

EUROPEAN PARLIAMENT

1999



2004

Session document

FINAL
A5-0356/2001

17 October 2001

REPORT

on the Commission White Paper on Strategy for a future Chemicals Policy
(COM(2001) 88 – C5-0258/2001 – 2001/2118(COS))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Inger Schörling

Draftsmen (*): Hans Peter Mayer, Committee on Legal Affairs and the
Internal Market
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Research and Energy

(*): Hughes procedure

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(*) Hughes procedure

PROCEDURAL PAGE

By letter of 28 February 2001, the Commission forwarded to Parliament its White Paper on Strategy for a future Chemicals Policy (COM(2001) 88 – 2001/2118(COS)).

At the sitting of 2 July 2001 the President of Parliament announced that she had referred the White Paper to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Employment and Social Affairs, the Committee on Legal Affairs and the Internal Market and the Committee on Industry, External Trade, Research and Energy for their opinions (C5-0258/2001).

At the sitting of 5 July 2001, the President announced that the Committee on Legal Affairs and the Internal Market and the Committee on Industry, External Trade, Research and Energy, which had been asked for their opinions, would be involved in drawing up the report, under the Hughes procedure.

The Committee on the Environment, Public Health and Consumer Policy had appointed Inger Schörling rapporteur at its meeting of 12 March 2001.

It considered the Commission White Paper and the draft report at its meetings of 26 June 2001, 27 August 2001 and 16 October 2001.

At the last meeting it adopted the motion for a resolution by 31 votes to 21, with no abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Guido Sacconi, Alexander de Roo and Ria G.H.C. Oomen-Ruijten, vice-chairmen; Inger Schörling, rapporteur; Per-Arne Arvidsson, María del Pilar Ayuso González, David Robert Bowe, John Bowis, Martin Callanan, Dorette Corbey, Chris Davies, Anne Ferreira, Michael Gahler (for Marialiese Flemming pursuant to Rule 153(2)), Cristina García-Orcoyen Tormo, Jas Gawronski (for Avril Doyle pursuant to Rule 153(2)), Laura González Álvarez, Françoise Grossetête, Cristina Gutiérrez Cortines, Catherine Guy-Quint (for Béatrice Patrie), Jutta D. Haug (for Karin Scheele), Ruth Hieronymi (for Giacomo Santini pursuant to Rule 153(2)), Anneli Hulthén, Christa Kläß, Eija-Riitta Anneli Korhola, Bernd Lange, Giorgio Lisi (for Peter Liese), Torben Lund, Minerva Melpomeni Malliori, Patricia McKenna, Jorge Moreira da Silva, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Jens Dyhr Okking (for Hans Blokland pursuant to Rule 153(2)), Karl Erik Olsson, Marit Paulsen, Frédérique Ries, Didier Rod (for Hiltrud Breyer), Dagmar Roth-Behrendt, Ulla Margrethe Sandbæk (for Jean-Louis Bernié), Ursula Schleicher (for Giuseppe Nisticò), Horst Schnellhardt, Jonas Sjöstedt, Renate Sommer (for Robert Goodwill), María Sornosa Martínez, Bart Staes (for Marie Anne Isler Béguin), Catherine Stihler, Antonios Trakatellis, Roseline Vachetta, Kathleen Van Brempt (for Joaquim Vairinhos) and Phillip Whitehead.

The opinions of the Committee on Legal Affairs and the Internal Market and the Committee on Industry, External Trade, Research and Energy are attached; the Committee on Employment and Social Affairs decided on 25 April 2001 not to deliver an opinion.

The report was tabled on 17 October 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the Commission White Paper on Strategy for a future Chemicals Policy (COM(2001) 88 – C5-0258/2001 – 2001/2118(COS))

The European Parliament,

- having regard to the Commission White Paper (COM(2001) 88 – C5-0258/2001¹),
- having regard to Articles 6, 95 and 174 of the EC Treaty,
- having regard to the international obligations of the European Community and its Member States under the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic, the Barcelona Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean, the Helsinki Convention on the Protection of the Baltic Sea Area, and to the upcoming international obligations under the Stockholm Convention on Persistent Organic Pollutants,
- having regard to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters,
- having regard to the Community legislation in force on chemicals²,
- having regard to the Community legislation in force in the field of water policy³,
- having regard to the Community legislation in force on biocides⁴ and cosmetic products⁵ and to its position at first reading on the proposal for a European Parliament and Council directive amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products⁶,
- having regard to the Fourth⁷ and Fifth Community Action Programmes on the Environment⁸, and to its position at first reading on the proposal for a European Parliament and Council decision laying down the Community Environment Action Programme 2001-2010⁹,

¹ Not yet published in OJ

² OJ B 196, 16.8.1967, p. 1; OJ L 200, 30.7.1999, p. 1, p. 14; OJ L 84, 5.4.1993, p. 1; OJ L 262, 27.9.1976, p. 201

³ OJ L 327, 22.12.2000, p. 1

⁴ OJ L 123, 24.4.1998, p. 1

⁵ OJ L 151, 23.6.1993, p. 32

⁶ Minutes of 3.4.2001, p. 4

⁷ OJ C 337, 21.12.1992, p. 34

⁸ OJ L 275, 10.10.1998, p. 1

⁹ Minutes of 31.5.2001, p. 21

- having regard to its resolution of 14 December 2000¹ on the Commission communication on the precautionary principle and to the Council resolution, annexed to the conclusions of the Presidency on the Nice European Council,
 - having regard to its resolution of 26 October 2000² and to the Council conclusions of 30 March 2000 on the Commission communication on a Community strategy for endocrine disrupters,
 - having regard to the Council conclusions of 7 June 2001 on Chemicals Policy and to the Strategy on Sustainable Development adopted by the Göteborg European Council,
 - having regard to the stakeholders meeting organised by the European Commission on 2 April 2001, to the workshop on chemicals in products organised by the Swedish Presidency on 5-6 April 2001 and to the submissions received by interested parties,
 - having regard to Rule 47(1) of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Legal Affairs and the Internal Market and the Committee on Industry, External Trade, Research and Energy (A5-0356/2001),
- A. whereas the Commission is consulting the European Parliament on the strategy for a future chemicals policy with a view to proposing a new regulatory framework on chemicals; whereas the European Parliament should contribute to the development of this framework in a clear and ambitious way, seeking above all to promote sustainable development, reconfirming that protection of human health and the environment must have priority, taking due account of economic and social considerations,
- B. whereas Article 3 of the EC Treaty calls for the competitiveness of Community industry to be strengthened, research and technological development to be promoted, a high level of health protection to be attained, and a system to be established to ensure that competition in the internal market is not distorted,
- C. whereas Article 6 of the EC Treaty states that environmental protection requirements shall be integrated into the definition and implementation of Community policies and activities referred to in Article 3, in particular with a view to promoting sustainable development,
- D. whereas Article 157 of the EC Treaty requires the Community and the Member States to create the conditions necessary for the competitiveness of the Community's industry and to work to encourage an environment favourable to initiative and to the development of undertakings throughout the Community, particularly small and medium-sized undertakings,
- E. whereas, Article 174(1) of the EC Treaty says that Community policy on the environment shall contribute to pursuit, among other things, of the objectives of preserving, protecting

¹ OJ C 232, 17.8.2001, p. 207

² OJ C 197, 12.7.2001, p. 220

and improving the quality of the environment and protecting human health; whereas paragraph 2 of that Article also stipulates that this policy shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should, as a priority, be rectified at source and that the polluter should pay; and whereas under paragraph 3 of that Article, available scientific data, the benefits and costs of action or lack of action, and the economic and social development of the Community as a whole must be taken into account,

