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Information and Notices

Notice No	Contents	Page
	I Information	
	Council	
95/C 320/01	Common position (EC) No 25/95 of 23 October 1995 adopted by the Council acting in accordance with the procedure referred to in Article 189b of the Treat establishing the European Community, with a view to adopting a Regulation of the European Parliament and of the Council on novel foods and novel food ingredients	ey ne od
95/C 320/02	Common position (EC) No 26/95 of 23 October 1995 adopted by the Council acting in accordance with the procedure referred to in Article 189b of the Treat establishing the European Community, with a view to adopting a Directive of the European Parliament and of the Council on investor-compensation schemes	y ie
95/C 320/03	Common position (EC) No 27/95 of 7 November 1995 adopted by the Council acting in accordance with the procedure referred to in Article 189b of the Treat establishing the European Community, with a view to adopting a Directive of the European Parliament and of the Council amending Directive 88/77/EEC on the approximation of the laws of the Member States relating to the measures to be take against the emission of gazeous and particulate pollutants from diesel engines for us	y ie ie n

I

(Information)

COUNCIL

COMMON POSITION (EC) No 25/95

adopted by the Council on 23 October 1995

with a view to adopting Regulation (EC) No .../95 of the European Parliament and of the Council concernnig novel foods and novel food ingredients

(95/C 320/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty establishing the European Community and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

Whereas, differences between national laws relating to novel foods or food ingredients could hinder the free movement of foodstuffs; whereas they may create conditions of unfair competition, thereby directly affecting the functioning of the internal market;

Whereas, in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety evaluation through a Community procedure before they are placed on the market within the Community; whereas in the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients a simplified procedure should be provided for:

Whereas food additives, flavourings for use in foodstuffs and extraction solvents are covered by other Community legislation and should therefore be excluded from the scope of this Regulation;

Whereas appropriate arrangements should be made for the placing on the market of novel foods and novel food ingredients derived from plant varieties subject to the provisions of Council Directive 70/457/EEC of 29 Sepember 1970 on the common catalogue of varieties of agricultural plant species (4) and Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed (5);

Whereas risks to the environment may be associated with food or food ingredients which contain or consist of genetically modified organisms; whereas Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (6) has specified that, for such products, an environmental risk assessment must always be undertaken to ensure safety for the environment; whereas, in order to provide for a unified Community system for assessment of a product, provisions must be made under this regulation for a specific environmental risk assessment, which in accordance with the procedures of Article 10 of Directive 90/220/EEC must be similar to that laid down in that Directive, together with the

⁽¹⁾ OJ No C 190, 29. 7. 1992, p. 3.

⁽²⁾ OI No C 108, 19. 4. 1993, p. 8.

⁽³⁾ Opinion of the European Parliament (not yet published in the Official Journal). Council Common Position of ... (not yet published in the Official Journal) and Decision of the European Parliament of ... (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 225, 12. 10. 1970, p. 1. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48)

⁽⁵⁾ OJ No L 225, 12. 10. 1970, p. 7. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

⁽⁶⁾ OJ No L 117, 8. 5. 1990, p. 15. Directive as last amended by Directive 94/15/EC (OJ No L 103, 22. 4. 1994, p. 20).

assessment of the suitability of the product to be used as a food or food ingredient;

Whereas the Scientific Committee for Food instituted by Decision 74/234/EEC (1) should be consulted on any question relating to this Regulation which may have an effect on public health;

Whereas Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (2) and Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (3) apply to novel foods or food ingredients;

Whereas, without prejudice to the other requirements in Community legislation relating to the labelling of foodstuffs, additional specific requirements on labelling should be laid down; whereas these requirements must be subject to precise provisions in order to ensure that the necessary information is available to the consumer; whereas defined population groups, associated with well established practices regarding food should be informed when the presence in a novel food of matters which are not present in the existing equivalent foodstuff gives rise to ethical concerns as regards those population groups; whereas, with respect to labelling, information to the consumer on the presence of an organism which has been genetically modified within the meaning of Directive 90/220/EEC, where it does not correspond solely to a modification of its agricultural characteristics, constitutes an additional requirement applicable to the foods and foodstuffs referred to in this Regulation;

Whereas, in respect of this Regulation, provision should be made for a procedure instituting close cooperation between Member States and the Commission within the Standing Committee on Foodstuffs set up by Decision 69/414/EEC (4),

HAVE ADOPTED THIS REGULATION:

Article 1

- 1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.
- 2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human

consumption to a significant degree within the Community and which fall under the following categories:

- (a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC:
- (b) foods and food ingredients produced from, but not containing, genetically modified organisms;
- (c) foods and food ingredients with a new or intentionally modified primary molecular structure;
- (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and which have a history of safe food use;
- (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.
- 3. Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls under paragraph 2 of this Article.

Article 2

This Regulation shall not apply to:

- (a) food additives falling within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (5);
- (b) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (6);

⁽¹⁾ OJ No L 136, 20. 5. 1974, p. 1.

⁽²⁾ OJ No L 186, 30. 6. 1989, p. 23. Directive as last amended by Directive 93/99/EC (OJ No L 290, 24. 11. 1993, p. 14).

⁽³⁾ OJ No L 290, 24. 10. 1993, p. 14.

⁽⁴⁾ OJ No L 291, 19. 11. 1969, p. 9.

⁽⁵⁾ OJ No L 40, 11. 2. 1989, p. 27. Directive as last amended by Directive 94/34/EC (OJ No L 237, 10. 9. 1994, p. 1).

⁽⁶⁾ OJ No L 184, 15. 7. 1988, p. 61. Directive as last amended by Directive 91/71/EEC (OJ No L 42, 15. 2. 1991, p. 25).

(c) extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of he Member States on extraction solvents used in the production of foodstuffs and food ingredients (1).

Article 3

- 1. Foods and food ingredients falling within the scope of this Regulation must not:
- constitute a danger for the consumer,
- mislead the consumer,
- differ from foods or food ingredients which they are intended to replace in such a way that their normal consumption would be nutritionally disadvantageous for the consumer.
- 2. For the purpose of placing the foods and food ingredients falling within the scope of this Regulation on the market within the Community, the procedures laid down in Articles 4, 6, 7 and 8 shall apply on the basis of the criteria defined in paragraph 1 of this Article and the other relevant factors referred to in those Articles.

However, in the case of foods or food ingredients referred to in this Regulation derived from plant varieties subject to Directives 70/457/EEC and 70/458/EEC, the authorization decision referred to in paragraph 7 of this Regulation shall be taken in accordance with the procedures provided for in those Directives, provided they take account of the assessment principles laid down in this Regulation and the criteria set out in paragraph 1 of this Article, with the exception of the provisions relating to the labelling of such foods or food ingredients, which shall be established, pursuant to Article 8, in accordance with the procedure laid down in Article 13.

- 3. Paragraph 2 shall not apply to the foods and food ingredients referred to in Article 1 (2) (b) where the genetically modified organism used in the production of the food or food ingredient has been placed on the market in accordance with this Regulation.
- 4. By way of derogation from paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1 (2) (b), (d) and (e) which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent food assessment bodies mentioned in Article 4 (3) are substantially equivalent to existing foods or food ingredients as regards their

composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls under this paragraph.

Article 4

- 1. The person responsible for placing on the Community market (hereinafter 'the applicant') shall submit a request to the Member State in which the product is to be placed on the market for the first time. At the same time, he shall transmit a copy of the request to the Commission.
- 2. An initial assessment as provided for in Article 6 shall be carried out.

Following the procedure referred to in Article 6 (4), the Member State referred to in paragraph 1 shall inform the applicant without delay:

- that he may proceed with placing the food or food ingredient on the market, where the additional assessment referred to in Article 6 (3) is not required and that no reasoned objection has been presented in accordance with Article 6 (4), or
- that, in accordance with Article 7, an authorization decision is required.
- 3. Each Member State shall notify to the Commission the name and address of the food assessment bodies responsible in its territory for preparing the initial assessment reports referred to in Article 6 (2).
- 4. Before the date of entry into force of this Regulation, the Commission shall publish recommendations concerning the scientific aspects of:
- the information necessary to support an application and the presentation of such information,
- the preparation of the initial assessment reports provided for in Article 6.
- 5. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 5

In the case of the foods or food ingredients referred to in Article 3 (4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the relevant details provided for in Article 3 (4). The Commission shall

⁽¹⁾ OJ No L 157, 24. 6. 1988, p. 28. Directive as last amended by Directive 94/52/EC (OJ No L 331, 21. 12. 1994, p. 10).

transmit to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the 'C' series of the Official Journal of the European Communities.

