CONFIDENTIAL BUSINESS
INFORMATION (CBI) WITHIN THE
FRAMEWORK OF REACH

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REACH requires safety and exposure data, including new testing in some cases, on an estimated 30,000 chemicals that will be sold in Europe. In this context, protection of CBI is a real challenge. Moreover, the exchange of information between companies may increase the risk of breaching EC competition law. This report provides some insight into the ways chemical companies protect CBI. Exchange of information on both horizontal and vertical levels is analyzed with the aim of determining efficient tools to protect CBI and minimize the risk of breaching competition law.

The detailed information that is expected to be exchanged in the REACH framework is a concern for companies and may also affect their strategic products. For example, the information in the safety data sheet (SDS) may enable a company to guess who is supplying its supplier. This pitfall of the SDS could be a nightmare for many chemical companies since everyone is selling other company’s chemicals. “When filling in the SDS, the registration numbers of the substances in a preparation will have to be provided. Moreover, the identity of the manufacturer or importer, which was provided in the registration of a substance, shall be provided. If you are clever enough, you can make a link between the companies and the components of the preparation and find out which company produces such ingredient of the preparation. In other words, you can determine who produces what. What would then prevent a customer from directly contacting your supplier in order to reduce his costs?” asks Craig Barker, head of regulatory affairs at CIBA. REACH acknowledges that “links between a manufacturer or importer and his distributors or downstream users” shall be kept confidential (Article 118.2(d)). It can therefore be anticipated that the pitfall of the SDS may in certain cases violate Article 118.2(d). However, this issue is still open since the definition of the registration number is under discussion. “The European Chemical Industry Council (CEFIC) protests against any numbering system which allows the manufacturing or importing legal entity to be identified,” explains Uwe Wolfermeier, head of corporate product safety at Clariant. Nevertheless, it is still unclear whether a neutral registration number will be enough in order not to allow any more any connection to be made between a substance and a company and, as a result, to keep the SDS fully neutral.

System’s Flaws
Companies fear that competitors will be able to exploit the many flaws this new system still suffers from. As a recent example, two companies have pre-registered the entire EINECS inventory comprising over 100,000 substances, a practice that, according to ECHA, is in

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breach of REACH Article 3 (20) which defines 'phase-in' substances. The question arises as to whether breaching the REACH rules may be effectively punished by enforcing authorities. “Enforcement of the REACH legislation is crucial to safeguard equal terms for all actors in the market and is a general problem. Only a few countries up to now have the legally effective means of enforcing REACH. Severe violations of the REACH obligations are regarded as ‘criminal’ not as 'administrative' offence and can be punished with imprisonment,” explains Wolfmeier. Such an action allowed its perpetrators to have access to all the pre- Substance Information Exchange Fora (pre-SIEFs) corresponding to the list of EINECS entries and to information such as who is interested in a particular EINECS entry. Thus, we can identify one flaw of the pre-registration system: companies can pre-register with the only aim of gathering information, such as who is interested in a particular substance. Since pre-registration does not have to be followed by registration and only requires a brief set of information, pre-registration is a convenient tool to do so. In consequence, companies have to carefully identify the companies they are speaking to in the (pre-)SIEFs. “If the other SIEF members are pharmaceutical or chemical groups that we can trust and we know that we share the same interests, sharing of data will happen smoothly. In the case of a company we never heard before or we don’t trust, we will be much more suspicious,” says Bernhard Pellascio, head of corporate safety and environment protection services at F. Hoffmann-La Roche. Of course, the possibility of staying anonymous by appointing a third party representative may make the identification more difficult, but since most “spying companies” only want to gather information without any effort, they will most likely not resort to a third party. However, appointing a third party for oneself can be a good protection. Another example of the system’s flaws was provided by the “cascading pre-SIEF access” problem, a process where jumping from pre-SIEF to pre-SIEF on the REACH-IT system allows access to related substances and its pre-registrants. This process was blocked by ECHA in September 2008. “In order to anticipate such events that could undermine CBI protection, we do not indicate other substances with similar chemical structures that may be suitable for “read-across” of data at pre-registration. We prefer to go for more tests rather than using this approach, even if it could potentially save us money. We consider this approach too risky,” explains Barker.

These examples highlight that companies are generally suspicious of the way CBI is protected in the REACH regime. Even if ECHA could remedy the system’s deficiencies in the two above examples, questions remain as to whether ECHA can efficiently manage and enforce the current system. This point is crucial since the accumulation of flaws could endanger companies.

Only Representative
A non-EU manufacturer of a preparation being exported to the EU cannot directly (pre)-register it. Either registration is done by the EU importer(s) or, alternatively, by an Only Representative (OR), who is based in the EU. It is worth noting that in the case the (pre)-registration is made by the EU importer(s), the non-EU manufacturer will have to disclose to the EU importer(s) which substances are present in the preparation to be sure they are complying with the law. Therefore, it is recommended that a non-EU manufacturer (pre)-registers the different substances of said composition through its OR if the composition of the preparation is CBI. Moreover, by appointing an OR, the non-EU manufacturer does not encourage his EU customers to look for alternate suppliers who have REACH-compliant products. An even more efficient and safer way to control CBI is to have in the EU one or several legal entities of the company which act as an OR. Indeed, appointing an OR adds a new actor to the registration process and thus slightly increases the risk of leakage of CBI.

The non-EU manufacturer needs to provide the OR with a lot of data to allow him to comply with his REACH obligations. This extensive exchange of information and the fact that the OR can represent several non-EU manufacturers at a time increases the probability of a CBI leakage. “You have to make clear in the contract what your rights and interests are,” says Paul Vesel, a REACH negotiator for the Swiss chemicals trade association (SGCI). It is worth noting that the German Chemical Industry Association has recently published a model for a contract between a non-EU manufacturer and an OR. In summary, having its own entity acting as an OR provides the best protection against loss of CBI.

Third Party Representative at pre-registration
In case a company wants to keep its identity secret, it can appoint a third party representative at pre-registration. “We may also appoint a third party in the case where we do not want to disclose the identity of our supplier to our competitors,” says Barker. Many reasons can justify that a company does not want to disclose who has manufactured its chemicals. As already pointed above, REACH acknowledges that this kind of information is confidential through Article 118.2(d). In consequence, at the pre-SIEF stage or later within the SIEF discussion, the question of the identity of its supplier(s) must never be raised. However, it can happen that companies do not want the names of their suppliers to be associated to a particular substance if there is any risk that competitors could guess a connection between the companies and the suppliers. In such a case, the company can ask its secret supplier to appoint a third party when pre-registering. If the supplier is based outside the EU, his OR has then to keep his identity secret. Another possibility of preventing a substance from being associated to any supplier is to pre-register the substance oneself. If the supplier is a non-EU manufacturer, the company can pre-register it as the EU importer. In this case, the supplier has of course to be ready to disclose the substances of the preparation. However, if the supplier is based in the EU, the company cannot make the pre-registration as it is neither a manufacturer nor an importer. Accordingly, pre-registration by the company would constitute a breach of Article 6.1. The company can provide very valuable assistance to the supplier for the preparation of the registration dossier and could also be appointed to represent a supplier in discussions with other companies regarding preparation of the joint submission of hazard data. However, the actual registration shall be done by the supplier. Therefore, in the case where the supplier is based in the EU, the only legal solution is to let him pre-register and convince him to use a third party, a responsibility that the company itself may also fulfil. In fact, in the same way as having its own entity acting as an OR for a non-EU manufacturer provides the best protection against loss of CBI, it is recommended that the company acts as a third party representative of the manufacturer as it gets a better control over the exchange of information. It is of course of crucial importance that ECHA keeps the identity of the manufacturer/importer secret in order to preserve anonymity. However, the fact that the lead registrant must be told who the manufacturers are can compromise the anonymity of the registrant towards other SIEF members. “This means that the information on the identity may basically flow to all the SIEF members. We really think that we should agree on a new mechanism to be implemented into the guidance in order not to disclose the identity of the manufacturer to the lead registrant in case a third party representative is appointed,” says Barker. This question is still open and has gone to the Commission. It is worth noting that this is also built into the REACH-IT system.

Exchange of information in the pre-SIEF and in the SIEF
To the extent that the information that must be exchanged within the SIEF for the purposes of registration contains CBI, parties may enter into confidentiality agreements, may prepare non-confidential versions of the documents, or may appoint an independent third party. Managing
the many discussions that will take place will be a complex task for each company. “The discussions and negotiations in the final SIEF are expected to become very difficult. You can have one SIEF, but the different members may not agree on classification & labelling, on endpoints, on exposure scenarios, etc.” says Wolfmeier. Moreover, Vesel notes that “during the data sharing process, the companies, that have more resources, may prefer sharing data with other SIEF members only when needed.” Here, Vesel refers to the individual route which basically consists of reducing contacts with other SIEF members and sharing studies only when a SIEF member requests them. When signing confidentiality agreements and hiring a third party are not deemed sufficiently, a registrant can opt-out and submit his own registration dossier. However, many companies are reluctant to use this possibility as the registration fee may be higher and a justification has to be given. “The opt-out possibility is a waste of time. You have to provide a justification as to why a joint submission would cause commercial detriment. The decision of ECHA to accept such a justification is arbitrary and adds legal uncertainty to this process. Therefore, we consider the opt-out possibility as a not very efficient protection. For example, regarding the risk assessment in the dossier that the lead registrant is going to submit on behalf of all the SIEF members, we make generic proposals to put together the risk assessment instead of separately submitting it,” says Barker. Moreover, if companies opt-out, they become a “preferred” candidate for dossier evaluation.

12-year protection
REACH accords a 12-year protection to the study summaries and robust study summaries. One concern about the 12-year data protection is that data of new chemicals become protected when registering, that is from now on, although the protection of old chemicals’ data may start as late as in 2018. “This is illogical. Why would new substances not benefit from a much longer protection? This does not encourage innovation,” says Barker. The fact that the (robust) study summaries of new substances will be made available to competitors for the purposes of registration after 12 years is a concern since a lot of resources may have been invested into generating these data. “We feel particularly affected by this issue since the new substances we have to register account for 8% of the total new substances produced by chemical companies in Europe.” Therefore, the problem of data protection is less in the rather short period of 12 years than in the differentiation that is made between old and new chemicals.

Non-disclosure on ECHA’s website
The registrant can make a request for non-disclosure on ECHA’s website of certain elements of the dossier. However, REACH is very specific as to what can be claimed confidential according to Article 119(2). Among these elements one finds the SDS. However, the full composition of a preparation has not to be given on it. It is very difficult to find the full composition of a preparation unless a company is unfortunate enough to have a preparation consisting of only hazardous components above certain concentration limits. “You do not have to give individual figures for the concentration of each hazardous component, but only its concentration range. We consider asking for a confidential treatment of information such as the SDS on a case-by-case basis,” says Barker. “However, we are not enthusiastic about asking for such a treatment because of the extra fees that would incur. Moreover, a justification has to be given, which adds legal uncertainty to this process. These extra fees and the justification may encourage people to either use only generic terms or to not declare information considered as CBI in the SDS (or the chemical safety report). The REACH legislation suffers from its complexity and no one will be able to check whether some information is missing in the different documents.” Therefore, the lack of incentives for companies to take the necessary steps to protect CBI may have severe consequences for the
objectives that REACH has set up. For example, when filing the SDS or the CSR, we can anticipate from the analysis above that a company may try to resort to very generic terms when referring to a confidential use, which could have the effect of compromising the quality of the risk characterization, or may even not declare information considered as confidential.

