doi:10.2533/chimia.2006.672 CHIMIA **2006**, *60*, No. 10

Chimia 60 (2006) 672–676

ISSN 0009–4293

Do I Have to Register My Substances for REACH? The Impact of REACH on Swiss Chemical Manufacturers

Craig A. Barker*

Abstract: The developing European legislation on REACH is one of the major changes to chemical control legislation seen anywhere in the world for over two decades. Not since the introduction of substance inventories and developments for the notification of new substances have there been such significant changes. The proposed changes will have consequences on the global industry and not least on the Swiss industry due to its clear association and proximity to the European Community. Ciba Specialty Chemicals has been associated with the development of the REACH requirements over many years as we have an invested interest in ensuring that we can meet the requirements of REACH in the most cost effective manner. Swiss companies associated with products being supplied to the EC will need to understand the requirements of REACH, especially with regard to the registration of the chemical substances they contain. Failure to do so may lead to significant financial consequences not least the ability to market their product.

Keywords: REACH · Swiss Chemical Industry

Introduction

The European Council's proposal of the 13th December 2005 [1], now superseded by the Councils Common Position 27.6.06 [2], outlines in detail the aims, scope and application of the proposed regulation concerning the registration, evaluation, authorisation and restriction of chemical, most commonly referred to as REACH. The basic requirements of REACH have not changed significantly from those defined by the European Commission in October 2003 [3].

The main emphasis of REACH remains the requirement to register substances manufactured, or imported into the European Community, the evaluation of substances to define if further information or control is required, authorisation of uses for certain substances and finally authorisation's counterpart requirement, the restriction of some substances and their applications.

Clearly, the later requirements will not function as intended without the correct implementation of the sections related to registration. This also includes exclusions and exemptions as these play an important role in defining the total workload and the focus on concern chemicals.

The registration requirements must be unambiguous and offer clear advice to those required to undertake this task. It must be ensured that best use is made of available data, especially those data derived from animal studies, and that those owning such data are compensated for their use, without the need for armies of accountants to make this function.

It is expected that with the Council's common position being agreed, the second reading in the European Parliament can take place towards the end of 2006. If this is correct, the legislation should be in statute before the middle of 2007. Much though still needs to be undertaken to define the required guidance to interpret REACH. Whether this guidance can be completed before the start of the pre-registration period, which begins twelve months after the implementation of REACH, is far from certain.

Ciba Specialty Chemicals' geographical situation in Europe, with its locations in Switzerland and a significant manufacturing base in the EC requires the company to be involved as both manufacturer and importer within the context of REACH. Being a specialities manufacturer means that most of our registration work could be conducted in the later stages of the phase-in registration period, due to the smaller quantities we utilise. It also means that we will have many substances to register owing to our large portfolio. In order to make best use of our resources we will need balance the workload as to when we register our substances and not just undertake the work as defined by the regulation. As a company, we have been evaluating the best path forward when it comes to REACH for a number of

*Correspondence: C.A. Barker
Global Head Regulatory Affairs
Ciba Specialty Chemicals Inc.
Klybeckstrasse 141
CH-4002 Basel
Tel.: +41 61 636 25 61
Fax: +41 61 636 59 70
E-Mail: craig_anthony.barker@cibasc.com

years. It is still difficult however, to assess just how the supply chain will react once the regulation comes into force. It should be expected that peer pressure from within industry will play a significant role in defining when registrations will be undertaken and not just defined by the legal requirements.

REACH will affect the global economy due to the changes it introduces. This will happen not only within the chemical industry but also, anywhere chemicals are utilised. The consequences for the Swiss industry, due to Switzerland's island position in the sea of the European Community, will be significant. Swiss companies who wish to make full use of their unique political geography should evaluate the many advantages they have over their EU-based counterparts. If Swiss companies utilise the opportunities brought by REACH to their best advantage, the Swiss chemical industry will continue to be a strong player in the European chemical market.

REACH Registration Requirements

General Exemptions

Although, for the vast number of substances in commerce within the EC, there will be a need for registration, there will be a number of substances or applications for which REACH will not or only partially apply. The main areas related to total exclusion from REACH are somewhat limited and this is understandable if there needs to be consistency across the Member States. This ensures the functioning of the internal market and minimises the introduction of national requirements for those substances or their uses that are outside the scope of REACH. The REACH requirements do not apply to the following; radioactive substances, substances under customs supervision, non-isolated intermediates, the carriage of dangerous substances and preparations by road, rail, inland waterways, sea, and air; wastes, and certain substances defined by EC Member States as being of interest for national defence. Significant for Switzerland are the provisions for those substances under customs supervision, where they may be brought or stored in the EC, under defined conditions, without falling under the requirements of REACH. Clearly, the ability for transportation through the Community's Member States without having to register under REACH supports the free movement of Swiss raw materials or final products through the EC to its major ports.

