

REACH

Vinçotte Environment:
your partner in REACH conformity



Do you manufacture, use or trade chemicals? Then Vinçotte Environment can help you!

Since 1 June 2007, companies that produce, import, use or trade chemical substances have been subject to the new European Regulation 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH).

As from this year, the entire industrial value chain will be responsible for the safe use of chemical products. Depending on its activities, a company may be subject to new obligations. REACH forces you to think about your sales policy, production process, R&D and communication on chemical substances and articles with your customers and suppliers.

Since 1 June 2008, a number of new requirements have been imposed. For one of these, namely the registration of 'phase-in substances'¹, you can benefit from the transitional regime to register if the substances concerned were pre-registered before 1 December 2008. It may have serious consequences if you miss this deadline or not comply with other obligations.

For this reason, Vinçotte Environment has drawn up a specific REACH service provision programme, based on years of experience with environmental and risk management. Thanks to partnerships with external parties in legal and IT fields, Vinçotte Environment can expertly guide any companies, active in the chemical value chain, throughout the entire REACH process.

REACH IS NOT APPLICABLE TO:

- radioactive substances
- substances under customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit
- non-isolated intermediates
- the transport of dangerous substances

WHICH PRODUCTS ARE COVERED BY REACH REGULATIONS ?

- substances
- preparations (mixtures of substances)
- articles

Although only substances need to be registered under specific conditions, REACH provisions apply to the manufacture, import and use of the substances on their own, in a preparation or in articles.

Substances in articles that are intended to be released under normal conditions of use – tissues with lotion – have to be registered.

WHO HAS REACH OBLIGATIONS ?

- manufacturer (M): the manufacture of substances or preparations
- producer (P): the production of articles
- importer (I): the import of substances, preparations or articles in the EU
- downstream user (DU): the use of substances or preparations in the course of their industrial processes
- supplier (S): any M, P, I, DU and distributor of substances, preparations or articles who places them on the market

¹ 'existing substances' that have not yet been notified under the existing substance regulation (phase-in substances)

How can you comply with the European REACH regulation?

REACH is a complex process with a number of strict deadlines. The first deadline ended on 1 December 2008. Every producer or importer who produces 'a 'phase-in substance' in volumes of 1 tonne or more per year or imports them from outside the EU, could pre-register this substance electronically with the **European Chemical Agency** (ECHA). All 'new substances' must be immediately registered.

Manufacturers and importers of chemical substances must prepare a **Chemical Safety Report** (CSR) for all substances in quantities of 10 tonnes or more per year. The CSR describes the risks to humans and the environment linked to the substance. In addition to the assessment of the hazards, exposure scenarios and exposure estimations are included. The conditions of use under which substances can be used safely throughout their entire lifecycle must be identified.

In addition to registration, communication requirements, authorisation of SVHC² substances and restrictions are important components of REACH. These may be applicable to all actors in the supply chain, notwithstanding the registration requirement. So-called **downstream users**, i.e. users of chemical substances, must also be aware of REACH requirements as they also have obligations in this respect.

REACH's basic principle is simple: **'no data, no market'**. In other words, if there is no information about the substance: no manufacture and no placing on the market. Due to the large number of 'phase-in substances', this deadline runs until 2010, 2013 or 2018, depending on the volume and the hazard linked to the substance (potential to present a higher risk): Pre-registration brings together companies dealing with the same substance (SIEF - **Substance Information Exchange Forum**) and should result in submission of a joint registration dossier so new tests can be avoided.