- F. whereas sustainable development should serve both to protect human health and the environment and to promote balanced development of economic activities and hence, in particular, safeguard employment and guarantee a high level of social protection,
- G. whereas public health and the environment need to be protected to the same degree in all the Member States,
- H. whereas the Lisbon European Council pointed out that the competitiveness and buoyancy of the markets depend directly on a regulatory framework to encourage investment, innovation, and entrepreneurship,
- I. whereas Parliament is calling for measures to be taken to give encouragement and support, especially to small and medium-sized enterprises, in order to develop facilities to help them surmount technical and organisational obstacles and establish a 'fast track' within the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European research area (COM(2001) 94),
- J. whereas the substitution principle - the promotion of safer practices and substances to replace hazardous practices and substances - must be implemented as a key aim of EU chemicals policy and as primary risk reduction option; whereas research into and the development of alternative new products whose life cycles conform to the principles set out by the Commission in the Green Paper on Integrated Product Policy (COM(2001) 68) should be fostered,
- K. whereas diffuse sources, such as the use of chemicals in products, are estimated to be the biggest source of exposure for man and the environment; whereas, however, chemicals are used mainly in products from which society derives benefit,
- L. whereas data on basic properties and relevant uses is either missing or not made available to authorities for the large majority of chemicals, despite the fact that 99% of the currently marketed chemicals have been on the market for more than 20 years and that disclosure of existing data would significantly reduce the need for animal testing; whereas information on basic properties and uses must be made publicly accessible, bearing in mind that the data that the industry supplied to the European Chemicals Bureau until 1999 on high-volume existing substances (over 1 000 tonnes a year) satisfied the base set requirements for 14% of these chemicals entirely, for 65% partly and for 21% not at all,
- M. whereas the chemical industry needs to offer greater transparency so as to respond to the public health and consumer protection problems with which citizens are increasingly

having to contend,

- N. whereas the Commission's review of current legislation on existing substances revealed the immediate concern that man and the environment are potentially exposed from a large number of sources to a large number of chemical substances for which the hazardous properties have not been identified; whereas this is of particular concern for chemical industry workers; whereas these substances may furthermore add up to have bigger adverse impact as compared to when acting in isolation, or interact to produce unknown effects; whereas this situation needs to be improved in the interests of protecting human health and the environment,
- O. whereas many substances suspected of being endocrine disruptors have already been identified and included in other priority chemicals lists because of their negative effect on human health and wildlife without concrete action being taken,
- P. whereas the current system governing existing chemicals is characterised by a lack of transparency for consumers and industry, inconsistencies in cumbersome procedures or rules that have not been harmonised, a large amount of red tape, and an unclear division of responsibilities,
- Q. whereas the current system of risk management is not functioning and needs to be replaced by a new and effective instrument within the new system,
- R. whereas the use of chemicals in products manufactured within the European Union is sufficiently monitored, but the necessary supervision is not being exercised over products imported into the European Union,
- S. whereas the current system cannot achieve the objective of sustainable development,
- T. whereas the need for a complete structural reform of Community legislation on chemicals is fully supported,
- U. whereas the many and varied legal requirements applying to chemicals need as a matter of urgency to be formed into a unified whole so as to improve transparency for all concerned in order to achieve coherent, harmonised, and comprehensive legislation in the European Union,
- V. whereas the new chemicals policy should contribute to sustainable development and ensure a high level of protection for human health, including workers' health, and the environment as the best means to promote innovation and the competitiveness of the European industry concerned,
- W. whereas the new policy should cover the entire life cycle of chemicals, including the point at which chemicals and products which consist of or contain chemicals become waste,
- X. whereas the competitiveness of the chemicals industry and its associated industries is a legitimate political objective in itself, which draws its legitimacy from its potential to achieve a higher quality of life for present and future generations, but only insofar as this

- potential is actually fulfilled, whereas the development of safer products in an environmentally sensitive manner, enhanced transparency and consumer information and promotion of sustainable development are positive marketing benefits which can enhance the competitiveness of the European chemicals industry,
- Y. whereas the chemicals industry in Europe directly employs 1.7 million people and several million jobs depend on it,
- Z. whereas most of the firms operating in both the chemical industry and the downstream processing industry are small and medium-sized enterprises, which in numerical terms make up 96% of the total,
- AA. whereas the available empirical evidence suggests that the adverse impact of environmental regulation on the competitiveness of the EU chemicals industry is unclear or may indeed be positive for the competitiveness of proactive firms that already aim at sustainable development; whereas despite the additional requirements imposed on firms and on small and medium-sized enterprises in particular, the new regulatory framework, once implemented, could boost innovation and growth in the European chemicals industry,
- AB. whereas the creation of a single system for existing and new substances will facilitate innovation, as new substances will no longer undergo stricter regulation than do existing substances,
- AC. whereas the new policy should aim to achieve the target of cessation of emissions, discharges and losses of hazardous substances to the marine environment within one generation (2020), with hazardous substances being defined as substances that are persistent, bioaccumulative and toxic, or of equivalent concern, in line with the water framework directive and with commitments that the European Community and its Member States have undertaken in international fora,
- AD. whereas the principles of environment policy laid down in the EC Treaty, as well as the substitution principle - the promotion of safer practices and substances to replace hazardous practices and substances - should be fully applied in the new policy as key drivers to stimulate innovation towards a sustainable chemicals industry,
- AE. whereas the new policy should be designed in a way that it is transparent, comprehensive in scope, practicable and effective in action against releases of hazardous substances to the environment so as to protect human health as well as the environment,
- AF. whereas the smooth operation of the single market implies that there should be no discrepancies in the Member States' perceptions of the risks associated with a product,
- AG. whereas, given international competition, employees, especially in small and medium-sized enterprises, are anxious in the interest of their livelihood to see as practicable, efficient, and cost-effective arrangements as possible, sufficient data protection and protection of property rights,

- AH. whereas the new policy should guarantee the safe use of all chemicals and provide for effective supervision of chemicals whose use gives cause for concern,
- AI. whereas imported products should fulfil the same requirements as EU products and whereas the international standard-setting requirements applying to trade should be observed by the Commission and the Member States, not least within the World Trade Organisation,
- AJ. whereas animal toxicity tests must be replaced with more humane alternatives, and coordinated action is needed to bring new non-animal tests into use,
1. Welcomes the Commission's initiative to propose a strategy for the new Chemicals Policy as a first step towards a complete reform of European chemicals policy to achieve the goal of sustainable development which meets the criteria of improving consumer and environmental protection, promoting the competitiveness and innovative capacity of industry while taking account of the social context within the European Union and supports the Council conclusions of 7 June 2001;
 2. Calls on the Commission to make a detailed analysis of the impact of a modified chemicals policy on the number of jobs and social standards in the Community – with particular reference to the special situation of small and medium-sized business and their employees – and to ensure that no disproportionate, adverse effects are to be expected and, if necessary, to propose environmental protection measures, and restructuring aid or measures;
 3. Welcomes the Commission's proposal for a single system for existing and new substances called REACH (Registration, Evaluation and Authorisation of Chemicals), while all efforts should be made to assign priority to chemicals which meet the criteria for concern; priority may be assigned by means of rapid screening, based on data modelling, e.g. quantitative structure activity relationships (QSAR) using existing data as well as information on use patterns and volumes produced;
 4. Welcomes the intended closure of continuing gaps in the knowledge of some 30 000 existing substances in a manageable time-frame and on the basis of the extensive data already in the possession of Member State authorities and chemical-industry enterprises;
 5. Calls for clearly specified allocations of European Commission and Member State assessment activities to be guaranteed by maintaining a centralised approach to registration, evaluation and authorisation laying down binding deadlines for the various stages of the REACH procedure and thereby avoiding incomplete or incorrect registration;
 6. Considers it essential to draw attention to the need for close coordination of the work of the European body that will be called upon to administer the REACH system with the activities of the various existing scientific expert groups (which deal with classification and labelling of substances, limit values, health effects, the environmental impact of pesticides, etc.);
 7. Calls on the Commission to present as soon as possible in sufficient time to meet the

target dates laid down in the White Paper, its first proposal for a new, comprehensive, effective, practicable and transparent regulatory framework for chemicals, in the form of one regulation; calls on the Commission not to delay its proposal because of the studies it commissioned on the business impact and the central entity or any other studies, but rather to take them into account in the further decision-making process with the European Parliament and the Council;

