# REACH – chemicals safe for health and the environment

Zbigniew ŚLĘZAK* – Committee of Chemical Legislation at the Polish Association of Engineers and Technicians of Chemical Industry (SITPChem)

Please cite as: CHEMIK 2015, **69**, 4, 192–199

The development of manufacturing industry, especially chemical one, for many years was focused on finding methods to obtain materials with desired properties. Firstly, the aim was to replace naturally occurring substances or to improve them, and then to produce substance with new characteristics. Over time, the technologies were improved, considering increasing the production scale, while decreasing the costs. Study of possible effects of obtained products on human health and environment not always had the highest priority, to say the least. The hazards exposed during use of harmful substances in the end led to their withdrawal from some of the applications. Some of the examples include synthetic tetraethyl lead (TEL) in gasoline or natural asbestos roofing. Substances suspected of harmful effects were tested by governmental agencies. The results of these studies were as valuable as humble, as they only cover less than 1% of all known chemicals, which number is estimated to exceed 100 thousands.

In practice, only at the beginning of the 21st century, the discussions regarding health and environmental protection became vocal and common. In 2002, during the global Earth Summit in Johannesburg the general programme for sustainable development was drafted. It later became an inspiration for further actions, among others regarding safe use of chemicals. The Global Chemical Congress held in Dubai in 2006 has adopted the Strategic Approach to International Chemicals Management (SAICM). On the basis of the aforementioned declarations, the European Union has issued two fundamental Regulations of the European Parliament and of the Council: 1. (EC) No. 1907/2006 of 18th December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH** – *Registration, Evaluation and Authorisation of CHemicals*) and establishing the European Chemicals Agency; 2.(EC) No. 1272/2008 on classification, labelling and packing of substances and mixtures (CLP – *Classification, Labelling and Packing*).

The European Union set itself a goal to ensure that by 2020 chemicals are produced and used in a manner leading to minimization of significant negative effects on human health and environment. During the consultations of draft REACH and CLP Regulations, entrepreneurs and associations representing chemical industry expressed distrust and were critical with respect to planned procedures. While the environmental organizations accused industry of hiding hazards and urged to quickly implement restrictions or bans for using the most dangerous substances. Both Regulations have superseded tens of different legislations on chemicals and transferred to the industry responsibility for management of chemical related risk and for delivering relevant safety information to their users. At the same time, they provide possibility of taking preventive actions at the level of the Community. The European Chemicals Agency (the Agency) was established to coordinate implementation of new procedures.

Substances subject to new chemical legislation must be registered and classified. Until 1st December 2010, substance registrations had to be made at the Agency, for substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR), and marketed in quantities >1.000 t/r as well as for substances classified toxic to aquatic environment (marked with symbol R50/53), if they are manufactured or imported in quantities >100 tonnes/year). By 1st June 2013 the registration shall be completed for substances marketed by the registrant in quantities >100 – 1.000 tonnes/year, while by 1st June 2018 substances marketed in quantities >1 – 100 tonnes/year are to be registered. By 1st December 2010, substances had to be classified and labelled under new provisions, while by 1st June 2015 mixtures are to be classified and labelled. The conducted so far two rounds were considered in the Agency to be an organisational success and example of good cooperation of all parties participating in implementation of REACH. Industry representatives admit that the registration process was easier than expected, but it was a big financial burden (high costs of compilation of registration dossier). The third registration round planned for 2018 may prove to be the hardest one, as it applies mainly to small companies, majority of which is not prepared for that, neither in terms of expertise nor finances. It must be also noted that the sole substance registration, despite the collection of available knowledge does not directly translate to its safety.

**Assessment/Evaluation**

The Agency and Member States assess information submitted by the companies to check the quality of registration dossier, test proposals and clarify, whether a given substance poses hazard to human health or to the environment. The Agency checks compliance of dossier with REACH requirements and evaluates if the proposed complementary tests, in particular animal testing, are necessary to evaluate the substance. The specified Member States in accordance with adopted 3-year Community rolling action plan CoRAP perform (within 1 year) assessment of given substance and check all available information regarding it. In 2012 53 substances were evaluated, in 2013 – 41, in 2014 – 46, while plan for 2015 assumes at least evaluation of 23 chemicals. Based on the conducted evaluation, the Agency may request additional information from the applicant or decides to proceed further with the evaluated substance.

