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ISSN 0350-350X

GOMABN 48, 1, 29-74

Pregledni rad/Review

UDK 351.824.1 : 658.8 : 661 : (083.83) : 620.26 (4-62)(497.13)"2006-2010"

## REACH REGULATION AND ITS INFLUENCE ON BUSINESS ACTIVITIES

### *Abstract*

*Legislative changes in the Republic of Croatia in the field of chemicals management are taking place in the atmosphere of a new strategy for managing chemicals on the European Union level, which has the two most important objectives: to improve protection of human health and the environment from the risks of chemicals, and simultaneously to increase competitiveness and innovativeness in chemicals industry. REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (EC 1907/2006) [1] stands for the new European regulations on registration, evaluation, authorisation, and restriction of using chemicals marketed in the EU Member States, which entered into force on 1 June 2007.*

*The Regulation provides a comprehensive flow of information on the risks regarding particular substances (on their own, in preparations and in articles) from the production to a consumer, and it has been adopted after many years of communication between the representatives of industry and environmental protection organisations. It is assumed that more than 30,000 chemicals will pass through the process of registration, evaluation, authorisation, and restriction.*

*According to this Regulation, the companies that produce, use, or export hazardous chemicals bear the responsibility for evaluating and managing the risks involving human health and the environment, which means that the industry has to take over the costs of procuring the prescribed data on the substances and measures to be taken for the efficient risk management, while authorities are focussed on the Regulation implementation control. The central coordination body supervising the REACH system implementation is the European Agency for Chemicals, in Helsinki.*

*The Croatian companies exporting their products to the EU market are under obligation to comply with the REACH Regulation regardless of the fact that Croatia is not a member of the EU. Obligations commence already on 1 June 2008 when the pre-registration of chemicals began at the European Agency for Chemicals. Confronted with the new European trends in the field of chemicals management and changes in Croatian legislation, INA as a manufacturer of oil, gas, and oil products, an exporter of certain products to the European market and a user of chemicals, is*

*preparing for a gradual harmonisation with the REACH system, using advantages from its membership in CONCAWE (European organisation of oil companies for the environment, health, and safety) and the experience of major companies in the field of REACH Regulation implementation.*

## **1. Introduction**

Although many European laws were implemented during forty years in the field of chemical management, politics and chemical industry<sup>1</sup> recognized a number of problems related to their implementation, which directly influence functioning of the internal market and the efficiency of health, safety and environment protection. Analysis results of the current state have shown that this kind of legislation is imprecise, inefficient and uncoordinated; information about most of the chemicals and their risks are insufficient; possibilities for research and innovations are limited.

At the same time, the European public opinion shows mistrust in chemicals; a number of surveys proved that there is a great public concern due to the unavailability of information and suspicions relating harmful effects of chemicals towards human health and the environment (here we have to emphasize the intensive lobbying activities of non-governmental organizations, "green activists", for example, Greenpeace "Chemicals out of Control"....).

The old legislative system (before the REACH Regulation came into force) distinguished between *existing substances* (on the market up to 1981) and *new substances* (on the market after 1981). *New substances* were tested and based on these data, risks and their restrictions of placing them to the market have been estimated, together with their use, while for *existing substances* the legal system was very slow so the risk assessment has been completed for a small number of existing substances only. The control of substances after they have entered the chain production of preparations and other kinds of goods was not satisfactory. Safety Data Sheet (SDS) as the basic document for assessment of chemical danger was not of satisfactory quality.

Since new chemicals had to be notified and tested already starting with amounts of 10 kg/year, there was not any encouragement for innovation or study of new substances (which would substitute harmful chemicals as safer alternatives), but the

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<sup>1</sup> There were four basic legal instruments in the field of protection against chemicals/chemical management in the Community before the REACH Regulation: Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; European Parliament and Council Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations; Commission Directive 76/769/EEC on the approximations of the laws, regulations, and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations; Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

circumstances stimulated the development/use of non-tested existing substances (since it was easier and cheaper). Nevertheless, for new substances for the amount of 10 kg/year just 1 experiment on animals was needed, while with 1 ton a number of such experiments had to be done. A lot of money was spent on repetition of procedures/tests and assessments of chemicals on the level of each EU Member State.

### 1.1. REACH Regulation – a single system for existing and new chemicals

In 2001 the European Commission suggested a strategy for the new EU politics in the field of chemicals by introducing the so called White Paper (*White Paper "Strategy for a future Chemicals Policy"*) [3] in which a new legislative system called REACH is included. Two basic objectives of this new strategy for chemicals in the EU: to improve the protection of human health and the environment and to increase competitiveness and innovation of the industry of chemicals in the EU.

The REACH Regulation of the European Parliament and of the Council EC No. 1907/2006 on registration, evaluation, authorisation, and restriction of using chemicals in the EU (the Regulation, further in the text) entered into force on 1 June 2007. The aim of this regulation is to provide all the preconditions for achieving efficient chemical safety on the level of the whole EU. The Regulation combines about 40 directives and other regulations that direct "existing" and "new" substances. For example, in Directive 67/548/EEC, among other things, the notification system of "new substances" is replaced by the REACH system, and by 30 November 2010 the system of the classification and labelling will be replaced by the *UN Globally Harmonised System of the Classification and Labelling of Chemicals (UN GHS)*; Directive 1999/45/EC [7] is being changed and amended and Directives 76/769/EEC and 93/793/EEC are eliminated. In accordance with the data from the literature, information gained by the Regulation implementation will provide other regulations in the field of chemicals to be more efficient.

### 1.2 Key processes of the REACH system

The Regulation is based on substances and the registration process of data on substance properties and the risk management deriving from substance use. Registration dossier with data on substances is electronically submitted to the data base which is controlled from one centre by the European Agency for Chemicals located in Helsinki, Finland [4] (it started to operate on 1 June 2008).

**Substance registration.** REACH Regulation recalls the difference between "old and new" substances and in accordance with the established uniform criteria of the new system, all the substances (in amounts >1 ton/year) have to be registered and evaluated in order to continue to be produced/imported/marketed/used in the EU.

