Luxembourg Presidency
of the Council of the European Union

Luxembourg Presidency Workshop on REACH

Presidency report

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Executive Summary

The Luxembourg Presidency REACH Workshop brought together important actors from the Commission, the European Parliament and the Council. In addition, representatives from industry (UNICE/CEFIC), environmental NGOs (EEB/WWF) and trade unions (ETUC/EMCEF) involved in the REACH High Level Group as well as the European Economic and Social Committee were invited to participate in the workshop.

The Workshop's objective was to facilitate inter-institutional discussions on the further impact assessment work, on progress of REACH in Parliament and Council and on complementary or alternative proposals of Member States that aim at improving the efficiency and workability of key REACH processes.

The first part of the Workshop focused on results from the further work on impact assessment undertaken in the framework of the Memorandum of Understanding between the European Commission (Directorate General Enterprise and Directorate General Environment) and industry (UNICE/CEFIC). The Commission presented its conclusions that are publicly available.

The second part of the workshop addressed the debate in the European Parliament's key committees. The rapporteurs Guido Sacconi from the Environment-Committee, Lena Ek from the Industry Committee and Hartmut Nassauer from the Internal market Committee confirmed their intention to follow the timetable leading to completion of the first reading by autumn 2005. The main elements of their reports were presented.

In addition, three proposals from Member States dealing specifically with potential improvements to registration were thoroughly discussed by the participants; Hungary and United Kingdom's proposal that a substance should only be registered once "one substance – one registration" (OSOR), Malta and Slovenia's alternative approach to the registration and evaluation of low volume substances (1-10 tons/year) and Swedish reflections on substances in articles.

The Presidency welcomes the active participation of all who attended. The stimulating discussion allowed the Presidency to highlight the following points:

- From the results of the case studies, there is no evidence to suggest that the Commission's extended impact assessment of REACH contained fundamental flaws. However, the results seem to have identified mechanisms that are key to assuring the workability of REACH, particularly with respect to indirect costs that would result from substance withdrawal for commercial reasons.
- Although the case studies give little evidence that critical substances for downstream users would be withdrawn from the market, improved information in the supply chain (chain transparency) will lessen the likelihood of substance withdrawal further.
- In turn, if the likelihood of substance withdrawal is further lessened, resource-intensive reformulation and approval procedures are less likely to be needed indicating a reduced overall cost of REACH.

- The need for further chain transparency and the resulting reduction of indirect costs must be balanced against legitimate claims to commercial confidentiality, particularly with respect to downstream users.
- The initial cost of registration may, in some cases, be significant. In this respect, lower volume substances are most sensitive to any additional cost burden.
- Due to limited resources SMEs are expected to face more difficulties when complying with the new REACH legislation.
- With respect to SME workability, those proposals that were presented during the second day as well as the subsequent discussions highlighted ways of:
    - reducing one-off registration efforts per substance through more targeted information requirements and enhanced use of available knowledge;
    - reducing one-off registration costs per registrant through improved incentives for cost-sharing (consortia);
    - reducing registration burden on resources other than financial (e.g., time, legal) through easy-to-use guidance, national helpdesks;
- A more targeted approach to information requirements for low volume substances may make registration require less effort.
- Further clarification of the registration requirements for certain materials will reduce the uncertainty.
- Enhanced cooperation between registrants may lessen resource requirements.
- Furthermore, several proposals have focused on the need to involve downstream users, many of which are SMEs, as early as possible in the process, thus increasing supply chain transparency which has been shown to decrease the likelihood of indirect costs at downstream user level due to substance withdrawal for commercial reasons.
- Sufficient information is now available from impact assessments to allow the further consideration of complementary proposals to the Commission's text.
- A possible way of continuing further work on complementary proposals could be the combined consideration of several aspects of these proposals and of the Commission's proposal, in order to encounter the targeted areas for improvement and to achieve a coherent overall result.
- These proposals must provide solutions to the identified problems without jeopardising the underlying objectives of REACH.

Introduction

On May, 10th-11th, 2005 the Luxembourg Presidency hosted a Workshop on REACH that focused on the outcome of the further work on impact assessment and on the workability of key processes in the legislation proposal. The proposal for the EU's new chemical policy, REACH (Registration, Evaluation and Authorisation of Chemicals) is one of the Presidency's priorities both on the competitiveness and the environment agendas.

