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- Council Conclusion

Delegations will find in Annex the Conclusions of the Council on a Strategy for a Future Chemical Policy adopted by the Environment Council on 7/8 June 2001.

STRATEGY FOR A FUTURE CHEMICALS POLICY

COUNCIL CONCLUSIONS

The Council

RECALLS

1. the discussions about the need to reform 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 Council adopted a first set of conclusions on this matter on 21/22 December 1998. A second set of conclusions on a community policy for chemical products was adopted on 24/25 June 1999;
2. the Conclusions adopted by the Council (Internal Market) on 25 May 2000 on Better Regulation/Simplification of Legislation (SLIM), the conclusions adopted by the Industry Council on 14 November 1996 on an Industrial Competitiveness Policy for the European Chemical Industry, and the conclusions adopted by the Environment Council on 30 March 2000 on the Commission's communication on a Community strategy for endocrine disrupters;
3. the Council resolution of 4 December 2000 on the Precautionary Principle, which was endorsed by the European Council in Nice on 7-9 December 2000;
4. the resolution of 1 February 1993 of the Council and the representatives of the governments of the Member States on the European Community programme of policy and action in relation to the environment ("the 5th EAP") that set objectives i.a. to assess high production volume chemicals, develop risk reduction programmes for priority chemicals and achieve a reduction in vertebrate animal testing;
5. **TAKES NOTE OF** national strategies in the field of chemicals adopted in several Member States as well as the results of several inspection reports on the actual compliance with the regulations concerning classification and labelling in certain Member States;
6. **WELCOMES** the publication of the Commission's White Paper - Strategy for a Future

Chemicals Policy and considers it as an important first step in the development of the new Chemicals Policy;

7. **RECALLS** the discussions on the White Paper in the Environment Council on 8 March 2001, in the Internal Market, Tourism and Consumer Affairs Council on 12 March 2001 and the outcome of discussions in the Industry Council on 14-15 May 2001;
8. **TAKES NOTE OF** the discussion on the White Paper that took place at the Stakeholders meeting arranged by the Commission on 2 April 2001;
9. **REAFFIRMS** its commitment to the development of a new chemicals policy and a new Community system for the management of chemicals (substances and preparations) including how the issue of chemicals in products will be addressed in legislation.
10. **ACKNOWLEDGES** that the White Paper addresses many of the concerns identified earlier by the Council, but considers that further elaboration of the proposed mechanism is required in order to introduce workable and effective controls for chemicals.

RECOGNISES that

11. the new chemical policy must contribute to a sustainable development and ensure a high level of protection for human health, including workers' health, and the environment, while promoting innovation and the competitiveness of the European industry concerned. The policy must reflect the diverse and complex nature of the EU industry, including downstream users, and in particular the specific needs of SMEs including, if appropriate, the need for any support measures;

12. The policy should aim to achieve that, within one generation (2020), chemicals are only produced and used in ways that do not lead to a significant negative impact on human health and the environment, which is also in line with the water framework Directive and with commitments that Member States and the Community have undertaken in international fora;
13. the new chemicals policy will be an important part of the new action programme for the environment that is currently being considered by the European Parliament and the Council, especially in relation to the environment and health, and will also contribute to the European sustainable development strategy;
14. the precautionary principle must be a basis for the new chemical policy, in accordance with the Council Resolution mentioned above and the Commission Communication on the Precautionary Principle;
15. Chemicals that are dangerous should be substituted with safer chemicals or with safer alternative technologies not entailing the use of chemicals, with the aim of reducing risks to man and the environment;
16. innovation as regards the development of new chemicals and alternative technologies needs to be stimulated, in particular in order to ensure that safer alternatives to problematic existing chemicals will become available and to promote a sustainable chemicals industry;
17. the new chemicals policy must be developed at Community level in order to ensure the integrity of the internal market and must be consistent with WTO rules as well as with relevant multilateral environmental agreements;
18. the new chemicals policy must develop streamlined, pragmatic and effective procedures to overcome the present lack of knowledge about the properties, use and exposure of existing substances as well as the slow pace in the development of risk assessments and risk management measures. The requirements for registration of substances must be set reflecting what is realistically achievable in the Community while providing a high level of protection for human health and the environment;