Certain substances or their applications will also be exempt from the requirements of registration, namely; substances on their own or in preparations manufactured in the EC or, where any EC importer, imports a substance either on its own or in a preparation below one tonne per year. This one tonne threshold is one of the most significant features of REACH when related to a need to register. For the first time in twenty-five years, a reasonable commercial evaluation can be undertaken on new substances within the EC without an expensive registration being undertaken prior to the supply and where there is no surety of a positive commercial outcome.

Furthermore, polymers do not require registration under REACH. Their monomers or other substances chemically bound within the polymer matrix at levels above 2% by weight will require registration, should a monomer or substance *per se* exceed the one tonne per year threshold. As the subject of polymers has been a long and somewhat unfinished debate within the development of REACH, a separate section on polymer registration is offered later in this text.

The one tonne threshold also has a relationship to articles, that is, substances or preparations that during production are given a shape, surface, or design that determines its function to a greater degree than does its chemical composition.

Any *producer* in the EC or any importer of articles will be required to register any substance contained in the said articles if the quantity totals are more than the one tonne per year and the articles are intended to release the substance under reasonably foreseeable conditions of use. How exactly these requirements will function is still open to interpretation. As a typical example of an article that intends to support release, let us consider the ballpoint pen. Clearly, the casing of the pen does not, in normal use release substances. The ink it contains however, is an intended release. Therefore, any substance within the ink that, if imported, above one tonne should be registered. Taking this position to be correct, an importer of ballpoint pens from Switzerland into the EC must know how many pens they import and calculate the quantity of every component of the ink to make sure they do not exceed the one tonne threshold. If above one tonne, the registration of the substance in the ink must be registered by the importer for the correct tonnage level.

The importer must not forget that the substances in the ink may also be in other articles they import, for example in whiteboard markers. The substances from these articles must be added to the quantities of substance in the ball-pens in order to define the total amount of the substance imported. If this is regarded as a simple example of a normal supply chain for articles entering the Community I personally, see little chance of importers meeting the registration requirements without a thorough and extremely expensive analysis of their value chain and the associated substances. What is not yet clear and may well take a legal determination is whether an importer who cannot guarantee they can be compliant with the requirements must cease import.

This complete area brings with it many deep routed problems for companies who wish to obey the requirements of REACH but cannot, either due to a lack of understanding or the overwhelming financial considerations one must incur to ensure total compliance.

For articles not intended to release substances but meeting the other conditions related to articles with intended release, there are specific requirements that may include registration. For these articles where the contained substances in question meet the criteria for Annex XIV listing (candidate list for authorisation), together with them being present in the article above a 0.1% by weight threshold, a decision regarding the registration of these substances will be taken following an assessment undertaken by the Agency. These assessments will be conducted for substances possibly released from articles and follows the submission of a notification. The notification takes the form of a submission to the Agency of certain core information on the producer or importer's identity, the registration numbers, if known, identity of the substance, a brief description of the use and the tonnage range. There are no requirements for such a notification when the producer or importer can exclude exposure to humans or the environment during reasonably foreseeable use including disposal.

Other substances or applications exempt from registration are medicinal products for human or veterinary use, food and feeding stuffs including any additives or flavourings and animal nutrition products.

Further exemptions from registration under REACH are for those substances included in Annex IV. These are the substances generally regarded as causing minimum risk due to their intrinsic properties. Annex V also exempts certain substances, as these are deemed inappropriate for registration, for example, the substance formed following a chemical reaction when an antioxidant acts as intended or the hydrated form of a substance.

Substances on their own or in preparations, registered then exported from the EC and re-imported by an actor in the same supply chain may be exempt from registration, if it can be shown that the re-imported substance is the same as that exported and they have met the provisions related to safety data sheets or where a safety data is not required for the information that must be communicated down the supply chain. This exemption is especially useful to Swiss companies where their active components are manufactured in the EC and sent to Switzerland for formulation before being supplied to the EC market.

