

German Environment Agency

Umwelt 
Bundesamt

REACH Compliance workshop

The importance of REACH registration data for authorities

Lars Tietjen

Content

REACH

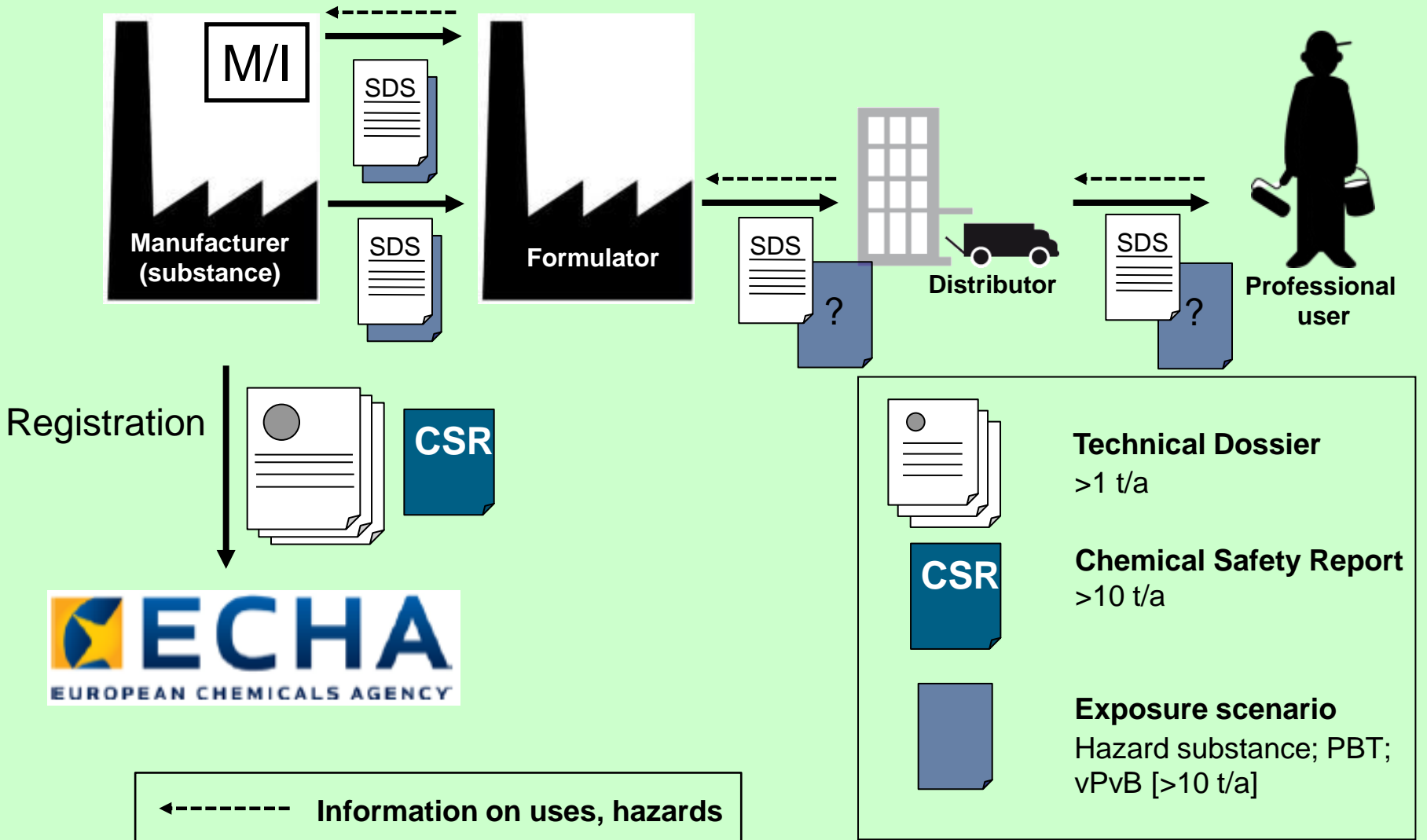
Substances

Selection of candidates for further work

Registration data

Outlook

Communication in the supply chain



REACH regulation

Recital 14

This Regulation will generate **information on substances and their uses**. Available information, including that generated by this Regulation, should be used by the **relevant actors in the application and implementation of appropriate Community legislation**, for example that covering products, and Community voluntary instruments, such as the eco-labelling scheme. The Commission should consider in the review and development of relevant Community legislation and voluntary instruments **how information generated by this Regulation should be used**, and examine possibilities for establishing a European quality mark.

