Legal Backgrounder

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EUROPE'S "REACH" INITIATIVE WILL IMPACT TRADE SECRETS

by

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The European Union has passed the draft Regulation on Registration, Evaluation and Authorisation of Chemicals ("REACH") in a first stage of the European legislative process. Some conclusion can be drawn at this moment: (1) The REACH legislation will substantially influence the way companies will have to do business in Europe; (2) there are serious implications for confidential and proprietary data that are used to produce and test chemicals; and (3) there is still time to obtain changes or influence the drafting of implementing rules that can mitigate the confidentiality and proprietary data problems.

The next and final stage will likely be completed this summer. The legislation has a direct effect in all member states of the European Union and therefore does not have to be converted into national law. It will in all likelihood enter into effect in 2007. REACH is also the foundation of a new Chemical Agency, whose institution will probably take the process into 2008. Only with the establishment of this Agency can REACH be fully implemented.

This LEGAL BACKGROUNDER will briefly summarize the REACH proposal and identify and discuss the proposal's disclosure requirements.

REACH Overview. REACH replaces about 40 national and European legislative instruments, and aims to harmonize chemical authorization procedures. A number of EU Regulations and Directives remain in force, such as those on food additives and flavoring, pharmaceuticals, veterinary products, feed additives, and radioactive materials. Generally, REACH is not applicable to such products; however, the REACH proposal incorporates earlier grandfathered chemicals that now need to be registered, evaluated and authorized. In order to spread the burden over time (for all parties involved), Article 21 provides for submission periods of three to eleven years. The shorter period will apply for more dangerous or high tonnage products. Both manufacturers and importers will be required to register all chemicals (and compositions containing chemicals) produced or imported in volumes of one tonne or more per year, per party. Importers include any company that makes articles comprising chemical substances. Furthermore, downstream users in the EU have certain disclosure obligations as well. Thus, the REACH legislation will impact thousands of companies, worldwide.

With respect to "content," REACH makes a distinction in three categories of substances, also known as "Annex no." compounds. Annexes II and III name compounds that are exempted: (1) clearly safe and much used, like specifically named oils, sugars, amino acids and fatty acids; (2) accidental or by-products in a number of conditions; or (3) well-known inorganic products like minerals, gas condensates, oxygen and nitrogen gas. Annexes V-VIII relate to "normally regulated" substances, for which the tonnage amount per producer/importer or manufacturer is important, and defines the information to be supplied for substances in amounts, with

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threshold values of more than 1, 10, 100 and 1000 tonnes/year. For each category, more information is required. Annexes XII and XIII define criteria for compounds to be Persistent, Bioaccumulative or Toxic (PBT) or very Persistent or very Bioaccumulative (vPvB), or name substances subject to authorization.

These categories require different registration and information obligations. Downstream producers of compositions and articles have extensive obligations in case they use the third category, "potentially dangerous substances." It is expected that this will pressure companies to use safer substances.

Much discussion arose on the burdensome requirement of the registration procedure, and on the effect of the authorization procedure for (potentially) dangerous substances. The latter received significant attention because banning certain substances may not only be detrimental for certain companies, but will affect entire areas of industry. The result could be that only second best products would become available in the European Union, to the detriment of the consumer. The issue of trade secrets and compulsory information disclosure has triggered less discussion, as some of the obligations have only been introduced recently.

Issues in REACH on Information Disclosure. Rules on registration and data sharing are contained in REACH Titles II-V. They require industry to collect information, develop risk management measures, and provide safety information on substances.

When is Information to be submitted. A registration has to be filed for substances that may be in preparations or articles.[1] A bottom threshold is 1 tonne per year per substance per manufacturer or importer:

* Each manufacturer or importer should file a registration (i) in case of *substance*, (ii) in case the *substance is in a preparation*,
* Producers or importers of polymers shall register any *monomers used to make polymers* present in more than 2%.
* In case the *substance is in an article*, 3 rules apply: Registration is necessary in case the substance is intended to be released,

or, if the Agency has grounds for suspicion that the substance is released, and the release presents risk to human health or the environment, at request of the Agency,

or if present in more than 0.1% by weight for substances subject to authorization, or on a "watch list" (Art. 56.1), unless exposure can be excluded.

