REACH in practice - challenges for the life sciences sector

Darren Abrahams, Laura Atlee, Jim Searles and Craig Simpson,
Steptoe & Johnson LLP Brussels

www.practicallaw.com/3-378-7868

REACH, the EU's new chemicals regime, will have a significant impact on companies across the life science sector. The first deadline for compliance - "pre-registration" of existing (so-called "phase-in") substances - expires on 1 December 2008. As soon as possible before then, inventories must be created of substances manufactured, imported and used in the EU (non-EU manufacturers must assess all substances exported to the EU), supply chain communications made and crucial compliance decisions taken in preparation for pre-registration. Across the board, systems must be put in place to effectively protect commercial interests and reduce what could be substantial compliance costs. Some 30,000 chemical substances, used on their own, in preparations or incorporated into finished articles will be affected. REACH will impact all actors in the supply chain. Crucially, those who fail to pre-register a phase-in substance must suspend marketing of that substance in the EU pending complete registration and may face penalties. Marketing rights generally are subject to REACH's "no data, no market" principle.

Key aspects of the regulatory framework (set out in Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Directive 2006/121/EC) and immediate challenges for the sector are explained below, in particular focusing on the following:

- REACH policy objectives.
- Registration (and pre-registration) by manufacturers or importers.
- Content of registrations.
- Data and cost sharing.
- Substances in articles.
- Authorisation of "substances of very high concern" (SVHC).
- Information in the supply chain.
- Classification and labelling inventory.
- Treatment of various life sciences sectors.
- Action items.

In addition to the legislation itself, the official guidance documents, which are being issued on an ongoing basis, have also been referenced where appropriate. To date, the guidance is already greater in volume than the mammoth REACH legislation itself and, at points, conflicts with the legislation - an ominous sign for those hoping for compliance requirements to become clearer with time.

REACH POLICY OBJECTIVES

The central policy objective of the REACH regime is to transfer responsibility for the generation of data on the safety of chemical substances from governmental authorities to the parties placing them on the EU market. Placing on the market means supplying or making available to a third party, whether for payment or free, including importation into the EU.

Another key concern is transparency, to be achieved initially by requiring registration with the newly established European Chemicals Agency (ECHA) of all chemical substances placed on the market. Registration will entail submission of detailed information about the substance, its uses, related risks and guidance on safe use. Transparency also entails making certain (non-confidential) information available throughout the supply chain as well as to final consumers, for example, concerning certain dangerous substances ("substances of very high concern") in the finished products they purchase.

REGISTRATION (AND PRE-REGISTRATION) BY MANUFACTURERS OR IMPORTERS

The registration of substances manufactured or imported in quantities of one metric tonne per year or more is the fundamental requirement of REACH, whether such substances are manufactured or imported:

- On their own.
- In preparations.
- In finished articles.
- As (isolated) intermediates.

Each substance must be individually registered. What specific information has to be submitted for the registration, and when the registration must be submitted, depends on the hazard of the substance in question and the volume manufactured or imported (*see below*).

The REACH Regulation provides for transitional registration periods for so-called "phase-in" substances (mainly existing substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)) according to the volumes manufactured or imported if the substances in question are pre-registered between 1 June and 1 December 2008. Pre-registration will be carried out through the REACH IT system managed by the ECHA.

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Downstream users (DUs) of a substance essential to their production process and that has not been pre-registered can ask the ECHA to extend the pre-registration period by six months to give them time to find a supplier or to pre-register the substance themselves. DUs are defined as any EU natural or legal entity that uses a substance in the course of its industrial or commercial activities, excluding distributors and consumers.

The ECHA must publish a list of the pre-registered substances by 1 January 2009 and DUs can see from the list whether the substance of concern has been pre-registered or not.

If properly pre-registered, the extended registration deadlines for phase-in substances are:

- 30 November 2010 for phase-in substances:
  - manufactured or imported in quantities of 1,000 or more tonnes per year per manufacturer or importer;
  - classified as very toxic to the aquatic environment and manufactured or imported in quantities of 100 or more tonnes per year per manufacturer or importer;
  - classified as carcinogenic, mutagenic or toxic to reproduction (CMRs) and manufactured or imported in quantities of one or more tonnes per year per manufacturer or importer.
- 31 May 2013 for phase-in substances manufactured or imported in quantities between 100 and 1000 tonnes per year per manufacturer or importer.
- 31 May 2018 for phase-in substances manufactured or imported in quantities between 1 and 100 tonnes per year per manufacturer or importer.

