Lesson of REACH

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Please cite as: CHEMIK 2012, **66,** 3, 241-246

According to the REACH Regulation [1] the first registration deadline of substances has passed already. Now the industry can relax a little, make first conclusions and begin to prepare for the next steps in the registration process. Some fears had come true, some problems were easier to resolve than anticipated at the beginning, something was completed at the last minute, but certainly we have gained practical experience. In this article I would like to provide some summaries of REACH implementation, to show practical tips and solutions with the hope that this knowledge will be useful to anyone who just started preparing for the upcoming registration deadlines.

Let's remind again from where REACH appeared to better understand the intention of its creators. In the middle of 20th century, numerous cases of poisoning by chemicals have shown that chemical industry placed on the market substances with good usable properties, but have not been sufficiently tested for exposure to humans and the environment. Conducted lawsuits have shown not only a negligence of industry, thaw was not interested in bearing additional costs of tests, but also the imperfection of legislation in chemicals management. European Commission believed that there is the lack of complete information on properties and directions for use of substances. Data on physicochemical properties allowed to assess the risks arising only from these properties of substances, but did not give answers about their impact during the long period of time. So far the approach existed that if the substance is used for a long time, it is generally safe. The fact that people in contact with some chemical compound does not get sick at the same moment or do not die, does not means, that contact with it will not have negative effect to their health after many years. It was concluded that responsibility for assessing the substance applied to authorities is ineffective, because decisions to perform additional testing by manufacturers were made through a complicated procedures, only in situations if it was proved that the substance is dangerous. It was decided to move responsibility for the assessment of substances to the industry. So, such approach was the basic assumption for development of a new legislative system, which led to the REACH appearance.

For many people REACH is associated only with the duty of substances testing, imposed on the chemical industry, which should be finished by the registration in the European Chemicals Agency (ECHA). For experts registration is just one of many other duties that applied not only to producers and importers, but every company which uses substances in its activities, including distributors, downstream users, manufacturers of articles for other sectors of the economy. Therefore, it is worth to check how REACH influences to my business.

How registration was performed? Skipping the preparation period, it can be said that practical activities for industry started on 1 June 2008, when pre-registration of substances became possible. This process continued until 1 December 2010. It was quite easy to perform, excepting few weeks before deadline, because of great difficulties to login to REACH-IT. As it turned out the number of pre-registrations has exceeded 2 million, although the European Commission expected about 170 thousands. Pre-registration is free of charge and does not oblige for the registration. I suppose that this motivated many companies to pre-register more substances than they place on the market in reality. Sometimes it was worth to pre-register even more, because of the interpretation difficulties of REACH requirements, it was not always possible to decide whether a substance is exempt from registration or not. For example, on 8 October 2008 during pre-registration the Commission Regulation (EC) no 987/2008 has appeared which changed Annexes IV and V of REACH, concerning the exemption from registration of some substances. Another example is the confusion related to the interpretation of wastes in the context of REACH (waste which is placed on the market is not waste any more and substances contained therein are subject to registration). Some substances could also be pre-registered just in case of their production in the near future. It is hard to resist the impression that some companies deliberately registered more, since becoming a member of the Substance Information Exchange Forum (SIEF) it could be possible to get knowledge about the substance's fate in the European Union. There were also some dodgers, who decided to exploit the nervousness of the situation and lack of people's knowledge. They pre-registered substances just for profit purposes. Getting contact details from SIEFs they proposed later to be a facilitator in preparation of registration documentation for considerable price.

Just after pre-registration finished somebody could be glad from the fact that in many SIEFs there were so many companies (up to several hundreds or thousands). Taking into account that if only half of them will register it is hope that the final cost of developing the registration documentation per single registrant should not be so high. Disappointment came quickly, when it turned out that the intention to register substances in 2010 expressed around several dozen percent of the total number of SIEF's members. Besides of the previously mentioned reasons we should remember about companies for which the registration deadline will come in 2013 and 2018. On the other hand, nobody knows how many of these companies will decide to register in the coming years, because at a smaller tonnage of substance's production / import profits may not cover the costs of registration and this business will not be a profitable venture any more.

After pre-registration, the next step was organization the activities in SIEFs, to clarify who is in a possession of data, who will want to cover the costs of preparation the registration documentation (dossier), or who will be willing to manage this process. Sometimes situation happened when for a long time nobody wanted to be a leader, or several registrants for one substance expressed their willingness to be a leader. Finally, one lead registrant was chosen who supervised the preparation of documentation and was responsible for its submission to ECHA. Other companies that did not feel strong enough to prepare dossier and perform registration individually, in practice, had a choice of two routes - to join a consortium or to buy so-called Letter of Access (LoA) to the dossier. Before making a decision it was worth to check the status of your substance, because for example, dossier for on-site isolated intermediate can be prepared and registered individually. Such dossier consists of information that registrant is in possession already without the need to conduct additional tests. Article 49 of REACH informs that for such intermediates that are used in strictly controlled conditions (Article 18(4)), neither dossier nor substance evaluation is applied. In case of a substance's manufacture at a little bit over 1000 tonnes per year it could be considered the possibility of keeping production below that limit in order to move registration deadline to the middle of 2013.

