

# The REACH of EU chemical rules

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Since June 2007, manufacturers, importers and suppliers of medicinal products, medical devices, foods and cosmetics must comply and closely monitor the requirements of the EU's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH imposes rigorous requirements that are additional to EU product-specific vertical legislation.

REACH is characterised by the following features:

- REACH shifts the burden of proof from regulators to producers by imposing the principle of “no data, no market”. It requires producers to know the substances that are contained in their products, their properties and to prove that the products are safe.
- REACH assumes the existence of an information chain starting with the substance's manufacturer and ending with the final supplier, the retailer of the finished product. REACH requires each party in the supply chain to gather and share information on the substances contained in their products, and imposes different obligations on them based on the information they are assumed to have. All members of the chain must closely monitor REACH compliance of their suppliers and customers, and significantly improve communication with them. This increased communication and co-operation, however, also triggers new anti-trust and confidentiality concerns.
- REACH establishes fast-track procedures for the phasing out of particular dangerous substances on the basis of the precautionary principle. Target substances include so-called “substances of very high concern” (SVHCs):
  - category 1 and 2 carcinogens, mutagens and toxic to reproduction substances (CMRs);
  - persistent, bioaccumulative and toxic substances (PBTs);
  - very persistent and bioaccumulative substances (vPvBs); and
  - substances raising an equivalent level of concern.

REACH also allows the European Commission (Commission) to ban, under the so-called “restrictions” procedure, any substance posing an “unacceptable risk” to human health or the environment.

These phase out and restriction procedures are accompanied by the regulatory discretion provided by REACH (that the European Court of Justice tends to confirm), to the European Chemicals Agency (ECHA) and the Commission.

Against this background, this article sets out the key aspects of the regulatory framework set out in REACH, in particular:

- The main REACH requirements.
- Medicinal products.
- Food and feedingstuffs.
- Medical devices.
- Cosmetic products.
- Packaging.
- Legal entities, foreign manufacturers, Only Representatives and third party representatives.
- SIEFS, data sharing and consortia.

## THE MAIN REACH REQUIREMENTS

REACH imposes different requirements on substances on their own, in preparations or in finished articles, and depending on whether they are manufactured in, or imported into, the EU/European Economic Area (EEA). Preparations are defined as mixtures or solutions of two or more substances, such as toothpastes, foods, dental filling materials, most medicines, lubricants, shaving creams and contact lens solutions. Articles are objects that are given a special shape, surface or design during production, which determines their function to a greater degree than their chemical composition. Examples of articles include cardiac pace makers, catheters and razors.

REACH will progressively introduce a set of key requirements (see box, *Timetable for introduction of REACH requirements*).

While REACH contains broad exemptions for medicinal products, food and feedingstuffs, manufacturers, importers and suppliers of medical devices and cosmetic products are likely to be subject to virtually all REACH obligations.

## MEDICINAL PRODUCTS

REACH has different impacts on:

- Medicinal products in the finished state for the final user.
- Medicinal products in bulk.
- Active substances and excipients that are intended to be used in medicinal products (without any chemical transformation).

## TIMETABLE FOR INTRODUCTION OF REACH REQUIREMENTS

**As of June 2007. Supply of safety data sheets to professional customers**

Suppliers of individual substances or products in preparations must provide their professional customers with safety data sheets if:

- Their supplied substances or preparations are classified as dangerous under the Directive 67/548/EEC (Dangerous Substances) or the future Regulation on the Global Harmonised System.
- The supplied substance meets the criteria of a PBT or vPvB substance, or is later identified as a SVHC.
- On request of their customers, preparations contain substances classified as dangerous, PBTs or vPvBs, substances that are identified as a SVHC, or substances subject to workplace exposure limits, in concentrations above specified thresholds.

This information will allow manufacturers of medicines, cosmetics, foods and medical devices to learn more about the properties of the substances they use and, on that basis, assess the applicable REACH requirements.

