REACH – Restrictions

This leaflet provides a brief introduction to the REACH restriction provisions.

The leaflet is in two parts. In Part 1, we look at what restrictions are and what they could mean for companies within the EU. In Part 2, we look at how a substance becomes subject to restriction and the processes involved.

Part 1

What is restriction?

Restriction is one way REACH operates to reduce the risks posed by hazardous substances. Under restriction, the manufacture, import, placing on the market or use of a substance can be made subject to certain conditions, going as far as prohibition in some circumstances.

A restriction can apply to a substance on its own or in a mixture, or to an article containing the substance. It can apply to any substance, including those that do not require registration. There are no tonnage thresholds for restrictions. The substances to which restrictions apply and the terms of those restrictions are listed in Annex XVII of the REACH Regulation.

Restrictions take many forms and include, for example: general bans on all uses; bans on specific uses (e.g., as a flame retardant); a ban for products available to the general public; or limits on the concentration of the substance in consumer products such as tyres, clothing or jewellery.

The concept of restriction is not new; it first existed in the Marketing and Use Directive (76/769/EEC). On 1 June 2009, this Directive was repealed and all its provisions transferred to Title VIII and Annex XVII of REACH. Title VIII describes the legal basis for the restrictions and Annex XVII gives the details of each separate restriction. Annex XVII contains the restrictions that existed under Directive 76/769/EEC, plus new restrictions that have come into force since 1 June 2009.

The European Chemicals Agency (ECHA) has produced a table to help companies find out which substances are subject to a restriction. The table contains all of the restrictions from Annex XVII of REACH, with links to further guidance and information. You can find the table on the ECHA website under the restrictions part of their section on ‘Addressing chemicals of concern’.

Examples of restrictions

Asbestos (entry 6 of Annex XVII)

The historical legacy of widespread asbestos use is well known and because of this the different forms of asbestos, and any articles that contain it, are now subject to a restriction. This severely limits the uses of asbestos and the sale of any existing article that had been produced before the ban came into place.

Lead carbonates and sulfates (entries 16 and 17 of Annex XVII)

Lead compounds were once widely used in paints and this led to a number of human health problems due to poisonings (especially in children) or because of worker exposure. Long-running problems in controlling these risks led to a ban on the use of lead in paints. To allow for restoration work on, for example, historic buildings, member states can permit some leaded paint to be used for that purpose only.

Polycyclic-aromatic hydrocarbons (PAH) (entry 50 of Annex XVII)

This is a group of substances that persist in the environment for a very long time, tend to build up through the food chain and have toxic effects on man and wildlife. They can be present in the oils used in tyre production and can be released from the tyres as they wear down. To control these risks there are limits on the amount of PAH substances that can be in the oils used and limits on the amount in the tyres themselves.

Who is affected by a restriction?

Anyone who manufactures, imports, uses or supplies substances (on their own, in a mixture, or in an article) could potentially be affected by a restriction.

Manufacturers and importers of substances

If you manufacture or import a substance that is listed in Annex XVII, either on its own or in a mixture, you should check whether this is permitted under the conditions of the restriction. If you have registered the substance, ECHA will inform you if a notification is submitted to the Registry of Intentions (RoI). This indicates that a proposal for a restriction is being prepared for that substance, and will enable you to plan for and contribute to the public consultation process if you wish to do so (see Part 2). You may wish to communicate with others in your supply chain to coordinate your contributions.

Producers and importers of articles

If you produce or import articles containing a restricted substance, you will need to check whether this is allowed or whether the article complies with any limits set. Importers are often familiar with the products they import, but may have limited knowledge of the chemical substances used to produce the products. In these cases, searching the chemical names may not be the best approach and looking at the conditions of the restrictions in Column 2 of Annex XVII may be a better option. Column 2 of Annex XVII gives information on the types of product to which the restriction applies. Using this information could allow an importer to conclude that some restrictions will not affect them. For example, an importer of books would probably not need to worry about restriction 43 on azo-dyes in fabrics.

Suppliers

If you supply a substance that is subject to a restriction, you will need to check that the supply is still permitted under the restriction. If it is, you need to communicate information about the restriction down the supply chain. If the substance or mixture requires a safety data sheet (SDS), you should include information about the restriction in Section 15. If a SDS is not required, you will need to provide the information in a separate communication.

