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REACH FOR NON-EU MANUFACTURERS[1]

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1. INTRODUCTION

1.1 The EU Regulation on the registration, evaluation, and authorisation of chemicals ("REACH") has been adopted and will enter into force on 1 June 2007.[2] REACH is a landmark overhaul of EU chemicals regulation – it will replace 40 existing legal acts to create a single control system that, subject to a limited number of exceptions, will affect most chemical substances manufactured, imported and used in the EU.

1.2 REACH will have direct legal effect in all EU Member States. It will impact the supply into the EU of substances used across almost all industry sectors, not just the chemicals sector. REACH also covers to a more limited degree substances contained in products supplied into the EU.

1.3 Whilst REACH is aimed primarily at the protection of human health and the environment, the definition of a "substance" falling within the scope REACH is very broad. 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*."

1.4 After REACH enters into force, it will take between 12 and 18 months for the main operational requirements to be applied. The key compliance date is **1 June 2008**. Considerable planning and preparation by non-EU manufacturers is required ahead of this date in order to ensure continued lawful supply of substances into the EU after 1 June 2008 and to manage other impacts, such as the use to which information submitted to EU and national authorities under REACH may be used by competitors, the media, and others.

2. OVERVIEW AND MAIN OBJECTIVES OF REACH

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

(a) **Registration:** A registration system requiring manufacturers and importers to submit a detailed technical in respect of all chemical substances manufactured in or imported into the EU in quantities of one tonne or more per annum. The principle underpinning registration is that industry, rather than national authorities as before, bear the burden of proving that substances are safe.

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[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF

(b) **Authorisation:** The most hazardous substances must not be used unless the use has been formally authorised.

(c) **Agency:** A new European Chemicals Agency will be established in Helsinki to facilitate the administration of REACH.

(d) **Access to information:** REACH demands potentially wide-ranging disclosure to the public, via the internet or upon request, of voluminous information submitted by industry to the Agency.

2.2 The European Commission is preparing technical guidance documents for industry and authorities in the form of REACH Implementation Projects ("**RIPs**").[3] The full package of guidance will not be available until the end of 2007, and as a result, industry may be obliged to prepare for the new regime in the absence of some of key guidance.

3. NON-EU MANUFACTURERS – "ONLY REPRESENTATIVES"

3.1 It is important to note that manufacturers outside the EU will not have direct obligations under REACH. However, the EU importers of non-EU companies which export to the EU substances, preparations or products containing substances will have significant obligations which will in turn impact non-EU manufacturers. In order to fulfil registration and other obligations, EU importers will for instance require information on substances from their non-EU suppliers.

3.2 Non-EU manufacturers may, however, appoint an "only representative" established in the EU to fulfil the obligations on importers under REACH. If they do so, they must inform all importers within the same supply chain, who then are free of obligations as importer of that substance. This will avoid potentially many different importers each having to submit an almost identical, but potentially expensive registration under REACH.

3.3 Potential advantages of appointing an only representative include: the non-EU manufacturer avoids having to disclose potentially sensitive information to its EU importer(s); and that it will relieve importers of their obligations to act as a registrant under REACH. The latter is likely to be attractive to some importers, particularly smaller ones or those who import only limited quantities and for whom the costs involved in registration could therefore be disproportionately high.

3.4 However, the only representative would cover the total volume of a substance being imported into the EU per year from the non-EU manufacturer and hence quantities would have to be aggregated. Depending on the tonnage involved, this could increase the reporting obligations and bring forward the deadline for registration if the total falls into a higher tonnage band (see below).

4. REGISTRATION – "NO DATA, NO MARKET"

4.1 The registration of substances is the key requirement under REACH. Importers are required to register substances imported into the EU in quantities of one tonne or more per year. Substances subject to registration may not be placed on the market until they have been registered (this is referred to as the "no data, no market" principle).