19. there is a need to shift to industry, including downstream industrial users, the responsibility to generate knowledge about chemical substances and to assess and manage the risks arising from their use, enabling the authorities to focus on chemicals of highest priority;
20. a Community register for chemical substances needs to be established based on a tiered approach for data requirements. Substances that give rise to very high concern should only be used in justified and well-defined cases, and must be subject to authorisation, while other chemicals of concern must be subject to an effective decision procedure enabling rapid risk management measures to be taken whenever the need arises;
21. international co-operation on the management of chemicals has made substantial progress, i.a. through the signing of the Stockholm Convention on persistent organic pollutants (POPs), the progress made on the Globally Harmonised Hazard Classification and labelling System (GHS) and the decision by the UNEP Governing Council to study the need for a strategic approach to international chemicals management. The new EU chemical policy will be an important input to this work and to the work in other fora, such as the OECD.
22. **SUPPORTS** the proposal in the White Paper to meet these challenges through the development of the REACH system for the management of chemicals (Registration, Evaluation and Authorisation of Chemicals), where new and existing substances in principle will be subject to the same requirements, but stresses that the REACH approach needs to be developed to ensure the streamlined identification and risk management of chemicals of concern;

UNDERLINES that

23. animal testing should be limited to the level necessary to deliver the objectives of the strategy, including a high level of protection for human health and the environment. Industry should make all existing data available to avoid duplication of testing. Mechanisms are needed to ensure that unnecessary testing requirements are avoided. Adequate resources must be provided for research, development and validation of globally accepted test guidelines for alternative in vitro test methods, so that work can be accelerated at all levels. Activities under the new Framework Programme for Research should consider these requirements among its priorities. In addition to promoting this issue in ECVAM (European Centre for the Validation of Alternative Methods), the Community should play a more active role in the OECD, to encourage wider adoption of validated, alternative, non-animal testing methods;
24. additional research is needed in order to improve our knowledge about the impact of chemicals on human health and the environment, including the development of risk-assessment methods. It is essential that sufficient funding is made available for such research through public research programmes at Community level and at national level;
25. a general obligation should apply for industry to obtain enough knowledge and to take the measures needed to ensure the safety of chemicals (duty of care) irrespective of production volume and even if no specific data requirements have been established;
26. to verify compliance with the duty of care, industry should keep records of data, including information on properties, volumes and use, on all chemicals produced and used, including uses in products, and make any of these records available to the authorities if so requested;
27. industry should also ensure the quality of their risk assessments and risk reduction strategies e.g. through auditing/peer review or by other means;
28. in general, it must be ensured in the new system that a chemical cannot be marketed or used if the information required under the REACH system is not provided by the industry within the reasonable time periods to be set within the system;

29. the timetable for registration of information on substances is generally supported, provided that the system is flexible enough to allow for earlier registration and screening of substances of concern; the system needs to be complemented by prioritisation as regards the substances to be assessed and by additional time limits for the assessment and data evaluation and for the decisions on risk management measures, including authorisation in order to ensure cost-effectiveness and that the goal of a sustainable use of chemicals can be met;
30. as regards the use of chemicals in products, the approach set out in the Green Paper on an Integrated Product Policy (IPP) can make an important contribution that needs to be developed further in line with the Conclusions on the Green Paper adopted today by the Council;
31. all uses of concern of chemicals in products must be covered by the new system. The Commission therefore needs to undertake further study and present proposals by the end of 2001 with a view to covering products produced outside the Community in the same way as products produced within the Community;
32. Manufacturers and downstream users should develop an effective communication process within the product chain based on a shared commitment to the safe use of their products; information that is relevant for the safe use of chemicals as well as products must be made available to all users. Stakeholder access to the non-confidential information on the central system database is important but not sufficient. Further means to improve access to information should be worked out to enable consumers and professional users to make the best choice from an environmental and health point of view. Such measures could be based on a general duty for manufacturers, downstream users and distributors to provide comprehensive information on the content of chemicals in products and their hazards and risks in an accessible and understandable form and to label products appropriately, while taking intellectual property rights into account. Moreover, the link between data registration under the new system and the existing legislation pertaining to labelling and classification should be clarified;

33. responsibility for the administration of the REACH system has to be shared between public authorities in the Member States, the Commission and a central entity. The central entity should handle specific tasks, such as the administration of the central register and the preparation of decisions on the Community level, as well as supporting the public authorities in their evaluation of chemicals. The sharing of responsibilities between Member States needs to be clarified;
34. the Member States and the Commission need to commit themselves fully to an effective implementation of the new system by ensuring sufficient resources at all levels and through Community measures to facilitate the implementation by the Member States;
35. it is necessary to elaborate and implement all the relevant provisions of the new chemicals policy fully in line with the requirements laid down in the UN-ECE Aarhus Convention on access to information, public participation and access to justice.