The REACH Workshop brought together key members from the Commission, the European Parliament and the Council. In addition, representatives from industry (UNICE/CEFIC), environmental NGOs (EEB/WWF) and trade unions (ETUC/EMCEF) involved in the REACH High Level Group[1] as well as the European Economic and Social Committee were invited to participate in the workshop. The workshop's objective was to facilitate inter-institutional discussions on the further impact assessment work recently presented to the high level group, on progress of REACH in Parliament and on complementary or alternative proposals of Member States that aim at improving the efficiency and workability of key REACH processes.

The Presidency welcomes the active participation of all who attended.

I. Presentation of the further work on impact assessment

The first day of the workshop focused on the further work on impact assessment that had been undertaken to provide a sound analytical basis to assess the impacts of REACH in selected downstream user sectors (KPMG study on the automotive, inorganic, flexible packaging and electronics sectors and the Institute of Prospective Technological Studies (IPTS) study on the impact of REACH on the New Member States and the Commission study of the REACH impact on the textile sector).

These sectors rely heavily on the steady supply of chemicals in their daily production processes and have often invested heavily in R&D activities to find innovative ways of using the supplied chemicals in their products or preparations.

The Commission stressed that even though the results from the studies had been validated and presented both to the working and high-level groups established under the framework of the MoU, these results would remain under the sole responsibility of the consultants that had carried them out. However, the Commission was able to present the workshop participants with ten key conclusions[2] it draws from these studies and which are shared amongst those Commission services directly involved with REACH.

The objectives of the studies were to deal with the potential withdrawal of substances for commercial reasons, with innovation and with the potential impact on New Member States. On the first point, the Commission concludes that "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". On the second point, the Commission concluded that

[1] Under the Memorandum of Understanding on Further Work concerning the Impact Assessment of REACH a High-Level Group was set up to oversee the work on the studies. It was designed to provide a forum for high-level dialogue between stakeholders and the Commission, Council (Presidency) and the European Parliament.
[2] downloadable under: http://www.europa.eu.int/comm/enterprise/reach/docs/reach/note_further_ia.pdf

"there is no evidence, for the cases investigated in the study, that R&D resources will automatically be diverted due to REACH," although "for a limited time period, resources might be used to cope with an accelerated rationalization" of their producer's portfolios which "may reduce the diversity of substances at their disposal" for innovation. On the third point, the Commission has not yet finalized its position as explicitly because the study on New Member States has not yet been verified and validated as thoroughly as has been the case with the KPMG study.

In addition to the objective of the KPMG study, the Commission was able to draw the following conclusions that were directly linked to the subject:

- the experience with confidentiality issues during the study demonstrated the importance of balancing the transparency and co-operation requirements under REACH with the existing confidentiality needs in the market;
- if a substantial withdrawal of critical substances occurred, the extent and costs of reformulation and re-engineering costs could be significant;
- the one-off costs of registration for chemicals can in some cases be significant and may result in the rationalization of portfolios, mainly of substances not considered by chemical suppliers to be technically critical to their customers;
- there is limited evidence that higher volume substances are vulnerable to withdrawal following the REACH registration requirements. Lower volume substances under 100 tonnes per annum are most likely to being made less or non profitable by the REACH requirements;
- parts of the registration costs are likely to be passed on to formulators and downstream users;
- users of raw materials in the inorganics sector need further clarification on the REACH registration provisions. It is also important to clarify 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;
- Companies, in particular downstream users, have recognized some business benefits from REACH;
- SMEs generally have more limited resources (financial, human) to implement the new legislation. SMEs also have been shown to face more difficulties in passing-through testing costs to downstream users.

Further to the work on impact assessments undertaken in the framework of the MoU, DG Enterprise, following a recommendation by the High-level Group on the Competitiveness of the textile industry, has agreed to undertake a study of the potential impacts of REACH on the EU textile industry, which is an advanced user of specialty chemicals that might potentially face problems from REACH in addition to those caused by the phasing out of quotas in the international textiles trade (January 2005).