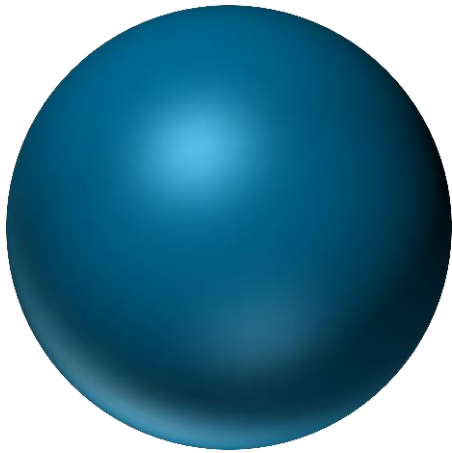
Recital 21

Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, **it may also be used to initiate the authorisation or restrictions procedures** under this Regulation or **risk management procedures under other Community legislation**. Therefore it should be ensured that this information is available to the competent authorities and may be used by them for the purpose of such procedures.

Authorities

- Support actors (ECHA, MSCAs)
- Receive and manage registrations (ECHA)
- Dossier Evaluation (ECHA, MSCAs)
- Substance Evaluation (MSCAs, ECHA)
- Propose further action on chemicals (ECHA, MSCAs, other authorities)
- Inform the public (COM, ECHA, MSCAs)

Substances



Ca. 145.000 substances in C+L inventory



Ca. 21.500 registered substances [+? exempted from registration (polymers etc.)]

- **352 Substances on CoRAP; 452 in PACT**

SVHC Roadmap



COUNCIL OF
THE EUROPEAN UNION

Brussels, 6 February 2013

5867/13

COMPET 62
IND 25
RECH 27
ECOFIN 69
ECO 15
SOC 62
ENV 73
SAN 32
CONSOM 13
MI 63
CHIMIE 11
ENT 28

COVER NOTE

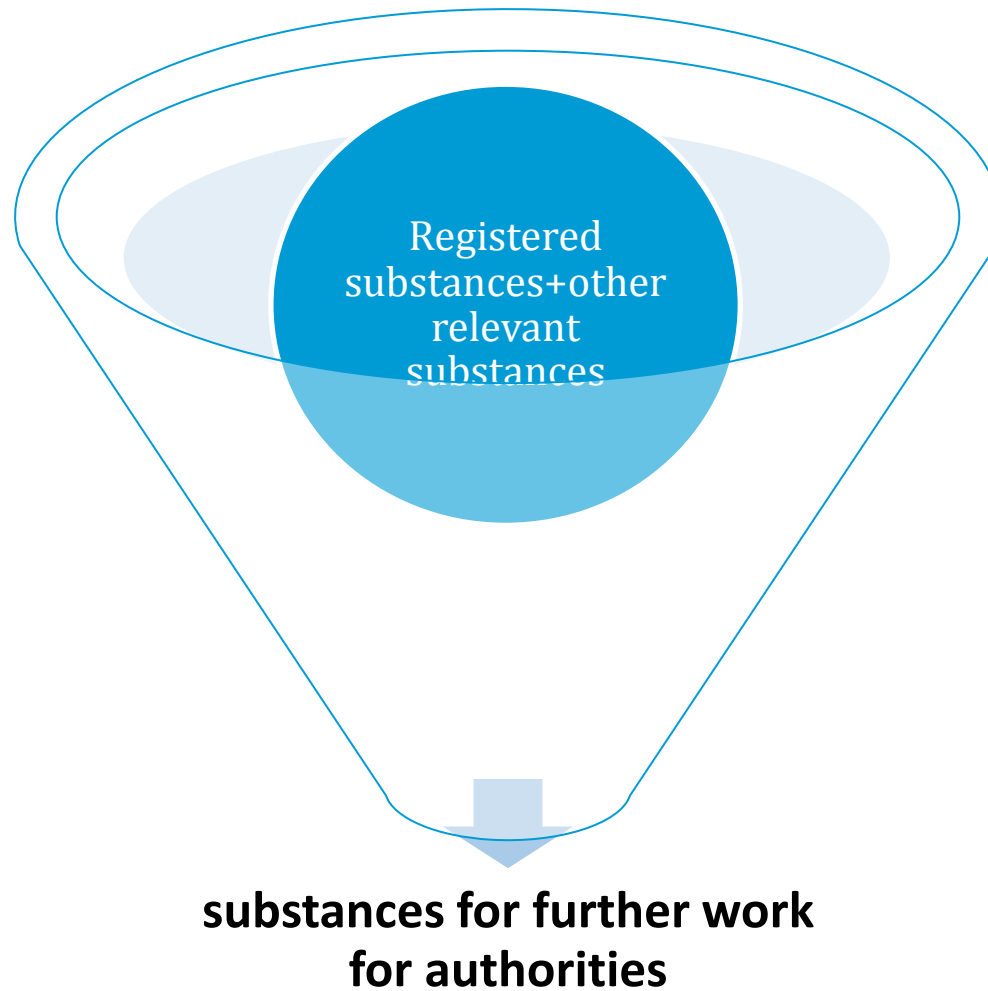
from:	European Commission
date of receipt:	5 February 2013
to:	COREPER/Council

