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Proposal for a second directive on the harmonization of laws and regulations governing branded pharmaceuticals

(Submitted by the Commission to the Council on 24 February 1964)

Explanatory Memorandum

I. GENERAL

The present directive, which is complementary to the directive issued by the Council of Ministers on 5 November 1962, is intended to amplify it by laying down certain provisions concerning the testing of branded pharmaceuticals.

As stated in the explanatory memorandum of the first directive, the problem of tests is one of the most important that have to be solved before there can be fuller harmonization of the regulations governing the offer for sale of branded pharmaceuticals in the Member States.

In making the present proposal the Commission is acting in response to the recommendations of the European Parliament and the Economic and Social Committee which, on being consulted concerning the text of the first directive, urged the Executive to pursue the work of harmonization that had been undertaken in this field.

The aim of this second directive is, in fact, to narrow the more outstanding disparities between the regulations applicable in the different Member States, and so to facilitate the mutual recognition of licences for sale of branded pharmaceuticals, which is the ultimate objective.

This directive contains two sets of provisions prompted by two distinct, but complementary, considerations. It defines the obligations laid upon manufacturers of branded pharmaceuticals by way of guaranteeing the quality of their products, both at the production stage and at the time when the application is made for a licence for sale. The relevant provisions are contained in Chapters I and III.

It was also considered necessary to define the scope of the functions of administrative bodies responsible for the protection of public health. These are concerned with:

- 1) Action taken before the licence for sale is issued, and in particular the examination of the application, so as to make certain that the conditions for granting these licences, as set out in the directive of 5 November 1962, have been fulfilled.
- 2) General supervision by the authorities during the manufacturing process and when the branded pharmaceuticals are offered for sale.

The relevant provisions are contained in Chapters II and IV.

The directive also contains special provisions concerning notification of the competent authorities' decisions to the persons concerned, and the communication of certain of these decisions to the authorities in other Member States: these provisions are contained in Chapter V.

Finally the directive contains provisions concerning implementation and transitional arrangements; among these, Article 13 is of special importance. It is examined in the second part of this Explanatory Memorandum, in which the directive is discussed in detail article by article.

II. COMMENTARY ON THE ARTICLES

Chapter I

Application for licence for sale

The provisions in this chapter are complementary to those in the directive of 5 November 1962. In particular, the chapter contains certain detailed regulations concerning the documentation to be submitted in accordance with Article 4 of that directive.

Article 1

Under the terms of this article, the manufacturer or any other person applying for a licence to sell a branded pharmaceutical must submit to experts, whom he may nominate, the documents specified in Article 4 of the first directive, points 7 and 8. These concern the methods of testing used by the manufacturer, and the results of various trials made by him before deciding to market the product. It should be noted that while the manufacturer has the prerogative of choosing the experts, he is not entirely free, in that he may only choose persons with a certain competence in this field, and the authorities have the power not to approve this choice if the expert is not sufficiently competent.

Article 2

This article sets out the functions of the experts mentioned in Article 1.

Their first duty is to give an opinion on the testing methods used by the manufacturer and on the results they yield.

The object is to ensure that the manufacturer's methods provide a satisfactory test of the product.

Secondly, the experts are asked to give their opinion on the trials the manufacturer has carried out to prove the harmlessness of the product and its therapeutic potency.

Article 3

The intention of this provision is clear. Failure to observe the provisions laid down in Articles 1 and 2 will incur the same penalty as failure to comply with the rules laid down in Article 4 of the first directive concerning the documentation submitted in support of the application for a licence: this penalty consists in rejection of the application.

The severity of the penalty underlines the importance attached to the work of the experts

Chapter II

Examination of the application for a licence for sale

This chapter deals with the powers vested in national authorities to satisfy themselves that branded pharmaceuticals fulfil the conditions laid down.

Article 4

This article deals with the powers of examination enabling the authority to decide whether to grant a licence or refuse it.

These powers include in the first place the examination of documents, including opinions given by the experts. If on examination it is found that the conditions for obtaining a licence have not been fulfilled, the authority is obliged to withhold the licence. It is possible, however, that the documents supplied by the applicant may have an omission or leave room for doubt on certain points. If such shortcomings are not of overriding importance in assessing the documentation, it would appear excessive for a refusal to follow automatically. Allowance has therefore been made for supplementary information or tests to be requested from the manufacturers. This option should only be used in exceptional cases at the discretion of the authorities.

Provision is also made whereby the competent authorities may use their discretion, again in exceptional cases, to order the tests to be repeated by a government laboratory or a laboratory chosen by them, by the same

methods as the manufacturer claims to have used. In this way the authority, should there be any doubt, can satisfy itself that the product conforms to the stated formula.

Article 5

Under this article the competent authorities must ascertain that the manufacturers possess the testing facilities necessary to use the methods described in the documentation. Although this checking by the authorities is prescribed by law in some countries as part of the procedure for licences to manufacture medicinal products, it was considered necessary, pending the harmonization of national regulations on this point, to include the principle in the present directive. The rule is that the manufacturer must himself possess, that is to say on his own premises, these testing facilities.

However, in special cases and on adequate grounds, the competent authority may grant exemption from this regulation, the testing then being carried out by a specialized laboratory.

Chapter III

Testing of the branded pharmaceutical by the manufacturer

Article 6

This provision is an extension of Article 8 of the directive of 5 November 1962, which makes it compulsory for the manufacturer to carry out tests on finished products and supply proof that they have been carried out. Article 6 of the present directive extends this obligation to carrying out tests on the raw materials used, and on products during manufacture, when the nature of the products makes this necessary.

