

# Meeting 2020 WSSD targets – Advance in ECHA regulatory strategy

*'REACH Compliance – A BfR-Workshop  
on data quality in registration dossiers'*

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**Towards REACHing the 2020 goals**



## 2002 Johannesburg World Summit on Sustainable Development:



*By 2020...chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment*

REACH and CLP are the key EU instruments that help achieving this goal

# Success factors for 2020 goal (*extract*)

(ECHA Programming document 2018-2020, p. 13-14 [https://echa.europa.eu/documents/10162/22837330/spd\\_2018-2020\\_mb\\_48\\_2017\\_mr\\_en.pdf/2360d15e-07b0-26a8-71e9-a022d575d235](https://echa.europa.eu/documents/10162/22837330/spd_2018-2020_mb_48_2017_mr_en.pdf/2360d15e-07b0-26a8-71e9-a022d575d235))

## 1. Robust data is available on all chemicals in Europe

a) Registration dossiers are compliant, up to date, and contain the data covering the hazards and uses of substances adequately.

c) ECHA has concluded, preferably in co-operation with the relevant stakeholders, which high-volume substances (above 100 tonnes per year):

Are of concern;

Are currently not of concern;

Need more data for a judgement to be made.

e) A plan describes how ECHA will identify candidates for further evaluation and/or risk reduction amongst the lower volume substances

## Success factors for 2020 goal (*extract*)

### **2. Effective regulatory risk management of the most dangerous chemicals takes place**

a) Substances of concern are identified, either individually or in groups. The most appropriate regulatory risk management measure to protect health or the environment, either under REACH and CLP or other legislation has been initiated.

[...]

## Success factors for 2020 goal (*extract*)

**3. Effective communication takes place about the safe use of chemicals up and down the supply chain**

a) Information about substances flows effectively up and down the supply chain. [...]

[...]

## Success factors for 2020 goal (*extract*)

### 4. A step-change for citizens, businesses and the regulators takes place

a) Information on chemicals is reliable, understandable, freely available, and easy to use. [...]

b) The experience of REACH and CLP, the information, methods and tools developed are increasingly recognised and used worldwide.

c) Companies experience firm, and fair enforcement [...]

## Where are we now?

### Key questions:

- Data quality and availability
  - Do we get the information we need?
- Regulatory risk management
  - Do we address substances of concern quick enough?
- Supply chain communication
  - Is this information being used by industry?



## Good progress has been made

- Classification information on > **144 600** chemicals
- ~ **89 000** registration dossiers for ~**21 600** substances
- [**> 2**] million study summaries on properties and effects of chemicals (NB: figure from 2017)
- **Almost 900** substances are under generation of data or assessment
- **270** RAC opinions for harmonised classification
- **191** substances of very high concern identified
- **65** substances of concern require prior authorisation
- **70** substances under restrictions on placing on the market and use



## REACH and CLP have brought benefits to everyone

- ✓ Chemicals are being used more safely and there is much more safety information freely available to everyone on ECHA's website
- ✓ EU Member States can use the information to propose EU-wide risk management actions and enforce chemical legislation
- ✓ Industry understands and communicates the risks of its chemicals better and has an improved worldwide reputation

**But there are still also  
challenges which need to  
be overcome**

To mention the few: ...





## Improve supply chain communication

- Currently there are deficiencies in the chemical safety information flowing up/down the supply chain

### **Recommendations:**

- Downstream users to demand better information
- Better enforcement of REACH provisions by Member States
- COM to consider how to strengthen supply chain communication