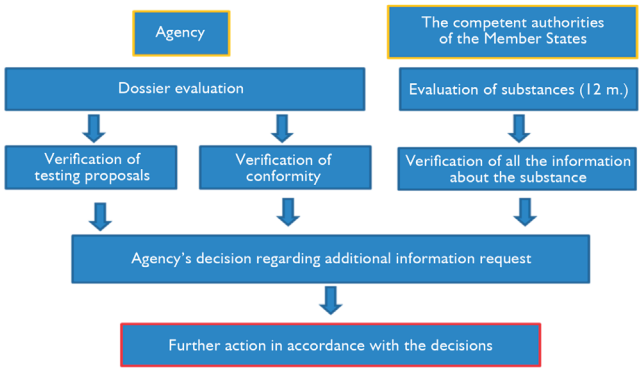


**Fig. 1 Evaluation/assessment process**

Corresponding author:
Zbigniew ŚLĘZAK – M.Sc., Eng., e-mail: zbig_1@onet.com.pl

A thorough evaluation of dangerous chemicals is expected in order to carefully investigate substance of very high concern (SVHC). Those are mainly substances meeting classification criteria for carcinogens cat. 1 or 2., mutagenic cat. 1 or 2., ot toxic for reproduction cat 1. or 2. (i.e. CMR substances), or persistent, bioaccumulative and toxic (*PBT*), very persistent and very bioaccumulative (vPvB) in accordance with the detailed provisions and other substances such as endocrine disruptors or PBT, or vPvB substances that previously did not meet these criteria, for which exists scientific evidence of possible effects on human health and environment, which give rise to an equally large concern. The priority is usually given to PBT or vPvB substances or substances commonly used or used in large quantities. The substances included in the SVHC group can be subject to restrictions or to authorization procedure. The documentation justifying the inclusion of SVHC in the Annex XIV (to be subject to authorization) or the Annex XVII (to be subject to restrictions) can be compiled by any Member State or the Agency, provided that documentation must be in accordance with the requirements of REACH. Manufacturers and importers are obliged to provide downstream users with information regarding risks and safe substance use. This is done through classification and labelling system, as well as SDSs (Safety Data Sheets). Substance evaluation is a basis for implementing appropriate safety measures. However, it must be noted that hundred-odd chemicals have been evaluated so far, which represents just a small percentage thereof.

**Limitations/Restrictions**

The restrictions are a tool to protect human health and environment against unacceptable risk posed by chemicals. The European Commission can implement restrictions on production, use or marketing of substances posing unacceptable risk to human health and/or environment. The first restrictions regarding use of dangerous substances have been already announced with the REACH Regulation – in Annex XVII and new ones are being gradually implemented.