REACH Regulation is based on the principle that manufacturers, importers and users need to provide evidence that the substance they manufacture, place on the market or use are not hazardous for human health and the environment.

A substance supplier outside of the EU can appoint a company from the EU as its only representative which will, on the supplier's behalf, fulfill all the obligations for the registration needs from the Regulation.

The Regulation sets the priorities for larger amounts of substances which are manufactured/imported and placed on the market as well as for substances of very high concern.

Entrepreneurs have to collect all the available data on substance properties, based on which they are to study and evaluate the potential risks a substance has for human health and the environment. Also they can suggest the measure that could be taken in the risk management deriving from substance use.

Subsequently, new conditions are being made to identify areas where human health and the environment need to be more controlled or market restrictions and substance use are being reconsidered.

According to the motto "No data no market" of the Regulation it is said in the Article 5: "... substances on their own, in preparations and articles can not be manufactured in the Union or placed on the market if they are not registered according to the Regulation ...".

With its mechanisms the Regulation promotes research on substance properties which are not based on animals (testing of a substance involving vertebrate animals is only carried out as a last resort). The Regulation supports the Commission, the EU Member States, the industry and other participants to continue with their efforts to promote alternative test methods (*in silico*, *in vitro* and other methodologies) at the international level.

The Regulation significantly influences the role of the national competent authorities since finding evidence of safe use of the substance (during its lifetime in the supply chain), responsibility for different solutions and spreading all the information on the substances is transferred to the industry, while the implementation of the Regulation is still the responsibility of the national competent authorities.

**Information in the supply chain.** The Regulation sets the mechanism for improving the communication in both directions of the supply chain (manufacturer/importer-downstream user-distributor-consumer), in order to estimate the risks of the substance use thoroughly. Intensive communication in the supply chain in two directions will provide better understanding of the needs of other actors for the companies included in the supply chain (at the same time, the conditions for "new market" are made since companies will be able to sell different solutions to their users).

**The evaluation** of the registration dossier and substances (with potential risks to human health or the environment) is conducted by ECHA and the Member States. It is based on all the relevant information submitted about the substance and all the previous assessments (also including *the related substances* which are used with alternative methods in the identification process of certain properties of a given substance).

Only substances of very high concern (SVHC) are subjected to the **authorisation**, and substances with unacceptable risks are subjected to the **restriction**. Authorisation is approved only if the risk is adequately controlled. The Regulation stimulates the industry to create innovations (substitutes for substances of very high concern) to improve the protection of human health and the environment.

The REACH Regulation [1] represents a single system for all "existing and new" substances by describing *phase-in substances and non-phase-in substances*, and it defines the phase-in substance which meet at least one of the following criteria (Regulation, Article 3 (20)):

1. it is listed in the *EINECS*;
2. the substance was produced in the Community, or in the countries which became the Member States on 1 January 1995 or 1 May 2004, but they were not placed on the market by the manufacturer/importer for at least once in 15 years before the REACH Regulation entered into force provided the manufacturer/importer has adequate documentary evidence of this;
3. the substance which is classified as "no-longer polymers"; the manufacturer/importer placed these substances on the market in the Community, or in the countries acceding to the EU on 1 January 1995 or on 1 May 2004, before the REACH Regulation entered into force and was considered as having been notified in accordance with the Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in REACH Regulation, provided the manufacturer/importer has documentary evidence of this. The list of these substances is available at the ESIS.

All the other substances defined as "non-phase-in substances" (they do not meet any of the criteria mentioned above, under No. 1-3):

- they are registered according to the REACH Regulation dating from 1 June 2008;
- the substances notified for the first time between September 1982 – May 2007 according to the Directive 67/548/EEC are considered to be registered. According to the Article 24 of the Regulation ECHA assigns a registration number by 1 December 2008. Mentioned substances are listed in the *ELINCS*.

## 2. Registration and pre-registration

### 2.1 Registration

The aim of the registration process is to provide an adequate way for the industry to manage risks relating substances that are being manufactured, imported, marketed and used. According to the Regulation, each company in the EU manufacturing/importing substance (either on its own or in one or more preparations) in quantities of 1 tonne per year or more, is to register data on substance properties, identified uses and safety of a certain substance, and to submit registration dossier to ECHA, with a fee submitted (in accordance with the Regulation).

Substances in articles are also registered, under the condition that this substance is present in quantities of > 1 ton/year/manufacturer or importer, is intended to be released during foreseeable conditions of use from an article (or ECHA assesses risk for it) or if the concentration of SVHC is > 0,1 m/m% in an article. All the substances (hazardous, non-hazardous, existing and future new substances) manufactured/imported in the EU have to be registered, but some substances are excluded by the REACH Regulation (article 2):

- substances in quantities < 1 ton/year/manufacturer/importer; but they still need to be classified and labelled,
- radioactive substances and substances under customs supervision (they are temporarily stored to be re-exported or transported; the condition is that they are not treated/processed),
- non-isolated intermediates,
- waste (according to the Directive 2006/12/EZ, waste is not a substance, a preparation nor an article).

Table 1: Registration fees

Substances in the range of (tonnes/year)	Standard fee (euro)	Reduced fees for small and medium enterprises (% reduction)	
		Medium.....	Small .....
1-10	1600	30%	60%
10-100	4300	90%	
100-1000	11500	All: .....25% for joint submission of registration dossier	
> 1000	31000		

Some substances are excluded from the registration process, but they can be subjected to the authorisation process:

- polymers (obligatory registration is associated with monomers, if they are in the polymer in quantities > 2% of mass portion),
- substances/groups listed in Annex IV (list of low hazard substances) and Annex V of the Regulation which also include naturally occurring substances (without chemical change); some of them are natural gas, liquid gas, natural gas condensate, process gases and their components, crude oil, gas coke...,
- substances in food and medicines.

Other substances have tailored provisions within the REACH Regulation:

- *Internal isolated intermediates* (used in the production of other substances, produced on-site) and *Transported isolated intermediates* (transported under controlled conditions between or delivered to other sites/locations); a manufacturer/importer has to confirm that these intermediates are manufactured and used under strictly controlled conditions where they are unable to be released during their life-cycle.

- PPORD substances manufactured/imported in small quantities.