There are further requirements for "down-stream or up-stream users," (which are users within the EU)

Which Information is to be submitted The lists of required information include:

* identity and contact details of the producer or importer;
* identity of the substance;
* brief description of the use in the article or all uses;
* study summaries, or robust study summaries depending on the category

There is a continuous obligations on the registrants, to inform about changes of such information. Upstream and downstream users have a duty to pass on relevant information on use and products used, which duty includes the registry number, which bears with it the precise chemical name and the manufacturers.

Data sharing and avoidance of unnecessary testing. It is encouraged to jointly submit registrations, and share test data. Data sharing is subject to the next "rules":

* Results on animal testing have to be shared;
* Other test results may be shared and are subject to permission from the earlier registrant. However, by objecting to data sharing, the earlier registrant only can obtain an about six month delay, as the Agency is expected to virtually always grant access to the earlier data;
* Costs are to be shared, if the earlier registrant agrees in sharing the information.

A registrant may not join for reasons of costs or secrecy, but this requires explanation to the Agency. In

[1]Substance is used in stead of the more common word "compound;" Preparation is used in stead of the more common word "composition," which is any mixture of substances. In this article, the words "substance" and "preparation" are used throughout, to conform to REACH practice.

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practice, a new registrant is entitled to refer to earlier studies, if it can show its product to be substantially the same substance. Any submitted study summary information is freely available for later registrants after ten years. Additionally, potential, new, and earlier registrants are informed about each of their names and addresses if requests for potential new registration are filed, unless all test-data are freely available.

Information and secrecy. Article 116 defines what is normally not considered to be confidential: trade name or EINECS name; classification and labeling; analytical methods to detect the substance (if the substance is an Annex VII or VIII substance); and results of toxicological studies and results of physicochemical data, including pathway and environmental fate.

Article 115 defines which information normally is considered to be confidential. This is: details of the full composition of a preparation; the precise use, function or application of a substance or a preparation; the precise tonnage amount manufactured or placed on the market; and links between a manufacturer or importer and its downstream users. As is readily apparent, little of the definitions in articles 115 and 116 conform to the articles on disclosure requirements.

There is a third category of information, which *may* be kept secret, if the agency is convinced that publication of the data harms the commercial interest of the registrant. This information concerns study summaries and robust study summaries; in certain cases, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous; and the total tonnage band within which the substance has been registered. Subject to the same rule, a registrant, according to article 9, may indicate which information he wants to keep secret in his registration. These exceptions, however, are likely to be subject to a required fee, and it is unclear when the Agency accepts secrecy.

One further option is important to mention – Article 3a defines that for registration with multiple registrants and for data sharing, a company can appoint a third party. That party can perform all filing and communication with third parties, without mentioning the name of the client. Companies may in this way at least preclude that third parties know whose products the registration concerns (at the cost of hiring a third party to take on this task).

Article 7 requires information to be submitted (as a notification) for products used in product and process *research*, even though the product need not be registered. The information is largely the same as that required for normal registration. Yet, according to Article 7.9, the Agency will keep this information secret. This is interesting, as the legislators herewith acknowledge that all this type of information – in principle – can be subject to trade secret protection. Only in this specific case, however, have the legislators given full trade secret protection.

It should also be noted that the Parliament wanted much more information to become freely available. Hence, there are risks that in the future legislation process confidentiality may be further compromised.

Discussion: Two Critical Issues: 1. **Information on the Value Chain of Certain Substances, What Can be a Trade Secret**. It is necessary to disclose to the Agency the details of manufacturers, importers and uses of substances. Downstream users are obliged to either inform suppliers upon their use and/or to register the substance. Hence, much information is available within the Agency that potentially is accessible to third parties. However, some of this information actually represents trade secrets. Often, for more generally used substances, information on the value chain is not considered secret, nor will suppliers be interested in keeping uses secret. Nevertheless, it would be interesting for competitors to know whether specific potential new uses (in a new field of industry) actually materialize. Developments may be seen in patent literature, but a confirmation that something is put into practice (in substantial amounts > 1 tonne/yr) may be very relevant. In the more specialized chemical arena (fine chemicals or performance materials) the situation is drastically different: some products have only one or very few customers; also, it is often true that only very few suppliers are available. Thereby, the option to keep the name of the registrant secret is hardly helpful. Information on registered manufacturers and users, and the tonnage range, can be very valuable information for a newcomer. It is uncertain to what extent the Agency will accept arguments in confidentiality requests according article 116-1bis.