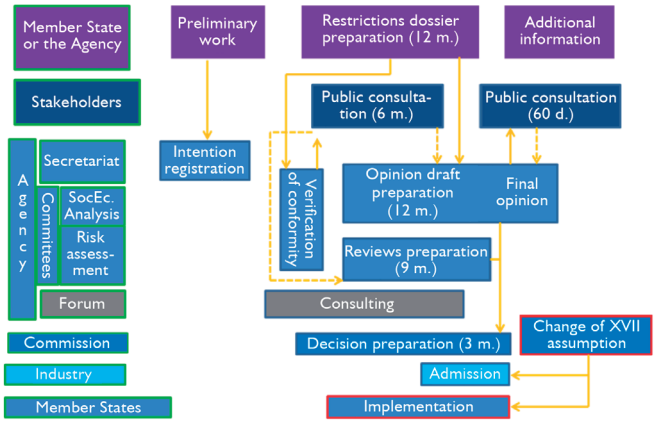


**Fig. 2 Limitation/restriction process**

Currently Annex XVII includes limitations of use for over 60 substances or groups of substances. For example (in simplified version): No. 5. **Benzene** – Not permitted in toys or parts of toys as placed on the market where the concentration of benzene is in excess of 5 mg/kg or in concentrations equal to, or greater than, 0.1 % by mass in substances or preparations placed on the market. (except fuels and safe industrial processing); No. 6. **Asbestos fibres** – manufacturing, placing on the market and use is prohibited, No. 18 a. **Mercury** – The following mercury-containing measuring devices intended for industrial and professional uses shall not be placed on the market – Barometers, Hydrometers, Manometers, Sphygmomanometers, Tensiometers, Thermometers and other non-electrical thermometric applications, as well as Strain gauges to be used with plethysmographs; No. 47. **Compounds of chromium VI** – prohibited to use in cements above 0.0002% and in leather products, as well as in leather parts of products, that may contact with human body, if Cr VI concentration exceeds 0.0003%; No. 51. **The following phthalates: bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP)** – prohibited to use in concentration exceeding 0.1% in toys and childcare articles; No. 52. **The following phthalates: di-isononyl phthalate (DINP) di-isodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP)** – prohibited to be used in concentration exceeding 0.1% in toys and childcare articles, which can be placed in the mouth by children; No. 58. **Ammonium nitrate** – prohibited to market in concentration exceeding 28% as a fertiliser, unless the fertiliser is compliant with technical provisions on fertilisers, No. 63 **Leads and its compounds** – prohibited to use to market if lead concentration exceeds 0.05% by weight of any part of jewellery article, including: bracelets, necklaces, rings, piercing, wrist watches, brooches, cufflinks and in articles which can be placed in the mouth by children (excluding keys – available technology is based on alloys containing Pb). The restrictions apply to specified used of dangerous substances and are in force in the Community. The list of restrictions is relatively short, but each item introduces important changes in the production and use package of some substances due to previously unknown risks.

**Authorisation/ Licence**

Authorization procedure is to ensure proper handling of SVHC and force their gradual replacement with safer substitutes or chaning technology, if it is economically and technically viable, or to allow further use only if general socio-economic benefits outbalance the risks. Such substances are prioritized in terms of risks – and if found a priority – listed in Annex XIV of REACH (which was empty on the date of issuing the Regulation). Manufacturer, importer or downstream user of SVHC cannot market such substance, allowing its use or cannot use the substance by itself, if the substance is listed in Annex XIV, unless use of substance on its own, as a mixture component or in the article, as well as own uses of substance are covered by authorization or have been exempted from the authorization. The authorization can be granted only if risk to human health or environment resulting from use of a given substance and being an effect of its specific priorities is controlled adequately. For CMR, PBT and vPvB substances as well as for substances of similar concerns or if th erisk is not adequately controlled, the authorization can be granted only if the applicant proves that socio-economic benefits outweigh the risk to human health or the environment and there are no suitable alternative substances or technologies. The decision on granting or refusing the authorization is made by the European Commission. Since 2009, the Agency publishes so-called candidate list of substances of chemicals that are to be subject to authorization, and after 3 month public consultation – recommends to the Commission introduction of priority SVHC in Annex XIV. Over 160 substances have been selected – candidates for authorization, and the Annex XIV of REACH lists over 30 SVHC subjected to authorization, e.g. 5-tert-butyl-2,4,6-trinitro-m-xylene (**Musk xylene**) – vPvB substance; 4,4-Diaminodiphenylmethane (**MDA**) – due to properties Car.1B; Hexabromocyclododecane (**HBCDD**) – substance classified as PBT; Bis(2-ethylhexyl) phthalate (**DEHP**), Benzyl butyl phthalate (**BBP**), Dibutyl phthalate (**DBP**) – substances classified as Rep.1B. It is expected that Annex XIV will contain few hundreds of SVHC. Different communities insist that many more substances of very high concern shall be subject to authorization, and eventually to be substituted.