A list of substances which are excluded from the registration is in the Regulation, Articles 2, 9, Annexes IV and V. New chemicals coming to the market should be registered immediately, while in-phase substances can be pre-registered without charge within a simple on-line process in the period from 1 June 2008 to 30 November 2008. It is estimated that 30 000 substances is to be pre-registered.

The registration of a certain substance is fully completed after the ECHA assigns it a registration number and a registration date which will be used for all the following correspondence related to the registration.

**Third Party Representative.** Any manufacturer/importer can appoint a *Third party representative* for all proceedings relating shared data and costs during the registration process. A third party representative is usually appointed when a company does not want to reveal certain substance data which represent its production/commercial secret.

**Only Representative.** As it was already said in the introduction, a supplier outside the EU can (based on mutual agreement) appoint a company established in the EU to act as their *only representative* (a natural and legal person established in the EU), to fulfill all its obligations under REACH. In this case, this manufacturer/importer shall be regarded as a downstream user.

#### **2.1.1. Data submitted for the registration purpose**

The number of data requirements prescribed by the Regulation depends on quantity, intrinsic properties and conditions of substance/preparation/product use. Within a registration process a manufacturer/importer has to collect, classify and evaluate all the available and relevant data on the substances, including standard information under REACH, Annexes VII – X (so called *Testing Annexes* prescribe data on *intrinsic* properties of substances: physiochemical, toxicological, ecotoxicological properties).

If a potential registrant of a substance does not dispose of data for final points established by these annexes, the Regulation sets a number of regulations on evaluation of all the available data before conducting new tests: for example, studies on accidental or professional exposure, epidemiological and clinical studies, data based on techniques such as *in vitro*, *in vivo*, *in silico*.

Results of the use of alternative methods for the assessment of the hazardous properties of substances i.e. QSAR and read across on structurally related substances, can additionally prove presence/lack of hazardous substances, so it is not necessary to test each final point (which means that these results can replace testings).

Prior to testing one also needs to consult additional guidance documents on strategies for testing (developed by ECHA).

Still, if new testings need to be conducted (in case when the existing information and alternative methods are not sufficient), the Regulation sets a general requirement for

the use of good laboratory practice (GLP) for toxicological and ecotoxicological tests and analysis (anticipated in the Directive 2004/10/EZ or other international norms approved by ECHA).

If a potential registrant for a substance in quantities >100 and >1000 tonnes/year does not dispose of data prescribed by the Regulation, Annexes IX and X, a testing proposal and timeline for complying with the requirements need to be submitted for the purposes of the registration.

Since this kind of testing can be costly or include testings conducted on vertebrate animals, ECHA will be checking all the testing proposals in the evaluation process to save animals' lives and unnecessary costs.

### 2.1.2 Components of the registration dossier

Components of the registration dossier are shown in the table 2.

**Technical dossier.** For a substance manufactured/imported in quantities >1 tonnes/year, a manufacturer/importer submits the technical dossier (the Regulation, Art. 10), with information on properties, use, classification and labelling, and guidance instructions for safe use of the substance to ECHA.

Chemical Safety Report (CSR)

**Chemical Safety Report (CSR).** According to the Regulation (Art. 14), for each substance manufactured/imported in quantities >10 tonnes/year, a Chemical Safety Assessment (CSA) needs to be prepared and it needs to document this assessment in its CSR as part of his registration dossier (as such it is submitted to ECHA), according to the Regulation, Annex II, section 7.

The CSA complying with the Regulation, Annex 1 (*General Provisions for Assessing Substances and Preparing CSR*), start with the analysis of available information on the substance, based on the assessment of potential hazard to human health and the environment; then substances are classified and labelled (according to Directive 67/548/EEC to determine if the substance meets the CMR cat 1 or 2).

As a novelty in the assessment, properties of PBT/vPvB are also identified/documented to reduce their emission into the environment and human and environmental exposure to these properties.

The assessment also includes the identification of DNELs for human health and PNECs for the environment.

If the hazard assessment classifies a substance as not hazardous or does not identify any PBT properties, that fact needs to be documented in the CSR. Nevertheless, for those substances that are either classified as hazardous or identified as a PBT or vPvB, the Regulation requires further information: the relevant exposure assessments (which includes the exposure scenario and the exposure evaluation) and the risk characterisations for these substances.

**The exposure scenario** describes how the substance is manufactured or used during its life-cycle: *operational conditions*, e.g. who is exposed, where, how, to which quantity, how often, for how long: substance emissions, the exposure of the



workers and the consumers to the substance. The exposure scenario also includes *the risk management measures* (to reduce/avoid the human exposure – the workers and the consumers and the environmental exposure to the substance) and the *waste management measures* (to reduce/avoid the human and environmental exposure during disposal/recycling of substances in the phase of waste).

Table 2: Registration dossier

<b>Substance for registration &gt; 1 tonnes/year</b>	<b>Technical dossier</b> (Data shared by all the registrants) <ul style="list-style-type: none"> <li>- The identity of the manufacturer/importer, Annex VI (1)</li> <li>- The identity of the substance, Annex VI (2)</li> <li>- Information on the manufacture, quantity of the manufactured substance and its use (all the uses identified by the registrant), Annex VI (3)</li> <li>- Classification and labelling of the substance, Annex VI (4)</li> <li>- Guidance for safe use of substances, Annex VI (5)</li> <li>- Study summaries – substance properties (physiochemical, toxicological, ecotoxicological – information deriving from the appliance of Annexes VII - XI)</li> <li>- Note/indication as to which information has been reviewed by an assessor</li> <li>- Testing proposals, where listed in Annexes IX and X</li> <li>- Exposure information as for the substances in quantities of 1-10 tonnes, Annex VI (6)</li> <li>- Request protection of company secrets according to Art. 119 (2)</li> </ul>	
<b>&gt; 10 tonnes/year</b>	<b>Technical dossier</b> (above)	<b>Chemical safety report</b> <ul style="list-style-type: none"> <li>- <b>Hazard assessment</b></li> <li>- <b>PBT/vPvB properties assessment</b></li> </ul>
<ul style="list-style-type: none"> <li>- <b>Hazardous substances</b></li> <li>- <b>PBT/vPvB</b></li> </ul>	<b>Technical dossier</b> (above)	<b>Chemical safety report</b> <ul style="list-style-type: none"> <li>- <b>Hazard assessment</b></li> <li>- <b>PBT/vPvB assessment</b></li> <li>- <b>Exposure assessment</b></li> <li>- <b>Risk characterisation</b></li> <li>- <b>Exposure scenario</b></li> </ul>

The information from the exposure scenario are implemented in/annexed to the SDS (so called *extended SDS, e-SDS*) and in this way they are recommended to the users in the supply chain. According to the Article 31 of the Regulation, each actor in the supply chain who has to develop the CSR, should list all the relevant exposure scenarios in the e-SDSs.

**The exposure estimation** has to be developed for each exposure scenario and it contains three elements: *the emission estimation* (deriving from the production and each identified use); *the assessment of chemical fate and pathways*; *the estimation of exposure levels* for all human populations and all environmental spheres.

**The risk characterisation** is a synthesis of the hazard assessment of substances and the exposure assessment (according to the Regulation, Annex II, section 6):

within an exposure scenario, a risk for human health and the environment (deriving from the production and all the identified uses of the substances) is subjected to the appropriate control during the life-cycle of the substance, if the conditions are met:

- *the exposure levels* for all human populations and the environment do not exceed the appropriate DNEL or PNEC,
- *the probability of occurrence and severity of events* associated to the physicochemical properties of the substance are negligible. With evaluation of each physicochemical property (explosiveness, volatility, oxidation potential) one needs to evaluate at what measure the substance is likely to produce such an effect during the production and identified uses.

The risk assessment, the risk management and the risk communication are an integral part of the CSA and they represent a new way of thinking in the field of legislation on chemicals; with the REACH Regulation the centre of attention is moved *from the hazard assessment to the risk assessment*.

The procedure of the chemical safety assessment is shown in the Figure 1.

### **2.1.3 Safe use of chemicals, two way communication and responsibility in the supply chain**

Information on safe use of substances are covered by already mentioned documents: registration dossier (technical dossier, CSR) and SDS/e-SDS. The Regulation establishes the mechanisms of communication which enable all the actors in the supply chain to dispose of data on the risk management/safe use of chemicals, so there is a two way communication, from the supplier to the recipient and vice versa (e.g. manufacturers, importers, distributors, users, consumers). If a given substance/preparation is classified as hazardous (it is on the *List of substances subject to authorisation* according to the Regulation, Art. 57), the manufacturer/importer has to develop an SDS/e-SDS and submit it to a recipient.

**The transmission of information on substances/risk management along the supply chain.** Primarily, manufacturers/importers are responsible for safe use of hazardous substances/preparations. They have to collect data on human and environmental exposure, analyse the risks of substance use, document the risk assessment, manage these risks efficiently and submit data on safe chemical use (deriving from their production, use on their own, all the identified uses that they are familiar with or submitted by users) to the supply chain under them, for example, to downstream users and distributors. The Regulation defines substance users as "downstream users", that could be industry and professional chemical users, for example preparation formulators, chemical users in other industry processes or article manufacturers (e.g. electronic components).

Based on data received by their suppliers (from the SDS/e-SDS), the downstream users have to manage the risks deriving from their uses of substances.

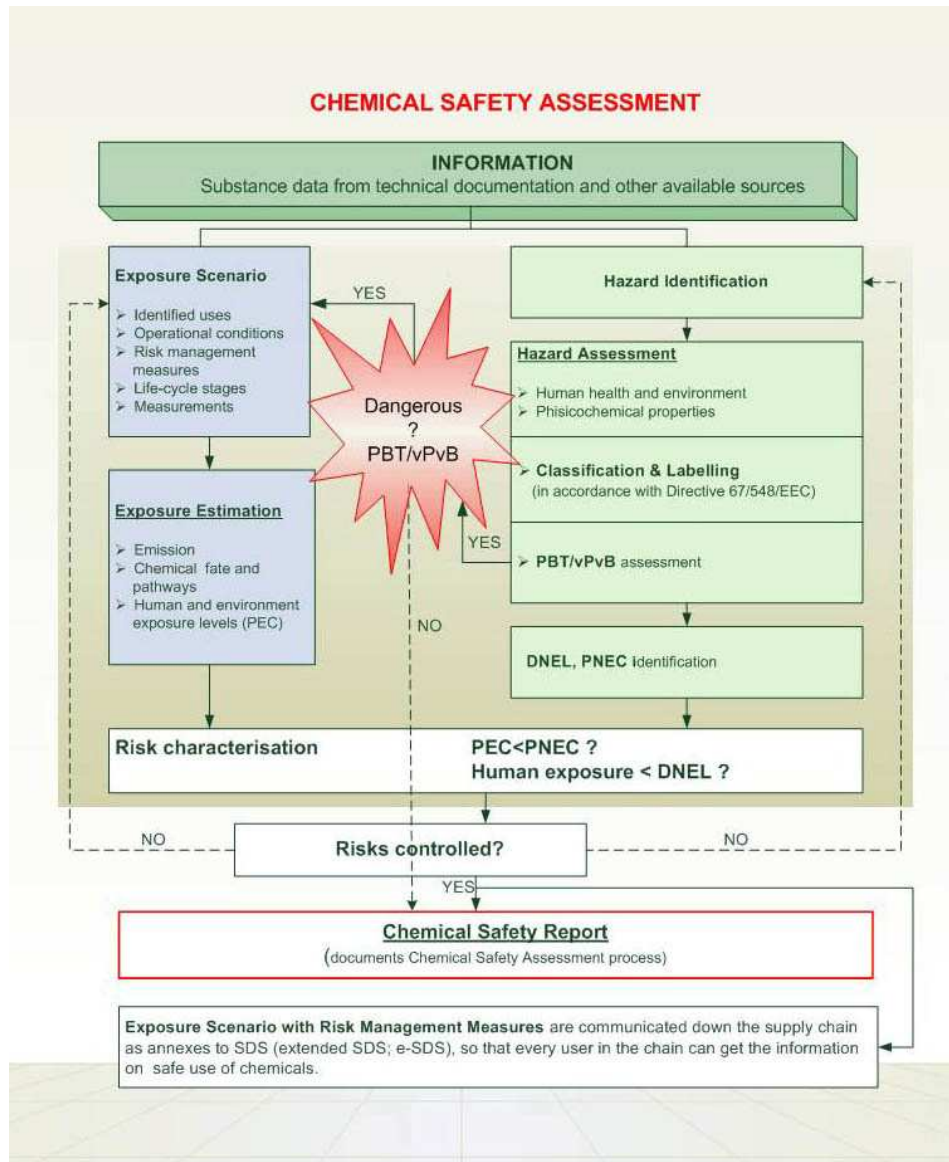


Figure 1: Chemical safety assessment

If the downstream user's risks of substance use are not covered by the supplier's SDS or the supplier does not recommend a certain use, a downstream user has to assess and document that the risks of this kind of use are controlled. A downstream user can submit information collected in this way to the supplier who will develop the exposure scenario for that kind of use or the CSA, in other words the CSR which has to be submitted to ECHA.

In this way an intensive communication between a supplier and a downstream user is developed, aiming to include the downstream user's way of substance use in the supplier's SDS .

**The transmission of information along the supply chain.** Each actor in the supply chain has to provide every new information on the hazardous properties of the substances and the information on appropriateness of the risk management measures (for the certain identified use) stated in the SDS/e-SDS to the actor above.

**The obligation of information exchange on the substances in articles.** Any supplier of an article containing a substance (from the Candidate List for authorisation) above a concentration of 0.1% weight by weight (w/w) has to submit information sufficient for safe use of articles to the recipient and to the consumer upon request.

**Access to information for workers.** The employer has to provide an access to information which workers will use to avoid the potential exposure to the substances while working.

The objective of establishing an intensive two way communication along the supply chain is the efficient risk management during the entire life-cycle of the substance.

**The exposure scenario** describes under what working conditions and the risk management measures from forming and the professional/industry use, these risks are adequately controlled.

According to the Regulation (Art 31) all substances which comply with the classification criteria according to Directive 67/548/EC, or PBT properties (the criteria in the REACH Regulation, Annex XIII) or the substances from the *Candidate List* for authorisation have to develop their SDS/e-SDS.

#### **2.1.4 Data sharing**

One of the objectives of REACH is to limit (to replace/improve/reduce) vertebrate animal testing and to collect data on the intrinsic properties of substances, which are necessary for registration technical dossier. Tests on vertebrate animals shall only be undertaken as a last resort and can not be repeated. REACH sets the mechanisms which enable potential registrants to come to an agreement on the existing data sharing for the substances registered by other manufacturers/importers during last 12 years.

A potential registrant *has* to make an inquiry for the existing data on substances (studies) which resulted from the tests on vertebrate animals. Information that does not involve tests on vertebrate animals (such as, in vitro studies, QSARs) are used

only if a potential registrant makes an inquiry for them. The agreement also sets a fee which has to be paid to the manufacturer/importer that carried out these testing or made these data available. The objective of data sharing is to avoid duplicate testing and to reduce the number of vertebrate animal testing and costs deriving from it.

#### 2.1.5 Joint submission of data

The Regulation defines the way according to which all the companies within the EU manufacturing/importing *the same substance*, submit a single set of information for this substance. Specified data on the same substance which are jointly submitted are prescribed by the Article 11 (mostly data on the intrinsic properties of the substance from the technical dossier, for example, classification and labeling of substances, robust study summaries of physiochemical, toxicological and ecotoxicological research, research proposals, CSR etc.). In this article there is a list of data which are to be submitted by each registrant separately. Some business sensitive data can be submitted separately by a company, along with the written explanation. The data are submitted by "the registrant who leads the joint submission" (in the agreement with other registrants). After this each registrant can separately submit other data from the technical dossier which are related to a manufacturer/importer, production, application, exposures – for the substances in the range from 1 to 10 tonnes, and the other.

#### 2.2. Pre-registration of phase-in substances

The Regulation assumes a (optional) pre-registration process for phase-in substances (>1 tpa), where pre-registrants can use the advantage of registration deadline postponement, and in this way a registrant can prepare and submit all the registration dossier without stopping the production/import process till the date of the registration deadline (2010 – 2018; Table 3.).

Pre-registration dossier [9] must be electronically submitted, without charge, in the period between 1 June 2008 and 1 December 2008, and it must include these data (according to the Regulation, Article 28):

- substance names (including EINECS, CAS, and other identifiers),
- information on contacts with a pre-registrant (contact person, third party representative),
- envisaged registration deadline and quantity range,
- substance names for using alternative methods for determining substance intrinsic properties, for example QSAR,
- grouping substances and read across approach.

If a manufacturer/importer does not use the pre-registration process, the substances have to be registered before any further production/import.

After the pre-registration is completed, on its website ECHA publishes (by 1 January 2009) a *list of pre-registered substances*, with substance names (including EINECS and CAS numbers and other identifiers) and the first envisaged registration deadline.

Substance names of similar pre-registrants, relevant for the use of alternative methods for determining data from the test requirements will also be included in the list. A pre-registrant who submitted data on the similar substance which can be compared (e.g. in read across approach) will be the only one to have insight into another pre-registrant's data from the list.

Table 3: Deadlines in the process of the REACH Regulation implementation, for substances (on their own, in a preparation, in a product) which are manufactured or imported in the EU > 1 tpa

Deadline	Activities
1 June 2007	REACH entered into force
1 June 2008	Pre-registration for existing (phase-in) substances starts Registration for non-phase-in substances starts Articles that release their substance are also included
30 November 2008	Pre-registration for phase-in substances ends
1 December 2008	Registration for phase-in substances (that have not been pre-registered) starts
1 January 2009	ECHA publishes the List of pre-registered substances Participation in SIEF
1 June 2009	First recommendation of priority substances to be subjected to authorisation (published by ECHA)
1 December 2010	Registration for phase-in (pre-registered) substances: > 1000 tpa > 1 tpa classified as CMR, category 1 or 2 > 100 tpa classified as very toxic to aquatic organisms R50/53, may cause long-term adverse effects in the aquatic environment (ecotoxic substances) Substances causing serious and irreversible effects
1 June 2013	Registration for phase-in (pre-registered) substances > 100 tpa
1 June 2018	Registration for phase-in (pre-registered) substances > 1 tpa

### 2.2.1 Electronic access and data submission

For the purposes of data submission, ECHA prepared the submission forms (for example, a submission form for technical dossier), which one can use (free of charge) and software applications to provide free access to its website. Pre-registration can be done in two ways: a) on-line data entry submitted in the REACH-IT system, or b) for submitting XML documents IUCLID 5 installation can be used to generate the required XML files.

The REACH-IT portal on the ECHA website is the main channel for companies to submit data to ECHA.

REACH-IT supports the creation of company accounts, on-line entry and pre-registration of single substances.

A non-EU company prepares all the information, but for the (pre)registration process (on-line/through IUCLID or XML file) it appoints an only representative.

Information on the substances on their own, in preparations and in articles which were submitted to ECHA will be available to public through the Internet, free of charge (exceptions are the registrants who submitted the explanation why their data could harm their business interests). These data will be published on the ECHA website [4], free of charge (Article 119):

- the identity of the substance,
- classification and labelling,
- physicochemical information on the substance and its fate and pathway in the environment,
- results of toxicological and ecotoxicological studies,
- DNELs, PNECs,
- guidance on safe use (according to Annex VI, sections 4 and 5),
- analytical methods for the identification of hazardous substances released in the environment and the human exposure assessment (if relevant according to Annexes IX and X).

#### **2.2.2. Substance Information Exchange Forums (SIEF) [4]**

After the pre-registration process ECHA will form SIEF (which does not have prescribed legal form); all the potential registrants, downstream users and third party representatives that pre-registered substance with the same identity are the participants in SIEF for a given substance in order to provide more efficient implementation of the following activities:

- they will share data needed for the registration; SIEF members provide other participants with existing studies, they will collectively identify needs for further studies and make arrangements to perform the identified studies (the costs of new tests are shared among the SIEF members);
- the potential registrants will cooperate on the joint data submission from the technical dossier; if the participants agree, they can also use SIEF for the exchange of the data which are required in the CSA or CSR and they have to make an agreement on guidance for safe use of the substance;
- they will have to make an agreement on classification and labelling of the substances (if the registrants do not originally agree on these issues).

The costs of data use and new testings are shared among the SIEF members (they pay for costs of the information which has to be submitted in order to comply with the requirements from their registrations).

By working together the companies agree on shared data use in SIEF; details on how it is achieved depend on the SIEF members. The companies with joint submission of registration data through SIEF can pay the reduced registration fee.

### 3. Evaluation

The ECHA in cooperation with the national competent authorities on substances of the EU Member States evaluates the documentation for the registration of substances:

a) the compliance of the submitted information with the requirements on the registration under REACH is being checked, testing proposals for a specific substance are being considered (listed in the registration technical dossiers or report by a downstream user) in order to check the quality of the information (Annexes IX and X).

Annexes VII-X of the Regulation contain standard information on physicochemical, toxicological and ecotoxicological tests (they can also be obtained by alternative methods) which should be submitted for substances in quantities >1 tonne a year; Annexes IX and X relate substances which are manufactured/imported in quantities >100 and > 1000 tonnes a year.

b) substance evaluation has been prioritised for potential regulatory action because of concerns about hazardous properties of substances and (if necessary) ECHA can require some additional information from the industry due to further evaluation, which can lead to proposing: the imposition of restrictions on the manufacture/placing certain substances on the market, substances being added to the priority list for authorisation or a proposal to change the classification and labelling.

### 4. Authorisation

By the authorisation process the Regulation ensures that risks of use of SVHC are controlled in an appropriate way and, if possible, substituted by alternative substances or technologies.

SVHC substances subjected to the authorisation (meeting the criteria from the Regulation, Article 57) will be published in the Regulation, in a form of Annex XIV.

The ECHA will publish a priority list containing substances to be considered for the authorisation process by 1 June 2009 (Annex XIV<sup>2</sup>).

Substances on the priority list:

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<sup>2</sup> SVHC which are considered to be included in Ann. XIV (crit. from the Ar. 57):

- Substances that have been proven to cause cancer, genetic mutations or reproduction problems (CMR cat 1 and 2 (in accordance with the Directive 67/548/EEC) ,
- Substances that are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) (in accordance with criteria from Annex XIII of REACH Regulation),
- Substances that have been scientifically proven to have probable serious and irreversible effects on human health and the environment, which are as concerning as effects of substances from sec.1, 2.



- substances with PBT/vPvB properties,
- substances of wide dispersive use,
- substances used in large quantities.

For placing on the market or use of a certain substance from Annex XIV, the industry has to submit a request for the approval to ECHA. According to the Regulation, Art. 62 (7), Section IX, with this request a fee has to be paid.

Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks.

Applicants must also analyse whether there are safer suitable alternatives or technologies (if they are economically and technically sustainable). If there are then they must prepare substitution plans or provide information on research and development activities.

Decisions on authorisation are made by the European Commission (based on ECHA's proposal) which also grants/denies authorisation (by imposing certain conditions) for use of substances, taking into consideration all the releases, emissions and losses as well as risks deriving from diffusive and dispersive substances, possibilities of use of alternative substances/technologies. Commission decisions will be published in the Official Journal of the EU and the ECHA will maintain a database on the registered substances.

## 5. Restrictions

A restriction process regulates the manufacture, placing on the market and use of hazardous substances, preparations and articles.

All the substances that pose an unacceptable risk to human health and the environment are subjected to the restriction.

A hazardous substance (any substance on its own, in a preparation or in an article) for which a restriction is foreseen in Annex XVII of the REACH Regulation, may be manufactured, placed to the market and used only if it meets restriction criteria from the Annex.

The European Commission makes a final decision (based on the dossier prepared by the ECHA committees through the analysis of risks and socioeconomic aspects of restriction advantages/disadvantages) on the risk management and it imposes a ban (total/partial or other limitations) for the substance use or both.

## 6. Helping companies to fulfill REACH requirements

Practical help in understanding, implementation of regulatory, technical and economic aspects of the REACH Regulation can be found at these addresses:

- ECHA provides the technical and scientific guidance and tools for the Regulation implementation; <http://echa.europa.eu>,

- *National helpdesks* are parts of the network also consisting of the ECHA and the European Commission services (the ECHA website containing a helpdesk section: [http://echa.europa.eu/reach/helpdesk\\_fr.asp](http://echa.europa.eu/reach/helpdesk_fr.asp). [4],
- "*Navigator tool*" [http://reach.jrc.it/navigator\\_en.htm](http://reach.jrc.it/navigator_en.htm) [5],
- *ECB*, European Chemicals Bureau,
- *ESIS*, <http://ecb.jrc.it/esis/> [13],

In Croatia: Ministry of Health and Social Welfare, [www.mzss.hr](http://www.mzss.hr) [12].

Groups of leading European manufacturers and organizations which develop guidance documentation in order to promote and exchange the consistent tools in the global supply chain and to achieve the optimal REACH implementation. For example:

- *CONCAWE*, [www.concawe.be](http://www.concawe.be) [6]
- *CEFIC*, [www.cefic.be](http://www.cefic.be) [7]

### 6.1. Basic technical dossiers

The European Commission started 7 projects (*REACH Implementation Project (RIP)* [9]), which aim to develop guidance documents and tools (not required by the law), which facilitate the Commission, ECHA, member states, manufacturers, importers and downstream users to fulfill their obligations to the Regulation as it follows:

- RIP 1: Description of the REACH process
- RIP 2: REACH-IT
- RIP 3: Technical guidance and tools for the Industry
- RIP 4: Technical guidance and tools for the competent authorities
- RIP 5 and 6: Implementation of ECHA
- RIP 7: Preparation for new tasks for the Commission

Within RIP 3 there are 10 guidance documents developing (RIP 3.1– 3.10), for example, on preparing the technical dossier for the registration, SDS, on information requirements on intrinsic properties of substances, on data sharing and others. Within RIP 4 there are 5 guidance documents starting to develop (RIP 4.1-4.5).

Some projects/documents are already completed and submitted to ECHA which decides on the availability of the documents, and some documents are still in the phase of preparation (for more information, see: [http://reach.jrc.it/guidance\\_en.htm](http://reach.jrc.it/guidance_en.htm)).

In the "REACH literature" these guidance documents are stated to be the primary information source for the companies asking pieces of advice on fulfilling their obligations from the Regulation.

## 7. Implementation of the Regulation in INA d.d.

**Regulatory framework.** The Croatian Parliament made the Law on the implementation of the REACH Regulation (*NN 53/08*), on 9 May 2008, by which Croatia has to fully comply with the REACH implementation by the date of Croatia's EU entry. Up to that date the existing *Law on chemicals (NN 150/05)* and its

amendments and executive regulations deriving from it (in accordance with the EU regulations) will be in force.

The competent authority for the implementation of the Regulation is the Ministry of Health and social welfare [15], in cooperation with ECHA and the European Commission.

**Specificities of petroleum substances under REACH.** Almost all the petroleum substances are listed in EINECS. Petroleum substances listed in the Official Journal of the European Commission (OJ 84, 5 April 1993) are regarded as phase-in substances. All the petroleum substances have EINECS number and its name, and most of them also defined by their origin and chemical nature of the substance.

Since almost all the petroleum substances are manufactured in quantities >1000 tonnes/year, they need to be registered by 30 November 2010.

For the needs of the Regulation, most of petroleum substances are classified into the UVCB group of substances, i.e. complex blends of hydrocarbons, with changeable content depending on the origin of crude oil and natural gas and their treatment. These substances can not be precisely defined by their content, but other identifiers (origin, production processes and the like) are also needed. According to the Regulation, they can be registered as mono-constituent substances, under the condition that "...their hazardous properties do not show any considerable variation..."

Being classified in this way, they are regarded as mono-coconstituent substances regardless of the fact that their quantity and quality system can not be precisely defined.

The quantity and quality system can be precisely defined for some petroleum substances and they are identified as single-component (main constituent > 80%) and multi-component substances (constituent parts >10% and < 80%). The data for such substances fully comply with factors for the substance identification listed in the Regulation (Annex VI (2)).

Different composition and physical properties can be a problem when it comes to testing of petroleum substances according to the standardized protocols (they need to be modified).

The names of petroleum substances are usually defined by the final phase of the production process, the hydrocarbon type, the range of hydrocarbon structures, the approximate boiling point range. Petroleum substances are necessarily defined in very broad terms in regard to different initial materials, different catalysts, different process conditions (temperature, pressure and other). Each refinery has its uniform range of variables for the identical basic production process. Substances resulting from different processes can share the same name and definition, have the same carbon atom structure, have the same boiling point and be of the same hydrocarbon type, but due to different treatment processes they have new names and CAS numbers; or in some cases one EINECS entry covers several substances or more EINECS entries correspond to one substance.

Although there are hundreds of petroleum substances, the real number of commercial products deriving from them is considerably smaller. CONCAWE classified the petroleum substances into 20 categories based on their similarities in the treatment process, physiochemical, toxicological and ecotoxicological properties, the number of carbon atoms which provides finding the best way to comply with the requirements of the Regulation for petroleum substances in regard with their intrinsic properties and the risk management (the exposure scenario). This classification provides the use of alternative methods (e.g. *read across*, QSAR) for the identification of similar substances, which makes the risk assessment and the substance data exchange easier.

According to the Regulation the registration is mostly conducted on the level of substances on their own, while the registration of petroleum substances and similar products is conducted on the category level.

Some petroleum substances which are the result of blending processes have dual nature; depending on the circumstances they can be registered as substances/preparations. According to ECHA, if these substances are manufactured within the integral refinery complex, according to REACH they are regarded as substances.

The companies located outside of the refinery complex which, in the blending process, add some other substances to a given substance, according to REACH are regarded as formulators/downstream users, and their product is regarded as a preparation.

The following documents are available on the CONCAWE website:

- guidance for registration of petroleum substances/preparations.
- *Classification and labelling of petroleum substances according to the EU DSD directive*, which contribute to the promotion of better coordination of classification and labelling of petroleum substances in Europe (which are important for developing SDSs, for the preparations containing petroleum substances), and they include substances that are manufactured and marketed as final products or used as components in the formulations of fuels, bitumens, lubricants, waxes and other products.
- "short lists" of CAS and EINECS numbers which are submitted for description and identification of the imported petroleum substances (they are not prescribed, but it can make things easier for the importers – they offer guidance in cases when the importers can choose 2/more possible CAS numbers.
- CONCAWE [6] develops methodologies associated with the petroleum substances (in the form of annexes for RIP), for example, guidance to develop the CSR, the risk assessment for human health and the environment, the development of QSARs, analytical methods and others.
- For its members the CONCAWE *Risk Assessment Programme* develops guidance for obligatory elements of registration dossiers and for those elements

of the registration dossier which can be submitted jointly on a voluntary basis. For the needs of the REACH registration CONCAWE develops guidance for the risk assessment associated with petroleum substances and other substances.

- CONCAWE gives the framework for the obligatory and voluntary cooperation.
- On a voluntary basis CONCAWE will control the processes of SIEF, for example, it will develop cooperation of all pre-registrants of petroleum substances in the same category (SIEFs for substances in the same category joint into Super SIEFs).

**Activities of INA d.d.** As it was said in the abstract, INA, d.d. as a manufacturer of oil, gas and oil derivatives, an exporter of certain articles on the European market and a user of chemicals, is in the preparation process for complying with the REACH system. The company is facing the obligations:

- to register its substances, their commercial use and human and environmental exposure to these substances,
- to guarantee that its products are managed in a safe way,
- to inform its business partners on its compliance with the Regulation.

At the time the authors were writing this paper, INA was finishing with its pre-registration activities (inventarisation of all substances, contacts with importers from the EU, suppliers, issues associated with the oil sector are being discussed with the CONCAWE, ECHA, CEFIC [7], Ministry of health and social welfare [12], by studying the literature ...) of its substances via Only Representative.

## 8. Costs and benefits of the implementation of the REACH Regulation

According to the European Commission's estimates, *the registration* costs (including testings) for the chemical industry will be 2.3 billion EUR, throughout the period of 11 years (since REACH entered into force) or cca. 0,5 EUR a year per EU inhabitant, while the total costs (including downstream users) will be between 2,8 – 5,2 billion EUR (less than 1 EUR a year per EU inhabitant).

Since these cost estimates do not include 'the cost' of human and animal health, they may be considered incomplete.

Among numerous *benefits* of the Regulation implementation, the most important one is to reduce risks to human health and to improve the environmental quality through better and earlier identification of chemical substance properties. Hazard detection and improved risk management in chemical use will contribute to the protection of health problems caused by the chemical exposure (e.g. reduced disease occurrence, death prevention, reduced costs for the national health care system).

By gradual implementation of more and more substances into the REACH system, the expected benefits for human health and the environment are becoming even more significant. In its *Impact assessment* the Commission has also developed this scenario: if the REACH implementation reduces the number of diseases caused by chemicals exposure for 10%, the benefits for the health care system will be cca. 50

billion EUR, for the period of 30 years (data from the presentation: <http://www.ekn.hr/dokumenti/reach-prezentacija-04-2007.ppt>). [14]

The expected benefits for the environment are not stated in terms of money.

## 9. Conclusion

Implementation of the safe chemical management such as REACH provides maximum utilization of all positive effects of chemicals in order to improve economic development and the quality of life by efficiently protecting potential hazardous chemical influence on human health and the environment.

It is in the interest of each country to take care for and support the development of chemical safety system.

As we have mentioned several times: REACH represents the unique opportunity to improve the legislative system in the field of chemicals management and provide the identification of the most hazardous substances and their gradual elimination; subsequently Europe has to find a solution and take this challenge in order to improve the environmental protection and public health on the global level.

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*Acknowledgement*

Authors would like to thank M. Sc. Lidija Bertović, the manager of Health, Safety and Environment Sector (INA) for her support in publishing this paper.

**Abbreviations**

CAS RNs	Chemical Abstracts Service Registry Numbers
CEFIC	European Chemical Industry Council
CMR	Carcinogenic, Mutagenic and Reprotoxic substances
CONCAWE	Conservation of Clean Air and Water in Europe
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DSD	Dangerous Substances Directive (67/548/EEC)
EC	European Council
ECHA	European Chemical Agency
EINECS	European Inventory of Existing Commercial chemical Substances
ELINCS	European List of Notified Chemical Substances
ESIS	European chemical Substances Information
EU	European Union
GLP	Good Laboratory Practice
IUCLID	International Uniform Chemical Information Database
NLP	No-Longer Polymers
PBT/vPvB	Persistent, Bioaccumulative and Toxic/Very Persistent, very Bioaccumulative
PNEC	Predicted No-Effect Concentration
PPORD	Product Process Oriented Research and Development
REACH	Registration, Evaluation and Authorisation of Chemicals
RIP	REACH Implementation Project
SIEF	Substance Information Exchange Forum
SDS/e-SDS	Safety Data Sheet/extended-Safety Data Sheet
SVHC	Substance of Very High Concern
UN GHS	UN Globally Harmonised System of the Classification and Labelling of Chemicals
UVCB	Substances of Unknown Variable composition, Complex reaction products or Biological materials
(Q)SAR	(Qualitative/Quantitative) Structure Activity Relationship

UDK	ključne riječi	key words
351.824.1 : 661	zakonodavne i upravne mjere u oblasti kemijskih proizvoda	legislative and administrative measures concerning chemical products
658.8 : 661	marketing kemikalija	chemical marketing
(083.83)	registri	registers
620.26	opasni materijali	dangerous goods
(4-62)	Europska unija	European Union
(497.13)	Hrvatska	Croatia
"2006-2010"	razdoblje 2006-2010 g.	period 2006-2010 y.

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**Received**

25.11.2008.

**Accepted**

29.1.2009.