# REACH 2018 AND BEYOND

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# AGENDA

- Registrations
- Evaluations
- Authorisations
- Hot Topics
- Practical Advice provided thoughout
- Q&A

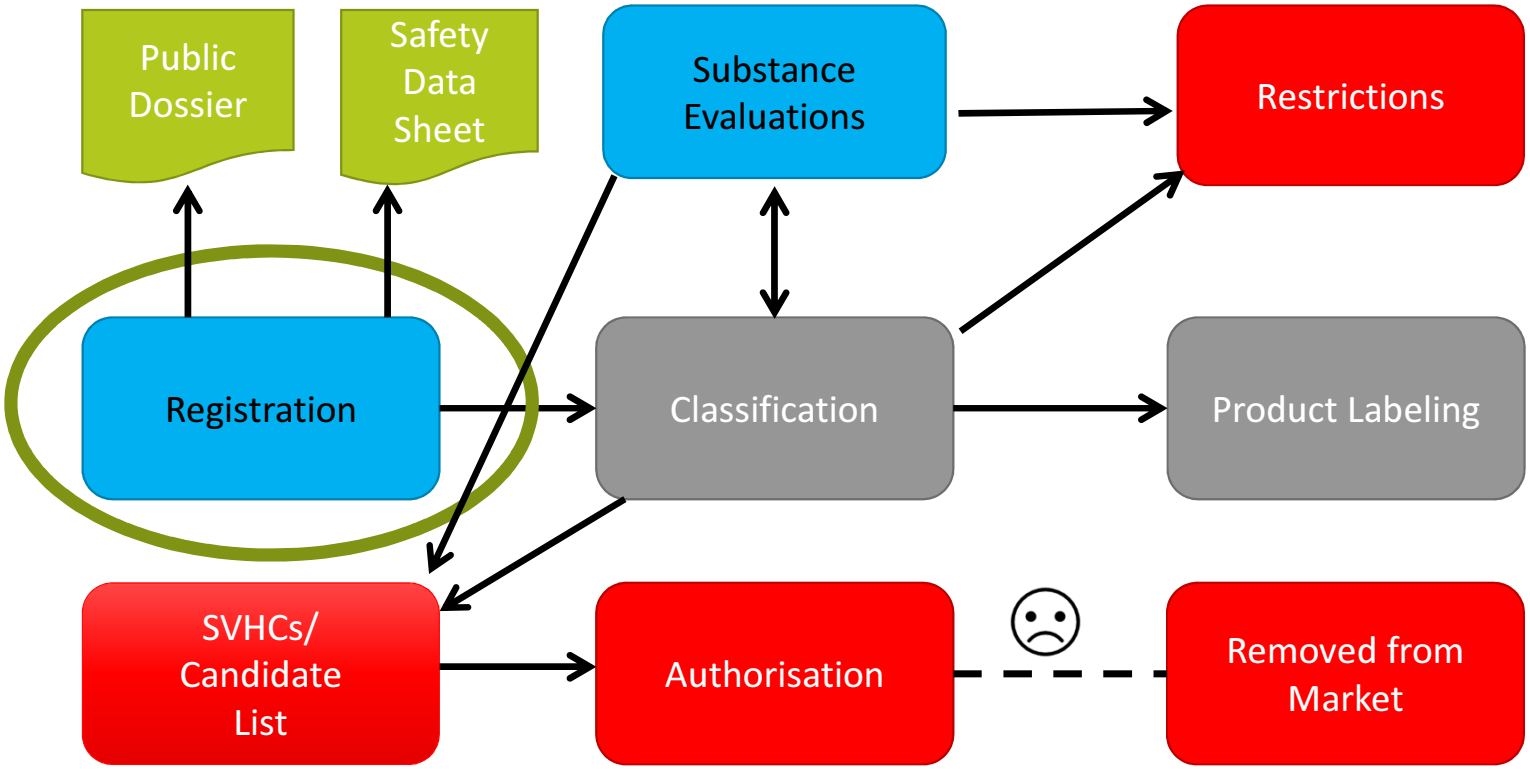
# REACH - OVERVIEW

- Objective: "*to ensure the protection of Human Health & Environment*"

