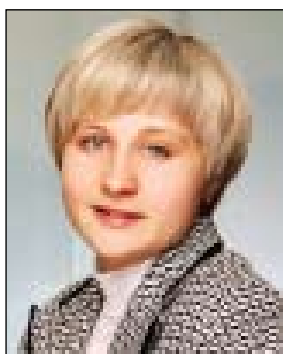


REACHing success

under the New Rules Applicable to Chemicals in EU



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On 1 June 2007, when the *REACH Regulation*¹ aimed at ensuring a high level of protection of human health and the environment and enhancing competitiveness and innovation in chemical industry came into force, the honeymoon period for all companies in any way involved in manufacture, supply or distribution of chemicals in Europe ended.

Even though the said new comprehensive regulation directly stipulates that it covers EU-manufacturers and importers only, it also presents a myriad of pitfalls for non-EU companies, including Ukrainian companies exporting their chemical products to Europe. Ukrainian companies were forced already to overcome plenty of stumbling blocks (e.g. anti-dumping and countervailing measures, safeguards, etc.) to capture the European market, but now a new “serious enemy” in terms of the *REACH Regulation* has appeared. In order to survive and to continue exporting chemical products to the EU, Ukrainian companies will have to follow all the terms and conditions of the said regulation.

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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

In this article we do not intend to analyze the provisions of the *REACH Regulation* that have been already touched upon in other articles in this issue, but to focus mainly on the practical hints to be followed by Ukrainian companies exporting products containing chemical substances to the EU market.

Understanding the nature of the REACH Regulation

The foundation stone to successfully manage the REACH process is understanding that the *REACH Regulation* is not just a single requirement to be followed (e.g. to obtain a certificate), but a very comprehensive “vehicle” consisting of different stage-by-stage requirements, obligations, terms and conditions to be duly and strictly abided.

Besides, as the *REACH Regulation* provides directly for further introduction of the amendments thereto (e.g. list of substances subject to authorization or restrictions), it is crucial not just to learn by heart the *REACH Regulation* and all related guidelines, but also to constantly monitor all updates and amendments thereto to keep abreast of all further developments.

Determining all applicable requirements

It is worth noting that the *REACH Regulation* applies different requirements depending on the features, kinds

of use or quantities of substances placed on the European market, e.g.:

(i) The *REACH Regulation* shall not apply at all to radioactive substances or non-isolated intermediates;

(ii) In general terms, registration requirements shall be imposed on any manufacturer or importer of a substance, either on its own or in preparations manufactured or imported in quantities of one tonne or more per year. Otherwise, the “no data, no market” principle shall apply.

At the same time, some substances (e.g. active substances manufactured or imported for use in biocidal products only) shall be regarded as already registered; while substances used in medicinal products for human or veterinary use or in food or feeding stuffs shall be completely exempted from registration requirements.

Substances contained in articles shall be registered only if they are present in articles in quantities totalling over one tonne per producer or importer per year and intended to be released under normal or reasonably foreseeable conditions of use;

(iii) Authorisation requirements may be imposed on substances to be indicated in Annex XIV e.g. classified as carcinogenic, or mutagenic, or toxic for reproduction, or being persistent, bio-accumulative and toxic or very persistent and very bio-accumulative, etc. At the same time, the latter shall not apply to uses of substances in the protection of plant products. In addition, substances used in medicinal products for human or veterinary use or in food or feeding stuffs shall also be exempted from authorisation requirements;

(iv) Substances on their own, in preparations or in articles, for which Annex XVII contains a restriction shall, not be placed on the market or used unless it complies with the conditions of that restriction, etc.

Hence, to ensure compliance with all REACH obligations, Ukrainian companies shall, first of all, create an inventory of all substances on their own, in preparations or in articles, types of use and volumes thereof exported to the EU market and to define all requirements applicable to each substance. It is also essential to develop and implement an efficient compliance program for the company by

assessing implications and defining specific day-to-day actions for each division of the company to duly perform new REACH obligations on a daily basis.

Registration

Registration is the first very important stage to be performed by Ukrainian companies.

Pre-registration

It should be pointed out that the *REACH Regulation* sets out transitional registration periods for phase-in substances depending on volumes and features thereof. For example, substances classified as carcinogenic, mutagenic or toxic to reproduction and manufactured or imported to the EU, in quantities reaching one tonne or more per year per manufacturer or per importer shall be registered by 1 December 2010, while substances manufactured or imported in Europe in quantities reaching one tonne or more (up to 100 tonnes) – by 1 June 2018. If companies have not pre-registered their substances, they shall not benefit from transitional periods and their substances will only be allowed to be placed on the European market if registration requirements are met starting from 1 June 2008.

“Late” pre-registration

Pre-registration process took place from 1 June 2008 to 1 December 2008. However, the *REACH Regulation* allows potential registrants manufacturing or importing for the first time a phase-in substance in quantities of one tonne or more per year after 1 December 2008 to benefit from transitional periods if companies pre-register their substances within six months of first manufacturing, importing or using the substance in the said quantities, but not later than 12 months before the applicable transition period deadline.

Choosing a proper vehicle to comply with REACH registration requirements

It should be emphasized that Ukrainian companies have the following options to be involved in the REACH registration process:

(i) Through their importers. At the same time, while considering such an option, Ukrainian companies shall bear in mind the following disadvantages: the registration process shall be

carried out by each importer separately, which will result in significant time, organisational and financial expenses for Ukrainian companies; Ukrainian companies will be bound to disclose sensitive commercial information to each importer; the substance will be registered in the name of an importer that will be in a position to further dictate its terms.