Article 6

- 1. The request referred to in Article 4 (1) shall contain the necessary information, including a copy of the studies which have been carried out and any other material which is available to demonstrate that the food or food ingredient complies with the criteria laid down in Article 3 (1), as well as an appropriate proposal for the presentation and labelling, in accordance with the requirements of Article 8, of the food or food ingredient. In addition, the request shall be accompanied by a summary of the dossier.
- 2. Upon receipt of the request, the Member State referred to in Article 4 (1) shall ensure that an initial assessment is carried out. To that end, it shall either notify the Commission of the name of the competent food assessment body responsible for preparing the initial assessment report, or ask the Commission to arrange with another Member State for one of the competent food assessment bodies mentioned in Article 4 (3) to prepare such a report.

The Commission shall forward to the Member States without delay a copy of the summary provided by the applicant and the name of the competent body responsible for carrying out the initial assessment.

- 3. The initial assessment report shall be drawn up within a period of three months from receipt of a request meeting the conditions laid down in paragraph 1, in accordance with the recommendations referred to in Article 4 (4), and shall decide whether or not the food or food ingredient requires additional evaluation as referred to in Article 7.
- 4. The Member State concerned shall without delay transmit the report of the competent food assessment body to the Commission which shall circulate it to the other Member States. Within a period of 60 days from the date of circulation of the report by the Commission, a Member State or the Commission may make comments or present a reasoned objection to the marketing of the food or food ingredient concerned. The comments or objections may also concern the presentation or labelling of the food or food ingredient.

Comments or objections shall be forwarded to the Commission, which shall circulate them to Member States within the period of 60 days referred to in the first subparagraph.

The applicant shall, where a Member State asks for it, provide a copy of any pertinent information appearing in the request.

Article 7

- 1. Where an additional assessment is required in accordance with Article 6 (3) or an objection is raised in accordance with Article 6 (4), an authorization decision shall be taken in accordance with the procedure laid down in Article 13.
- 2. The decision shall define the scope of the authorization and shall establish, where appropriate:
- the conditions of use of the food or food ingredient,
- the designation of the food or food ingredient, and its specification,
- specific labelling requirements as referred to in Article 8.
- 3. The Commission shall without delay inform the applicant of the decision taken. Decisions shall be published in the Official Journal of the European Communities.

Article 8

- 1. Without prejudice to other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply, to ensure that the consumer is informed of:
- (a) any characteristic or food property such as:
 - composition,
 - nutritional value or nutritional effects,
 - intended use of the food,

which renders a novel food or food ingredient significantly different from an equivalent existing food or food ingredient.

In such case, the labelling must mention the characteristics or properties modified, accompanied by an indication of the method by which that characteristic or property was obtained;

- (b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff, and which may have implications for the health of certain sections of the population;
- (c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff, and which may give rise to ethical concerns;
- (d) the presence of a genetically modified organism within the meaning of Directive 90/220/EEC where,

according to a decision adopted in accordance with the procedure laid down in Article 13 of this Regulation, it does not correspond solely to modification of its agricultural characteristics.

- 2. In the absence of an existing equivalent food or food ingredient, appropriate provisions shall be adopted where necessary in order to ensure that consumers are adequately informed of the nature of the food or food ingredient.
- 3. Any detailed rules for implementing this Article, including those for the definition of the agricultural characteristics referred to in point (d) of paragraph 1, shall be adopted in accordance with the procedure laid down in Article 13.

Article 9

- 1. Where a food or food ingredient falling within the scope of this Regulation contains or consists of a genetically modified organism within the meaning of Article 2 (1) and (2) of Directive 90/220/EEC, the information required in the request for placing on the market mentioned in Article 6 (1) shall be accompanied by:
- a copy of the written consent, if any, from the competent authority, to the deliberate release of the genetically modified organisms for research and development purposes provided for in Article 6 (4) of Directive 90/220/EEC, together with the results of the release(s) with respect to any risk to human health and the environment.
- the complete technical dossier supplying the relevant information requested in Article 11 of Directive 90/220/EEC and the environmental risk assessment resulting from this information; the results of any investigations performed for the purposes of research and development or, where appropriate, the decision authorizing the placing on the market provided for in part C of Directive 90/220/EEC.

Articles 11 to 18 of Directive 90/220/EEC shall not apply to food or food ingredients which contain or consist of genetically modified organisms.

2. In the case of food or food ingredients falling within the scope of this Regulation containing or consisting of genetically modified organisms, the decision mentioned in Article 7 shall respect the environmental safety requirements laid down by Directive 90/220/EEC to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release of genetically modified organisms. During the process of evaluating requests for the placing on the market of

products containing or consisting of genetically modified organisms, the necessary consultations will be held by the Commission or the Member States with the bodies set up by the Community or the Member States in accordance with Directive 90/220/EEC.

Article 10

Detailed rules for the protection of the information provided by the applicant shall be adopted in accordance with the procedure laid down in Article 13.

Article 11

The Scientific Committee for Food shall be consulted on any matter falling within the scope of this Regulation likely to have an effect on public health.

Article 12

- 1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.
- 2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may retain it until the measures have entered into force.

Article 13

- 1. Where the procedure defined in this Article is to be implemented, the Commission shall be assisted by the Standing Committee for Foodstuffs, hereinafter referred to as the 'Committee'.
- 2. Matters shall be referred to the Committee by the Chairman, either on his own initiative or at the request of the representative of a Member State.
- 3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down

according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

- 4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.
 - (b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14

No later than five years from the date of entry into force of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation accompanied, where appropriate, by any suitable proposals.

Article 15

This Regulation shall enter into force 12 months following the day of its publication in the Official Journal of the European Communities.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...

For the European Parliament
The President

For the Council
The President

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

- 1. On 7 July 1992 the Commission submitted to the Council a proposal for a Regulation on this subject, based on Article 100a of the Treaty (1).
- 2. In response to the European Parliament's opinion, delivered on 27 October 1993 (2), the Commission submitted an amended proposal to the Council (3).
- 3. The Economic and Social Committee delivered its opinion on 23 February 1993 (4).
- 4. On 23 October 1995 the Council adopted a common position on the amended proposal in accordance with the procedure laid down in Article 189b (2) of the Treaty.

II. OBJECTIVE

5. The objective of the proposal is to introduce assessment criteria and procedures for the marketing in the Union of novel foods, i.e. foodstuffs which have not hitherto been used for human consumption to a significant degree.

The proposal is of considerable importance Union-wide for technical progress in the agri-foodstuffs sector, for the proper operation of the internal market and for consumer protection and information.

III. ANALYSIS OF THE COMMON POSITION

- 6. In general terms, the text has been extensively revised during discussions. The wording of the common position reflects the European Parliament's wishes on a number of important points broadly indicated below. All of the amendments to the original proposal which were approved by the Council have been accepted by the Commission.
- 7. The scope (European Parliament amendments 14, 15 and 29) has been extended and specified more clearly in Article 1 (2) in comparison with the original proposal. However, the Council and the Commission were unable to include part of amendment 15, taking the view that additives are already covered by specific Community provisions and should therefore be excluded from the scope of the prospective Regulation.

In line with European Parliament amendments 19 and 30, the general criteria for the assessment of products are included in the enacting terms (in Article 3 (1)).

The Council also found a need to make clearer the relationship between this text and the Community provisions on seeds, particularly as regards assessment procedures and labelling rules (see Article 3 (2)).

- 8. The common position has considerably improved the provisions concerning the procedures in Articles 4 to 7 for the marketing of products coming within its scope (amendments 18, 20 and 21). The main points are as follows:
 - (a) a clearer and more specific breakdown of tasks between the Member States and the Commission as compared with the original proposal;

⁽¹⁾ OJ No C 190, 29. 7. 1992, p. 3.

⁽²⁾ OJ No C 315, 22. 11. 1993, p. 139.

⁽³⁾ OJ No C 16, 19. 1. 1994, p. 10.

⁽⁴⁾ OJ No C 108, 19. 4. 1993.

- (b) wider publication of the results of decisions taken (see Articles 5 and 7), in response to the European Parliament opinion (amendment 24);
- (c) clear, detailed requirements for the preparation and presentation of the documentation to be submitted to the authorities regarding products coming within the scope (Article 6);
- (d) clearer indication of the cases in which the Member States or the Commission may present a reasoned objection to the marketing of a product (Article 6 (4));
- (e) greater clarification of the procedure for taking a formal decision to authorize the marketing of products as well as clarification of the scope of such decisions (Article 7).
- 9. As regards labelling requirements (amendment 22), the Council has decided on a number of rules (Article 8) under which the consumer is to be informed systematically of:
 - differences in respect of the characteristics or food properties of a novel food compared with a conventional product; in such cases the method used to obtain the characteristics or properties in question is to be stated for the consumer's information,
 - the presence in the product of material which is not present in the equivalent existing product and which may have implications for the health of certain sections of the population, e.g. allergens,
 - the presence in the product of material which is not present in the equivalent existing product and which may give rise to ethical concerns for specific population groups with established practices regarding food,
 - the presence of a genetically modified organism not corresponding solely to modification of agricultural characteristics.

In laying down these rules, the Council felt it very important that they should be complete, that the information given to the consumer should be useful and that the rules should be amenable to effective checking by the appropriate authorities.

