

**NOTE ON THE STUDIES UNDERTAKEN IN THE FRAMEWORK OF THE
MEMORANDUM OF UNDERSTANDING ON FURTHER WORK CONCERNING
THE IMPACT ASSESSMENT OF REACH**

1. THE MEMORANDUM OF UNDERSTANDING

The further complementary work on the Commission's REACH impact assessment was carried out under a Memorandum of Understanding between the European Commission (DG Enterprise and DG Environment) and industry (UNICE/CEFIC) dated 3 March 2004. Studies on the impact of the Commission's proposal were undertaken based on a business case study approach dealing respectively with the potential withdrawal of substances for commercial reasons, innovation and the potential impact on New Member States.

A High Level Group was set up under the Memorandum of Understanding to oversee the work. It was designed to provide a forum for high-level dialogue between stakeholders and the Commission, Council (Presidency), and European Parliament. In order to ensure a transparent and inclusive process, a Stakeholder Working Group was established with the aim of monitoring the progress of the studies. The Memorandum also allowed for the appointment of external experts to act as advisers to the Working Group.

2. THE STUDIES

Two studies were undertaken within the terms of the Memorandum of Understanding.

A study by KPMG for the UNICE/CEFIC industry consortium focused on the first two areas. This study examined four downstream sectors (i.e. automotive industry, high-tech electronics, flexible packaging industry, inorganic material producers) and included 6 SME's¹.

A second study was undertaken by the Institute of Prospective Technology Studies (IPTS) of the Joint Research Centre (JRC) on the potential impacts of REACH on the New Member States, including both a general survey of the chemical industry in the New Member States and a focus on the impacts of REACH on the specialty chemicals industry.

Methodology

A common methodological approach for the studies was developed in a series of discussions between KPMG, IPTS, and the Commission. Both KPMG and IPTS produced various methodological documents and presented their Questionnaires to the

¹ The results on SME's have to be looked at with this in mind.

Working Group. Both studies involve the assessment of the vulnerability² of chemical substances (or materials) that are critical to downstream users³.

Third-party verification of the KPMG results was carried out by the two expert advisers, who concluded that although all verified data were presented anonymously, the KPMG team had derived the findings presented in the sector workshops from the information documented in the spreadsheets.

KPMG submitted the results for validation across a wider group of firms operating in these supply chains through workshop discussions. The advisors concluded that these workshops were well structured, facilitating the feedback from the participants who were reacting from company perspectives rather than the perspective of the sector association.

A similar process of verification and validation has not yet been finalised for the IPTS/JRC study or for the case study on the electronics sector.

The methodology and the detailed assumptions in particular on testing and registration costs used in the studies were discussed at length in the Working Group but did not result in an explicit agreement. Although the outcome of the studies was endorsed to a large extent by the Working Group, it was agreed that the results remain the responsibility of the contractors.

Approach

The case study approach implies analyses of particular cases within selected sectors, involving a limited number of substances and specific supply chains. This methodology was considered to be a most useful complement to the Commission's Impact Assessment on REACH which was largely based on an economic modeling approach.

Contractors were asked to clearly separate factual evidence as a result of the case studies from indications and additional information provided by industry (companies from the same sector but not participating in the case studies as such) in the context of the sectoral and validation workshops.

In certain cases, the use of scenarios has been accepted as a useful instrument to understand and illustrate the mechanisms triggered by possible substance withdrawal.

² The vulnerability of a substance for withdrawal from the market for commercial reasons is assessed by whether the future profitability of a substance is high enough to sustain the cost of REACH registration, determined by the Net Present Value method (NPV). The concept of timing of registration (3/6/11 years) proved particularly difficult to integrate fully.

³ Substances or materials are called critical as they are technically essential for particular downstream user processes or are needed for the achievement of particularly important qualities of final downstream user products.

3. MAIN CONCLUSIONS ON THE FINDINGS OF THE STUDIES

1. There is limited evidence that higher volume substances are vulnerable to withdrawal following the REACH registration requirements. Lower volume substances under 100 tonnes are most vulnerable to being made less or non profitable by the REACH requirements.

The KPMG study is based on 10 case studies in 4 areas. Out of the 76 substances assessed in detail, 10 substances were found to be vulnerable to commercial withdrawal as they became less or non profitable. An additional 76 substances investigated were found not vulnerable.