Furthermore, specific substances may be regarded as trade secrets by themselves. Even if a substance has

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an EINICS number, it still may be unknown that a product is made in substantial quantities (e.g. if made only for one specific customer). At the substance level, this may be rare; however, at preparation level, this is very common. For example, in specific binders for industrial paints, emulsifier compositions, or polymer compositions, it is very easy to enter in the >1 or >10 tonne area, even with an additive which is present in 1 wt%. Which additives are used is normally regarded and kept as trade secret. The same is true for the requirement to have any monomer used in a polymer to be registered if present in more than 2 wt%. A manufacturer of a preparation who wants to import in the EU will have to request his suppliers to declare that he has registered all monomers which are present in their polymers. Otherwise, the importer will need information about which monomers are used, and in which percentage (to get the correct tonnage band) in order to be able to register. The latter is a type of information that generally is considered a highly guarded trade secret.

Interestingly, the wording of Articles 115.1bis and 116 only partly conforms to the language of the articles on disclosure requirements. Thus, for the next years it will be unclear what route the Agency and the legislator will take in writing the implementing regulations.

2. Mandatory Data Sharing: "Compulsory Licensing" of Valuable Investment. The information to be supplied as study summaries or robust study summaries represents substantial investments in time and money. The Title on data sharing requires mandatory data sharing, with cost sharing as sole remuneration. With respect to cost sharing, it is unclear what is considered as reimbursable costs. Are only out-of pocket costs contemplated, or are fully integrated costs calculations accepted? Time spent by in-house regulatory and research persons, including overhead, are *de-facto* actual costs that companies bear when making a technical dossier. Yet, these in-house costs are often not very transparent (which is a requirement to have costs shared). Again, most likely, implementing rules or agreements between joint registrants will have to shed some light on this issue.

A more fundamental question is whether it is reasonable to give a follower a "half-price, no-risk" access to registration data. CEFIC, the European chemical industry trade group, had proposed to share only test data on vertebrates, but not to share non-vertebrate testing information. The first to take the decision to perform all the tests necessary for registration generally takes a several-year commitment with an uncertain outcome: (1) Testing may reveal that the substance was not as safe as hoped, which may render commercially or environmentally not viable to make and sell the substance; (2) if testing is acceptable, and a dossier is filed, the Agency may require further or other testing, creating time delays and cost increases, unforeseen at the beginning; and (3) by the time a substance is registered, market economics may have changed, so that the substance is no longer a viable product to make and sell. Such a registration process takes at least several years. In contrast, a follower has the certainty that someone else successfully completed the registration process, and apparently is still selling the products (otherwise the registration ceases to be effective). So, the worst that can happen to the follower is that he has to pay half of the price of the actual tests, as far as necessary for his purposes, and he will have to wait for up to six months. Hence, if the follower has planned well (as he will need these six months anyhow to prepare), he begins by requesting the consent to use earlier submitted test results. In course of that process, he will further learn of other registrants (manufacturers and users) which is of utmost interest. From the innovator perspective, this certainly will be judged as unreasonable as the information normally viewed as trade secrets are used. Careful planning for trade secrets will be necessary.

Conclusion. REACH requires a substantial amount of trade secret information to be disclosed, which will be or may be shared with other registrants, users, or potential registrants. Still much is to be defined in further rules. The mandatory character of data sharing leads to *de facto* compulsory licensing of know how, obtained in valuable investments by companies with very little remuneration. If companies wish to protect their trade secrets, they should seek proper advice. Also, it will be of utmost importance for industry to keep influencing the further legislative process. A substantial number of issues still are unclear, and the "details" which will have to be defined may strongly impact the detrimental effect of this legislation.

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