- 10. The Council has taken into account amendment 17 concerning independent experts.
- 11. The Council has accepted the principle of amendments 54 and 55 concerning the protection of information supplied in the course of the procedures laid down by the Regulation (see Article 10).
- 12. The Council has accepted the aim of amendment 45 to confirm that the general foodstuffs control system is applicable to the products in question and has included it in a recital.
- 13. In the case of amendment 58, the Council is setting the entry into force of the Regulation 12 months after its publication in the Official Journal to enable the Commission and the Member States to take the measures necessary to give effect to it.
- 14. All in all, three years after the submission of the original proposal, having accepted the European Parliament amendments taken up by the Commission and having also taken into consideration European Parliament concern on other points, the Council considers it has finally struck the right balance between the differing views which have been expressed for some while on the matter, particularly as regards key points such as:
 - the scope,
 - marketing procedures,
 - labelling.

COMMON POSITION (EC) No 26/95

adopted by the Council on 23 October 1995

with a view to adopting Directive 95/.../EC of the European Parliament and of the Council on investor-compensation schemes

(95/C 320/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 57 (2) thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Having regard to opinion of the European Monetary Institute.

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

- 1. Whereas on 10 May 1993 the Council adopted Directive 93/22/EEC on investment services in the securities field (4); whereas that Directive is an essential measure for the achievement of the internal market for investment firms;
- 2. Whereas Directive 93/22/EEC lays down prudential rules which investment firms must observe at all times, including rules the purpose of which is to protect as far as possible investors' rights in respect of money or instruments belonging to them;
- 3. Whereas, however, no system of supervision can provide complete protection, particularly where acts of fraud are committed;
- 4. Whereas the protection of investors and the maintenance of confidence in the financial system are an important aspect of the completion and proper functioning of the internal market in this area; whereas to that end it is therefore essential that each Member State should have an investor-compensation scheme that guarantees a

harmonized minimum level of protection at least for the smaller investor in the event of an investment firm's being unable to meet its obligations to its investor clients;

- 5. Whereas small investors will therefore be able to purchase investment services from branches of Community investment firms or on the basis of the cross-border provision of services as confidently as from domestic investment firms, in the knowledge that a harmonized minimum level of protection would be available to them in the event of an investment firm's being unable to meet its obligations to its investor clients;
- Whereas, in the absence of such minimum harmonization, a host Member State might consider itself justified, by considerations of investor protection, in requiring membership of its compensation scheme when a Community investment firm operating through a branch or under the freedom to provide services either belonged to no investor-compensation scheme in its home Member State or belonged to a scheme which was not regarded as offering equivalent protection; whereas such a requirement might create serious difficulties for the operation of the internal market;
- 7. Whereas although most Member States currently have some investor-compensation arrangements those arrangements do not in general cover all investment firms that hold the single licence provided for in Directive 93/22/EEC;
- 8. Whereas, therefore, every Member State should be required to have an investor-compensation scheme or schemes to which every such investment firm would belong; whereas each scheme must cover money and instruments held by an investment firm in connection with an investor's investment operations which, where an investment firm is unable to meet its obligations to its investor clients, cannot be returned to the investor; whereas this is entirely without prejudice to the rules and procedures applicable in each Member State as regards the decisions to be taken in the event of the insolvency or winding up of an investment firm;
- 9. Whereas the definition of investment firm includes credit institutions which are authorized to provide

⁽¹⁾ OJ No C 321, 27. 11. 1993, p. 15 and OJ No C 382, 31. 12. 1994, p. 27. (2) OJ No C 127, 7. 5. 1994, p. 1.

⁽³⁾ European Parliament opinion of 19 April 1994 (OJ No C 128, 9. 5. 1994, p. 86), Council common position of ... (not yet published in the Official Journal) and European Parliament Decision of ... (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 141, 11. 6. 1993, p. 27.

investment services; whereas every such credit institution must also be required to belong to an investor-compensation scheme to cover its investment business; whereas, however, it is not necessary to require such a credit institution to belong to two separate schemes where a single scheme meets the requirements both of this Directive and of Directive 94/19/EC of the European Parliament and of the Council of 30 May 1994 on deposit-guarantee schemes (1); whereas, however, in the case of investment firms which are credit institutions it may in certain cases be difficult to distinguish between deposits covered by Directive 94/19/EC and money held in connection with the conduct of investment business; whereas Member States should be allowed to determine which Directive shall apply to such claims;

- 10. Whereas Directive 94/19/EC allows a Member State to exempt a credit institution from the obligation to belong to a deposit-guarantee scheme where that credit institution belongs to a system which protects the credit institution itself and, in particular, ensures its solvency; whereas, where a credit institution belonging to such a system is also an investment firm, a Member State should also be allowed, subject to certain conditions, to exempt it from the obligation to belong to an investor-compensation scheme;
- 11. Whereas a harmonized minimum level of compensation of ECU 20 000 for each investor should be sufficient to protect the interests of the smaller investor where an investment firm is unable to meet its obligations to its investor clients; whereas it would therefore appear to be reasonable to set the harmonized minimum level of compensation at ECU 20 000; whereas, as in Directive 94/19/EC, limited transitional provisions might be required if compensation schemes are to be able to comply with that figure since this applies equally to Member States which, when this Directive is adopted, do not have any scheme of this type;
- 12. Whereas the same figure was adopted in Directive 94/19/EC; .
- 13. Whereas in order to encourage investors to take due care in their choice of investment firms it is reasonable to allow Member States to require investors to bear a proportion of any loss; whereas, however, an investor must be covered for at least 90 % of any loss as long as the compensation paid is less than the Community minimum;
- 14. Whereas certain Member States' schemes offer levels of cover higher than the harmonized minimum level of protection under this Directive; whereas,

- however, it does not seem desirable to require any change in those schemes in that respect;
- 15. Whereas the retention in the Community of schemes providing levels of cover higher than the harmonized minimum may, within the same territory, lead to disparities in compensation and unequal conditions of competition between national investment firms and branches of firms from other Member States; whereas, in order to counteract those disadvantages, branches should be authorized to join their host countries' schemes so that they may offer their investors the same cover as is provided by the schemes of the countries in which they are located; whereas it is appropriate that, in its report on the application of this Directive, the Commission should indicate the extent to which branches have exercised that option and any difficulties which they or the investor-compensation schemes may encountered in implementing those provisions; whereas the possibility that home Member States' schemes should themselves offer such supplementary cover, subject to the conditions such schemes may lay down, is not ruled out;
- 16. Whereas market disturbances could be caused by branches of investment firms established in Member States other than their Member States of origin which offer levels of cover higher than those offered by investment firms authorized in their host Member States; whereas it is not apppropriate that the level or scope of cover offered by compensation schemes should become an instrument of competition; whereas it is therefore necessary, at least during an initial period, to stipulate that neither the level nor the scope of cover offered by a home Member State's scheme to investors at branches located in another Member State should exceed the maximum level or scope offered by the corresponding scheme in the host Member State; whereas any market disturbances should be reviewed after a number of years, on the basis of the experience acquired and in the light of developments in the financial sector;
- 17. Whereas a Member State must be able to exclude certain categories of specifically listed investments or investors, if it does not consider that they need special protection, from the cover afforded by investor-compensation schemes;
- 18. Whereas some Member States have investor-compensation schemes under the responsibility of professional organizations; whereas in other Member States there are schemes that have been set up and are regulated on a statutory basis; whereas that diversity of status poses a problem only with regard to compulsory membership of and exclusion from schemes; whereas it is therefore necessary to take steps to limit the powers of schemes in that area;

⁽¹⁾ OJ No L 135, 31. 5. 1994, p. 5.