A new level of communication
REACH will modify the way companies were communicating. “We have to realize that a new philosophy has to be implemented when addressing communication. Up to now we have only communicated as much as necessary, but not more. We are now adding a new level of communication since communication from downstream users to upstream users is new,” says Vesel. This strengthened communication, which is referred to as a “big challenge”, increases the risk of loosing CBI, as reflected by the requirement of filing in a CSR where exposure scenarios for each use have to be developed. In such cases, the registrant needs to know the uses of its customers. This situation may be problematic since downstream users (DUs) are often reluctant in disclosing their specific uses of chemicals. Information on further processing or formulation of the chemicals may potentially allow the upstream actor to make himself the product. If a DU does not want to make his use known to his supplier, he can prepare his own CSR. “As a downstream user, we only need to say in most cases that we use the chemicals as intermediates in a chemical process. If we use a preparation, it will be decided on a case-by-case basis whether we want to go for our own CSR,” says Wolfmeier. However, suppliers may not want their DUs to go for their own CSR because they do not know any more what the DUs are doing with their products. “In the case where a specific customer uses one of our products for a very specific application, we will sign a confidentiality agreement with him. This information will then be kept secret to anyone else,” says Barker. Overall, companies will use terms as generic as possible when describing applications in order to reduce the amount of exchanged information. It is worth noting that specific uses of a substance can be declared as CBI, according to Article 118. Companies consider the confidentiality issue as a barrier in the communication between the suppliers and the DUs. “You have to control much more what you are saying. It is a learning process where you learn by doing,” says Vesel. This learning process is paving the way for a new communication, which operates on both horizontal and vertical levels and which has still to be tested and developed by each company, with the aim of being routinely used without compromising its own interests. In this respect, it is crucial that CBI is properly channelled in external discussions and in-house counsels may have a major role to play in ensuring that. Moreover, people dealing with SIEFs should be properly trained on what can be said in the course of the different discussions.

Competition Law
Information that is likely to induce a distortion of competition must not be communicated within the SIEFs, as opposed to “typical company know-how” which may have to be exchanged in the SIEFs as required by the REACH regulation. The measures which are undertaken to avoid any breach of competition law are often similar to those used to protect CBI, such as appointing an independent third party or refraining from using individual figures. We also note that the frontiers between these two types of information may also be blurred as both types of information may in some cases enable competitors to align their market behaviour. Among the information which is sensitive under EC competition law, individual production, import or sales volumes are particularly vulnerable to disclosure risk since they may be exchanged in the context of a joint CSR/CSA or when sharing REACH related costs. Wolfmeier explained the potential risk of getting them disclosed: “let us assume a scenario where there are only a small number of companies in a SIEF: although the precise
volume must not be communicated, information about the volume bands must be exchanged. If you know the total volume of produced and imported substances – your market - and the individual volume bands, you can at least guess the individual volumes of each actor much better than in the past. It’s a balancing act between the REACH requirements on one side and competition law as well as CBI on the other side.” Therefore, hiring a third party consultant is recommended as he can request from each actor to provide the confidential individual input. He will then aggregate the inputs into a composite return that should not allow the SIEF members to deduce individual figures. When signing a confidentiality agreement on data exchanged among members, the confidentiality agreement can apply for an undetermined period of time since the 12-year period provided for in REACH is not relevant for this purpose. Overall, a third party expert can play a crucial role in providing guidance on minimizing the risk of contravening competition law.

**Patents**

If there is any chance that companies can get a patent on a product and/or process, companies will never disclose it to other actors. “If we think that we can get a patent granted on a new product and/or process, we will first apply for a patent, before disclosing anything in order not to lose any patent rights. We always have to think about patents first when registering a new or – in the REACH language – non-phase-in substance. A downstream user will also not be prepared to disclose his use if he sees a chance to get a patent on it. In this case, he will go for his own CSR. This may be problematic for SMEs which may lack the necessary resources or know-how,” says Wolfmeier. However, getting a patent is expensive and time-consuming. Therefore, Vesel suggested that in many cases a product and/or process should be rather kept secret, which is most often the route that SMEs choose. In this case, a company would face the same situation as with a product/process which it does not want to disclose in order to get a patent. Vesel shed light on the best way to proceed: "how to disclose a use that is kept secret and is crucial for the prosperity of a company while complying with REACH? Try to use terms as generic as possible or go for your own CSR.” It is however very likely that more and more companies which can afford patents will consider patents as a very efficient way to protect their products and/or processes in the light of the REACH obligation to share data. “Our prediction is that REACH may trigger more patent applications as you better control your assets. REACH will certainly raise awareness in patent matters,” concludes Barker.