**As of 1 June 2008. Registration of substances manufactured or imported in quantities of one ton or more per manufacturer/importer per year**

All manufacturers and importers of substances on their own, in products in the form of preparations, and in some cases articles, must register the substances they manufacture or import in quantities of one ton or more per manufacturer/importer per year, unless an exception applies. Registration will require submitting a:

- Technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will involve substantial testing and data gathering.
- Chemical safety report assessing the hazards, exposure and risks of use during the entire life cycle for substances manufactured or imported in quantities of ten tons or more per manufacturer or importer per year. Registration will be substance and company specific. Only chemical manufacturers and importers that register will be allowed to manufacture or import, and therefore supply, their substances or products containing them.

Importers and manufacturers of articles (that is, objects) intended to release substances can also be required to register the releasing substances if all of the following thresholds are met:

- The substances are present in articles in quantities exceeding one ton per manufacturer per importer per year.
- The substances are intended to be released during normal or reasonably foreseeable conditions of the article's use.
- The use of the substance in articles is not already registered by any third party.

Examples of articles intended to release substances include intelligent packaging releasing preservatives and razors with comfort strips.

A limited number of substances are exempt from registration. These include polymers (but their monomers may be subject to registration), and substances and categories of substances listed in Annexes IV and V to REACH. Non-isolated intermediates are also exempt from registration, while isolated intermediates may benefit from limited registration requirements under certain conditions.

- Intermediates and processing aids that are used in the manufacture of active substances and excipients of medicinal products.
- Investigational products used in clinical trials.

**Medicinal products in finished state**

All substances contained in finished medicinal products intended for final users are exempt from most REACH requirements, including registration, downstream user requirements, evaluation, information through the supply chain, and authorisation of SVHCs. This exemption is also likely to apply to medicinal products intended to be marketed in third countries.

However, any substance contained in medicinal products may be subject to REACH marketing and use restrictions unless the specific entry for each restricted substance specifies otherwise.

**Medicinal products in bulk**

Substances contained in medicinal products (in their pharmaceutical form) but in bulk (such as pills in bulk that are not yet placed in the final packaging) are also exempt from the REACH requirements of registration, downstream users, evaluation, and authorisation. This exemption is also likely to apply to medicinal products intended to be marketed in third countries.

However, substances in medicinal products in bulk will normally be subject to REACH information through supply chain

## TIMETABLE FOR INTRODUCTION OF REACH REQUIREMENTS (CONTINUED)

**By 1 December 2008. Pre-registration of phase in substances**

While registration is due as of 1 June 2008, REACH provides a phase in period for producers that pre-register their phase in substances by 1 December 2008. Phase in substances include:

- Around 100,000 substances listed in the European Inventory of Existing Commercial Substances (EINECS).
- So-called “No-Longer Polymers”.
- Substances manufactured in the EU/EEA or an acceding Member State but not placed on the market between 1 June 1992 and 1 June 2007.

Manufacturers and importers that pre-register their phase in substances will benefit from a phase in registration period with the following deadlines:

**1 December 2010. Registration of:**

- Substances manufactured or imported in volumes of 1000 tons or more per manufacturer/importer per year.
- Category 1 and 2 CMRs.
- Substances classified with the risk phrase R50/53 (that is, substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment), if they are manufactured or imported in volumes of 100 tons or more per manufacturer/importer per year.

**1 June 2013.** Registration of substances manufactured or imported in volumes of 100 tons or more per manufacturer/importer per year, except for substances classified with the risk phrase R50/53.

**1 June 2018.** Registration of all substances manufactured or imported in volumes of one ton or more per manufacturer or importer per year.

Manufacturers and importers that do not pre-register or register their phase in substances by 1 December 2008 are liable for manufacturing, marketing or importing the substances without a registration as of 1 June 2008. Downstream users must not purchase phase in substances from suppliers that have not pre-registered them as of 1 December 2008.

REACH also allows “latecomers” to pre-register after 1 December 2008 and benefit from the registration phase in deadlines. Entities that manufacture or import substances in quantities of one ton or more for the first time after 1 December 2008 may still pre-register if they do so:

- Within six months of the first manufacture or import of the substance in quantities of one ton or more per year.
- No later than 12 months before their relevant phase in registration deadline.

requirements, which may include the provision of safety data sheets. Furthermore, substances in medical products in bulk may also be subject to REACH marketing and use restrictions, unless the specific entry for each restricted substance specifies otherwise.

