

## **Austrian Comments on the Consultation Document for the new European Chemicals Policy**

**(Common position - coordinated by the Federal Ministry for Agriculture, Forestry, Environment and Water Management; in Cooperation with the Federal Ministry for Economy and Labour, the Austrian Federal Economic Chamber and the Austrian Federation of the Chemical Industry; NOTE: These organisation may deliver additional, individual contributions beyond this one which is reflecting elements of their common ground )**

A first picture of the European Commission's intentions on how to re-arrange the European Chemicals Policy was given in the White Paper on the future European Chemicals Policy, issued by the European Commission on 13 February 2001.

After a phase of exchanging views on the essentials for a future European Chemicals Policy e. g. in Council, in stakeholder fora, etc., in spring 2003 the European Commission has come up with a more detailed outline for a new system for the **Registration, Evaluation and Authorisation of Chemicals (REACH)** as key element of the Commission's proposals for a new policy on chemicals. Currently the Consultation Document for a Regulation concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH) is undergoing a public consultation via internet to give all interested parties and stakeholders the possibility to comment on the REACH-system as presented by DG Environment and DG Enterprise.

Being well aware that the Consultation Document is not a formal Commission proposal and without prejudice to the detailed Austrian positions that might be put forward during Council discussions of a future European Chemicals Policy, Austria has made some observations concerning the Consultation Document, that might serve as a basis for further improvement of the Document.

As the main objective of the REACH system is to ensure a high level of protection for human health and the environment, while enabling the efficient working of the internal market, and stimulating innovation and competitiveness in the chemical industry, Austria welcomes the objectives of the presented REACH system.

The effort put in drawing up the proposal for the REACH-system is well received. Austria is awaiting further discussions on the proposed REACH-system - to enhance the sustainable use of chemicals - with interest.

It is also recognized that the internet consultation procedure is assuring a broad forum for commenting the aims and contents of the REACH system. Austria has taken up the opportunity to discuss the Consultation Document with interested parties, stakeholders and especially representatives of the authorities and the chemicals industry in Austria. The following observations have incurred broad public support in Austria:

- The policy proposed will require significant resources as well as effective structures and procedures for obtaining reliable information on the health and environmental effects of chemicals and articles on the market, and for underpinning and speeding up risk management measures.

- Registration of new and existing substances together with well chosen data on the substances and their uses as a key part of the envisaged REACH-System as described in the European Commission's Consultation Document should be a simple and efficient procedure for enabling also downstream users to meet the requirements without having to put too much resources into the registration and information procedures. The provisions concerning the registration and information through the supply chain should be as clear and streamlined as possible.
- Regarding the provisions concerning the general duty of care, it should be investigated further, how distributors can be adequately addressed as well as how the general duty of care could be allocated in the suitable intensity to the different actors in relation to their possibilities to influence the risk assessment and the risk management procedures.
- To aim at a new dimension in data exchange between all involved actors, especially up and down the supply chain, including also smaller enterprises and (professional) end users, as the Consultation Document does, is very ambitious and desirable. The concept of the information flow chain –and the amount of information that should be transmitted seems over-boarding and the process burdensome, and, thus, should be refined thoroughly.
- As it is especially important to take into account the necessary exchange of information on the substances between the different actors in the supply chain in the whole life-cycle of a substance as such, in preparations or in articles, the idea to create a “safety assessment” format related to substances for information flow purposes as presented in the Consultation Document is well received. However, to administrate the production and exchange of this additional information paper for substances might be too great an effort for small and medium size enterprises (SMEs), putting mainly preparations on the market.
- As an alternative for the information exchange between enterprises and for registration by downstream users by means of the safety report, other existing information formats as well as other simplifications should be considered. The main existing tool to exchange data on chemicals between enterprises is the safety data sheet according to Directive 91/155/EEC. The requirements in the safety data sheet should be extended to cover information needs for registration of specific uses of substances – as such or in preparations - under REACH. The safety data sheet for substances and preparations – maybe in an advanced format, inter alia adequately reflecting risks management considerations and recommendations- could cover large section of the planned chemical safety report. Therefore it should be investigated further, if the introduction of the chemical safety report as a separate format is necessary.
- To keep the REACH-procedures in general as simple as possible and yet gathering all data that is needed to predict the possible risks for humans and the environment, the registered chemical substances might pose at the different stages of their life-cycles, it is of high concern how the collection of data and the data-exchange up and down the supply chain as well as between companies, authorities and the Agency, will be organized in respect of practicalities and formats to be used.
- For the registration-procedure foreseen in the REACH System the existing procedures for data-submission and data-exchange for new and existing substances like the safety data sheet or the IUCLID-database should be used for registration purposes, in a combined, streamlined way to have clear data-submission formats and to provide for a single, comprehensive database. In principle it might be sufficient to adapt existing databases and existing information formats, e.g. as used within the European Community or the OECD or in Chemical Industry initiatives.
- The need to perform tests on animals for registration purposes should be kept at the very minimum that is necessary for the risk characterisation and risk management of the registered substances and their uses.

- To facilitate exposure estimation and risk assessment as well as risk management measures for SMEs in a simple way, a set of standardized exposure categories should be established and used for the risk evaluation process for uses by downstream users.
- After the registration of substances the subsequent evaluation of the data provided during the registration process should be foreseen in a regular, uniform way. Also to avoid the need for too much resources, the evaluation should be done on Community level – under the responsibility of the new European Chemicals Agency. In relation to Member State Authorisations, the Commission should check whether this is really appropriate because it may result in different enforcement in different MS.
- The new requirements will involve added responsibilities and a new assignment of responsibilities for the new European Chemicals Agency, the European Commission, for the competent authorities in the Member States, as well as for industry and other stakeholders. To assure the smooth functioning of the envisaged system, clear responsibilities for the administration of the system on EU-level should be established.
- As the new European Chemicals Agency shall be the responsible body for the implementation, the management and the operation of the new general Chemicals Regulation it is clear that the Agency should operate as independently and efficiently as possible and that the Agency should have the necessary responsibilities and duties to administrate the whole REACH system. Therefore the legal status of the Agency should be similar to the European Air Traffic Control Institutions. By reducing any double work and by creating synergies to the highest extent possible, all relevant decisions making processes should be concentrated at the Agency, including the responsibility of the Agency for the Evaluation process of the REACH system. Basis for the Agency's technical work regarding data flow and communication should be a database (p. 67 d) which is highly reliable and complete in regard to the identity of the substances, their classification and labelling and relevant EC-legislation, even MS-legislation and provides the information to the general public. There should be no double structures within the European Commission and the Agency.
- To avoid more than one major change in the regulatory system for chemicals within a rather short period of time, the introduction of the REACH-System should also take into account the "Globally Harmonized System" for the Classification and Labelling of Chemicals set up by the United Nations.
- International co-operation and global environmental policy initiatives in the field of safe management of chemicals are steadily increasing. Especially the emerging Global Strategy on Chemicals (SAICM) will have a certain impact on the EU-Strategies and vice versa. Therefore the participation of third countries (p. 90) and the participation of international organisations (p. 91) - such as UNEP, FAO, IFCS, UN-ECE, etc. - as well as the industry should be foreseen with the Agency as the focal point.