8. Insists that the whole new chemicals policy strategy must be developed at European level so as to guarantee a high level of protection and prevent splintering of the European internal market;
9. Calls on the Commission to ensure that it takes a high level of protection for health, safety, the environment and consumers as its basis for creating a common legislative framework, taking account in particular of any new development based on scientific findings pursuant to Article 95 of the EC Treaty, and extending these criteria to cover imports;
10. Calls for the measures to be adopted in order to lay down the new comprehensive regulatory framework to allow for the precautionary principle, whereby the advantages and costs resulting from action or failure to act would have to be considered, to be commensurate with the degree of protection being sought, enforced without discrimination, and consistent with steps already taken in similar situations, following similar approaches, and to be reviewed and, if necessary, altered in the light of the findings of scientific research and assessment of their impact;
11. Calls on the Commission to develop effective measures to ensure that imported products (including end products) comply with the same high safety standard with regard to protection of consumers and the environment and health and safety at work as will apply to substances and products within the EU, and to enforce these measures; this will require, inter alia, clear monitoring and review methods, penalties and international agreements;
12. Calls on the Commission to issue a regulation as soon as possible requiring all manufacturers and importers to report forthwith on an annual basis to the ECB the volumes of chemicals they produce and import so that it is possible to determine exactly which substances are still on the market at all and how many substances would fall below which quantity thresholds, should a quantity threshold system be retained;
13. Welcomes the reversal of the burden of proof, making industry responsible for data collection, risk assessment and risk management, subject to evaluation by the authorities, and registration as a condition of importing and placing on the market;
14. Asks the Commission to ensure a clear division of responsibilities between the Commission and the Member States in regard to evaluation and , at the same time, to maintain a central approach to registration, evaluation and authorisation;
15. Asks the Commission to ensure that all chemicals produced in, or imported into, the European Union as substances, preparations, or in products above 1 tonne be registered in the new system, in order to obtain an overview of the basic properties and actual use of

these chemicals from which to establish priorities for further risk evaluation and/or risk reduction; for chemicals above 1 tonne that are exclusively used in research and development activities or exclusively used as intermediates in manufacturing processes within closed systems that prevent all releases to the environment, a simplified registration should be envisaged consisting of a minimum standard of information concerning their hazardous properties in order to protect workers' health as well as the environment in the event of accidents;

16. Suggests that all chemicals produced in, or imported into, the European Union as substances, preparations or in products below 1 tonne be registered in the new system in a simplified, practicable procedure by 2012 without jeopardising the main objectives of the new policy as a whole, unless screening based on data modelling, e.g. quantitative structure activity relationships (QSAR) and use patterns to be undertaken by 2008 at the latest reveals that these substances are of potential concern, in which case full registration shall be undertaken, followed by evaluation and/or authorisation, where necessary; for chemicals below 1 tonne, exemptions should only be allowed for chemicals exclusively used as intermediates in manufacturing processes within closed systems that prevent all releases to the environment or for chemicals used in research and development activities;
17. Calls for the introduction of a registration requirement for all chemicals irrespective of production volume, in respect of which the following minimum data must be supplied:
 - physical and chemical properties
 - persistence
 - bioaccumulation
 - acute oral toxicity
 - acute aquatic toxicity
 - corrosive and irritant effect
 - Ames test (for carcinogenicity and mutagenicity)
 - intended uses;
18. Endorses the Council's conclusions of 7 June 2001 that manufacturers should be subject to a general requirement to obtain sufficient knowledge and take the necessary measures to guarantee the safety of chemicals (the precautionary principle) irrespective of production volume and even if no specific information requirements have been laid down. To check that the precautionary principle has been observed, manufacturers should keep registers of the data, including data concerning properties, scope and use for all chemicals manufactured and used, including use in products, and upon request make all these registers available to the authorities;
19. Requests the use of screening procedures based on simplified risk assessment using data modelling, e.g. quantitative structure activity relationships (QSAR) and use patterns to prioritise substances of possible concern for early registration, in addition to tonnage considerations, in order to speed up risk assessments and/or risk management measures of such substances;
20. Believes that the proposed information system on environmental concentrations and releases should take account of the need to detect substances which are not identified through the REACH system itself, and also provide information on concentrations of

chemicals in the environment;

21. Emphasises the need to encourage early registration to ensure efficiency of the system, by introducing tiered fees that increase the later a substance is registered;
22. Calls for the introduction of appropriate and harmonised risk assessments throughout the European Union and appropriate sanction mechanisms as a means of achieving effective implementation of all measures in order to promote efficiency and performance, while avoiding distortions of competition within the European Union;
23. Recommends that all data required for registration and evaluation of substances be based on internationally recognised test methodologies and risk assessment procedures;
24. Proposes that industry cooperate in the delivery of data/information on the identity and properties of the substances to be registered, so as to share the workload and related costs and to avoid unnecessary duplication of tasks;
25. Stresses the need for independent peer review by an agreed independent body of the registration data at the expense of the industry prior to submission to the authorities;
26. Accepts tonnage thresholds based on production or import volumes by a single producer or importer as a starting point for the future system, but requests that aggregate tonnage be calculated, and that in all cases where aggregate tonnage exceeds the next tonnage threshold for a single producer or importer, the data requirements for that threshold should apply;
27. Welcomes active participation of downstream users – including non-industrial users – from the outset and considers that time limits for the provision of information should be inclusive of the total product chain and calls for all operators, in particular those at the processing and end-user stages of the production chain and product life-cycle, to be included in the chemicals security scheme;
28. Insists that failure to register a substance as well as incomplete or incorrect registration thereof within the reasonable time limits to be set within the system shall render illegal the production or import of the substance, preparation or article in which it is found (no data - no market);
29. Asks that a mechanism of sanctions be introduced into the system against producers, distributors, professional users or importers who withhold required, or other information which might reasonably be considered to be relevant for risk assessment and management (including information about animal tests, whenever and wherever they took place), or who do not comply with the legislation;
30. Requests that any person who imports into the Community a product for sale, hire, leasing or any form of distributing in the course of his business shall ensure that the chemicals contained in the product meet the requirements laid down in chemicals legislation;
31. Calls for the creation of a working party to deal with the exchange of data and information within the value-added chain with the aim of ensuring safe use of substances through the

entire life cycle, respecting the confidentiality of the test data and protecting the company-specific know-how concerning the use and application of substances;

32. Calls on the Commission to ensure that animal testing is reduced to the absolute minimum, firstly by ensuring that all relevant data is made available and considered, secondly by basing further tailor-made tests on exposure and use and thirdly by implementing, as far as possible, a step-wise non-animal testing strategy, that makes full use of computer models that predict hazards based on chemical structure (QSAR), as well as of physico-chemical tests for persistency and bioaccumulation, and cascades of *in vitro* tests which are recognised by the authorities, also with a view to reducing testing time and costs;
33. Requests that the use of animal tests be prohibited where alternative tests recognised by the authorities are available, in accordance with the principles in Council Directive 86/609, and that more resources be provided immediately to accelerate the development and validation of further scientifically reliable, recognised and standardised alternative tests to replace animal tests in the implementation of the new system;
34. Requests that substances, as soon as they are shown to meet the criteria for very high concern, either from existing classification including industry self-classification, registration or evaluation, shall be phased out according to strict deadlines, unless it is shown that the use in question is essential to society, that the hazardous properties of the substance in question are essential for the intended use and that no safer alternative exists at substance, material or process level, in which case it may be submitted to the authorisation process;
35. Considers that tailor-making of evaluations for substances produced in quantities above 100 tonnes or those of concern shall be based on simple categories of use (industrial/non-industrial) and be simplified, to the extent possible, by the use of decision trees to avoid lengthy procedures, while the evaluations themselves shall have clear time limits;
36. Considers that simplified risk assessments - such as hazard assessments combined with qualitative estimates of human and environmental exposure on the basis of use patterns - based on the best available scientific information, shall be taken as an essential basis for regulatory action, given the major uncertainties resulting from the enormous complexity of ecotoxicological effects and the wide range of sources of exposure;
37. Believes that effects on children's health and also on the unborn child shall be used as reference for human health risk assessments, (outside the occupational health framework), given the enhanced sensitivity to chemical exposure;
38. Insists that persistent and bioaccumulative substances, endocrine disrupters, sensitisers and substances that are carcinogenic, mutagenic and toxic to reproduction (CMR) category 3, shall also be considered substances of very high concern, subject to authorisation; considers that individual chemicals should be brought into the authorisation system when scientific studies have provided evidence of their endocrine disrupting properties;
39. Urges the Commission to ensure that substances of very high concern only receive

temporary authorisation subject to regular review for specific applications, including their use in preparations and products, upon proof by industry;

