REACH post 2018 - what happens next?

REACH&CLP – Implementation and future challenges for companies

6 December 2018,
Luxembourg

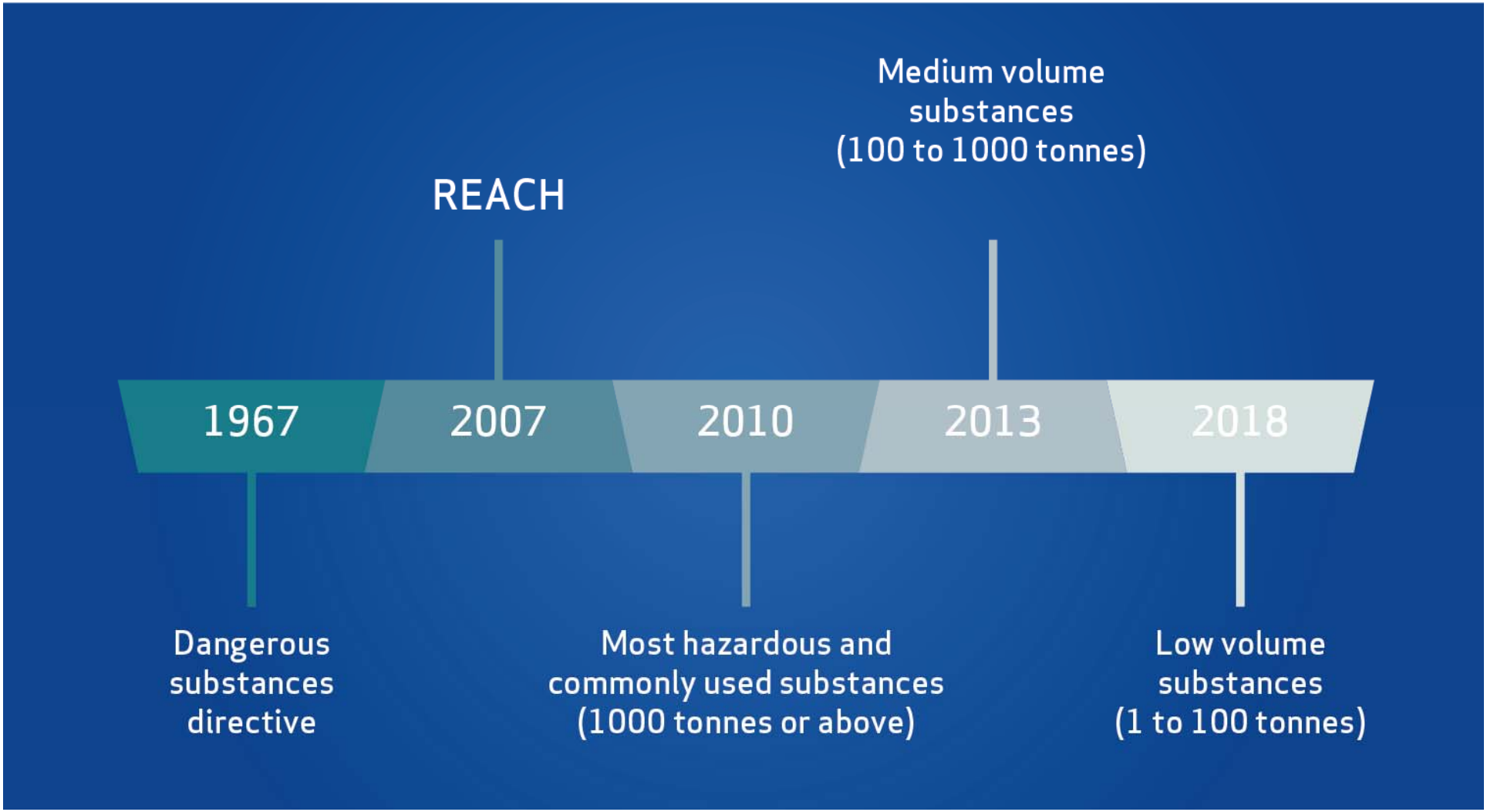
Slides prepared by
the European Chemicals Agency

Overview

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

ECHA
EUROPEAN CHEMICALS AGENCY

The REACH journey



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

2018 deadline: how did it go?