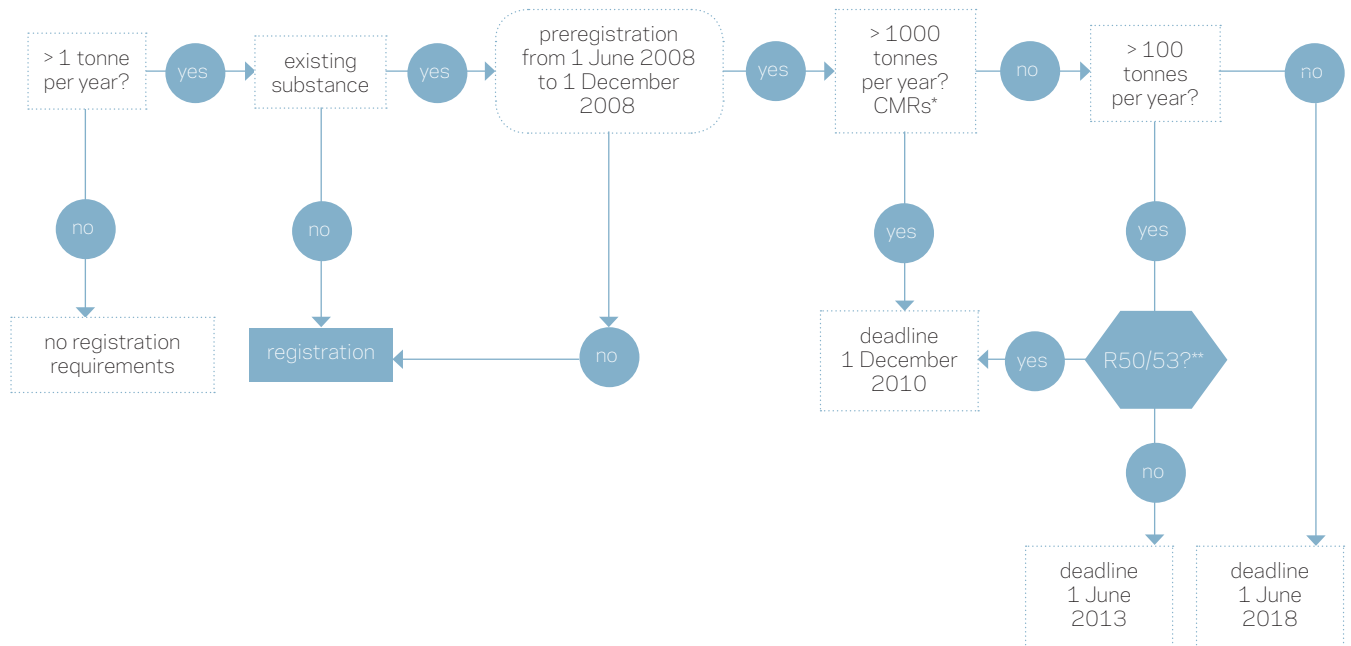
Thanks to this REACH approach – a unique, integrated system for registration, assessment and authorisation of chemical substances – the EU will be able to ensure a high level of protection of human health and environment while enhancing the competitiveness of the European chemical industry.

WHAT HAPPENS IF A SUBSTANCE HAS NOT BEEN PRE-REGISTERED?

- information request to the ECHA
 - joint use of data and participation in SIEF
 - joint submission of data
- drawing up of a registration dossier
- 3 weeks after submission of your file you can continue

² SVHC: Substances of Very High Concern

Schedule of requirements for reach implementation:



* Substances that are classified as carcinogenic, mutagenic or toxic for reproduction.

** Classified as very toxic to aquatic organisms that may cause long-term adverse effects in the aquatic environment.

REACH WILL BE INTRODUCED IN VARIOUS TRANSITION PHASES DEPENDING ON THE TONNAGE AND CHARACTERISTICS OF THE PHASE-IN SUBSTANCES (IF PRE-REGISTERED):

- Must be registered 3½ years after coming into force (1 December 2010):
 - Substances that are classified as carcinogenic, mutagenic or toxic to reproduction, of 1 tonne or more per year.
 - R50/53 substances (substances that could have damaging effects on the aquatic environment in the long term) of 100 tonnes or more per year.
 - Any substances manufactured or imported in quantities of 1,000 tonnes or more per year.
- Must be registered six years after coming into force (1 June 2013):
 - Any substances manufactured or imported in quantities of 100 tonnes or more per year.
- Must be registered eleven years after coming into force (1 June 2018):
 - Any substances manufactured or imported in quantities of 1 tonne or more per year.
- The quantities concerned must be calculated per year and per manufacturer or importer (legal entity).

