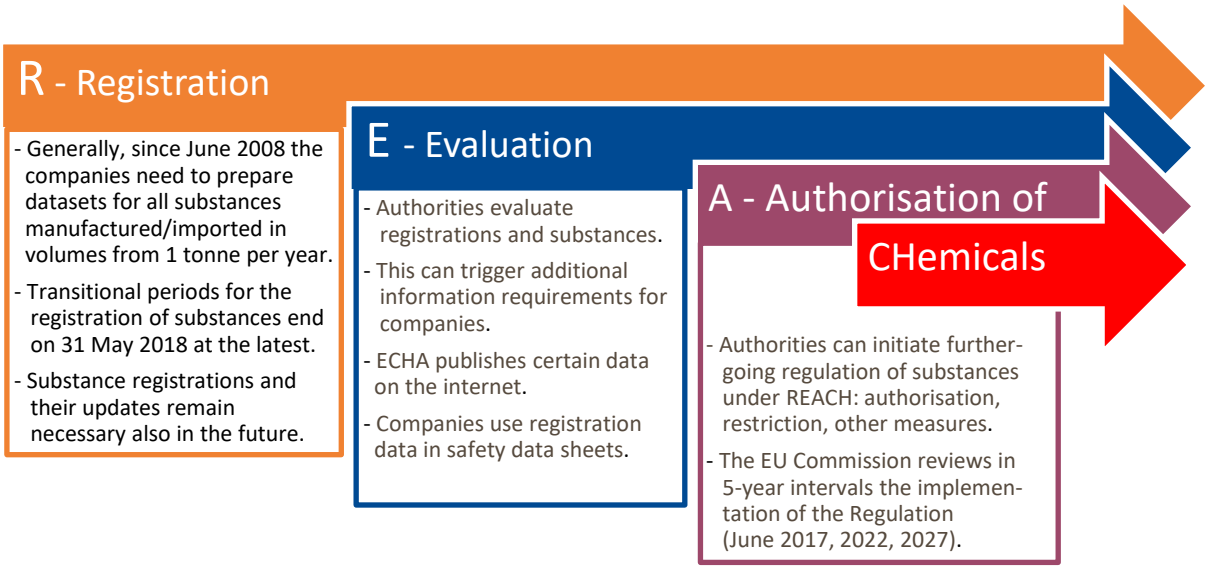
*REACH implementation post-May 2018*

# Work focuses are shifting – the workload remains high for authorities and companies![1]

The European Chemicals Regulation REACH[2] needs to be implemented stepwise by authorities and industry; it has no expiry date.

The acronym REACH stands for "Registration, Evaluation, Authorisation and Restriction of Chemicals". The various elements of REACH have different target years, and the various REACH processes build on each other.

Evaluations refer to the registration dossiers and possibly to further substance data. Based on evaluated data, substances can be prioritised for further regulatory measures such as authorisation or restriction procedures. Certain substance data and safe use conditions for substances and mixtures are communicated along the supply chains.




**Conclusion:**

**The work focuses in REACH implementation are shifting away from registration to dossier updates, evaluation, authorisation/restriction and work on the extended safety data sheet (eSDS). The workload will remain high for companies and authorities.**

[1] This information addresses basic REACH obligations; for relevant details, readers are referred to the VCI's service platform "REACH and CLP".

[2] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The acronym REACH comes from the English-language name of this Regulation.

**This means the following for further REACH implementation:**

## General activities

- The companies have established in-house structures, work processes and tools for adequate REACH implementation, observing the given deadlines (e.g. REACH coordinator/team, reporting routes, IT, monitoring of substance volumes). Numerous adaptations were already made due to changed submission formats, tools and technical requirements.
- Particularly the IUCLID software that is mandatory for registrations, REACH-IT and ECHA's Chesar tool – but also the SDS software – undergo adaptations. Input in terms of staff (adaptation work, training) and investments (soft and hardware, studies, consultants) continues to remain necessary for this.
- Regulatory developments under REACH (and CLP) have to be monitored continually for the entire substance portfolio – not only for substances of own manufacture.
- Moreover, the companies must be ready at all times for enforcement activities by authorities. Additionally, there are internal audits that include product safety activities.

## Registration

- Up until the end of the last transitional period for the registration of substances in tonnage bands from 1 to 100 tonnes per year on 31 May 2018, the companies are to submit the required registrations (comprehensive substance data) to the European chemicals agency (ECHA). Many of these data will be published by ECHA.
- The substance portfolios of companies change continuously, so that new registrations will become necessary also post-May 2018. The REACH data sharing obligations continue to apply, as a matter of principle.
- Registrations require updates in certain cases, e.g. where the next tonnage band with stricter data requirements is reached, further uses need to be taken into account in the chemical safety report, or new safety-relevant knowledge is available (Article 22 of the REACH Regulation). Furthermore, updates or new studies can become necessary following ECHA decisions based on compliance checks or substance evaluations.