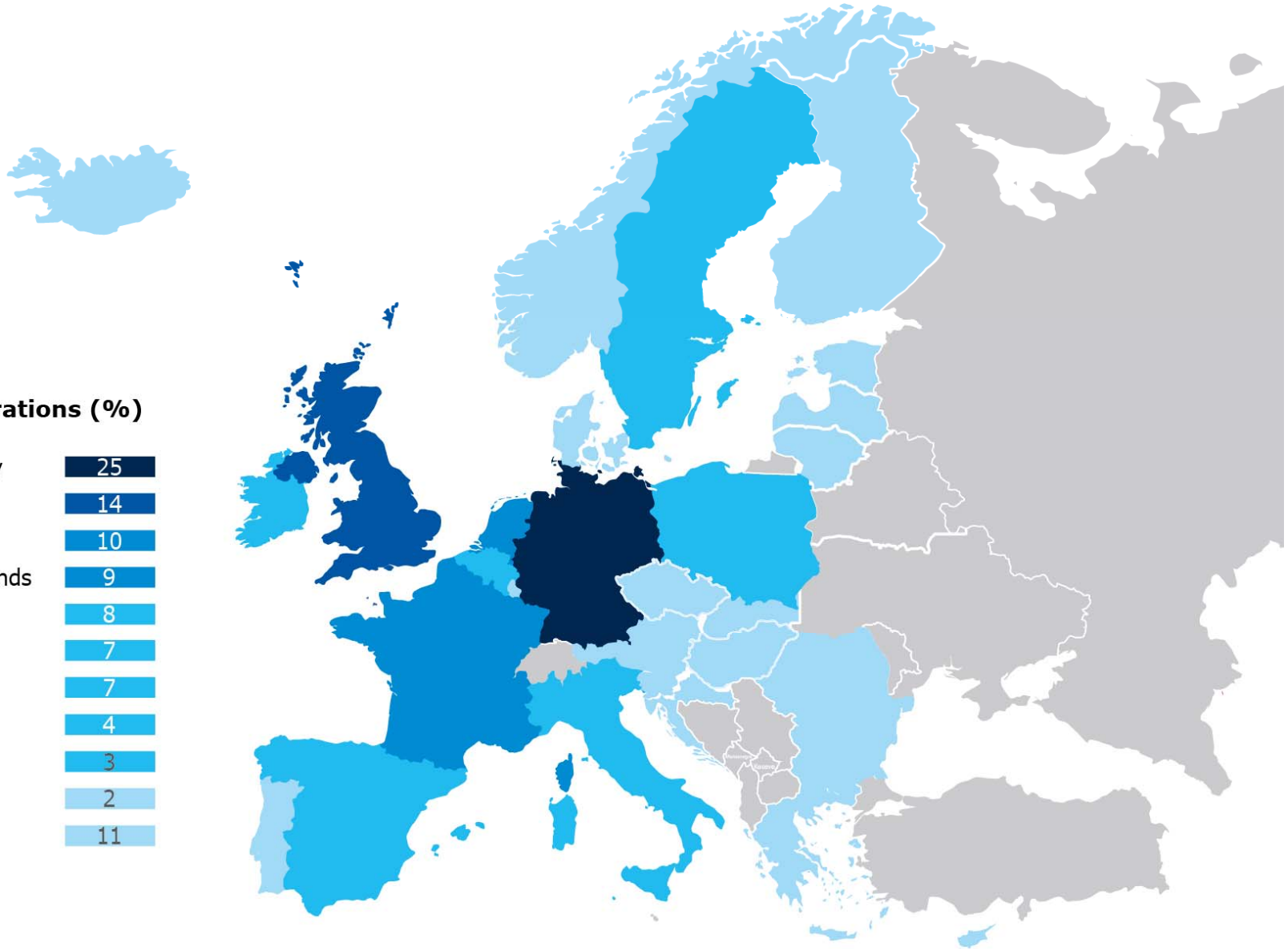
Main outcome of the 2018 deadline

	All	DL 2018
Registrations	90 627	33 363
Substances	21 601	10 708

- All registrations processed
- Deadline-relevant submissions continue (>2000)
- 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

