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REACH REGULATION AS A FORM OF PROTECTION OF THE ENVIRONMENT. REACH PRE-REGISTRATION AND REGISTRATION – SUMMARY AND STATISTICS

ROZPORZĄDZENIE REACH JAKO FORMA OCHRONY ŚRODOWISKA. REJESTRACJA WSTĘPNA I WŁAŚCIWA – PODSUMOWANIE I STATYSTYKI

Abstrakt: The REACH Regulation is a Directive of the European Parliament and Council concerning the safe use of chemicals through their registration, authorisation and evaluation. An important change from the previous EU chemicals legislation is that, under REACH, responsibility for the management of the risks lies with the company that manufactures, imports, places on the market or uses a substance in the context of its professional activities. The safe use of chemicals is the core objective of REACH. Industry is responsible for establishing the safety of chemicals. Companies must demonstrate that they use their substances safely and provide accurate data in their registration dossiers. The results of these tests must be submitted to the Chemical Agency in Helsinki. Pre-registration, which took place between 1st June and 1st December 2008, required manufacturers and importers to provide a limited set of information on the phase-in substances they intend to register (no data, no market), in order to be entitled to take advantage of the transitional provisions for registration. Pre-registration is the starting point for the formation of Substance Information Exchange Fora (SIEF), where manufacturers and importers who pre-register can exchange information and jointly prepare the information to be submitted for registration. The next stage (which is anticipated to last for 10.5 years) is the registration, which is taking place now. The registration requires performing many specific tests of produced or imported substances, depending on their tonnage and influence on human health and the environment. The reports published by the Agency allow tracking the statistics concerning the course of the registration and the share of individual countries in the process. At this stage of implementing the Regulation, the course of the pre-registration can be summed up and a general assessment of the course of the registration can be performed. After completing the registration, there will be started the process of verifying the data presented by the registering entities, which can last for a long time. The new system results in the necessity of

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bearing the administrative costs and the costs of preparing the data required for European registration, but it also offers an opportunity of learning about the influence of chemicals on the environment and on health of humans and animals. This knowledge will surely allow avoiding many threats connected with the use of unknown and untested chemicals.

Keywords: REACH, pre-registration, registration, statistics

The REACH Regulation: R – Registration, E – Evaluation, A – Authorisation of CH – CHemicals.

The main requirement of the Regulation addressed to the industry is the necessity of registering chemicals in accordance with its contents and the timeline imposed by it (Fig. 1).

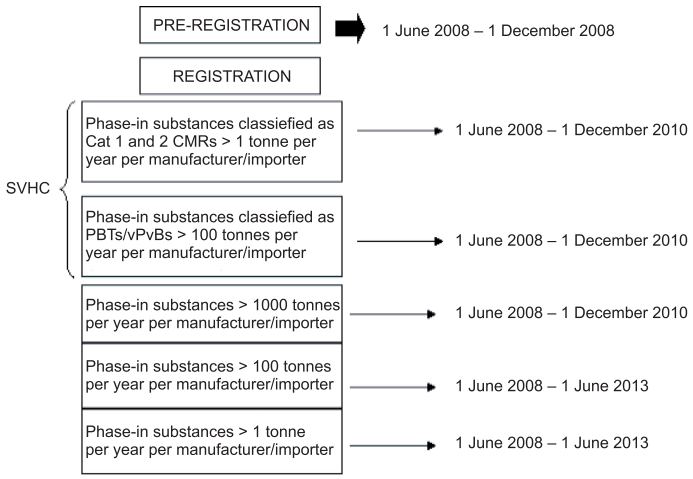

Fig. 1. Registration time limits (SVHC – Substances of Very High Concern; CMRs – Carcinogenic, Mutagenic or toxic Reproduction.; PBTs – Persistent Bioaccumulative Toxics; vPvBs – substances which are very Persistent and very Bioaccumulative)

In compliance with the provision II of the Regulation (EC) No. 1907/2006, known as REACH Regulation, each substance, on their own, contained in a preparation or a product imported into the territory of EU in an amount higher than 1 Mg a year must be registered in accordance with the provisions of this Regulation [1]. Substances, on their own means a 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, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. Preparation means a mixture or solution composed of two or more substances and 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 [1].

The period for implementing the REACH system, in particular, preparing and performing the registration of chemicals produced in or imported into the territory of the

European Union was foreseen for 11 years. However, this is not the total time required for implementing this system, because after completing the registration, there will begin the process of verifying the data presented by the registering entities, which can last for a long time.