Subject:	Roadmap on Substances of Very High Concern
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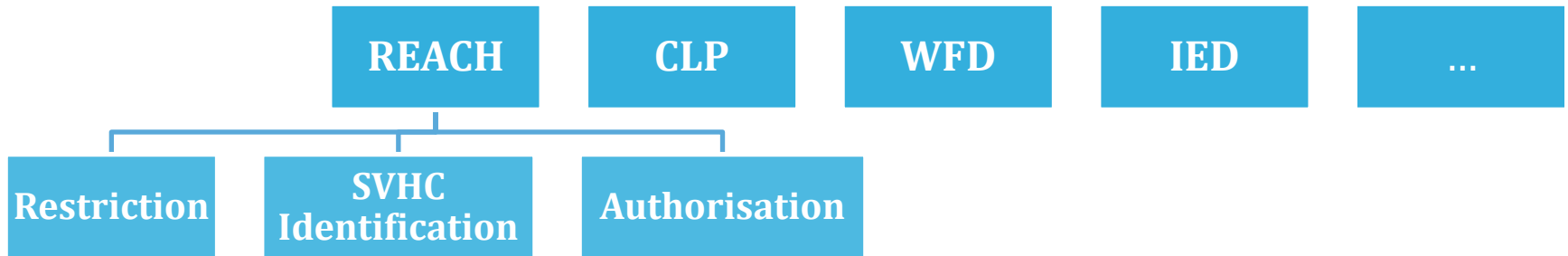
“The starting point remains the Commissioners' commitment to identify and include in the candidate list all SVHCs, relevant for the European Union, by the end of 2020.”

Delegations will find attached Commission document.