- 19. Whereas the investor must be compensated without excessive delay once the validity of his claim has been established; whereas the compensation scheme itself must be allowed to fix a reasonable period for the presentation of claims; whereas, however, the fact that such a period has expired may not be invoked against an investor who for good reason has not been able to present his claim within the time allowed;
- 20. Whereas the notification of investors regarding compensation arrangements is an essential element of investor protection; whereas Article 12 of Directive 93/22/EEC required investment firms to inform investors, before doing business with them, of the possible application of a compensation scheme; whereas, therefore, this Directive should lay down rules on the information of such intending investors regarding the compensation schemes covering their investment business;
- 21. Whereas, however, the unregulated use in advertising of references to the amount and scope of a compensation scheme could affect the stability of the financial system or investor confidence; whereas Member States should therefore lay down rules to limit such references;
- 22. Whereas in principle this Directive requires every investment firm to join an investor-compensation scheme; whereas the Directives governing the admission of any investment firm the head office of which is in a non-member country, and in particular Directive 93/22/EEC, allow Member States to decide whether and subject to what conditions to permit branches of such investment firms to operate within their territories; whereas such branches will not enjoy the freedom to provide services under the second paragraph of Article 59 of the Treaty, nor the right of establishment in Member States other than those in which they are established; whereas, accordingly, a Member State admitting such branches must decide how to apply the principles of this Directive to such branches in accordance with Article 5 of Directive 93/22/EEC and with the need to protect investors and maintain the integrity of the financial system; whereas it is essential that investors at such branches should be fully aware of the compensation arrangements applicable to them;
- 23. Whereas it is not indispensable in this Directive to harmonize the ways in which investor-compensation schemes are to be financed given, on the one hand, that the cost of financing such schemes must, in principle, be borne by investment firms themselves and, on the other hand, that the financing capacities of such schemes must be in proportion to their liabilities; whereas that must not, however, jeopardize the stability of the financial system of the Member State concerned;

- 24. Whereas this Directive may not result in the Member States' or their competent authorities' being made liable in respect of investors if they have ensured that one or more schemes for the compensation or protection of investors under the conditions prescribed in this Directive have been introduced and officially recognized;
- 25. Whereas, in conclusion, a minimum degree harmonization of investor-compensation arrangements is necessary for the completion of the internal market for investment firms in order to give investors confidence to deal with firms, especially those from other Member States, and to avoid the difficulties that might arise from the application by host Member States of national investor-protection requirements that are not coordinated Community level; whereas a binding Community Directive is the only appropriate instrument for the achievement of the desired objective in the general absence of investor-compensation arrangements corresponding to the coverage of Directive 93/22/EEC; whereas this Directive restricts itself to the minimum harmonization that is required, allows Member States the freedom to prescribe wider or higher coverage if they desire and gives Member States the necessary margin of freedom as regards the organization and financing of investorcompensation schemes,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

For the purposes of this Directive:

- 1. 'investment firm' shall mean an investment firm as defined in Article 1 (2) of Directive 93/22/EEC,
 - authorized in accordance with Article 3 of Directive 93/22/EEC, or
 - authorized as a credit institution in accordance with Council Directive 77/780/EEC (¹) and Council Directive 89/646/EEC (²), the

(2) Second Council Directive 89/646/EEC of 15 December 1989 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of credit institutions (OJ No L 386, 30. 12. 1989, p. 1). Directive as last amended by Directive 92/30/EEC (OJ No L 110, 28. 4. 1992, p. 52).

⁽¹⁾ First Council Directive 77/780/EEC of 12 December 1977 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of credit institutions (OJ No L 322, 17. 12. 1977, p. 30). Directive as last amended by Directive 89/646/EEC (OJ No L 386, 30. 12. 1989, p. 1).

authorization of which covers one or more of the investment services listed in Section A of the Annex to Directive 93/22/EEC;

- 2. 'investment business' shall mean any investment service as defined in Article 1 (1) of Directive 93/22/EEC and the service referred to in point 1 of Section C of the Annex to that Directive;
- 3. 'instruments' shall mean the instruments listed in Section B of the Annex to Directive 93/22/EEC;
- 'investor' shall mean any person who has entrusted money or instruments to an investment firm in connection with investment business;
- 5. 'branch' shall mean a place of business which forms a legally dependent part of an investment firm and which provides investment services for which the investment firm has been authorized; any number of places of business set up in the same Member State by an investment firm the head office of which is in another Member State shall be regarded as a single branch:
- 6. 'joint investment business' shall mean investment business carried out for the account of two or more persons or over which two or more persons have rights that may operate against the signature of one or more of those persons.
- 7. 'competent authorities' shall mean the authorities defined in Article 22 of Directive 93/22/EEC; those authorities may, if appropriate, be those defined in Article 1 of Council Directive 92/30/EEC of 6 April 1992 on the supervision of credit institutions on a consolidated basis (1).

Article 2

1. Each Member State shall ensure that within its territory one or more investor-compensation schemes are introduced and officially recognized. Except in the circumstances envisaged in the second subparagraph and in Article 5 (3), no investment firm authorized in that Member State may carry on investment business unless it belongs to such a scheme.

A Member State may, however, exempt a credit institution to which this Directive applies from the obligation to belong to an investor-compensation scheme where that credit institution is already exempt pursuant to Article 3 (1) of Directive 94/19/EC from the obligation to belong to a deposit-guarantee scheme, provided that the protection and information given to depositors are

Any Member State that avails itself of that option shall inform the Commission accordingly; it shall, in particular, disclose the characteristics of the protective systems in question and the credit institutions covered by them for the purposes of this Directive, as well as any subsequent changes to the information supplied. The Commission shall inform the Council thereof.

- 2. A scheme shall provide cover for investors in accordance with Article 4 where either:
- the competent authorities have determined that in their view an investment firm appears, for the time being, for reasons directly related to its financial circumstances, to be unable to meet its obligations arising out of investors' claims and has no early prospect of being able to do so, or
- a judicial authority has made a ruling, for reasons directly related to an investment firm's financial circumstances, which has the effect of suspending investors' ability to make claims against it,

whichever is the earlier.

Cover shall be provided for claims arising out of an investment firm's inability to:

- repay money owed to investors or belonging to investors and held on their behalf in connection with investment business, or
- return to investors any instuments belonging to them and held, administered or managed on their behalf in connection with investment business,

in accordance with the legal and contractual conditions applicable.

- 3. Any claim under paragraph 2 on a credit institution which, in a given Member State, would be subject both to this Directive and to Directive 94/19/EC shall be directed by that Member State to a scheme under one or other of those Directives as that Member State shall consider appropriate. No claim shall be eligible for compensation more than once under those Directives.
- 4. The amount of an investor's claim shall be calculated in accordance with the legal and contractual conditions, in particular those concerning set off and counterclaims, that are applicable to the assessment, on the date of the determination or ruling referred to in paragraph 2, of the amount of the money or the value of the instruments belonging to the investor which the investment firm is unable to repay or return.

also given to investors on the same terms and investors thus enjoy protection at least equivalent to that afforded by an investor-compensation scheme.

⁽¹⁾ OJ No L 110, 28. 4. 1992, p. 52.

Article 3

Claims arising out of transactions in connection with which a criminal conviction has been obtained for money laundering, as defined in Article 1 of Council Directive 91/308/EEC of 10 June 1991 on prevention of the use of the financial system for the purpose of money laundering (¹) shall be excluded from any compensation under investor-compensation schemes.

Article 4

1. Member States shall ensure that schemes provide for cover of not less than ECU 20 000 for each investor in respect of the claims referred to in Article 2 (2).

Until 31 December 1999 Member States in which, when this Directive is adopted, cover is less than ECU 20 000 may retain that lower level of cover, provided it is not less than ECU 15 000. That option shall also be available to Member States to which the transitional provisions of the second subparagraph of Article 7 (1) of Directive 94/19/EC apply.

- 2. A Member State may provide that certain investors shall be excluded from cover by schemes or shall be granted a lower level of cover. Those exclusions shall be as listed in Annex I.
- 3. This Article shall not preclude the retention or adoption of provisions which afford greater or more comprehensive cover to investors.
- 4. A Member State may limit the cover provided for in paragraph 1 or that referred to in paragraph 3 to a specified percentage of an investor's claim. The percentage covered must, however, be equal to or exceed 90% of the claim as long as the amount to be paid under the system is less than ECU 20 000.

Article 5

- 1. If an investment firm required by Article 2 (1) to belong to a scheme does not meet the obligations incumbent on it as a member of that scheme, the competent authorities which issued its authorization shall be notified and, in cooperation with the compensation scheme, shall take all measures appropriate, including the imposition of sanctions, to ensure that the investment firm meets its obligations.
- 2. If those measures fail to secure compliance on the part of the investment firm, the scheme may, where national law permits the exclusion of a member, with the

- express consent of the competent authorities, give not less than 12 months' notice of its intention of excluding the investment firm from membership of the scheme. The scheme shall continue to provide cover under the second subparagraph of Article 2 (2) in respect of investment business transacted during that period. If, on expiry of the period of notice, the investment firm has not met its obligations, the compensation scheme may, again having obtained the expess consent of the competent authorities, proceed to exclusion.
- 3. Where national law permits, and with the express consent of the competent authorities which issued its authorization, an investment firm excluded from an investor-compensation scheme may continue to provide investment services if, before its exclusion, it made alternative compensation arrangements which ensure that investors will enjoy cover that is at least equivalent to that offered by the officially recognized scheme and has characteristics equivalent to those of that scheme.
- 4. If an investment firm the exclusion of which is proposed under paragraph 2 is unable to make alternative arrangements which comply with the conditions imposed in paragraph 3, the competent authorities which issued its authorization shall revoke it forthwith.

Article 6

After the withdrawal of an investment firm's authorization, cover under the second subparagraph of Article 2 (2) shall continue to be provided in respect of investment business transacted up to the time of that withdrawal.

Article 7

1. Investor-compensation schemes introduced and officially recognized in a Member State in accordance with Article 2 (1) shall also cover investors at branches set up by investment firms in other Member States.