Every interested business entity can read the candidate list and Annex XIV of REACH – published at the Agency website and in

advance decide to prepare possible submission of application for authorization for specified use of given SVHC. The Agency has set dates for submitting application for authorization of specific substances, so called submission windows (e.g. in 2013 – 20th May-3rd June, 7st-21th August, etc., up to the first quarter of 2016), setting also final deadlines, up to which use of given substances is allowed if the application for their authorisation has been submitted – not later than 18 months before the final date. It was also determined, that review period of granted authorisation will be 7 years, which should be sufficient to find suitable substitutes. In the justified cases, this period can be prolonged up to 12 years, e.g. in the case of very long investment and legislation process related to introduced alternative solutions. This period can be also shortened if the applicant submits no evidence regarding lack of alternative solution, if socio-economic benefits only slightly outbalance existing hazards or if the applicant needs only a short-time to introduce substitute. It could be expected that company knowing available and cheaper alternative solution would introduce them without applying for authorisation of basic solutions. In practice, the substitution of given SVHC can be accompanied by the increase in costs, which will have negative impact on financial results. In case of a small decrease of profits, when the continuation of business is still sensible, it can be stated that considered alternative is feasible on the verge of profitability. However, if the costs will increase drastically, the economic feasibility of alternative would be highly unrealistic. The company applying for authorisation shall focus on thorough identification of existing alternatives and full and correct evaluation of costs related to their application. The interested third parties can deliver information regarding alternative substances or technologies. The authorization procedure involves the following phases:

a) Notification of intent to apply for authorization,
b) Submission of application and payment,
c) Check application conformity,
d) Public consultation regarding requested uses,
e) Prepare RAC and SEAC* draft opinions,
f) Comment on draft opinions,
g) Adopt RAC and SEAC* opinions,
h) Decision of the European Committee,
i) Submissions of downstream users,
j) Review of granted authorisation.

* Agency consultative committees – RAC – *Risk Assessment Committee* and SEAC – *Socio-economic Analysis Committee*. It must be noted that Comittees' members have to declare possible conflict of interests according to applicable criteria regarding substance subject to authorisation (or restriction). This involves for examples professional or capital connections with the applicant company (during few past years). Such person does not vote on the made decisions.

The first application for authorisation was submitted on 20th May 2013 from Rolls-Royce and involved use of **Bis(2-ethylhexyl) phthalate (DEHP)** as a plasticizer retarding diffusion welding in the process of manufacture of blades of aviation engine turbines. The applicant imports and uses this substance in form of a mixture in quantity of approx. 1 ton/year containing approx. 5% of DEHP. The application indicated that use of DEHP is performed with maintaining suitable risk control, and the hazards are small. Moreover, if contained information regarding search for alternative, however none of them is acceptable in technical or economic sense. Two expected and consequences were considered: positive (of granting the authorization) and (sever) of not granting the authorization. It was highlighted that rejection of application would have practically not significant effect on health of the employees and the environment. The RAC has confirmed data regarding reproductive toxicity of DEHP and related risks, as well as adequacy of used risk management, while the SEAC has confirmed lack of suitable/realistic alternatives. On 7th April 2014, the EC has granted authorisation No REACH/14/1 with review date up to 22nd February 2022.

In August 2013 more applications were submitted to the Agency, but so far the Commission has not published the decision. For example – one of the applications awaiting decision is the application of company GA ZAK for authorisation of 2 uses of **Bis(2-ethylhexyl) phthalate (DEHP)** – substance produced by the company and delivered to downstream users for manufacturing components and plastic processing. The RAC has confirmed data regarding reproductive toxicity of DEHP, question the adequacy of risk control and indicated possibility of substituting DEHP, while the SEAC has confirmed lack of suitable/realistic alternatives and concluded that benefits of use outbalances the risk and recommended 4 year review period (in case of granting the authorization). The opinions indicated many substitutes of DEHP, quite apart of economical conditions of substitutions. There is also no final decision on application by DEZA regarding use of **dibutyl phtalate (DBP)** – substance produced by the company and used as absorptive solvent in the manufacturing process of maleic anhydride. The RAC has confirmed data regarding reproductive toxicity of DBP and adequacy of risk control, while the SEAC has confirmed lack of suitable/realistic alternatives and recommended 12 year review period, in case of positive EC decision. Advisers considered suggesting change of technology in order to eliminate use of DBP. An interesting case is an application by VINYLOOP for authorization of use **Bis(2-ethylhexyl) phthalate (DEHP)** substance present in recirculates of soft PVC, that company processes (without addition of fresh plasticizer). The RAC has confirmed data regarding reproductive toxicity of DEHP, lack of suitable/realistic alternatives and found lack of appropriate measures of risk control, while the SEAC has confirmed lack of suitable/realistic alternatives and concluded that authorisation is justified and recommended 7 year review period. It seems that requested processing of used PVC containing DEHP plasticiser requires authorisation – approval of the EU authorities, but so far the decision has not been made. Authorization applicationsshall take into account high costs of professional preparation of application, authorization fee, need of timely substitution of SVHC, possibility of cancellation or revision of the authorization and uncertainty of response of chain supply partners. Implementation of the novel REACH Regulation in the European Union is connected with employing hundreds of specialists responsible for system management, checking and giving feedback to submissions, as well as preparation of dossier for substance registration, restriction or authorization.