**Active substances and excipients intended to be used in medicinal products**

While legally unclear, the current position of ECHA is that substances intended to be used as active substances or excipients of medicinal products (and that are not already contained in the medicinal products) are also exempt from REACH requirements of registration, evaluation, downstream user requirements, and authorisation. This exemption is also likely to apply to active substances that are exported for the manufacture of medicinal products in third countries, but the status of excipients exported to third countries is unclear.

Manufacturers, however, are likely to be required to submit documentary evidence proving the substances will be used for medicinal purposes. Where a substance is manufactured or imported for use in a medicinal product and for other non-exempt uses, only volumes of non-exempt uses will be subject to registration.

The exemption for excipients and active substances is likely to apply only when there is no chemical transformation of the substances in question. However, where there is such transformation, the substance may still benefit from limited REACH requirements that apply to intermediates, provided it is intended for that use.

Processing aids used in the manufacture of medicinal products (such as ingredients for growth media used in the manufacturing of biotechnology medicines) are also not exempt from REACH requirements.

## TIMETABLE FOR INTRODUCTION OF REACH REQUIREMENTS (CONTINUED)

**As of 1 June 2008. Additional information requirements**

ECHA and member states can impose additional information requirements for priority substances under REACH evaluation procedures.

**As of the registration of their suppliers by June 2008 or later dates for phase-in substances, downstream users may be required to draft a chemical safety report and notify their uses to the ECHA**

Once their suppliers have registered their substances, downstream users may be required to prepare a chemical safety report and notify ECHA if their particular use of the substance is not included in the registration of their suppliers and they use the substance in quantities of one ton or more per year. The chemical safety report must assess risks arising from the downstream user's use, and cover the substance's lifecycle. Downstream users include all entities established in the EU/EEA using substances in the manufacture of their products, provided they have purchased their substances from EU/EEA suppliers. Where an entity imports a downstream good into the EU/EEA or imports substances for the manufacture of its goods in the EU/EEA, it can be subject to full registration and evaluation requirements for imported substances, as part of the product or on their own, in quantities of one ton or more per year.

**As of 28 October 2008. The provision of information on SVHCs contained in supplied articles**

On 28 October 2008, the ECHA identified a first list of 15 SVHCs. As of that date, suppliers of articles containing SVHCs in concentrations above 0.1% w/w must provide their professional customers (such as health institutions) with information to allow the safe use of the article, which at a minimum must include the name of the substance. Suppliers of articles must supply consumers the same information within 45 days from their request. The list of substances to be reported will increase as ECHA periodically expands the list of substances identified as SVHC.

**As of 1 June 2009. The Commission can start using the so-called "restrictions" fast-track procedure to ban the marketing and use of any substance that poses an "unacceptable risk" to human health or the environment**

This restrictions procedure will, in effect, incorporate and periodically update the current restrictions of the Directive 76/769/EEC restricting the marketing and use of certain dangerous substances and preparations, which apply to virtually all product categories unless the specific restriction provides otherwise.

**By 1 December 2010. Submission of the chemical classification of substances marketed on their own, in preparations or in articles and that are subject to registration**

EU manufacturers and importers of substances on their own, in preparations or articles and subject to registration must submit the chemical classification of their substances to ECHA. This requirement, however, will not apply where the producer has already reported the substance's chemical classification as part of its registration.

Furthermore, active substances and excipients intended to be used in medicinal products are normally subject to information through the supply chain requirements (such as provision of safety data sheets) and may also be subject to REACH marketing and use restrictions, unless the specific restriction entry provides otherwise.

**Substances used in investigational medicinal products**

Substances used in investigational medicinal products are not likely to benefit from the exemption for substances used in medicinal products. However, substances used in investigational products may benefit from the temporary registration exemption for product and process oriented research and development ("PPORD"). This exemption is conditional on submission of a notification to ECHA, payment of a fee, and an affirmative decision of ECHA. The exemption is for five years and can be extended up to a maximum of ten additional years. With the REACH prior authorisation procedure, the decision whether to exempt the use of the substance in investigational products as PPORD, must be adopted on a case-by-case basis when the substance is listed as subject to authorisation.

**SUBSTANCES USED IN FOODS AND FEEDINGSTUFFS**

REACH contains broad exemptions for food and feedingstuffs, but some important regulatory obligations are likely to remain. However, the REACH exemptions may be interpreted as not applying to many processing aids and intermediates used in the manufacture of food and feedingstuffs, but that are not themselves food or feed ingredients.

