

EU REACH Registration: 10 years of collecting information on existing chemicals

REACH Conference 2018

3rd September 2018, Bratislava

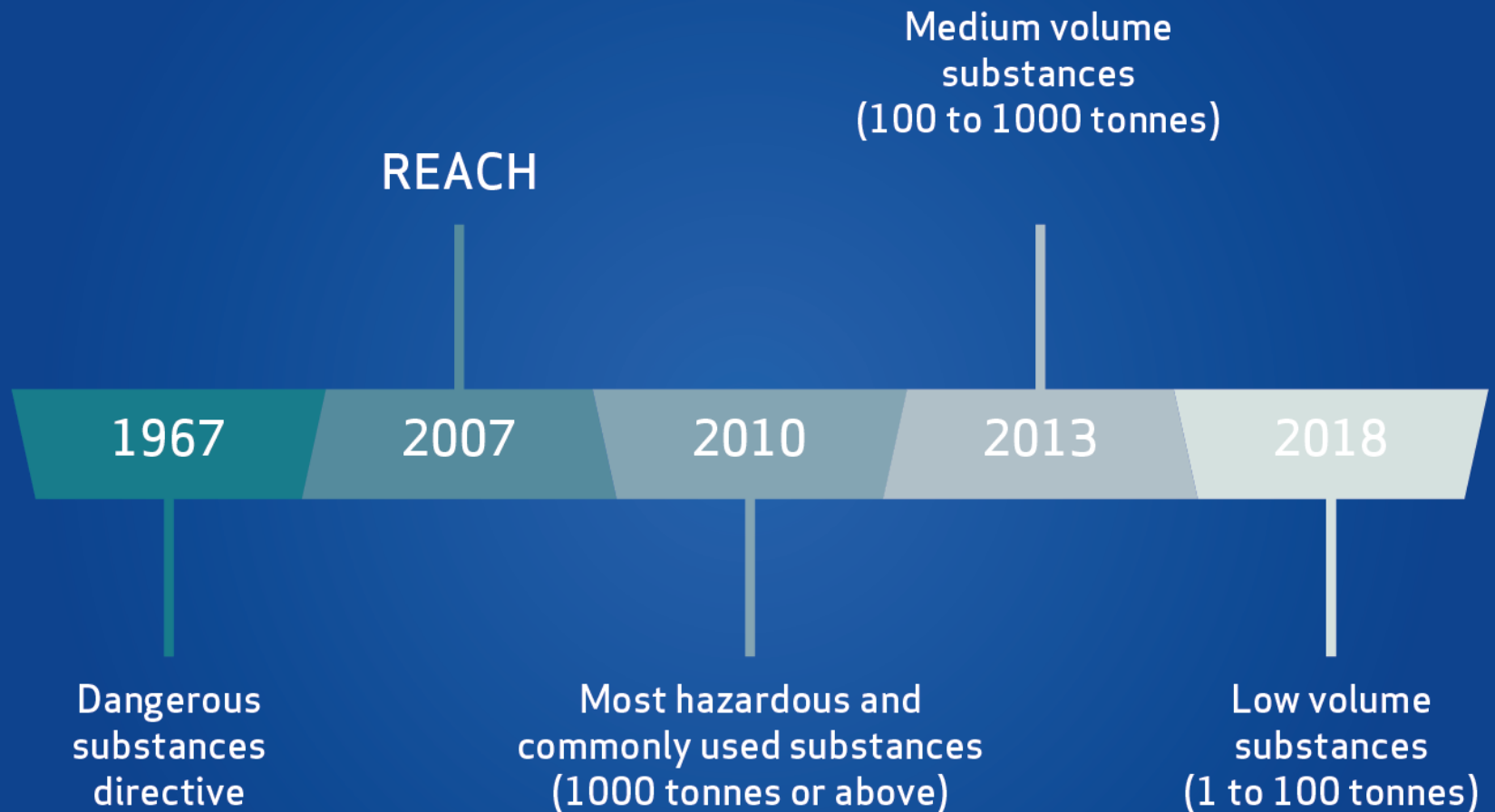
María Ottati



2018 deadline: what happened?