An indirect requirement of the Regulation is the necessity of performing many specialist tests, the scope of which would depend on the tonnage and type of a substance as well as on its impact on the health of people and animals and on the environment.

The work on the Draft REACH Regulation

The problem of possible negative influence of chemicals attracted attention before 1981, when it was found that over 100 000 substances, which had not been earlier subject to any legal obligation of testing them in respect of their possible harmful effects on human health and negative influence on the environment, had been placed on the market of the European Economic Community. In that year, EEC introduced the requirements about testing chemical substances as a response to the increased incidence of cancer and other diseases caused by these substances. In this way, a broad review and tests of the chemicals being marketed were started. In 1998, the European Council for the Environmental Issues decided to revise the community law concerning chemicals and to propose a new system, which would allow evaluating the chemical substances being marketed in a profound and harmonized manner [2]. On 18 December 2006, EU Council adopted, without any discussion, the REACH package in the wording that was approved also by the European Parliament, and on 30 December 2006 this package was promulgated in the Official Journal of the European Union. As of 1st June 2008, European manufacturers and importers of chemicals were obliged to report, within six months, the fact of producing or importing any substances being marketed in the area of EC countries in the quantities over 1 Mg a year [3].

Pre-registration and registration

Pre-registration, which took place between 1st June and 1st December 2008, required manufacturer and importer to provide a limited set of information on the phase-in substances they intend to register (no data, no market), in order to be entitled to take advantage of the transitional provisions for registration [5].

When drawing up the REACH Regulation, the Commission estimated that over 130000 pre-registrations would be received from industry, for more than 70000 chemical substances and intermediates. By the end of the pre-registration period, ECHA had received 20 times more pre-registrations than expected (Fig. 2).

Many of these pre-registrations were – for a number of reasons – submitted by companies that will not submit a registration later in the process. However, the high volume of pre-registrations created a significant additional workload for ECHA staff and resulted in a temporary overload of the IT system, which led to an intense

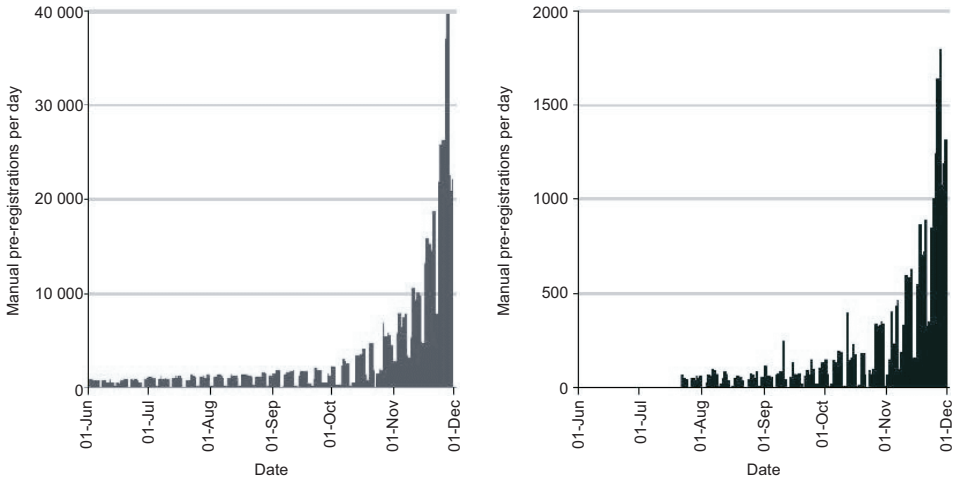

Fig. 2. Number of pre-registrations per day from 1st June to 1st December 2008 [6]

period of communication with stakeholders regarding the progress on the system usability.

Breakdown of pre-registrations and legal entities per country is presented in the figure below (Fig. 3).