**Substances that are food or feedingstuffs**

Substances that are food or feedingstuffs or that are intended to be used in food and feedingstuffs are likely to be exempt from the REACH requirements on registration, evaluation, authorisation, and downstream use of substances. But these substances may be subject to the provision of safety data sheets if they are not in the finished state intended for the final user, and they may also be subject to REACH marketing and use restrictions, unless the specific restriction entry provides otherwise.

## TIMETABLE FOR INTRODUCTION OF REACH REQUIREMENTS (CONTINUED)

**By the end of 2009. The Commission is likely to have published the first list of SVHCs also subject to a prior authorisation requirement**

The list will specify the date by which manufacturers, importers and users of substances, on their own or in preparations, must ensure that they, their suppliers or customers have applied for an authorisation to use the substance, and the date (so-called "sunset date") after which non-authorisation applicants or non-authorisation holders must no longer market or use the substance. The first sunset date is expected by the second half of 2011. This authorisation requirement, however, will not apply to substances contained in imported articles.

Authorisation applicants will be required to show that risks resulting from the use of their substances are adequately controlled, or that socio-economic benefits of the use outweigh the risks and there are no suitable alternative technologies. Applicants will also have to search for substitutes and present a substitution plan where substitutes are available. Applicants who do not obtain authorisation will be banned from using listed substances, unless their supplier or downstream user has obtained such authorisation. Granted authorisations will be subject to review taking into account the substitutes that become available.

**As of 1 June 2011. Notification to ECHA of the presence of SVHCs in articles manufactured or imported**

Manufacturers and importers of articles will be required to notify ECHA of the presence of substances that ECHA has identified as SVHCs in their manufactured or imported articles if all of the following conditions are met:

- The SVHC is present in articles in concentrations above 0.1% w/w.
- The SVHC is present in articles manufactured or imported in quantities above one ton per manufacturer or importer per year.
- The use of the substance in the article has not already been registered by any other third party.
- The manufacturer or importer cannot exclude exposure to the substance during the normal or reasonably foreseeable conditions of use of the article, including its disposal.

**Processing aids and other substances not used as ingredients**

It is likely that the REACH exemptions for food and feedingstuffs do not apply to processing aids and intermediates used in the EU manufacture of food and feed, but that are not intended as food or feed ingredients.

Processing aids and intermediates, however, can be exempted from the registration requirement if they are natural, not chemically modified, and not classified as "dangerous". Certain substances listed in Annex IV to REACH, which are widely used in the manufacture of food and feedingstuffs, such as pure sucrose and lactose, are also exempt from the registration requirement. These substances could still be subject to other REACH requirements.

In addition, food intermediates may benefit from REACH specific exemptions for intermediates. For example, so-called "non-isolated" intermediates, that is, intermediates that during the synthesis of another substance are not intentionally removed from the equipment where synthesis takes place, can be entirely excluded from the scope of REACH. On-site and transported isolated intermediates "manufactured and used under strictly controlled conditions" can be subject to limited registration requirements, and are exempt from the prior authorisation requirements.

**MEDICAL DEVICES**

REACH provides only very limited exemptions for substances used in medical devices:

- The risk to human health resulting from the use of substances in medical devices must not be considered when deciding whether to grant an authorisation for the use of substances subject to authorisation.
- Medical devices in the form of preparations are not subject to information through the supply chain requirements (such as safety data sheets) if:
  - the medical devices are in the finished state intended for the final user;
  - the medical devices are invasive or used in direct physical contact with the human body; and
  - other EC legislation requires the classification and labelling of substances that are contained in medical devices.

Except for these limited exemptions, manufacturers, importers and suppliers of medical devices are subject to all REACH requirements. In particular, substances in medical devices in the form of preparations (such as, lubricants, bone cement, contact lens solutions, and anti-clotting agents in medical devices) should be treated as any other substance under REACH.