Selection of substances for further work

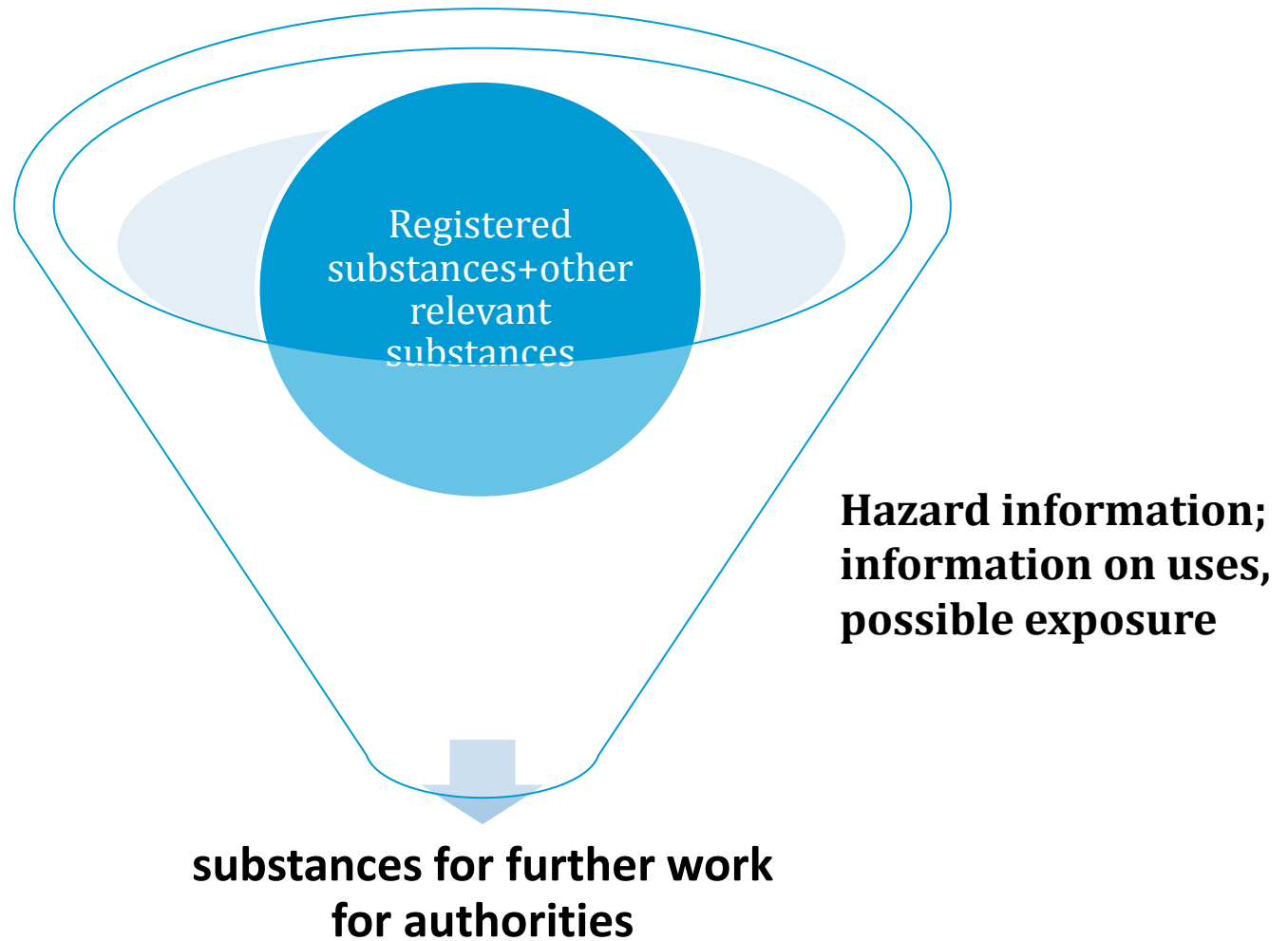


Possible regulatory action



WFD=Water Framework Directive
IED=Industrial Emissions Directive

Selection of substances for further work



Screening (Information used)