Until 31 December 1999, neither the level nor the scope, including the percentage, of the cover provided for may exceed the maximum level or scope of the cover offered by the corresponding compensation scheme within the territory of the host Member State. Before that date the Commission shall draw up a report on the basis of the experience acquired in applying this subparagraph and shall consider the need to continue those provisions. If appropriate, the Commission shall submit a proposal for a Directive to the European Parliament and the Council, with a view to the extension of their validity.

Where the level or scope, including the percentage, of the cover offered by the host Member State's investor-

⁽¹⁾ OJ No L 166, 28. 6. 1991, p. 77.

compensation scheme exceeds the level or scope of the cover provided in the Member State in which an investment firm is authorized, the host Member State shall ensure that there is an officially recognized scheme within its territory which a branch may join voluntarily in order to supplement the cover which its investors already enjoy by virtue of its membership of its home Member State's scheme.

If a branch joins such a scheme, that scheme shall be one that covers the category of institution to which the branch belongs or most closely corresponds in its host Member State.

Member States shall ensure that objective and generally applied conditions are established concerning branches' membership of all investor-compensation schemes. Admission shall be conditional on a branch's meeting the relevant membership obligations, including in particular the payment of all contributions and other charges. Member States shall follow the guiding principles set out in Annex II in implementing this paragraph.

2. If a branch which has exercised the option of voluntary membership under paragraph 1 does not meet the obligations incumbent on it as a member of an investor-compensation scheme, the competent authorities which issued its authorization shall be notified and, in cooperation with the compensation scheme, shall take all measures necessary to ensure that the branch meets the aforementioned obligations.

If those measures fail to ensure that the branch meets the obligations referred to in this Article, after an appropriate period of notice of not less than 12 months the compensation scheme may, with the consent of the competent authorities which issued the authorization, exclude the branch. Investment business transacted before the date of exclusion shall continue to be covered after that date by the compensation scheme of which the branch was a voluntary member. Investors shall be informed of the withdrawal of the supplementary cover and of the date on which it takes effect.

Article 8

1. The cover provided for in Article 4 (1), (3) and (4) shall apply to the investor's aggregate claim on the same investment firm pursuant to this Directive irrespective of the number of accounts, the currency and location within the Community.

Member States may, however, provide that funds in currencies other than those of the Member States and the ecu shall be excluded from cover or be subject to lower cover. This option shall not apply to instruments.

2. Each investor's share in joint investment business shall be taken into account in calculating the cover provided for in Article 4 (1), (3) and (4).

In the absence of special provisions, claims shall be divided equally amongst investors.

Member States may provide that claims relating to joint investment business to which two or more persons are entitled as members of a business partnership, association or grouping of a similar nature, which has no legal personality, may, for the purpose of calculating the limits provided for in Article 4 (1), (3) and (4), be aggregated and treated as if arising from an investment made by a single investor.

3. Where an investor is not absolutely entitled to the sums or securities held, the person who is absolutely entitled shall receive the compensation, provided that that person has been or can be identified before the date of the determination or ruling referred to in Article 2 (2).

If two or more persons are absolutely entitled, the share of each under the arrangements subject to which the sums or the securities are managed shall be taken into account when the limits laid down in Article 4 (1), (3) and (4) are calculated.

This provision shall not apply to collective-investment undertakings.

Article 9

1. The compensation scheme shall take appropriate measures to inform investors of the determination or ruling referred to in Article 2 (2) and, if they are to be compensated, to compensate them as soon as possible. It may fix a period during which investors shall be required to submit their claims. That period may not be less than five months from the date of the aforementioned determination or ruling or from the date on which that determination or ruling is made public.

The fact that that period has expired may not, however, be invoked by the scheme to deny cover to an investor who has been unable to assert his right to compensation in time.

2. The scheme shall be in a position to pay an investor's claim within three months of the establishment of the eligibility and the amount of the claim.

In wholly exceptional circumstances and in special cases a compensation scheme may apply to the competent

authorities for an extension of the time limit. No such extension may exceed three months.

3. Notwithstanding the time limit laid down in paragraph 2, where an investor or any other person entitled to or having an interest in investment business has been charged with an offence arising out of or in relation to money laundering as defined in Article 1 of Directive 91/308/EEC, the compensation scheme may suspend any payment pending the judgment of the court.

Article 10

1. Member States shall ensure that each investment firm takes appropriate measures to make available to actual and intending investors the information necessary for the identification of the investor-compensation scheme of which the investment firm and its branches within the Community are members or any alternative arrangement provided for under the second subparagraph of Article 2 (1) or Article 5 (3). Investors shall be informed of the provisions of the investor-compensation scheme or any alternative arrangement applicable, including the amount and scope of the cover offered by the compensation scheme and any rules laid down by the Member States pursuant to Article 2 (3). That information shall be made available in a readily comprehensible manner.

Information shall also be given on request concerning the conditions governing compensation and the formalities which must be completed to obtain compensation.

- 2. The information provided for in paragraph 1 shall be made available in the manner prescribed by national law in the official language or languages of the Member State in which a branch is established.
- 3. Member States shall establish rules limiting the use in advertising of the information referred to in paragraph 1 in order to prevent such use from affecting the stability of the financial system or investor confidence. In particular, a Member State may restrict such advertising to a factual reference to the scheme to which an investment firm belongs.

Article 11

1. Each Member State shall check that branches established by an investment firm the head office of which is outwith the Community have cover equivalent to that prescribed in this Directive. Failing that, a Member State may, subject to Article 5 of Directive 93/22/EEC, stipulate that branches established by an investment firm the head office of which is outwith the Community shall join investor-compensation schemes in operation within its territory.

- 2. Actual and intending investors at branches established by an investment firm the head office of which is outwith the Community shall be provided by that investment firm with all relevant information concerning the compensation arrangements which cover their investments.
- 3. The information provided for in paragraph 2 shall be made available in the manner prescribed by national law in the official language or languages of the Member State in which a branch is established and shall be drafted in a clear and comprehensible form.

Article 12

Without prejudice to any other rights which they may have under national law, schemes which make payments in order to compensate investors shall have the right of subrogation to the rights of those investors in liquidation proceedings for amounts equal to their payments.

Article 13

Member States shall ensure that an investor's right to compensation may be the subject of an action by the investor against the compensation scheme.

Article 14

No later than 31 December 1999 the Commission shall submit a report to the European Parliament and to the Council on the application of this Directive together, where appropriate, with proposals for its revision.

Article 15

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive no later than . . . (*). They shall forthwith inform the Commission thereof.

When the Member States adopt those measures, they shall contain references to this Directive or shall be accompanied by such references on the occasion of their official publication. The methods of making such references shall be laid down by the Member States.

2. The Member States shall communicate to the Commission the texts of the essential provisions of national law which they adopt in the field covered by this Directive.

^(*) Eighteen months after the entry into force of this Directive.

Article 16

Article 18

Article 12 of Directive 93/22/EEC shall be repealed with effect from the date referred to in Article 15 (1).

This Directive is addressed to the Member States.

Article 17

Done at ...

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

For the European Parliament
The President

For the Council
The President

ANNEX I

LIST REFERRED TO IN ARTICLE 4 (2)

- 1. Professional and institutional investors, including:
 - investment firms as defined in Article 1 (2) of Directive 93/22/EEC,
 - credit institutions as defined in the first indent of Article 1 of Council Directive 77/780/EEC,
 - financial institutions as defined in Article 1 (6) of Council Directive 89/646/EEC,
 - insurance undertakings,
 - collective-investment undertakings,
 - pension and retirement funds.

Other professional and institutional investors.

- 2. Supranational institutions, government and central administrative authorities.
- 3. Provincial, regional, local and municipal authorities.
- 4. Directors, managers and personally liable members of investment firms, persons holding 5 % or more of the capital of such investment firms, persons responsible for carrying out the statutory audits of investment firms' accounting documents and investors with similar status in other companies within the same group as such a firm.
- 5. Close relatives and third parties acting on behalf of the investors referred to in 4.
- 6. Other firms in the same group.
- 7. Investors who have any responsibility for or have taken advantage of certain facts relating to an investment firm which gave rise to the firm's financial difficulties or contributed to the deterioration of its financial situation.
- 8. Companies which are of such a size that they are not permitted to draw up abridged balance sheets pursuant to Article 11 of the fourth Council Directive 78/660/EEC of 25 July 1978 based on Article 54 (3) (g) of the Treaty on the annual accounts of certain types of companies (1).

⁽¹⁾ OJ No L 222, 14. 8. 1978, p. 11. Directive as last amended by Directive 94/8/EC (OJ No L 82, 25. 3. 1994, p. 33).

