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A NEW APPROACH TO IMPLEMENT THE REACH DIRECTIVE IN ENGINEERING DESIGN

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1. Introduction

The REACh regulation (Registration, Evaluation and Authorization of Chemicals) has to be applied since 01/06/2007 by all the companies in Europe. It gives a new framework to better manage substances used in production, but also to design new products and to upgrade current products. This framework will be mandatory from 01/06/2009 [REACh 2007]. Companies have to react quickly to adapt their industrial procedures to this regulation and their products to the evolving market without waiting for the deadlines in order secure their business.
The paper aims at proposing a new engineering design approach to support the regulation and throughout thewhole product development.
The paper is featured as the following. Section 2 highlights the principles of the REACh regulations and the consequences on product design. Section 3 gives literature knowledge on product development and chemicals hazardness evaluation. Section 4 presents the new engineering design approach developed and Section 5 the tools to support it. Conclusions are drawn in Section 6.

2. REACh regulation and its consequences on engineering product design

Originally the REACh regulation comes from the willing of minimising, and better fully removing, risks for health and environment due to the chemicals used in industry. The main motivations were that the hazardness of substances[1] were more or less unknown and that the linked information was not enough accurate when they were put on the market; moreover when the information was known it was not publicized. The objectives of the regulation are to protect human health and environment, to make information clear and to force exchange of information and to progressively substitute hazardous substances by less hazardous ones. It addresses the whole life cycle of products through their production, delivery and usage phases and the concerns are about the chemical substances themselves but also as a mix of substances (paintings for example) used within the processes of realisation, and in the product itself (system, equipment, component, product, part…). European manufacturers are concerned and European importers as well. The REACh procedure is in 4 steps: registration of substances used based on the principle of transparency (no data means no access to market), authorisation of substances based on the principle of first care (not allowed means forbidden), notification by tracking hazardous substances in every product, and restriction by removing hazardous substances when substitution is possible.
What are the consequences to companies, and particularly what are the main advantage for them and the impact on their engineering product development process? First of all, the companies would have a

[1] In this paper, the term « substance » refers to a chemical molecule related with a CAS, EINECS or ELINCS number

better knowledge on the health and environment risks for both their workers and their customers. However, their business could be limited by the problem of obsolescence of some substances that would disappear from the market and which supply would not be secured. Moreover, the REACh authorisation procedure that is time consuming could not fit well with the research and qualification procedures. How to adapt to this new regulation? Four main principles are suggested. First, every product coming out from the company should be labelled with the substance content information. It means that tools to assist designers and methods and organisation to support the objective should be developed. Secondly, the design and development process should be more rigourous (with more qualification procedures for example) to make products reliable and substance robust. Thirdly, it is very important to work very closely with the suppliers in order to match perfectly in time with their own evolution towards substances use and tracking. And fourthly, the development of new solutions to substitute the hazardous ones is crucial. Finally, anticipating the regulation is vital for companies.

3. Literature on product development and chemicals hazardness evaluation

Taking into account environmental concerns during the engineering design process has been studied for' various life cycle stages, for example the end-of-life strategies [Brissaud 2004]. It has also been proposed to integrate it within an environmental management system [Ammemberg 2005, Donelly 2006]. These authors proposed to address the conceptual design phase to mix product development and environmental concerns.

The toxicity is one of the criteria used to choose a material when designing products. Some attempts of material choice guidelines based on such criteria have been developped. For example, Ljunberg [2004] proposed a very simple scale from 1 to 3 and a classification of the main materials family. Fairbrother [2007] helps in the methodology to analyse toxicity of materials and summaries toxicologic knowledge. Their approaches variate from very pragmatical to complex, taking into account only generic types of materials, which are commonly used .Quantifying the impact of toxicity and eco-toxicity is very difficult, notably when the product is a compound of several materials and substances (coatings, glues…). Jolliet [2003] proposed the IMPACT 2002 + method based on life cycle analysis methods; unfortunately the method uses information that is not available in conceptual design generally. When dealing with one hazardous substance substitution used in a particular production process, Harscoet [2007] proposed an appraoch based on LCA as well. Balsat [2003] proposed a composed method to measure the chemical risk in production activities, that can be used by non expert persons.This approach can be considered as an intermediate one, between simple choices scale and LCA, even if its scope only concerned production activities.

4. Principles of the new engineering design approach

4.1 Hierarchy of substances

Chemical substances used in a company should be known and tracked. The first principles was to create of clustering of substances for many reasons [Lartiguet 2007]. First of all, the clustering should match the steps of the regulation. Secondly, it should be relevant to the activities of the company. Thirdy, it should give priorities for the company to look for substitutes. Fourthly, it should anticipate new regulations. Fifthly, it should be managed by users. This hierarchical clustering needs to be standardised among companies of the same industrial sector to be efficient in enhancing companies to comply with REACh regulations. Figure 1 illustrates this hierarchy.