40. Requests that the Community's chemicals policy also include authorisation of pesticides (plant protection products and biocides);
41. Insists that authorisation, in the sense of dispensation for the use of particularly hazardous substances on which, ultimately, there will be a total ban, should be granted only as an absolute exception for a short, temporary period and only where there is documentation to show that development work is in progress to find alternatives or alternative methods;
42. Insists that no uses of substances of very high concern shall be authorised in consumer products as soon as appropriate safer alternatives are available and at the latest after 2012, and that, in principle no other uses of substances of very high concern which lead to releases to the environment during their life-cycle shall be authorised after 2020; in other words, such substances may then only be used as intermediate products in manufacturing processes within closed cycles that prevent all releases to the environment;
43. Considers that authorisations should, in general, be taken at Community level;
44. Insists that all national decisions and particularities of the overall procedure which are required of Member States should be adequately justified by them before they adopt national provisions, in accordance with the EU standards in force, and stresses that the Commission must examine and decide on all applications for national differentiation and particularities in relation to the overall procedure on the basis of EU law, taking all circumstances into account;
45. Calls for the authorisation exemption arrangements allowed for certain uses to be strictly supervised and for concepts such as 'controlled industrial use' to be assessed and defined in advance;
46. Believes that an authorisation decision should go hand in hand with specific risk management measures (conditions for the use of the product timetable for reassessments, etc.);
47. Stresses that the substitution principle - the promotion of safer practices and substances to replace hazardous practices and substances - should apply to all chemicals of concern, not just those subject to authorisation; chemicals that are of concern should be substituted with safer chemicals, or with materials or safer technologies not entailing the use of such chemicals, especially where safer alternatives already exist, taking account of socio-economic aspects in the choice of the best substitute; substitution should become a duty for manufacturers and downstream users to avoid risks to workers as well as to human health and the environment in general; firms should be required to publish annually a list of all substances of concern which they have not yet replaced; considers that Integrated Product Policy (IPP) should be an additional tool to the new chemicals policy to promote sustainable consumption;
48. Calls for intensified research into alternatives in the sense not only of alternative chemicals but also other material and alternative methods; also calls on the Commission

- to encourage and support small and medium-sized firms working on alternative solutions;
49. Calls for the assessment with a view to replacement to be performed on the basis of a complete life cycle analysis; possible alternatives must likewise be subjected to a life cycle analysis in order to ascertain possible risks and dangers and to facilitate an integrated assessment;
 50. Suggests that the Commission further encourages the promotion of safer practices and substances to replace hazardous practices and substances by facilitating the creation of a publicly accessible database containing meaningful and relevant information for the purpose of protecting human health and the environment, drawing on the best available knowledge on processes and materials that reduce or eliminate the use of substances of concern;
 51. Calls on the Commission to provide the means required for flexible coordination of the European databases to be set up in the future with those existing in other parts of the world so as to allow a continuous exchange of information and experiences among the different countries which manufacture and market chemical substances and preparations that might pose dangers;
 52. Calls on the Commission to develop criteria to put substances, which do not fall under the authorisation system, in categories of concern based on hazard criteria and use pattern, which then trigger consistent and rapid risk reduction measures;
 53. Requests that a tiered approach be used for risk management decisions under the accelerated risk management system: a committee procedure may be used to allow for quick adoption of temporary measures; the Commission shall thereafter make proposals for permanent measures on each of the temporary measures subject to co-decision to ensure that the European Parliament is fully involved in the decision-making;
 54. Welcomes the intention to create a publicly accessible database containing meaningful and relevant information about chemicals and their regulatory status with reference to human health and environment protection; considers that key information such as production volumes, use patterns and sources of exposure, shall not remain confidential but be included in the database, and calls on the Commission to propose arrangements for the publication of data from past animal tests (whenever and wherever they took place) where this may reduce the need for further animal testing;
 55. Considers that manufacturers, importers, downstream users and distributors should have a duty to provide publicly available, meaningful and relevant information on the content and properties of chemicals in products with reference to human health and environmental protection (including data from animal tests, whenever and wherever they took place); in this connection, an appropriate balance must be found between the need for transparency to allow consumer choice and the need to respect justified business secrets;
 56. Requests that an information service should be set up by industry to be reached via a toll free number in all European countries to provide consumer information about chemicals in products;

57. Insists that labelling of consumer products with regard to the content of substances of concern is imperative as long as they are still contained in them, to allow consumers to make informed choices, and that realistic and practical provisions on that matter be included in the future proposal; products containing substances of very high concern must be labelled with a proper and simple warning;
58. Suggests that the Commission facilitates the compilation of such information in publicly available product registers, starting with the most relevant consumer product categories, based on the registers available in Member States and countries of the European Economic Area;
59. Calls upon the Commission not to restrict harmonised classification to CMR properties but to retain the same range as hitherto and at the same time to simplify the classification in order to make the system more effective and practical;
60. Calls on the Commission, especially in view of the compulsory registration of new substances that will result from the White Paper, to intensify still further the Community efforts to promote proper training for workers who have to handle hazardous products;
61. Calls for the assessment of the additional resources necessitated by the new chemicals policy proposed in the White Paper to be spelt out in fuller detail, especially as regards the resources to be mobilised in Member States and fee systems;
62. Believes that the new Chemicals Policy should provide the basis for the regulation, evaluation and authorisation of all chemicals and consequently impact all consumer product legislation and calls on the Commission to make provision for the recast of all relevant community legislation, including legislation on pesticides, in line with the future chemicals directive;
63. Requests that future Community legislation on environment liability is based on strict liability for damages to human health and the environment, covering all chemicals and their uses, as an additional driver towards safer chemicals and products;
64. Requests the Commission to carry out a detailed analysis of the relationship between chemicals legislation and Community legislation on waste;
65. Urges the Commission to take more account of international aspects in developing the REACH system and to work for worldwide convergence of the essential systems of law regulating chemicals (at least those in the EU, the USA and Japan); the recognition of findings from tests in OECD countries is one important aspect;
66. Advocates, in the interests of international convergence, that the OECD's definition of endocrine disruptors be adopted as soon as agreement has been reached there;
67. Calls on the Commission to involve the Eastern European applicant countries in the development of the new EU law on chemicals at an early stage;
68. Calls on the Commission to establish an institution to advise and assist small and medium-sized enterprises on/with management of chemicals; this institution should

- directly assist smaller businesses with registration and assessment procedures, etc;
69. Calls on the Commission to establish a fast track within the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European research area (COM(2001) 94), with a view to encouraging small and medium-sized enterprises in particular to develop new products that will protect health, safety, and the environment to an increasingly greater degree;
 70. Insists that the property rights of processing and user enterprises in data and risk assessment must be protected vis-à-vis European and non-European competitors;
 71. Calls, in connection with the development of future provisions and implementing measures, for the active involvement of the social groups concerned, particularly European works councils, workers' representatives and their trade unions;
 72. Calls on the Commission to draw up new proposals with a view to increasing the transparency of data relating to substances manufactured by the chemical industry, without undermining industrial secrecy, so as to deal with public health and consumer protection problems;
 73. Calls on the Commission to address a recommendation to the Member States urging them to pay greater attention to the training of more toxicologists so that Europe will in the future have sufficiently well qualified experts to ensure that the White Paper is put into practice;
 74. Calls on the Commission to submit a brief annual report of some ten pages outlining the progress made and problems associated with implementing the REACH system so that any misdevelopments are detected by the other Community bodies earlier than in the case of the pesticide review pursuant to Directive 91/414;
 75. Calls on the Commission to submit a comprehensive analysis and study of all substance- and product-related rules by mid-2002, together with proposals as to which of the rules ought to be amended, simplified or even rescinded in the light of the new chemicals policy;
 76. Calls on the Commission to compile a coherent and consolidated collection of all the provisions banning or imposing restrictions on substances or products (including those incorporated under other subject-headings), or to bring them together in a single EU legislative instrument, thereby ensuring legal clarity and certainty (particularly including provisions in the fields of the Water Framework Directive, the directives on electrical appliances and cars for disposal, and health and safety at work), to make those texts available on the Internet and to update them at least once a year;
 77. Calls for all new legislation to be as practical and transparent as possible, so that implementation to improve the protection of consumers, the environment, workers and all parties concerned – particularly by the authorities and small and medium-sized enterprises – can be undertaken swiftly;