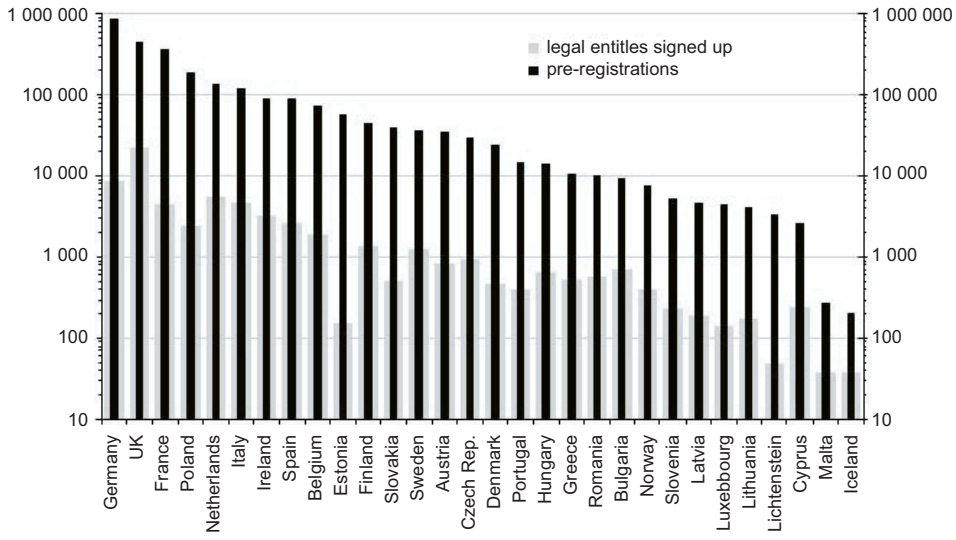

Fig. 3. Breakdown of pre-registrations and legal entities per country [6]

Registration began on 1st June 2008. By 31st December 2008, 1538 dossier submissions (810 inquiries, 487 PPORD notifications (*Product and Process Oriented*

Research and Development) and 241 registrations covering 28 phase-in substances) had been manually handled and processed within the deadlines set by the legal text. Approximately 70 % of dossiers passed the initial checking procedure (which included a virus check) and were then subject to a technical completeness check. The most common causes for not passing the check included inconsistencies in identification of the dossier, substance or company, or basic errors such as failure to include the requested submission form. When a dossier failed the initial technical completeness check, ECHA provided the company responsible for the dossier with a description of the information needed to allow successful re-submission. Duly, many of the submissions, in the above table, concern a second submission of the same dossier.

Table 1

Data submission from 1st June 2008 until 31st December 2008 [6]

Dossier type	Submitted	Accepted for processing	Technical completeness check passed	Complete
Inquiry	810	619	N/A	243
Registrates Intermediates on-site	40	24	12	12
Registrates Intermediates transported	107	70	50	46
Regular Registration dossiers	94	36	10	10
PPORD notifications	487	335	234	228
Total	1538	1084	306	539

The breakdown of registrations by individual countries in 2009 is presented in the figure below. It takes into account the number of registration forms submitted at the Agency in the periods to May, to August, to October and to December.

The basic institution involved in the implementation of the REACH regulation is the European Chemicals Agency (ECHA), established on 1st June 2007, having its office in Helsinki. ECHA's mission is to manage all REACH and CLP tasks by carrying out or coordinating the necessary activities, in order to ensure a consistent implementation at Community level and to provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals. This is achieved by ensuring a credible decision-making process, using the best possible scientific, technical and regulatory capacities and by working independently in an efficient, transparent and consistent manner [6]. The Agency, located in Helsinki, Finland will manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry. In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimize animal testing [4].