Addressing concerns raised on methodology, validation, and stakeholder involvement in the textile study, DG Enterprise confirmed its intention to validate the report through a workshop and to present the report to the High Level Group on Textiles. Such an approach would ensure a continuity in the findings, particularly since the textile study seems to have brought to light additional and unexpected information on the (complex) utilisation of chemicals in this sector.

Main points raised during the discussion

Participants welcomed the opportunity to comment on both the results and on the Commission's conclusions on the impact assessments realized in the framework of the MoU. While acknowledging that results from case studies might not apply in general, there was nevertheless satisfaction that the case studies had not provided evidence suggesting (fundamental) flaws in the results of the Commission's extended impact assessment of REACH.

Some stakeholders urged, in the light of both the diversity and the complexity of the impacts on industry, to apply precaution in the ongoing legislative process, particularly with respect to international competitiveness (e.g., article 6). They also pointed to the necessity of finding the right balance between transparency in the supply chain and confidentiality issues. Other comments related to the need to avoid duplicate legislation with other *lex specialis* such as worker protection.

In the debate, several mechanisms were discussed that could prove to be key in influencing the extent of the burden on industry in the registration phase:

- how communication up and down the supply chain could be facilitated;
- how to focus limited resources on providing the most useful information on substances with respect to the underlying REACH objectives;
- how to reduce the burden of one-off registration effort, which was found to be particularly important for SMEs.

The Commission explained that benefits on environment and health had not been the subject of the study and were thus not subject to discussion at this Workshop. However, the Commission fully stands behind its extended impact assessment, which in addition had found these benefits to be considerable.

II. Presentation of the reports of the competent EP rapporteurs on REACH

The first part of the second day of the workshop addressed the debate in the European Parliament's leading committees on REACH. The invited rapporteurs Lena Ek from the Industry Committee, Hartmut Nassauer from the Internal market Committee and Guido Sacconi[3] from the Environment Committee confirmed their intention to follow the timetable leading to a first reading by autumn 2005.

They presented the main elements of their reports; with a particular emphasis on improving workability and/or reducing the burden on small and medium sized enterprises (SMEs) as well as on optimizing the balance between costs and benefits of the REACH proposal.

Although agreeing with the main principles of the Commission's proposal, **Ms Lena Ek** addressed some specific areas for improvement of REACH. Her presentation included suggestions about:

- a more narrowly defined scope of REACH, achieved by explicitly exempting substances (or groups of substances) from the obligations to register;
- a right for downstream users and for consumers to receive the kind of information about chemicals which enables them to bring consumer choices in line with preferences concerning the protection of the environment and human health;
- a simplified registration system, which would combine additional information requirements for low tonnage bands (acute mammalian toxicity, biodegradability, algae toxicity) with a more targeted request for information;
- the involvement of the Agency in the management of substances of very high concern (SVHC) in articles;
- sharing of test data should as far as possible be the guiding principle in REACH, and steps should therefore be taken towards a system of "one substance - one registration". However, according to Ms Ek, companies ought to be able to opt-out of consortia formation if they have legitimate reasons. Furthermore, the splitting of costs should be ruled clearly and possible disputes should be solved via arbitration;
- a strengthened role of the Agency with respect to all aspects of dossier evaluation, collection and compilation of all existing data on substances, and in formulating the rolling plan together with the assigning of competent authorities to perform the actual evaluation of the substances;
- links to be set up between the REACH system and international programs (such as 'Global HPV Portal') to secure WTO compatibility and an effective information exchange between the authorities and companies in different countries;
- bilateral agreements with third countries to share non confidential data about substances and tests;
- assistance to developing countries from the EU in order not to limit trade with these countries due to REACH requirements for import;
- concerning SMEs in particular, Ms Ek proposes a three year moving average production threshold to account for SME production volatility around the currently

[3] As Mr Guido Sacconi could not attend the meeting, he provided the workshop participants with a written contribution.

fixed volume threshold values; reduction of one-off registration costs through an enhanced data and cost sharing; more targeted, or prioritized information requirements in markets where cost reductions through data sharing are less effective because there are only few producers/importers; (specific state aids to SMEs; possibly use of the "Growth and Adjustment Fund" currently set up under the new Structure and Cohesion Funds are additionally mentioned in this perspective in her draft report).