Substances on their own, in preparations or articles, which have been registered and *recovered* in the EC and can be shown to be the same as the substance registered may be exempt from registration if, like exported and re-imported substances, they also meet the requirements relating to communication down the supply chain.

For plant protection and biocidal products meeting the appropriate European Directives, these shall be regarded as registered under REACH for those applications. Care must however be taken to ensure that these products do not have a dual use, as the alternative use would require registration under REACH in accordance with the quantities manufactured or imported for that specific use.

For substances notified as new substances, under Directive 67/548/EEC, the notification shall be regarded as a registration under REACH and the substance will be assigned a registration number. However, if a quantity threshold under REACH for the notified new substance is exceeded, the substance will require an update and the data requirements equivalent to the appropriate threshold in REACH, together with data required in all the lower thresholds unless already submitted must be supplied. Basically, these substances would then fall completely under the requirements of REACH.

Substances manufactured or imported into the Community for the purpose of product- and process-orientated research and development by the manufacturer or importer or in co-operation with listed customers, do not require registration for a period of five years. The manufacturer or importer shall notify the Agency of certain information as detailed in Article 9.2 of the Council's proposals. The Agency shall undertake a completeness check and assign a notification number and any conditions they perceive as being needed to ensure safe handling. The notifier may request, with good reason, an extension for a further five years for general substances or ten years for medicinal products.

The advantage a Swiss manufacturer has with regard to this situation is that EC manufacturers will, in future, have to request a PPORD for substances new under the definition of REACH even within their own facility. This is due to the legal change brought about by the REACH regulation. 'Placed on the market' was previously the point of initiation for such requirements. Under REACH, the rule will be 'manufactured or imported'. Process development, where new substances above one tonne are formed could perhaps be more easily undertaken in Switzerland rather than the EC.

Finally, although on-site isolated intermediates or transported isolated intermediates are not exempt from registration the requirements are limited. The latter type, transported intermediates, may hold significant benefits for Swiss manufacturers as long as the European Commission agrees that the definition, as stated in the text of the regulation, does allow for *transported intermediates* to be defined also for substances supplied not only to the EC but also from the Community.

Pre-registration

For substances or their applications not exempt from REACH or the registration requirements, *per se*, they will require registration. Those substances, including intermediates, meeting the provisions for phase-in status, that is:

a) substances that are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
b) were manufactured in the EC, or the countries acceding to the EU at least once during the fifteen years prior to the entry into force of REACH and not placed on the market. *(A typical example of this would be a substance manufactured in the EC then totally exported to Switzerland without re-import)*;
c) were placed on the market in the Community, or in the countries acceding to the European Union before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but do not meet the definition of a polymer as set out in this Regulation. *This reference relates to the no-longer-polymer substances*.

In order to obtain *phase-in* status for such substances the potential registrant, or a person representing him must pre-register the substances 12 to 18 months after entry into force of REACH by sending to the Agency the following information:

i) The name of the substance
ii) Name and address for the contact person
iii) The proposed deadline for registration/tonnage band
iv) Potential read-across/grouping substances or QSAR support information

Should this pre-registration not be completed within the required period, except in cases where the manufacture or import of a substance meeting the phase-in criteria is done for the first time, the potential registrant would lose their phase-in status and would need to register immediately.

For those substances meeting the phase-in criteria but manufactured or imported for the first time after the 12 to 18 month period has elapsed you will have up until six months after your first manufacture or import to pre-register. This must though be no later than twelve months before the relevant registration deadline.

A consequence of submitting a pre-registration is that you shall be required to participate in a *substance information exchange forum* SIEF.

SIEF is designed to facilitate the exchange of information between manufactures and importers and avoid duplication. It is also hoped to support the agreement on classification and labelling.

The timeframes related to the SIEF are extremely onerous and companies will need to define early what required data they hold and what further information they need.

Registration Requirements

The registration requirements under REACH are based upon a mixture of specific information related to quantity thresholds and timings based upon the same quantity thresholds or specific concerns such as carcinogenicity. The Table indicates the data requirements and the standard timing for registration. It further indicates when a chemical safety report should be included in the registration dossier.

Table. Data requirements for different production volume ranges

Tonnes	**1–10**	**10–100**	**100–1000**	**>1000 R50–53 >100 tonnes CMR >1 tonne**
Data - Annex	VII non-phase-in & phase-in Annex 1c VII physicochemical phase-in non-Annex 1c	VII & VIII	VII–VIII + testing proposal IX	VII–VIII + testing proposal IX & X
CSR	No	Yes	Yes	Yes
Time after Introduction	11 years	11 years	6 years	3 years

The actual quantities to be used are those defined at least once following entry into force of the regulation.