**Summary and conclusions**

Management of chemicals in accordance to REACH, leaves the initial phase, i.e. substance registration, while the third round of registration planned for 2018 may prove to be the hardest one, as it applies mainly to small companies, majority of which is not prepared for that, neither in terms of expertise nor finances.

The random evaluation of chemicals started soon after the registration that leads to selection of substances of the highest concerns and taking appropriate preventive actions, is undoubtedly conducted very thoroughly, but very slowly; after 3 years it has covered only approx. 1% of the registered substances.

Restrictions introduced along with the REACH Regulation and successively added restrictions on use of substances that have harmful effect on human health or environment, are the first, real preventive action increasing the chemical safety and involving all the Member States.

The procedure of granting applicants authorisations for given use of substance that meets criteria for substance of very high concern is ineffective due to possible arbitrariness of formulating opinion and lengthy decision procedure (so far only 1 authorization has been granted).

Knowledge on substances gathered during the registration, evaluation, as well as submitting and preparing opinions on applications for restrictions or authorization is interesting for a small circle of specialists, but it cannot be expected to become a subject of study for a general public of the Community.

Aim of the European Union, implemented by the system REACH, to ensure that by 2020 chemicals are produced and used in a manner leading to minimization of significant negative effects on human health and environment, will be hard to fully satisfy.

Expectations of some communities that REACH will cause quick elimination of the majority of dangerous substances from use, must be confronted with need to keep caution and sense, if only because some substitutes may prove to be equally or even more hazardous than the substituted SVHC.

So far the activities within the REACH – introducing restrictions on common applications and introducing authorization procedure or control to cover special uses of substances of very high concern – help to improve the chemical safety.

**Literature**

Data from the REACH Regulation (Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 – OJ L 396 of 30th December 2006) and information from the publication of the European Chemicals Agency (http://echa.europa.eu/).

*Zbigniew ŚLĘZAK – M.Sc., Eng., has graduated from the Faculty of Chemical Technology and Engineering of the Silesian University of Technology (1969). In the years 1969-2009 he worked at ZAK S.A. (Zakłady Azotowe Kędzierzyn). He authored numerous presentations regarding REACH. Since 2007 he has chaired the Committee of Chemical Legislation at the Polish Association of Engineers and Technicians of Chemical Industry (SITPChem).

In the years 2011-2014 he was a Member of the Committee for Socio-Economic Analysis at the European Chemicals Agency.

