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Subject : – Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}

– Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

Delegations will find in Annex a Progress Report from the Presidency which is addressed to the Council for its sessions on 2 March 2004 (Environment) and 11 March 2004 (Competitiveness), respectively.

Progress Report

I. Introduction

On 29 October 2003, the Commission adopted its proposal for a Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

On 10 November 2003, Commissioner Liikanen presented the proposal to the Competitiveness Council and on 22 December 2003, Commissioner Wallström presented the proposal to the Environment Council.

In line with the European Council's Conclusions of 16/17 October 2003, the Permanent Representatives Committee decided on 5 November 2003 to establish an Ad-hoc Working Party on Chemicals with a mandate to assist the Permanent Representatives Committee in its preparation of the Competitiveness Council's examination of the proposal in co-ordination with other Council formations.

Under the Irish Presidency, the Working Party has to date met on 12/13 January, 2/3 February and 23/24 February 2004 for a "high-level" reading of the main "building blocks" of the proposal. This examination has two aims:

- To give the Commission the possibility to explain in greater detail the structure and contents of the Proposal as well as the reasoning behind it.
- To help identify issues of particular policy concern.

The "high-level" reading will be followed by in-depth examination focused on the issues of particular policy concern and the related text.

It should be stressed that all delegations have, at this stage, general scrutiny reservations on the proposal as a whole.

II. Impact assessment

A number of factors contribute to placing the chemicals policy at the heart of the Community's sustainable development strategy. Major goals in relation to the environment are to avoid chemical contamination of air, water, soil and buildings, and to prevent damage to biodiversity. A key objective of the Community chemicals policy is also to improve the health and safety of workers and the general public. The chemicals industry plays a very important economic role, stimulates innovation and contributes to economic development. It is therefore essential to correctly assess both the benefits of REACH and its effects on the competitiveness of European industry, including at the level of SMEs.

The Commission, in consultation with industry, has agreed that there are a number of areas where the impact of REACH has to be better clarified and understood. These areas include:

- Impact on business throughout the supply chain

Many down-stream users are worried that low-volume chemicals might be withdrawn from the market as a result of the requirement to register. The reasons for and mechanisms behind withdrawal of substances for commercial reasons require further study. Another important aspect is the time from first synthesising to actual marketing of substances.

- Impact on Innovation

REACH is likely to have an influence on the rate of introduction of new products. On the one hand, it might stimulate innovations, because of an interest in substituting certain substances by more environment- or health-friendly alternatives, or because of the exemptions from registration for research and development and since registration will start at 1 tonne (as opposed to 10 kg under the current system for new substances). On the other hand, an increased procedural burden on industry might diminish the interest in developing new substances. There is a need to understand how the balance between these effects will influence the innovative capacity of the chemicals sector.

- Impact on Accession Countries

REACH will apply to the chemicals industry of the 10 new Member States in the same way as to the industry of the current Member States. More data on the effects in the Acceding Countries is needed to verify the impact of REACH on the entire (EU 25) internal market.

It is understood that additional issues may be subject to further work, in agreement with stakeholders.

The Presidency notes that many delegations have highlighted the necessity of adequate impact assessment and have emphasised the importance of undertaking additional work. The Presidency therefore welcomes the Commission's agreement to undertake further impact assessment in consultation with stakeholders. It is understood that work will start at the beginning of March with the objective of providing interim reports from the studies by early May 2004, with final reports being available by November 2004. Further investigations of the impact of REACH, through these detailed additional studies will complement the extended impact assessment of the REACH proposal.

The Commission will be invited to report regularly to the Ad-hoc Working Party on progress on this additional Impact Assessment and progress reports will be made to Council. The Presidency notes that Member States are also conducting a range of economic impact and other assessment studies, which will inform the ongoing discussions in the Working Party.

III. Main issues emerging from the examination

In the framework of the on-going "high-level" reading, the Working Party has to date examined Titles 1 - 8 and 10 of the proposal, comprising Articles 1 - 70 and 109 - 113.