It should be noted that above 100 tonnes, the dossier should also include a proposal for further testing and that testing should not be conducted without the approval of the Agency. This is one of the initial tasks of Evaluation under REACH.

The basic data requirements for the registration in addition to the data needs are:

Registrant:
- Name, address, telephone number, fax number, and E-Mail address of the registrant
- Contact person
- Location of the registrant's production and own use site, as appropriate (*not required for non-EC manufacture*)

Substance identity:
- Name or other identifier of each substance
- Name in IUPAC nomenclature or other international chemical name
- Other names (usual name, trade name, synonyms)
- EINECS or ELINCS number (if available and appropriate)
- CAS name and CASRN (if available)
- Any other identity (if available)
- Information related to molecular and structural formula of each substance
- Molecular and structural formula (including Smiles notation, if available)
- Information on optical activity and typical ratio of (stereo) isomers (when appropriate)
- Molecular weight or molecular weight range

Composition of each substance:
- Degree of purity (%)
- Nature of impurities, including isomers and by-products
- Percentage of (significant) main impurities
- Nature and concentration any stabilising additives
- Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
- High-pressure liquid chromatogram, gas chromatogram
- Description of the analytical data

Information on manufacture and use (information on non-EC manufacture is not required):
- Manufacture/imports in tonnes per manufacturer or importer per year for:
- The calendar year of the registration (estimated quantity)
- In case of a manufacturer: Brief description of the technological process used in manufacture
- An indication of the tonnage used for own use
- Form (substance, preparation or article) and/or physical state under which the substance is made available to downstream users including approximate concentrations in preparations and quantities of the substance in articles.
- Brief general description of use
- Information on waste quantities and composition of waste resulting from production and uses in the EC
- Uses advised against

Hazard classification of the substance and resulting hazard label:
- Any specific concentration limits

Guidance on safe use consistent with that in the Safety Data Sheet including:
- First-aid measures
- Fire-fighting measures
- Accidental release measures
- Handling and storage
- Transport information

Where a chemical safety report is not required, add the additional information on:
- Exposure controls/personal protection
- Stability and reactivity
- Disposal considerations
- Information on recycling and methods of disposal for industry
- Information on recycling and methods of disposal for the public

Information on exposure for substances registered at 1–10 tonnes

Main use category:
- a) Industrial use and/or b) professional use and/or c) consumer use

Specification for industrial and professional use:
- a) Closed system and/or b) inclusion in matrix and/or c) non-dispersive use and/or d) dispersive use

Significant route of exposure:
- Human exposure:
  - a) Oral and/or b) dermal and/or c) inhalation
- Environmental exposure:
  - a) Water and/or b) air and/or c) solid waste and/or d) soil
  - Pattern of exposure:
  - a) accidental/infrequent and/or b) occasional and/or c) continuous/frequent

A formal Chemical Safety Report will be required for substances registered above 10 tonnes per year. Intermediates will not require a CSR.

Rules for Non-phase-in Substances or Substances Not Pre-registered

The potential registrants of non-phase-in substances or substances meeting the criteria for phase-in status but have not been pre-registered shall enquire from the Agency if a registration has already been submitted. Upon a positive response from the authorities, the name of companies involved in the registration or potential registration will be disclosed to each other. The data on vertebrate animal studies and in certain cases information not involving vertebrate animals would be made available upon agreement of cost sharing where this is required. If the substance has not been previously registered, the registrant must file a registration with the Agency in accordance with the tonnage band requirements.

Use of an Only Representative

Rather like the present situation for new substances under 67/548/EEC with the sole representative, a manufacturer outside the Community who imports a substance on its own, in preparations or in articles may appoint an only representative within the EC to fulfil the obligations on importers. That is to say, the only representative can undertake the responsibilities of all importers from the same manufacturer and thus alleviate multiple registrations by several importers of the same substance. The only representative must meet the requirements placed upon him for keeping up-to-date information on quantities imported, customers, and safety data sheets. If these requirements are met, the importers within the same supply chain may be regarded as downstream users under REACH.