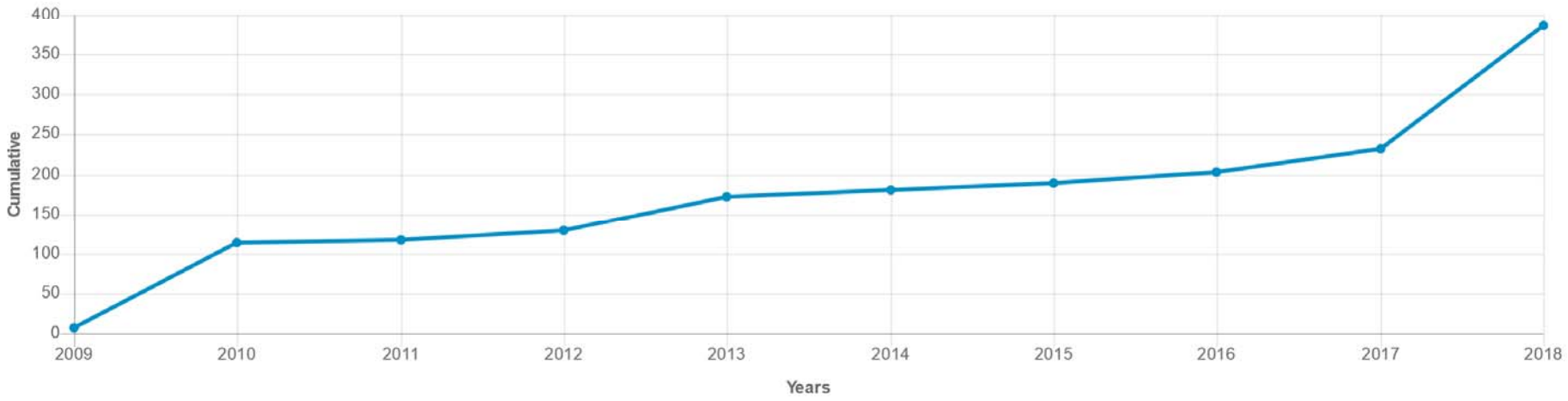
Registration Luxembourg

2018: place 15 amongst MS
1.6 % of substances, 0.6 % of registrations

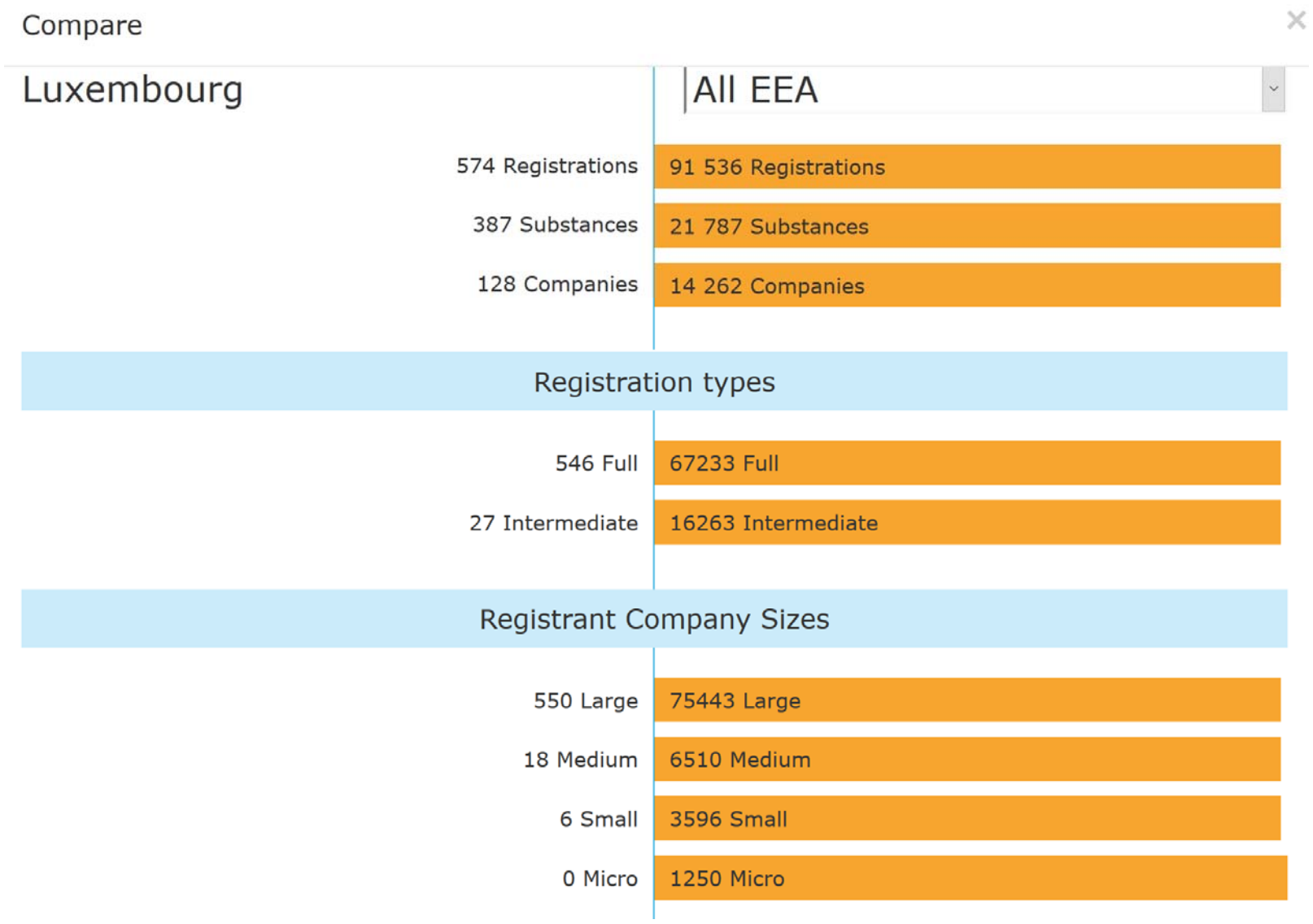
	# Registrations	# Substances
Germany	8 463	4 792
United Kingdom	4 396	2 298
France	3 455	2 124
Italy	2 926	2 049
Netherlands	2 751	1 653
Spain	2 467	1 794
Belgium	2 235	1 461
Ireland	1 237	832
Sweden	1 133	983
Hungary	825	651
Czech Republic	614	573
Austria	363	338
Poland	366	270
Finland	306	266
Luxembourg	199	176
Denmark	149	138