ANNEX II

GUIDING PRINCIPLES REFERRED TO IN

the fifth subparagraph of Article 7 (1)

Where a branch applies to join a host Member State's scheme for supplementary cover, the host Member State's scheme will bilaterally establish with the home Member State's scheme appropriate rules and procedures for the payment of compensation to investors at that branch. The following principles will apply both to the drawing up of those procedures and in the framing of the membership conditions applicable to that branch (as referred to in Article 7 (1)):

- (a) the host Member State's scheme will retain full rights to impose its objective and generally applied rules on participating investment firms; it will be able to require the provision of relevant information and be entitled to verify such information with the home Member State's competent authorities;
- (b) the host Member State's scheme will meet claims for supplementary compensation after it has been informed by the home Member State's competent authorities of the determination or ruling referred to in Article 2 (2). The host Member State's scheme will retain full rights to verify an investor's entitlement according to its own standards and procedures before paying supplementary compensation;
- (c) the host Member State's and the home Member State's schemes will cooperate fully with each other to ensure that investors receive compensation promptly and in the correct amounts. In particular, they will agree on how the existence of a counterclaim which may give rise to set off under either scheme will affect the compensation paid to the investor by each scheme;
- (d) the host Member State's scheme will be entitled to charge branches for supplementary cover on an appropriate basis which takes into account the cover funded by the home Member State's scheme. To facilitate charging, the host Member State's scheme will be entitled to assume that its liability will in all circumstances be limited to the excess of the cover it has offered over the cover offered by the home Member State regardless of whether the home Member State actually pays any compensation in respect of claims by investors within the host Member State's territory.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 22 October 1993 the Commission forwarded to the Council the above proposal for a Directive, based on Article 57 (2) of the EC Treaty.

The Economic and Social Committee and the European Parliament delivered their opinions on 26 January and 19 April 1994 respectively. The European Monetary Institute gave its opinion on 28 July 1995.

Following these opinions, the Commission submitted an amended proposal on 14 December 1994.

2. On 23 October 1995 the Council adopted its common position pursuant to Article 189b of the Treaty.

II. OBJECTIVE

The objective of the proposal is to complete the single market in investment services and ensure its proper functioning:

- by providing for minimum compensation for investors which would apply throughout the Community in the case of failure of an investment firm, where the firm proved unable to refund to investors the money or securities belonging to them, and
- by introducing a necessary supplement to the single authorization system by placing the investor-compensation arrangements under the supervisory system of the country of origin.

The proposal follows on from the undertaking given by the Commission when Directive 93/22/EEC on investment services in the securities field was adopted, on 10 May 1993, to submit proposals on the harmonization of arrangements for compensating investors.

III. ANALYSIS OF THE COMMON POSITION

1. General comments

In order to ensure legislative consistency between the Directive and other Community acts in the financial services sector, the Council has endorsed the approach adopted by the Commission in its amended proposal, namely alignment on the corresponding provisions of Directive 94/19/EC on deposit-guarantee schemes.

The common position therefore broadly takes up the amended proposal while making a certain number of amendments. In addition to purely technical drafting adjustments, the amendments are aimed mainly:

- either at ensuring the most complete consistency possible with Directive 94/19/EC,
- or at improving the transparency of the text and including in it some useful points of clarification.

2. Specific comments

- (a) In comparison with the Commission's amended proposal, in order to ensure consistency with Directive 94/19/EC the common position:
 - provides that any Member State that avails itself of the derogation provided for in the second subparagraph of Article 2 (1) must inform the Commission accordingly (third subparagraph of Article 2 (1)),

- aligns the conditions set out in the first indent of the first subparagraph of Article 2 (2) concerning determination of a firm's inability to meet its obligations on the relevant provision of Directive 94/19/EC,
- introduces a transitional period, the essential aspects of which (amounts and duration) correspond to those adopted for deposit-guarantee schemes (Article 4 (1)),
- provides that, until 31 December 1999, neither the level nor the scope of the cover provided by a branch in the host Member State may exceed the level or scope of the cover offered by the compensation scheme of that Member State. This provision is temporary, in parallel with Directive 94/19/EC, and may be extended only if the Commission submits a proposal to that effect (Article 7 (1)),
- aligns the conditions concerning optional membership on the conditions laid down in Directive 94/19/EC (fifth subparagraph of Article 7 (1)),
- gives Member States the option to exclude funds, but not instruments, in currencies other than those of the Member States and the ecu (second subparagraph of Article 8 (1)),
- allows extension of the time limit for payment of claims by the compensation scheme (Article 9 (2)),
- allows suspension of payment of compensation where an investor has been charged with an offence arising out of or in relation to money laundering (Article 9 (3)),
- provides for restriction of advertising concerning compensation schemes in order to avoid advertising which, without strictly speaking being misleading, could affect the stability of the financial system or investor confidence (Article 10 (3)),
- provides that the right to compensation may be the subject of an action by the investor against the compensation scheme (Article 13),
- aligns the date for submission of the Commission report on application of the Directive on the date set for submission of the report on application of Directive 94/19/EC (Article 14). By bringing forward the date for submission, this amendment incorporates the substance of amendment No 7 proposed by Parliament.
- (b) In comparison with the amended proposal, in order to improve transparency and make the text of the Directive more precise, the common position:
 - amends the definition of the term 'investment firm', replaces the term 'joint investment' by 'joint investment business', and adapts the definition accordingly, and introduces a definition of 'competent authorities' (Article 1). In broadly incorporating the amended Commission proposal with regard to the definition of the terms 'investment firm' and 'branch', the common position follows amendment Nos 1 and 3 proposed by Parliament,
 - states that the exemption provided for in Article 2 (1) applies only if the investor is given information and protection equivalent to that afforded by an investor-compensation scheme,
 - broadly incorporates the text of the amended proposal with regard to the second indent of the second subparagraph of Article 2 (2) concerning the extent of cover, thereby following the spirit of amendment No 5 proposed by Parliament,

- makes it clear that investment business transacted before the date of a firm's exclusion from a compensation scheme is covered by the scheme in the case of both compulsory membership (Article 5 (2)) and voluntary membership (Article 7 (2)),
- provides that the characteristics of the compensation arrangements laid down in Article 5 (2) must be equivalent to those of the officially recognized scheme in the Member State concerned,
- adds the date of exclusion to the information which must be given to the investor under the second subparagraph of Article 7 (2),
- clarifies the provisions concerning the calculation of the time limit for compensation and sets at least five months as the period which may be fixed by the scheme during which investors must submit their claims (Article 9 (1) and (2)),
- adds to the information which must be given to the investor pursuant to Article 10 a reference to any rules laid down pursuant to Article 2 (3),
- sets the time limit for implementation with reference to publication of the Directive (Article 15),
- merges points 1 and 2 of Annex I.

The common position also makes some drafting changes to the text, in particular to Articles 2, 6 and 12.

(c) By incorporating the wording of the amended Commission proposal with regard to the first subparagraph of Article 2 (1) and the last sentence of Article 5 (2), the common position endeavours to cover the objectives sought by amendment Nos 4 and 6 proposed by Parliament.

The common position does not follow amendment No 2 proposed by Parliament, for the same reasons as those which led the Commission not to include that amendment in its amended proposal.

(d) The preamble has been amended as a result of the above amendments.

IV. CONCLUSIONS

The Council considers that the amendments to the amended Commission proposal all comply with the aims of the Directive. It has endeavoured to ensure legislative consistency with other Community legal acts, in particular with the Directive on deposit-guarantee schemes, and to improve the transparency of the text, while respecting all the essential principles of the proposal.

COMMON POSITION (EC) No 27/95

adopted by the Council on 7 November 1995

with a view to adopting Directive 95/.../EC of the European Parliament and of the Council amending Directive 88/77/EEC on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from diesel engines for use in vehicles

(95/C 320/03)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 189b of the Treaty (3),

Whereas measures should be adopted within the framework of the internal market;

Whereas the first programme of action of the European Community on protection of the environment (4), approved by the Council on 22 November 1973, called for account to be taken of the latest scientific advances in combating atmospheric pollution caused by gases emitted from motor vehicles and for Directives adopted previously to be amended accordingly; whereas the fifth programme of action, which in its general approach was approved by the Council and by the Representatives of the Governments of the Member States, meeting within the Member States, in the resolution of 1 February 1993 (5), provides for additional efforts to be made to effect a considerable reduction in the present level of pollutants emitted from motor vehicles;

Whereas the objective of reducing the level of pollutant emissions from motor vehicles and the smooth functioning of the internal market for vehicles cannot be sufficiently achieved by individual Member States and can therefore be better achieved by the approximation of the laws of the Member States relating to measures to be taken against air pollution by motor vehicles;

Whereas it is recognized that the development of transport in the Community has entailed significant constraints for the environment; whereas a number of official estimates of the increase in traffic density have proved to be lower than the actual figures; whereas for that reason stringent emission standards should be laid down for all motor vehicles;

Whereas Directive 88/77/EEC (6) laid down the limit values for the emissions of carbon monoxide, unburnt hydrocarbons and nitrogen oxides from diesel engines for use in motor vehicles on the basis of a test procedure representative for European driving conditions for the vehicles concerned; whereas Directive 91/542/EEC provides for two stages, the first stage (1992/93) coinciding with the implementation dates of the new European emission standards for passenger cars; whereas the second stage (1995/96) established a longer-term guideline for the European motor industry by fixing limit values based on the expected performance of technologies still under development, whilst granting industry a lead time for perfecting such technologies;

Whereas under Article 5 (2) of Directive 91/542/EEC the Commission is to report to the Council before the end of 1993 on progress made regarding the availability of technologies for controlling air-polluting emissions from diesel engines, particularly those of 85 kW or less; whereas this report should cover also new statistical methods to monitor production conformity; whereas in the light of the conclusions of this report the Commission is invited, if necessary, to submit a proposal to the Council for revising upwards the limit values for particulate emissions;

Whereas, in the opinion of the experts consulted, it is possible to introduce new provisions on production conformity;

Whereas the very stringent limit value for particulate emissions set in Directive 91/542/EEC for 'Stage 2' cannot, at the present state of technology, be met by

⁽¹⁾ OJ No C 389, 31. 12. 1994, p. 22.