Phase-in substances that must be registered but which miss the pre-registration period become subject to the "no data, no market" rule, that is, the party is barred from placing the substance on the EU market pending proper registration. As mentioned above, the company may also face penalties under national law for the marketing that took place between the suspension of marketing and 1 June 2008 (the start of the pre-registration period).

Pre-registration does not necessarily have to be followed by registration (where, for example, the potential registrant decides to cease manufacture or import of the substance or the quantity drops below the one tonne per year threshold before the registration deadline), so it is best to pre-register to at least preserve the possibility of using the transitional deadlines. Further, the data required for pre-registration is not extensive (name of substance including CAS and EINECS number, contact body, foreseen deadline for registration and tonnage band).

Companies with a legal presence in the EU will be able to register directly. Manufacturers outside the EU must ensure proper registration to protect their market but cannot register themselves. They have two options:

- Hand all of the data necessary for registration to the EU importer of the substance in question so that it can register (although this raises inevitable concerns about the protection of sensitive data and the fact that the importer may be also acting for competitors).
- Appoint a trusted "only representative" (duly qualified and based in the EU, such as a law firm) to fulfil all of an importer's obligations on its behalf (in which case the importer is treated as a DU).

Given that registration deadlines (assuming that pre-registration is undertaken) are based, in part, on the volumes of a substance concerned, companies who export to the EU and have multiple legal entities in the EU may wish to engage in strategic splitting of import volumes between these legal entities to reduce the total tonnage per entity. As discussed below, lower volumes also require less information to be submitted, so reducing the cost of registration (*see below, Data and cost sharing*). It will be necessary to ensure that each entity becomes a valid importer for this purpose. While registration applies to each legal entity, the guidance on pre-registration and data sharing creates the possibility (not envisaged in the REACH legislation) for parent companies or head offices to submit pre-registration for several legal entities belonging to the same company group (a so-called "Super User") provided that all legal entities are informed by the parent company or head office and have access to the information submitted in the pre-registration.

CONTENT OF REGISTRATIONS

All registrations must include, at minimum, the "technical dossier", which will include:

- The identity of the manufacturer or importer.
- The identity of the substance.
- Information on the manufacture and use(s) of the substance.
- The classification and labelling of the substance.
- Exposure information.
- Guidance on safe use.

Study summaries (or robust study summaries in specified cases) must also be provided concerning information derived from testing required under Annexes VII to XI (*REACH*). The level of testing required varies according to the tonnages manufactured or imported (for example, the most extensive testing applies for substances manufactured or imported in quantities of 1,000 or more tonnes per year). If further testing is needed, proposals must be submitted first.

In addition, chemical safety assessments and a chemical safety report (CSR) are required for substances manufactured or imported in quantities of ten or more tonnes per year. The CSR sets out the hazards and classification of the substance and whether it is persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB). The CSR must also provide exposure scenarios, including recommendations for measures to ensure that risks to humans and the environment are adequately controlled, regarding the registrant's own uses and all uses identified by DUs in the chain. If the assessment is required but a DU does not notify its use to its supplier/registrant or uses a substance outside the conditions covered in the registrant's CSR, the DU itself must perform the safety assessment concerning its uses.

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DATA AND COST SHARING

Given the extent of data that must be compiled for an individual registration, REACH provides for sharing of data, both to avoid duplication of animal testing and reduce associated costs. The pre-registration of phase-in substances (*see above, Registration (and pre-registration) by manufacturers or importers*), for example, results in establishment of a Substance Information Exchange Forum (SIEF) for each substance.

Each SIEF will group all intended registrants of the same particular substance (manufacturers, importers, only representatives, other holders of information on the substance and potentially also DUs) and enable them to share certain information and determine, for example, which studies are available and/or still need to be carried out. Owners of full study reports are required to permit reference to their existing vertebrate testing reports and, if requested, also their non-vertebrate testing reports. The SIEF parties must agree on, and collectively generate, any required new testing.

Costs for testing must be shared fairly. Fines might be imposed if a study owner refuses to provide either proof of the cost of its study (for purposes of cost sharing and, on payment, granting permission for the other party to refer to the full study report in its own registration) or the study itself.

A SIEF is not a consortium, since membership of the SIEF is required under REACH and not voluntary. However, although there is no express requirement to do so under REACH, it is likely that SIEF participants will voluntarily co-operate through consortia to best protect their interests in fulfilling both their data sharing and registration obligations.

