the Committee in the macroeconomic dialogue can contribute considerably to the Community's policy of convergence and thus to greater economic and social cohesion in the Community.

Done at Brussels, 27 February 1991.

The Chairman
of the Economic and Social Committee
François STAEDELIN

Opinion on the proposal for a Council Regulation (EEC) on the evaluation and the control of the environmental risks of existing substances [1]

(91/C 102/12)

On 3 October 1990 the Council decided to consult the Economic and Social Committee, under Article 100A of the Treaty establishing the European Economic Community on the abovementioned proposal.

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee's work on the matter, adopted its Opinion on 8 February 1991. The Rapporteur was Mr Vidal.

At its 284th plenary session (meeting of 28 February 1991) the Economic and Social Committee adopted the following Opinion unanimously.

The Committee generally agrees with the reasons for the proposed Regulation, subject to the following comments.

1. Introduction

1.1. The proposal in question, based on Treaty Article 100A, establishes procedures for standardized, Community-level compilation of information on existing chemical substances and for the evaluation and control of the associated environmental and health risks.

1.2. The proposal flows from the Fourth Action Programme on the Environment and meets the recommendations made in the Committee's Opinion on that subject [2]. The proposal is also compatible with the strongly held views voiced in the ESC Opinion on the Sixth Amendment to Directive 67/548/EEC [3] concerning restrictions on the scope of that Directive.

1.3. In this latter Opinion (points 1.5 and 1.6) the Committee expressed regret that the Directive's scope on notification was limited to new substances and urged that all dangerous substances be covered.

1.4. The present proposal covers the 100 000-odd chemical substances listed in the EINECS (European inventory of Existing Chemical Substances) inventory which were already on the Community market on 18 September 1981.

1.5. Because it would be impossible, as the Commission argues in the introduction, to compile information on all existing substances and at the same time assess the associated risks, a systematic, step-by-step approach is proposed, starting with substances whose production or import volume exceeds 1 000 tons per year per manufacturer/importer and then turning to substances whose production or import volume is

[1] OJ No C 276, 5. 11. 1990, p. 1.
[2] OJ No C 180, 8. 7. 1987, point 2.3.3.
[3] OJ No C 114, 11. 5. 1977, points 1.5 and 1.6.

between 10 and 1 000 tons per year per manufacturer/importer.

1.6. For substances whose production or import volume is even lower, compilation of information and risk evaluation will be carried out on a case-by-case basis.

1.7. On the basis of information provided by manufacturers and importers, and centralized by the Commission, lists of priority substances will be prepared by a Management Committee [procedure variant II(a)] working hand in hand with the Commission. The criteria for determining priority substances have not yet been laid down but will be adopted under the Regulatory Committee procedure.

1.8. Work on the priority substances will then be divided up amongst the Member States, making full use of experience already acquired in this area and encouraging new contributions. Rapporteurs will also be appointed to deal with each substance so that risks can be assessed and appropriate recommendations made.

1.9. These recommendations should be forwarded to the Commission and adopted at Community level under the procedure laid down in Article 11; once adopted, risk evaluation conclusions, together with any recommendations made, would be published in the *Official Journal* (Article 8).

1.10. Where appropriate, the Commission will, on the basis of the recommendations, propose measures within the framework of Directive 76/769/EEC [1] (on the restrictions on the marketing and use of certain dangerous substances and preparations), or under other existing Community instruments (Article 8.5).

2. General comments

2.1. The Committee reiterates the importance it attaches to all measures designed to ensure a full and reliable flow of information and effective checks so that risks can be evaluated, and existing substances controlled, in the interests of a high level of human and environmental protection.

2.2. The Committee agrees with the decision to opt for a Regulation since this instrument will ensure that information on existing chemical substances is compiled and evaluated using standardized, cross-Community procedures and methods, thereby precluding fragmentation and distortion of the Community market in chemical products.

2.3. The Committee notes with concern, however, that five Member States (Ireland, Spain, Portugal, Greece and Luxembourg) still have no legislation in this specific field and recommends that the Commission take appropriate steps to help them implement the planned measure, so as to ensure that the Regulation is applied consistently.

2.4. In line with the principle of subsidiarity, and in order to ensure maximum efficiency, the Committee recommends that Member States be actively involved in the systematic compilation of data from the outset. To this end, the Committee wonders whether it might not be preferable for information to be forwarded to the relevant national authorities, with the Commission being informed, particularly since it is the national authorities' responsibility to ensure compliance with the Regulation and, where appropriate, to impose sanctions (Article 13).

2.5. In line with the recommendation made in the Opinion on the Seventh Amendment [2], the Committee would reaffirm the need to ensure that the Commission's programme dovetails with current international work on chemical substances being carried out by UNEP (United Nations Environment Programme), WHO (World Health Organization), IPCS (International Programme on Chemical Safety) and, in particular, under the Organization for Economic Co-operation and Development (OECD) programme. The aim is to avoid duplication of work and to use limited resources more effectively by spreading the burden of risk evaluation around the international community.