The most hazardous substances, which are subject to authorization according to REACh regulation are grouped in the nucleus. Theses substances mainly consist in already banned ones (such as asbestos), but their number should increase within time.The company must look for removing them from their processes and products because if they are not yet regulated, they will be very soon. An authorization procedure is needed from REACh when lawed or from the company when not lawed yet. The second set of substances is composed of all of them that are very worrying in hazardness, in particular those presenting high toxicity for animals and the environment. They must be mandatory tracked through an official notification at REACh level or at the company level if not. A third group has been defined

based on the main substances used on a specific company that are not in the two first groups: the level of hazardness has still to be proven but evidences gives clues for that. Their potentiality of hazardness is only suspected because of lack of testings and studies, but the company has interest to track them from now. The list C is company dependent and the procedure of an internal evaluation should help manage them.

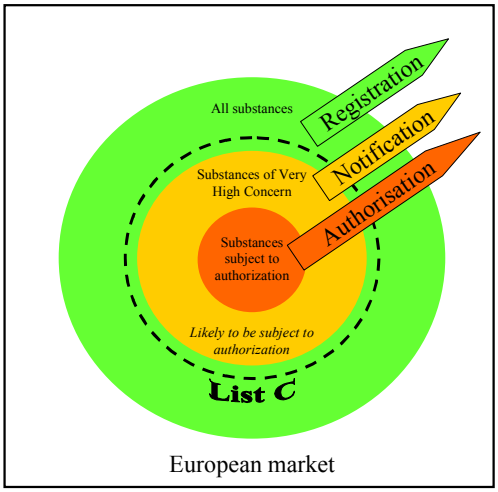

Figure 1. The substances clustering hierarchy

4.2 The design approach

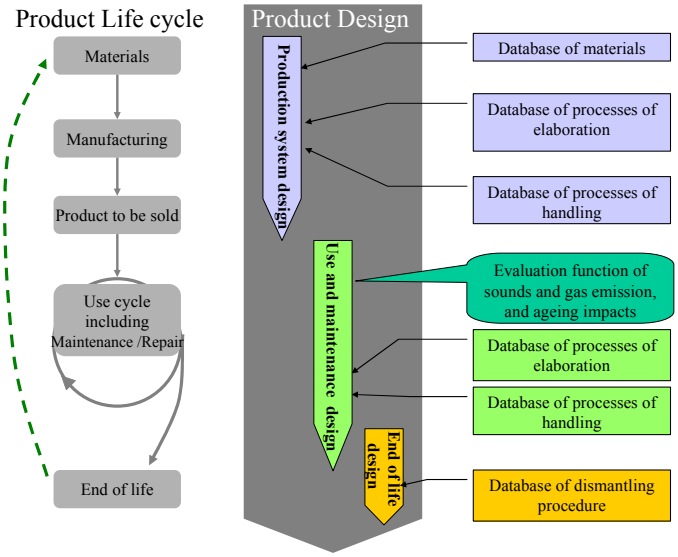

Figure 2. Product life cycle and design principles

The approach consists in adressing the environment and health impacts generated throughout each stage of the life cycle of the product. It is based on an analysis of the toxicity and the eco-toxicity of

every product from the systematic analysis of the toxicity and the eco-toxicity of every process operated in the life stages of the product. Figure 2 highlights the principles of the engineering design method for the assessment of the toxicity and the eco-toxicity risks that would occur at each stage of the product life cycle.
The most pragmatic engineering design method should merge the design method used by the designers and the new environmental procedure to add in a way that let designers work as usually, or almost as usually. It was retained to develop databases that are called from designers' usual parameters as materials, manufacturing processes, assembly, delivery and disassembly processes (called handling processes). The most accurate information on the substances, from industry shared sources or from internal sources, are registered in these databases and are upgraded by specialists at any time. Designers will be instrumented with aggregated functions to carry each individual information from their own parameters to an aggregated one handled by substance lists.

5. Tools to support the proposed approach

5.1 The substances classification

The first step of the proposed approach consists in establishing a substances list, based on REACh criteria, as developped in former paragraph. The cluster is divided into 3 levels, which each are associated with a label: B in black for banned substances, T in red for regulated substances (subject to authorization according to REACh), R in yellow for recommended reduction for substance (likely subject to authorization according to REACh and potentialy hazardous). The objective is to label every substance and product handled in the company by the BTR label, meaning that, at least, any substance, mixture or finished product is labelled B or T or R, and giving an idea of its toxicity and eco-toxicity risk potential.
B is said for substances banned for manufacturing, use or marketing according to applicable regulation (European Union, US Federal). More than 100 substances are in this class. T is said for substances and products submitted to EU regulation. More than 3000 substances are currently in this class. It includes substances targeted by a regulatory requirement with a legal target date for phasing out and/or reduction, substances only banned for particular applications, substances of very high concern (VHC) according to REACh regulation due to risk phrase concerns and radioactive elements activity levels for example. R is said for substances and products with recommended phasing out or reduction for use because of their intrinsic hazards. It includes substances with specific risk phrases, volatile organic compounds (VOC), but also green house gas (GHG) with global warming potential (GWP) >15 according to UNEP guide.
All the other substances that are not listed, are supposed to present non significant toxicity and eco-toxicity risks (or even risk free) and are not labelled or labelled HL ("Hors Liste": out of list) with no valor associated with.