78. Calls on the Commission to test new legislation and its possible implementation immediately in practice by means of special projects in order to ensure that it is as efficient and practical as possible for all parties concerned in terms of bureaucracy, cost and collection of data, particularly for the authorities and small and medium-sized enterprises;
79. Invites the Commission to consider the possibility that the JRC and in particular the European Chemical Bureau of this centre may become the centralised site for registration, evaluation and authorisation of new chemical substances, thus avoiding heterogeneous criteria in the different Member States;
80. Calls for the approach adopted in the White Paper of a consistent and integrated European substances and products law not to be confined to chemicals, but for acquired data collection and risk assessment procedures to be applied also to other areas of EU legislation on workplace, consumer and environmental protection;
81. Asks the Commission to produce a consistent and clear definition in European law of the so-called 'substitution principle';
82. Calls on the Commission to encourage other countries to (a) make existing and future animal test data publicly available and (b) accept the validity of data from non-animal tests which are accepted within the European Union;
83. Requests the Council and Commission to urge all parties at the UN Rio+10 meeting in Johannesburg to make a commitment to a global chemicals policy built on sustainable development and the precautionary principle;
84. Instructs its President to forward this resolution to the Council and Commission.

EXPLANATORY STATEMENT

1. Introduction

The Commission's White Paper Strategy for a future Chemicals Policy is much welcomed. It is overdue to develop a new strategy for controlling chemicals as the current policy largely failed to identify and prevent dangerous chemicals from being released to the environment, thus damaging human health and the environment.

The increase in production of chemicals during the last 70 years has been explosive – from 1 million tonnes in 1930 to 400 million tonnes today, and the share of hazardous chemicals therein grew overproportionately. However, the knowledge about the properties of thousands of chemicals and their uses in millions of products is often insufficient or totally lacking. Furthermore, the main source of releases to the environment has shifted from point sources such as industrial chimneys to diffuse sources such as products, rendering traditional end-of-pipe controls ineffective. And we have no clear understanding of how different chemicals interact in the environment and the human body.

The insufficient knowledge about the impact of chemicals on human health and environment is a cause of deep concern, as measures to prevent the release of dangerous chemicals to the environment cannot wait. Each one of us carries several hundred synthetic substances in his body, chemicals that persist and bioaccumulate. They are found in breast milk and placenta, thus affecting foetus and new-born babies. They are found in deep-sea living organisms and in the Arctic, where they were never used. A significant number of industrial chemicals can act as endocrine disrupters, posing the risk of interference with the reproductive, immune or nervous system at very low concentrations. Various diseases are on the increase, such as testicular cancer and reproductive disorders, and a link to chemicals exposure seems likely.

The request of the European Council in Gothenburg to have the new chemicals policy in place by 2004 is therefore welcome. In order to meet this time limit, the Commission should present its proposal for the new regulatory framework by the beginning of 2002 at the latest.

The EU is the world's leading producer of chemicals. With the new strategy for chemicals, we have a unique opportunity to influence not only the conditions in the European Union but also in the rest of the world.

2. Current legislation

The current system of EU chemicals legislation consists of four legal instruments¹. While two instruments are the responsibility of DG Environment, the other two, including the directive which implements actual restrictions, are the responsibility of DG Enterprise.

¹ Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances. European Parliament and Council Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations. Council Regulation (EEC) 793/93 on evaluation and control of risks of existing substances. Directive 76/769 relating to restrictions on the marketing and use of certain dangerous substances and preparations.

The primary goal of the three directives - given their creation from the 60's to the 80's - was harmonisation, mainly to facilitate trade in the internal market. Environmental protection aspects only arose later and are as such underdeveloped in these instruments.

Current legislation distinguishes between so called existing substances and new substances. Existing substances have been put on the market before 1981, and account for ca. 99% of total market volume. 100,106 existing chemicals are registered, however, the exact number of existing chemicals put on the market is not known, as there are no reporting requirements for production volumes below 10 tonnes per year and manufacturer. Above 10 tonnes, around 10,000 substances are marketed. New substances were first put on the market after 1981. They currently amount to around 2700 chemicals, ca. 1% of total market volume.

2.1. Lack of data and lack of action

When drawing up a new policy, it is important to understand the failures of the current system in order not to repeat them.

While currently new substances in volumes of more than 10 kg have to undergo certain testing before they are allowed to be put on the market, the vast majority of existing substances – on the market since at least 20 years! - have never been properly tested. According to the European Chemicals Bureau, for the 2700 high production volume chemicals, the most well researched chemicals manufactured in quantities above 1000 tonnes, full base set data is available only for 14%, incomplete base set data for 65% and no data for 21%. Even less is known for the many lesser volume chemicals.

The immediate concern is therefore that man and the environment are potentially exposed to a large number of chemicals substances for which the hazardous properties have not been identified. This concern had already been identified in the Fourth Environment Action Programme (1987-1992).

Regulation 793/93 was adopted in 1993 to tackle this deficiency. The regulation foresees in-depth risk assessment for a certain number of high production volume chemicals on a priority list, with a view to adopting recommendations on possible risk reduction measures, if deemed necessary. Until now, 140 chemicals have been put on priority lists. To date, only 11 of these 140 risk assessments were concluded, and not a single risk reduction measure was adopted following them, although such measures were shown to be necessary for most of the substances. Clearly, the current approach failed to overcome the lack of knowledge about most chemicals and to take effective action.

2.2. Problems of approach: Risk assessment and burden of proof

The current approach based on risk assessment poses even more fundamental problems. It tolerates a general contamination of the environment, wildlife and humans with hazardous substances, assuming that nature can deal with a certain amount, instead of trying to prevent it.

Moreover, the attempt to set a "tolerable dose" is not only ethically questionable, but also scientifically inappropriate in many cases. Firstly, there are many inherent uncertainties involved when trying to analyse complex living organisms, turning the setting of a tolerable

dose largely into guesswork. Secondly, no tolerable dose can be set for a whole series of substances (substances that are carcinogenic, mutagenic, toxic to reproduction - they may be toxic at any dose; substances that are persistent or bioaccumulative - the dose increases over time; endocrine disrupters - the timing of the exposure is more relevant than the dose). Thirdly, assessment of whether a tolerable dose has been respected requires full knowledge of the exposure to the substance in question, which becomes as Sisyphus task when one considers the countless possible sources of exposure. And lastly, exposure to chemicals is always only looked at substance by substance, ignoring the overall combined exposure to multiple chemicals with potentially similar effects, hereby introducing a systematic underestimation of the risks.

The current system assumes that chemicals pose no problems unless shown otherwise. The burden of proof that a chemicals poses an unacceptable risk is on the authorities. Until that moment, the chemicals can be marketed without restrictions. If the authority does not receive information that allows assessing the eventual risk, no measures can be taken. Even if it receives information, it is not enough to show that the chemicals is hazardous, and that it is released to the environment. It furthermore needs to be shown that the likely exposure is so high that it will have adverse effects. However, data on exposure are almost always deficient and simple relationships between one chemicals and specific adverse effects are difficult to prove in complex living organisms. As a result, not only is the burden of proof on the wrong side, but it is also unacceptably high.

2.3. Problems of structure: Split responsibilities

Currently, effective actions are not only delayed by lengthy risk assessments, but also by split responsibilities. Different services in the Commission are responsible for risk assessment and for risk management, respectively, and often there is no link from risk assessment to risk management, resulting in further delays or inappropriate follow-up.

2.4. Lessons from the current system

The current system failed to protect human health and the environment, because it tolerated releases of hazardous chemicals to the environment and rewarded ignorance or incomplete knowledge about a chemicals with non-action. Large resources are spent on assessing a few chemicals in detail, while most other chemicals remain largely unaddressed, and even where problems are shown, little restrictive action is taken too late. The uncertainties inherent in ecotoxicology and the limits of science are ignored. The burden of proof is on the authorities instead of on those who intend to commercialise a certain chemicals. The system is incoherent and not transparent.

We need a new chemicals policy strategy that is proactive instead of reactive, that makes it possible to have a basic grasp of all chemicals with the limited resources available, and to effectively manage chemicals of concern before damage is done.