If this concerns a new substance (or to be more accurate, a 'non phase-in substance') or if pre-registration was not carried out, the 'no data, no market' principle shall apply. These substances may not be manufactured or placed on the market without prior registration.

Vinçotte Environment and REACH: you can rest assured

The first deadline in REACH legislation has passed. Negotiations in pre-SIEF (Substance Information Exchange Forum) are also ongoing. However...

- how should the next steps in the REACH process be taken?
- what action should be undertaken next and when?
- what information has to be submitted, how and to whom?
- what pitfalls are there and how can they be avoided?
- how can product safety be ensured in your organisation?

The approach to REACH is case specific. Vinçotte Environment therefore likes to offer a tailored solution. An internal REACH status can provide a clear idea of the present situation. Working with a product list, we can determine whether or not there are any obligations and which requirements are applicable. Our REACH services may be a total REACH package or merely a step in the right direction.

▪ Vinçotte REACH Assistance on Chemicals (VRACH)

Our VRACH approach focuses on the technical, scientific and administrative fulfilment of your obligations. We provide guidance to both SIEF/consortia and individual companies. Intrinsic risks are determined on the basis of scientific research. Building up an exposure scenario and estimating the exposure requires a combination of theory and practice. This part of the safety report, will mainly be company-linked and drawn up outside an SIEF. The determination of the hazard characteristics of substances, and possible proposals for new tests, always take place within the SIEF. Regarding the completion of a safety report, we can support you in tasks required under the SIEF (third party representative) and for any remaining requirements.

▪ Vinçotte REACH Assistance on Products (VRAP)

If there are any doubts about the REACH status of a specific product (substance, preparation or article), we can provide a quick and expert service. After determining your status in the supply chain, the REACH compliance will be based on product data.

▪ Vinçotte REACH Auditing & Monitoring (VRAM)

As a result of REACH, the communication in the supply chain will strongly increase. However, what is the value, legal or otherwise, of all these declarations? Are you really certain that your suppliers have done everything to be compliant with the regulations? Vinçotte ensures that you get a clear view of the status of your suppliers so that you can evaluate the risks effectively. As we are also experts in the field of chain communication (with regard to customers and suppliers), we can offer the guidance needed: on the basis of a validation scheme, we can check whether your system is REACH compliant.

▪ Classification, Labelling and Packaging (CLP)

The regulation regarding classification, labelling and packaging (CLP) of chemical substances is strongly linked to REACH. Exchange of information is a precisely defined obligation in REACH. The hazard information will be based on criteria defined in the CLP regulation. All actors in the supply chain are expected to comply both with REACH and CLP. Vinçotte can guide you in drawing up your communication strategy. This can be done by providing support when preparing safety data sheets, assistance when collecting information about substances in articles or advice about other actions that contribute to the correct implementation.

REACH for excellence !

Vinçotte Environment has for many years offered a whole range of services that are closely related to REACH's area of operations. The combination of theoretical knowledge with extensive practical experience is an excellent basis for developing pragmatic solutions. Due to our extensive network and partnerships with legal and IT experts, Vinçotte Environment can always offer you an integrated solution. In addition, we can provide specific tailor-made training for your staff so that you can monitor all REACH requirements yourself.

As Vinçotte is at home in various fields, our services can also be placed in a wider framework. For instance, compliance with REACH can be integrated into your management system.

Our contribution to the success of our customers and to the world around us

With its all-encompassing service for environmental, energy and safety studies, Vinçotte Environment occupies a prominent place in the international environmental and safety sector. Whether these services cover soil testing, environmental impact studies, safety management or sustainable entrepreneurship, Vinçotte Environment can offer the appropriate expertise. Our team of more than 70 engineers, scientists, geologists, biologists and safety experts fully understand local sensitivities and have an overall view of relevant international legislation and developments. Among the characteristics of our environmental solutions and recommendations is that they are scientifically based, strategically viable and socially responsible. Proactive environmental, energy and safety management is no longer a luxury but a matter of course. You can rely 100% on the professional environment of Vinçotte Environment.

This brochure only contains a limited overview of the REACH regulation. For additional information and the current state, please contact Vinçotte Environment.



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