## Evaluation

- After the end of the transitional periods for registration, ECHA needs to examine by 1 June 2022 all submitted proposals for vertebrate animal studies and bring about decisions on their implementation.
- With IT support, ECHA screens all registrations and identifies dossiers for more detailed examination. Switching to manual work, in the next step especially toxicological and ecotoxicological data are checked as to compliance with REACH requirements.[3,4] ECHA publishes several times annually which substances are anticipated to undergo a compliance check by the Agency. Moreover, substances are prioritised for a furthergoing risk-based evaluation. Every year, the Member State authorities carry out ca. 50 more profound substance evaluations, according to an annually updated action plan (Community Rolling Action Plan / CoRAP).
- ☒ Companies might still update their dossiers prior to examination. In the further course of the procedure, they have the possibility to comment draft decisions by ECHA that are addressed to them. Here, close contact with authorities is recommended. Companies have to implement the final decisions within given deadlines, i.e. quite often they need to carry out additional studies and update their registration dossiers and chemical safety reports.

## Supply chain communication / Safety data sheet

- The format of the safety data sheet (SDS) has been adapted several times under REACH. Newly introduced are the exposure scenarios for substances (description of recommended use conditions[5] in case of exposure to a substance). The relevant scenarios for ingredients need to be taken into account when preparing SDSs for mixtures.
- There are further communication obligations, e.g. for candidate substances (for the authorisation procedure) in articles.
- ☒ This means for the companies that the new format requirements, available registration data and exposure scenarios call for a review – and possibly an adaptation – of all SDSs. Here, changes in substance classification under the CLP Regulation are another trigger.

---

[3] Cp. ECHA „Programming Document 2017-2019“, p. 11: „*ECHA's ambition is by the end of 2018, to gradually map the universe of registered substances above 100 tonnes through a number of actions.*"

[4] Cp. ECHA "Progressing together to identify substances of concern", April 2017, Executive Summary: *„From this exercise [screening of REACH/CLP substance database], around 900 substances have been proposed to the Member States for further manual screening and in the last three years, more than 600 of them have been scrutinized. In 2016, 184 were manually screened and 72% needed follow-up action. Usually more data is needed, which is requested either as a result of a dossier compliance check or a substance evaluation."*

[5] Use conditions = Operational conditions and risk management measures

## Authorisation and restriction

- The authorities regularly review the data of registered substances, and potential candidate substances are identified for further regulatory measures. Here, it has proven its worth to initially find out whether there is a need for further regulation and which measures (e.g. authorisation or restriction) are suited best for this purpose.
- In a second step, procedures are launched for including substances in the candidate list for the authorisation procedure or the restriction procedure (or for harmonised classification under the CLP Regulation or other measures).
- ECHA annually issues recommendations to the European Commission for the inclusion of further substances in the Authorisation list.
- ☒ Therefore, the companies should check regularly which procedures are initiated for their substances. Also, the companies should make use of commenting options in ongoing procedures, observe enacted use restrictions, change products where necessary, or submit applications for authorisation.

## Review and further development of the REACH Regulation

- The REACH Regulation is subject to constant technical adaptation. The European Commission is free to enact implementing regulations. This can have direct impacts on which uses of substances remain permitted under what conditions and might bring changes in data requirements, processes or submission formats. Quite often, e.g. also existing registrations have to be adapted after a transitional period. This can be expected regarding the adaptation of REACH annexes for nanomaterials, as announced for 2017.
- The European Commission reviews every 5 years the “functioning” of REACH implementation and whether targets are met (deadlines: 1 June 2017, 2022, …). The Commission publishes the outcome of this examination (“Communication”) and possibly names planned or preferred follow-up activities. These can be legislative or non-legislative measures.
- ☒ For this reason, companies and associations should intensively monitor such reviews and bring forward their needs and arguments (as was done most recently within a consultation on the REACH Review under the Commission’s Regulatory Fitness and Performance Programme/REFIT in early 2017).

**Annex**

***Overview:***

## Major REACH work focuses for companies post-2018

(non-exhaustive list)

- Providing and adapting the **organisational structure, work processes and tools** for implementing the REACH Regulation – taking into account the interfaces to other regulations, the necessary training measures and external support.
- **Registrations** due to changes in portfolios of substances of own manufacture/importation and possibly after a legal entity change.
- Organisation of **data sharing and joint submission of registrations**.
- **Tonnage tracking** for manufactured and imported substances.
- **Check of registration status when purchasing chemicals.**
- **Check of own use conditions for raw materials**; where necessary, **communication of deviating uses** to suppliers or ECHA; where necessary, adaptation of the chemical safety report or downstream user chemical safety report.
- **Update of registrations** (spontaneous for relevant new information/changes e.g. in tonnage band, intrinsic properties, classification and labelling, additional identified uses; on demand after compliance check of registrations and after substance evaluations; because of technical adaptations of the REACH Regulation).
- **Monitoring the activities of authorities** (regarding evaluation, authorisation, restriction, classification); where necessary, commenting of screening results/ substance prioritisation, identification of candidate substances for the authorisation procedure, ECHA recommendations for including substances in the Authorisation list, proposals for restrictions.
- **Adaptation of (extended) safety data sheets** in consequence of new formats, registration data, uses, exposure scenarios, updated classifications etc.
- Observing **restrictions** of chemicals, where necessary, submitting **applications for authorisation** or **reformulate products**.
- Monitoring of reports from ECHA and Commission on REACH implementation overall (inter alia, **REACH Review 2017**, 2022) and on part-aspects (e.g. evaluation procedure). Follow-up activities of authorities can be e.g. changes to processes or technical adaptations of the Regulation.
- … and **compliance with the numerous further detailed requirements** of REACH, e.g. regarding communication on substances of very high concern (SVHC) in articles.