3. General comments on the new strategy

The overall objective of the strategy is to achieve sustainable development. The rapporteur considers that the Commission proposal has much merit and supports it in general terms. But to realise this objective, more is needed. That is why the rapporteur proposes the following

additions and changes:

- *Implementation of a clear objective:* By 2020, discharges, emissions and losses of hazardous substances (persistent, bioaccumulative and toxic, or of equivalent concern) shall cease, in line with commitments given in international fora.
- *Need for one legal instrument:* In the interest of transparency, coherence, effectiveness and rapid adoption, the new regulatory framework should take the form of one legal instrument, preferably a regulation.
- *Substitution principle:* Manufacturers and users of chemicals need to be obliged to choose a less dangerous alternative as soon as this is possible.
- *Public information:* The information gathered in the future chemicals strategy should be publicly available, confidentiality should be limited to a minimum, products need to be labelled for their content of hazardous substances, and an EU product register should be facilitated.
- *Coherence:* Related legislation in other areas needs to be subsequently recast to achieve coherence.
- *EU global initiative:* The EU should request all parties at the UN Rio+10 meeting in Johannesburg to make a commitment for a global chemicals policy built on sustainable development and the precautionary principle.

4. Specific comments to the REACH system

The Commission's proposal for a chemicals strategy is based on the so-called REACH system (Registration, Evaluation and Authorisation of Chemicals). All chemicals produced by a manufacturer in more than 1 tonne/year should be registered. This will give basic data about production volumes, intended uses and basic properties for about 30,000 substances, while testing of substances below 10 tonnes (ca. 20,000) is limited to *in vitro* tests. All substances in volumes above 100 tonnes as well as certain chemicals of concern irrespective of tonnage will be evaluated (ca. 5,000 substances). Chemicals of very high concern – those that are carcinogenic, mutagenic or toxic to reproduction (CMR substances categories 1 and 2), and those with characteristics of persistent organic pollutants (POPs) will be authorised for specific uses, provided that the applicant can show that the use presents a negligible risk.

The rapporteur welcomes the proposal for a single system for existing and new substances. The principle of "no data, no marketing" that has been implicitly applied in the new strategy – chemicals that have not undergone certain testing by a certain date may not be put on the market anymore – is fully supported. Similarly, the reversal of the burden of proof for substances of very high concern is strongly supported. The responsibility to show that a substance of very high concern can be safely used in a specific application should be on the industry, not the authority.

However, the rapporteur wishes to raise the following concerns:

- *Tonnage threshold:* Chemicals under 1 tonne must be included in the system. Otherwise, many new chemicals would fall out of the system, as they start with low tonnages. There may well be dangerous chemicals produced in very low quantities, which should not escape the system. No incentive should be given to avoid registration by staying below the threshold, all the more that the total tonnage may be well over 1 tonne as soon as there are several manufacturers.
- *Conditions for registration:* Registration needs to be structured so that a maximum of substances of concern can be identified early to allow swift action on these.
- *Risk assessment:* Where risk assessments are undertaken, they need to be independently verified, and the reference point should be the child, instead of the average adult, given its increased sensitivity.
- *Link registration/evaluation to authorisation:* A substance needs to be subjected immediately to authorisation as soon as the existing data, registration or evaluation data identify it to have one of the properties of very high concern;
- *Animal tests:* International exchange of information must be increased in order to make use of all available data and to avoid the duplication of tests. Models for grouping chemicals and other methods must be used to identify chemicals of particular concern. The use of animal tests should be prohibited where alternative tests are available, and more resources need to be given to accelerate the development and validation of further alternative tests.
- *Use of substances in products/import products:* While the new system envisages controlling the use of substances of very high concern in products via authorisation, it is unclear how the use of chemicals of less than very high concern in products will be addressed. Furthermore, import products may contain unregistered chemicals with unknown risks to humans and the environment. It is important that all uses of chemicals of concern in products are covered by the new legislation.
- *Conditions for authorisation:* The authorisation of substances of very high concern should be limited in time, and should only be given upon proof by industry that the use in question is essential to society and that no safer alternative exists. The authorisation process should also comprise persistent, bioaccumulative and toxic substances, and those of equivalent concern, such as very persistent and very bioaccumulative substances, endocrine disruptors, sensitisers and substances that are carcinogenic, mutagenic and toxic to reproduction (CMR) category 3, while substances that are persistent and bioaccumulative should be added to the authorisation system as soon as possible. No uses of substances of very high concern, which lead to releases to the environment during their life cycle, should be authorised after 2020.

11 October 2001

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND THE INTERNAL MARKET

for the Committee on the Environment, Public Health and Consumer Policy

on the Commission White Paper on strategy for a future chemicals policy
(COM(2001) 88– C5-0258/2001 – 2001/2118 (COS))

Draftsman (*): Hans-Peter Mayer

(*): Hughes procedure

PROCEDURE

The Committee on Legal Affairs and the Internal Market appointed Hans-Peter Mayer draftsman at its meeting of 11 April 2001.

It considered the draft opinion at its meetings of 27 August, 18 September and 11 October 2001.

At the last meeting it adopted the following conclusions by 21 votes to 2.

The following were present for the vote: Ana Palacio Vallelersundi, chairperson, Ward Beysen, vice-chairman, Paolo Bartolozzi, Luis Berenguer Fuster (for Carlos Candal), Maria Berger, Willy C.E.H. De Clercq (for Diana Wallis), Bert Doorn, Francesco Fiori (for Hans-Peter Mayer pursuant to Rule 153(2)), Marie-Françoise Garaud, Evelyne Gebhardt, Françoise Grossetête (for Janelly Fourtou), Gerhard Hager, Heidi Anneli Hautala, The Lord Inglewood, Kurt Lechner, Klaus-Heiner Lehne, Neil MacCormick, Luís Marinho, Manuel Medina Ortega, Ria G.H.C. Oomen-Ruijten (for Antonio Tajani), Fernando Pérez Royo (for Enrico Boselli pursuant to Rule 153(2)), Joachim Wuermeling and Stefano Zappalà.

SHORT JUSTIFICATION

A comprehensive framework for chemicals control has been created at EC level which currently includes notification of new substances and the systematic evaluation of existing substances. A harmonised system for classification, packaging and labelling of dangerous substances and preparations, as well as for limiting the marketing and use of dangerous preparations and substances, has been set up.

The White Paper's objective is to ensure a high level of protection for human health and the environment, while ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry.

As a central part of the White Paper is a proposal to adopt a new regulatory framework based on the Registration, Evaluation and Authorisation of Chemicals (hereafter REACH). This system is designed to apply both to new and existing substances and thereby respond, as regards the latter, to the shortcomings of the current evaluation system. Your draftsman welcomes this approach of converting the current double registration of chemicals systems into the new REACH system.

He also fully supports the political objectives of the Commission's White Paper that should lead to the implementation of a more coherent, transparent and workable European framework for the safe use of chemicals.

Consumers' access to information in matters concerning the environment and, in particular, chemical substances, is of paramount importance in ensuring effective implementation of Community environmental law. Your draftsman considers it essential to reinforce the synergies between consumer protection and environment policies.

With this in mind, your draftsman wishes to raise the following concerns:

- *Provision of data under the REACH system:* Allocation of responsibilities between producers, importers and downstream users, the registration of products and other obligations must be clearly established.
- *Focus on problematic uses:* the new chemicals policy must focus on problematic uses of a given chemical rather than its intrinsic hazardous properties.
- *Legal security:* time limits for fulfilling the obligations must be established; fees must not be excessive and be reconciled with the requirements of the internal market.
- *Commercial secrecy:* data affecting commercial and industrial confidentiality, including intellectual property should be an exception from the duty to provide access to information.
- *Comitology:* the type of committee in charge of assisting the Commission in the exercise of its implementing powers should be clearly defined.
- *Protection of consumers:* consumers are entitled to basic information on chemical substances which could, in particular, take the form of a list of indicators on the risk of chemical substances.
- *Sanctions:* while respecting the Member States' competence in this area, sanctions should be dissuasive, effective and proportionate.

