Opinion of the European Economic and Social Committee on the

— 'proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}' and the

— 'proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals'

(COM(2003) 644 final - 2003/0256 COD - 2003/0257 COD)

(2004/C 112/24)

On 8 December 2003 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the above-mentioned proposals

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 4 March 2004. The rapporteur was Mr Braghin.

At its 407th plenary session (meeting of 31 March 2004), the European Economic and Social Committee adopted the following opinion with 129 votes in favour, no dissenting votes and two abstentions.

1. **Introduction**

1.1 Over the last thirty years, control of chemicals has steadily been transferred to Community level. The first Community instrument in this field was Directive 67/548/EEC on the approximation of rules relating to the classification, packaging and labelling of dangerous substances. Alongside these rules, the directive also made provision for a future requirement to provide further information on chemicals placed on the market ([1]). The sixth amendment to this directive (contained in Directive 79/831/EEC) introduced a procedure for the notification of 'new substances', i.e. substances first placed on the market after 18 September 1981. The seventh amendment (contained in Directive 92/32/EC) laid down uniform principles and rules for the notification procedures.

1.2 The legislation was subsequently extended to cover the determination, evaluation and control of the risks of both new and existing substances. The basic principles for this were laid down in Council Regulation 793/93, as supplemented by Regulation 1488/94 in the case of existing substances and by Directive 93/67/EEC in the case of new substances.

1.3 The Chester Environment Council in April 1998 decided that the existing legislation should be reviewed in order to develop a new coherent and integrated approach to chemicals policy in line with the precautionary and sustainability principle, with an appropriate distribution of responsibilities between the parties involved in the control of chemicals. The matter was discussed again by several subsequent Councils. The Commission, working in the broader context of the sustainable development espoused by the Helsinki European Council in December 1999, then put forward its white paper on chemicals, entitled Strategy for a future chemicals policy (COM (2001) 88 final). The white paper was drawn up jointly by the Environment and Industry DGs, so as to take balanced account of both the competitiveness objectives of the chemicals industry and environmental protection requirements ([2]).

1.4 The new system envisaged in the white paper (termed REACH: Registration, Evaluation, Authorisation of Chemicals) involved a uniform regulatory framework for both existing and new substances, based on three elements: registration, evaluation and authorisation of substances with hazardous properties. The overriding aim was to guarantee a high level of protection for human health and the environment. To this end, the onus and responsibility of providing appropriate information and an initial risk evaluation was transferred to the manufacturer/importer and, in specific cases, to downstream users. The system was to be introduced within a precise timeframe, giving precedence to particularly problematic products and to substances produced in particularly high quantities.

2. **Key points of the proposal**

2.1 The present proposal for a regulation and a directive therefore aims to replace the existing legislation because the Commission thinks that it is inefficient, not conducive to innovation and unable to guarantee sufficient protection for human health and the environment. The new system is designed to meet five key objectives:

— to establish a coherent registration system that progressively covers both new and existing substances, over a differentiated timeframe of around ten years from the entry into force of the new regulation;

([1]) OJ 196 of 16.8.1967, p.1.

([2]) EESC opinion: CESE 1327/2001 of 17 October 2001 in OJ C 36 of 8.2.2002.

— to move the burden of risk assessment from government agencies to the producing/importing companies, who at the same time remain responsible for providing complete information dossiers on the characteristics of the substance which they intend to register;

— to include downstream users in requests to supply information and in the testing of substances, when necessary and appropriate;

— to introduce an authorisation procedure for hazardous substances;

— to ensure greater transparency and openness for the public by providing easier access to information on chemicals.

2.2 The proposal seeks to simplify the complex existing legislation on the use of chemicals and enshrine it in a single instrument. This will entail the repeal of a number of existing directives and regulations. The proposal is based on the above-mentioned REACH system obliging companies which produce or import more than a tonne of a chemical per year to register it on a single central database. Producer and importer firms will have to supply not only technical information on the properties, uses and safe handling of substances (as already required under existing legislation), but also on their safety and on management of the risk to man and the environment. This information will then have to be passed on in the successive stages of the production chain, so that users can use or market the substances responsibly and wisely and without risking the health of workers, final consumers or the environment.

2.3 The proposal as it now stands was drafted with involvement of all interested parties. The process included an internet consultation, beginning in May 2003 and lasting two months, on an initial draft regulation. This yielded some 6000 opinions, from all the parties concerned. On the basis of the various views expressed, the draft was amended to produce the present version. The requirements have been simplified in accordance with the quantities produced or imported. In the Commission's view, the direct and indirect costs of implementation will therefore be considerably lower than previously forecast.