- REACH entered into force in 2007 across all EU Member States

| | |
|---|---|
| Registration | *all substances manufactured or imported above 1 tonne/yr.* |
| Evaluation | *targeted assessment of registered substances* |
| Authorisation | *process to phase out selected Substances of Very High Concern* |
| Restriction | *targeted limitation on uses of certain substances* |
| CHemicals | *all substances, manufactured, imported as such, in mixture or article* |

# REGISTRATION: THE "CORNERSTONE" OF REACH

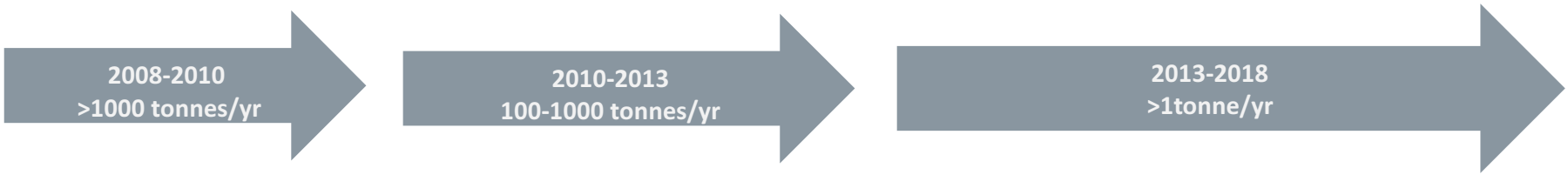



Registration & Classification: Main starting point for pro-active product stewardship; statement from ECHA

# REGISTRATION UNDER REACH

**Manufacturers and Importers**

- All substances manufactured or imported above 1 tonne/yr must be registered
- Staggered approach for substances already on the EU, phase-in substances (if pre-registered)
- Only 8 Months to the last *phase in* deadline of May 31st, 2018
- Pre-registration closed May 31st, 2017
- ECHA estimated 30K substances to be registered by 2018; only ~ 50% completed to date
- New substances (Non-Phase-in or if not Pre-Registered) must be registered before exceeding > 1 tonne/yr



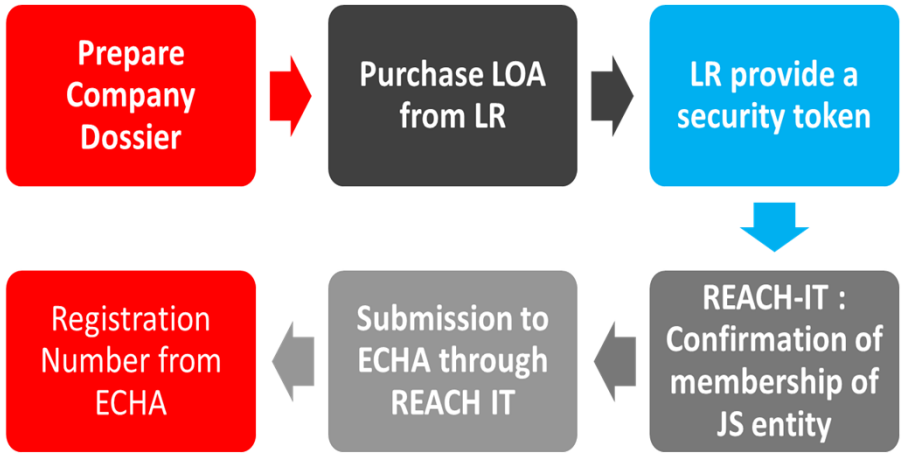
# REGISTRATION: ONE SUBSTANCE- ONE REGISTRATION (OSOR)