The journey



Main outcome

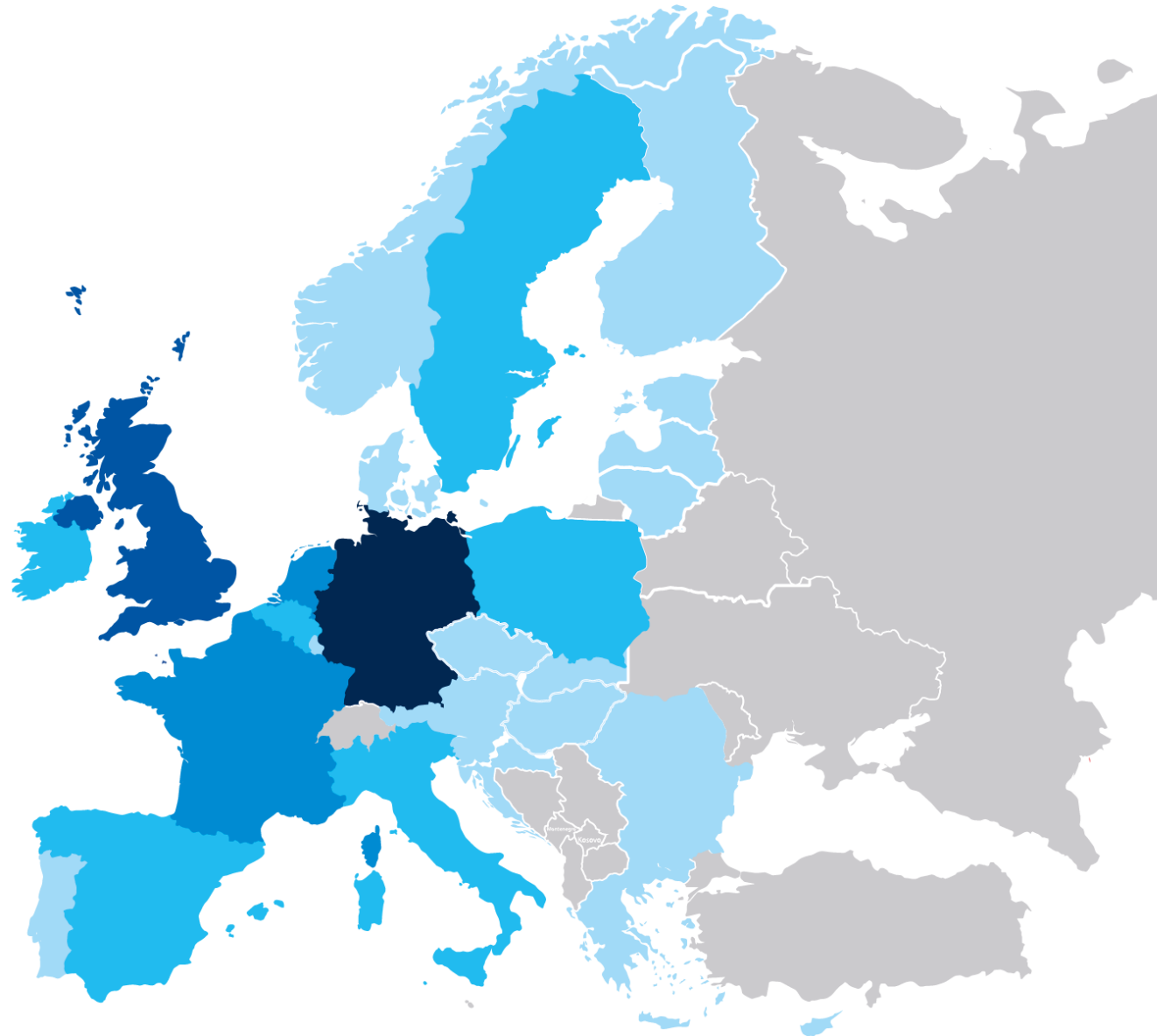
	All	DL 2018
Registrations	88 319	33 363
Substances	21 551	11 114