Luxembourg

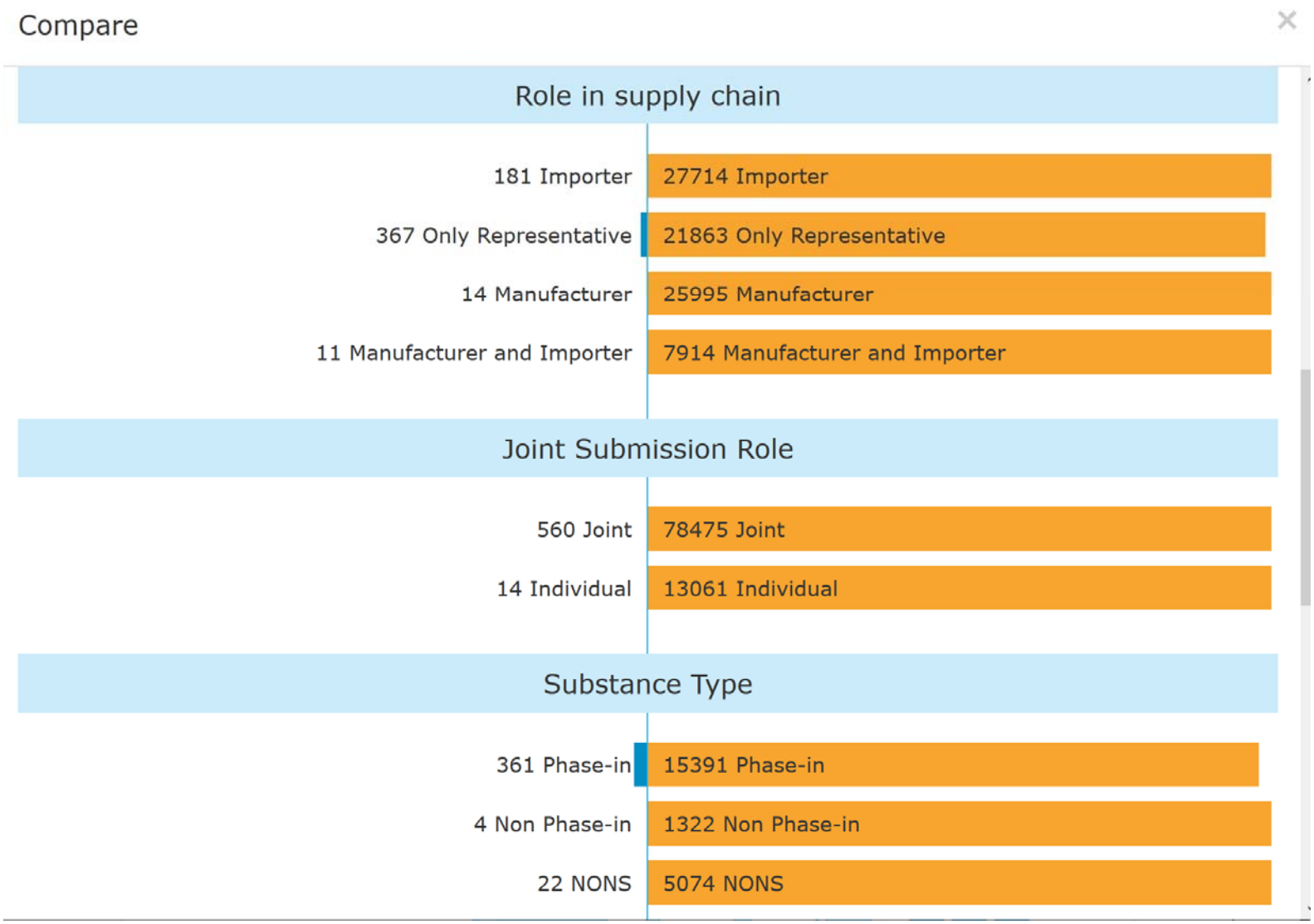
Substances



Registration - Luxembourg

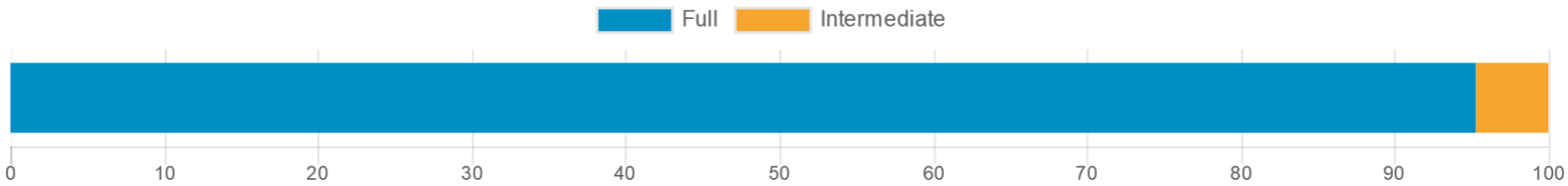


Registration - Luxembourg



Registration - Luxembourg

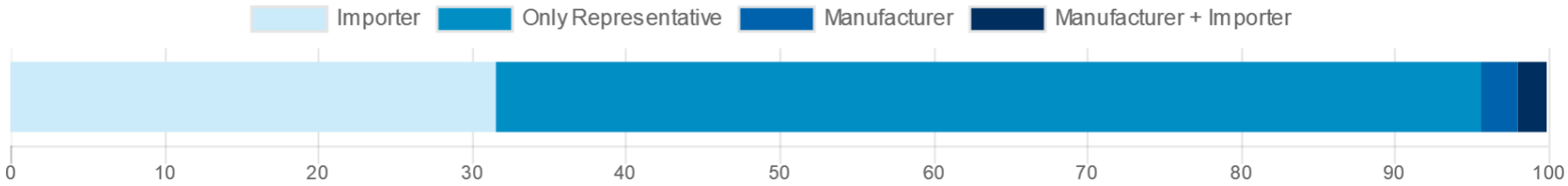
Registration types



Full registration: Substance registrations that include the full set of information required