Article 7

As in the provisions of the directive of 5 November 1962 in respect of infringement of Article 8 thereof, failure to meet the requirements of Article 6 involves penalties. These penalties are, however, different from those laid down in the first directive, since infringement of Article 6 of the present directive is less serious. Failure to carry out or furnish proof of tests on finished products incurs the withdrawal or suspension of the licence for sale; the penalty for failure to carry out or furnish proof of tests on raw materials or during manufacture, will only be an order to cease or suspend production.

Chapter IV

Supervision

This chapter deals with the general supervisory duties of public health authorities in connection with the manufacture and sale of branded pharmaceuticals.

Article 8

The first paragraph states the object of inspections, which is to ensure that the legal provisions governing the production and sale of branded pharmaceuticals are observed. The persons carrying out these inspections must be members of the authority's staff. Their powers are specified in the third paragraph. It is laid down that these inspectors must have access to the manufacturing establishments, and also, when certain tests are carried out outside, in accordance with Article 5(2), to the laboratories carrying out these tests; they may take samples, and examine any documents relevant to the inspection. The right to obtain information on the manner in which the product is prepared has, however, been kept within limits; in order to safeguard manufacturing secrets, this power is limited to the descriptions given by the manufacturers in their application for a licence for sale.

Article 9

This is a measure to prevent branded pharmaceuticals already on the market from continuing to be distributed when they have incurred a penalty as provided in the directive of 5 November 1962 or in the present directive.

Chapter V

Miscellaneous

Article 10

This article does not appear to call for any special comment.

Article 11

This article does not appear to call for any special comment.

Article 12

This article provides for exchange of information between national authorities on the more important decisions which they are called upon to take concerning the sale of

branded pharmaceuticals, so as to avoid discrepancies and possible repercussions thereof. This provision has been introduced in response to the recommendations of the Economic and Social Committee (see Opinion of 25 April 1963 — doc. 18/3) and international organizations such as the World Health Organization and the Council of Europe.

This provision can also be considered as inaugurating closer co-operation between national authorities.

Chapter VI

Implementing arrangements and transitional measures

Article 13

The need for general quality standards for medicinal preparations (as regards purity, stability, etc.), has been stressed on several occasions. Concurrently with work being done by the World Health Organization and the Council of Europe, the Commission has undertaken the preparation of a European pharmacopoeia.

The Commission also felt it desirable to take the initiative of studying, in collaboration with the competent authorities of the Member States and with the assistance of scientific circles in the Community, standardized methods for carrying out various tests on medicinal products (physico-chemical, biological, microbiological, pharmacological, toxicological and clinical tests), and for evaluating their results.

Two interconnected series of studies are consequently in progress, the results of which should have a favourable influence from both the public health and economic points of view.

From the public health angle, the work on the pharmacopoeia and on test procedures is unquestionably of interest, because of the advantages and guarantees that any normalization brings to the scientific sector, and also because these studies will enable all manufacturers of pharmaceuticals in the Community to make use of the most advanced technical knowledge.

On the economic side, the compilation of a pharmacopoeia will be particularly valuable as regards rationalizing production; so far as test procedures are concerned, they will enable those who carry out tests of medicinal products to know the rules for carrying out tests (their duration, the means applied, etc.) and for assessing and presenting the results.

All this work will also add to the efficiency of the competent authorities' tests of medicinal products, and to a large extent avoid discrepancies in assessing the results of tests submitted with an application for a licence to sell a branded pharmaceutical.

Establishing the standards and procedures provided for in this article will call for complex studies over a long period. Continual revision will also be necessary. However, it seemed advisable to stress the gradual nature of this work and the need to apply the first results as soon as possible, in the interests of both public health and production, by setting a date for the first phase.

Article 14

Paragraph 1 of this article does not appear to call for any special comment. Paragraph 2 was included to enable the Commission to be informed reasonably promptly of any plan drawn up by Member States in the fields covered by the present directive, so that the Commission may present its comments.

Article 15

This article does not appear to call for any special comment.

Article 16

This article does not appear to call for any special comment.

Proposal for a second directive on the harmonization of laws and regulations governing pharmaceutical products

(Submitted by the Commission to the Council)

The Council of the European Economic Community,

Having regard to the provisions of the Treaty establishing the European Economic Community, and particularly Articles 100 and 155 thereof;

Having regard to the directive on the harmonization of laws and regulations governing pharmaceutical products of 5 November 1962;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Having regard to the opinion of the Economic and Social Committee;

Whereas disparities in certain national laws have the effect of hindering trade in pharmaceutical products within the Community, and whereas this affects the establishment and operation of the Common Market;

Whereas the directive of 5 November 1962 laid down certain principles with a view to achieving the harmonization of laws concerning the sale of branded pharmaceuticals;

Whereas it is important to pursue the harmonization begun by the directive of 5 November 1962 and to ensure that the principles laid down by that directive are applied;

Whereas among the remaining disparities, those affecting the testing of branded pharmaceuticals are of primary importance;

Whereas with a view to reducing these disparities, it is important to establish rules which manufacturers of branded pharmaceuticals must observe in testing their products, and to define the duties to be carried out by national authorities to ensure that legal requirements are observed;

Whereas so as to ensure the operation and development of the Common Market the Commission must be able to exercise certain powers for the execution of the directive of 5 November 1962,

Has issued the present directive:

Chapter I

Application for licence for sale

Article 1

Member States shall take the necessary measures to ensure that the particulars and supporting documents referred to in Article 4(2), points 7 and 8 of the directive of 5 November 1962 shall be referred by the applicant to experts having the necessary technical or professional qualifications before being submitted to the competent authorities.