CONCLUSIONS

The Committee on Legal Affairs and the Internal Market calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its motion for a resolution:

1. Welcomes the Commission's proposal for a strategy on a new chemicals policy and supports the Council conclusions of 7 June 2001 on that matter.

2 . Practicability and transparency of the registration system

The proposed registration system must be practicable, transparent and fully consistent with article 95 of the Treaty on completion of the Internal Market. Here there is a need for particular care to ensure that the extent of the data does not cause the system to clog up; and that a sense of proportion applies when deciding on the extent of the data submitted for registration. For this reason we urgently recommend excluding small quantities, of an annual production figure of up to one tonne, from the registration system altogether. The same principle of due proportion means that the required definition of a product's intended use must properly reflect the interests concerned, in other words it must be possible for manufacturers to restrict it to the uses they intend it to have. For practical reasons, and also to preserve confidentiality, it appears necessary to extend the time limits for submitting the registration files for existing substances beyond the dates proposed in the White Paper. And there is no discussion of time limits for forwarding information on, for instance, new uses. Finally, it is worth pointing out that fees must reflect the actual administrative costs incurred.

3. Requests that future Community legislation on chemicals be comprehensive in scope and effective in action against releases of hazardous substances to the environment so as to protect human health as well as the environment.

4. Extent of responsibility

Manufacturers' and processors' responsibilities should be clearly laid down, as the White Paper says, but beyond that the requirement to provide information should not be exaggerated to include any commercial or private user.

5. Consumer protection

The improvement in consumer protection to which the White Paper aspires is not precise enough. The precautionary principle should be applied in accordance with the guidelines adopted by the Commission and the European Parliament. In the case of chemicals policy consumer protection should, apart from risk prevention, be primarily a matter of clear and comprehensible information. This seems not to be the case, particularly in view of the quantity of information to be conveyed. Asks the Commission to produce a consistent and clear definition in European law of the so-called "substitution principle".

6. Data protection

The White Paper's comments on data protection do not seem adequate to ensure that trade secrets will be protected by all the authorities involved. The extent of the requirement to

publish must take such needs into account. And copyright must be safeguarded in the Safety Data Sheet, to protect those submitting the information from unauthorised use of the data.

7. Protection of property

The proposal's ideas for dealing with the property rights applying to the data submitted seem extremely problematical and should not be implemented. Instead, there must be adequate protection of test data, as for instance the biocide directive requires. In view of Article 295 of the Treaty it would also seem worth considering introducing a supplementary protection certificate under the law on medicinal products, so as to compensate for a possible reduction of copyright terms under patent law as a result of the registration procedure.

8. Procedural issues

The question arises as to whether an independent central body needs setting up for chemicals policy in addition to the authorities in the Member States. We should avoid duplicating administrative authorities; it would be worth considering whether simpler procedures are feasible. And there is no comment on the comitology procedure that will apply. In view of the uncertainties surrounding the allocation of responsibilities between the Commission, the new body and the Member State authorities, this matter needs taking up as a priority.

10 October 2001

OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Consumer Policy

on the Commission White Paper on Strategy for a future Chemicals Policy
(COM(2001) 88 – C5-0258/2001 – 2001/2118 (COS))

Draftsman(*): Werner Langen

(*): Hughes procedure

PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed Werner Langen draftsman at its meeting of 27 March 2001.

It considered the draft opinion at its meetings of 12 and 18 September and 10 October 2001.

At the last meeting it adopted the following conclusions by 33 votes to 7, with 11 abstentions.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman; Peter Michael Mombaur, vice-chairman; Werner Langen, draftsman; Nuala Ahern, María del Pilar Ayuso González (for Concepció Ferrer), Ward Beysen (for Willy C.E.H. De Clercq), Renato Brunetta, Gérard Caudron, Giles Bryan Chichester, Nicholas Clegg, Dorette Corbey (for Rolf Linkohr), Raina A. Mercedes Echerer (for Olga Zrihen Zaari), Ilda Figueiredo, Francesco Fiori (for Massimo Carraro), Christos Folias, Pat the Cope Gallagher, Cristina Gutiérrez Cortines (for Jaime Valdivielso de Cué), Michel Hansenne, Hans Karlsson, Wolfgang Kreissl-Dörfler (for Erika Mann), Bernd Lange (for Harlem Désir), Caroline Lucas, Angelika Niebler, Giuseppe Nisticò (for Guido Bodrato), Elly Plooi-j-van Gorsel, John Purvis, Alexander Radwan (for Godelieve Quisthoudt-Rowohl), Bernhard Rapkay (for Eryl Margaret McNally), Daniela Raschhofer, Christian Foldberg Røvsing, Paul Rübig, Ulla Margrethe Sandbæk, Esko Olavi Seppänen, Helle Thorning-Schmidt (for Reino Paasilinna), Claude Turmes (for Astrid Thors), W.G. van Velzen, Dominique Vlasto and Anders Wijkman.

SHORT JUSTIFICATION

The Commission White Paper pursues the ambitious objective of launching a comprehensive modernisation of EU law relating to substances and products. In doing so, the objectives of merging provisions relating to existing and new substances, together with a uniform registration and evaluation procedure for all substances produced in excess of 1 tonne annually, are on the right lines.

Those objectives are to be achieved by strengthening management of chemicals by the industry on its own responsibility. On the basis of experience hitherto with individual provisions of chemicals policy, in particular the regulation on existing substances, extensive measures are proposed that are merged in the White Paper's REACH model.

The intention to shift responsibility for risk assessment and chemicals management to the industry points in the right direction. On the basis of existing data, it might be possible, on a manageable timeframe, for all existing substances to be registered and assessed by the year 2012.

Quantities of chemicals are not however a sufficient criterion for assessing risk. The opinion therefore proposes introducing a two-stage procedure like that used in the USA that will provide for risk assessment independent of quantity by industry, scientists and the authorities before further evaluations or collecting of data, which may have to be conducted in association with animal experiments, are carried out. It is in that connection disproportionate to call for animal testing where the results can at best confirm the precautionary measures already taken by enterprises. The limited resources of enterprises, in particular small and medium-sized ones, can be more efficiently deployed on practical protection measures than on multiple data-confirmation.

The purpose of comprehensive chemicals legislation must be the safe use of substances during their entire life-process. Special conditions must also apply to the use of chemicals in the production process and in industrial parks on the basis of existing workplace-protection and safety provisions and the experience and expertise of chemical-industry employees.

With the bureaucratic authorisation procedure proposed, the White Paper departs from its own declared priorities of reversal of the burden of proof and balanced reform in so far as it seeks to strike a balance between improving health, workplace and environmental protection on the one hand and strengthening competitiveness and capacity for innovation in the chemical industry and the processing industries dependent on it on the other.

The report therefore calls for further studies on the economic impact, deployment of a working party of experts and examination of alternatives to the proposed authorisation procedure, which, as it stands, will lead to significant delays in decision-making and dramatically increase the costs to industry. A working party should at the same time also be set up to look into imports of chemicals produced outside the EU, the impact of the proposed scheme on small and medium-sized enterprises and the structure of the chemical industry as a whole.

Only when those additional results have been obtained should a start be made on implementing the legislative package.

