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PROTECTION OF TRADE SECRETS UNDER REACH

IMPLICATIONS OF THE INFORMATION SHARING REQUIREMENTS FOR NON-EU COMPANIES IMPORTING SUBSTANCES INTO THE EU[1]

Sarah Turner (of Counsel), Lovells LLP

1. INTRODUCTION

One of industry's major concerns about REACH so far is its treatment of confidential information.

Technical and commercially sensitive information must be provided to the European Chemicals Agency in order to obtain registration of a substance under REACH. Non compliance is not an option - failure to provide the necessary information for a registerable substance will mean that the substance cannot be placed on the market. Registrants are also encouraged to share certain information in order to share costs and to limit unnecessary animal testing. By providing information to the Agency and other manufacturers there is a risk that valuable confidential information may be used by them or disclosed to third parties to the detriment of the registrant or another party who owns the information.

This note considers the disclosure obligations under REACH and some of the steps registrants can take to protect their confidential information while complying with the Regulation. It should be read in conjunction with Lovells' note entitled "REACH for non EU manufacturers" which explains the basic REACH requirements in more detail.

2. WHAT INFORMATION MUST REGISTRANTS PROVIDE?

All registrations must be accompanied by a technical dossier and any registrations relating to quantities of 10 or more tonnes a year must include a chemical safety report.

2.1 The technical dossier

Under Article 10 (a), the technical dossier must include:

(a) the identity of the manufacturer(s) or importer(s);

(b) the identity of the substance;

(c) information on the manufacture and use(s) of the substance, which shall include all the registrant's identified uses;

(d) the hazard classification and labelling of the substances;

(e) guidance on safe use of the substance;

(f) information on exposure (for substances in quantities of 1 to 10 tonnes);

(g) information on physicochemical, toxicological and ecotoxicological properties of the substance (the precise extent of which will vary according to the tonnage in question);

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[1] Sarah Turner (sarah.turner@lovells.com) is Of Counsel in Lovells' Intellectual Property, Technology & Media group and is based in the firm's London office. She has a broad range of experience in both intellectual property disputes and commercial intellectual property and her current practice extends to both patent litigation and the protection of trade secrets.

The dossier may also contain:

(a) proposals for further testing of the substance; and

(b) a request as to which of the information the manufacturer or importer considers should not be made available on the Internet, including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

2.2 **The chemical safety report**

The chemical safety report is a chemical safety assessment of the substance being registered and must include:

(a) a human health hazard assessment;

(b) a human health hazard assessment of physicochemical properties;

(c) an environmental hazard assessment; and

(d) an assessment as to whether the substance is persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB).

If the registrant concludes that the substance meets the classification criteria for dangerous substances under Directives 67/548/EEC or 1999/45/EC, or if the substance is PBT or vPvB, the chemical safety assessment must also include:

(a) an exposure assessment; and

(b) risk characterisation.

Much of the information in these reports will be considered to be commercially valuable. While some information may be protected by other intellectual property rights, such as patents, the majority of the information will only be protected by the law of confidence. It is therefore important that registrants are aware how their information might be used and what they can do to protect it.

3. **DATA SHARING BETWEEN REGISTRANTS**

An immediate risk of disclosure of confidential information arises under the registrant data sharing obligations:

3.1 **General Obligation**: There is a general objective for registrants to share data to avoid unnecessary animal testing (Article 25).

3.2 **Specific Obligations**: The following specific data sharing obligations are also provided for under REACH.

(a) **Pre-registration**: Registrants for phase-in substances are required to share data within substance information exchange forums ("**SIEFs**") (Articles 29-30).

(b) **Registrants:** Registrants may also submit information jointly where there are multiple registrants for one substance through the preparation of joint submissions for registration (Article 11).

(c) **Subsequent Registrants**: Previous registrants are required to provide information involving tests on vertebrate animals to subsequent registrants of the same substance (Article 27).

3.3 **Exemptions**: Under Article 11 registrants may refuse to share data when preparing a joint submission where:

(a) the costs of sharing data would be disproportionate; or

(b) sharing data would be commercially prejudicial and likely to cause substantial detriment; or

(c) there is a disagreement with the lead registrant on the selection of information to be submitted.

Before embarking on a joint submission, a registrant should identify whether any of the information it may be required to submit could be considered to be a trade secret or otherwise commercially sensitive such that sharing it would be detrimental to the registrant's commercial interests. An early audit of the information that will be required for submission under REACH is recommended to identify and separate highly confidential information. Then steps can be taken to protect its confidentiality before it is inadvertently disclosed.