Producers and importers of medical devices in the form of articles (such as cardiac pace makers, catheters, corrective glasses, surgical gloves, and defibrillators) will also be subject to virtually all REACH requirements that apply to manufacturers and importers of articles. For example, producers and importers of medical devices in the form of articles may be required to notify ECHA of the presence of SVHCs in their articles. Where articles are intended to release substances during the normal and reasonably foreseeable conditions of use, producers and importers can also be required to register their substances. Similarly, all suppliers of medical devices in the form of articles will be required to provide their customers (such as health institutions) with information on the presence of SVHCs in their articles in concentrations of above 0.1%.

## COSMETIC PRODUCTS

Substances used in cosmetic products will be subject to most REACH requirements. In particular, importers of cosmetic products are liable for REACH compliance as importers of all substances contained in their products, including registration and prior authorisation requirements. In contrast, EU/EEA manufacturers of cosmetic products are only subject to REACH requirements that apply to downstream users, unless they manufacture or import the substances.

Substances used in cosmetic products benefit only from three limited exemptions, which reflect the principle that REACH is intended to address the environmental risks of cosmetic products:

- The chemical safety report that must be included in the registration of substances or that must be prepared by downstream users, does not have to consider the risks to human health resulting from the use of the substance in a cosmetic product. However, the chemical safety report must address the environmental risks resulting from the use of the substance in the cosmetic product.
- REACH also makes clear that the use of Category 1 and 2 CMRs in cosmetic products can never be authorised, and that the authorisation requirement does not apply to substances used in cosmetic products if such substances are identified as substances raising “an equivalent level of concern” to Category 1 and 2 CMRs. In contrast, the use in cosmetics of PBTs, vPvBs and substances with an equivalent level of concern to PBTs and vPvBs may be subject to prior authorisation.
- REACH's restrictions procedure cannot be used to address risks to human health resulting from the use of a substance in cosmetic products. Such risks must be addressed under the procedures of Directive 76/768/EEC on the approximation of the laws of the member states relating to cosmetic products.

## PACKAGING

The packaging of medicines, food, feedingstuffs, cosmetics and medical devices is subject to virtually all REACH requirements that apply to substances in articles.

For example, producers and importers of packaging, including importers of packed goods, may be subject to the requirement to notify ECHA of the presence of SVHCs in their packaging in concentrations of 0.1% or more. Similarly, they may be required to provide their customers with information on the presence of SVHCs in their packaging in concentrations above 0.1%. Substances used in the EU/EEA manufacturing of packaging may be subject to most REACH requirements.

For food contact materials, however, the chemical safety report of substances used in food contact materials need not address the health aspects of substances used in food contact materials. Similarly, the prior authorisation requirement does not apply to substances used in food contact materials that are Category 1 and 2 CMRs or substances raising an equivalent level of health concern. However, substances used in food contact materials are subject to the environmental aspects of REACH.

Substances released from packaging material (such as preservatives released from intelligent packaging) may be subject to registration requirements that apply to substances that are intended to be released from articles.

## LEGAL ENTITIES, FOREIGN MANUFACTURERS, ONLY REPRESENTATIVES AND THIRD PARTY REPRESENTATIVES

### Legal entities

With corporate groups, the REACH requirements, including tonnage thresholds, apply to each of the legal individual entities of the corporate group that is engaged in the manufacture, import, use or supply of substances or products containing them and that is established in the EU/EEA, and not to the corporate group as a whole. Therefore, each legal entity of the group must ensure it assesses all substances that are contained, or it uses, in products it manufactures, imports, uses, or supplies. The fact that legal entities, and not the corporate group as a whole, are liable may mean that some REACH requirements that are dependant on volume will not be triggered (such as registration of substances manufactured or imported in quantities of one ton or more per manufacturer or importer per year).

### Foreign manufacturers

Only physical persons and legal entities established in the EU/EEA must comply with REACH requirements. REACH imposes no obligations on foreign suppliers of substances or goods containing them.

### Only Representatives

However, to facilitate imports, REACH allows foreign manufacturers to appoint a so-called “Only Representative”, who will be responsible for the substance's pre-registration and registration, and for all other obligations that apply to importers under REACH. Where the foreign manufacturer appoints an Only Representative, its importers of the substance, or the products containing them, will only be liable for the REACH obligations that apply to downstream users.

REACH's wording suggests that a foreign manufacturer may only appoint one Only Representative per substance exported to the EU/EEA. It also suggests that foreign distributors of substances (rather than manufacturers) cannot appoint an Only Representative. It is likely that both the foreign manufacturer of the substance as well as the foreign manufacturer of the product containing the substance can appoint an Only Representative in the EU/EEA. In both cases, the importers of the finished products would only be liable for REACH obligations that apply to downstream users.