Article 2

The experts mentioned in Article 1 shall give their opinion:

1. On the methods of testing referred to in Article 4(2), point 7 of the directive of

5 November 1962 and the results obtained by these methods:

2. On the results of physico-chemical, biological, micro-biological, pharmacological, toxicological and clinical tests carried out.

Article 3

In the event of infringement of the provisions of Articles 1 and 2 of the present directive, Article 5(2) of the directive of 5 November 1962 shall be applicable.

Chapter II

Examination of application for licence for sale

Article 4

The Member States shall take the necessary measures to ensure that the competent authorities shall, within the time-limits laid down in Article 7, paragraph 1, point 2, and paragraph 2 of the directive of 5 November 1962 examine the application in order to satisfy themselves that the conditions for obtaining a licence for sale have been fulfilled.

To this end, the competent authorities:

1. Shall check the particulars submitted in accordance with Article 4 of the directive of 5 November 1962 and shall verify that the opinions given by the experts in accordance with Article 2 of the present directive are comprehensive and conclusive;

2. May request the manufacturer to supply additional information or carry out additional tests;

3. May submit the product to a State laboratory or a laboratory designated for this purpose to repeat the tests carried out by the manufacturer, by the methods described in the documentation in accordance with Article 4(2), point 7, of the directive of 5 November 1962.

When the competent authorities exercise the prerogative mentioned in point 2 of the foregoing paragraph, the time-limits laid down in Article 7, paragraph 1, point 2 and paragraph 2 of the directive of 5 November 1962 shall be waived.

Article 5

The Member States shall take the necessary measures for the competent authorities to check that the manufacturers are able:

1. To make the tests by the methods described in the documentation and mentioned in Article 4(2), point 7, of the directive of 5 November 1962;

2. In exceptional cases, good cause being shown and provided the competent authorities are in agreement, to have some of the tests prescribed in point 1 above carried out on their own responsibility.

Chapter III

Tests of branded pharmaceuticals by the manufacturer

Article 6

The Member States shall take the necessary steps to ensure that the holder of a licence to sell a branded pharmaceutical shall be obliged to furnish proof, whenever requested, that tests on raw materials have been carried out and also tests in the course of production in so far as the latter are necessary for a manufacturing process in accordance with the regulations in force.

Article 7

The Member States shall take the necessary steps to ensure that the production of a branded pharmaceutical shall be temporarily or permanently stopped if, after receiving a formal notice, the holder of the licence for sale cannot furnish the proof specified in Article 6.

Chapter IV

Supervision

Article 8

The competent authorities shall ensure by carrying out inspections that the regulations concerning the production and sale of branded pharmaceuticals are complied with.

The inspections referred to in the foregoing paragraph shall be carried out by the appropriate personnel of the competent authorities.

The above-mentioned personnel must be empowered:

1. To visit manufacturing establishments and laboratories responsible for carrying out tests on behalf of the manufacturer in accordance with the provisions of Article 5, point 2;

2. To take samples;

3. To take note of all documents relevant to the object of the inspections, apart from descriptions of methods of preparation when these descriptions go beyond those contained in the documentation submitted in support of the application for a licence for sale in accordance with Article 4(2), point 4, of the directive of 5 November 1962.

Article 9

The Member States shall take the necessary measures to ensure that deliveries of the branded pharmaceutical shall be forbidden and that the product shall be withdrawn from the market, in cases where:

1. When used under normal conditions, the product appears to be harmful;
2. The product is deficient in therapeutic potency or the applicant supplies inadequate proof of it;
3. The product has not the qualitative and quantitative composition claimed for it;
4. Tests on the finished product have not been carried out;
5. Production has been stopped in pursuance of Article 7 of the present directive.

Chapter V

Miscellaneous provisions

Article 10

Any decision taken under the terms of the present directive shall be accompanied by a precise statement of grounds. It must be notified to the person concerned, with an indication of the procedure for appeal under the existing law and of the time-limit within which such appeal must be lodged.

Article 11

No order for the permanent or temporary stoppage of manufacture, ban on deliveries of the product, or withdrawal from the market may be made except for the reasons stated in the present directive.

Article 12

Member States shall take the necessary measures to ensure that decisions to refuse or withdraw licences for sale, to stop manufacture permanently or to withdraw products from the market, and the grounds therefor shall immediately be brought to the notice of the other Member States.

Chapter VI

Arrangements for implementation and transitional measures

Article 13

On publication of the present directive, the Commission, in collaboration with the competent authorities of the Member States, shall undertake the establishment of common standards and of procedures for the testing of medicinal preparations as provided for in Article 4(2), point 8, of the directive of 5 November 1962.

Article 14

The Member States shall enact the necessary laws and regulations to conform with the provisions of the present directive within twelve months of its notification and shall inform the Commission immediately.

The Member States shall inform the Commission, in time for it to submit comments, of any further draft laws or regulations which they may contemplate adopting in the matters covered by the present directive.

Article 15

The regulations provided for by the present directive shall be applicable to products which have been granted a licence for sale by virtue of previous provisions two years after the notification referred to in Article 14.

Article 16

The present directive is addressed to the Member States.