There are no exemptions in REACH from the other data sharing obligations identified above (i.e. those under Articles 29-30 and Article 27). Thus registrants for phase-in substances may be forced to share data as will early registrants in relation to animal testing. When sharing data with other registrants, since there are no express confidentiality obligations under REACH, companies should strongly consider imposing such obligations contractually in any SIEF or consortia agreements. While it may be implied that information provided to subsequent registrants under Article 27 is provided for the limited purpose of obtaining registration, again it would be prudent to set out in writing the terms on which the information is given.

4. DISCLOSURE BY THE AGENCY UNDER REACH

The majority of information disclosed under REACH will be held centrally by the Agency. The Regulation envisages that the Agency may be required to disclose this information as set out below. In some (but not all) cases the Regulation does expressly provide protection for commercially sensitive information. These are highlighted below:

4.1 To Competent Authorities

The Agency may share information with Member States' Competent Authorities ("**Competent Authorities**"), particularly through the Agency's database (Article 20(4)).

4.2 The following information will be available in the Agency's database:

(a) the registration dossier and the submission or registration number;

(b) the submission or registration date;

(c) the result of the completeness check; and

(d) any request for further information required for incomplete registrations, and the deadline set, in accordance with the third subparagraph of Article 20(2).

4.3 Further, Competent Authorities will be responsible for collecting and holding information from the Agency, registrants and others relating to substance evaluation and enforcement, which is very likely to be shared with the Agency and other Competent Authorities.

4.4 **Under REACH generally**

(a) Certain basic information will be made publicly available by the Agency on the Internet as a matter of course (Articles 77(2)(e) and 119(1)) and may include:

(i) the name in the IUPAC Nomenclature, for dangerous substances;

(ii) the name of the substance as given in EINECS;

(iii) the classification and labelling of the substance;

(iv) physicochemical data concerning the substance and on pathways and environmental fate;

(v) the results of each toxicological and ecotoxicological study;

(vi) any derived no-effect level or predicted no-effect concentration;

(vii) guidance on safe use;

(viii) analytical methods (if requested) which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

(b) The following information will be made available on the Internet unless the Agency is satisfied that disclosure would be commercially prejudicial (Articles 77(2)(e) and 119(2)):

(i) the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous, if essential to classification and labelling;

(ii) the classification and labelling of the substance;

(iii) the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1,000 tonnes or over 1,000 tonnes) within which a particular substance has been registered;

(iv) the study summaries or robust study summaries of the information referred to in paragraph 4.4(a) (iv) and (v) above;

(v) information, other than that listed in paragraph 4.4(a) above, contained in the safety data sheet;

(vi) the trade name(s) of the substance;

(vii) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;

(viii) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:

(1) as an intermediate;

(2) in scientific research and development; and

(3) in product and process orientated research and development.

(c) Under Article 120, information received by the Agency may be disclosed to any government or national authority of a third country or an international organisation in accordance with any agreement concluded between the Community and the third party concerned, provided that both the following conditions are met:

(i) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by REACH; and

(ii) the third party protects the confidential information as mutually agreed.

4.5 **"Commercially prejudicial" disclosures under REACH**

Under Article 118, the Agency would normally consider disclosure of the following information to undermine the protection of the commercial interests of the concerned person (and thus should keep it confidential):

(a) details of the full composition of a preparation;

(b) the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;

(c) the precise tonnage of the substance or preparation manufactured or placed on the market;

(d) links between a manufacturer or importer and his distributors or downstream users.

However, it should be noted that where urgent action is essential to protect human health, safety or the environment, the Agency may disclose this information.

5. **OTHER DISCLOSURE REGIMES**

(a) In terms of other disclosure regimes, the Agency is subject to:

(i) The EC Regulation on public access to information (EC 1049/2001) (the "**Public Access Regulation**") (Article 118). Under the Public Access Regulation, all European Community institutions, and any agencies which they establish, are obliged to make all of their documents accessible to the public. There are certain exceptions to this rule whereby documents do not have to be disclosed, for example in order to protect public security, defence, a person's commercial interests or intellectual property, legal proceedings and the privacy of individuals; and

(ii) The EC Regulation implementing the Aarhus Convention in respect of EC institutions (EC 1367/2006) (the "**Aarhus Regulation**"). The Aarhus Convention imposes binding obligations on states to ensure that "public authorities" facilitate public access to environmental information. "Public authorities" is widely defined and applies to Community institutions and bodies acting in a legislative capacity. "Environmental information" covers information related to a decision affecting the environment and analyses of the environment, including any information in any form on the state of the environment. The Aarhus Convention also creates active obligations to collect and disseminate information including product information, pollutant release and transfer information, and information relating to laws, policies and strategies.

(b) It should be noted that although the disclosure of certain information may be presumed to be commercially prejudicial under REACH (see paragraph 4.5

above), this may not be sufficient to prevent disclosure under these regimes, particularly given the various public interest tests. It is not possible to advise at this stage how the Agency will deal with what are potentially conflicting obligations under REACH on the one hand, and these disclosure regimes:

(i) Under the Public Access Regulation, the presumption is against disclosure where it relates to a commercial interest, legal proceedings/advice or inspections/investigations. Only where the public interest in disclosure overrides this presumption will information be disclosed.