CALLS UPON the Commission

36. to present by the end of 2001 its main proposals for a simple, clear and transparent regulatory framework to implement the strategy, including clarifying the responsibilities of producers and downstream users and procedures to establish risk reduction measures rapidly, in order to ensure that the timetables in the strategy can be met;
37. to set up a task force as soon as possible with representatives from Member States, working in consultation with industry, NGOs and other stakeholders concerned in the transitional period until the new legislation has come into force, to explore ways in which chemicals of concern can be identified to allow prioritisation for taking action, developing clear and transparent screening criteria, essential information requirements, and exploring the use of chemical grouping and modelling techniques. The availability of information to allow such prioritisation, such as data provided by industry on existing chemicals produced in high volumes (ICCA) should also be assessed. The first results of the work in the task force should be available by the end of 2002 to enable industry to commence data collection before the legislation comes into force, so that deadlines can be met.

INVITES the Commission, when drawing up its proposals, to

38. study more deeply the relation to legislation in other areas, as stated in the Council Conclusions of June 1999, and consider measures to avoid duplication of legislation work and to achieve coherence and the same level of protection in all fields of Community legislation such as occupational safety, major accident hazards, consumer protection, food packaging, water, waste, plant protection products, biocides, cosmetics, toys, etc;
39. study the case for introducing within the REACH system a simple register including substances produced in volumes below 1 tonne, with the aim of allowing, if possible, prioritisation of substances of concern;
40. study how to develop screening procedures to effectively identify chemicals with potentially harmful properties or uses of concern for the purposes of prioritising substances for which further information is urgently needed and those requiring accelerated risk management;
41. study how to develop criteria for classifying substances in categories of concern and explore the use of decision trees to apply consistent control measures, based on hazard criteria and use patterns, in line with a prudent and precautionary chemicals management;
42. study further the data requirements for substances produced in volumes below 10 tonnes in order to ensure that the information provided will be sufficient for classification and labelling and to assess the need for risk reduction measures. The data sets must also provide appropriate information for handling cases of unintentional releases and to enable the protection of the health and safety of workers whilst ensuring a minimum of animal testing;
43. develop procedures that can be used both by authorities and by the industry to simplify the identification of the relevant testing strategies and reduce the need for animal testing, including the use of decision trees and specific screening methods for all chemicals, such as validated computer modelling and the testing to identify chemicals that are persistent and bio-accumulating, taking into account the cost of testing requirements;

44. exploit, in order to limit the costs and efforts involved in the novel authorisation procedure, all realistic means of simplifying the procedure and of making use of available information; to this end authorisations that have an impact on the internal market should have general validity and be taken on Community level;
45. add PBT (Persistent, Bioaccumulative and Toxic chemicals) and VPVB-substances (Very Persistent, Very Bioaccumulative chemicals) to the groups of substances of very high concern that will be subject to authorisation as soon as the necessary criteria for their identification are established;
46. envisage the addition of known endocrine disrupters to the authorisation system when agreed scientifically valid test methods and criteria are established, and study whether other substances with properties of concern, such as sensitisers and chronic toxic substances, need to be included in the authorisation system;
47. co-ordinate in co-operation with Member States the input into the international work on the Globally Harmonised Classification and Labelling System (GHS) and also analyse its implications for the Community legislation and consider, as appropriate, the need to submit proposals for its implementation;
48. further investigate how a central entity such as an expanded ECB (European Chemicals Bureau) or other body should best be organised and financed to avoid duplication of tasks as well as how fees, funds and other means of financing can support the resources of such an entity as well as the tasks carried out by Member States and to assess and minimise the overall costs for their public administrations, with the aim not to exceed, if possible, the costs implied by full implementation of the existing legislation;

49. develop mechanisms and define practical rules, to be operational when the system is implemented, through which the industry makes testing data and other information available in order to avoid duplication of tests and market distortions, while ensuring an equitable sharing of costs taking due account of the property rights of the party who generates the data;
50. investigate ways to ensure the effective implementation and study the adequacy of industry's data quality assurance system, and the enforcement of the new legislation, including provisions for a review of its implementation to allow for adjustments if the objectives are not being met.
