



Second REACH review – and next steps

*International conference on
chemicals regulation and policy*

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Entrepreneurship and SMEs*



Objectives of REACH

- *Protection of health and environment*
- *Free circulation of chemicals*
- *Competitiveness and innovation*
- *Non-animal test methods*



Legal obligation



Numerous Information source



Timing



Milestones	
Roadmap	18 May 2016
Public consultation and SME panel	November 2016 to January 2017
Studies completed	2015 to Q4 2017
Adoption and publication of second REACH review	5 March 2018





Commission communication

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE

Commission General Report on the operation of REACH and review of certain elements

Conclusions and Actions

{SWD(2018) 58 final}

Staff Working Document



Conclusions and actions

- Improved environment and human health*** ✓
- Promoted alternatives to animal testing*** ✓
- Ensured free movement of chemicals*** ✓
- Contributes to SDGs*** ✓
- Actions to further improve REACH*** ✓
- No need to change its enacting terms*** ✓



After 10 years

A comprehensive data set

*Progress in the phasing out
substances of very high concern.*

*Improvement of the risk
management measures at the workplace.*

*Improvement of the communication
and transparency in the supply chain.*

European Chemicals Agency



Costs/benefit relationship?

Main direct costs estimated so far
(only for registration and communication
in the supply chain for the first
and second registration
deadlines)

EUR 2.3-2.6 billion



The estimated scale of
potential **benefits** for
human health and the
environment: around **EUR
100 billion** over 25-30
years

ACTION

16 concrete actions

**Open debate with
all interested
parties**



Action 1

Encourage updating registration dossier

**Improve
compliance
and rectify
important
data gaps
/ quality
issues**

**Updates by
companies
considered
insufficient**

Actors involved : COM, ECHA, Member States and industry



ACTION 2

Improve evaluation procedures

**Admini-
strative
process
too long**

**Too low
number of
ECHA
decisions**

**Compliance
check
target of 5
%
considered
ineffective**

Actors involved : ECHA



ACTION 3

Improve workability and quality of extended safety data sheets

**Too lengthy
Information
not targeted
to users**

**Expand the
use of
harmonised
formats
and IT
tools**

**Deficiencies
on
information
in the
exposure
scenarios**

**Actors involved : Commission and ECHA with industry.
ECHA to develop a methodology of SDS for mixtures.**





ACTION 4

Tracking substances of concern in the supply chain

Difficulties to track SVHCs

Facilitate recycling

Transfer of information on chemicals

Actors involved : Commission (Circular Economy Action Plan and the chemical product waste interface)



Proposed actions

ACTION 5: Promote substitution of SVHCs.

Why?

- 1) Facilitate substitution of SVHCs by companies early enough to avoid applying for authorisation
- 2) Enhance use of REACH data set for the development and uptake of safer alternatives to SVHCs
- 3) Support informed and meaningful substitution, avoiding "regrettable substitution"

Actors involved : Commission, ECHA and Member States.





Proposed actions

ACTIONS 6, 7: Making authorisation more workable and predictable. *Why?*

- 1) Address practical challenges and make authorisation more cost-effective
- 2) Clarify requirements for applications for authorisation to simplify the procedure in specific cases
- 3) Use relevant socio-economic information to establish the most appropriate regulatory measure

Actors involved: Commission, ECHA and Member States. Regulatory actions for simplification of authorisation in 2018. Revision of fees in force since July 2018.



Proposed actions

ACTIONS 8,9: Improve restriction procedure and enhance Member State involvement. *Why?*

- 1) Need to further increase the efficiency of restriction process to meet original expectations
- 2) Enhance cooperation among authorities to tackle difficulties for Member States to prepare restriction dossiers
- 3) Enhance identification of relevant candidates for restriction

Actors involved: Commission, ECHA and Member States. Need to continue the activity of the Task force on restrictions





Proposed actions

ACTIONS 10,11: Precautionary principle and interplay authorisation-restriction. *Why?*

- 1) Better evaluation of the scientific uncertainties
- 2) Comparable risk management and substitution between authorisation and restriction
- 3) Level playing field for EU and non-EU companies in relation to substances subject to authorisation (i.e. listed in Annex XIV)

Actors involved : Commission, ECHA and its Committees and Member States.