The benefit resulted from the joining to the consortium was the possibility to influence on the decisions in consortium. On the other

hand, this required the involvement of some human resources to participate in this work actively, which I think was workable only for large companies. Being of the owner of study results useful for dossier, it was possible to sell them to consortium, or submit our uses in purpose they become identified uses covered in Chemical Safety Report (CSR) as well. Additionally, registrant could expect potential reimbursements from the future sale of LoA. If someone wanted to join the existed consortia, each new company had no possibility to change the content of the agreement and had to accept it as-is.

The advantage of purchasing LoA was that the registrant did not have to track the progress of work in the consortium. It was enough just to buy the access to the already completed dossier. However, such solution was risky, because there was no certainty about the quality of dossier. Firstly, you had to pay and after receiving the dossier, you could have a view of the data it contains. On the other hand, in case of absence of some uses the registrant had to perform later chemical safety assessment by himself. Sometimes there was no other choice than to buy LoA, because no consortium was established for substance of our interest, or the company which was able to prepare the documentation was not interested to create a consortium. There have been situations when for a long time no one wanted or could not be a leader, until the danger of the upcoming deadline has forced someone to active actions. This resulted to that LoA sale proposals appeared sometimes shortly before the deadline and this led to the extra nervousness among waiting registrants. Let's remember that joint registration meant the cooperation with competitors who are not interested in our well-being, unless by the relevant law requirements they are forced to cooperate with us.

At the beginning of REACH's introduction, it was an opinion that chemical industry will begin to conduct tests of substances with purpose to generate data about properties of substances. Undoubtedly, laboratories benefited from the possibility to earn money given by REACH. On the other hand, every company wants to reduce operating costs, therefore the first and obvious step was to search the literature in order to find required data. This was a much cheaper solution than the commissioning of studies, which may continue over several years. We see that the majority of the data in dossiers of registered substances is the information transferred from scientific publications. On the one hand, it may looks like a little absurd but on the other hand, from the entrepreneur's point of view, this approach allowed to reduce costs of meeting the REACH requirements. Due to the possibility to use the literature data the final cost of preparation of the registration documentation for one substance was typically several hundred thousand Euros. Of course this is a lot, but it was better solution for companies, taking into account the full cost of the substance testing, that by today's prices can be up to several million Euros.

The question may appeared - if in many cases data from the literature just was used, why companies did not create dossiers by themselves that would be even cheaper? The seemingly easy task in practice proved to be difficult, if you will try to look deeply into details. Firstly, excellent knowledge of English is required as well as knowledge in chemistry, toxicology, ecotoxicology, analytical techniques, in order to understand the content of scientific publications. Another obstacle appeared when it was necessary to interpret the results and select the most reliable (e.g. according to the Klimisch scale). After the treatment of information the next step was transformation it to the IUCLID format, which was not so easy task as well. Finally, remember that REACH encourages many registrants of the same substance to submit one joint dossier to ECHA. This resulted that individual registration became risky. Many interesting facts from the life of REACH-man in 2008-2010 may be mentioned here to better understand the ground on which he was working and making decisions.

Many times I have heard that small, medium and micro enterprises are more vulnerable to the negative effects of the implementation of REACH, because of the lack of knowledge and experience in this matter. I hope that a brief scheme of actions described below will help such firms do not get lost.

If after pre-registration you did not logged into REACH-IT [2] for a long time, it is worth to refresh the password (password's update is required every three months) and look whether lead registrant in SIEF did not leave information on the conditions of accession to the joint registration. Also on the ECHA's website [3] in database of the published dossiers you can check whether someone has already registered the substance of your interest in 2010. If you find that no one has registered it, you must firstly assess whether to register as so-called standard substance or as transported / on-site intermediate and when the registration deadline. In case if you buy a substance (as its own, in mixtures or in articles) from abroad, you need to check whether such purchase falls under the category of import or downstream using. REACH is valid in countries of the European Economic Area (EEA), i.e. in the EU plus Norway, Iceland and Liechtenstein, excluding Switzerland. Registration requirements depend from the results of this evaluation and as a result the final cost for your company. If you will conclude that it is not possible to prepare dossier individually, I would propose to look for external help among experts of this matter. Searching can be started from consultations in national HelpDesk [4].

It may happen that you may find a company that has registered substance of your interest and is ready to sell LoA to his registration dossier. When you will collect all information to estimate the final cost of registration, every one of us must decide himself whether it is still profitable to continue production or import. I understand that the decision may be painful, but sanctions for failure to comply with polish law will be more severe [5].