REACH requires Only Representatives to meet two conditions:

- They must have sufficient background in the practical handling of substances and information related to them.
- They must be established in the EU/EEA.

Only Representatives must also keep available and up to date information on quantities imported, customers and supply information on the latest safety data sheet.

Only Representatives can represent more than one foreign manufacturer for the same substance. However, in that case, they cannot cumulate the volumes they represent and they must submit a pre-registration and registration per represented foreign manufacturer, even if it is for the same substance.

For corporate groups, one of the corporate group's legal entities established in the EU/EEA can act as the Only Representative of all other foreign legal entities of the group. The pre-registration and registration of this Only Representative legal entity will then cover the imports of all other EU legal entities of the same group.

Foreign manufacturers who appoint an Only Representative must inform their importers/customers of this appointment. They are also advised to write a letter of appointment to their Only Representative so that it can prove to ECHA and national enforcement authorities that it is representing a foreign manufacturer. Foreign manufacturers are advised to specify in their letters the substance(s) covered, the importers, and the volumes exported to the EU. It is best practice if the Only Representative writes to the importers/customers of the foreign manufacturer, confirming that it will assume their obligations as importers and indicating the substance(s) and volumes covered.

Foreign manufacturers and their importers should ensure that the Only Representative meets certain technical and quality standards and has good financial standing. Foreign manufacturers should also ensure their contractual agreements with their Only Representatives include strict confidentiality and competition law provisions, and ensure the liability of the Only Representative in case of non-compliance with REACH. This is for the following reasons:

- While REACH provides that the Only Representative is liable for registration and pre-registration and other REACH requirements, there is the risk that enforcement authorities may also hold importers liable.

- Only Representatives are likely to represent more than one foreign manufacturer with respect to the same substance, and have data about many different importers of the same substance.
- As a result, Only Representatives are likely to communicate with many of the foreign manufacturer's and importers' competitors.

The contract with the Only Representative should also require the Only Representative to facilitate the transition where the foreign manufacturer decides to change its Only Representative. In particular, under REACH, the Only Representative (and not the foreign manufacturer) is the registration holder. Therefore, the contract should oblige the Only Representative to allow the foreign manufacturer and newly appointed Only Representative to use all data submitted as part of registration or pre-registration.

### Third party representatives

Third party representatives are different to Only Representatives. EU manufacturers, importers and downstream users of substances (and probably also Only Representatives) can appoint a third party representative in order to ensure that their identity is not disclosed to third parties, including their competitors. A third party representative can be used for purposes of participation in the Substance Information Exchange Forum, data sharing, joint submission of registrations, evaluation discussions, and presumably also in consortia. Where a third party representative is appointed, the liability for pre-registration, registration and data sharing and all other REACH requirements remains with the manufacturer, importer, or Only Representative.

## SIEFS, DATA SHARING AND CONSORTIA

### SIEFS

Pre-registrants will automatically join a Substance Information Exchange Forum (SIEF) for each substance they pre-register. The purpose of the forum is to facilitate sharing of data for the purposes of registration, and to agree on the classification and labelling of a substance when there is disagreement between potential registrants. These *fora* will operate until 1 June 2018.

REACH foresees that the following third parties who are not potential registrants can also join the SIEF for a particular substance, if they have data on that substance (so-called "data holders"):

- Manufacturers or importers of the substances in volumes below one ton.
- Downstream users, such as EU/EEA manufacturers of cosmetics, foods, medical devices and medicines.
- Any third party, including public institutions and NGOs.

Data holders may wish to join the SIEF to share (and sell) their data, to monitor and control the information that is available on the substance, and to identify those suppliers that have pre-registered (unless they use a third party representative). NGOs, institutes and other entities, are not likely to be able to use a third party representative; instead, they must disclose their identity when they participate in a SIEF.

On pre-registration, pre-registrants will be directed to a website created for all substances with the same EINECS or other identifiers. The website will display the:

- Corresponding entry in the EINECS, or Chemical Abstract Service (CAS) number or other identification codes.
- Details of all pre-registrants (or third party representatives).
- Tonnage band of the different pre-registrants and whether they are willing to act as “facilitators” in the SIEF.