CONCLUSIONS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its motion for a resolution:

- A. whereas the new chemicals policy should contribute to sustainable development and ensure a high level of protection for human health, including workers' health, and the environment,
- B. whereas the new chemicals policy should build on the EU's declared objective of sustainable development and promote and stimulate innovation towards a sustainable chemicals industry encompassing the entire life cycle of chemical substances from product development through use, phasing-out and disposal;
- C. whereas the new policy should be designed in a way that it is transparent, comprehensive in scope, practicable and effective in action,
- D. whereas import products should fulfil the same requirements as EU products,
- E. whereas the use of animal testing should be reduced to the absolute minimum,
- F. whereas the Lisbon European Council pointed out that the competitiveness and buoyancy of the markets depend directly on a regulatory framework to encourage investment, innovation, and entrepreneurship,
 1. Welcomes the submission of a White Paper as a first step towards a necessary comprehensive reform of European chemicals policy, which must pursue in a balanced manner the twin objectives of improving health, workplace and environmental protection on the one hand and strengthening competitiveness and capacity for innovation in the chemical industry and the processing industries dependent on it on the other;
 2. Calls for the conditions necessary for the competitiveness of the Community's industry to be assured, and for their efforts to be directed to encouraging an environment favourable to initiative and to the development of undertakings throughout the Community, particularly small and medium-sized undertakings, in accordance with Article 157 of the EC Treaty,
 3. Calls for a fast track to be established within the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities aimed at contributing towards the creation of the European research area (COM(2001) 94), with a view to encouraging small and medium-sized enterprises in particular to develop new products that will protect health, safety, and the environment to an increasingly greater degree;

4. Calls on the Commission to encourage the Member States to provide means of financial support for small and medium-sized enterprises with a view to developing facilities and operating arrangements to help them cope with the technical and organisational burdens stemming from REACH;
5. Welcomes the intended closure of continuing gaps in the knowledge of some 30 000 existing substances in a manageable time-frame and on the basis of the extensive data already in the possession of Member-State authorities and chemical-industry enterprises;
6. Welcomes the shifting to the industry of responsibility for generating and assessing data and evaluating its impact on the economy (reversal of burden of proof), and the associated relaxation of pressure on the authorities;
7. Considers that development of safer products in an environmentally sensitive manner, enhanced transparency and consumer information are positive marketing benefits which can enhance the competitiveness of the European chemicals industry;
8. Welcomes the fact that under the proposed scheme, no imports, production or marketing will be possible without registration;
9. Asks that a mechanism of sanctions be introduced into the system against producers or importers who withhold relevant information;
10. Welcomes the Commission initiative for developing validated alternative testing procedures so as to avoid animal experiments;
11. Calls on the Commission to ensure that animal testing is reduced to the absolute minimum by: 1. ensuring that all quality data are considered; 2. that requirements for additional testing are based only on risk considerations; 3. that a strategy based on non-animal testing is progressively implemented; and 4 that the 'worst-case scenario' risk-management procedures are adopted in order to rule out the use of animals in tests, not to make other possible experiments redundant;
12. Calls on the Commission to encourage other countries to (a) make existing and future animal test data publicly available and (b) accept the validity of data from non-animal tests which are accepted within the European Union;
13. Calls for all operators, in particular those at the processing and end-user stages of the production chain and product life-cycle, to be included in the chemicals security scheme, and for transparency vis-à-vis the public to be increased;
14. Calls in that connection for a comprehensive study of the economic impact of the proposed new chemicals policy and its evaluation to be conducted before any practical legislation is enacted;
15. Believes that the new Chemicals Policy should provide the basis for the regulation, evaluation, and authorisation of all chemicals and consequently impact all consumer

product legislation;

16. Calls for a review of the regulations proposed in the White Paper for substances within the closed systems of an enterprise and for applications in the production process;
17. Welcomes the merging of legislative provisions applicable to existing and new substances, and the proposed uniform registration and evaluation procedure for all substances produced in excess of 1 tonne annually; rejects calls for an additional register for all substances produced at under 1 tonne annually;
18. Welcomes the fact that a uniform database for the approximately 1 000 substances marketed in large quantities worldwide will be available by 2004; calls, however, for the approach submitted in the matter of registration deadlines to be reviewed;
19. Calls for processing and end-user stages to be included in the overall approach, and for a special status to research and development activities and intermediate chemicals exclusively used in the manufacturing process within closed systems, on the basis of environmental - and workplace - protection regulations in force;
20. Welcomes the involvement of downstream users – including non-industrial users – at all stages in the production chain, and calls for measures to ensure that small users and intermediate users are not burdened disproportionately; insists in particular that the property rights of processing and user enterprises in data and risk assessment must be protected vis-à-vis European and non-European competitors and the international standard-setting requirements applying to trade also be observed under the WTO, in order to guarantee that imported products satisfy the same requirements as EU products;
21. Considers that small and medium-sized enterprises cannot be expected to cope with too great a burden of red tape, and that risk information and warning measures should in any event be strengthened by way of product labelling;
22. Supports in principle the quantity-oriented inspection requirements for substance registration; calls however for a two-stage procedure to ensure appropriate risk assessment since the amount of a substance used cannot in itself provide a decisive criterion for risk assessment;
23. Rejects calls for regulatory measures that would impose restrictions on substances solely on the strength of 'qualitative' considerations and not on the basis of a scientific risk assessment;
24. Stresses that the substitution principle should apply to all chemicals of high concern, not just those already authorised; chemicals that are dangerous should be substituted with safer chemicals, or with materials or safer technologies not entailing the use of such chemicals; substitution should become a duty for manufacturers and downstream users to avoid risks to workers as well as to human health and the environment in general;
25. Considers that the REACH-model authorisation procedure could lead to increased bureaucratic complexity in relation both to industry and to the authorities and could cause

- significant delays in decision-making and so increase costs to industry; calls therefore for a working party to develop proposals to streamline the REACH-model authorisation procedures;
26. Considers that the risks even of especially dangerous substances are containable with the registration and evaluation model set out in the White Paper and risk-management measures derived from it and requests the use of screening procedures based on risk assessment in order to prioritise substances for early registration;
 27. Invites the Commission to consider the possibility that the JRC and in particular the European Chemical Bureau of this centre may become the centralised site for registration, evaluation and authorisation of new chemical substances, thus avoiding heterogeneous criteria in the different Member States;
 28. Calls for the authorisation procedure to be confined to CMR substances (categories 1 and 2) and POP as defined in Annex D to the Stockholm Convention;
 29. Believes that effects on children's health must be properly taken into account in the risk assessment procedure;
 30. Fears that the proposed authorisation procedure will force small and medium-sized enterprises in particular off the market because the high authorisation costs will make it impossible for them to maintain a viable market position;
 31. Rejects the call for time-limited authorisations, since despite substantial commitments in costs and time, significant legal uncertainty will still apply to the future marketing of substances; rejects also the requirement that only so-called 'socially necessary' substances should be authorised as being tantamount to state economic planning and a state-run economy;
 32. Welcomes active participation of downstream users from the outset and considers that time limits for the provision of information should be inclusive of the total product chain;
 33. Considers that the only acceptable kind of authorisation procedure is one under which decisions by the authorities will be made as directly as possible on the basis of the information obtained at the registration and evaluation stage; calls for consistent adherence to the precautionary principle advocated by the Commission, which provides for risk-management measures, scientific risk-assessment, proportionality and a cost-benefits estimate;
 34. Calls for clearly specified allocations of European Commission and Member State assessment activities to be guaranteed by maintaining a centralised approach to registration, valuation and authorisation laying down binding deadlines for the various stages of the REACH procedure;
 35. Insists that any specific derogations requested by Member States must be justified and granted in accordance with clear procedures drawn up at Community level;

36. Requests that any person who imports into the Community a consumer product for sale, hire, leasing, or any form of distributing in the course of his business shall ensure that the chemicals contained in the product meet the requirements laid down in chemicals legislation;
37. Insists that chemicals produced in the EU and products derived from them must not be disadvantaged vis-à-vis imports and that imported products must not contain chemical substances that are banned in the EU;
38. Considers that liability legislation in force is adequate to the purposes of restructuring chemicals policy;
39. Insists that the proposed right of public access to information about substances must be so structured as to do justice both to consumers' needs for information and producers' needs for protection of confidential information; considers it inappropriate for complete product data, applications and composition to be revealed in minute detail in the form of a public product register;
40. Considers that labelling of consumer products with regard to all substances shall be based on risk assessment to allow consumers to make informed choices;
41. Calls for the approach adopted in the White Paper of a consistent and integrated European substances and products law not to be confined to chemicals, but for acquired data collection and risk assessment procedures to be applied also to other areas of EU legislation on workplace, consumer and environmental protection;
42. Believes that the new Chemicals Policy should provide the basis for the regulation, evaluation and authorisation of all chemicals and calls on the Commission to make provision for the integration of all relevant Community legislation in line with the future chemicals directive;
43. Insists that the whole new chemicals policy strategy must be developed at European level so as to guarantee a high level of protection and prevent splintering of the European internal market;
44. Insists that before any future regulations are enacted, their socio-economic impact, in particular that on small and medium-sized enterprises, having regard in particular to the possible effects on employment and jobs in European industry as a whole, must be analysed and taken into consideration, and calls consequently on the EU Commission to engage in permanent dialogue with the industry and the trade-unions.