Monitoring

Data from Registration

**Research
Projects
(external)**

Published Data

**Research
Projects
(internal)**

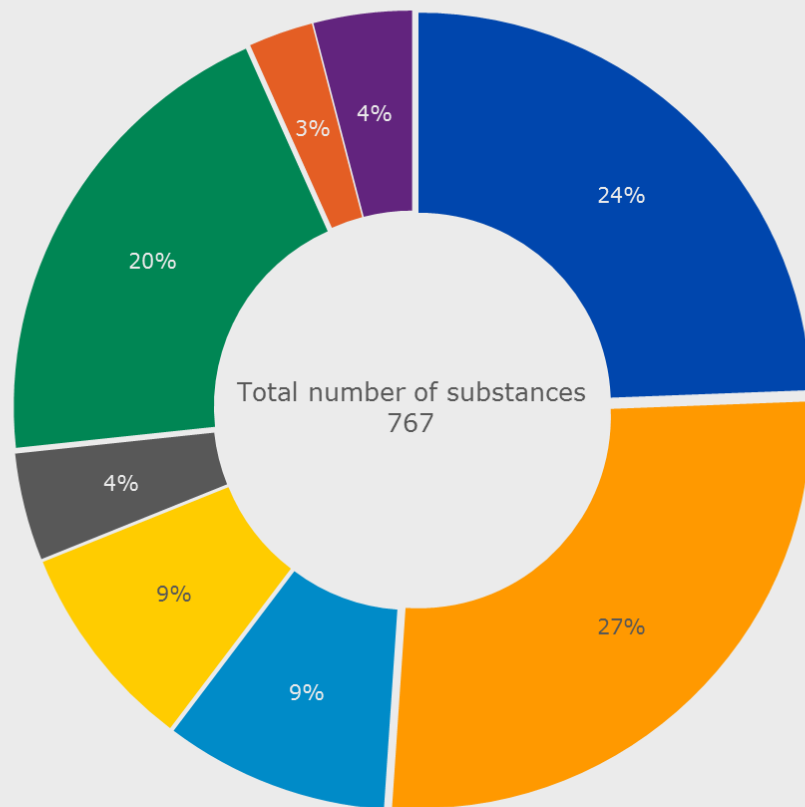
QSAR; SAR

**Groups of
Substances**

**Internal
Databases
(UBA)**

Manual Screening

Overview of manual screening rounds (2014-2017)



- Compliance Check
- Community Rolling Action Plan
- Other
- Further assessment
- Harmonised Classification and Labelling
- Regulatory Management Option Assessment
- Currently no action
- Under development

Source ECHA 2018

REACH registration data

Very much data on substances is available publicly and additional data for authorities

Last updated 23 August 2018. Database contains 21250 unique substances and contains information from 88862 dossiers.

Substance identity

Substance name: CAS number:

EC / List number: Other Numerical Identifiers:

Administrative data

Substance data

Uses and exposure

[View all Registered Substances](#)

Page 1 of 474 50 Items per Page Showing 1 - 50 of 23,655 results. ← First Previous Next Last →

Name	EC / List no.	CAS no.	Registration type	Submission type	Total tonnage band	
((1-ethoxy-1-oxo-4-phenylbutanyl)-substituted)-heterobicyclic-3-carboxylic acid hydrochloride, 2-Propanone Solvate	919-408-3	-	Intermediate		Intermediate Use Only	
((2-ethyl-1-oxohexyl)oxy)-(1-phenyl-1,3-decanedionyl)diocetyl stannane	422-920-5	-	NONS		Tonnage Data Confidential	

REACH registration data - observations

Hazard Information

- not enough data to decide on SVHC properties
- P/vP or B/vB accepted from registrant – additional data needed for SVHC identification?
- documentation of (Q)SAR, read-across
- limited long-term ecotoxicity data, bioaccumulation simulation studies on degradation

Exposure Information

- limited information on downstream uses
- exposure assessment sometimes difficult to assess
- real data on volumes used missing (only generic information)

Outlook (1/2)

REACH Review/COM Art. 117 report:

Action 1: Encourage updating of registration dossiers

The Commission in collaboration with ECHA, Member States and industry will identify why registrants are not **updating their dossiers** and make proposals for improvements by first quarter 2019, as appropriate.

Action 2: Improve evaluation procedures

ECHA is requested to significantly increase the efficiency of the evaluation procedures by 2019 by:

- (1) **identifying the main reasons for non-compliance of registration dossier and developing remedies;**
- (2) where appropriate, applying the various evaluation procedures in parallel;
- (3) systematically implementing a grouping approach, where this is possible;
- (4) improving work-sharing across evaluation activities with Member States; and
- (5) improving decision-making procedures.

Action 16: Review of registration requirements for low tonnage substances and polymers

The Commission will further investigate information necessary to assess the affordability of additional information requirements for **low tonnage substances or to identify relevant polymers that could be subject to registration.**

Outlook (2/2)

- **Percentage of Dossier evaluations by ECHA**

Article 41 Compliance check of registrations

[...]

5. To ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking. The Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria: [...]
7. The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article 133(4).

- **Registrants should improve and update the dossiers when needed**
- **Authorities should support actors and help to improve guidance, tools etc.**

Thank you for your attention!

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<https://www.umweltbundesamt.de/en/topics/chemicals>