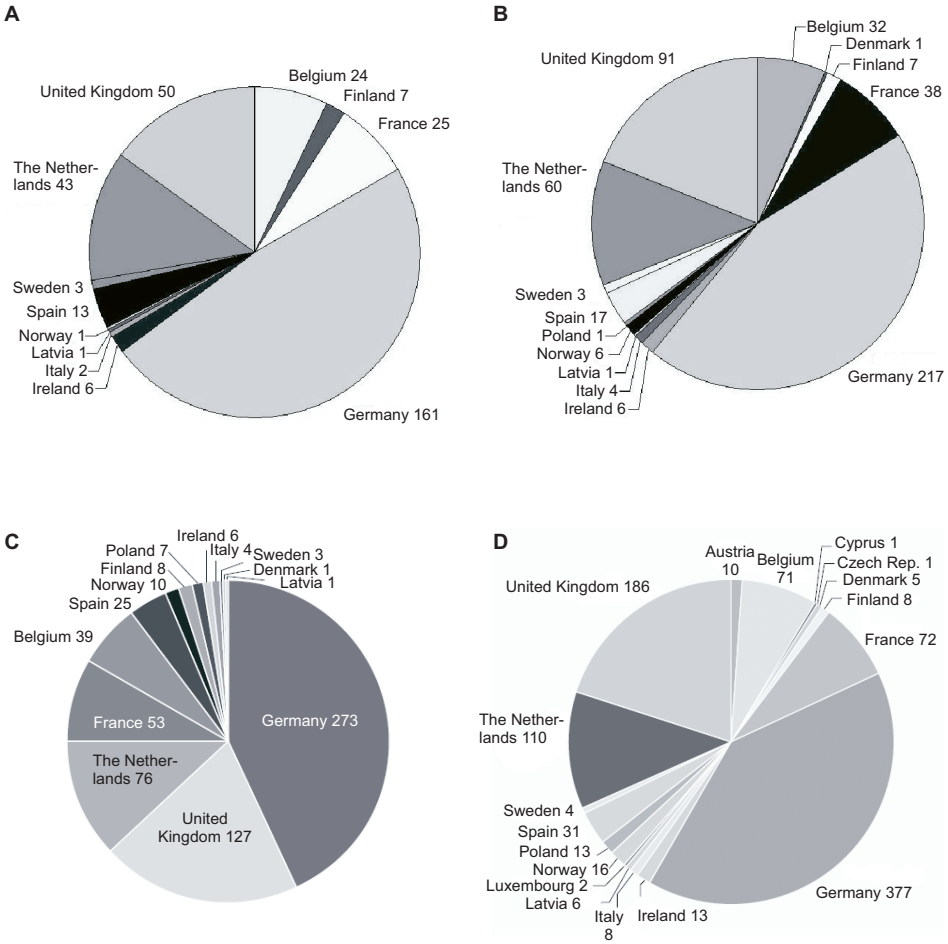

Fig. 4. Submitted registration dossiers by country in 2009 by 3 May (A) – total 336, 4 August (B) – total 484, 5 October (C) – total 633, 11 December (D) – total 939 [7]

Conclusions

One of the aims of the REACH Regulation is to generate information on chemical substances in order that they can be adequately controlled during their manufacture and use. The main mechanisms established in REACH to meet this aim are the registration and pre-registration processes. These processes depend strongly on the scientific IT-tools available to the agency. The tools were developed externally, and were initially the responsibility of the European Commission prior to handover to ECHA [6].

During the six months of the pre-registration period, more than 65000 companies signed up to REACH-IT, submitting more than 2750000 pre-registrations, which covered nearly 150000 different substances. Almost half of the pre-registrations were submitted during the last two weeks of the pre-registration period.

Other notable statistics are that:

– 82 % of companies indicated that they are SMEs (*Small and Medium Sized Enterprises*);

– 25000 companies indicated their intention to register before the first deadline of 30 November 2010, which covers approximately 50000 different substances;

– 18 % of substances were pre-registered without indicating an EC number.

These include mainly:

– substances that do not have an EC number, substances presumably manufactured in the Community but not placed on the market by the manufacturer or importer, and which have phase-in status according to Article 3 [20] (b) (so-called "intermediates");

– substances that have an EC number, which was not used by the potential registrant. These will be identified by ECHA;

– Almost half of the REACH-IT sign ups and pre-registrations were from companies in Germany and the United Kingdom. Other countries with more than 100000 pre-registrations were France, Poland, the Netherlands and Italy [6].

The REACH Regulation is the largest legislative project adopted by the European Union in recent years and the most ambitious chemicals legislation in the world. It aims to address a number of serious shortcomings of the former EU chemicals legislation, in particular the lack of information on risks to human health and the environment for the majority of chemical substances on the EU market and the slowness of the system for dealing with substances identified as hazardous. Chemicals bring real benefits to our everyday life. Some chemicals can, however, also cause serious damage to human health and/or the environment. REACH will make those who place chemicals on the market responsible for understanding the potential adverse effects and managing the risks associated with the use of dangerous chemicals. REACH also aims to enhance the competitiveness of the EU chemicals industry by creating incentives for innovation and by removing distortions of the internal market inherent in the formerly fragmented legislative regime. It was clear from the beginning that implementation of REACH would be a challenging undertaking; not only for the companies concerned but also for ECHA, which is the heart of the new system. The task of breathing real life into REACH operations will very much depend on the quality and effectiveness of the Agency's work, as regards both its own operating procedures, IT systems and the advice and assistance it provides to companies and to Member States [5].