In the case of non-phase-in (new) substances and phase-in substances that have not been pre-registered, each potential registrant must inquire to the ECHA if a registration has already been submitted for the substance in question. If so, it will be put in contact with previous registrants so that information and costs can be shared if necessary to make the registration.

To help reduce registration costs, REACH provides that certain data (for example, on hazardous properties of the substance and classification) should normally be submitted jointly. Therefore, a "lead registrant" would submit the data with the agreement of the other registrants. Specified other data must be individually submitted given its commercial sensitivity. Certain data, including the CSR, can be submitted jointly but nonetheless might be submitted separately if, for example, this would result in disclosure of commercially sensitive information or a joint submission would be disproportionately costly to the company in question.

In complying with their data sharing and registration obligations, registrants should limit exposure to allegations of anti-competitive behaviour by avoiding both the exchange of commercially sensitive information and discrimination regarding consortium entry or costs sharing. Adherence to a strict anti-trust policy, including maximum transparency in dealings with competitors, is advisable.

SUBSTANCES IN ARTICLES

A special regime applies concerning substances contained in articles (finished products). Clearly, many articles placed on the EU market contain a large number of substances that are subject to REACH, with some of these substances being potentially dangerous if released from the article during its use.

All substances intended to be released from articles during normal and reasonably foreseeable conditions of use must be registered by the producer or importer according to the normal REACH rules (including pre-registration, volume deadlines and information rules) if those substances are present in the articles above one tonne per year per producer or importer. Although the guidance on articles is not expected to be issued until early 2008, it is already apparent that it will rule that the volume which needs to be registered is the entire amount of a substance in an article and not only the amount which is expected to be released from it.

The ECHA also has a residual power to require registration of any unintentionally released substance if both:

- The substance is present in an article in a quantity over one tonne per year per producer or importer.
- The ECHA has grounds for suspecting that:
  - the substance is released from the articles; and
  - the release of the substance from the articles presents a risk to human health or the environment.

In addition, the producer or importer must notify the ECHA and provide certain specified information for each substance in the article that meets the "substances of very high concern" (SVHC) criteria and is identified in the "candidate list" of substances considered by the ECHA to meet the SVHC criteria if three conditions apply:

- The substance is present in those articles in quantities totalling over one tonne per year per producer or importer.
- The substance is present in those articles above a concentration of 0.1% weight by weight.
- The producer or importer cannot exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use of the article, including disposal.

These provisions on registration/notification of substances in articles do not apply to substances that have already been registered for that use.

AUTHORISATION OF SVHC

Annex XIV of REACH will comprise a list of substances determined to be of very high concern in respect of human and environmental safety. Substances to be listed in Annex XIV are those which meet the criteria set out in Article 57 (*REACH*), including CMRs, PBTs, vPvBs as well as certain other substances, such as endocrine disrupters, for which there is scientific evidence of probable serious effects "which give rise to an equivalent level of concern".

A producer, importer or DU can only place a substance on the market which is included in Annex XIV if, among other things, the use(s) of that substance on its own, or in a preparation, or the incorporation of the substance into an article, has been properly authorised.

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Applications for authorisation can:

- Be made by one or several parties.
- Cover one or several substances if they are part of the same group.
- Concern one or multiple uses (own uses and/or uses intended downstream).

The application must include an analysis of potential alternative substances (including any relevant research and development undertaken by the applicant) and, if suitable alternatives exist, a substitution plan including a timetable for actions proposed by the applicant.

The provisions on authorisation criteria distinguish between the different hazard classifications and situations where safety thresholds can or cannot be determined. In general, authorisations will be granted if the risk to humans or the environment is "adequately controlled". However, more restrictive conditions apply concerning:

- CMRs and certain other SVHC for which safety thresholds are not possible to determine.
- PBTs and vPvBs.
- Other SVHC identified has having PBT or vPvB properties.

In these cases, authorisation can be granted only if it is shown that socio-economic benefits outweigh the risk to human health or the environment and there are no suitable alternative substances or technologies. In this context, consideration will be given, among other things, to the information submitted by the applicant and/or other parties about alternatives.

Decisions on the suitability of alternatives will take into account technical and economic feasibility for the applicant and whether substitution would actually result in reduced overall risks. When granted, authorisations will be subject to time-limited reviews determined on a case-by-case basis and normally certain conditions, such as monitoring.