2.6. The Committee therefore calls upon the Commission to tackle the objectives set out in the Explanatory Memorandum and to play an active part in the OECD programme, and by providing valuable expertise and experience, coupled with Community standards and regulatory provisions, further the world-wide adoption of such standards.

2.7. The Committee considers that systematic compilation of available data on chemical substances of a high production and/or import volume imposes a heavy and complex burden on Community firms. To ensure that data is both accurate and complete, the Committee urges the Commission to review the planned time limits in the light of national conditions and the nature of the different substances. A period longer than the 6 months prescribed in Article 3 of the proposed Regulation should be considered, enabling the achievement of satisfactory and reliable results before the sanctions envisaged in Article 13 become applicable.

2.8. The Commission's step-by-step approach, based on the quantities of substances produced or imported

[1] OJ No L 262, 27. 9. 1976, p. 201.

[2] OJ No C 332, 31. 12. 1990.

does not necessarily provide absolute guarantees, since there is no connection between the quantity and the degree of risk presented by substances.

2.9. While noting that Article 6.2 stipulates that any new information indicating that a given substance presents a risk must be reported immediately, the Committee wonders whether this is sufficient to offset the purely quantitative criterion.

2.10. In the interests of lightening the workload and speeding up completion with regard to the highest-risk substances, though should be given to the possibility of initially excluding from the data-collection system those chemical products generally recognized as being harmless or whose potential danger is well known and placing them on a separate list but without classifying them as risk-free substances.

2.11. Lastly, the Committee emphasizes the need to avoid duplicating work on substances already being analyzed under international programmes and welcomes current cooperation between OECD to provide uniform computerized forms for data compilation.

2.12. The Committee is concernd that the provisions of the proposed Regulation may involve an excessive number of tests on animals and so be at variance with Directive 86/609/EEC on the protection of animals used for experimental and scientific purposes. The Committee therefore recommends as far as possible the acceptance of findings already obtained by non-standardized testing methods, as well as by screening or other valid alternative methods.

2.13. Finally, the Committee recommends that the willingness displayed by the industrial associations involved [the European Council of Chemical Manufacturers'Federations (CEFIC), the Oil Companies' International Study Group for Conservation of Clean Air and Water in Europe (CONCAWE), EUROMETAUX, etc.] be used to maximum effect in coordinating data compilation, so as to reduce the information communication burden on individual manufacturers/importers. Contacts already made in connection with the Management Committee referred to in Article 11 should be consolidated.

2.14. On the basis of Articles 8 and 11, the Commission may ask manufacturers/importers to carry out further tests on the effects of substances on health and the environment. The Committee considers it essential that, before any such decision is taken, the Management Committee referred to in Article 11 must consult experts designated by the parties concerned (manufacturers/importers, workers' representatives, consumer groups) and discuss whether further tests are scientifically necessary.

2.15. The Committee would finally recommend maximum guarantees of confidentiality for information with a potentially adverse commercial impact; it calls for the greatest possible openness in the light of Directive 90/313/EEC [1] on freedom of access to information on the environment and in this connection the Committee notes that Directive 90/313/EEC does not exclude from possible confidential treatment information which could, on rare occasions, have commercially adverse impact such as the name of the manufacturer or importer, or certain physico-chemical data concerning the substance in question, which are specifically excluded in Article 12 paragraph 1 of the proposed Regulation (see Article 3 of Directive 90/313/EEC).

3. Specific comments

3.1. *Article 2*

3.1.1. A clearer definition of 'substances' and 'preparations' should be made, since the current definition could lead to some EINECS entries being considered as preparations.

These definitions are based on those in Directive 67/548/EEC: the matter should therefore be examined in conjunction with an amendment to that Directive.

3.1.2. The definition of 'importing' implies that the present Regulation does not cover substances for own use imported from outside the Community. The defintion of 'producing' implies that substances for own use are covered.

An inconsistency arises at this point, since in one case only substances made available to third parties are covered, while in the other, substances which never leave the plant are also covered.

Since this Regulation is based on the European Inventory of Existing Chemical Substances (EINECS) intermediate substances produced but not placed on the market should not be covered.

Producing should therefore be defined as follows:

> "producing' means the production of substances to be placed on the market in solid, liquid or gaseous form;'

[1] OJ No L 158, 23. 6. 1990.

The definition of 'importing' also fails to specify whether substances imported for use in preparations are covered. In order to make it clear that these substances should be included, the definition of 'importing' should read:

"importing' means supplying or making available to third parties substances from outside the Community customs territory (in the form of substances or included in preparations); ...'