This website will be accessible only to entities that have pre-registered, and therefore, required to join the SIEF, and to third parties holding data who wish to join the SIEF.

The identity of pre-registrants will not be disclosed to persons other than those who pre-register and other third parties who join the SIEF. In particular, in January 2009, once the pre-registration period has concluded, ECHA must publish the list of pre-registered substances. This list will not include the name of the pre-registrants, but only the name of the substances, their EINECS and CAS numbers if available or other identity codes, and the first envisaged registration deadline (for all pre-registrants of the same substance).

Pre-registrants of a substance with the same identification codes will have to agree on the “sameness” of the substance. This is because some EINECS numbers include different substances, and some of them are erroneous entries. Therefore, it is possible that a significant number of SIEFs will be split into different *fora* with different substances.

### Data sharing

REACH provides complicated rules on sharing data. The main principle is that all data resulting from testing on vertebrate animals must not be repeated and, if available, must be shared. This data sharing must be made in return for costs, which must be determined in “a fair, transparent, and non-discriminatory way”, and it is likely that the interpretation of this standard will, in many cases result in disputes among SIEF members.

Data owners who fail to share their data will be penalised through fines or preventing the owner from registering its substance. In the case of pre-registered substances it is possible that data owners who do not need to pre-register until a later deadline (for example 2018) will have to share their data with those registering first. However, in practice, it is more likely that those that register first will have to share their data with those registering at a later time. This is because on registration, other parties will know the registrant has the data.

REACH protects the data owner for 12 years from the date of registration. Therefore, where data was submitted under the Dangerous Substances Directive notification requirements, it may be possible that new registrants will have access to the data for free if the notification took place at least 12 years ago. Further, REACH is not likely to prevent registrants from using data that was submitted in third countries under these countries’ regulatory regimes and that has later become publicly available.

### Consortia

Many trade associations and ad hoc groups of manufacturers, importers and users of substances have created different forms of co-operation in order to comply with REACH requirements. These different forms of co-operation are called “consortia”.

REACH, however, does not require nor regulate the creation of consortia. In particular, there is no equivalence between SIEFs and consortia. For example, among the manufacturers and importers participating in a SIEF, there may be different consortia to deal with different classification issues, volumes and so on. Consortia may also cover more than one substance, while REACH requires the creation of one SIEF per substance. SIEFs are mainly intended to deal with the requirement of registration, while consortia can also be used to defend a substance during its authorisation procedure. A consortium may also start before the SIEF and can last longer.

Consortia are likely to be useful to most manufacturers. For example, it is likely that after the pre-registration deadlines many SIEFs will be created and these will include many different types of participants. Therefore, it might be best to have consortia clearly regulating how the costs of generating data will be shared. Consortia may also be useful to ensure proper communication and REACH compliance between suppliers and customers manufacturing goods outside the EU. Consortia can be used to defend together a particular substance during the entire REACH process. Consortia can also deal with authorisation issues.

Consortia are subject to basic principles of contract law and, most importantly, EC competition rules. A consortium agreement is likely to regulate:

- The purpose and scope of the consortium.
- Membership criteria.
- Bodies of the consortium.
- Ownership of the data.
- Data compensation issues.
- Rules on protection of confidential information.
- Financing aspects.
- Liability.
- Governing law and dispute resolution issues.

Companies should always bear in mind that a consortium is an association among competitors. Therefore, EU and national competition rules will apply to consortia. In general, this requires taking into account two main principles:

- The consortium must establish transparent and non-discriminatory criteria for membership. This means, among other things, that membership cannot be exclusively based on size or turnover, or limited only to members of a trade association.



- The exchange of information must be limited to that required by REACH. The consortium should not exchange information on prices, production capacities, cost of production, sales volumes or future plans regarding investment.

Therefore, entities participating in consortia should ensure that their representatives in the consortia are adequately trained on EU and national competition rules and that participation is always monitored by a lawyer. They are also recommended to ensure that the consortium appoints a third party trustee responsible for dealing with the exchange of information among consortium members. All meetings and discussions in the consortium should be well documented. Entities should ensure a co-ordinated strategy if they participate in different consortia.

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