e-mail: zbig_1@onet.pl

# Aktualności z firm

News from the Companies

*Dokończenie ze strony 195*

**Trójfazowy program naprawczy przebiega zgodnie z planem**

W sierpniu 2014 r. LANXESS przedstawił trójfazowy program naprawczy. Pierwsza faza, polegająca na poprawie konkurencyjności działalności koncernu oraz udoskonaleniu pionu administracyjnego, w tym zmniejszeniu zatrudnienia o ok. 1000 osób na całym świecie, została w dużej mierze zrealizowana. Ograniczenie zatrudnienia w Niemczech o ok. 500 miejsc pracy dotyczyło przede wszystkim stanowisk administracyjnych i odbyło się bez zwolnień z powodów operacyjnych. Zmniejszenie zatrudnienia o kolejne 500 etatów nastąpi poza rynkiem niemieckim. Od końca 2015 r. działania podejmowane w ramach pierwszej fazy programu przyniosą LANXESS oszczędności rzędu 120 mln EUR. Z końcem 2016 r. suma ta wzrośnie do 150 mln EUR rocznie. Koncern rozpoczął też pierwsze działania w ramach drugiej fazy programu. Celem tego etapu jest poprawa konkurencyjności operacyjnej. W świetle obecnych nadwyżek mocy produkcyjnych w obszarze kauczuków syntetycznych LANXESS optymalizuje swoje sieci produkcyjne w zakresie kauczuku EPDM i NdPBR. Koncern planuje wstrzymanie produkcji kauczuku EPDM w swoim zakładzie w niemieckim Marl pod koniec 2015 r. W związku z reorganizacją swoich sieci produkcyjnych kauczuków EPDM i NdPBR koncern przewiduje zmniejszenie zatrudnienia o ok. 140 miejsc pracy, a ponadto nadzwyczajne obciążenia na poziomie ok. 55 mln EUR. Celem trzeciej fazy programu jest poprawa konkurencyjności portfela biznesowego, szczególnie poprzez współpracę w branży kauczuku. *(kk)*

*(Komunikat prasowy Lanxess, 30.03.2015)*

**Wyniki Grupy CIECH – potwierdzenie pozytywnych efektów restrukturyzacji**

W 2014 r. Grupa CIECH odnotowała bardzo dobre, znormalizowane wyniki operacyjne, które były znacząco wyższe niż w 2013 r.. Przychody netto ze sprzedaży w okresie od 1 stycznia do 31 grudnia 2014 r. wyniosły 3.244 mln zł. Zysk brutto ze sprzedaży wyniósł 681 mln zł. Zysk na działalności operacyjnej osiągnął poziom 320 mln zł. Tak dobre` wyniki są efektem konsekwentnie realizowanego programu głębokiej restrukturyzacji Grupy CIECH, trwającej od 2012 r., a także sprzyjających warunków rynkowych, zwłaszcza w kontekście rosnących marż w segmencie sodowym. W 2014 r. wszystkie spółki Grupy nadal wdrażały indywidualne programy restrukturyzacyjne, czego rezultaty znajdują odzwierciedlenie w wynikach skonsolidowanych. W 2014 r. istotnie zwiększone zostały moce produkcyjne Grupy. Zainstalowany w Rumunii nowy kalcynator podniósł zdolności produkcyjne tamtejszych zakładów do 460 tys. t/r; uruchomiona w październiku ub. r. ` rozbudowana instalacja do produkcji nasyconych żywic poliestrowych w Nowej Sarzynie pozwala na zwiększenie produkcji tego asortymentu o 100% – do 12 tys.t produktu rocznie. Kontynuowany jest główny projekt rozwojowy segmentu sodowego – SODA+200 (rozbudowa mocy produkcyjnych w Inowrocławiu o dodatkowe 200 tys.t produktu rocznie – do poziomu 800 tys.t rocznie w 2016 r.).

W ubiegłym roku miały miejsce istotne zmiany w strukturze akcjonariatu spółki – w czerwcu 2014 akcjonariuszem większościowym została KI Chemistry – spółka z grupy Kulczyk Investments. Ta zmiana stwarza spółce nowe możliwości i daje perspektywy dalszego rozwoju. W najbliższym czasie spółka skupi się na wzroście organicznym i kontynuacji dotychczasowej działalności w segmencie sodowym i organicznym. Kontynuowana też będzie polityka podnoszenia efektywności Grupy. CIECH będzie rozwijać się dwutorowo koncentrując się na optymalizacji kosztów i dbając przy tym o rozwój i budowę nowych linii produkcyjnych. *Przed nami kolejne ambitne wyzwania i projekty rozwojowe. Wartość firmy wzrasta, a spółka z sukcesem rozwija się w skali globalnej. Z optymizmem patrzę w przyszłość i jestem przekonany, że CIECH jest dziś już zupełnie inną, bardziej dynamiczną firmą i solidnym partnerem biznesowym. Nasz cel pozostaje niezmienny: będziemy nadal budować wartość naszej spółki dla akcjonariuszy.* – podsumował plany Zarządu Prezes Dariusz Krawczyk. *(abc)*

*(inf. prasowa CIECH SA, 23 marca 2015 r.)*

*Dokończenie na stronie 210*