Proposal for a Council regulation concerning the application of Article 85(3) of the EEC Treaty to certain classes of agreements, decisions and concerted practices

(Submitted by the Commission to the Council on 28 February 1964)

Explanatory Memorandum

Article 85(3) of the Treaty provides that, subject to four conditions therein specified, the prohibition contained in Article 85(1) may be declared inapplicable to certain agreements between undertakings, decisions by associations of undertakings, or concerted practices considered either separately or by classes. In the light of the experience and knowledge gained since Regulation No. 17 was issued ⁽¹⁾, the Commission now proposes that the Council should also, on the basis of Article 87 of the Treaty, make regulations governing procedure for exemption by classes, which would contribute towards implementing the principles laid down in Articles 85 and 86 in such a way as to meet the requirements of Article 87 (2 b) regarding effective supervision and simplicity of administrative control. Exemption by classes would make it possible to deal with some of the notifications immediately. Moreover, its effect would be to reduce appreciably the number of subsequent notifications, because class exemption would offer a certain guidance: it would lead undertakings to conclude, in future, only such agreements as do not contain any restrictions other than those allowed in exemption by classes.

The Commission had itself considered instituting exemption for certain classes of exclusive dealing agreements, and announced this intention in a communication of 9 November 1962 ⁽²⁾. On 13 December 1962, however, the Consultative Committee on Cartels and Monopolies advised against this course on the grounds that Regulation No. 17 did not provide the Commission with a legal basis for applying Article 85(3) by classes. Three of the members recommended "submitting a proposal to the Council that it should empower the Commission to apply Article 85(3) to classes of agreement" and the other members of the Committee raised no objection. The Economic and Social Committee expressed the hope that regulations concerning class exemptions would be drawn up as soon as possible ⁽³⁾. Members of the European Parliament have on various occasions shown interest in this matter ⁽⁴⁾.

When the Council has approved the present regulation, class exemption should be consid-

ered in the first place for bilateral exclusive dealing agreements, in view of the fact that 31 000 such agreements have been notified in pursuance of Regulation No. 17. They frequently concern common or comparable factual situations, so that the conditions of Article 85(3) can be assessed in terms of a type of agreement in which the interests of the third parties concerned, competitors and consumers, are largely identical. The regulation would be mainly on the lines of the communication of 9 November 1962 ⁽⁵⁾ and would take into consideration the experience gained in the meantime.

With a view to uniform application, the proposed class exemption follows as closely as possible the procedure provided under Regulation No. 17 for individual exemptions.

The Commission can only make an enactment providing for class exemption if the classes of agreements, decisions, or concerted practices ⁽⁶⁾ concerned (Article 1) satisfy the four conditions of Article 85(3) of the Treaty. Exemption is granted by way of special regulation (Article 2) setting out those conditions explicitly. Its content, in order to provide legal security, must be sufficiently concrete for the exempted situation to be easily distinguished from non-exempted situations.

Agreements which are covered by the exemption and already notified need no longer be examined, which means a substantial reduction in the amount of work to be done by the Commission and its relevant departments.

As it is only proper that the parties concerned should enjoy legal security, the Commission may only in exceptional cases alter or revoke a class exemption, when circumstances have substantially changed since the regulation was made [Article 2(2)]; such revocation or alteration will not be retrospective. The Consultative Committee on Cartels and Mono-

(1) Official gazette of the European Communities, No 13, 21 February 1962, p. 204.

(2) *Ibid.*, No 113, 9 November 1962, p. 2627.

(3) Opinion rendered by the Economic and Social Committee on 30 October 1963, Document CES 234/63, Chap. II, p. 4.

(4) See M. Deringer's Written question No 95 and M. Blaisse's Nos 119 and 126 (Official gazette of the European Communities, No 112, 7 November 1962, p. 2617; No 2, 12 January 1963, p. 13; No 13, 26 January 1963, p. 141).

(5) Official gazette of the European Communities, No 113, 9 November 1962, p. 2627.

(6) Hereinafter referred to collectively as agreements (Translator's note).

polies must first be heard [Article 6 (1 a)]; the essential content of the proposed regulation must be published (Article 5); then the Consultative Committee on Cartels and Monopolies must again have the opportunity of expressing its views [Article 6 (1 b)]. By this procedure the parties will have the assurance that a class exemption will not be substantially altered except after careful consideration of the circumstances.

Should an individual agreement affected by a class exemption produce exceptional effects incompatible with the four conditions set out in Article 85(3) of the Treaty, the Commission will be empowered to make the future validity of the exemption subject to certain conditions (Article 7). In these cases also the Consultative Committee on Cartels and Monopolies must be heard (Article 10 of Regulation No. 17), after the parties concerned have been given a hearing in accordance with the provisions of Regulation No. 99/1963/EEC ⁽¹⁾.

It is advisable that class exemption should have retrospective effect as provided under Article 6 of Regulation No. 17 in the case of agreements considered individually (Article 3).

Agreements already in existence on 13 March 1962 in which only two undertakings are concerned should also be eligible for class exemption in respect of the period during

(1) Official gazette of the European Communities, No 127, 20 August 1963, p. 2268.

which they did not fulfil the conditions imposed, as soon as they have been appropriately adjusted (Article 4). Such adjustment must be made within three months of the putting into effect of the class exemption and notified to the Commission. This notification will not involve a great deal of extra work for the Commission: it will simply be a matter of filing a document certifying that an agreement has been modified. The intention is to prevent unlawful agreements from continuing in existence and being adjusted only after a number of years, whilst obtaining retrospective validity on the pretence that they were adjusted within the prescribed time-limit. To avoid needless notifications, it is provided that there is no need, in order to benefit by this clause, to make the notification provided for under Article 7(2) of Regulation No. 17 before 1 January 1967.

The interests of the parties concerned in class exemptions will be borne in mind; the essential content of the draft regulation granting, renewing, altering or revoking an exemption will be published, so that the parties can submit their comments (Article 5).

The Commission must twice seek the opinion of the Consultative Committee on Cartels and Monopolies (Article 6): first before the above-mentioned publication, and again before the adoption of the regulation.