Downstream users of chemicals

Your supplier should advise you whether the substances they supply are subject to a restriction. This information will be in Section 15 of the SDS or in a separate communication if a SDS is not required. You should compare the conditions of the restriction with your conditions of use, your risk management measures and the mixtures or articles you produce. If you are a formulator, and you include a substance subject to a restriction in a mixture that you place on the market, you must include information on the restriction in the SDS, or in a separate communication if a SDS is not required.

If a new restriction is proposed for a substance that you use, or an existing restriction is amended, you will have the opportunity to comment on the proposal and provide information during the public consultations. Other people in your supply chain may contact you to try and organise a coordinated response to the consultation (see Part 2).

Exemptions from restriction

Restrictions do not apply to:

- the manufacture, placing on the market and use of a substance for scientific research and development;
- the use of a substance as an on-site isolated intermediate;
- the use of substances in cosmetic products as defined in Directive 76/768/EEC, with regards to restrictions addressing the risks to human health within the scope of that Directive.

For entries 1–58 of Annex XVII, the restrictions do not apply to the storage, keeping, treatment, filling into containers, or transfer from one container to another of the substances for export (unless the manufacture of the substance is prohibited).

Substances used for product and process orientated research and development (PPORD) may be exempt from restriction. The Annex XVII entry for a substance will specify if the restriction does not apply to PPORD, as well as the maximum quantity exempted.

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Enforcement of restrictions

The restrictions under the Market and Use Directive were transferred to Annex XVII of REACH on 1 June 2009. The duty to enforce these restrictions lies with the national enforcing authorities in the member states. In the UK, restrictions are enforced by the Health and Safety Executive (HSE), the Health and Safety Executive for Northern Ireland (HSENI), local authorities and the environment agencies as appropriate. There have already been EU-wide coordinated enforcement projects looking at breaches of restrictions and, given the generally hazardous nature of the restricted substances, breaches of Annex XVII are taken very seriously by the enforcing authorities. Non-compliance with a restriction will almost always lead to a prohibition of the activity and a number of successful prosecutions have been taken against companies breaching restriction requirements.

Part 2

How do substances become subject to a restriction?

A restriction can be proposed if there is a concern that a particular substance poses an unacceptable risk to human health and/or the environment.

In the first step, an EU member state government or the European Commission (via ECHA) signals its intention to propose a restriction by notifying the REACH Registry of Intentions (RoI). The RoI is published on the ECHA website, and gives industry and other interested parties advance warning of the proposal. ECHA informs any registrants of the substance that a restriction is being prepared.

The member state or ECHA then prepares a dossier proposing the restriction. The dossier must be compiled according to Annex XV of REACH and include the identified risks, information on alternatives to the substance and the associated costs, as well as the environmental and human health benefits that would result from the restriction. In the UK, the dossier would be prepared by HSE and/or the Environment Agency, following clearance from a Defra minister. During the process, HSE and the Environment Agency communicate with stakeholders in a number of ways (via their respective websites, eBulletins, the UK Chemical Stakeholder Forum etc.).

Once the dossier is submitted, it is checked to ensure it conforms to the requirements of Annex XV and then published on the ECHA website. This is followed by a public consultation lasting six months; during which interested parties can comment on the proposal, or contribute additional information or analysis for consideration alongside the Annex XV dossier. The interested parties could be, for example, companies that use the substance, data holders, organisations representing industry or civil society, individual citizens or public authorities.

Within nine months of the proposal being published, ECHA's Risk Assessment Committee (RAC) gives its opinion as to whether a risk to human health or the environment has been demonstrated and whether the proposed restriction would be effective in reducing that risk. The opinion is based on the dossier and the information received during the public consultation.

At the same time, ECHA's Committee for Socio-economic Analysis (SEAC) prepares a draft opinion on the socio-economic impacts of the restriction. This takes into account the comments and any socio-economic information submitted during the public consultation. The opinion is published on the ECHA website, and interested parties have 60 days in which to comment. SEAC can then adopt its final opinion, taking any additional information received on the draft opinion during the public consultation into account.

As the opinions are being developed, the REACH Enforcement Forum (composed of representatives from the national enforcing authorities of the member states) provides advice to the committees on the enforceability of the proposed restriction.

The opinions of RAC and SEAC are then passed to the European Commission. Within three months of receiving the opinions, if it agrees to the restriction, the Commission will provide a draft amendment to the list of restrictions in Annex XVII. The final decision is taken in a voting procedure involving the member state governments and the European Parliament.