5.2 The database

The second step of the approach is to link substances list to the different processes staking out the product life cycle. According to simple translation rules, materials and processes used for the product development can be associated with BTR labels, and registered in a life cycle stage specific sub-database. Agregated into a unique database, the different subdatabases, completed with other information sources, aims at providing an helpdesk relevant to design activities.
The main interests and objectives of the database are:

- To manage the safety data sheets (SDS). SDS encapsulate the official chemical risks of each substance. Its management is crucial for a company.
- To label substances with BTR code. It is the first objective of the system: giving a level of risk to each substance to improve the knowledge of the company on risks.
- To label components and products with BTR code. It is the main objective of the system from the product development perspective. Information on risk will be given to designers as aggregated risk translated in coloured labels.

- To manage all the data that designers need to work with. It addresses the parameters handled by designers in their usual job . It was divided into
  - a specific database for materials with their exact chemical composition,
  - a specific database for the elaboration processes operated in the company with the bill of materials and components used,
  - a specific database for the handling processes operated in the company for assembly and maintenance phases mainly with the bill of materials and components used.
- To analyse the risks of obsolescence of substances and components. Here are relevant results for the company coming from the knowledge encapsulated in the database. Offical deadlines of regulations can be monitored. But the knowledge base also enables to understand the evolution of suppliers by monitoring their own data attached to the new component imputs.
- To plan the R&D development needed for substituting substances and components. Here also is a good benefit of the knowledge base for the company. All the issues can be listed and ranked according to their criticity and their life time and therefore it enables the company to plan its R&D workload and their purchase prospects.

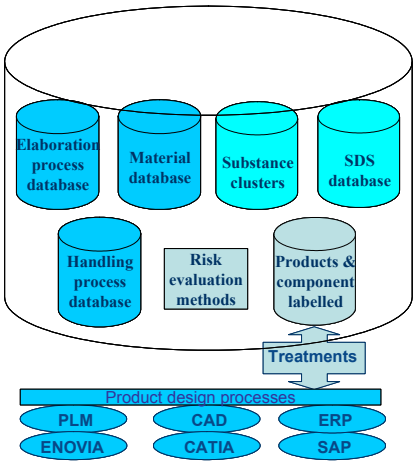

Figure 3. The design support system

The information encapsulated in the database is more or less accurate and reliable depending on the way it was obtained. If companies have benefit in taking time to know exactly what they put on the market, it is not clear that the components and products that were bought by the company were correctly labelled. It can be assumed that the components and products coming from an EU manufacturer will be soon properly labeled. But the problem remains open for all the components imported from outside the EU where manufacturers have no concern with EU regulations.

5.3 Quantification of the chemical risks

The third step of the approach is to discriminate toxicity and eco-toxicity risk level, associated with materials and process, and to guide and treace the designers' choice. Giving materials or process a coloured label isn't precise enough to give insight for decision during the design activity, mainly because of its global meaning. The new method of quantification that was employed was derived from the initial method developed by INRS [Vincent 2000] to evaluate the chemical risk. The chemical risk results from the combination of the hazard level (one of the three BTR class of hazard the component belongs to) and the potential exposition to this danger. The exposition results from the quantity of components used in the company reference area and the component's handling frequence. The INRS method was developed for people working in workshop. The way to estimate the different values of the parameters of the method needed to be adapted to the design activity. A new clustering of hazard

level was defined, the frequency evaluation was clarified and a next simplified method to estimate the quantity of components was developed. Finally and in practice, the calculated value is translated in a 3 level scale of risk: high and reduction is expected immediately then substitution is an average term, medium and improvement are expected in medium term, low and the solution can be validated even if the risk should be reduced in long term. This approach finally aims at checking and validating the product bill of substances, through the differents gates of its design process, and providing to the final client a chemical risks "identity card"of the product.

6. Conclusion

The paper presented an new engineering design method to support the chemical risk assessment throughout the design process that was initiated from the REACh regulation. The process might be long for companies to manage properly chemical risks when designing due to the initial lack of information on both the hazardness of actual components and the chemical risks estimation methods, and due to the highly dynamic process of this information life. The proposed method is the first step of a general method to be developed, which answers to the urgence in knowing more about the substances handled and the risk associated with. A database and an initial formal method to quantify the chemical risks have been developed and implemented in a company. Initial tests have been very good and designers are starting to use them in practical projects.

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