4.2 Registration involves submission of a detailed technical dossier containing information relating to matters including:

(a) identity of the registrant and substance;

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[3] http://ecb.jrc.it/reach/rip/

(b) manufacture and use(s) of the substance;

(c) physicochemical, toxicological and eco-toxicological test results (and proposals for further testing where gaps in current knowledge are identified);

(d) classification and labelling.

4.3 The amount of information to be submitted depends in part on the quantity of the substance imported, and a series of tonnage thresholds are set. If the substance is imported in quantities in excess of 10 tonnes per year, the importer is obliged to prepare an additional chemical safety report which requires detailed hazard assessments to be carried out and documented. Extensive guidance is expected concerning the preparation and content of registration dossiers and chemical safety reports.

4.4 Non-EU manufacturers should ensure that information is gathered on the uses of the substances that are supplied to EU customers, and that these uses are included in any registration dossier submitted by their importer or "only representative". If their uses are not included, customers may be responsible for performing a chemical safety assessment and, as a result, seek alternative supplies.

5. DEADLINES

5.1 As a general rule, substances imported into the EU in quantities of one tonne or more per year will have to be registered with the European Chemicals Agency prior to the point of import on or after 1 June 2008. However, to facilitate transition to REACH, the registration provisions will be applied in stages to existing or "phase-in" substances. Phase-in substances are those:

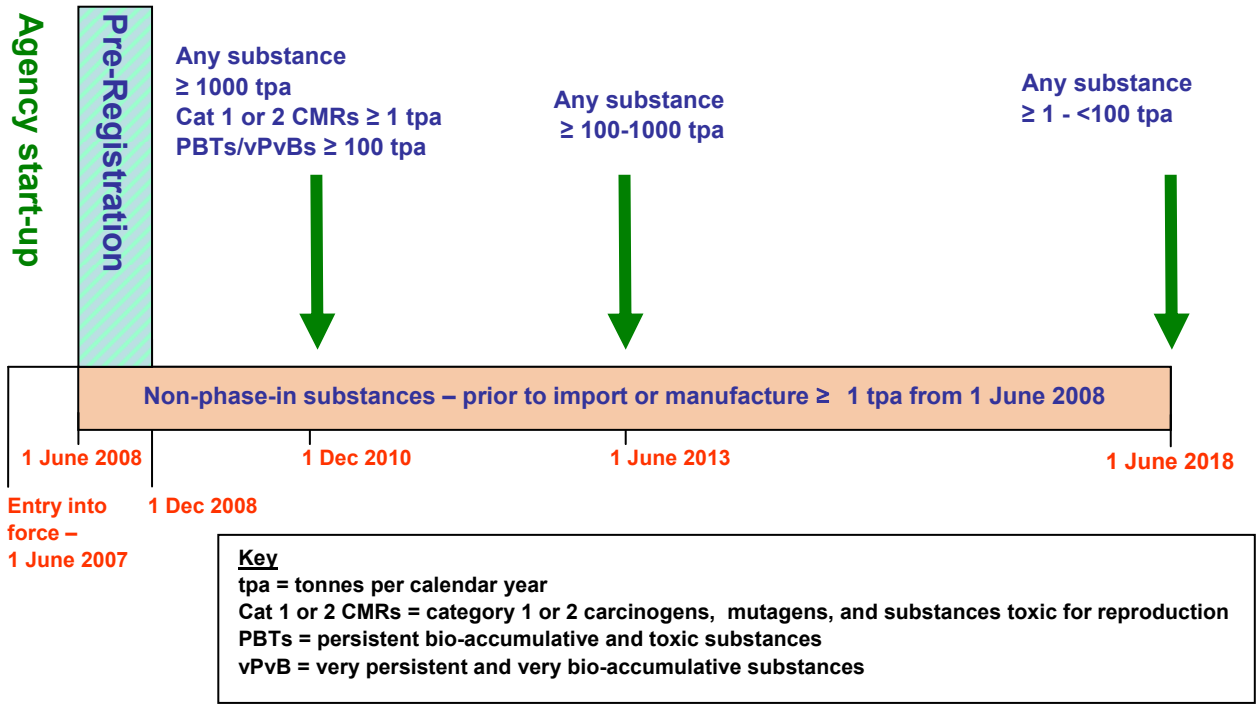
(a) listed in the European Inventory of Existing Commercial Substances ("**EINECS**"), or

(b) manufactured in the EU at least once in the 15 years preceding entry into force of REACH but not placed on the EU market[4];

(c) placed on the EU market prior 1 June 2007 and was considered as notified under existing dangerous substances legislation.