2.4 A new European Chemicals Agency will manage the substances database, receive the registration dossiers, and be responsible for providing the public with non-confidential information. The agency will have a number of committees with differing roles, and a board of appeal.

2.5 All substances of which more than a tonne is produced or imported in a year must be registered. The Commission thinks that for around 80 % of these, no further action will be required.

2.6 The dossiers will be evaluated by competent authorities set up by the Member States, who will check their compliance with the registration requirements (which vary according to the quantities produced or imported), the animal testing conditions, and the quality and completeness of the assessments of the risk for human health and the environment. The substance evaluation programme will be based on a rolling plan prepared by the relevant national authority, using the priority criteria set by the Agency.

2.7 Substances which cause particular concern, such as CMRs, PBTs, vPvBs [1], and other substances with serious and irreversible effects on health or the environment, will require authorisation for specific uses by the Commission. Authorisation will only be granted if the use of the substance can be properly controlled; otherwise an analysis will be made of the level of the risk, the socio-economic importance and the existence of substitutes, in order to ascertain whether authorisation is justified. In order to ensure that the risks are acceptable, restrictions can be introduced following a proposal from the Commission or a Member State, according to the procedure set out in Article 130. These restrictions can include a ban on use.

2.8 To safeguard the competitiveness of the sector, the current version of the proposal has reduced the number of test requirements and made them less complex than in the initial version (which reflected existing legislation), particularly as regards substances with volumes between 1 and 10 tonnes. A number of substances are being exempted, including polymers and some intermediaries, and the rules for downstream users have been simplified. The Commission proposes that safety information may be exchanged in the form of safety data sheets (SDS). These sheets are already used in the existing legislation, but they are now being modified. The new measures should help companies achieve the desired results with minimum cost.

2.9 Innovation should be encouraged by raising the current threshold for new substances, exempting quantities between 10 kg and 1 tonne from the test requirements, making it easier for downstream users to find new innovative substances, and extending to 10 years (15 in the pharmaceutical sector) the exemption period for substances at the research stage.

2.10 These measures have significantly reduced the estimated costs – both the direct costs to industry and the indirect costs, which are much lower than the anticipated benefits for human health.

[1] Substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs), substances that are persistent, bio-accumulative and toxic (PBTs) and substances that are very persistent and very bio-accumulative (vPvBs).

3. **General comments**

3.1 The Committee reiterates its view that sustainable development and protection of health and the environment should be among the EU's priority objectives. The Committee's earlier opinion on the white paper thus supported the introduction of the REACH system and endorsed its objectives, including the move to make manufacturers, importers or users responsible for preparing documentation on chemicals with a view to registration and an initial risk assessment. The Committee also supported the establishment of an EU registration system and of a Community body to manage it. The Committee recognises that the regulation proposed by the Commission has identified the right objectives and that it will reduce the requirements for registering new substances; these requirements are viewed as one reason why so few new substances have been registered in Europe in the last twenty years. The new regulation should thus encourage innovation. At the same time, however, it will form a significant undertaking not just for the chemicals sector but for the production system as a whole.

3.1.1 The EU economy is going through a period of modest growth, and legislative initiatives that could threaten competitiveness, industrial growth and jobs must therefore be scrutinised very carefully. As many stakeholders have pointed out, the impact assessment available does not definitively establish that the proposed REACH system strikes an effective costs/benefits balance. The Committee agrees that as far as possible and bearing in mind the need to fulfil safety requirements, the competitive capacity of the EU chemical industry must not be hampered, as the industry is a world leader and is a key sector in almost all Member States. The repercussions for all the other production sectors which use chemical substances and preparations must also be addressed, including sectors that might appear to be less affected (e.g. iron and steel, textiles, engineering, electronics) and those in which SMEs could face special difficulties, bearing in mind the new dimension of the 25-member Union.

3.1.2 The Committee urges that consideration be given to amendments to the regulation that help to simplify procedures. In this context, the dialogue with stakeholders which was launched very fruitfully in the extended consultation process in 2003 should be continued, so as to safeguard legitimate health protection requirements and the equally legitimate requirements of competitiveness and employment. To this end, the Committee calls for more effective practical measures to promote development and innovation opportunities. Such measures are particularly necessary for SMEs, as the costs of the REACH system could eat into a significant percentage of their turnover.