Mr Hartmut Nassauer underlined the need for a new chemicals policy and recommended to concentrate the efforts on key aspects such as the scope of REACH and the registration phase, including the provisions for substances in articles.

- Mr Nassauer suggested to include risk-based factors into the registration mechanism and explained the procedure for pre-registration and registration, as described in the draft opinion of the Internal market Committee.
  - such a procedure would require registrants to submit a core data set together with a categorization of the substance into use and exposure categories;
  - such a core data set would consist of data requirements according to Annex V plus two additional data requirements for all substances regardless of tonnage band (acute toxicity and biodegradability);
  - this information is to be supplied 3½ years after a pre-registration phase which would start 18 month after the entry into force of REACH;
  - during the subsequent prioritization phase, the Agency is to prioritize substances for registration on the basis of risk and the delivered core information;
  - further data demands should be based on the exposure situation.

  The aim of this system is to provide industry with a greater planning security and allow the Agency to further reduce animal testing;
- to alleviate the burden on low volume substances, Mr Nassauer suggests to drop the registration fees for substances in the 1-100 t band;
- regarding the scope, Mr Nassauer stressed that it was important to avoid overlaps between REACH and more specific pieces of legislation (lex specialis vs. lex generalis).

The contribution from the Environment Committee **rapporteur Guido Sacconi** underlined the will of the Parliament to set up a REACH system as soon as possible and stressed the need to concentrate further common efforts on:

- an increased role for the Agency in the substance evaluation phase;
- a better definition of the duty of care;
- a more efficient communication system ;
- the development of alternative testing systems to avoid the use of animals for testing purposes;
- the possibility of a collective substance registration.

Main points raised during the discussion

In the ensuing lively debate, much time was spent on possible alternative approaches and the effects on the underlying objectives of REACH.

In relation to the introduction of further "risk-based" prioritization, much of the debate focused on whether a standardized core data set would be sufficient to allow prioritization of registrations based on risk. Some doubts were also voiced on whether a system of use and exposure categories could reflect the complex reality of substance uses.

More fundamentally, some participants wondered whether an approach based on the premises that a central Agency would adjust information requirements based on its own judgement of the risk posed by a substance (from a combination of a core data set and use and exposure categories) would not reverse the objective of industry responsibility.

It was also pointed out that the Agency's resources would need to be adapted to avoid overburdening the Agency with the additional workload created by such an alternative system. In addition, concerns were raised that a tiered approach could possibly lead to late(r) registrations of CMR substances.

Finally, some participants underlined that although a "risk-based" approach may lead to less burdensome requirements for high volume substances, comparably more data might be required at an earlier stage for low volume substances.

III. Presentation of Member State proposals

Within the scope of the work of the Council Ad Hoc Working Party on REACH, some Member States have prepared complementary or alternative proposals that aim to improve the efficiency and workability of key REACH processes. One of the drivers behind these proposals were the conclusions of the The Hague-Scheveningen workshop on impact assessment held under the Netherlands Presidency in October 2004. These recommendations highlighted aspects of REACH that could be improved in order to reduce the impact of REACH on industry without jeopardising the underlying objectives of protection of human health and the environment. As a consequence, the Luxembourg Presidency Workshop on REACH had set as one of its objectives to facilitate inter-institutional discussions on selected complementary or alternative proposals put forward by the Member States.

Crucial to the workability of REACH is the registration of chemical substances. Three proposals dealing specifically with potential improvements to registration were discussed by the participants:

- Hungary and UK's proposal " one substance – one registration" (OSOR),
- Malta and Slovenia's alternative approach for the registration and evaluation of low volume substances (1-10 tons) and
- Sweden's reflections on substances in articles.

III.a One Substance, One Registration (OSOR)

In essence, the Hungarian and UK proposal for OSOR includes:

- Mandatory sharing of both animal and non-animal hazard data.
- Joint submission of one agreed set of information on the intrinsic properties of each substance.
- Sharing of costs amongst registrants to be established by means of guidelines – based on criteria included in the legislation.

