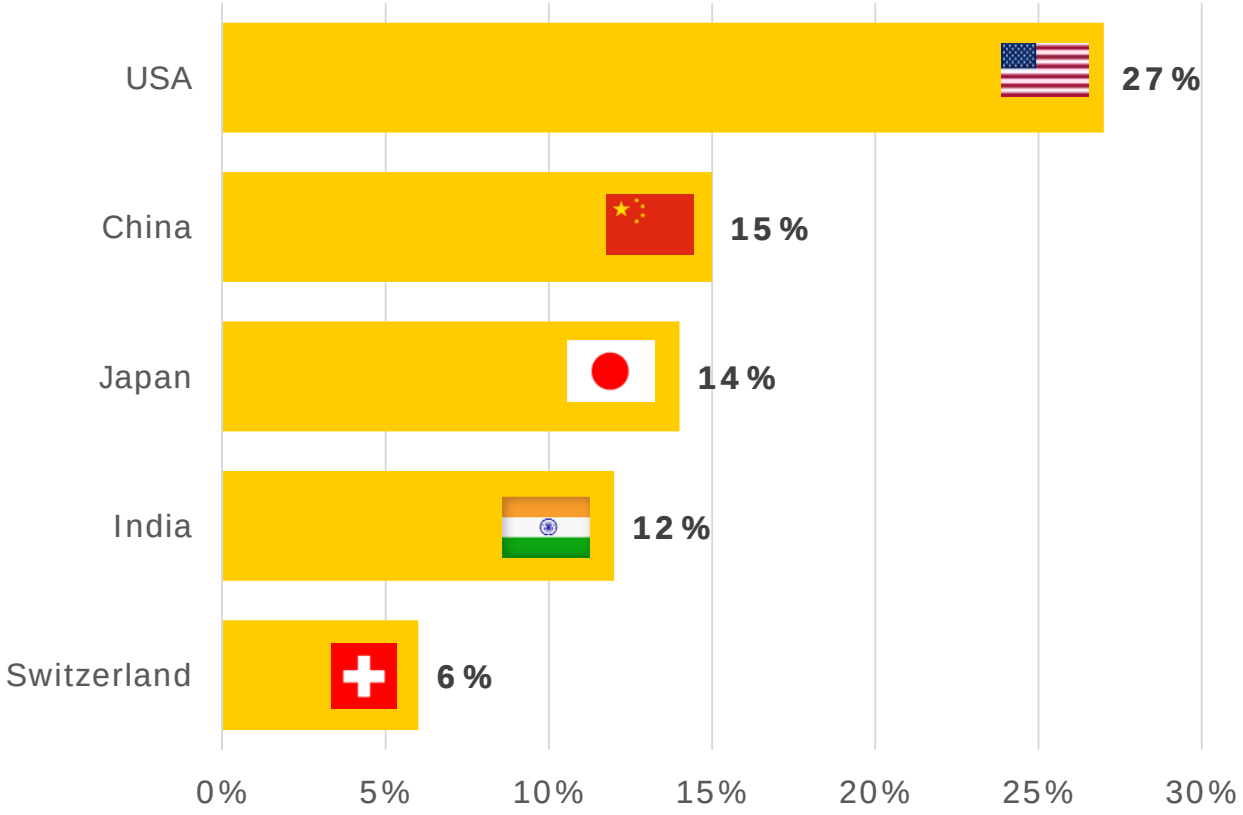
EU / EEA countries (all)



Registrations (%)

Germany	25
UK	14
France	10
Netherlands	9
Italy	8
Belgium	7
Spain	7
Ireland	4
Sweden	3
Poland	2
Others	11

Top 5 non-EU countries (with ORs)



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

Summary

- 21 601 chemicals registered - we know more than ever about the chemicals used in the EU
- Companies have done their part - information flows in the supply chain improving workers' safety and resulting in safer products
- EU has established clear and harmonised rules for all companies and all substances
- Registration is only the start

Life after the deadline

Late comers / new players

- REACH principle of ‘no data, no market’ → no manufacturing or importing in EU over 1 tonne per year without registration
- First step: submit an inquiry to ECHA to get in contact with co-registrants, or
  - Until the cut-off date to be clarified by the European Commission, you can use your pre-registration
- If you should have registered before the deadline: bring yourself to compliance as soon as possible and document all efforts for enforcement activities

Registration of new substances

- Need to register under REACH before manufacture/import above 1 tonne starts
- Consider PPORD: applies as exemption during product and process research and development phase (5 years, extendable)
  - Closed list of customers, not supplied to the public
  - Also for new uses of existing substances
  - Can be used in parallel with a registration (split tonnages for PPORD and supplying to the public)