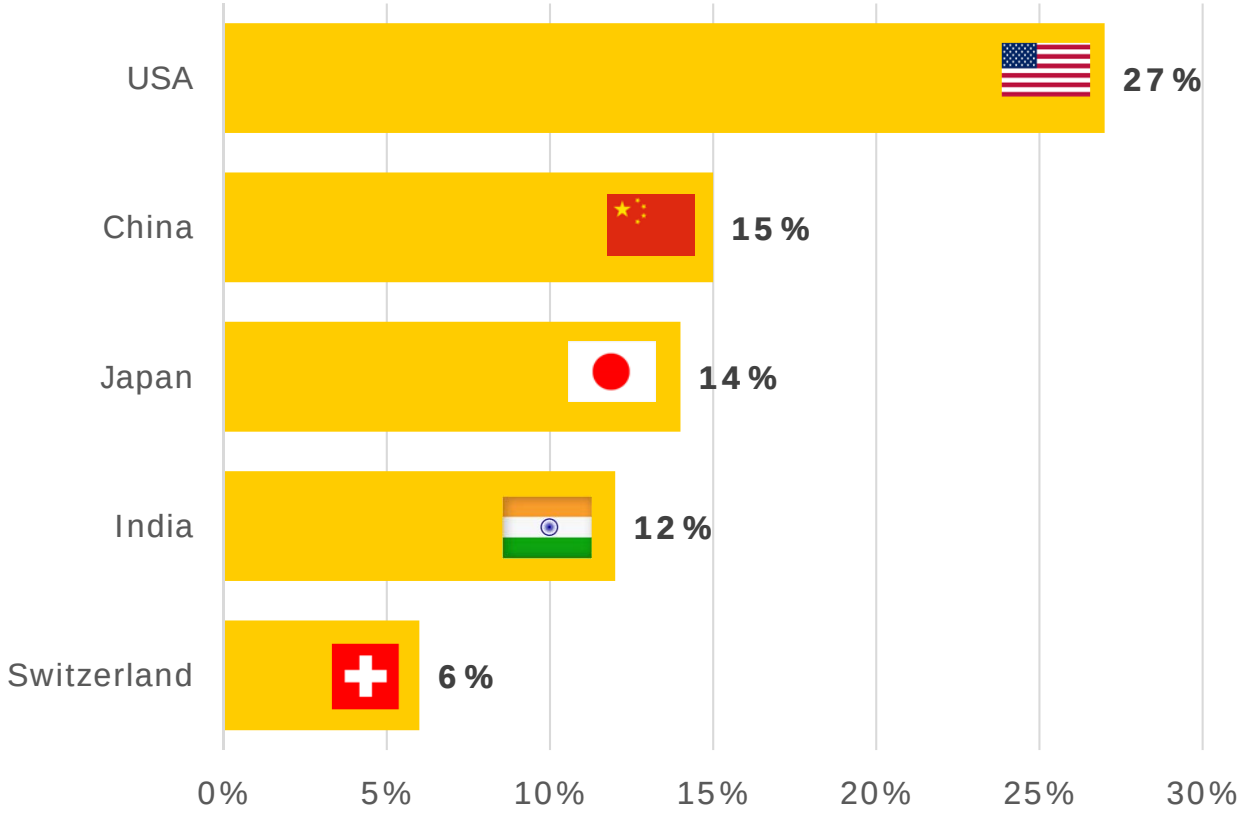
Intermediate registration: Substances registered for intermediate use only and under conditions that prevent exposure to humans and the environment, require less data for registration.

Role in supply chain



Only representative: Appointed by a non-EU company to register a substance on its behalf.

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

Existing substances phased into REACH

- 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

Dossier updates

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

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

Obligation to keep dossiers up-to-date

Updating is a legal obligation (Article 22)

- On your own initiative, without undue delay, after certain changes
- 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

Update on own initiative required

- Without undue delay
- After changes in:
  - 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
  - …

Obligation to keep dossiers up-to-date

- 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

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.