Dossier types

**Lead (LR) or Individual Registration**: Prepare the full data requirements.

**Joint Registration (JR):** Lead registration has been submitted, other companies share the data

- Individual Substance Identity (analytical data)
- Confirm that your uses are covered
- Need to sign an Agreement & Letter of Access (LOA) - review closely
- LOA costs can vary widely



# REGISTRATIONS: PRACTICAL ADVICE

*If you have registrations to do – get started as NOW*

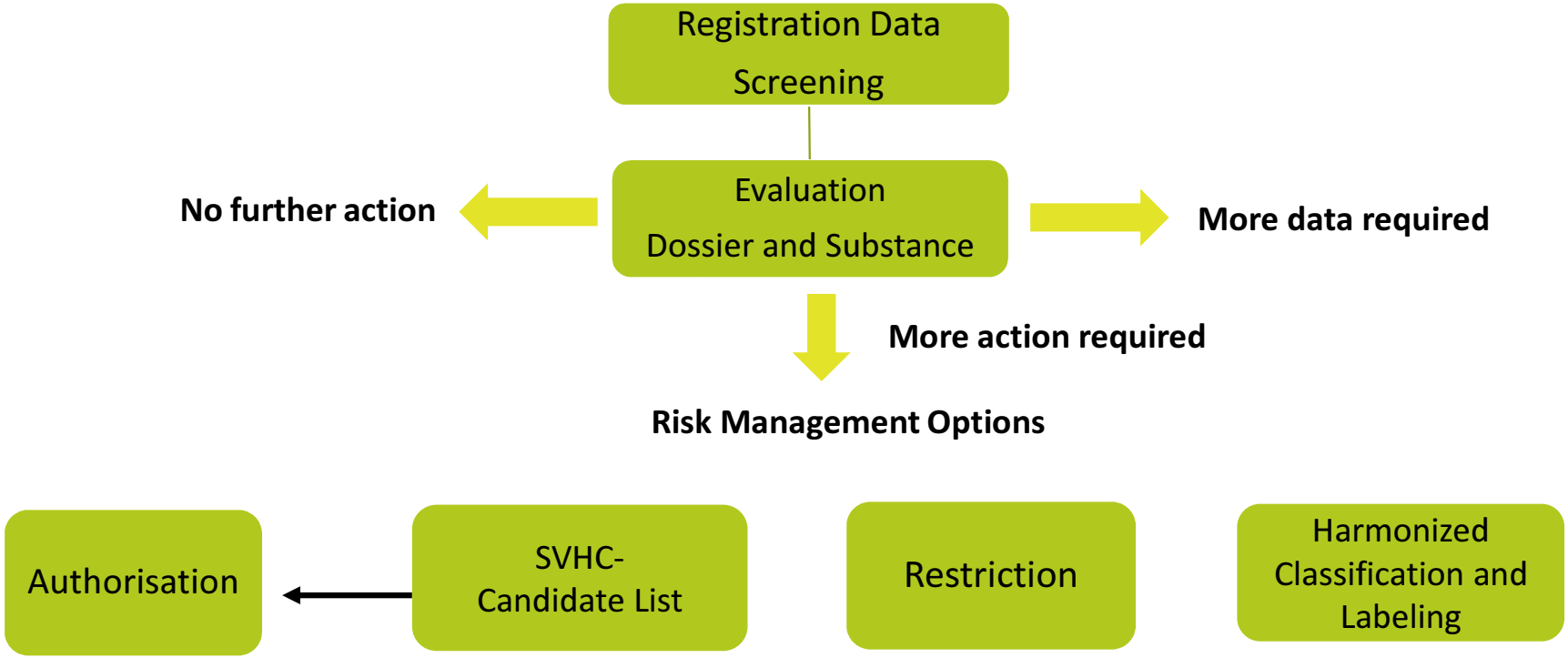
- ***Confirm your substance,*** tonnage band and supply chain
- ***Check registration status*** - is it registered?
- ***Communicate*** with Substance Information Exchange Forum (SIEF) and/or Lead Registrant
- ***Review*** closely the LOA information
- ***Determine*** what analytical information you have in house
- ***The later you submit*** the longer the review will be
- Be prepared to ***step in as lead registrant*** - is there enough time?