3.1.2.1 The Committee notes and endorses the initiatives launched by the Commission and the European Chemicals Bureau as part of an 'interim' strategy pending finalisation of the legislative instruments by the European Parliament and the Council. The strategy includes involvement of stakeholders in the preparation of more user-friendly technical guidance documents, more detailed impact assessments for specific sectors, and the formation of strategic partnerships for pilot implementing projects. Having acquired direct knowledge of experience in this field in North-Rhine Westphalia, the Committee applauds this approach and hopes that it will be involved in it too. It reserves any further comments until the results of the pilot stage are known.

3.1.3 Regulatory simplification, the possibility of a more rapid evaluation based on more extensive knowledge, and the provision of more detailed information on the characteristics and risks inherent in the production and use of chemicals throughout the production chain could all have beneficial effects: productivity could increase and there could be positive spin-off for the whole development of environmental legislation ([1]). A competitive advantage could also be secured: such an advantage is obvious in the case of the waste treatment sector, or other sectors which manufacture products for the final consumer, provided there are appropriate mechanisms (e.g. a label recognisable to the consumer) to act as a form of market recognition and 'reward' for manufacturers who adapt to environmental and consumer health protection legislation. These objectives must be pursued expressly, and could become operational if EU standards are adopted internationally following targeted action by the Community authorities. To achieve this, a constructive dialogue will also be needed with the relevant authorities, economic operators and the world of work, together with an information and education policy for the final consumer.

3.2 *The European Chemicals Agency*

3.2.1 The Commission proposes the establishment of a European Chemicals Agency to manage the technical, scientific and administrative aspects of the REACH system and ensure the consistency of the evaluation and decision-making process at Community level. Under the proposal, the Agency is to provide criteria to guide Member States' selection of substances for evaluation and will also issue opinions and recommendations in the authorisation and restriction procedures, as well as giving guidelines on data confidentiality.

3.2.2 The Committee fully endorses the decision to set up an Agency rather than merely extending the duties of the European Chemicals Bureau within the Joint Research Centre (as had been proposed in the white paper). However, the Committee feels that the powers and responsibilities assigned to the Agency are too limited. According to the Commission proposal, its role is solely to provide scientific and/or technical advice, while the operational management of the system appears to be largely left to the Member States, who are to operate on the basis of guidelines, opinions and recommendations from the Agency. The Committee wonders whether under such a system it will be possible to select evaluation priorities in a truly effective and consensual manner, and ensure that every decision draws on the wider spectrum of competences and specialisations presumably to be found in the Agency's committees.

([1]) For example the water framework directive, the IPPC directive, and the directives on hazardous waste.

3.2.3 The example of the European Agency for the Evaluation of Medicinal Products (which the proposal rightly considers as the most similar body) shows that analysing dossiers centrally makes it easier to strike a fair balance between differing viewpoints, while national agencies – especially when faced with a new responsibility – have a tendency to apply the precautionary principle. The Committee believes that it is both possible and desirable to harness the national authorities in a network in which they can continue to carry out well coordinated and jointly defined operational duties. The experience of the European Chemicals Bureau confirms that involving local authorities in a network and giving them responsibilities is important for establishing a consensus in the decision-making process.

3.2.4 The Committee therefore thinks that the new Agency should be given precise duties and responsibilities in a number of areas: for setting the criteria for deciding evaluation priorities; for drawing up opinions on authorisation requests; for participation in the adoption procedure for restrictions on some dangerous substances and preparations; and for drawing up proposals for EU harmonisation of classifications and labelling. The tasks and membership of the Agency's bodies (the management board, committees, forum and board of appeal) will have to be revised in the light of this new definition of duties and responsibilities.

3.2.5 In particular, the Committee does not think that setting up a body made of national representatives is the best way of settling disputes or dealing with appeals arising as a result of divergences between national authorities. The Committee advocates the establishment of a forum for collecting and disseminating useful information, updating databases, and providing technical assistance for the relevant authorities and businesses (especially small firms). This forum should include scientists and experts chosen by the Agency, inter alia from the industry.

3.2.6 In general, the Committee hopes that the Agency will be structured and financed in such a way that it can immediately assume full responsibility for evaluation, albeit involving and drawing on the expertise and staff of the competent national authorities where necessary or appropriate but without a priori limiting its powers and responsibilities. Pending the establishment of the Agency, the Committee also hopes that the European Chemicals Bureau, in conjunction with national and local authorities and stakeholders, will be in a position to verify the smooth operation of the processes devised during pilot schemes or in specific fields.