This will ensure close and constant liaison with the authorities of the Member States and liberal collaboration by those authorities in instituting class exemption.

Proposal for a Council regulation on the application of Article 85(3) of the EEC Treaty to classes of agreements, decisions, and concerted practices

(Submitted by the Commission to the Council)

The Council of the European Economic Community,

Having regard to the provisions of the Treaty establishing the European Economic Community and in particular Article 87 thereof;

Having regard to the Commission's proposal:

Having regard to the Economic and Social Committee;

Having regard to the opinion of the European Parliament;

Whereas Article 85(1) of the Treaty may, in accordance with paragraph 3 of the said Article, be declared inapplicable to classes of

agreements, decisions or concerted practices ⁽¹⁾ that satisfy the conditions prescribed therein; whereas this way of applying Article 85(3) will simplify administrative control without impairing efficacy of supervision; and whereas Regulation No. 17, the first implementing regulation pursuant to Articles 85 and 86 of the Treaty, needs to be supplemented by provisions for applying Article 85(3) by way of regulation;

Whereas the application of Article 85(3) by decisions relating to individual cases has been entrusted to the Commission by virtue of Regulation No. 17; whereas it is advisable

(1) Hereinafter referred to collectively as agreements (Translator's note).

that the Commission should also have sole competence to apply Article 85(3) by way of regulations concerning classes of agreement, so as to ensure uniform application of Article 85 within the Common Market; and whereas in either case the Commission should exercise these powers in close and constant liaison with the competent authorities of the Member States;

Whereas at the date of entry into force of a regulation exempting a certain class of agreement from the ban of Article 85(1) there may already exist numerous agreements which fall within this class and which may also, in accordance with Article 6 of Regulation No. 17, benefit retrospectively by Article 85(3); and whereas it is advisable that regulations exempting classes of agreement should have retrospective effect, and thus render unnecessary any individual decision to apply Article 85(3), which would be a mere formality;

Whereas Regulation No. 17 makes special provision in favour of agreements already in existence on 13 March 1962 which have been notified to the Commission within a specified time-limit and which fall under the prohibition of Article 85(1) without qualifying for the application of Article 85(3); whereas by virtue of Article 7 of the said regulation, such agreements may be absolved from the said prohibition if they are modified in such a way as to meet the requirements of Article 85(3); and whereas it is expedient that the Commission should be empowered to grant, by way of regulation, the same advantages in respect of such agreements if they are modified so as to fall within a class defined by an exempting regulation;

Whereas legal security in respect of agreements which come within a class defined by an exempting regulation must, as far as possible, be identical with that arising from a decision to issue a declaration under Article 85(3) taken in accordance with Article 8 of Regulation No. 17; whereas it is proper that the undertakings and associations of undertakings concerned should be informed of the length of time for which exemption applies; and whereas, nevertheless, since exemption cannot be obtained except under the conditions laid down in Article 85(3) the Commission should be empowered to revoke or alter an exempting regulation where there is a change of circumstances in respect of one of the essential factors on which the regulation was based, and to stipulate the further conditions required if an agreement which by reason of particular circumstances gives rise to certain consequences that are incompatible with Article 85(3) is to remain exempt,

Has made the present regulation:

Article 1

The Commission shall have sole competence to declare the provisions of Article 85(1) of the Treaty to be inapplicable to certain classes of agreements, decisions and concerted practices ⁽¹⁾ in accordance with Article 85(3) of the Treaty.

Article 2

1. Class exemption shall be established by regulation for a specified term.
2. The Commission may, by way of regulation, revoke or alter a class exemption before the expiry of the term if there is a change of circumstances respecting an essential factor.

Article 3

The Commission may provide that a class exemption may apply retrospectively to agreements which, at the date of entry into force of the exempting regulation, were eligible for a retrospective decision under Article 6 of Regulation No. 17.

Article 4

1. In a regulation exempting a class of agreements, the Commission may stipulate that the prohibition in Article 85(1) shall not apply, for a stated period, to agreements which were already in existence on 13 March 1962 and which did not meet the requirements of Article 85(3) —

- a) if only two undertakings are concerned; and
- b) if the agreements are modified within three months of the entry into force of the exempting regulation so that they become eligible for class exemption; and
- c) if the Commission is notified of such modification within the time-limit it has prescribed.

2. Provided that the foregoing paragraph shall be applicable to agreements that were required to be notified before 1 February 1963, in accordance with Article 5 of Regulation No. 17, only if they were so notified.

Article 5

When the Commission intends to declare, renew, alter, or revoke a class exemption, it shall publish the essential content of the

(1) Hereinafter referred to collectively as agreements (Translator's note).

proposed regulation, inviting all interested parties to make known their comments within a specified time-limit which shall be not less than one month.

Article 6

1. The Commission shall seek the opinion of the Consultative Committee on Cartels and Monopolies —

a) before making the publication provided for in Article 5;

b) before declaring, renewing, altering or revoking a class exemption.

2. Article 10 (5 and 6) of Regulation No. 17, concerning reference to the Consultative Committee, shall be applicable by analogy.

Article 7

1. Should the Commission find, in consequence of a request or *ex officio*, that an agreement falling within a class defined in an exempting regulation nevertheless entails effects that are incompatible with the conditions laid down in Article 85(3) of the Treaty, it may, by means of a decision addressed to the undertakings or associations of undertakings concerned, make exemption subject to conditions designed to eradicate the said effects.

2. Article 10 (5 and 6), Article 19 (1 and 2) together with its implementing provisions, and Article 21 of Regulation No. 17, concerning respectively reference to the Consultative Committee, hearing of the parties concerned and of third parties, and the publication of decisions, shall be applicable by analogy.