# REGISTRATION SUBMITTED: WHAT HAPPENS NEXT?

- ECHA will issue a Registration number
  - Include the Registration number on the SDS
- However, a registration number does not mean compliance
  - It gives the right to market the substance in the EU
  - You have the obligation to keep your dossiers updated; includes changes in C+L
- After registration,  Authorities may step in with Evaluations
- Screened to identify substances of concern  & need for further risk management

# ADDRESSING CHEMICALS OF CONCERN

SVHC Roadmap: Implementation Plan for 2020



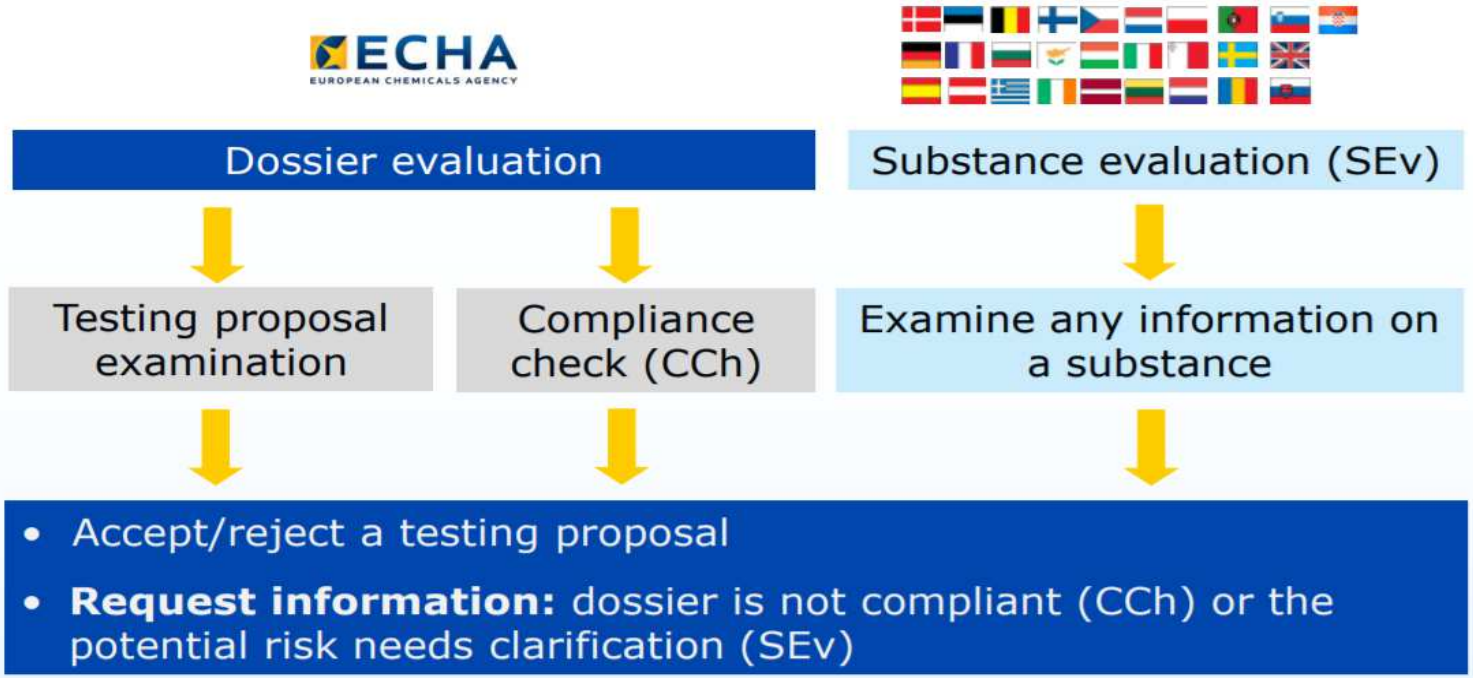
# WHAT ARE THE MOST HAZARDOUS SUBSTANCES? "CHEMICALS OF CONCERN"