3.2. *Article 3*

3.2.1. Manufacturers or importers who have exceeded a threshold of 1 000 tons per year, at least 'once in the three years preceding adoption of this Regulation' are required to submit information. The Committee would suggest that 'and following' be added; this would prevent manufacturers or importers whose first production or import an EINECS-listed substance takes place after adoption of the Regulation from evading registration and the consequent contribution to the cost of any subsequent tests. Point 4.1 and 4.2 should be amended accordingly.

3.2.2. In line with the comments made in point 2.7, the Committee suggests that the period of six months following the entry into force of the Regulation permitted for data compilation be reviewed.

3.2.3. Alternatively, the possibility of priority submission of the information required under paragraphs a), b), c) and d) might be considered, with a later deadline being set for the other information.

3.2.4. The meaning of 'easily obtainable' (final paragraph) should be clarified.

3.3. *Article 4*

3.3.1. The comment made in point 3.2.1 also applies here.

3.3.2. With regard to the time-limits for the submission of information on substances produced and imported in smaller amounts, the Committee notes that data compilation will involve a far greater number of mainly small and medium-sized companies, which are not always able to compile and supply this kind of data and therefore require assistance.

3.4. *Article 6.1* a)

3.4.1. Allowance must be made for cases where suppliers are unaware of new uses.

'a) the supplier is aware of a new use which ...'

3.5. *Article 6.2*

3.5.1. In accordance with point 2.9, it should be added that notification is compulsory, irrespective of the quantity produced or imported.

3.6. *Article 8*

3.6.1. Article 8.1

Proper reasons must be given if further data or testing is required.

3.6.2. Article 8.2

The time limit must take account of the delays involved in testing or documentary research.

3.7. *Article 9*

3.7.1. Article 9.2

'... provide all available information ...' should be amended to '... provide all available information relevant to risk analysis ...'.

3.7.2. Article 9.4

If some manufacturers supply further information while others do not, the question of whether all manufacturers should be barred from placing the substance on the market must be clarified.

3.8. *Article 12*

3.8.1. This Article should in general terms concur with the provisions on confidentiality, to be defined by the Council in the Seventh Amendment to Directive 67/548/EEC. An opportunity must be provided for appeal against decisions by the competent authority.

3.9. *Article 13*

3.9.1. Adequate opportunity for appeal should also be provided here.

3.10. *Annex II*

3.10.1. Data set for existing substances, point 1.19. Use patterns in percentage terms:

A number of important uses are omitted, with the result that many products will come under 'other uses'. Further important uses, such as 'fuel', should be added.

3.11. The Regulation is unclear about two cases: i) substances with only one EINECS number which may present varying data, such as those which may be sold in differing physical forms and with differing physical properties and ii) where a substance is both imported and manufactured. In such circumstances, it should be made clear whether one or two data sets have to be submitted.

Done at Brussels, 28 February 1991.

The Chairman
of the Economic and Social Committee
François STAEDELIN

Opinion on the proposal for a Council Directive (EEC) concerning the efficiency requirements for new, hot water boilers fired with liquid or gaseous fuels [1]

(91/C 102/13)

On 13 November 1990, the Council decided to consult the Economic and Social Committee, under Article 100A of the Treaty establishing the European Economic Community, on the abovementioned proposal.

The Section for Energy, Nuclear Questions and Research, which was responsible for preparing the Committee's work on the subject, adopted its Opinion on 5 February 1991. The Rapporteur was Mr Frandi.

At its 284th plenary session (meeting of 28 February 1991), the Economic and Social Committee unanimously adopted the following Opinion by a large majority, with 8 votes against and 12 abstentions.

1. General comments

The Committee welcomes the general thrust of the Commission proposal, but calls upon the Council to take account of the following comments in taking its decision.

1.1. The draft Directive in question is coordinated with and subordinated to the draft Council Decision on the promotion of energy efficiency in the Community (SAVE programme) [2], because the latter lays down general standards and specific actions covering the problems which this draft Directive seeks to regulate.

1.2. This is the best of introducing a general approach to simplify the procedures on action to be taken, which would provide certainty for producers, safety for consumers, and guarantees for the workers who install and maintain the appliances. Another Directive for liquid fuel appliances, not yet issued, must be coordinated with the Directive on gas-fired appliances, within the general framework of the Directive on energy efficiency.

1.3. The draft Directive adds to the recent Directive 90/396/EEC on gas appliances [3], adopted on 29 June 1990. This directive regulates the performance of gas appliances in terms of both safety and the rational use of energy (efficiency). The Commission has instructed the European Committee for Standardization (CEN)

[1] OJ No C 292, 22. 11. 1990, p. 8.
[2] OJ No C 301, 30. 11. 1990, p. 11.
[3] OJ No L 196, 26. 7. 1990, p. 15.