INFORMATION IN THE SUPPLY CHAIN

Suppliers of substances and preparations must provide recipients with safety data sheets (SDS) whenever a substance or preparation is:

- Classified as dangerous.
- A PBT or vPvB.
- Listed in the candidate list for substances requiring authorisation for other reasons.

Instances are also specified for when an SDS is required. Importantly, REACH requires any supplier of an article containing a SVHC to provide recipients (at no cost) with available information to allow safe use, including, at a minimum, the name of the substance. In these circumstances, the supplier must also provide the same information to any consumer who requests it.

CLASSIFICATION AND LABELLING INVENTORY

Any manufacturer, producer of articles or importer who places a substance requiring registration on the market must provide information to the ECHA to enable it to compile, and keep updated, a classification and labelling inventory that will be publicly accessible. The obligation to supply this information will apply from 1 December 2010.

Further, one of the purposes of the SIEF (*see above, Data and costs sharing*), beyond data sharing, is to secure agreement among the SIEF members on classification and labelling of their substance.

TREATMENT OF VARIOUS LIFE SCIENCE SECTORS

The life sciences sector is broad and it is apparent that certain industries have more to be immediately concerned about in the final REACH text than others, but all must treat REACH carefully. Key issues for certain sectors are examined below.

Biocides (antimicrobials) and plant protection products (PPP or pesticides)

Biocides and pesticides are poorly treated under REACH. Each is already strictly regulated under separate EU legislation (Directive 98/8/EC concerning the placing of biocidal products on the market, and Directive 91/414/EEC concerning the placing of plant protection products on the market, respectively) yet will be subject to significant REACH obligations as well.

In both cases, an excessively narrow exemption from the registration requirement has been granted, concerning active substances (meeting certain legislative criteria) used "only" in a biocidal or plant protection product. This means a company using an active substance in any other application (including in other parts of the life sciences sector) will not benefit from an exemption. In short, any dual use nullifies the possibility of relying on this exemption, making it much less effective than would appear on first reading and certainly less effective than exemptions granted by REACH for other substances that are similarly separately regulated (for example, food substances).

The guidance document on registration fails to acknowledge the limitation created by the "only" phrasing of the exemption and, as appropriate concerning other exemptions without this phrasing, would allow splitting of tonnages with registration required only for the quantity of non-PPP or non-biocidal product uses (rather than requiring registration of the total tonnage where there is dual use).

While the guidance produces a more commercially acceptable result, it could render company registrations applying it subject to legal challenge by either/both:

- Aggressive member states.
- Commercial competitors who are placed at a competitive disadvantage (because, for example, the splitting of volumes by a competitor brings it into a lower tonnage group and hence subject to lesser data requirements and more time to register).

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The pesticides exemption uniquely (not biocides) is drafted so as include co-formulants, but the conditions attached to co-formulants being exempted are in fact impossible to fulfil under the current regime established by Directive 91/414/EEC - a problem acknowledged by the guidance document on registration. It is to be hoped that the forthcoming revision of the Directive (already underway) will address this issue, though this would create an inconsistency with the biocides exemption which does not mention co-formulants.

Additionally, even in those narrow situations where a biocide or pesticide manufacturer or importer satisfies the criteria for the registration exemption, it will still have to participate in the SIEF for that substance, in which data-sharing is mandatory (*see above, Data and cost sharing*). This puts at risk proprietary data which is not currently required to be shared under Directives 98/8/EC or 91/414/EEC, and data owners will have to be attentive to ensure that data recipients under REACH do not try to use that data in other contexts, for example, to support national authorisations for pesticides and biocidal products in the EU and beyond.

Careful consideration will need to be given to the dual use problem and related issues created by REACH. There is a compelling case for amendment of the REACH text to remove the unjustified and arguably discriminatory burden it places on this sector.

It should also be noted that substances used in biocides and pesticides are exempt from REACH's authorisation provisions. Active substances used in other applications will, however, potentially be subject to authorisation and restrictions.

Food or feedingstuffs

REACH obligations on registration, provision of information in the supply chain, DUs, evaluation and authorisation, do not apply to substances used in food or feedingstuffs. This includes food and feed additives, food flavourings and animal nutrition substances, as regulated under the specified EU legislation.

It is important to note that the substance must actually be used in food or feedingstuffs to benefit from the exemption. If it is used in another application (not subject to exemption under REACH) the full effect of the regime still applies. Where there is dual use (a food/feed use and a non-food/feed use) only the tonnage used in the non-food/feed context will be subject to REACH requirements, as with any other substance.