- Some registrations still being processed by ECHA
- 18% of registrations from SMEs

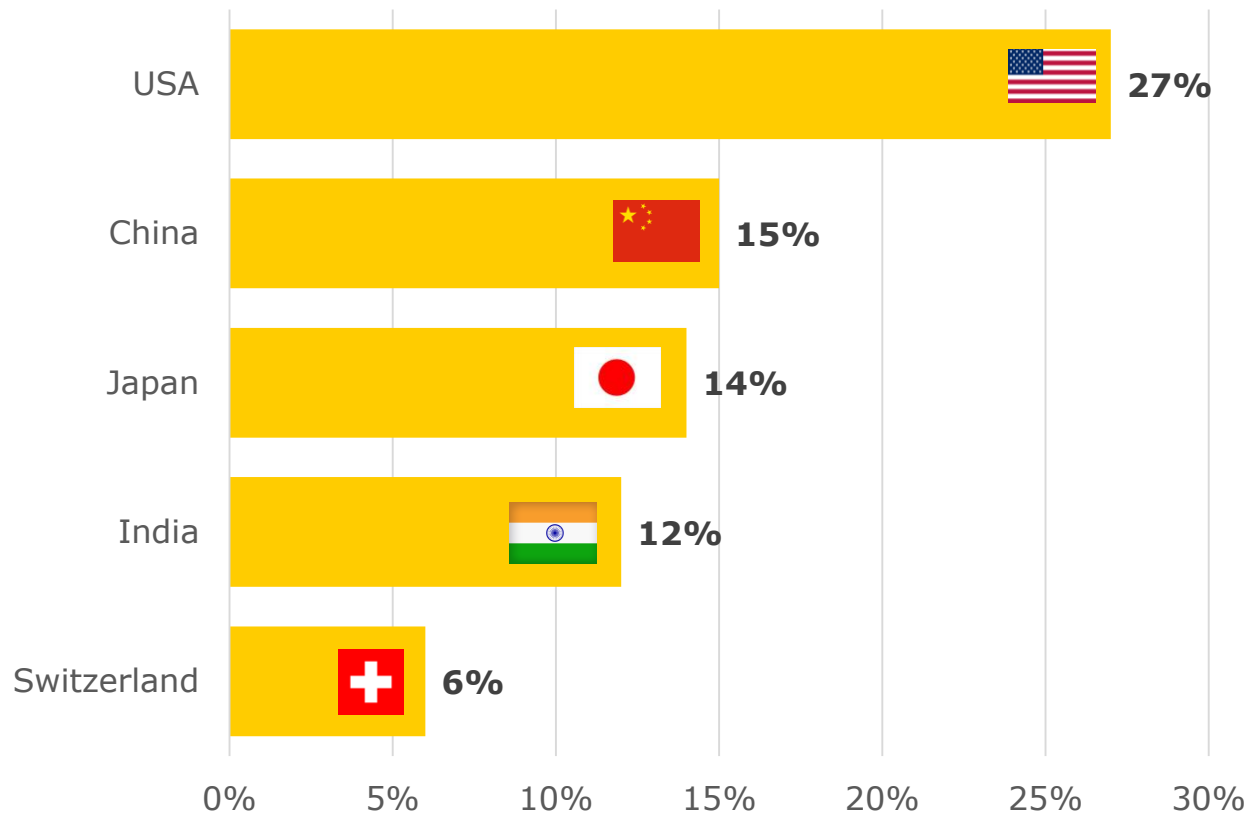
EU/EEA countries (all)

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 (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
- 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
- Registration is only the start

Life after the deadline



Finish processing dossiers (1/2)

Verification if dossiers are complete:

- If dossier is found incomplete, a deadline is given
- Contact ECHA if unclear
- Payment of fee needed for registration number