5.2 A series of more relaxed registration deadlines apply to phase-in substances provided that the importer or "only representative" pre-registers the substance with the Agency between 1 June 2008 and 1 December 2008. These extended deadlines are dependent on the tonnage imported, with tighter limits for the most hazardous substances, namely 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-accumulative ("**vPvBs**").

[4] http://ecb.jrc.it/esis/index.php?PGM=ein



5.3 Subject to concerns relating to participation in a Substance Information Exchange Forum ("**SIEF**") (see further below), we expect most non-EU manufacturers and importers will wish to ensure that the substances they intend to import into the EU on or after 1 June 2008 are pre-registered if possible so as to benefit from the extended deadlines for full registration.

6. SUBSTANCES IN PRODUCTS

6.1 REACH pertains to a limited extent 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*". In practice, almost all manufactured products will fall within this definition.

(a) **Registration:** There is a general obligation on importers and producers of articles to register a substance in the article where:

(i) the substance is not already registered for that use by an actor up the supply chain;

(ii) the substance is present in the article in quantities of over 1 tonne per producer or importer per year; and

(iii) the substance is intended to be released under normal and reasonably foreseeable conditions of use.

The draft technical guidance suggests that "intended to be released" will be interpreted restrictively. It states that a substance is intended to be released when the release is essential for the end use function of the article (eg the release of ink from felt tip pens) or contributes to a quality or minor function of the article (eg the release of perfume from a perfumed eraser).

(b) **Notification:** There is also an obligation on importers of articles to notify the Agency where they 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:

(i) the substance is present in the article in quantities totalling over one tonne per producer or importer per year; and

(ii) 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.

7. SUBSTANCES IN MIXTURES

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, the importer or "only representative" of a non-EU manufacturer 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 itself.

8. AUTHORISATION

8.1 Authorisation is an 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:

(a) category 1 and 2 carcinogens, mutagens, and substances toxic for reproduction;

(b) persistent bio-accumulative and toxic substances;

(c) very persistent and very bio-accumulative substances; and

(d) substances causing probable serious effects to human health and the environment equivalent to those above, to be identified on a case-by-case basis.

8.2 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 effectively become a blacklist, automatically discouraging the use of listed chemicals.

8.3 In order to lawfully market and use substances subject to authorisation, the importer or user must demonstrate to the European Chemicals Agency that the risk from the use of the substance concerned is:

(a) adequately controlled, or

(b) 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.

8.4 Each authorisation will be subject to review after a period to be determined on a case-by-case basis. On request by a consumer, a supplier of an article containing a substance subject to authorisation in a concentration above 0.1 per cent weight by weight must 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.

9. EXCLUSIONS FROM REACH

(a) **Total exclusions:** Certain very limited groups of substances are excluded in total from the scope of REACH. These are:

(i) radioactive substances;

(ii) substances subject to customs supervision;

(iii) 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

(iv) waste (as is very widely defined in the EU Waste Framework Directive).

(b) **Substances subject to other EU controls:** REACH expressly excludes from registration, evaluation, authorisation, and downstream user requirements substances covered by existing EU controls. Substances are exempt to the extent that they are used:

(i) in medicinal products for human or veterinary uses[5]; or

(ii) in food or feeding stuffs[6] (including as food additives in foodstuffs or flavourings in foodstuffs, or as additives in feeding stuffs, or in animal nutrition).

(c) **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, for example, substances occurring in nature such as mineral, ores, and crude oil, provided they are not chemically modified).

(d) **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 still need to be registered.