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
  - …

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

What happens next?

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

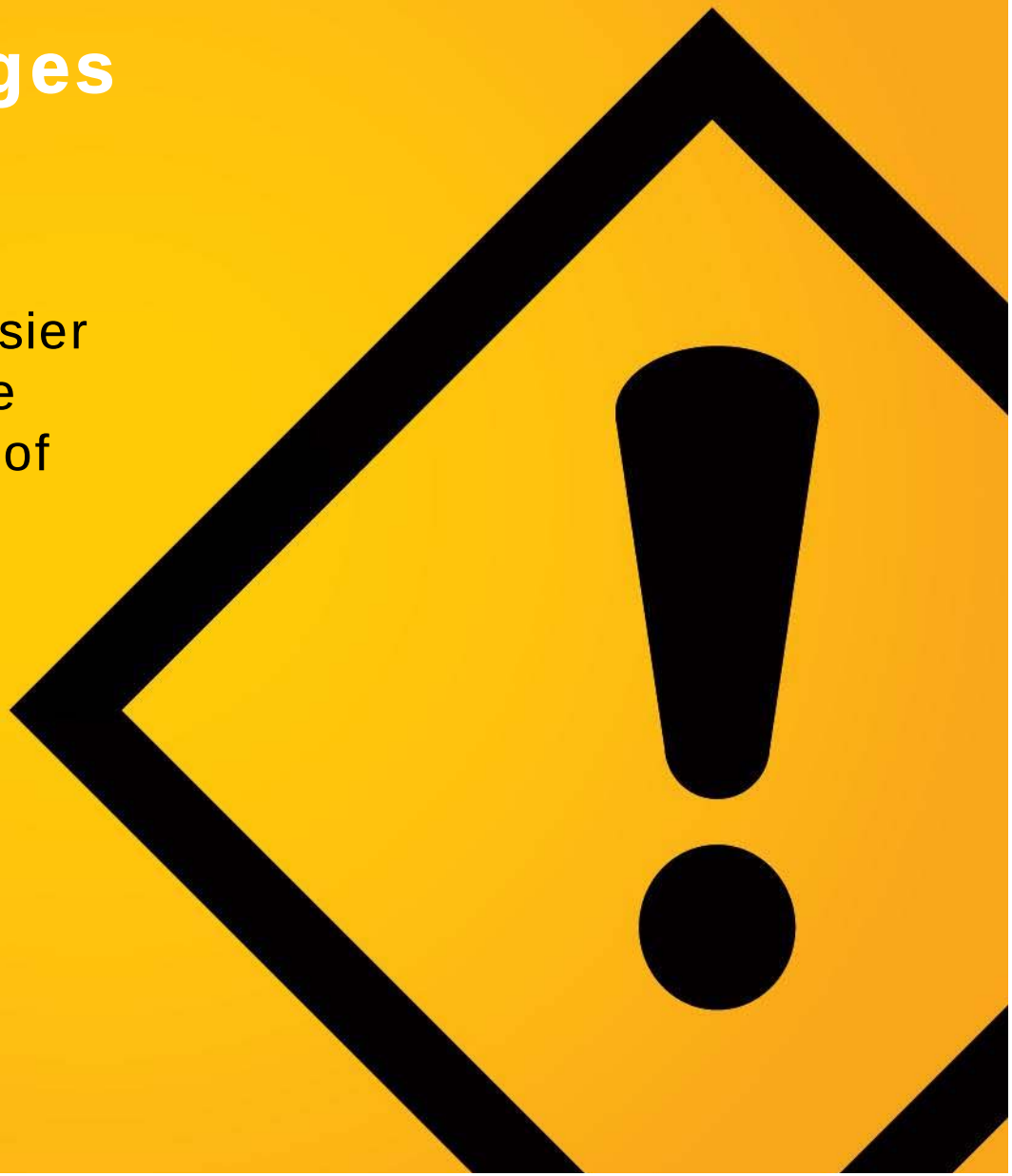
Keep up-to-date: Extended PACT

- 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	-	-	-	

Take-home messages

- ✓ Registration is not over
- ✓ 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



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