Proposed actions

ACTION 12: Interface REACH and OSH legislation. *Why?*

- 1) Need to clarify some overlaps
- 2) Better use of REACH tools under the OSH legislation
- 3) Improve the coordination between REACH and OSH national authorities
- 4) Alignment of the methodologies
- 5) Enhance the role of RAC to provide scientific opinions under OSH legislation

Actors involved : Commission, ECHA and Member States.





Proposed actions

ACTION 13: Enhance enforcement. *Why?*

- 1) Insufficient enforcement activities by Member States and unclear role of the customs authorities prevent a level playing field between EU and non EU companies
- 2) Differences in reporting and monitoring of enforcement by Member States
- 3) Need to improve perception how REACH is enforced across the EU

Actors involved : Commission, ECHA Forum and Member States. Presentation of options by first quarter 2019



Proposed actions

ACTION 14: Support SMEs compliance. *Why?*

- 1) Specific vulnerability compared to large companies in view of limited human and financial resources/capacity to absorb costs
- 2) Need to monitor possible impact for the registration deadline 2018
- 3) Support measures provided so far considered useful but need for practical and user-friendly information, available in national languages

Actors involved: Commission, ECHA and Member States.





Proposed actions

ACTION 15: Fees and future of ECHA. *Why?*

- 1) Need to maintain the mission of ECHA in the implementation of REACH, considering the budgetary constraints and situation beyond 2020
- 2) Consider potential of ECHA capabilities as a reference centre for sustainable management of chemicals
- 3) Need for ECHA to consider improvement in the allocation of its staff and identify efficiency gains

Actors involved : Commission and ECHA.



Proposed actions

ACTION 16: review of low tonnage and polymers. *Why?*

- 1) Obligation under Article 138 of REACH
- 2) Several studies finished providing relevant information that needs to be complemented
- 3) Need to further assess the affordability for companies (low tonnage) and identify relevant polymers

Actors involved: Commission.





Second REACH review: follow-up (1)

Environment and Competitiveness Council (5 March and 12 March)

WP Environment - 19 March and 18 May

WP Competitiveness and Growth - 17 September

European Parliament – ENVI committee (12 April)

Public conference with Member States and stakeholders on 11 June

Discussion with REACH Competent Authorities and Stakeholders (CARACAL) to implement the 16 actions



Second REACH review: follow-up (2)

➤ CARACAL June discussion actions

- 1 (update registration), 2 (evaluation)
- 5 (substitution SVHCs), 6 (simplification of authorisation),
- 8 / 9 (restriction), 10 (precautionary principle),
- 13 (enforcement)

➤ CARACAL November discussion planned actions

- 3 (extended Safety Data Sheets), 4 (tracking substances of concern),
- 7 (socio-economic considerations in RMOA),
- 12 (interface REACH/OSH)





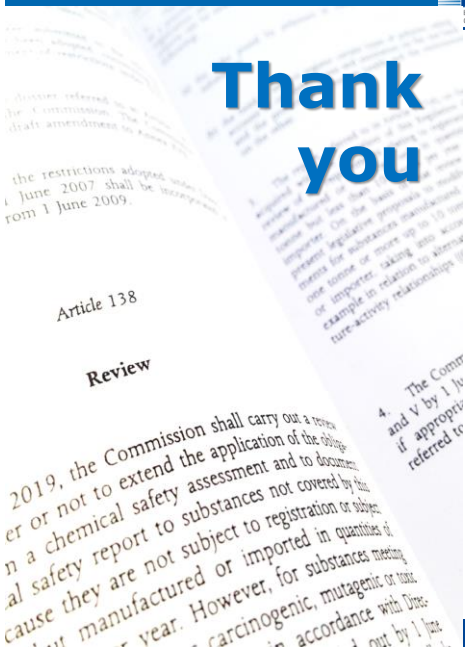
More information

REACH review websites:

- **Roadmap, consultation strategy, thematic studies**
- **Results of consultations**
- **Commission report on the operation of REACH – COM (2018)116 final and SWD (2018)58 final**

http://ec.europa.eu/growth/sectors/chemicals/reach/review_en

http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm



**Thank
you**

For further information on REACH and the REACH evaluation, please visit:

ec.europa.eu/growth/sectors/chemicals/reach/
ec.europa.eu/environment/chemicals/reach
echa.europa.eu
http://ec.europa.eu/growth/sectors/chemicals/reach/review_en
http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm