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SUBSTITUTION PRINCIPLE IN *REACH* AND THE EUROPEAN WAY TO SAFE AND GREEN CHEMISTRY

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ABSTRACT

The European Commission proposal for improving the chemicals policy aiming a high level of protection of human health and the environment both, more efficient functioning of the internal market and increased competitiveness of the chemical industry, can be considered the most comprehensive system of chemicals regulation in the world. The intent of REACH *(*Registration, Evaluation *and* Authorisation *of* CHemicals*) is a comprehensive overhaul of the chemical system that has failed to protect people and the environment from ongoing exposure to many different chemicals with unknown properties. The Commission's decision ends the lack of information on chemicals in wide use and targets the most hazardous chemicals for stringent measures. It has created a unique opportunity to protect human health and the environment, while at the same time stimulating development of safer chemical products and increasing industry's innovation activity.*

Keywords: EU chemicals policy, REACH, substitution principle, safe and green chemistry.

Synthetic chemicals take a great part in human lives. They may serve for achieving useful purposes and for gaining essential benefits to human lives and health. Meanwhile however, many of them are already known to possess hazardous properties and many others' safety has never been properly assessed. [1]

On the other hand, the chemical industry is one of the most significant pillars of the EU economy. It is the third largest branch of manufacturing industry with annual sales of EU 528 billion, which magnitude is greater than GDP of Denmark and Sweden put together. The EU chemical industry provides more than 1.7 million jobs and several million people more are employed in the supply industry or in branches involved in processing and using chemical products [2].

That is why the EU chemicals business is a subject of profound debates in regard to its regulation. The emerged necessity of more comprehensive chemicals regulatory system review aiming to provide functioning of the common European market with common standards, free products movement among the Member States and gaining high standards in human health and environment protection, finds expression in the EU Commission strategy proposed in February 2001 – White Paper on Chemicals. The new system will come to replace the current dual approach (for *new* and *existing* chemicals) together with the related regulatory cluster with a unified approach to all chemicals above certain production volumes. In the same time the White Paper tries to establish a proper balance between the substantial need of human health and environment protection and preserving and strengthening the innovation and competitive capacity of the chemical industry in the EU [3].

The core of the Commission's Draft is a uniform process for Registration, Evaluation and Authorisation of Chemicals *REACH* (Figure 1). Generally it includes

each substance that is manufactured or imported in Europe in various fields of application. There are only limited exemptions for groups of substances and products already regulated elsewhere.

Approximately 30 000 existing chemicals and all future new substances that are manufactured or imported in volume more than 1 tonne per year in the EU must be registered in a central Agency. The industry's task is collecting and assessing the required information and submitting it as a dossier. This information includes data on physicochemical, toxicological and ecotoxicological properties. In addition to these data on the substance, individual identified uses as well as assessments of the related risk and corresponding safety measures must be specified. [1]

There are two types of evaluation: a dossier evaluation and a substance evaluation. The dossier evaluation is a check of the substance dossier that has been submitted. For substances of annual volume of more than 100 tonnes, the submitted test plans shall be checked for completeness and for relevance of the particular studies. National authorities are responsible for this process. Furthermore, the relevant national body can check any substance dossier independently on the tonnage that has been submitted in the dossier.

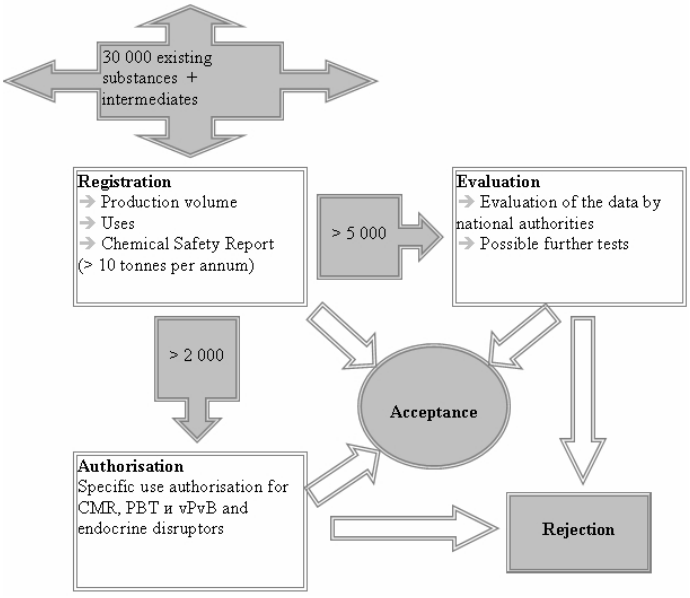

Fig. 1. *REACH*. Process for a uniform registration, evaluation and authorisation of substances

The substance evaluation, on the other hand, pursues a different goal. National authorities can subject to a more detailed check those substances that the body considers to constitute a risk identified on the basis of their structure or their total tonnage in the EU market.

Substances with high risk potential – hazardous substances of very high concern – CMR[1], PBT[2] and vPvB[3] as well as endocrine disruptors[4] - are subject to an authorisation process. Authorisation decisions are taken by the European Commission. That means that such substances may only be used for authorised applications. The registrant must provide evidence for each use that the risk emanating from the substance is controlled by technical or organisational measures. If such evidence cannot be provided, the authorisation can only be granted if the analysis demonstrates that socioeconomic advantages of the specific use are predominant (Figure 2) [1] [3].

All authorisations are subject to periodic checks in which the Commission will establish whether the circumstances existing at the time of authorisation have changed.

The authorisation process itself is based on substitution principle that states that hazardous chemicals of very high concern must be gradually and reasonably phased out and systematically substituted by less hazardous alternatives for which no hazardous are identified.

As a basis for human health and environment protection from hazardous chemicals, the Substitution Principle possesses several advantages.

• The Substitution Principle terminates the common practice of replacing a hazardous chemical under regulatory pressure with similar hazardous chemical that is less in the spotlight.

• If alternatives with less hazardous properties are available, use of hazardous sub-

[1] CMR – Carcinogenic, Mutagenic, Reproductively toxic
[2] PBT – Persistent, Bioaccumulative and Toxic
[3] vPvB – very Persistent, very Bioaccumulative
[4] Substances that affect the hormone system

stances is not permitted. That is a way of hazard potential reducing or totally avoiding.

• If an intrinsically less hazardous alternative is available, extensive assessment of the original hazardous chemical is not necessary.

• In many cases hazardous based substitution eliminates the need of notoriously difficult exposure assessment.

• The Substitution Principle provides incentives for *clean production* and *sustainable* product and system design. [1]

Under the conditions of deepening integration processes on the old continent, the common market functioning since 1st January 1993, the physical borders remove between the EU Member States and the realisation of one of the fourth movement liberties – the goods' one, the European leaders and specialists show tangible anxiety in regard to the chemical products. [4] The main challenge the governments, the industry and the other stakeholders face is providing a chemicals control mechanism that is aiming Lisbon Strategy realisation – *to make the EU the most competitive and dynamic knowledge-based economy in the world* – as well as achieving the sustainable development goals. Despite its disputable core, the European Commission Proposal for partially centralised regulation of the chemicals and especially the authorisation of hazardous chemicals of very high concern through applying the Substitution Principle specifies essentially the European way to safe and green chemistry.

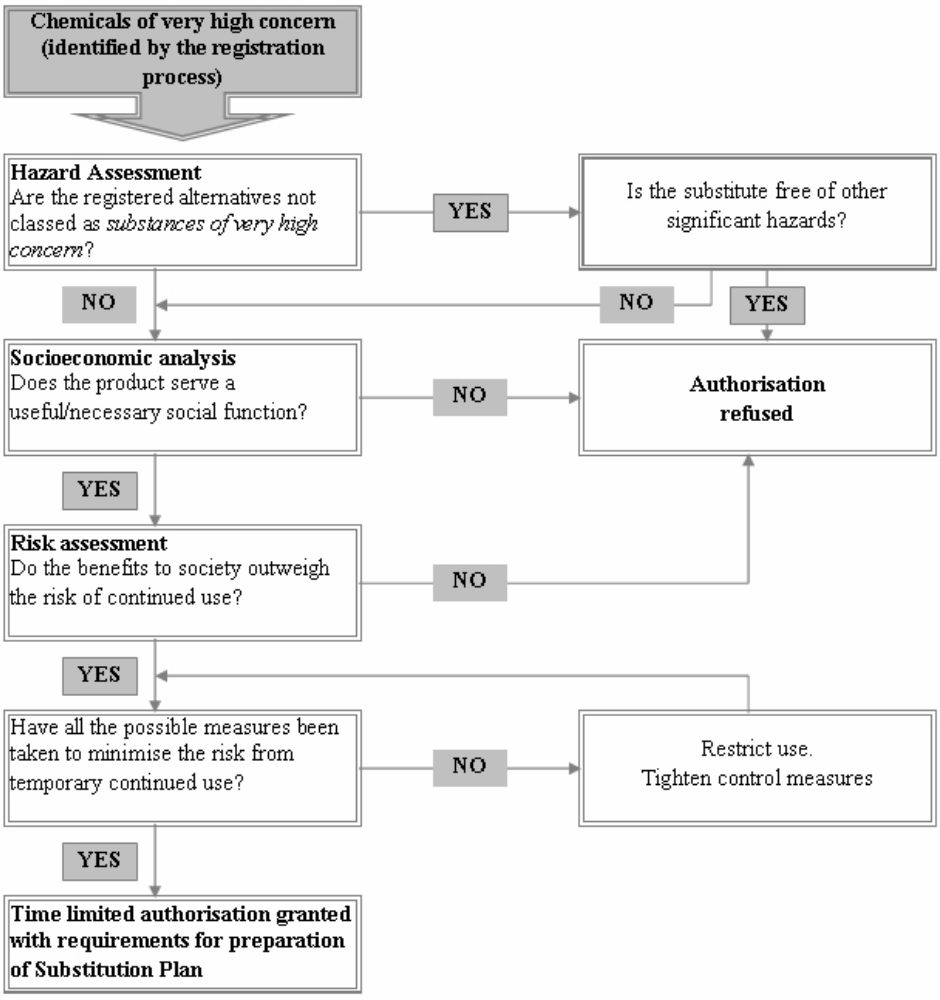

Fig. 2. Decision-making process for use of specific authorisation under REACH.

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