A range of issues of significant interest has been identified by delegations for further examination in the Working Party. These include, among others:

- Duty of Care

The proposed REACH Regulation is based on the principle that it is up to manufacturers, importers and downstream users of substances (within the meaning of the definition of substance in Article 3(1)) to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. This is explicitly included in the text of the proposal. The elaboration of this principle in a more general duty of care requirement that defines industry's responsibility for the safe handling of substances has been suggested by some delegations.

- Information requirements

The information to be submitted as part of the registration dossier for a substance is tiered to the volume of the substance manufactured or imported. The data sets for the different volume thresholds have been proposed on the basis of attempting to strike a balance between environmental and health protection requirements on the one hand and impact on industry on the other. The requirements in relation to substances in the 1 – 10 tonnes range, in particular, have been identified as an issue for further discussion.

- Prioritisation

The timetable (for phase-in substances) and information requirements for registration of substances are prioritised on the basis of volume. The proposal also gives priority to substances that are carcinogenic, mutagenic or reprotoxic. The prioritisation of substances on the basis of criteria other than volume has been suggested by a number of delegations.

- One substance - one registration

There is a strong desire to avoid unnecessary animal testing and to ensure the systems within REACH are efficient and effective. An alternative approach in regard to the registration of substances has been proposed, which would involve a single registration per substance. There are a number of issues that would require detailed examination in relation to this alternative approach.

- Substances in articles

As regards substances in articles, the proposal seeks to ensure protection of human health and the environment as well as being compatible with WTO rules. The provisions proposed require detailed examination to ensure clarity with respect to the terminology used, to ensure that the trade and competitiveness implications are fully explored and that potential adverse effects on human health or the environment from substances in articles are adequately addressed.

- Data sharing

In order to avoid unnecessary animal testing, testing on vertebrate animals for the purposes of the proposed Regulation is to be undertaken only as a last resort and a mechanism for mandatory exchange of such data is provided for. The details regarding the operation of consortia and issues such as commercial confidentiality, allocation of costs, provision of information by the Agency among others, will require further analysis by the Working Party.

- Role of Agency

The allocation of responsibilities between the Agency and Member States for the various activities under the Evaluation Title has been identified as an area for further discussion. A number of issues such as administrative bureaucracy, harmonisation, and resource requirements need examination.

- Authorisation

For substances of very high concern, the proposed Regulation provides for an authorisation system for the uses and the placing on the market of such substances. A wide range of important issues has been discussed including the inter-relationship between the authorisation and restrictions provisions.

- Interface with other legislation

A number of delegations have sought clarification on the relationship between the requirements of REACH and other legislation with particular focus on areas such as waste and worker protection. The Commission produced non-papers in response to the queries

raised, two on the interfaces with current waste legislation and a table of the interfaces with the existing legislation referred to under some of the main Titles within REACH.

The Working Party will return to substantive discussion of these and other issues in its further work, at which point Member States will have an opportunity to put forward detailed positions.

IV. Interim Strategy

The Ad-hoc Working Party was informed of a workshop hosted by the Commission on the development of an Interim Strategy in Arona from 11-13 February 2004. This Strategy provides a framework for arriving at a balance between the implementation of current legislation and preparing for REACH.

The Interim Strategy has two main components:

- Refocusing activities under current legislation, thereby freeing resources of the Commission and in the Member States for REACH preparatory work.
- Preparing for REACH by developing the necessary guidance documents, software tools and infrastructure, enabling a smooth start for REACH.

These two components are substantially linked and a key component in bridging them is the building of strategic partnerships between industry and authorities. These strategic partnerships will enable the smooth transfer of responsibility from the authorities under the current legislation to industry under REACH. The Interim Strategy will focus on the workability of the Commission's proposal and is meant to facilitate work on REACH.

V. Conclusion

The Presidency is encouraged by the progress achieved so far and intends to pursue work actively during the months ahead by embarking shortly on a more detailed examination of the

proposal. It is intended that the Council will be invited to hold policy debates on REACH at its Competitiveness and Environment sessions in May and June 2004, respectively.