Article 57 of REACH: Substances of Very High Concern (SVHCs)

- A Carcinogen, Mutagen or Reprotoxin (Category I & II)
- A persistent bioaccumulative toxin (PBT),
- Very persistent very bioaccumulative toxin (vPvB),
- Substances of equivalent level of concern (ELoC), e.g. endocrine disruptors, respiratory sensitizers, case by case

The regulators left themselves some flexibility by providing for substances of "equivalent concern" under Clause 57(f).

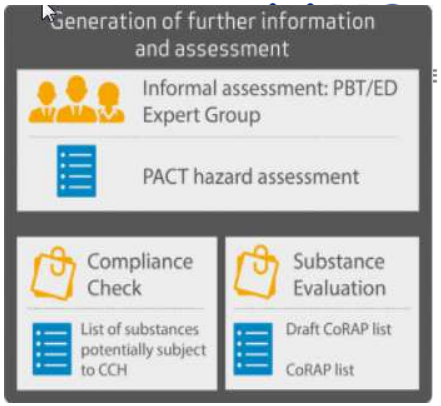
# Evaluation processes



# EVALUATIONS: COMPLIANCE CHECKS OF DOSSIERS

- ECHA is taking action against Registrations – rescinded registrations
- Manual verification- areas of continued attention
  - Unclear substance identity
  - Information requirements waived by registrants
  - Dossiers include testing proposals
  - Chemical safety report missing
- One Substance One Registration (**OSOR)** principle reinforced
- Read ECHA's annual evaluation reports

# SCREENING OF REGISTRATION DATA




- Substance Evaluations (SEv)
  - Community Rolling Action Plan (CoRAP) Listing; yearly
  - Risk-based approach: hazard profile, exposure & use/tonnage
  - 3 year cycle – first year Member States will decide if need for further information
    - 115 substances for evaluation by 22 Member States

- Persistent, Bioaccumulative & Toxic (PBT)/Endocrine Disruptor (ED) Assessment Group
  - Public Activities Coordination Tool (PACT): Substances under Informal assessment

# PRACTICAL ADVICE
## SHORTCOMINGS: WHAT YOU SHOULD DO?

- Be **proactive** in updating your dossiers
- **Monitor communication** from ECHA
- **Use** guidance and quality checks
- **Explain and justify** the approach for filling data gaps
- **Consistency** across and between endpoints and read-across
- **Respond to ECHA** with one voice during decision making
- **Involvement** of Downstream users
- **Provide Data in a timely manner** when requested
- **Bad data** - is it a business risk?


# AUTHORISATION

- Identification & **replacement of the most hazardous substances** when safer alternatives exist
- Applies to SVHCs -> **prioritised from the Candidate List** based on volumes & known hazards
- Use(s) of the substance **prohibited unless the use has been approved**

  **Latest Application Date**: Last date an application can be submitted to ECHA

  **Sunset Date**: Last date substance can be used without an Authorisation

- Authorisations are **Specific to** the company for a specific use/uses of a substance
- Authorisations are **limited in time**
- Authorisation application **require significant resources and time**
- **Authorisation number** should be included on SDS