The presentation of the proposal included the main differences between OSOR and the current Commission text, summarised in the table below:

1. Collection of what existing information on substances companies hold at pre-registration	
Options (data call and publication of list)	
One data call at each deadline including an indication of studies held – Commission proposal	**Two data calls** at each deadline (following publication of list), optionally including indication of studies held in first stage, and mandatory at second stage – OSOR proposal
Options (pre-Registration deadlines)	
Two deadlines (1000+ tonnes, 1-1000 tonnes) – Commission proposal	**Three deadlines** (e.g. 1000+ tonnes, 100-1000 tonnes, 1-100 tonnes) – OSOR proposal
2. A requirement to share all hazard information, including non-animal information	
Options	
Voluntary sharing of non-animal data – Commission proposal	**Mandatory sharing of all hazard data** – OSOR proposal
3. Agreement on the interpretation of information	
Options	
Voluntary agreement – Commission proposal	**Mandatory agreement of 'core data' package for hazard information, with 'get out' clause if can't agree a key study** – OSOR proposal
4. Cost-sharing	
Options:	
Encouragement to agree with fall back rules in legal text – Commission proposal	**Guidance only** – OSOR proposal

Some of the key points raised during the subsequent **discussion** on OSOR were:

OSOR aims to enhance co-operation between companies before registration, particularly in the field of data sharing, and to reduce the duplicate submission of information at registration. This may lead to an alleviation of the resource burden for registrants and a lowering of one-off costs.

Appropriate mechanisms must be in place to safe-guard legitimate claims to commercial confidentiality. The ability for companies to use a third party to represent them in the SIEF together with the option to submit information related to uses directly to the Agency may assist protection of commercial confidentiality.

OSOR aims to facilitate communication between companies through an alternative system of pre-registration and a promotion of harmonised hazard information.

There remains a question as to whether these aims of enhanced co-operation, reduction in duplication of work and improved communication should be sought through obligations (with

a potential reduction in flexibility) or through specific encouragement mechanisms in the legislation.

The OSOR (system and terminology) must be kept as simple as possible.

III.b Alternative approach to registration and evaluation of low volume substances

In essence, the Maltese and Slovenian proposal (MT/SI) envisages a tiered approach to information gathering for substances in the lowest tonnage band followed by an evaluation and prioritisation phase that includes a review cycle. The proponents argue that there is a justification for treating these substances differently as they are often specialty chemicals with a limited number of uses and, in many cases, limited exposure. The key elements of the proposal are:

- A targeted registration phase for the lowest tonnage band beginning with the submission of all available information held by registrants.
- Specific substances identified on the basis of defined prioritization criteria as requiring further consideration would be subject to further information requirements.
- A review cycle would enable a dynamic approach to information gathering in response to prevailing concerns.

The presentation allowed highlighting the following key aspects of the proposal:

1. Registration phase for substances in the lowest tonnage band	
Registration dossiers to be submitted within 11 years of entry into force of REACH with **a minimum hazard information package based on Annex V** of the proposal Commission proposal	Registration dossiers to contain **all available information on the substance and its use, including a basic set of physicochemical information, and a basic 'tick box' exposure assessment based on simple categories** Maltese and Slovenian proposal
2. Evaluation and identification of priorities	
Prioritisation of substance evaluations based on criteria developed by the Agency Commission proposal	**Prioritisation of further information requirements** following registration based on simple criteria developed by the Agency Maltese and Slovenian proposal
3. Review cycle	
	Prioritisation criteria **would be reviewed in light of emerging information** and substances re-assessed periodically Maltese and Slovenian proposal

Some of the key points raised during the subsequent **discussion** on the MT/SI proposal were:

MT/SI proposal could lead to a reduction of the resource requirements for the lowest tonnage band (where most substances produced by SMEs would fall) by introducing a tiered approach to information gathering.

The proposal could reduce the likelihood of substance withdrawal for what are thought to be the substances most sensitive to this.

MT/SI proposal could improve the cost-effectiveness through focusing of resources on substances with the greatest potential risk.

The possibility of a different approach to the registration of the lowest tonnage band must be compatible with the approach taken for the other tonnages.

The workability for SME of the proposed system should be ensured.

In exploring the possibility of an effective prioritisation for the lowest tonnage band, due consideration must be given to the possible limits in the availability of existing information.

A question remains as to whether this targeted approach is inconsistent with one of the main aims of REACH, which is to gather a basic set of information on all substances above 1 tonne.

Due consideration must be given to any change in the resource burden of the Agency.