(e) **Substances used for research and development:** The requirement to register substances shall not apply to substances 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

[5] Within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC
[6] Within the scope of Regulation (EC) No 178/2002 and certain other specified legislation

development of medicinal products if the importer can demonstrate that such an extension is justified. The importer must however notify certain information to the Agency, including lists of customers.

10. PUBLIC ACCESS TO INFORMATION

10.1 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.

10.2 The competent Member State authorities shall inform the general public about the risk arising from substances where this is necessary for the protection of human health or the environment.

11. DATA SHARING

11.1 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.

(a) **Pre-registration:** Persons who pre-register a substance - including an importer or an "only representative" of a non-EU manufacturer - must join a SIEF. SIEF participants are required to share information and test data in exchange for a share of the costs of obtaining that data. There are no exceptions to data sharing for SIEF participants.

(b) **Multiple registrants:** Where the same substance is intended to be registered by more than one person, 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 only submit information separately if he registrant demonstrates to the Agency that:

(i) it would be disproportionately costly for him to submit information jointly; or

(ii) submitting the information jointly would lead to disclosure of commercially sensitive information likely to cause substantial commercial detriment; or

(iii) he disagrees with the lead registrant on the selection of the information.

(c) **Consortia:** The requirement to submit registration data jointly is likely to encourage 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 issues under European competition law and take steps to minimise the risk of an infringement. The formation of consortia for registration purposes is an area which industry members and their legal advisers are currently addressing.

12. BUSINESS IMPLICATIONS

In addition to the primary obligations and associated costs arising under REACH, non-EU manufacturers face the following secondary implications:

(a) **Internal preparation and external communications:** Substantial internal planning and preparation is required to establish the extent of the obligations arising in respect of any particular substance imported into the EU, 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.

(b) **Costs and commercial viability:** The costs involved with registering a substance are potentially significant. These costs will be borne by the registrant – ie the non-EU manufacturer's only representative (whose costs in practice will likely be met by the non-EU manufacturer) or the importer. Some manufacturers and importers may decide to withdraw substances from supply because their continued production will not be viable once REACH takes effect. The Commission estimates that between one and two per cent of substances will be withdrawn from supply for this reason.

The exact costs of REACH are difficult to predict and will vary between chemicals and depend on the amount of existing data. British-based oil company, BP has announced that it anticipates to register around 1,000 substances at an estimated cost of $60,000 per substance. Meanwhile, German-based chemicals company BASF has announced that it anticipates costs of EUR 500 million over 11 years.

(c) **Public access to information and intellectual property rights:** Although lobbying efforts by industry to restrict the categories of publicly available information have had some success, there remain serious concerns surrounding:

(i) data exclusivity;

(ii) the protection of intellectual property rights and commercially sensitive information;

(iii) the use to which information submitted in accordance with REACH may subsequently be put (including by competitors, the media, and in litigation); and

(iv) 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 members and their legal advisers are looking at closely to ensure compliance whilst maintaining commercial confidentiality and protecting intellectual property rights.

13. PREPARATION CHECKLIST

13.1 All non-EU businesses exporting substances on their own or in preparations or articles should assess their portfolio of substances to verify the extent of their importers' obligations under REACH and to ensure continuity of operations once the operative provisions of REACH enter into force.

13.2 The following checklist provides a very brief guide as to the initial steps towards compliance that might be taken:

(a) Identify any substances that you manufacture and export into the EU in quantities of one tonne or more per year, including substances in preparations or articles.

(b) Determine whether the substances identified fall within the scope of REACH and will need to be registered or notified by your importer(s).

(c) Ensure that substances are registered or notified by the relevant deadline. Determine whether the substance is a phase-in substance qualifying for pre-registration.

(d) Gather information on the use of the substances that you supply to your EU customers. You must ensure that their uses are included in any registration dossier submitted by your importer or "only representative".

(e) Consider the pros and cons of nominating an "only representative" in the EU.

For further information contact Mark Halligan at mark.halligan@lovells.com, Chair IPO Trade Secrets Subcommittee on REACH.