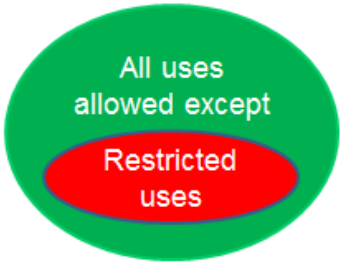
# AUTHORISATION VS. RESTRICTION

## Authorisation: no supply/use without permission

- –REACH Annex XIV
- –Applies to all uses unless exempt
- –Must seek and gain positive permission for use
- –No general tonnage threshold


## Restriction: specified supply/use not allowed

- –REACH Annex XVII
- –Applies to specific uses
- –No general tonnage thresholds
- –Not always an outright ban



# POST 2018: WHAT SHOULD YOU BE DOING?

- Monitor volumes for existing registrations and new substances
  - –Forecasting essential – now must register before crossing the > 1 tonne/yr threshold
- Monitoring your registered substances for ECHA evaluation activities
- Continue with Lead SIEF obligations
- List Tracking; Registry of Intentions, PACT, CoRAP, Candidate list (SVHC), Authorisation
  - –Implications of Risk Management options
- Harmonised C+L; impact on SDS
- Changes in Classification and Labelling; registration update
- Regulatory tracking; changes to REACH

# HOT TOPICS NOW AND BEYOND…

- One Substance- One Registration
- Intermediates
- Endocrine disruptors (EDs)
- Nanomaterials
- Polymers
- Use of data in other jurisdictions
- Circular Economy

# BREXIT: WHAT'S LIKELY TO HAPPEN?

Separation per Article 50 of the Nice Treaty will occur April 2019

Major Principles being actively negotiated currently; sub-strands not yet commenced – REACH

- BEST CASE: UK stays in the European Economic Area (EEA) like Norway; continues to remain party to REACH with little change
- MID-POINT: UK stays in the Free Trade Area - allowing for some REACH consolidation
- WORST CASE: Full separation requiring a UK version of REACH and duplication of Registrations

July 2017 statement from UK Minister:

# KEY TIPS IN MANAGING A SUBSTANCE THROUGH REACH

- *Start NOW:* 2018 is closing in
- *Keep your Dossier updated:* Be proactive.
- *Data Quality is the focus:* Registrations, Evaluations and Authorisations are not standalone but linked. A weak hazard assessment will impact all.
- *Track the developments in REACH* closely
- *Monitor* your substances; *List Tracking*
- *Manage your Substances:* Registration may seem to be the focus of attention within REACH, the "heavy lifting" comes with managing Evaluation, Authorisation or Restrictions
- ECHA philosophy is *Demonstrating safe use is a dynamic task*

# THANK YOU FOR YOUR ATTENTION

**After careful *evaluation,* I *authorize* you to stand up and stretch but *restrict* you from leaving the room.**

# Questions ?

**Feel free to contact me if you have further question**
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# REFERENCES AND LINKS

2016 Evaluation Report

http://echa.europa.eu/web/guest/regulations/reach/evaluation

REACH regulation, consolidated version (incorporates all amendments and corrigenda to REACH until the date marked in the first pages of the regulation)

https://echa.europa.eu/regulations/reach/legislation

Information on Chemicals

https://echa.europa.eu/information-on-chemicals

Tips for Registrants and downstream users

https://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf

ChemSec's 'Substitute it now' list of problem chemicals, SIN List, see http://www.chemsec.org/what-we-do/sin-list

# ACRONYMS

CL: Candidate List

CLH: Harmonized Classification + Labeling

CoRAP: Community Rolling Action Plan

CCh: Compliance Check

DU: Downstream User

EEA: European Economic Area

ECHA: European Chemicals Agency

EC or Commission: European Commission

LOA: Letter of Access

MSCA: Member State Competent Authority

MS: EU Member State

OSOR: One Substance- One Registration

PACT: Public Activities Coordination Tool

RMM: Risk management measures

ROI: Registry of Intentions

SIEF: Substance Information Exchange Forum

SEv: Substance Evaluation Process

SONC: Statement of non-compliance

SVHC: Substance of Very High Concern