## Focus on substances that matter

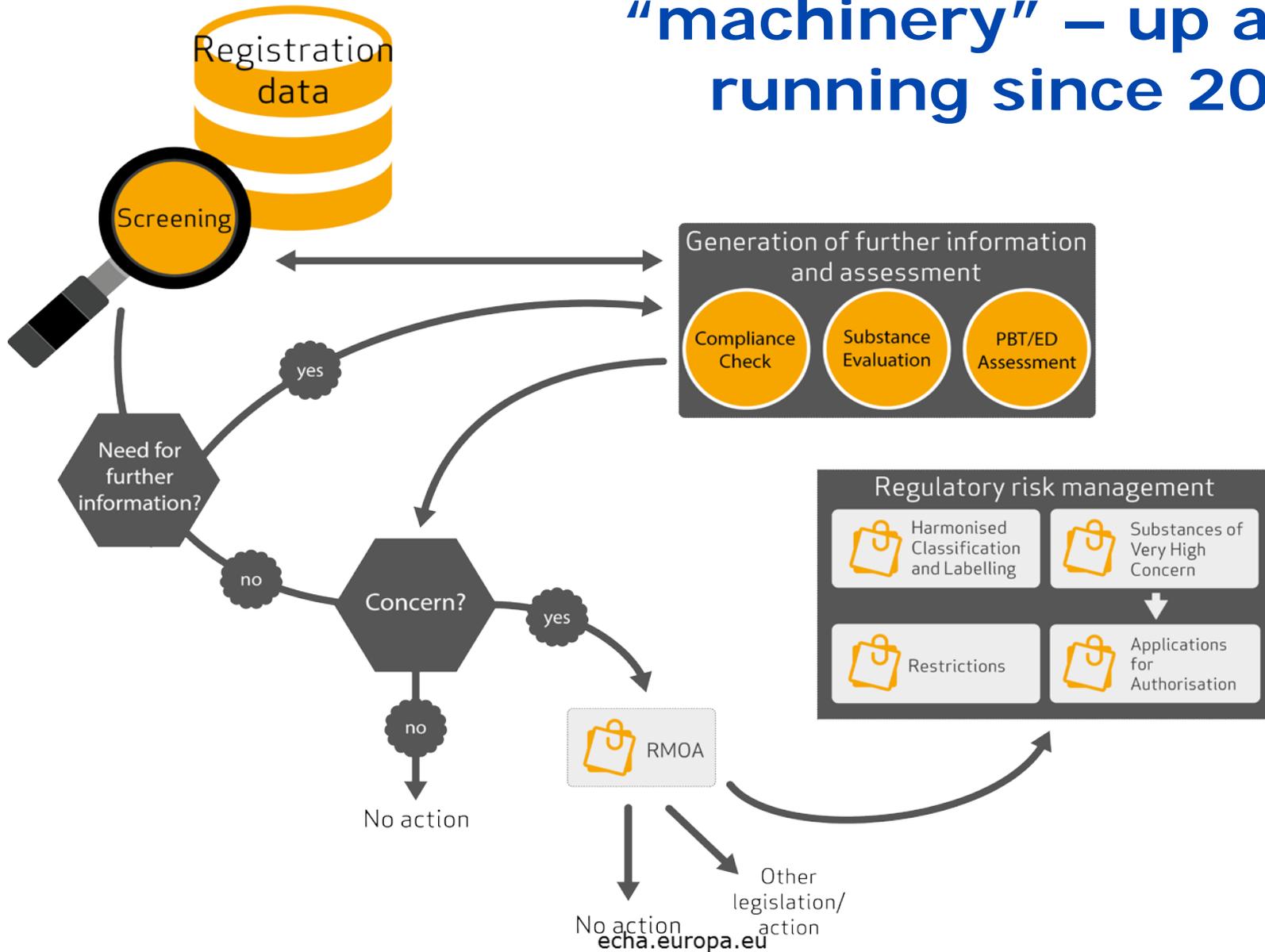
- Substances that matter: CMRs, PBTs and EDCs
- Better information in registration dossiers allow:
  - Better screening and priority setting
  - Identify best possible risk management action
  - Proposals for risk management: authorisation, restrictions and harmonised classification and labelling
- This will ensure good use of resources and that substances are not targeted for the wrong reasons
  - Make full use of ECHA's data (common screening approach) to identify substances that matter

# Integrated Regulatory Strategy in the heart of working towards WSSD 2020 goals

... Diving deeper



# Integrated regulatory “machinery” – up and running since 2016



# “Mapping our chemical universe”

## **1. High priority for further work by authorities**

Substances with identified concern and regulatory work has already been initiated or further work can be initiated based on currently available data