3.2.7 In particular, the Committee points out the inadequacy of the provisions in Article 105 for involving stakeholders, which merely mention 'contacts' with representatives of industry, consumer protection, worker protection and environmental protection organisations.

3.3 *The registration system*

3.3.1 The regulation requires companies which manufacture or import one tonne or more of a chemical to submit a technical dossier to the competent authorities containing information on the substance and a preliminary report on the determination and reduction of the risk. For volumes of 10 tonnes or more, 100 tonnes or more and 1000 tonnes or more, there is an increasingly tight scale of requirements for the tests to be used for drafting the report.

3.3.1.1 Companies are likely to have to develop new tests and knowledge about substances according to their importing and manufacturing needs, and hence their registration requirements, and use this knowledge to ensure that any possible risks are managed in a responsible and well informed manner. They will also have to inform downstream users of the risks involved in such uses, and these users will only have to produce a chemical safety evaluation if the product is to be used for a purpose other than the one foreseen.

3.3.1.2 The registration system will undoubtedly require significant commitment of time and resources, especially for importers and downstream users who have not had to fulfil similar obligations in the past. However, the new system is vital for protecting human health and the environment, and for the proper operation of the single market. Moreover, it could give the most innovative companies and those best able to adapt to the new market conditions the opportunity to extend their market.

3.3.2 There is a certain logic in requiring speedier action and more extensive information when larger volumes of chemicals are produced/imported; this approach is simple, and can be applied directly. However, it is not necessarily the best way of identifying real risk, either in terms of intrinsic hazard or of exposure. Retaining a criterion (that of volumes) which the Committee has already described as too rough could involve unjustified costs for companies ([1]).

3.3.3 The practical application of the system could be made more flexible, as regards the complexity of the dossier which every manufacturer/importer must submit in their registration application, and with a view to pinpointing substances which, although produced or imported in quantities of less than 10 tonnes, require a more thorough risk analysis. This flexibility could be achieved by making use of the analyses of intrinsic hazards and of the information on use and exposure that is already available or easily obtainable from data already in the possession of manufacturers and authorities, and also by drawing on existing knowledge and analysis of structural affinities with known problematic or dangerous substances. The Committee calls on the Commission to explore this avenue as a way of fine-tuning the operation of the REACH system.

([1]) See the Committee's earlier opinion on the white paper, point 5.1.

3.3.4 The Commission proposes a series of rules on data availability, with a view to reducing animal testing and the costs for companies. In particular, the most important data can be shared, subject to payment of a fee. Assistance will also be provided to find other registrants to exchange data with. However, this mechanism does not appear to have sufficient support nor to be able to encourage alliances, other than between partners who already cooperate or are already tied to each other for supply reasons.

3.3.5 Although the concern to reduce animal testing deserves support, this is only one aspect of the problem. More effective systems should be put in place for reducing if not eliminating unnecessary duplication of dossiers and tests, including analytical and in vitro tests. To this end, arrangements should be devised for encouraging cooperation between manufacturers, importers and downstream users, with mechanisms for sharing out costs in a way that is fair and that can also be borne by SMEs. The Committee thinks that it would be worth considering forms of assistance for the preparation of dossiers and encouraging interested parties (especially downstream users and SMEs) to form groupings on a voluntary basis, while guaranteeing the safeguarding of intellectual and industrial property rights.

3.3.6 Provision is made for information all along the production chain, both upstream and downstream, with the sheet required under Annex I replacing the safety data sheet currently provided under Directive 91/155/EEC. The two-track system that will inevitably exist for a number of years may pose problems for the smooth operation of the single market.

3.4 *Evaluation (Title VI)*

3.4.1 Evaluation – of both the dossier and the substances – is to be conducted by the Member States. The task of the Agency will just be to develop criteria for prioritising substances for evaluation and to intervene in the event of evaluation differences between Member States. During the start-up period in particular, the fact that a Member State's evaluation mechanism has to be approved by other Member States by means of a written procedure could slow matters down considerably, and perhaps even lead to cross-vetos.