The present regulation shall be binding in every respect and directly applicable in each Member State.

Draft Council directive concerning arrangements for freedom to supply services connected with agriculture and horticulture

(Submitted by the Commission to the Council on 3 March 1964)

Explanatory Memorandum

1. Basis of the proposal

The general programme for the removal of restrictions on the supply of services ⁽¹⁾, adopted by the Council on 18 December 1961, contains a special provision laying down for agriculture and horticulture a liberalization plan in three stages, as from the end of 1963 (Title V-C-d). The text of this provision is as follows:

“Title V: Time-table.

The removal of restrictions will take place:

[...]

d) For agriculture and horticulture:

1. Before the expiry of the second year of the second stage for:

i) Technical assistance;

ii) The destruction of weeds and vermin; spraying of plants and soil; pruning, picking, packing and packaging, the running of irrigation systems and the hiring out of agricultural machinery.

2. By the end of the second stage for work involving the care and dressing of soil or crops, harvesting, threshing, pressing and gathering whether done by hand or mechanical means.

3. By the end of the third stage for services not included in the above list.”

In accordance with Article 63(2) of the Treaty, the Commission submits the present proposal to the Council with a view to putting the above provision into effect.

The same article lays down that the Council must consult the Economic and Social Committee and the European Parliament before taking its decision by qualified majority.

2. Measure covering all agricultural and horticultural services.

1. In submitting its draft general programme to the Council, the Commission drew attention to the requirement in Article 63(3) of the Treaty that agricultural services should be given priority in liberalization, since they directly affect production costs (see second point in the considerations of the present proposal).

(1) Official gazette of the European Communities, No 2, 15 January 1962, p. 32/62.

It was therefore proposed that all these services should be grouped together to be dealt with at the earliest possible date compatible with the periods that must elapse before the various parts of the programme could be put into operation, i.e. by the end of the second year of the second stage of the transitional period. At the same time, without disputing the sound basis of this proposal, some of the Member States insisted that only a part of these services should be scheduled for liberalization before 31 December 1963. The Commission and the Council therefore decided that the liberalization measures should be split up, some being introduced before, others after the above date. The third group of services, the liberalization of which is not to take place until the third stage, was at that time considered to be mainly residual; subsequent studies showed that the importance of this group had been somewhat underestimated.

2. As in several other sectors of activity, the directive took longer to prepare than was expected at the time when the general programme was being drawn up, so that the measures applicable to the first group of services will come into force after a delay which will cause them to coincide with the second group (Article 6 1 a) of the proposal).

With a view to lightening the task, the Commission proposes that the Council should adopt immediately the provisions dealing with the third group, of which the content is practically speaking limited to services connected with stock-raising. In this way the liberalization of agricultural and horticultural services can be covered by a single Community text.

3. Favourable influence on agricultural development

Rapid progress has been made in agriculture within the Community, since it has been possible, after completing the initial stage of the removal of obstacles to trade, to go a long way towards drawing up a common policy. For this policy to succeed, it is important that progress should also be made in other sectors of economic integration which, while not coming under common policy, still have a certain relationship with it.

The growth of services and their improved efficiency due to the keener competition that springs from liberalization will have a favourable influence on the development of agriculture. Just as a healthy economic structure cannot exist on a national or regional level without a sufficiently developed services sector, the rapid adaptation of agriculture and its full integration into the economy are out of

the question unless the services required by this sector are fostered along appropriate lines.

In the growth of productivity without which the hoped-for development of agriculture cannot be realized, liberalization of the supply of services between Member States will encourage technical progress and the rationalization of agricultural production, as well as optimum use of the factors of production within the sector. Among the main activities likely to benefit from the liberalization of services, technical assistance, for instance, has a direct effect on the farmer's decisions and action, by acquainting him with new methods of management and techniques and persuading him to accept and assimilate them; with their aid he will be able to adapt his produce and marketing to economic needs. Similarly, the more ready availability of outside services, offered at competitive prices and using powerful or specialized equipment operated by skilled men, offers various advantages to the farmer. He can avoid being over-equipped and can solve temporary or permanent manpower problems; he can organize his work more rationally, correlate his means of production more efficiently, and adapt them to the needs of the market more easily (see second point in the considerations).

4. Persons benefiting by the measures proposed

A brief review of the present situation regarding the supply of services in agriculture within Member States will give an idea of the probable effects of the liberalization measures which the Commission proposes the Council should include in its directive.

1. Services in agriculture and horticulture are provided by different categories of suppliers.

Assistance in technical matters is most often provided by specialized firms or consultants, for instance in the field of management and accounting. It is also supplied as one of the activities of co-operatives or professional associations, or, as a supplementary service, by private firms selling primary products and other materials used in agriculture.

A large amount of agricultural work is done by contractors. There are approximately 8 000 of them in the Federal Republic of Germany, 3 000 in Belgium, 8 000 in France, 25 000 in Italy, 40 in the Grand Duchy of Luxembourg, and 4 000 in the Netherlands. From unofficial and unfortunately very incomplete figures, it appears that in Belgium, for example, where small contractors are still very numerous, the average capital invested in machines by each undertaking was over Bfrs. 2 million in 1961. The land improvement works now proceeding in most of the countries of the Community offer an incen-

tive to a growing number of contractors to acquire specialized heavy equipment. In view of the increasing variety of mechanized operations, a fair number of them can now work for most of the year ⁽¹⁾. In France 70% of the contractors extend their activities over nine months of the year.