## **2. Substances of unknown priority**

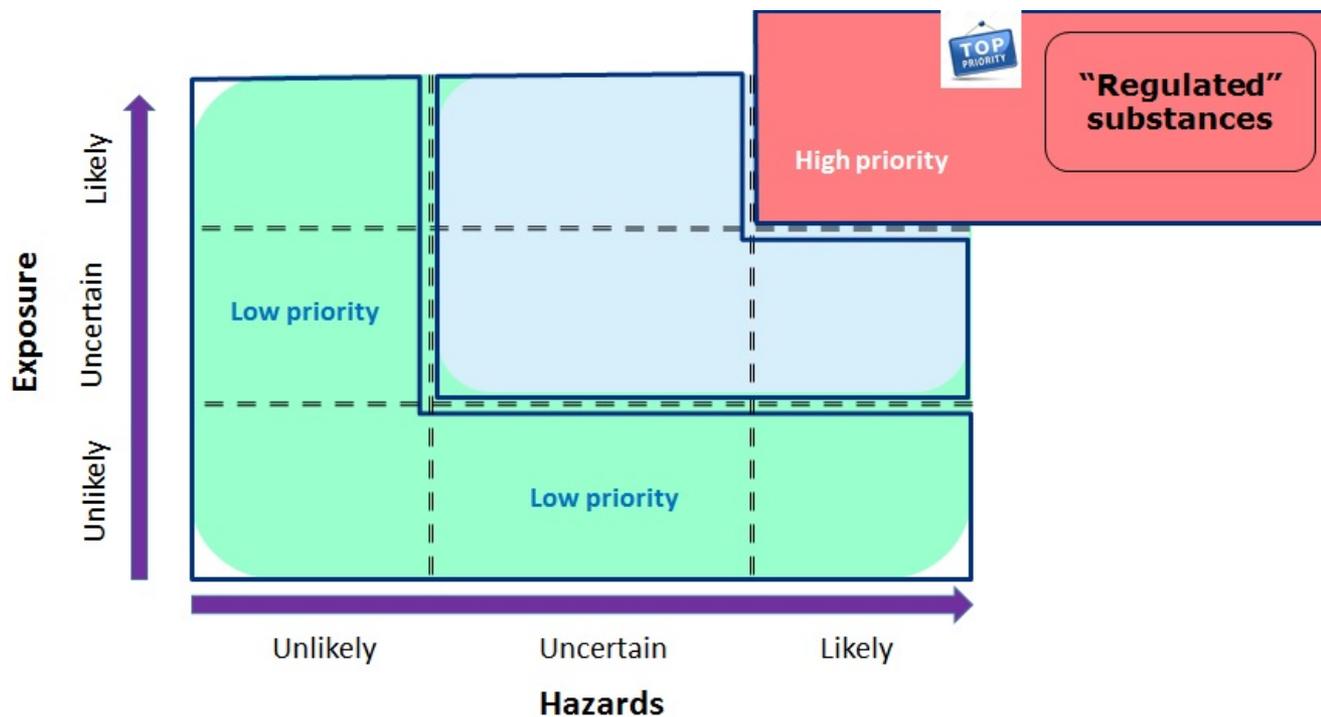
Substances for which there is at present uncertainty regarding the hazardous properties and/or the potential exposure; risk cannot be excluded although it cannot be established based on currently available data.

## **3. Low priority for further work by authorities**

Substances for which available data suggest that no further regulatory action is needed at present

## Universe of registered substances

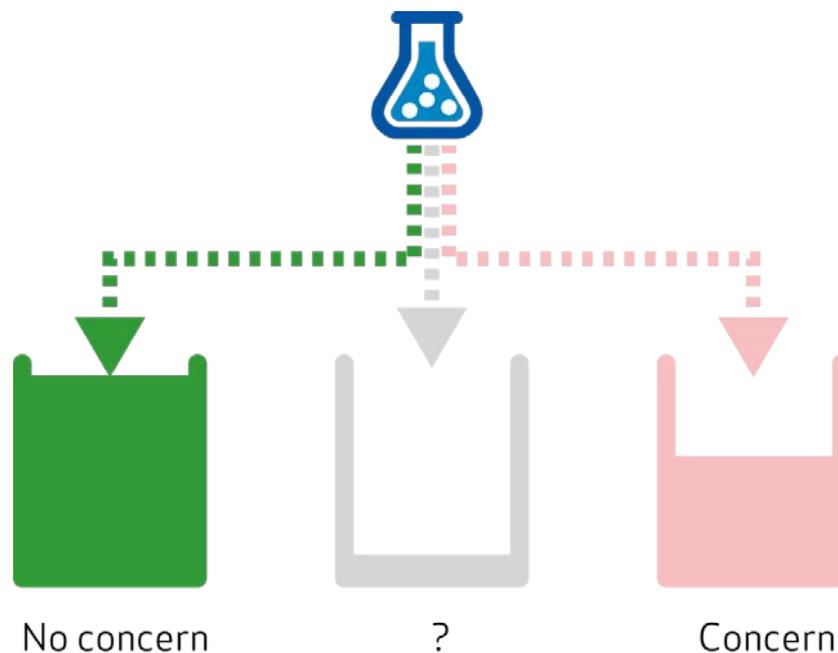
- All dossiers screened and prioritised for further assessment by authorities
- Use a set of (simple) criteria
- The likelihood of hazardous properties and release to environment/exposure of humans determined separately
- Three different “levels” for both aspects:
  - unlikely
  - uncertain
  - likely



