

Council conclusions

The Council

1. RECALLS the discussion on the current status of the Community's chemicals policy that took place at the informal meetings of environment ministers in Chester on 24/25 April 1998 and in Weimar on 8/9 May 1999. The Commission presented a report on the implementation of Community regulation of chemicals on 18 November 1998. The Council of 20/21 December 1998 adopted conclusions on this matter which affirms the need to work on the development of an integrated and coherent strategy for the future chemicals policy of the Community adequately reflecting the precautionary principle and the principle of sustainability and specifying the obligations incumbent on the parties involved in order to ensure a high level of protection for human health and environment in a rapidly developing market for chemicals and the efficient functioning of the internal market. The Commission organised on 24/25 February 1999 a brainstorming workshop with stakeholders and representatives of the Member States in order to consider the future outline for the Community chemicals policy;

RECOGNISES that

2. the chemicals policy within the European Community over the last thirty years has led to a high degree of harmonisation of laws and regulations on hazardous substances and preparations. This enables the chemical industry to operate within a common internal market. Moreover, the various legal instruments have created a basis for evaluating and, where necessary, limiting the adverse impact of hazardous substances and preparations on human health and the environment;
3. in connection with Community instruments on the evaluation and control of the risks from chemical substances and in the light of public interest and concern, an extensive discussion has begun within the Community on the best approach to managing the risks posed by chemicals to human health and the environment over the entire life-cycle (from cradle to grave);
4. NOTES that work has started within the Community on the issue of integrated product policy which is clearly linked to the chemicals policy;
5. TAKES NOTE of the fact that the contracting parties to the Helsinki Convention and the OSPAR Convention, in seeking to protect the marine environment of the Baltic Sea and the North-East Atlantic respectively, have agreed to the objective of preventing pollution of the marine area by continuously reducing discharges, emissions and losses of hazardous substances with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close-to-zero for man-made synthetic substances. The Parties of these Conventions have adopted a strategy to implement this objective progressively by making every endeavour to move towards the target of the cessation of discharges, emissions and losses of hazardous substances by the year 2020;
6. TAKES NOTE of the fact that the contracting parties to the Barcelona Convention, in the Barcelona Resolution of 10 June 1995, have agreed to the objective of reduction by the year 2005 of discharges and emissions which could reach the marine environment, of substances

which are toxic, persistent and liable to bioaccumulate, in particular the organo-halogens, to levels that are not harmful to man or nature, with a view to their gradual elimination;

7. RECOGNISES that the Community Chemicals Policy should make a major contribution towards enabling the Community and the Member States to meet such international obligations.
8. TAKES NOTE of the development taking place in other international fora aiming at establishing new international instruments for a better management of chemicals;
9. RECALLS the necessity for Member States and the Commission to reinforce their full commitment to an effective implementation of the existing instruments e.g. through the provision of sufficient resources and through appropriate Community measures to facilitate implementation by the Member States.

STATES that a number of conceptual and operational shortcomings exist in the current Community approach to assess and to regulate chemicals, in particular

10. the risk assessment of substances has imposed a considerable burden on the authorities of the individual Member States, the European Commission and in particular the European Chemicals Bureau (ECB), with regard to human, technical and financial resources. Moreover, the implementation of other Community instruments will lead to a further increase in the workload;
11. as risk assessments have only been drafted for a very small number of existing substances pursuant to the EC legislation on existing substances, but none have been adopted, maintaining the current approach is unlikely to tackle the problem of existing substances with the view to achieving an appropriate limitation of all the significant risks posed by these substances to man and the environment;
12. our current knowledge of toxicological and ecotoxicological properties and the behaviour in the environment is insufficient for an adequate risk assessment even in the case of most High Production Volume (HPV) substances (more than 1,000 tons per year) to which man and the environment are exposed to a considerable extent. There are concerns that certain chemicals may pose an immediate or future threat to human health and the environment;
13. the information even on the most relevant uses is often insufficient due to the fact that the current legislation only obliges the producers and importers of substances, but not the downstream users, to provide information about the uses of the substances. Nor does it require public authorities and other institutions to supply relevant data that they have at their disposal;