III.c Substances in articles

The reflections from the Swedish delegation on substances in articles focused on the following key areas.

1. The reasons for consideration of substances in articles under REACH

This included:

- the potential for wide-spread exposure to humans and the environment from the release of substances in articles,
- the need for information in order for industry to comply with existing community legislation and
- the provision of adequate information through the supply chain leading to more informed purchasing choices.

2. The perceived problems associated with the present proposal.

This included:

- the perceived difference between requirements for EU and non-EU companies,
- limited availability of information on substances in articles to actors in the supply chain,
- serious workability and enforcement difficulties particularly in relation to Article 6(2), the difference between intended and unintended release, the assessment of whether a release may lead to a concern for health and the environment and the definition of article type.

3. Possible options to address these problems.

These included the following:

- Focus on substances of very high concern in the early stages of REACH,
- Stepwise introduction of provisions on substances in articles,

- Development of guidance to increase level of knowledge of chemicals in the supply chain and
- Treating substances that are intentionally released similarly to substances in preparations.

Some of the key points raised during the subsequent **discussion** on substances in articles were:

The inclusion of adequate provisions on substances in articles in REACH may help to improve the protection of human health and the environment and may bring the aim of a level playing-field for EU and non-EU companies.

Provisions on substances in articles should be workable, enforceable and take into consideration the ability of companies to comply with them as well as considering the EU's international trade agreements if benefits are to be realised.

Further consideration should be given to the possibility of adopting a stepwise approach to this issue in REACH.

In this context, provisions relating to substances which are intended to be released may require less development in order to meet the aims above as compared to substances that are unintentionally released.

Within the concept of use and exposure categories articles could be considered as an exposure category.

An appropriate focus on substances of very high concern in the early stages of REACH may contribute to these aims.

Further consideration should be given to possible ways of improving information and knowledge in the supply chain.

IV. Presidency observations

The Presidency highlighted the following observations based on the results of the impact assessment, the conclusions drawn by various parties and the subsequent discussions on alternative or complementary proposals:

- From the results of the case studies, there is no evidence to suggest that the Commission's extended impact assessment of REACH contained fundamental flaws. However, the results seem to have identified mechanisms that are key to assuring the workability of REACH, particularly with respect to indirect costs that would result from substance withdrawal for commercial reasons.
- Although the case studies give little evidence that critical substances for downstream users would be withdrawn from the market, improved information in the supply chain (chain transparency) will lessen the likelihood of substance withdrawal further.
- In turn, if the likelihood of substance withdrawal is further lessened, resource-intensive reformulation and approval procedures are less likely to be needed indicating a reduced overall cost of REACH.
- The need for further chain transparency and the resulting reduction of indirect costs must be balanced against legitimate claims to commercial confidentiality, particularly with respect to downstream users.
- The initial cost of registration may, in some cases, be significant. In this respect, lower volume substances are most sensitive to any additional cost burden.
- Due to limited resources SMEs are expected to face more difficulties when complying with the new REACH legislation.
- With respect to SME workability, those proposals that were presented during the second day as well as the subsequent discussions highlighted ways of:
    - reducing one-off registration efforts per substance through more targeted information requirements and enhanced use of available knowledge;
    - reducing one-off registration costs per registrant through improved incentives for cost-sharing (consortia);
    - reducing registration burden on resources other than financial (e.g., time, legal) through easy-to-use guidance, national helpdesks;
- A more targeted approach to information requirements for low volume substances may make registration require less effort.
- Further clarification of the registration requirements for certain materials will reduce the uncertainty.
- Enhanced cooperation between registrants may lessen resource requirements.
- Furthermore, several proposals have focused on the need to involve downstream users, many of which are SMEs, as early as possible in the process, thus increasing supply chain transparency which has been shown to decrease the likelihood of indirect costs at downstream user level due to substance withdrawal for commercial reasons.
- Sufficient information is now available from impact assessments to allow the further consideration of complementary proposals to the Commission's text.
- A possible way of continuing further work on complementary proposals could be the combined consideration of several aspects of these proposals and of the Commission's

proposal, in order to encounter the targeted areas for improvement and to achieve a coherent overall result.

- These proposals must provide solutions to the identified problems without jeopardising the underlying objectives of REACH.