⁽²⁾ OJ No C 155, 21. 6. 1995, p. 10.

⁽³⁾ Opinion of the European Parliament of 20 September 1995 (not yet published in the Official Journal), Council Common Position of ... (not yet published in the Official Journal) and Decision of the European Parliament of ... (not yet published in the Official Journal).

⁽⁴⁾ OJ No C 112, 20. 12. 1973, p. 1.

⁽⁵⁾ OJ No C 138, 17. 5. 1993, p. 1.

⁽⁶⁾ OJ No L 36, 9. 2. 1988, p. 33. Directive as last amended by Directive 91/542/EEC (OJ No L 295, 25. 10. 1991, p. 1).

most small diesel engines of 85 kW or less by the date set in that Directive; whereas a considerable reduction in particulate emissions may nevertheless be obtained for these engines as from 1 October 1995; whereas, for small diesel engines with a swept volume of less than 0,7 dm³ and a rated power speed of more than 3 000 min⁻¹, the limit value for particulate emissions set in Directive 91/542/EEC should not be introduced until 1997; whereas this additional period would allow the industry to make the necessary changes to ensure compliance with the deferred limit value,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 88/77/EEC shall be amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before ...(*). They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate the main provisions of national law which they adopt in the field covered by this Directive to the Commission.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Communities.

Article 4

This Directive is addressed to the Member States.

Done at ...

For the European Parliament
The President

For the Council
The President

^{(*) (...)} after the date of adoption of this Directive.

ANNEX

AMENDMENTS TO THE ANNEXES TO DIRECTIVE 88/77/EEC

- (1) Section 6.2.1.: the following footnote (**) is added to the figure '0,15' of the last line of the table (B(1. 10. 1995)), last column (Mass of particulates (PT) g/kWh):
 - '(**): until 30 September 1997 the value applied to the particulate emissions of engines having a swept volume of less than 0,7 dm³ and a rated power speed of more than 3 000 min⁻¹, is 0,25 g/kWh.'
- (2) Section 8 now reads as follows:
 - '8. PRODUCTION CONFORMITY
 - 8.1. Measures to ensure production conformity must be taken in accordance with the provisions of Article 10 of Directive 70/156/EEC. Production conformity is checked on the basis of the description in the type-approval certificates set out in Annex VIII to this Directive.
 - Sections 2.4.2 and 2.4.3 of Annex X to Directive 70/156/EEC are applicable where the competent authorities are not satisfied with the auditing procedure of the manufacturer.
 - 8.1.1. If emissions of pollutants are to be measured and an engine type approval has had one or several extensions, the tests will be carried out on the engine(s) described in the information package relating to the relevant extension.
 - 8.1.1.1. Conformity of the vehicle subjected to a pollutant emission test.

After submission of the engine to the authorities, the manufacturer shall not carry out any adjustment to the engines selected.

8.1.1.1.1. Three engines are randomly taken in the series and are subjected to the test referred to in Section 6.2. The limit values are given in Section 6.2.1 of this Annex (*).

- "(*): until 30 September 1998 the value applied to the particulate emissions of engines having a swept volume of less than 0,7 dm³ and a rated power speed of more than 3 000 min⁻¹, is 0,25 g/kWh."
- 8.1.1.1.2. The test are carried out according to Appendix 1 to this Annex, where the competent authority is satisfied with the production standard deviation given by the manufacturer, in accordance with Annex X to Directive 70/156/EEC, which applies to motor vehicles and their trailers.

The tests are carried out according to Appendix 2 to this Annex, where the competent authority is not satisfied with the production standard deviation given by the manufacturer in accordance with Annex X to Directive 70/156/EEC, which applies to motor vehicles and their trailers.

At the manufacturer's request, the tests may be carried out in accordance with Appendix 3 to this Annex.

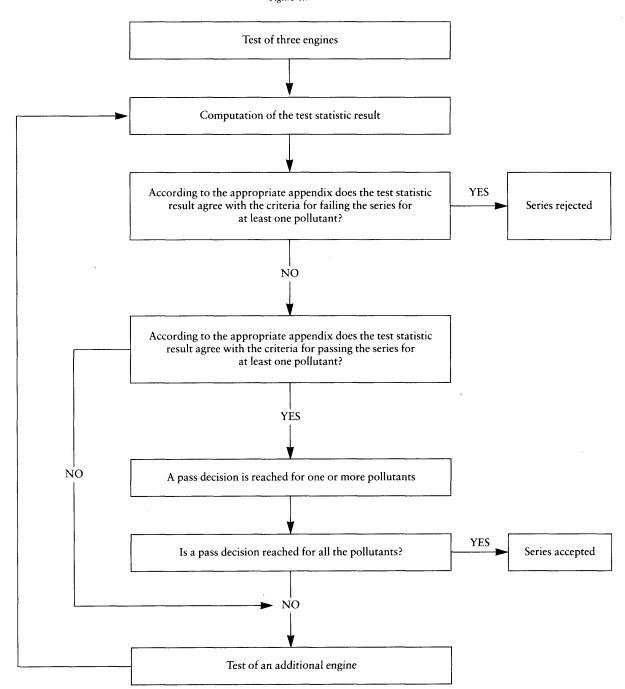
8.1.1.1.3. On the basis of a test of the engines by sampling, the production of a series is regarded as conforming where a pass decision is reached for all the pollutants and non-conforming where a fail decision is reached for one pollutant, in accordance with the test criteria applied in the appropriate Appendix.

When a pass decision has been reached for one pollutant, this decision may not be changed by any additional tests made in order to reach a decision for the other pollutants.

If no pass decision is reached for all the pollutants and if no fail decision is reached for one pollutant, a test is carried out on another engine (see Figure I.7).

If no decision is reached, the manufacturer may at any time decide to stop testing. In that case a fail decision is recorded.

Figure 1.7



- 8.1.1.2. The tests will be carried out on newly manufactured engines.
- 8.1.1.2.1. However, at the request of the manufacturer, the tests will be carried out on engines which have been run-in a maximum of 100 hours.

In this case, the running-in procedure will be conducted by the manufacturer who shall undertake not to make any adjustments to those engines.

- 8.1.1.2.2. When the manufacturer asks to conduct an running-in procedure (x hours where $x \le (100)$ hours), it may be carried out on:
 - all the engines that are tested,

OI

- the first engine tested, with the determination of an evolution coefficient as follows:
 - the pollutant emissions will be measured at zero and at "x" hours on the first engine tested.
 - the evolution coefficient of the emissions between zero and "x"a hours will be calculated for each pollutant:

Emissions "x" hours

Emissions zero hour

- It may be less than one.
- The subsequent test engines will not be subjected to the running-in procedure, but their zero hour emissions will be modified by the evolution coefficient.

In this case, the values to be taken will be:

- the values at "x" hours for the first engine,
- the values at zero hour multiplied by the evolution coefficient for the other engines.
- 8.1.1.2.3. All these tests may be conducted with commercial fuel. However, at the manufacturer's request, the reference fuels described in Annex IV may be used.'
- (3) The following Appendices are added:

'Appendix 1

- 1. This Appendix describes the procedure to be used to verify production conformity for the emissions of pollutants when the manufacturer's production standard deviation is satisfactory.
- 2. With a minimum sample size of three the sampling procedure is set so that the probability of a lot passing a test with 30% of the engines defective is 0,90 (producer's risk 10%) while the probability of a lot being accepted with 65% of the engines defective is 0,10 (consumer's risk = 10%).
- 3. The following procedure is used for each of the pollutants given in Section 6.2.1 of Annex I (see Figure I 7).

Let:

L = the natural logarithm of the limit value for the pollutant,

 x_i = the natural logarithm of the measurement for the i-th engine of the sample,

s = an estimate of the production standard deviation (after taking the natural logarithm of the measurements),

n = the current sample number.