WELCOMES

14. the voluntary initiatives of industry and in particular on the part of the International Council of Chemical Associations (ICCA) including the Conseil Européen des Fédérations de l'Industrie chimique (CEFIC) to make available a base set of data on the toxicology and ecotoxicology of approximately 1,000 High Production Volume substances, including a preliminary hazard assessment, within the next five years;
15. the ongoing discussion among the OECD member countries on the evaluation of this data. Such an evaluation could contribute to the EU activities in this field;

16. the intention of the Commission to present a communication on the application of the precautionary principle as the first step towards establishing a risk management approach which reflects this principle.
17. the intention of the Commission to present a policy document outlining a new chemicals strategy, including different legislative options;
18. 18. CALLS UPON the Commission to base this strategy on the precautionary principle, the goal of sustainable development and the environmental safety and the efficient functioning of the internal market;

CALLS UPON the Commission, when drawing up its proposals, to consider measures which:

19. aim at an efficient, integrated and coherent design of the various legal instruments for regulating chemicals in the fields of human health and environment with a view to facilitating their implementation and which are designed to achieve coherence with other fields of legislation taking into consideration relevant recommendations arising from other reviews, for example the SLIM review of Directive 67/548/EEC;
20. place the main responsibility on manufacturers, importers, formulators and industrial users for generating and assessing data and preparing risk assessment reports for substances, as well as for providing adequate information to users and the public on the safety of their products for the part of the life cycle to which they contribute (shifting the burden of proof). This information should be presented in a transparent and accountable way. The role of public authorities should be maintained with regard to monitoring and the efforts of the authorities should be focussed on the assessment of substances of major concern;
21. lead to better co-ordination and co-operation, and clarify responsibilities, in particular between the bodies responsible for the risk assessment and risk management measures;
22. overcome the existing deficits in collecting data on exposure and in the selection of existing substances for priority assessment through improving access to information about the uses of the substances, and to data available on emissions /environment levels.;
23. establish a more flexible approach to risk assessment with the aim of targeting it, e.g. to the most likely relevant uses of substances or to those populations or environmental compartments potentially at risk (targeted risk assessment). A comprehensive risk assessment may not be necessary before preparing risk management measures. This shall not preclude the extension of the risk assessment at a later stage in the light of new data;
24. establish strategies to achieve effective risk management measures for certain substances which may cause threats of serious or irreversible damage to human health or the environment as a result of their inherent properties by giving appropriate weight to their use pattern and the possibility of exposure;
25. encourage the simultaneous assessment of several substances used for the same purposes or having a similar chemical structure (grouping) with the aim of accelerating and improving decisions on risk-reduction;
26. encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available or the substitution of substances which pose a risk by substances which pose a lower risk;

27. set strict time frames for appropriate risk assessments of existing substances on the priority lists while ensuring adequate consequences, if the requested time targets are not met;
28. aim at streamlining the existing labelling legislation to make the labels easier to understand and aim at improving the self-classification by the producer or importer;
29. encourage the sharing of data to minimise the need for animal testing and reduce costs;

INVITES the Commission, while considering the role of the different actors in the development of the chemicals policy

30. to examine the introduction of an obligation for the producers or importers of preparations to provide for an assessment of safety during use (product safety assessment), where appropriate, identifying potential adverse effects on human health or the environment and documenting the results;
31. to consider the feasibility of a publicly accessible data base at Community level presenting an overview of the current state of the assessment process for each High Production Volume substance as well as of ongoing and planned activities as part of this process;
32. to submit, as soon as possible, a policy document on how to identify and evaluate substances which affect the endocrine system, taking into account existing instruments and programmes that serve this purpose;
33. to undertake a review of the present structures and instruments, including the resources, with the aim of organising more efficiently the work assigned to the Community with regard to the evaluation of substances, and to ensure that the high quality of the work carried out by the European Chemicals Bureau (ECB) in performing its assigned tasks will be maintained and reinforced;
34. to co-ordinate in co-operation with Member States, input into the international work on the Globally Harmonised Hazard Classification and Labelling System (GHS) in support of targets agreed under Chapter 19 of Agenda 21. The Council also INVITES the Commission to analyse the implication of the agreements for Community legislation and consider, as appropriate, submitting proposals for implementation;

CALLS UPON the Commission

35. to submit the policy document outlining a new chemicals strategy at the latest by the end of the year 2000 and to report to the Council on the progress made on a regular basis, beginning in the second half of 1999.