3.4.2 A precondition for using substances safely and minimising the risk to people and the environment is the availability of scientifically sound data that have been collected in a uniform manner and validated (i.e. undergone a control process – the evaluation provided for in Title VI), with a solid analysis of the costs/benefits ratio in specific uses. The first stage in determining the risk is the establishment of a chemical safety report, which is now to be the responsibility of the manufacturer/importer (whereas in the present system it is up to the competent authority), together with the provision of substance data. The ensuing dossier and substance evaluation procedure is a delicate and complex matter, based on the information provided by manufacturers/importers, and the resulting decisions are extremely important. The Committee therefore thinks that it should primarily be the job of the Agency, albeit in close cooperation with the relevant national authorities, as this would ensure speedier action, a more consistent approach and the involvement of wider competences.

3.4.2.1 Giving this task to the Agency does not mean wresting power from the relevant national authorities: the Agency's specialist and political bodies should draw up evaluation priorities and give the national authorities the task of carrying out the specific evaluation activities. The national authorities could always propose independently that a substance be evaluated if they so wish, explaining why they take this view and then including it in the centralised decision-making process.

3.4.3 One shortcoming of the current proposal is that, except in the case of particular substances that have already been singled out, it makes no explicit provision for the evaluation of possible interactions and accumulation processes which might render the use of certain chemicals more dangerous. The Committee thinks that rather than being left up to companies, this aspect should be included in the Agency's operating programmes, in cooperation with the relevant national authorities.

3.4.4 An unforeseen threat could be posed by substances, preparations, products and articles imported from regions of the world that conceivably do not have adequate controls and do not respect the GLP required for compiling the data that are to be supplied for registration and risk evaluation. The competent authorities should be particularly attentive to this, inter alia so as not to give an undue competitive advantage to non-EU producers.

3.4.5 The Committee calls for clearer identification of the responsibilities of manufacturers, importers and downstream users – in the form of specific provisions if necessary – in order to deal with cases in which they fail to meet the regulation's requirements regarding documentation, risk evaluation and measures to ensure more controlled and safer use.

3.5 *Authorisation*

3.5.1 The aim of the authorisation system is to guarantee the smooth operation of the single market and ensure that the use of substances of particular concern is properly controlled or that these substances are replaced by safer alternative substances or technologies. The Committee endorses this aim, and therefore agrees that the producer/importer should be required to supply further data in order to show that the risks can be controlled or that they are outweighed by the socio-economic benefits. The Committee also agrees that authorisation should be granted for a single specific use, so that use can be controlled more effectively and so that downstream users can be properly informed.

3.5.1.1 The Committee thinks that in any event the authorisation should apply for a limited time. It therefore suggests that after five years a further evaluation and ensuing authorisation be undertaken, if necessary, as is the case with other authorisation procedures. This would stimulate innovation for the development of safe alternatives and would encourage application of the substitution principle as a first alternative for dangerous chemicals.

3.5.2 The restrictions laid down in the authorisation must be introduced across the whole EU and must be independent of production/import volume, so as to avoid any serious risk to health or the environment. The Committee agrees that a recast version of Directive 76/769/EEC should provide the starting point for the new procedure regarding restrictions, but calls for early action to update the lists of dangerous substances in cases where there is a sound scientific basis for so doing.

3.5.3 The Committee points out that the legislation governing the protection of the health and safety of workers from the risks related to the use of chemical substances should continue to apply and to be developed, without prejudice to REACH. Consideration should doubtless be given to determining the extent to which it would be possible to incorporate provisions to this effect into the REACH legislation and to enhance its compatibility with Council Directive 98/24/EC, which sets out obligations to carry out assessments, in consultation with the parties concerned.

3.5.4 The Committee thinks that other substances with risks equivalent to those of CMRs, PBTs and vPvBs (already identifiable with clear, objective criteria and thus included in Annex XIII) should be taken into consideration as soon as the risks are identified, and should be subject to the authorisation process independently of the quantities used.

3.6 *Downstream users*

3.6.1 The Committee approves the move to oblige downstream users to consider the safety of their uses of substances, primarily on the basis of information from their supplier, and to take appropriate risk management measures. They are required to notify any new use which had not been envisaged (and therefore documented) by the supplier. For this requirement to be feasible, especially for SMEs, the supplier must have completed his registration and must provide the downstream user with non-confidential data regarding the substance. A weakness of the current proposal is that the producer/supplier is not likely to have to provide a complete set of information. This could place an excessive burden on the downstream user when it comes to obtaining documentation. The Committee thinks that this aspect, and the possibility of having recourse to the Agency, need further clarification if the implementing costs of the new system really are to be kept down.