2. There is limited evidence that downstream users will be faced with a withdrawal of substances of greatest technical importance to them.

The study shows that chemical suppliers and formulators will prefer to register substances that are technically important to downstream users in order to keep their portfolio and avoid the potentially high costs of reformulation and/or re-engineering which could otherwise result for their customers. This also applies for the limited number of substances within the assessed sample that could be regarded commercially vulnerable under REACH. Where there is limited communication in the supply chain, it is not possible to rule out the risk that some limited withdrawal of substances may occur in practice.

3. The one-off costs of registration for chemicals suppliers can in some cases be significant and may result in the rationalisation of portfolios by chemicals suppliers.

The one-off costs of registration can demand a significant share of the available cash flow for chemical producer, in particular SMEs. This may lead to a decision not to register part of their portfolios where the one-off costs of registration represent a substantial proportion of the annual profit.

This effect would mainly relate to substances which are not considered by chemical suppliers to be technically critical to their customers. However this could nevertheless trigger the need for some reformulation at formulator and downstream user level and may reduce the diversity of substances at the disposal of formulators for innovation.

4. If a substantial withdrawal of substances occurred, the extent and costs of reformulation and re-engineering costs could be significant.

Simulation of impacts based on scenarios and past experience shows that the loss of only a few critical substances might result in a large-scale reformulation. If this were to happen, reformulation and re-engineering costs would require time-consuming testing and approval procedures and may require fundamental changes at product or process-level.

5. The passing on of part of the registration costs to formulators and downstream users is likely, but may be more difficult for SMEs

Most of the chemical suppliers interviewed have indicated that they will be able to absorb or pass on part of the REACH costs. In both the automotive and flexible

packaging case studies, there are some fears of potential difficulties for formulators in passing-on costs to downstream users, particularly for SMEs.

6. The users of raw materials in the inorganics sector need further clarification on the REACH registration provisions.

The study showed that the regulatory status of some key raw materials in the inorganic sector under REACH needs further clarification. This relates to i) metal ores and ore concentrates, including those containing dangerous substances; ii) by products from production of energy and steel, i.e. steel scrap, fly ash, etc. iii) waste paper as a potential source of dangerous substances that may oblige a paper manufacturer to notify under article 6. It is important to clarify, in the legal text and/or through guidance, if and how REACH applies to materials that are i) waste, ii) substances extracted from waste and put on the market and iii) articles produced from recycled waste and put on the market.

7. The impact of REACH on innovation is uncertain

There is no evidence, for the cases investigated in the study, that R&D resources will automatically be diverted due to REACH, nor are increases in R&D expected. However, for a limited time period, resources may be used to adapt to REACH (e.g. to cope with the impact of potential accelerated rationalisation). However, if chemical producers proceed with an accelerated rationalisation of their portfolio this may reduce the diversity of substances at the disposal of formulators.

8. Concerns were expressed about specific workability and confidentiality problems.

Some concerns were expressed by formulators and downstream users that chemical producers might not want to include certain uses in their registration dossier. This would either limit how substances may be used or else force downstream users to carry out their own registration, thus taking on the extra burden of risk assessment and the design of appropriate risk management measures.

The experience with confidentiality issues during the study demonstrated the importance of balancing the transparency requirements and co-operation needs under REACH with the existing confidentiality needs in the market. Several companies see intellectual property and confidentiality business information at risk, because of communication and disclosure requirements under REACH.

9. Companies have recognised some business benefits from REACH

The study found a number of business benefits of REACH within the investigated supply chains, especially to formulators and downstream users. Benefits mentioned by certain companies include: better information about substance properties and dangerous components in preparations, easier risk management and rationalisation of substance portfolio.

10. SMEs can be particularly affected by REACH

SMEs generally have more limited resources to implement the new legislation. The study found that some SME chemical suppliers could face financial difficulties to comply with REACH, particularly if they would have to register many substances at the same time. Low volume substances produced by SMEs are more likely to be vulnerable to being

made less or non profitable. SMEs also have been shown to face more difficulties in passing-through testing costs to downstream users.

4. OVERALL CONCLUSION

The further work undertaken within the context of the Memorandum of Understanding has been a useful exercise in addition to the Commission's Impact Assessment. Despite the fact that some elements need finalisation, the above results constitute a useful further input into the REACH negotiations.