A large amount of work is also done for farmers by co-operatives and associations of farmers specially set up for the collective use of agricultural machinery. It is estimated that there are today around 850 organizations with more than 10 members and 5 000 smaller ones serving this purpose in Germany; in Belgium, 117 co-operatives with more than 10 members and 183 smaller ones, in France around 10 000 co-operatives with more than 10 members, in Luxembourg 153 associations and in the Netherlands 209 co-operatives. In Italy, collective ownership and use of machinery by groups of less than five farmers is very common, but the number of co-operatives is comparatively small.

It should also be remembered that in all the member countries many farmers occasionally use their machinery to do work for others, usually by way of mutual aid.

2. Probably agricultural engineers and contractors will be the principal beneficiaries of the liberalization measures proposed in the present directive.

Admittedly, up to now only a few of them cover a wide area. Moreover, the rendering of services across frontiers which should be possible as things stand, has so far come up against insuperable obstacles. There are discrepancies between regulations governing the movement and use of equipment (dimensions, licensing, safety standards, etc.), and in addition customs concessions for temporary imports have too often been withheld by Member States anxious to protect the interests of their own contractors, equipment co-operatives or machinery manufacturers.

However, the liberalization of services in agriculture and horticulture will take place at a moment when the situation is radically changing. As we have seen, these firms are now expanding rapidly. Some of them are specializing and increasing the number of their operating units; they can, for example, undertake extensive land consolidation works a long way from their base, or move combine harvesters several hundred kilometres in the course of a season to gather different crops (wheat, clover heads, maize and rice).

(1) Some operations often carried out by agricultural engineers and contractors (drainage, irrigation, silviculture and forestry) are, however, not covered by the directive. (see fifth point in the considerations).

Others prefer to widen the range of their equipment, so as to have a fleet capable of meeting most of the needs of farmers in their region. Under conditions which vary according to their size, their location and the kind of services they offer, there is no doubt that many of these firms will take advantage of the liberalization of services, whether it be in frontier areas, in the interior of a neighbouring Member State, or even at far greater distances. This extension of their activities will improve their productivity and the profitability of their equipment; thus the directive will be beneficial both to farmers, as we have seen above, and contractors.

It will also be easier to liberalize services at the conclusion of the work at present being done by the Community on the removal of the technical obstacles mentioned above, which do not legally fall within the purview of the directive. Furthermore the recommendation addressed by the Commission to Member States on 8 November 1962, proposing to make temporary duty-free admission the general practice for equipment used in supplying services, represents for the agricultural sector a great improvement on the previous situation (see penultimate point in the considerations).

As regards the consequences of the directive for the large sector constituted by agricultural service co-operatives, the picture is different.

Article 58 of the Treaty, which is referred to in Article 66 in the chapter on services, makes express mention of "co-operative societies" as being among the legal persons assimilated to natural persons benefiting from freedom to supply services. Co-operatives must therefore be included among the suppliers of services referred to in Title I of the General Programme and in principle will benefit from the directive (see Article 1 of the proposal).

The possibility of an agricultural co-operative supplying services in a Member State other than the one in which it is based can be examined in respect of two categories of farmers receiving the service, those who are members of the co-operative and those who are not. In the case of farmers who are not members of the co-operative, the latter would be considered as working for third parties; under national regulations at present in force for agricultural service co-operatives, this is entirely forbidden in one of the member countries and subject to certain restrictions in several others. In the case of the services to be supplied to farmers who are members of the co-operative, under existing regulations this does not appear to be permissible, at any rate in certain member countries, where agricultural co-operatives cannot supply services outside a strictly limited area.

From an examination of provisions now in force in member countries it would appear that the liberalization of services will have very little effect on the activities of agricultural service co-operatives, at least until some of these provisions are modified. The Com-

mission hopes that Community solutions will one day be found to the difficulties arising in this matter, solutions serving the interests of farmers as well as those of the agricultural service co-operatives, particularly in frontier areas.

Proposed draft Council directive on arrangements to liberalize services in agriculture and horticulture

(Proposal submitted by the Commission to the Council)

The European Economic Community,

Having regard to the Treaty establishing the European Economic Community and in particular Articles 63(2 and 3), 106(1) and 227(2) thereof;

Having regard to the General Programme for removal of restrictions on freedom to supply services ⁽¹⁾ and in particular Title V-C-d thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Having regard to the opinion of the Economic and Social Committee;

Whereas the General Programme has a special time-table for the removal of restrictions with regard to agriculture and horticulture; and whereas the removal of such restrictions was to take place before 31 December 1963 for a first group of services, before the end of the second stage of the transition period for a second group and during the third stage for other services;

Whereas these services directly affect production costs in agriculture and horticulture and assist technical progress, whereas their liberalization must therefore be achieved as soon as possible, in accordance with Article 63(3) of the Treaty and the aims of the common agricultural policy;

Whereas freedom of establishment in occupations covered by the directive is scheduled only for the end of the transition period ⁽²⁾, except for certain paid agricultural workers who benefit under the Council directive of 2 April 1963 ⁽³⁾; and whereas a person being

free to supply services in another member country must not be obliged to satisfy requirements which persons established in that country satisfy merely because their activities are stable and permanent, such as the requirement, in some Member States and in certain circumstances, that such persons be enrolled in the commercial register and affiliated to a professional organization;

Whereas, in view of this difference between the arrangements and timing for the right of establishment and those for freedom to supply services, it is necessary to state in the directive the meaning of supply of services as regards the category which involves the supplier moving to the client's country;

Whereas freedom to supply services in most operations concerned with water-catchment, irrigation, drainage and land reclamation — which are often necessary for certain agriculture and horticultural activities covered by the directive — should be instituted by applying the Council directives of ... and ..., concerning respectively manufacturing and craft industries ⁽⁴⁾ and public works contracts ⁽⁵⁾; and whereas, in accordance with the General Programme, the supply of services in sylviculture and forestry will be the subject of a later directive;

Whereas the arrangements applicable to paid workers accompanying suppliers of services or working on their account are governed, so far working conditions and social security are concerned, by measures taken in pursuance of Articles 48, 49 and 51 of the Treaty;

Whereas conditions relating to movement and residence for all persons exercising freedom of establishment and freedom to supply services are the subject of two directives issued by the Council on ... ⁽¹⁾;

Whereas for freedom to supply services in agriculture and horticulture special importance must be attached to the Recommendation

(1) Official gazette of the European Communities, No 2, 15 January 1962, p. 32/62.