4. For each sample the sum of the standardized deviations to the limit is calculated using the following formula:

$$\frac{1}{s} \sum_{i=1}^{n} (L - x_i)$$

- 5. Then:
 - if the test statistic result is greater than the pass decision number for the sample size given in Table I.1.5, a pass decision is reached for the pollutant,
 - if the test statistic result is less than the fail decision number for the sample size given in Table I.1.5, a fail decision is reached for the pollutant,
 - otherwise, an additional engine is tested according to Section 8.1.1.1 of Annex I and the calculation procedure is applied to the sample increased by one more unit.

Table 1.1.5
Minimum sample size: 3

Cumulative number of engines tested (sample size)	Pass decision number A _n	Fail decision number B _n
3	3,327	- 4,724
4	3,261	- 4,790
5	3,195	- 4,856
6	3,129	- 4,922
7	3,063	- 4,988
8	2,997	- 5,054
9	2,931	- 5,120
10	2,865	- 5,185
11	2,799	- 5,251
12	2,733	- 5,317
13	2,667	- 5,383
14	2,601	- 5,449
15	2,535	- 5,515
16	2,469	- 5,581
17	2,403	- 5,647
18	2,337	- 5,713
19	2,271	- 5,779
20	2,205	- 5,845
21	2,139	- 5,911
22	2,073	- 5,977
23	2,007	- 6,043
24	1,941	- 6,109
25	1,875	- 6,175
26	1,809	- 6,241
27	1,743	- 6,307
28	1,677	- 6,373
29	1,611	- 6,439
30	1,545	- 6,505
31	1,479	- 6,571
32	- 2,112	- 2,112

Appendix 2

- 1. This Appendix describes the procedure to be used to verify production conformity during the type I test when the manufacturer's evidence of production standard deviation is either unsatisfactory or unavailable.
- 2. With a minimum sample size of three the sampling procedure is set so that the probability of a lot passing a test with 30% of the engines defective is 0,90 (producer's risk = 10%) while the probability of a lot being accepted with 65% of the engines defective is 0,10 (consumer's risk = 10%).
- 3. The values of the pollutants given in Section 6.2.1 of Annex 1 are considered to be log normally distributed and should be transformed by taking their natural logarithms. Let m_0 and m denote the minimum and maximum sample sizes respectively ($m_0 = 3$ und m = 32) and let n denote the current sample number.
- 4. If the natural logarithms of the values measured in the series are x_1, x_2, \ldots, x_j and L is the natural logarithm of the limit value for the pollutant, then, define:

$$d_i = x_i - L$$

and

$$\overline{d}_n = \frac{1}{n} \sum_{j=1}^n d_j$$

$$V_n^2 = \frac{1}{n} \sum_{i=1}^n (d_i - \overline{d}_n)^2$$

5. Table I.2.5 shows values of the pass (A_n) and fail (B_n) decision numbers against current sample number. The test statistic result is the ratio \overline{d}_n/V_n , and shall be used to determine whether the series has passed or failed as follows:

For $m_0 \le n < m$:

- pass the series if $\overline{d}_n/V_n \leq A_n$,
- fail the series if $\overline{d}_n/V_n \ge B_n$,
- take another measurement if $A_n < \overline{d}_n/V_n < B_n$.
- 6. Remarks.

The following recursive formulae are useful for calculating successive values of the test statistic:

$$\overline{d}_n = \left(1 - \frac{1}{n}\right) \overline{d}_{n-1} + \frac{1}{n} d_n$$

$$V_n^2 = \left(1 - \frac{1}{n}\right) V_{n-1}^2 + \frac{(\overline{d}_n - d_n)^2}{n-1}$$

$$(n = 2, 3, ...; \overline{d}_n = d1; V_1 = O)$$

Table 1.2.5
Minimum sample size: 3

Cumulative number of engines tested (sample size)	Pass decision number A_n	Fail decision number B _n
3	- 0,80381	16,64743
4	- 0,76339	7,68627
5	- 0,72982	4,67136
6	- 0,69962	3,25573
7	- 0,67129	2,45431
8	- 0,64406	1,94369
9	- 0,61750	1,59105
10	- 0,59135	1,33295

Cumulative number of engines tested (sample size)	Pass decision number A_n	Fail decision number B _n
11	- 0,56542	1,13566
12	- 0,53960	0,97970
13	- 0,51379	0,85307
14	- 0,48791	0,74801
15	- 0,46191	0,65928
16	- 0,43573	0,58321
17	- 0,40933	0,51718
18	- 0,38266	0,45922
19	- 0,35570	0,40788
20	- 0,32840	0,36203
21	- 0,30072	0,32078
22	- 0,27263	0,28343
23	- 0,24410	0,24943
24	- 0,21509	0,21831
25	- 0,18557	0,18970
26	- 0,15550	0,16328
27	- 0,12483	0,13880
28	- 0,09354	0,11603
29	- 0,06159	0,09480
30	- 0,02892	0,07493
31	- 0,00449	0,05629
32	- 0,03876	0,03879

Appendix 3

- 1. This Appendix describes the procedure to be used to verify, at the manufacturer's request, production conformity for the emissions of pollutants.
- 2. With a minimum sample size of three engines the sampling procedure is set to that the probability of a lot passing a test with 30% of the engines defective is 0,90 (producer's risk = 10%) while the probability of a lot being accepted with 65% of the engines defective is 0,10 (consumer's risk 10%)
- 3. The following procedure is used for each of the pollutants given in Section 6.2.1 of Annex 1, (see Figure I.7).

Let

- L be the limit value for the pollutant,
- \mathbf{x}_{i} the value of the measurement for the i-th engine of the sample,
- n is the current sample number.
- 4. Calculate for the sample the test statistic quantifying the number of non-conforming engines, i.e.: $x_i > L$.

5. Then:

- if the test statistic is less or equal to the pass decision number for the sample size given in Table I.3.5, a pass decision is reached for the pollutant,
- if the test statistic is greater or equal to the fail decision number for the sample size given in Table I.3.5, a fail decision is reached for the pollutant,
- otherwise, an additional engine is tested according to Section 8.1.1.1 of Annex I and the calculation procedure is applied to the sample increased by one more unit.

In Table I.3.5 the pass and fail decision numbers are calculated by means of the International Standard ISO 8422/1991.

Table 1.3.5

Minimum sample size: 3

Cumulative number of engines tested (sample size)	Pass decision number	Fail decision number
3	_	3
4	0	4
5	0	4
6	1	5
7	`` 1	5
8	2	6
9	2	6
10	3	7
11	3	7
12	4	8
13	4	8
14	5	9
15	5	9
16	6	10
17	6	10
18	7	11
19	8	9'

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

- 1. On 19 December 1994, the Commission submitted a proposal based on Article 100a of the EC Treaty, amending Directive 88/77/EEC on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from diesel engines for use in vehicles.
- 2. The European Parliament delivered its opinion on 20 September 1995, proposing three amendments to the Commission proposal. In the light of that opinion, on 5 October 1995 the Commission submitted an amended proposal, incorporating the European Parliament's amendments.
- 3. The Economic and Social Committee delivered its opinion on 27 April 1995.
- 4. On 7 November 1995, the Council adopted a common position on the Commission proposal, in accordance with Article 189b of the Treaty.

II. OBJECTIVE

5. The purpose of the above proposal is, to grant low-powered diesel engines designed for use in commercial vehicles a derogation from the limit value, applicable from 1 October 1995, set in Directive 91/542/EEC, and to introduce a new statistical method for monitoring conformity of production.

III. ANALYSIS OF THE COMMON POSITION

6. The Council has basically made three amendments to the Commission proposal:

Firstly, with regard to the limit values, the Council adopted a position combining the essential points of the original Commission proposal and the European Parliament opinion; the Council accepted

- the intermediate limit of 0,25 g/kWh initially proposed by the Commission,
- the two-year reduction in the period for which this derogation will apply, as requested by the European Parliament.

The Council considered that, although vehicles with a low-powered engine could not at present comply with the limit of 0,15 g/kWh laid down in Directive 91/542/EEC, the current technology nevertheless makes it possible to comply with a more stringent limit than that applicable until 30 September 1995 (0,61 g/kWh for the new types of engines covered by the proposal for a Directive) and considered it important for environmental protection purposes to go along with the Commission proposal to introduce a value of 0,25 g/kWh.

However, by way of a signal to the industry, the Council agreed with the European Parliament that the period of application of the derogation should be reduced by two years. As a result, from 1 October 1997 new types of engine will have to comply with the limit of 0,15 g/kWh laid down in Directive 91/542/EEC.

For reasons of consistency and legal presentation, the Council moved point 2 of the Annex as proposed by the Commission (point 8.3.1.1 no longer appears in Section 8 on conformity of production) and included it as a footnote to point 8.1.1.1.1.

Secondly, and as a consequence of the above, the Council deleted the provisions on tax incentives (ninth and 10th recitals and Article 2), deeming them to be practically devoid of effect, given the short period for which they would apply.

Thirdly, the Council made corrections to the tables on the monitoring of conformity of production (Annex I, Appendix I, table I.1.5 and Appendix 2, table I.2.5).