

Developments related to the Existing Substances Regulation

There is much debate among Member States, the EU Commission, industry and NGOs at present regarding the future of chemicals control on existing substances in the European Community.

Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances, generally known as the 'Existing Substances Regulation' was adopted on 23 March 1993 and entered into force 60 days after its publication in the Official Journal of the EC on 4 June 1993. The aim of the Existing Substances Regulation is the protection of human health and the environment from exposures to dangerous substances. The basic principle of the Existing Substances Regulation is that controls on hazardous chemicals should be based on an assessment of the actual risks to human health and the environment, rather than on the intrinsic hazardous properties of the substance. This approach is based on sound science and was supported, and continues to be supported, by CONCAWE and other industries.

The Existing Substances Regulation consists of procedures for:

- the collection of data on existing substances produced or imported into the Community (i.e. HEDSET (Harmonized Electronic Data Set) dossiers);
- the preparation of lists of priority substances for which the need for risk assessment is greatest;
- the assessment of risks; and
- the identification of any measures needed to control those risks.

The risk assessment itself is conducted by a member state 'rapporteur', acting on behalf of the European Union. Since 1994, a total of 110 substances have been identified on three separate priority lists for the risk assessment process. It should be noted that although no petroleum substances, *per se*, have been identified on any of the priority lists, risk assessments have been initiated for certain hydrocarbons (e.g., benzene, toluene) which are present in various petroleum substances. Risk assessment conclusions for four substances, and strategies for risk reduction measures for only three of the substances, were to have been published by the end of 1998.

This slow rate of progress has caused concern among some Member States and non-governmental organizations as an indication of the failing of current chemicals control mechanisms in the EU. This has been attributed to a number of factors, including:

- underestimation of the effort involved;
- a lack of resources from Member States, the Commission and industry;
- a failure to identify the real priority substances which need risk assessments; and
- an over-burdensome data requirement.

The Commission has undertaken an initiative to review the current Community legislation governing industrial chemicals, in the form of a brainstorming workshop held in February 1999 under the theme 'Industrial Chemicals: Burden of the Past, Challenge for the Future'. Representatives from all stakeholder groups (i.e. regulators, scientists, industry and NGOs) were

invited to debate the issues of industrial chemicals in the Community in order to strengthen the level of protection for human health and the environment.

In her opening remarks, EU environment commissioner Ritt Bjerregaard stated that, despite the EU's 'impressive arsenal of instruments' governing chemicals, it was clear that 'the current Community legislation just isn't doing the job' and does not allow for a rapid response on emerging issues (e.g. persistent and/or bioaccumulative chemicals and endocrine disruptors). General themes expressed during the workshop included a need for increased commitment from Member States, the Commission and industry, the need for more effective coordination of activities, the need to give greater consideration to the application of the precautionary principle within a defined framework and, in the longer term, the need to consider a new legislative framework. The workshop will lead to a Commission communication, later in the year, to the Council and European Parliament, which will set out a strategy for the control of chemicals in the EU.

CONCAWE recognizes that the Existing Substances Regulation is a key legal instrument for ensuring the responsible management of existing substances in the EU. CONCAWE also recognizes that the current state of progress in the implementation of risk assessments under this Regulation falls short of desired objectives.

In an effort to improve upon the implementation of this important Regulation, CONCAWE member companies have volunteered to undertake initial risk assessments of representative streams for its major marketed petroleum groups having wide dispersive use (e.g. LPG, gasoline, diesel fuel, industrial gas oils, etc.).

A Risk Assessment Coordination group, chaired by a member of the Board and comprised of the Chairmen of the various CONCAWE management groups, as well as the Ecology, Industrial Hygiene and Toxicology Groups and the respective technical coordinators, has been constituted to provide guidance and management oversight for this important activity. The coordination group will also seek to liaise its activities with the American Petroleum Institute which is in the midst of planning its strategies to fill toxicity, eco-toxicity and physico-chemical data-gaps under the Vice-President's High Production Chemical Challenge Program to improve the amount of information which is available publicly on petroleum substances.