It is also notable that food/feed uses are not exempted from the REACH provisions on restrictions. REACH introduces a new procedure for adoption of restrictions, coming into force on 1 June 2009. It will be necessary to monitor how this operates as it includes the possible use of a fast track procedure for adoption, and restrictions are not linked to the duty to register a substance so may affect substances in volumes below the one tonne registration threshold.

Medicinal products (pharmaceuticals)

REACH obligations on registration, DUs, evaluation and authorisation, do not apply to substances used in medicinal products for humans or animals that are within the scope of the following:

- Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Directive 2001/82/EC on the Community code relating to veterinary medicinal products.
- Directive 2001/83/EC on the Community code relating to medicinal products for human use.

The substance must actually be used in those contexts covered by this legislation and, if this is not the case, the full effect of the REACH regime applies.

The new restrictions procedure (*see above, Food or feedingstuffs*) also applies. There will be a large number of substances used by the medicinal products industry that are not used in the final product regulated by the above EU legislation, but are part of the production process. Those substances will not benefit from the broad exemptions noted in this section.

The guidance document on registration expresses the view that active and non-active ingredients (excipients) in the product will both benefit from the exemptions.

The REACH requirements on provision of information in the supply chain do not apply to medicinal products, within the scope of the EU legislation, that are preparations in a finished state intended for the final user.

Medical devices

Narrow exemptions apply for medical devices. REACH requirements on provision of information in the supply chain do not apply to medical devices which are preparations in the finished state, intended for the final user if both:

- They are invasive or used in direct physical contact with the human body.
- EU law lays down provisions for their classification and labelling (which ensure the same level of information provision and protection as those in Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations).

Substances in medical devices already regulated by EU law will also be exempt from the REACH authorisation requirement.

As regards authorisation under REACH, the European Commission will not consider the risks to human health arising from the use of a substance in a medical device regulated by EU medical devices legislation. A large number of medical devices will be classified as articles, and the rules relating to these should be studied closely (*see above, Substances in articles*).

Cosmetic products

Substances used in cosmetic products (regulated by Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (as amended)) benefit from some limited exemptions:

- REACH requirements on the provision of information in the supply chain do not apply if the cosmetic products are preparations in the finished state, intended for the final user.

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- CSRs (*see above, Content of registrations*) do not need to include consideration of the risks to human health from cosmetic products.
- A narrow exemption from REACH's authorisation requirements also applies under certain conditions.
- Restrictions provisions do not apply as Directive 76/768/EEC already fully deals with these.

Certain substances used in life science products

Substances listed in Annexes IV and V of REACH are exempt from registration. Many of these listed substances are used in life sciences products, including:

- Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
  - a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
  - a substance solely intended to provide a specific physicochemical characteristic functions as intended.
- Substances occurring in nature (with certain exceptions) if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances (as amended).
- Basic elemental substances for which hazards and risks are already well known (hydrogen, oxygen, noble gases (argon, helium, neon, xenon), and nitrogen).
- Ascorbic acid.
- Glucose.
- Sucrose.
- Glycerol stearate.
- Carbon dioxide.
- Carbon.
- Water.
- Various oils (sunflower, linseed, corn, rape, castor, and so on).
- Dextrin.
- Starch.
- Various fatty acids.

ACTION ITEMS

It is clear that REACH imposes significant and complex obligations across the supply chain for life sciences products. This overview is necessarily brief and incomplete, so it is essential for companies to assess and understand all of the requirements applying to them and their supply chain and to prepare to comply. In summary, immediate action should include the following:

- Prepare an inventory of substances placed on the EU market or the manufacturer in the EU.
- Define a strategy focused on opportunities for reducing the financial and administrative burden of REACH (by, for example, directing imported tonnages through different legal entities where possible).
- Verify REACH requirements for each substance and the sufficiency of own data on each substance, having regard to the total data needed according to the volume band of the registrant and substance classification.
- Anticipate REACH SIEFs for each substance and how to meet own and other parties' data needs (sharing of existing data/costs, generation of necessary new tests/data, joint registration criteria).
- Consider partnerships/consortia to manage data/cost sharing and protection of confidential business information. If a non-EU manufacturer, decide whether to use an "only representative".
- Identify other parties in the supply chain and respective REACH responsibilities and confirm that each intends to comply (DUs particularly to confirm registration /authorisation upstream for your uses).

The authors' experience in assisting companies to understand and achieve compliance with other EU substance control regulations confirms that early action is essential.

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