Follow-up of specific situations:

- Late disputes
- Changes in Lead Registrants
- Companies who benefitted from Directors Contact Group's solutions

Finish processing dossiers (2/2)

Directors Contact group:

- Solutions for exceptional situations
- Broadly used for this 2018 deadline
- 671 applications
- Large majority for solution '10.3' on late availability of laboratory results
- Companies submit before the deadline but have more time to complete their dossiers

Late comers

- No manufacturing or importing in EU over 1 tonne without registration
- Bring yourself to compliance asap
- Submit an inquiry
- Document all efforts for enforcement activities
- Contact ECHA if you need help

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
- Upload evidence in REACH-IT





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
 - Registration decisions may be revoked if incompleteness not addressed

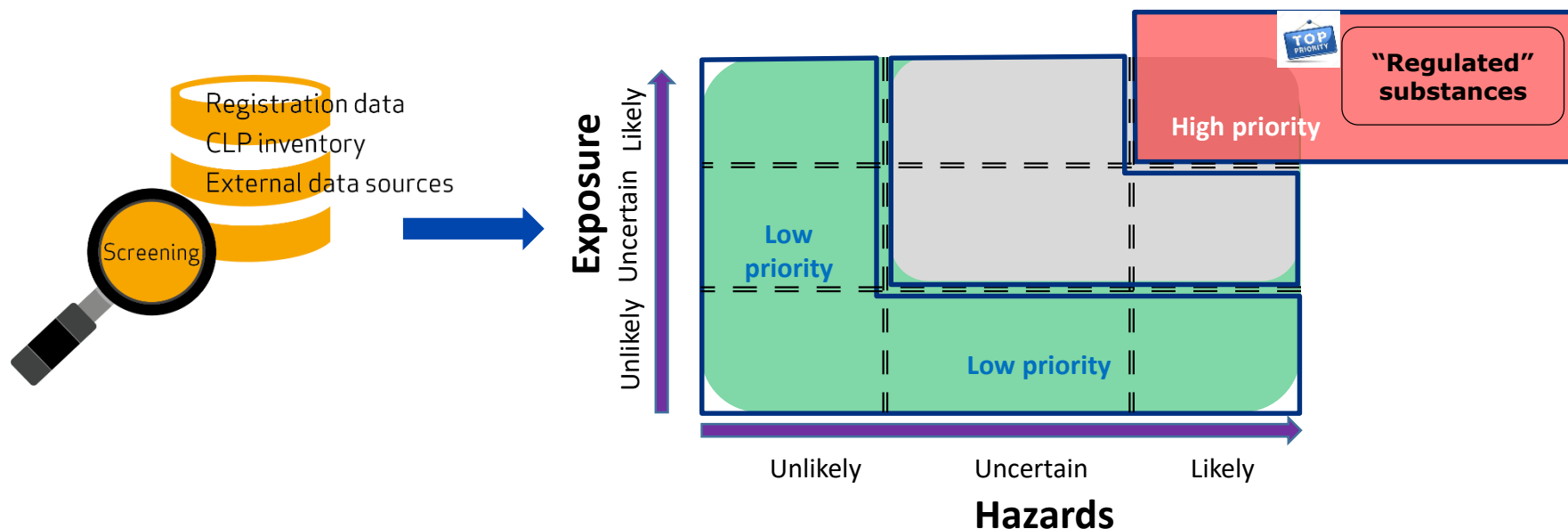
Enforcement by national authorities

- 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



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

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
 - Stay informed through our Weekly news
- Recommendations in annual Evaluation reports:
echa.europa.eu/evaluation

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

- 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



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

Keep your dossier up-to-date

- The reality:
 - 67% of all dossiers have never been 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
- Ensure that you and the authorities assess safe use based on up-to-date and reliable data
- Set-up a process within your joint submission to keep dossier up-to-date!

Take-home messages

- ✓ 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: follow the developments



Questions, comments?

Maria.Ottati@echa.europa.eu

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