3.6.2 In this context it would be helpful to hold a series of seminars or conferences with interested parties to check on the situation, both in the production sectors that are most likely to be affected (the paints and varnishes, pigments, tanning, timber and furniture, synthetics, electrical and electronic appliance industries would seem to be particularly hit by the cost of the documentation to be supplied) and in SMEs, as these are often dependent on a single supplier and thus lack bargaining power for obtaining data under economically acceptable conditions. Without further investigation and a clear regulatory framework, unfairness could arise in the abovementioned cases and in similar ones.

3.7 *Data sharing*

3.7.1 The Commission proposes a number of measures for sharing the data collected and avoiding unnecessary animal testing. The Committee supports this objective and agrees that new registrants should be able to use these data, either by making a direct payment to the originator or via an arbitration board. However, the Committee thinks that the proposed measures are not specific enough: the provisions for the use of shared data need to be fleshed out in order to ensure fair conditions for all operators, especially SMEs.

3.7.2 The Committee supports the pre-registration mechanism for firms that are preparing for a registration, so as to enable them to share the data already available, provided that there is a guarantee that confidential information will not be disclosed. It also supports the setting-up of 'substance information exchange fora' (SIEF), whose role could extend beyond the currently proposed aim of avoiding duplicate animal testing.

3.8 *Worker information and training*

3.8.1 The Committee thinks that the information provided by the REACH system is essential for evaluating and reducing risks relating not only to health and environmental protection but also to the health and safety of workers in the workplace. This information is thus extremely important for the conduct of any professional activity.

3.8.2 Experience built up in recent years in the chemicals sector, through regular dialogue between the social partners, shows that the availability and proper use of this information has enabled the sector to achieve a lower level of workplace accidents and environmental damage than other sectors.

3.8.3 In the light of this fruitful experience, which has not been widely reported, the Committee stresses the added value of providing workers and their representatives with any useful information obtained from the evaluation of the chemical safety of a substance or preparation and contained in the safety data sheets. The Committee therefore hopes that the fruitful experience in the chemicals sector will be extended to downstream sectors, for example by means of special training programmes for workers and their representatives, building on the protection instruments laid down in existing legislation on dangerous substances and promoting more harmonised application thereof.

3.9 *Impact assessment*

3.9.1 The Commission's figures for the direct and indirect costs of the system over the next ten years have been criticised by various parties as being too low. The Committee notes the new evaluation which takes account of the changes made to the earlier draft document following consultations. The impact assessment has thus been expressly updated and should be more realistic. However, a number of imponderables remain, particularly as regards indirect costs, downstream users, and the impact on the new Member States.

3.9.2 The Committee therefore asks the Commission to launch a specific debate on this with the various sectoral organisations at EU and national level, particularly in those sectors which private studies suggest will be particularly affected by the new regulation. The Commission should thus be able to ascertain whether its analysis is justified and review any measures that prove to be excessively burdensome.

3.9.3 The Committee is concerned about the possible economic impact and asks the Commission to make a more detailed assessment of this, bearing in mind the importance of the use of chemicals across all sectors of the economy, including agriculture and services. The Committee also asks the Commission to give more thought to the potential impact on the acceding countries.

3.9.4 It is thought that the new system will encourage innovation, and it is certainly true that some of the measures will make it easier to identify and market more new substances. The Committee therefore approves these changes. In general, however, it considers that the mechanisms (which are mostly automatic) designed to encourage innovation are still too generic, and that not enough has been done to gauge the impact in quantitative terms.

3.9.5 At first sight the costs/benefits ratio appears very favourable, especially in the health field. However, it must not be forgotten that while the costs are borne directly by economic operators, the benefits will generally be felt elsewhere or by society as a whole, and over a longer period than the costs. This may well explain many of the negative reactions and concerns voiced. To counter these, action is needed on two fronts. Firstly, efforts should be made to achieve a broader consensus, backed up by sectoral analyses (quantitative and otherwise). Secondly, a pro-active policy must be adopted to safeguard competitiveness, making the EU legislation a benchmark for other areas of the world. This calls for targeted action by the Commission in all international forums.

4. **Conclusions**

4.1 Whilst the Committee supports the objectives and application of the REACH system, it thinks that particular attention must be paid to the implementing arrangements, with a view to ensuring that the new legislation (however opportune) does not jeopardise the competitiveness and growth of the industry and hence aggravate employment problems. This requirement, which relates to the drive to pursue socially, economically and environmentally sustainable development, takes on a more concrete aspect in the present instance, as the impact assessment does not establish a proven balance between costs and benefits.