In case of the registered substance it is better to contact to the lead registrant in order to purchase LoA. Such purchase involves signing of agreement and payment of invoice. As a rule, such agreement is in English, based on a pattern developed by lawyers of CEFIC. If you will conclude that registration will still be profitable I encourage you to buy LoA as soon as possible, because later you will not have much possibilities to negotiate of agreement's conditions. Some leaders transferred the sale of their LoAs into ReachCentrum's hands that created the LoA-shop service [6]. To be able to login to there, you need to know yours company identification number in REACH system, so-called UUID, which is located on your account in REACH-IT. In this service LoA can be purchased only for those substances which are pre-registered by you and if leader transferred there the sale of his LoA. If you will want to buy a LoA through this service for the substance that we only intend to manufacture or import (from outside of the EEA) in the near future and it was not manufactured or imported after 1 June 2008, then the late pre-registration in REACH-IT must be done. In case of this activity you need to remember about deadlines specified in Article 28(6) of REACH regulation and Article 40(3) of CLP regulation [7]. At the LoA-shop the purchase is made by few clicks and acceptance of the agreement by clicking the button "accept". In many agreements lead registrants add the attachment Substance Identification Profile (SIP), which specifies criteria of identification of substances registered by them. Thus, if your substance is in accordance with these criteria, you can participate in the joint registration.

After passing through the process of signing or acceptance of agreement you will get invoice, after paying you should get an access code, so-called token, joint submission name, file of dossier in IUCLID 5 format and CSR. This is an important step for registration, but not the last. Before you reach this point you should already have results of identification of the substance, performed by methods listed in Annex VI, point.2 of the REACH regulation. I encourage you to order these analyses immediately after the decision about registration be made.

According to the Article 11(1) of REACH regulation, each registrant must submit some information individually, so the next step is developing

your own part of dossier. In practice, "the simplest way" to create a dossier is to use program IUCLID, which can be downloaded free of charge from the IUCLID-IT [8]. I must to point out that this might be the most difficult task. This program requires certain resources from the computer, a certain scheme of installation. It is available only in English and it is quite frequently updated and difficult to use. In case of the lack possibilities to prepare you own part of the dossier individually, I can only advise to look for external assistance in this matter.

The next step is the submission of your dossier to ECHA. This can be done only electronically via REACH-IT. Just after the submission, ECHA starts formal verification of the dossier to the compatibility with law, whether all required fields are filled. At this stage, ECHA does not yet assess the quality of data. In case of the founded inconsistency dossier is rejected, the reason of rejection is given and new dossier needs to be resubmitted. In case of the lack of inconsistency after a short time (usually during two days) in your account on REACH-IT invoice is appeared to download. ECHA issues invoices for registration fees [9] only in electronic form as a pdf. file. It should be noted that any kind of fees payable to the ECHA are not subject to conscription tax "at source" in accordance with the law on income tax from legal persons [10]. After the receiving payment from us, ECHA issues a document confirming the assignment of registration number, which can be also downloaded from REACH-IT.

After all of this one would like to say - I did it! At last, with a clear conscience we can continue our business. As I said at the beginning, REACH is not limited to the registration of substances only. We have also other tasks, such as: adjusting of safety data sheet to the requirements of Annex II of REACH, revised in 2010 [11]; gathering information on uses of manufactured / imported substances from our downstream users in accordance with descriptors system of guidance R.12, to be included in dossier and to develop exposure scenarios for them if required; update the registration dossier; preparation of responses to inquiries from ECHA and units that control the implementation of REACH; if the substance of our interest to be introduced into Annex XIV concerning authorisation of some uses, to decide about development of authorization application; checking the correctness of labels on packages according to requirements of the CLP Regulation; tracking changes in the law to not miss new important elements; etc. After completing the above tasks, we can say: meets the main requirements of REACH.

English translation by the Author

Literature

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International Symposium on Chromatography 2012 Toruń, 9 - 13 September 2012

The 29th international Symposium on Chromatography (the 29th ISC) will take place on 9 - 13 September 2012 in Toruń, Poland. For the first time the International Symposium of Chromatography Committee has made their decision to organize the event in a Central European country, in Poland. The theme of the 29th ISC is Chromatography & Separation Science. Past, Today, Future. The theme is of particular importance to us as the technique was developed in Warsaw, Poland by M.S. Tswett and the fundamentals of which were found by W. Nernst who was born in Wąbrzeźno, former Prussia. This significant meeting will be thoroughly devoted to the role modern separation methods play in scientific development. The co-organizers of the 29thISC are the European Society for Separation Science (EuSSS), Central European Group for Separation Sciences (CEGSS), and Nordic Separation Science Society (NoSSS). The Organizers, together with the Scientific Committee, have planned the program elements to inform and inspire, and to provide opportunities for increased collaboration among those involved in the separation techniques. The elements include plenary lectures, section lectures, oral and poster presentations or workshops. The Organizers will take full advantage of the opportunities for scholarly exchange and discussion on the latest achievements in the field of chromatography. With support from companies, we hope to reach the organizational success, from both, the scientific and social points of view.

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