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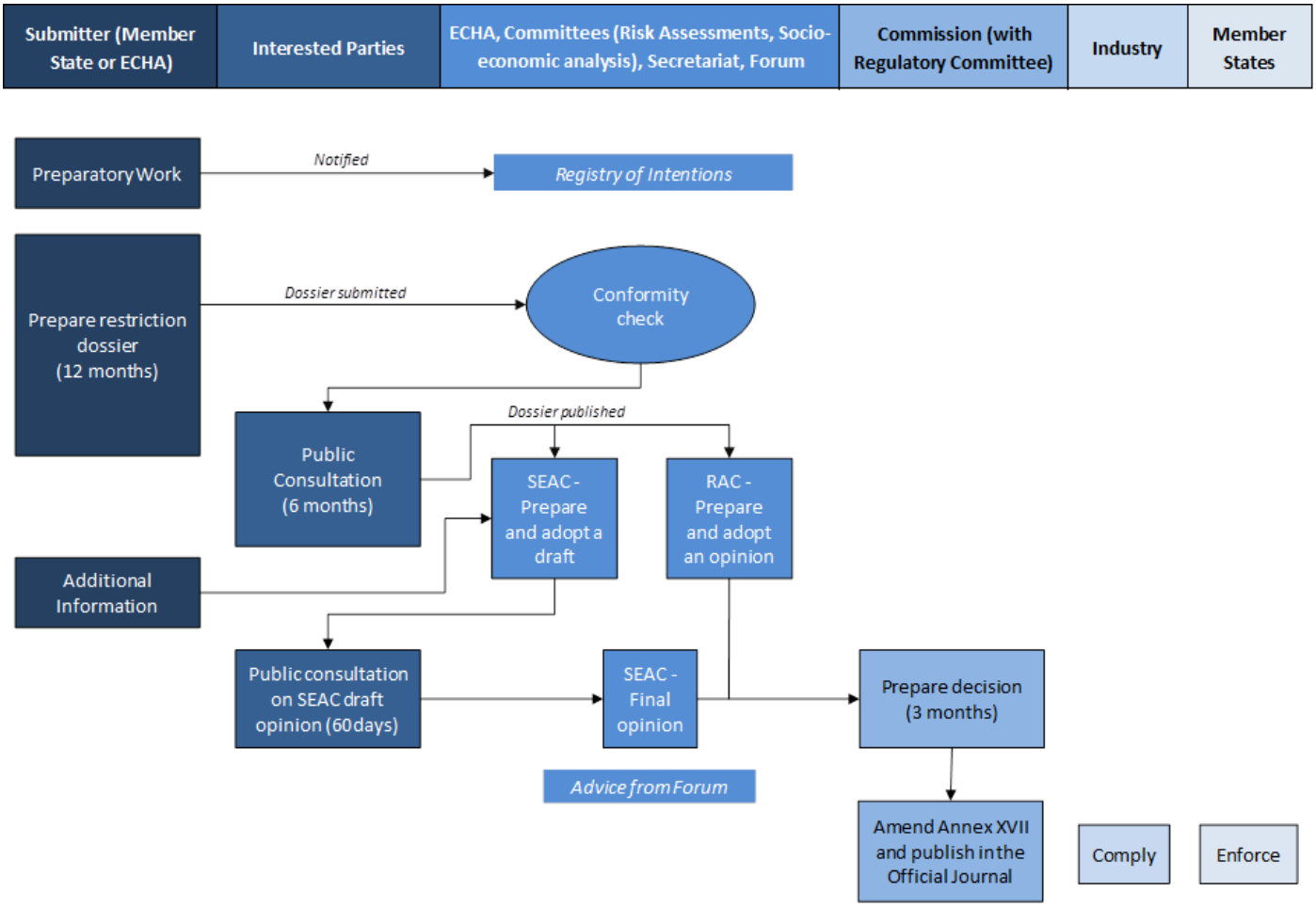
Once the restriction has been adopted, all companies must comply with the conditions set. Some companies may have no additional duties as the restriction will not directly affect their business. For newly introduced or amended restrictions there will usually be a transitional phase in which the necessary changes can be made to allow suppliers to comply. The competent authorities in the member states are responsible for enforcing the restriction. The steps in the restriction process are illustrated in Figure 1.

Figure 1 Overview of restrictions process



Further information

For advice on the application of REACH obligations, you can contact the UK REACH Competent Authority's national helpdesk.

Email: UKREACHCA@hse.gov.uk
Website: www.hse.gov.uk/reach

Further information on the processes relating to restriction, guidance on how to take part in public consultation exercises and guidance on how to interpret restrictions is available on the European Chemicals Agency's website.

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