4.2 The political commitment to provide legislation safeguarding health, safety and environmental impact for all chemical users and for the general public has to be met without damaging the competitiveness of the industry. The Committee therefore calls on the Commission, the European Parliament and the Council to give serious consideration to any amendment that could help to simplify procedures, cut red tape and thus reduce the attendant costs, continuing the consultations with stakeholders with this aim in mind.

4.3 The Committee also recommends devising measures to inform interested parties, and particularly SMEs and downstream users, of the content of the regulation and the changes introduced. This should help to counter the present negative attitude which does not fully appreciate the advantages of simplifying existing chemicals legislation, having a swifter and more efficient evaluation (with fewer risks and ensuing responsibilities), and easier application of environmental legislation (on emissions, waste, worker safety, etc.).

4.4 Similarly, it must be explained that the annexes contain implementing instructions, generic guidelines, and technical and scientific provisions regarding research and experiment methodology; they do not increase red tape but make the regulation easier to apply, nor are they any more voluminous than the annexes to the existing legislation. Where legally possible, it might therefore be useful to introduce a clear distinction between those annexes that are to have legal force and those which can be used as an 'operator's guide' or guideline for experts. These latter annexes could then be more easily updated in the light of technical and scientific progress.

4.5 The Committee appreciates the method used by the Commission to draw up the proposal, which has involved extensive consultations. It hopes that the consultation and involvement of stakeholders will continue so that the text can be further improved, notably by:

— making any alterations that help simplify procedures and therefore reduce costs, without changing the objectives being pursued;

— extending and strengthening the tasks of the future European Chemicals Agency (in particular in the dossier and substance evaluation procedure – Title VI) so that it becomes the hub of the new system, in close and constructive cooperation with the competent national authorities;

— modifying the duties and membership of the Agency's bodies so as to ensure balanced representation of the various responsible parties and bring in Europe's top scientists;

— setting up instruments and methods to prevent unnecessary duplication of dossiers and tests, and help reduce animal testing, and devising mechanisms to ensure a fair distribution of costs;

— clarifying the distribution of duties between manufacturers/importers and downstream users, as some of the chemicals produced/imported are subsequently purchased by businesses that market mixtures for a variety of uses;

— drawing up a support plan for SMEs and downstream users in particular, to facilitate the implementation of the REACH system and the setting-up of groupings for this purpose;

— finding more specific automatic instruments to encourage innovation and the identification and marketing of new substances.

4.6 The Committee stresses the need for a more detailed impact assessment, in particular as regards indirect costs, the costs for some key downstream user sectors, and the potential impact on the acceding countries, with a view to ascertaining whether the criticisms made of the studies conducted to date are justified.

4.7 Lastly, the Committee calls for a vigorous political campaign to promote the provisions of the REACH system worldwide, pressing home their essential role in protecting public and worker health and the environment and, last but not least, in defending the competitiveness of the European chemicals industry.

4.8 The Committee welcomes the pilot implementing schemes and practical trials already being conducted in some Member States and involving regional authorities and other interested parties, with a view to simplification and a more concrete impact assessment. The Committee also welcomes the work being done by the Commission and the European Chemicals Bureau, together with stakeholders, to draw up sectoral guidelines for the practical implementation of the REACH system. The Committee thinks that when drawing up the final legislative instruments, all the EU institutions should make use of the experience obtained during this interim stage. It reserves the right to issue an additional opinion assessing the results of the present exercise.

Brussels, 31 March 2004

The President
of the European Economic and Social Committee
Roger BRIESCH

APPENDIX

to the opinion

(Rule 39 of the Rules of Procedure)

The following amendments, which received at least one quarter of the votes cast, were defeated in the course of the debate:

Add a new point 3.4.4, as follows:

'In order to ensure the reliability of the information made available in respect of registered chemical substances, it is, in the EESC's view, vital to have an appropriate system of quality assurance. Such a system can be established (a) by means of internal quality assurance measures introduced by the economic players, backed up by external certification or (b) by independent experts. This will enable data and supporting documentation to be qualitatively comparable and useable throughout Europe, thereby making it possible for the authorities to hand over to the enterprises part of their responsibility for carrying out checks.'

Vote:

For: 27 Against: 64 Abstentions: 13