The new system results in the necessity of bearing the administrative costs and the costs of preparing the data required for European registration, but it also offers an opportunity of learning about the influence of chemicals on the environment and on health of humans and animals. This knowledge will surely allow avoiding many threats connected with the use of unknown and untested chemicals.

References

[1] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[2] Petelczyc G.: System REACH w praktyce 1.0. Verlag Dashofer, Warszawa 2007.

[3] http://www.prc.cnrs-gif.fr/reach/pl/usable_substances.html, Prévention du risque chimique, France 2007.

[4] European Chemicals Agency, http://echa.europa.eu/home_pl.asp, 20 January 2010.
[5] European Chemicals Agency, Multi-annual work Programme 2009–2012, Finland, Helsinki, 25.09.2008, 4–6, 11.
[6] European Chemicals Agency, General report 2008. The year of pre-registration, Finland, Helsinki, 24 April 2009; 6-8.
[7] European Chemicals Agency, *ECHA Newsletter*, No. 3, 4, 5, 6, Finland, Helsinki, May/June, July/August, September/October, November/December 2009, 7, 7, 10, 11.

ROZPORZĄDZENIE REACH JAKO FORMA OCHRONY ŚRODOWISKA. REJESTRACJA WSTĘPNA I WŁAŚCIWA – PODSUMOWANIE I STATYSTYKI

Instytut Technologii Nieorganicznej i Nawozów Mineralnych
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Abstrakt: Rozporządzenie REACH jest Dyrektywą Parlamentu Europejskiego i Rady dotyczącą bezpiecznego stosowania chemikaliów, poprzez ich rejestrację, autoryzację i ocenę. Dużą zmianą w stosunku do poprzedniego ustawodawstwa UE w zakresie chemikaliów jest to, że w systemie REACH odpowiedzialność za zarządzanie ryzykiem spoczywa na przedsiębiorstwie, które wytwarza, importuje, wprowadza do obrotu lub stosuje substancję w ramach swojej działalności zawodowej. Bezpieczne stosowanie chemikaliów jest głównym celem systemu REACH. Przemysł odpowiada za ustanowienie substancji chemicznych bezpiecznymi. Przedsiębiorstwa muszą wykazać brak zagrożenia podczas wykorzystywania ich substancji i podać dokładne dane w dokumentacji rejestracyjnej. Badania te muszą zostać przedłożone w Agencji Chemicznej w Helsinkach. Rejestracja wstępna, która trwała od 1 czerwca do 1 grudnia 2008 r., wymagała od producentów i importerów przedłożenia ograniczonego zestawu informacji o substancjach wprowadzonych, które zamierzają zarejestrować (brak danych, brak obrotu), aby nabyć prawo do skorzystania z przepisów przejściowych. Rejestracja wstępna to punkt wyjściowy do tworzenia forów wymiany informacji o substancjach (SIEF), na których producenci i importerzy dokonujący wstępnej rejestracji mogą wymieniać informacje oraz wspólnie przygotowywać je do przedłożenia na potrzeby rejestracji. Kolejnym etapem (przewidzianym na 10,5 roku) jest trwająca obecnie rejestracja właściwa. Rejestracja ta wymaga przeprowadzenia szeregu specyficznych i uzależnionych od tonażu, a także wpływu na zdrowie ludzkie i środowisko badań produkowanych bądź importowanych substancji. Publikowane przez Agencję raporty umożliwiają śledzenie statystyk przebiegu rejestracji jak również udziału w procesie poszczególnych krajów. Na tym etapie wdrażania rozporządzenia można podsumować przebieg rejestracji wstępnej, jak również w okresie do 2010 roku, dokonać poglądowej oceny przebiegu rejestracji właściwej, po zakończeniu której rozpocznie się, mogący trwać długi czas, proces weryfikacji danych przedstawionych przez rejestrujących. Nowy system powoduje konieczność poniesienia kosztów administracyjnych i kosztów przygotowania danych koniecznych do europejskiej rejestracji, ale daje także szansę na poznanie wpływu chemikaliów na środowisko oraz zdrowie ludzi i zwierząt. Wiedza ta z pewnością pozwoli uniknąć wielu zagrożeń związanych ze stosowaniem nieznanych i niezbadanych substancji chemicznych.

Słowa kluczowe: REACH, rejestracja wstępna, rejestracja właściwa, statystyki