(ii) Through the only representative (an individual or legal entity established in the EU). Ukrainian companies may benefit from appointment of the only representative as registration shall be passed through once only; confidential information shall be disclosed only to a single person and may be efficiently controlled by means of a confidentiality agreement to be concluded with the sole representative; EU importers shall not be bound to carry out registration and thus, chemical products of the respective Ukrainian company become more competitive.

However, to enjoy the said privileges, it is crucial to duly regulate all essential terms and conditions of cooperation in the agreement to be entered into with the only representative (e.g. ownership for registration number and registration dossier, confidentiality and liability issues, etc.);

(iii) Through own subsidiaries established in EU. It seems reasonable for large companies with significant volumes of export to use such an option. At the same time, prior to preference being given to such an option, all administrative and financial expenses shall be analyzed.

Registration

Registration process will require involvement of Ukrainian companies in the following procedures:

(i) Participation in substance information exchange forums (SIEF) aimed at (a) facilitating for the purposes of registration of the exchange of the information on a particular substance between potential registrants, thereby avoiding the duplication of studies; and (b) agreeing classification and labelling.

To be able duly and in the most efficient way to perform obligations set out by the *REACH Regulation* in the field of SIEF, it is crucial for Ukrainian companies to define which information shall be disclosed on a mandatory basis (e.g. tests on vertebrate animals) and which

penalties shall apply in case of non-performance of the respective obligations. In addition, participation in SIEF is helpful in terms of ensuring that the costs of tests to be conducted for registration purposes shall be determined and shared in a fair, transparent and non-discriminatory way among potential registrants;

(ii) Defining and collecting all relevant information to be submitted for registration. First of all, it is worth noting that the scope of information to be collected depends significantly on the features and bands of a substance. In this regard Ukrainian companies shall conduct research and review, data valuation, order testing from different research organisations (if needed), compile an internal inventory of their own, data, etc. It is also crucial for Ukrainian companies to evaluate all the pros and cons as well as risks related to joint or separate submission of data for registration purposes. In the event of separate submission of data Ukrainian companies shall be ready to prepare justified arguments supporting the separate submission due to commercial sensitivity, disproportionate cost, or disagreement with the lead registrant.

Post-registration requirements

After successful registration, Ukrainian companies shall update their registration with relevant new information. For example, in case of any change in the composition of the substance; changes in the annual or total quantities imported; new knowledge of the risks of the substance to human health and/or the environment leading to changes in the safety data sheet or the chemical safety report, etc.

However, Ukrainian companies may be released from the said obligation if they have ceased the import of the substance or an article and notified the European Chemicals Agency (ECHA) thereof.

In any case Ukrainian companies shall bear in mind that they will be bound to assemble and keep available all the information required to carry out their duties under the *REACH Regulation* for a period of at least 10 years after they last imported, supplied or used the substance or preparation.

Authorisation

The *REACH Regulation* provides for authorisation requirements aimed at ensuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies. In this respect, Ukrainian companies shall be ready to provide their importers with analysis of the availability of alternatives to be applied as well as with the technical and economic feasibility of substitution. Moreover, as under the *REACH Regulation* an authorisation may only be granted if it is shown that the socioeconomic benefits outweigh the risk to human health or the environment

“No other choice than go through the REACH provided processes”

arising from the use of the substance and if there are no suitable alternative substances or technologies, Ukrainian companies will probably be involved in the respective substantiation process.

Ukrainian companies should also bear in the mind a possibility to object to inclusion of the respective substances in Annex XIV (indicating the list of substances subject to authorisation) by submitting the comments of justification.

Restrictions

The *REACH Regulation* allows for restricting application of substances posing a risk to human health or the environment that is not adequately controlled. The list of such restrictions shall be

approved in Annex XVII. In respect of restrictions Ukrainian companies shall be ready to provide the ECHA with comments on the suggested restrictions and a socioeconomic analysis, or information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions to avoid inclusion of new restrictions in Annex XVII.

Creating a professional team

It goes without saying that to comply with all above burdensome requirements, each Ukrainian company concerned shall establish a working team consisting of different professionals able to weigh up all the possible benefits and risks, to move the whole process forward, e.g.:

(i) Chemists, employees in charge of purchase of raw materials, manufacture and export of the products to the EU market, who will help to interpret data, analyze data gap, conduct hazard assessment, prepare chemical safety assessments and reports, etc.;

(ii) Interpreters, who will provide not only proper translation of the *REACH Regulation* itself, but also of applicable guidelines and amendments/updates thereto;

(iii) Legal advisers, who will protect interests of the company by drafting tailor-made agreements e.g. for participation in SIEF, with the only representative, for confidentiality protection, cost-sharing, lead registrant obligations, and contracts with research organisations, help during appeal process (e.g. appeal of ECHA's decision on registration of substances) as well as ensure day-to-day monitoring of the recent developments of the *REACH Regulation*.

In addition, such a team normally consists of local and foreign professionals. Therefore, it is vitally important to divide up reasonably their obligations and responsibilities in order to ensure financial and time efficiency.

Moral of the tale

Broadly speaking, if Ukrainian companies want to remain and further capture the EU market, they have no other choice than to go through the REACH provided processes, overcoming all pitfalls and hidden reefs... ■