(ii) Under the Aarhus Regulation, the presumption is reversed. Information will be disclosed unless the prejudice caused by the commercial interest etc, is sufficient to override the public interest in disclosure. Due to the broad definition of "environmental information" under the Regulation (which is likely to cover most information provided to the Agency under REACH), this is likely to be the applicable test in most circumstances.

6. DISCLOSURE BY COMPETENT AUTHORITIES

6.1 Under REACH

Under Article 123, Competent Authorities shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Agency will provide guidance for the communication of information on the risks and safe use of substances, in consultation with the Competent Authorities.

There is nothing in REACH specifying the type of information Competent Authorities may disclose or restricting the disclosure of certain types of information by Competent Authorities. It is likely that this will be determined by each country's national disclosure regime.

6.2 National Disclosure Regimes

Disclosure regimes vary significantly from country to country. The UK has probably the most open and accessible freedom of information regime in Europe (through, principally, the Freedom of Information Act 2000 (the "**FOI Act**") and the Environmental Information Regulations 2004 (the "**EI Regulations**")) and thus gives a good indication of the levels of disclosure which may be required.

In theory, access to environmental information should be broadly consistent across Europe by virtue of the Aarhus Convention and implementing Directives. However, in practice there appear to be significant discrepancies in the application of these laws across the EU.

6.3 In the UK

In the UK, the Department of Environment, Food and Rural Affairs ("**DEFRA**") is responsible for implementing REACH. DEFRA has nominated the Health and Safety Executive ("**HSE**") to be the UK Competent Authority, working closely with the Environment Agency and others to manage key aspects of the REACH system in the UK.

Under the FOI Act, there is a general right of access to information held by public authorities, subject to certain exemptions. Under the Act, any individual, including foreign nationals and companies, can apply for access to any information held by a public authority. For the purposes of the FOI Act, the HSE is a public authority. "Information" is widely defined and includes information on environmental and health and safety reporting.

Certain types of information are protected from disclosure under the FOI Act by exemptions contained within the Act. In addition, public authorities can refuse to grant requests for information which are vexatious or repeated.

The sections of the FOI Act which are of most interest to businesses are section 41 (exemption for information provided in confidence) and section 43 (exemption to protect commercial interests). The exemption under section 41 is an absolute exemption and imposes a common law duty of confidence on a public authority which prevents disclosure of any information held by a public authority which would constitute an actionable breach of confidence.

The section 43 exemption covers trade secrets and other information, the disclosure of which would, or would be likely to, prejudice the commercial interests of any person (including the public authority itself). This exemption is qualified, and is subject to the public interest test. Therefore, even if it is established that the disclosure of the information would prejudice the commercial interests of a person, or if the information is a trade secret, if the public authority judges that the balance of public interest is in favour of disclosing the information, the information will be released.

Guidance on the application of the public interest test has been published by the Information Commissioner in the UK. Factors which would encourage disclosure of information include furthering public debate on issues of the day, promoting accountability and transparency of decisions made by public authorities, promoting accountability and transparency in the spending of public money, allowing individuals to understand and challenge decisions made by public authorities which affect their lives and bringing to light information affecting public health and safety.

The EI Regulations, which allow access to all information relating to the environment, are arguably even more "disclosure-friendly" than the FOI Act. In particular, although the Regulations list categories of information (including confidential information) which may be exempt from disclosure, none of these enjoy an "absolute" exemption. Disclosure must still be made by DEFRA unless the public interest weighs in favour of non-disclosure.

There are some steps which registrants can take to ensure that disclosure under the FOI Act or EI Regulations is minimised, such as:

(a) Adopting the working assumption that all information provided to the Agency which is passed onto Member States' Competent Authorities could be released into the public domain.

(b) Consider seeking agreement from the Agency/HSE that they will recognise certain information supplied under REACH (whether by the registrant or by the Agency) as commercially sensitive or supplied in confidence.

(c) Ask the Agency/HSE to notify or consult them in the event that requests are made for information they have provided to the Agency or to the HSE.

7. CONCLUSION

REACH raises a number of issues in relation to protection of confidential information. How they play out in practice remains to be seen. While the Regulation does acknowledge that certain types of information to be provided under the Regulation may be kept confidential there are risks of disclosure of this and other information to a wide range of parties if registrants are not vigilant in protecting their interests.

Potential registrants should start to identify their commercially sensitive information now. It is important to have proper procedures in place before the registration process begins to regulate (where possible) disclosure and use of confidential information by the Agency and others to avoid costly mistakes later on.