The use of such a system may support direct import of Swiss products into the EC and alleviate the number of registrations of the same substance. From experience with the sole representative scheme, this system is difficult to administer and does require the support of the importers to make the scheme function.

One worrying aspect of the scheme appears to be the omission of substances (monomers) in polymers thus not allowing importers of such substances in already synthesised polymers to participate. It is hoped that this issue can be rectified prior to the finalisation of the regulation or at least be allowed even though not clearly stated in the legal text.

Polymers and their Monomers

The draft text of the regulation clearly indicates that registration requirements do not apply to polymers. However it does, as already indicated, apply to monomers and substances chemically bound into the structure of the polymer if they are present above 2% by weight. For the importer of polymers the situation would appear almost impossible should they not have clear knowledge on the composition of the polymers and in many cases the support of the monomer manufacturer. One of the major talking points amongst polymer users in the EC is the term "already registered by an actor up the supply chain". As this is a clear change from what was originally stated in the Commission's text, it would appear to tie together those companies in a supply chain. What is not clear is what is defined as the supply chain and whether this means

that, it relates to a specific manufacturer of a monomer or to any such manufacturer of that monomer.

Clearly, polymer manufacturers in Switzerland would be best advised to decide on a clear strategy as to what to do about the monomers meeting the REACH requirements. One clear fact is that companies would not wish to be the sponsor of such registration dossiers should it mean that any other importer could make use of the registration without any recompense for the use.

From a personal perspective, the position on polymers would appear unsatisfactory to all involved. The EC polymer manufactures clearly wish to have the same competitive position as their non-EC counterparts and therefore have the monomers and substances above 2% registered. However, the ability for an importer of polymers to obtain the support required on the contained monomers and substances is untenable in most cases.

Post-registration

A major facet of REACH is the fact that the system is dynamic and requires continuous monitoring by the registrant. Any change to the status of the registration must be informed to the Agency. Such changes include variation in composition of the substance registered, change in the tonnage band of the substance or cessation of its manufacture or import, new uses or uses newly advised against, new knowledge on risks leading to a change to the safety data sheet, any change to the classification and labelling, changes to the chemical safety report. Proposals for additional testing or any changes to the granting of access to information in the registration must also be submitted to the Agency.

Determination as to Whether a Registration is Required

The most sensible manner for a company to define if their substances' require registration under REACH is to adopt a procedure similar to the following:

1) Define those substances they manufacture in, or import into the European Community (take care to ensure account is taken of raw materials directly imported by the company into the EC and the intermediates they synthesise).
2) From this list, determine which substances, either *per se* or due to their use, are exempt from REACH (care must be taken regarding substances of dual use).
3) Evaluate which substances or their uses are exempt from registration or require only partial registration, for example, intermediates.
4) Determine which substances they manufacture in, or import into the European Community at above the one tonne threshold (continuous evaluation).
5) Determine if the substances require a chemical safety report as part of the registration.
6) Determine the companies own strategy for the registration of the substances taking into account of such issues as potential problems with authorisation, the requirements of your customers – this may also require the early registration of substances to support a customer's strategy. The ease of data-sharing and consortia formation, the grouping of substances should also be taken account of in defining your registration strategy. Your commercial position in the market and your supported uses should also not be overlooked when defining the way forward. Not least, evaluate the advantages a non-EC company has, especially one with such close proximity to EC borders. These advantages should be exploited.

Conclusion

In conclusion, in order to continue and hopefully, develop the markets within the EC, a Swiss manufacturer supplying into any of the present 25 Member States should already have a reasonably good idea as to which substances they must register. They should know which raw materials their suppliers will register. They have or are developing a sound strategy for these registrations including, for example, who will act as registrant for their imports. For certain situations, a company may wish to keep the details of their supply-chain confidential, including such things as the use of toll manufacturers. In these cases, consider using a third-party company to handing the requirements to minimise information of relationships becoming apparent. Companies should evaluate whether they are making best use of their manufacturing units outside the EC (is it cost effective making a product in the EC when all the product is exported – can Swiss manufacture make things simpler)? Failure to at least develop such scenarios and determine strategies to deal with them could be extremely expensive and will probably negate their advantageous geographical position in Europe.

Received: August 28, 2006

[1] Council of the European Union, 15921/05, **2005.**
[2] Council of the European Union, Common position adopted by the Council (REACH); (7524/06) Luxembourg, **2006**, *http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf*
[3] Commission of the European Communities: Proposal for a Directive of the European Parliament and Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals.