

Client note

EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH")

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FURTHER INFORMATION

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EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH")

INTRODUCTION

The EU Regulation on the registration, evaluation, and authorisation of chemicals ("REACH") has been adopted and will enter into force on 1 June 2007. It will have direct legal effect in all EU Member States. REACH is a landmark overhaul of EU chemicals regulation – it will replace 40 existing legal acts to create a single control system that will affect most chemical substances manufactured, imported and used in the EU.

Whilst REACH is aimed primarily at chemicals and the protection of the environment, the definition of a "substance" falling within the scope REACH is very broad and will cover many substances manufactured, imported or used across almost all industry sectors. A substance means:

"...any chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used."

After REACH enters into force, it will take between 12 and 18 months for the main operational requirements to be applied. REACH will entail considerable planning and preparation for manufacturers, importers and users of chemical substances.

OVERVIEW AND MAIN OBJECTIVES OF REACH

The existing EU chemicals regulatory system is based on the distinction between "existing" chemicals placed on the EU market on or before 18 September 1981 and "new" chemicals placed on the market after that date. New chemicals are currently required to be notified and tested if they are produced in volumes above 10 kg per year, whereas most existing chemicals are subject only to basic data reporting requirements.

REACH imposes new obligations on industry to assume responsibility for ensuring and demonstrating the safe production, import, use and disposal of both new and existing chemical substances alike. The fundamental components of REACH are:

- **Registration:** To establish a registration system designed to provide basic hazard and risk information on both new and existing chemical substances whether manufactured in or imported into the EU.
- **Burden of proof:** To reverse the burden of proof on safety, moving it away from Member States' authorities to manufacturers and importers.
- **Downstream use:** To impose responsibility on downstream users requiring that they provide information on their uses of substances and associated risk management measures.
- **Restriction:** The Commission will continue to be able to restrict the use of certain dangerous substances at EU level, but REACH will introduce clearer procedures and allow for decisions to be taken more quickly than is currently.
- **Authorisation:** To establish an authorisation system under which a manufacturer, importer or downstream user may not place on the market for a use, or use himself, the most hazardous substances unless the use has been formally authorised.
- **Access to information:** To ensure greater transparency and openness for the public by providing easier access to relevant information on chemicals.
- **Agency:** To establish a European Chemicals Agency to facilitate the administration of REACH. The Agency will be based in Helsinki and is scheduled to become operational in June 2008.

The European Commission, in co-operation with stakeholders, is preparing technical guidance documents for industry and authorities to facilitate the implementation of REACH. The work is being undertaken within a framework of REACH Implementation Projects ("RIPs"), divided into 13 projects covering the main processes and requirements of REACH. The full package of guidance will not be available until the end of 2007. As a result, industry will be obliged to prepare for the new regime in the absence of some of the key guidance with the consequent risk of delays.

BUSINESS IMPLICATIONS

In addition to the compliance obligations and associated costs under REACH, manufacturers, importers and users of substances face the following secondary implications:

- **Potential material impact to supply chain:**
No substance subject to registration and/or authorisation may be lawfully placed on the market until it is registered and/or its uses authorised. Users of business critical substances may therefore need to educate and audit smaller suppliers to ensure that they comply with their obligations under REACH. This may be a particular issue for non-EU suppliers. Each actor along any particular supply chain should bring its substances to pre-registration if possible, thus enabling it to make maximum use of the transitional period for subsequent full registration.

There is a risk that suppliers may choose to withdraw substances from supply into the EU which could affect availability of starting materials. It was recently reported that two companies supplying intermediates to a major pharmaceuticals business required for production of two drugs have warned that they may no longer be able to guarantee supply. The Commission estimates that between one and two per cent of substances will be withdrawn because their continued production will not be viable.

- **Internal preparation and external communications:** Substantial internal planning and preparation is required to establish the extent of the obligations imposed on any particular business, and in compiling and submitting registration and authorisation dossiers. This will need to be done well in advance of the deadlines by which these obligations need to be fulfilled. Businesses will also need to consider the pros and cons of pre-registering substances and ensuring that pre-registration is done by the deadline if the the business wishes to benefit from the phase-in provisions.
- **Public access to information and intellectual property rights:** Certain categories of information submitted to the Agency will be publicly

- available on the internet in all cases, including, for example, physicochemical, toxicological and eco-toxicological test results. Certain other information, such as the identity of any impurities, will be made publicly available unless the party submitting the information can justify why publication is harmful to its commercial interests. A third category of information, including information on the precise use, function or application of a substance, will normally be kept confidential by the Agency, but there is no absolute bar to such information being made publicly available.

Although lobbying efforts by industry to restrict the categories of publicly available information have had some success, there remain serious concerns surrounding:

- data exclusivity
- the protection of intellectual property rights and commercially sensitive information
- the use to which information submitted in accordance with REACH may subsequently be put (including by competitors, the media, and in litigation), and
- the extent to which registrants of the same substance, or applicants for authorisation of the same use of a substance, will be required to actively share data (see above).

This is an area which industry and their legal advisers are looking at closely to ensure compliance whilst maintaining commercial confidentiality and protecting intellectual property rights.

- **Competition law:** REACH encourages registrants of substances to form consortia for the purpose of substance registration. The costs of registration are a strong incentive to jointly establish and submit registration dossiers. The members of such consortia must be wary of potential infringement of European competition law and take steps to minimise the risk of an infringement. For example, members must consider whether the consortium should be open to all potential registrants of the respective substance. Care should also be had to the nature of the information that is shared between members.

REGISTRATION – THE “NO DATA, NO MARKET” PRINCIPLE

The registration of substances is the key element of REACH. Substances subject to registration may not be manufactured or placed on the market until they have been registered (this is referred to as the “no data, no market” principle).

Manufacturers and importers must register substances manufactured or imported into the EU in quantities of one tonne or more per year. Registration involves submission of a detailed technical dossier containing information relating to matters including:

- identity of the registrant and substance
- manufacture and use(s) of the substance
- physicochemical, toxicological and eco-toxicological test results (and proposals for further testing where gaps in current knowledge are identified)
- classification and labelling.

The manufacturer or importer must also provide guidance on safe use. If the substance is manufactured or imported in quantities in excess of 10 tonnes per year, the manufacturer or importer is obliged to prepare an additional chemical safety report which requires detailed hazard assessments to be carried out and documented.

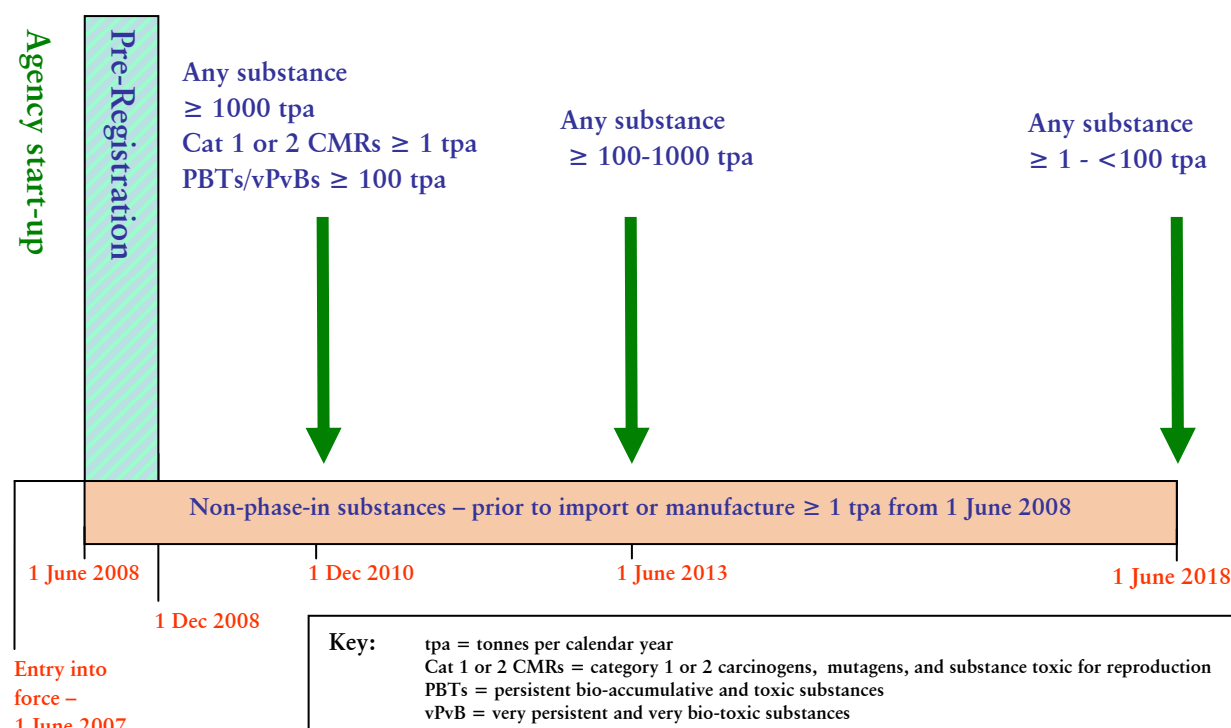
Phase-in substances and pre-registration

To facilitate transition to REACH, the registration provisions will be applied in stages to “phase-in” substances. Phase-in substances are those:

- listed in the European Inventory of Existing Commercial Substances (“EINECS”)¹, or
- manufactured in the EU at least once in the 15 years preceding entry into force of REACH (provided that if the substance was also placed on the market during this period, it was notified in accordance with Directive 67/548 on dangerous substances.).

A series of more relaxed registration deadlines apply to phase-in substances on condition that the manufacturer or importer pre-registers the substance with the Agency between 1 June 2008 and 31 December 2008. “Non-phase-in” substances will have to be registered prior to the point of manufacture or import on or after 1 June 2008.

The registration deadlines for pre-registered phase-in substances are dependent on the tonnage imported or manufactured, with tighter limits for substances classified as the most hazardous being: category 1 or 2 carcinogens, mutagens, and substances toxic for reproduction (“CMRs 1 or 2”), persistent bio-accumulative and toxic (“PBTs”), or very persistent and very bio-toxic (“vPvBs”)



¹ <http://ecb.jrc.it/esis/index.php?PGM=ein>

Data sharing

REACH encourages sharing of technical data, in particular information relating to the intrinsic properties of substances between registrants of the same substance in exchange for sharing the costs of such tests in a fair, transparent and non-discriminatory way. Refusal to share data could lead to penalties (these penalties are not specified in the Regulation and are required to be set by the Member States).

- **Multiple registrants:** Where a substance is intended to be registered by more than one manufacturer/importer, certain information including test studies is required to be submitted by a lead registrant acting with the agreement of the other assenting registrants. A registrant may submit information separately if a registrant demonstrates that:
 - it would be disproportionately costly for him to submit information jointly or
 - submitting the information jointly would lead to disclosure of commercially sensitive information likely to cause substantial commercial detriment or
 - he disagrees with the lead registrant on the selection of the information.
- **Pre-registration:** Persons who pre-register a substance must join a Substance Information Exchange Forum (“SIEF”), whose participants are required to share information, test data and existing studies in exchange for sharing the costs. There are no exceptions to data sharing for SIEF participants as there are for multiple registrants. This apparent disparity may be clarified by awaited guidance.

Substances in articles

REACH also pertains to substances contained in “articles”. For the purposes of REACH, an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. Most manufactured products will fall

within this definition although REACH will apply only to limited categories of substances in articles.

- **Registration:** There is a general obligation on importers and producers of articles to register a substance in the article where:
 - the substance is not already registered by an actor up the supply chain
 - the substance is present in the article in quantities of over 1 tonne per producer or importer per year, and
 - the substance is intended to be released under normal and reasonably foreseeable conditions of use.

According to draft technical guidance, a substance is intended to be released when the release is essential for the end use function of the article (for example, the release of ink from felt tip pens) or contributes to a quality or minor function of the article (for example, the release of perfume from a perfumed eraser).

- **Notification:** There is also an obligation on producers and importers of articles to notify the Agency where they manufacture or import articles that contain a substance which has not already been registered or authorised for that use and which would, on its own, need to be authorised, in cases when:
 - the substance is present in the article in quantities totalling over one tonne per producer or importer per year, and
 - the substance is present in the article above a concentration of 0.1 per cent weight by weight.

The obligation to notify does not however apply if the producer/importer can exclude exposure to humans and/or the environment during normal or reasonably foreseeable conditions of use including disposal. After receiving notification, the Agency may require such a substance to be registered if it considers that there is a risk to humans or the environment.

Preparations

As a general rule, the same obligations which apply in respect of substances on their own, also apply to substances in preparations (that is to say a mixture or solution composed of two or more substances). As such, any manufacturer or importer of a substance in a preparation in quantities of one tonne or more per year must submit a registration. There is no obligation to register the preparation.

Intermediates

REACH imposes an obligation on manufacturers and importers of intermediates to register intermediates manufactured or imported to the EU in quantities of one tonne or more per year. An intermediate is defined as a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. Although the registration requirements for intermediates are lighter than for other substances, registration will add a significant administrative burden on the industry sectors reliant upon use of multiple intermediates.

AUTHORISATION

Authorisation is a more onerous system applying to specified substances considered to be of very high concern of whatever quantity. The European Commission estimates that around 1,500 such substances are currently on the EU market. A candidate list of substances subject to the authorisation system has yet to be finalised, but expressly may include:

- category 1 and 2 carcinogens, mutagens, and substances toxic for reproduction
- persistent bio-accumulative and toxic substances
- very persistent and very bio-toxic substances, and
- substances causing probable serious effects to human health and the environment equivalent to those above, to be identified on a case by case basis.

It is thought that only around twenty substances from the candidate list will be brought within the

authorisation regime each year. As such, it will take decades for the all current substances of high concern to be subject to authorisation. Industry nevertheless fears that a candidate list will become a blacklist, automatically discouraging the use of listed chemicals. In order to lawfully market and use substances subject to authorisation, the manufacturer, importer or downstream use applicant must demonstrate to the European Chemicals Agency that the risk from the use of the substance concerned is:

- adequately controlled, or
- the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and there are no suitable alternative substances or technologies.

Each authorisation will be subject to review after a period to be determined on a case-by-case basis. On request by a consumer, any supplier of an article containing a substance subject to authorisation in a concentration above 0.1 per cent weight by weight shall provide the consumer with sufficient information, available to the supplier to enable safe use of the article, including, as a minimum, the name of the substance.

DOWNSTREAM USE

All downstream users of substances covered by REACH are required to consider the safety of the substances they use and take appropriate risk management measures. In addition they need to consider whether substances with which they are supplied will be registered and/or authorised as necessary such that their supply chain will not be jeopardised.

When a chemical safety report is submitted by a registrant, it will identify uses of the substance. Downstream users may only use substances that are included as an “identified use” in the substance registration. A downstream user would normally notify his supplier of the intended use and this information would be passed up the supply chain to the registrant. The registrant would then include the use as an identified use in the registration dossier.

A downstream user has the right not to identify a use to his supplier, but if the intended use of the substance is different from the uses communicated by his supplier, the downstream user may be responsible for performing its own chemical safety report. Downstream users will therefore have to consider carefully whether any advantage in not identifying their use up the supply chain outweigh the burden of performing a chemical safety report. Downstream users may also participate in a SIEF.

EVALUATION

- **Dossier evaluation:** The Agency will check at least five per cent of registration dossiers for compliance with registration requirements. Testing proposals will also be checked to prevent unnecessary animal testing and poor quality tests.
- **Substance evaluation:** The Agency may request further information from industry to clarify suspicions of risks to human health or the environment. Guidance will be developed on the prioritisation of substances for further evaluation.

EXCLUSIONS

- **Total exclusions:** Certain very limited groups of substances are excluded in total from the scope of REACH. These are:
 - radioactive substances (within the scope of Directive 96/29/Euratom)
 - substances subject to customs supervision
 - non-isolated intermediates (that is to say, intermediates that during synthesis are not intentionally removed (except for sampling) from the equipment in which the synthesis takes place), and
 - waste (as defined in the EU Waste Framework Directive).
- **Substances subject to other EU controls:** REACH expressly excludes from registration and authorisation requirements and obligations relation to downstream user and information in the supply chain, substances to the extent that they are used:

- in medicinal products for human or veterinary uses within the scope of Regulation 2309/93, Directive 2001/82, and Directive 2001/83 or
- in food or feeding stuffs in accordance with Regulation 178/2002 including:
 - as food additives in foodstuffs within the scope of Council Directive 89/107, or
 - as flavourings in foodstuffs within the scope of Council Directive 88/388 and Commission Decision 1999/217, or
 - as additives in feeding stuffs within the scope of Council Directive 1831/2003, or
 - in animal nutrition within the scope of Council Directive 82/471.
- **Specific substances:** Specific substances listed in Annexes IV and V to REACH are excluded from registration and downstream user obligations. Annex IV lists substances about which sufficient information is known that they are considered to cause minimum risk because of their intrinsic properties, such as glucose, lauric acid, and stearic acid. Annex V lists substances for which registration is deemed inappropriate or unnecessary bearing in mind the objectives of REACH, including:
 - basic elemental structures such as oxygen
 - substances which result from a chemical reaction incidental to exposure to environmental factors such as air or moisture
 - substances which result from a chemical reaction that occurs incidental to storage
 - substances which are not themselves manufactured, imported or placed on the market and which result from certain chemical reactions, such as those which occur when a stabiliser, flavouring agent, or colorant is used
 - by-products, unless they are imported or placed on the market themselves
 - the following substances which occur in nature unless they are chemically modified – minerals, ores, ore concentrates, natural gas,

liquefied petroleum gas, crude oil, coal, coke, and

- substances occurring in nature other than those listed above unless they are chemically modified or meet the criteria for dangerous according to Directive 67/548/EEC.
- **Polymers:** There is also an express exclusion from registration provided for polymers, broadly defined as a substance consisting of molecules characterised by the sequence of one or more types of monomer units.

However monomers in polymers will need to be registered.

- **Substances used for research and development:** The requirement to register substances shall not apply to substances manufactured or imported into the EU for the purposes of product and process orientated research and development (“PPROD”) for a period of five years, extendable to 15 years for substances used exclusively in the development of medicinal products if the manufacturer or importer can demonstrate that such an extension is justified.

PREPARATION CHECKLIST

All businesses should assess their portfolio of substances to verify the extent of their obligations under REACH and to ensure continuity of operations once the operative provisions of REACH enter into force. The following checklist provides a very brief guide as to the initial steps towards compliance that might be taken:

Manufacture/import

- Identify any substances that you manufacture or import into the EU in quantities of one tonne or more per year, including substances in preparations or articles.
- Determine whether the substances identified fall within the scope of REACH and need to be registered or notified.
- Ensure that substances are registered or notified by the relevant deadline. Determine whether the substance is a phase-in substance qualifying for pre-registration. For non-phase-in substances, this is at the point of manufacture and/or import on or after 1 July 2008.

- Gather information on the use of the substances that you supply to your customers. You must ensure that their uses are included in any registration dossier you submit. If you do not include their uses in the registration, there is a risk that they will terminate the supply.
- Consider pros/cons of joining consortia to reduce cost and administrative burden.

Downstream use

- Identify other substances that you use, prioritising those which are essential for the continuity of business operations.
- Liaise with suppliers to ensure that substances are registered where required by the manufacturer or importer by the relevant deadline and that your use of the substance is included in the registration dossier. If registrants do not include your uses in the registration, then operations may be at risk.

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