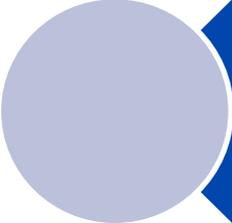
## Drawing conclusions at the substance (or group) level

Through:

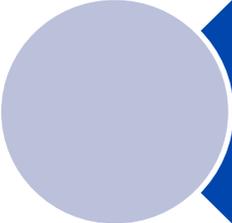
- IT-supported manual screening
- Compliance check
- Dossier evaluation follow-up
- Substance evaluation
- Risk Management Option Analysis



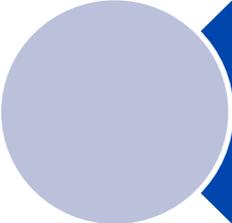
# Reporting on the progress



ECHA General Report



Until 2018: Annual Evaluation Report  
and SVHC Roadmap report



From 2019 onwards: (Combined)  
**Report on the implementation of the  
Integrated Regulatory Strategy**

## In conclusion

- The integrated regulatory strategy **integrates** all REACH and CLP processes, ECHA teams and expert groups, in cooperation with MSCAs
- It gives a **clear focus** on where to spend resources and time for maximum **impact**
- A lot has been achieved, the machinery is working....

*...but there are still many challenges and a lot of work ahead!*

# Challenges remaining

## Industry:

- Improve quality and compliance of registration dossiers → need regular updating
- Prioritise work in line with priorities of authorities:
  - Long-term effects, RAAF, use/exposure

## Authorities:

- Stay focused on effectiveness of our actions
  - Increased protection, support to substitution
  - Keep regulatory risk management need in mind!
- Increase the throughput keeping 2020 in mind
- Scientific and practical questions when assessing groups

## Working together - efficiently

# Outlook: ECHA's new 5-years strategic plan in the making

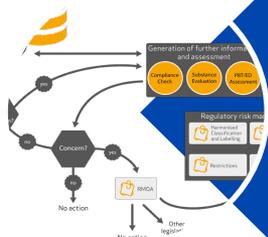


## **ECHA's (*draft*) Strategic Plan 2019-2023**

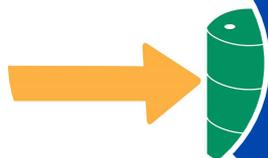
- Continuing working towards WSSD 2020 (and beyond) goal
- Responding to REACH Review-2 findings
- Adjusting the processes, priorities and ways of working to the post-phase-in period
- Absorbing new legislative and other tasks
- Adapting to resources assigned under the new EU multi-annual financial framework

*To be finalised by the end of the year for adoption by ECHA Management Board*

# Three strategic priorities



1. Identification and risk management of substances of concern



2. Safe and sustainable use of chemicals by industry



3. Sustainable management of chemicals through the implementation of EU legislation

# The priorities and the objectives

1. Identification and risk management of substances of concern

- [1] Accelerate data generation and intensify identification of substances of concern
- [2] Accelerate regulatory action on substances of concern

2. Safe and sustainable use of chemicals by industry

- [3] Effective communication up and down the supply chain becomes mainstream

3. Sustainable management of chemicals through the implementation of EU legislation

- [4] ECHA's information, knowledge and competences on safe use of chemicals support the implementation of EU legislation

# Priorities and Objectives turned to areas of operation

1. Identification and risk management of substances of concern

- 1) Prioritise (groups of) substances
- 2) Concerted regulatory action
- 3) Induce faster action by industry

2. Safe and sustainable use of chemicals by industry

- 1) Strengthen the knowledge base on substances in articles
- 2) Support to substitution and sustainable use of chemicals
- 3) Improved safety data sheets

3. Sustainable management of chemicals through the implementation of EU legislation

- 1) Consistency and synergies with the EU regulatory system for chemicals safety
- 2) Foster synergies at international level

# Concluding remarks



## Concluding remarks

**To reach the ambitious goal of WSSD, the work by all actors need not to only continue but be**

- Intensified
- Accelerated
- Better synchronised

**To do that, some fundamental aspects need to be addressed – in line with the REACH Review-2 actions**

- Incentivise industry to comply, improve the dossiers and the supply chain communication
- Get the most out of the work carried out by the Member States and ECHA – taking concerted action and finding new ways of working together

**A lot has been achieved in the EU –  
but more needs to be done by 2020  
by all actors ...**

**... and more time will be needed to  
reach the ultimate WSSD goal**



**A lot has been learned on the way ...**

**... and these learnings can be turned to new, smarter ways of working together and addressing the challenges!**



# Thank you!

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