Dissemination and SME verification

Publication of dossiers on ECHA's website

- 99.7% of completed registrations are already published
- Assessment of confidentiality claims (may lead to request for information on the claim)

SME verification

- All dossiers from SMEs
- For Only Representatives, it is the size of non-EU entity
- Upload evidence in REACH-IT

Retrospective checks of dossiers

Your older dossiers may be checked retrospectively for completeness and fulfilling OSOR

- Enhanced completeness check
  - Target: dossiers not updated, to ensure level playing field
  - First campaigns showed that registrants were able to fulfil information requirements, e.g. provide a missing study
- One substance, one registration (OSOR)
  - Implementing regulation from 2016 tasked ECHA to ensure joint submission
- If no reaction, registration decisions are revoked
- You are informed of a retrospective check via REACH-IT

Enforcement by national authorities

- REF-7 project on registration 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

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

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 up-to-date: extended PACT

- Public activities coordination tool: echa.europa.eu/pact
- Overview per substance of the authorities' activities
- 2nd level with details, e.g. nature of the concern, status, authority in charge, outcome, decision, …

Substance name	EC / List no	CAS no	Data generation and assessment				RMOA	Regulatory risk management			
			DEv	SEv	ED	PBT	RMOA	CLH	SVHC	Restriction	
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol, 2,2,6,6-tetrabromo-4,4-isopropylidenediphenol	201-236-9	79-94-7	1	1	1	1	1	-	-	-	
4,4'-isopropylidenediphenol Bisphenol A; BPA	201-245-8	80-05-7	1	1	2	-	2	2	3	2	
4,4'-sulphonyldiphenol, 4,4'-sulfonyldiphenol	201-250-5	80-09-1	5	1	1	-	1	-	-	-	

Compliance check

- Check if your information satisfies the requirements
- All registrants relying on the non-compliant information are responsible to satisfy the request for additional information following a dossier compliance check
  echa.europa.eu/-/member-registrants-will-start-receiving-dossier-evaluation-decisions-in-2019
- Other changes (Jan 2019): updates taken into account only in exceptional circumstances after draft decision
  echa.europa.eu/-/online-information-session-extending-dossier-evaluation-to-members-of-the-joint-submission
- Substances under compliance check are now published on our website at echa.europa.eu/information-on-chemicals/dossier-evaluation-status

Dossier updates

Action 1 in the REACH review

Proposed actions

ACTION 1: encourage updating registration dossier. *Why?*

1) Improve compliance and rectify important data gaps and data quality issues

2) Updates by companies considered insufficient

Actors involved : COM, ECHA, Member States and industry delivering proposals by first quarter 2019.

Obligation to keep dossiers up-to-date

Updating is a legal obligation (Article 22)

- The reality:
  - 45% of dossiers older than 4 years old were never updated
  - Feedback from registrants survey: 85% of the companies are familiar with the update obligation, but only 55% have already discussed how to handle future updates
  - Most updates follow a request by ECHA (dossier or substance evaluation) or letter campaign; few spontaneous updates
- Need to ensure that companies and the authorities assess safe use based on up-to-date and reliable data

Obligation to keep dossiers up-to-date

- On your own initiative, without undue delay, after certain changes
  - Company status
  - Composition of the substance
  - Tonnage band
  - New identified uses
  - New risks of the substance to human health and/or the environment
  - Classification and labelling of the substance
- When the Agency requests an update of the registration after a dossier or substance evaluation decision
- After an authorisation or a restriction for the substance

What companies need to have

In the own company

- Systems and alerts to signal if changes in your registration might be needed
  - Substance portfolio (e.g. new compositions, hazardous impurities, ...)
  - Volumes (registered substances and those below 1 tonne per year, cease import, ...)
  - Uses of the substance throughout the lifecycle
  - REACH-IT e-mail notification: keep your e-mail up-to-date

What companies need to have

In the joint submission

- Agreed process within the joint submission to keep the dossier up-to-date and monitor/review periodically the knowledge on the substance
- Keep the ‘SIEF’ alive for data and cost sharing
- Ensure your 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 – based on their data requirements

UK withdrawal from the EU

- UK-based registrants now need to be registered under REACH, subsequently subject to UK law
- Number of UK registrations (Oct 2018):
  - 10840 registrations of which 1319 lead dossiers
  - 1774 legal entities submitted registrations
  - 4802 substances registered
- Prepare for withdrawal date: 30 March 2019
- All registrants will be affected in various ways
- See details and follow developments at echa.europa.eu/uk-withdrawal-from-the-eu

Take-home messages

- ✓ Registration was not over on 1 June 2018
- ✓ You need to update your dossier and the proof that you take safe use of chemicals seriously
- ✓ Make sure you have a structure in place to handle updates
- ✓ Legislation evolves: follow the developments

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