

Are you ready for REACH?

*Implementation is
imminent. There is
no time to lose in
preparing for the
REACH challenge.*



Are you working in the EU chemicals industry? Will you be able to continue operations next year?

On June 1st 2007, the European Union will bring into force new rules that will restrict and in some cases prohibit the manufacture and import of several thousand substances. With only a 12-month implementation period, unless companies act now to ensure the chemicals in their supply chain are registered, these restrictions could come as a nasty surprise to producers, importers and even downstream users of chemicals.

Have you ever lost a key possession? Car keys, wallet, purse, passport, expensive watch, mobile phone – whichever, it is a miserable experience. And in most cases all the worse, because you never saw it coming. Right when you need it, you discover the valuable is gone, for instance your passport, just as you step up to immigration control.

Europe's industry is about to go through that 'losing' experience with some of its 30,000 most-common chemicals. Under a new regime known as REACH, (the Registration, Evaluation, Authorization and Restriction of Chemicals), the EU requires all chemicals manufactured or imported in quantities above one tonne per year to be assessed for safety. The chemicals of most concern (estimated to be around 2,000-5,000 substances) either will be restricted for use or in some cases totally withdrawn from the market. In turn, downstream users of chemicals may have to change processes and reformulate many thousands of existing products.

REACH is truly new and extremely complicated, and during the initial stages some chemicals are likely to be 'lost' to the market simply by being overlooked by manufacturers and importers who do not fully understand the changes. Yet for substances left behind, the regulation's 'default' ruling is (for a change) very simple: as REACH enters into force, unless they are registered they will effectively be banned – No Registration, No Market!

Is there a way to escape REACH's reach? Not entirely, says Sue Anderson, Ciba® Expert

Services' Head of Regulatory Services in Basel. Industry has an opportunity to take advantage of the favourable conditions that REACH will bring to research-based companies, but delivery of new, innovative products will take time. Companies should focus on their existing product ranges to identify 'vulnerable' substances, ones where they have limited influence on regulatory decisions to ban or restrict substances. Of course adequate preparation for pre-registration and registration is an absolute must to avoid the 'no registration no market' scenario. And in some cases, after weighing up costs and benefits, companies may choose to leave certain chemicals out, simply because it will not be worth the time and effort required to keep them on the market.

The implementation clock is ticking, and the job at hand may seem overwhelming, so here is a look at what lies ahead.

Don't know what you got 'til it's gone?

REACH, in force from June 2007 and fully implemented from June 2008, consists of four

main steps for manufacturers and importers of chemicals: pre-registration, registration, chemical safety assessment and authorisation.

Starting in June 2008, pre-registration is the EU's effort to scope its regulation, to define more closely the universe of substances to be REACHed. Companies making, using or importing

chemicals must report to a new Chemicals Agency in Finland. Information including the chemical name, a contact person, an expected deadline for full registration and estimated annual volumes must be reported within a 6-month 'window of opportunity'.

Simple and easy, except for naming chemicals at a substance level, according to the new reporting requirements, and identifying the chemical composition of products imported from your suppliers. Not only may there be confidentiality barriers, but breaking down products to a substance-by-substance level is a huge, resource-intensive task.

Do you have answers for all your raw materials and products?
<input checked="" type="checkbox"/> Are the substances I use subject to REACH?
<input checked="" type="checkbox"/> Do I need to pre-register?
<input checked="" type="checkbox"/> Do I need to prepare a partial/full registration?
<input checked="" type="checkbox"/> Do I need to prepare a chemical safety report?
<input checked="" type="checkbox"/> Where are the vulnerabilities?

Then comes registration, starting with high-volume and most hazardous substances,

To-do list: preparation for REACH

- Produce an inventory of all substances, no matter whether these are produced, purchased within the EU or imported from outside the EU.
- Identify each substance / CAS numbers
- Establish contacts names / addresses of suppliers, competitors and customers.
- Establish broad use categories and exposure scenarios
- Assess vulnerabilities
- Plan strategy and next steps

which must be registered by 2010, followed by medium volume substances in 2013 and finishing with lower volume ones in 2018.

REACH calls for each substance's dossier to contain a vast amount of technical data such as:

- Chemical names/identifiers
- Information on manufacture and uses
- Classification and labelling
- Guidance on safe use
- Summaries of physical, chemical, toxicological and ecotoxicological properties

This can be lengthy. A sample dossier published by the EU runs to nearly 70 pages. Much of the dossier requirements, however, will be met by combining resources. Multi-company consortia will be formed, and they will appoint a lead 'registrant' to work on their behalf. This pragmatic solution will particularly help European small and medium sized enterprises.

Of course the biggest challenge to the dossier will be the preparation of the chemical safety assessment (CSA) which brings a new element to chemicals management, not least with its requirement to analyse substances for 'PBT' activity. CSA will be required for all substances registered in quantities of greater than 10 tpa.

In this complex area, even identification of all known 'uses' for a particular chemical can be a time consuming process, let alone the compilation of exposure scenarios for each of these uses.

For most chemicals, filing a dossier and a chemical safety assessment will be the end of the exercise. Still, if supply tonnages increase, then the dossier must be updated and possibly more testing undertaken.

The most hazardous substances will be subject to further scrutiny in a process known as authorisation, which is a polite way of saying restriction of usage or even required substitution of a substance. Authorisations, or licenses, would run for several years at a time and then be subject to further review. Where a suitable alternative exists, substitution will be imposed and enforced.

Act now to avoid disappointment

Clearly, running REACH's gauntlet will be costly. Compiling even the most basic dossier will run a serious tab. The key to minimizing cost, says Sue Anderson, is early action. Grouping of substances, shared dossier filings and use of 'intelligent' testing strategies are also possible, but only with advance planning.

Why work with Ciba® Expert Services on REACH?

Because we are a regulatory powerhouse. Our 150-expert staff understands REACH's rules, and we have a history of success in dealing with government officials. We know how to get your company REACH ready – offering maximum compliance at optimal cost.

The same goes for preventing the biggest cost hits: a raw material outage or a production

shutdown. With a prompt start and a concerted effort, you can still avoid unpleasant surprises from REACH – and consultants like Ciba® Expert Services can help. But time is running out rapidly. As with the missing passport at immigration, if you wait to the last second to recognize the problem, it will already be too late.

What are PBT chemicals, why are they special?

The Problem: Persistent, bioaccumulative, and toxic pollutants (PBTs) are highly toxic, long-lasting substances that can build up in the food chain to levels that are harmful to human and ecosystem health.

The Solution: management of these substances of concern, throughout their entire life cycles, to prevent or minimize their release into the environment.