(2) General Programme for the removal of restrictions on freedom to supply services (Official gazette of the European Communities, No. 2, 15 January 1962, p. 36/62, Title IV-F-6 and Annex V ex group 012.

(3) Official gazette of the European Communities, No 62, 20 April 1963, p. 1323/63.

(4) Official gazette of the European Communities No. ... p./6

(5) *Ibid.*, No p./6

(6) *Ibid.*, No p./6

made by the Commission to member countries on 8 November 1962, (1) whereby "implements, appliances or equipment ... which are temporarily imported into one Member State from another Member State, to be used in the performance of any kind of work in the importing Member State, shall be covered by the rules governing temporary importation provided that they do not remain in the importing Member State for more than six months"; and whereas such temporary admission should be duty-free, save in exceptional cases where payment of a proportion of the duties imposed on permanent importation may be required:

Whereas freedom to supply services in agriculture and horticulture, particularly as regards technical assistance and the use of dangerous toxic products, will be facilitated by mutual recognition of diplomas, certificates or other qualifications, and by the co-ordination of certain national regulations; and whereas these matters should be the subject of later directives,

Has issued the present directive:

Article 1

The Member States shall remove, in respect of individuals and companies mentioned in Title I of the General Programme for the removal of restrictions on freedom to supply services, hereinafter referred to as beneficiaries, the restrictions mentioned in Title III of the said programme, regarding the supply of services in the branches of activity mentioned in Article 2 below.

Article 2

1. The provisions of this directive shall apply to the supply of services in agriculture and horticulture included under Title V-C-d of the General Programme, that is to say:

- a) Technical assistance;
- b) The destruction of weeds and vermin, the spraying of plants and soil;
- c) Pruning;
- d) Picking, packing and packaging;
- e) The operation of irrigation systems;
- f) The hiring out of agricultural machinery;
- g) The care of dressing of soil or crops;
- b) Harvesting, threshing, pressing and gathering whether or not by mechanical means;
- i) Other services not listed above.

2. By agriculture and horticulture, for the purposes of this directive, is meant the field of activity included in group 011 of the International Standard Industrial Classification of All Economic Activities (Statistical Office of the United Nations, Statistical Papers, Series M, No. 4, Rev. 1, New York 1958), i.e. mainly:

a) General agriculture, including vine-growing and tropical crops; stock-raising, poultry-raising, rabbit-raising, raising fur-bearing animals, and various other types of animal husbandry; bee-keeping; the production of meat, milk, wool, hides and furs, eggs and honey;

b) Market gardening, the growing of flowers and ornamental plants, whether or not under glass; fruit-tree cultivation and seed production.

3. A detailed list of the services to be included under each of the sections of paragraph 1 is given in an annex to the present directive.

Article 3

1. Freedom to supply services shall include, so far as the beneficiaries of the present directive are concerned, the right to undertake in the territory of Member States other than that in which they are established the preliminary operations necessary for the supply of services, especially seeking clients by advertising and canvassing and making contracts.

2. Should the supplier go to the country where his client resides to pursue his occupation, there is for the purposes of the present directive a supply of services if the supplier's place of business is and remains in a Member State other than that in which he supplies the service.

The supplier can, however, within this State and in the same way as its nationals, acquire, rent, use and dispose of movable or immovable property which he needs to perform his services. Provided that this property does not constitute a permanent establishment in the form of a branch or agency.

3. For the category of services mentioned in paragraph 2, the Member State in which the service is rendered may request the supplier to state the date from which he has been pursuing his occupation in its territory: the supplier may furnish proof of this in any legally valid form. If the supplier supplies several clients, he must if necessary furnish information on each service or series of services separately.

Article 4

1. When the performance of a service included in Article 2, or the enjoyment of rights and privileges attached to it are subject, in the

(1) Official gazette of the European Communities No. 125, 30 November 1962, p. 2767/62.

Member State where the service is rendered, either to enrolment in a commercial register, or to membership of a trade association or other organization of the kind, the beneficiaries of the present directive shall not be obliged to fulfil either of these conditions unless they are rendering a service or a series of services lasting more than three months in any one calendar year.

2. The Member States shall ensure that, in the latter case, it shall be open to beneficiaries of the present directive to enrol in the said register or join the said association with the same rights as nationals, with due regard to the special situation of these beneficiaries, and within the normal period of time.

The right of affiliation does not necessarily include, so far as the beneficiaries of the present directive are concerned, the right to be elected or appointed to office in such associations. In the Grand Duchy of Luxembourg, membership of the Chamber of Commerce does not imply that these beneficiaries have the right to take part in the election of the managing bodies.

3. When the enrolment or affiliation mentioned in paragraph 1 is subject, in a Member State, to furnishing proof of good character or of not having previously been bankrupt or both, the State shall accept as sufficient the production by beneficiaries of the present directive of an extract from their *casier judiciaire* (police record), or failing that an equivalent document, issued by the competent legal or administrative authority of the country where they are established, showing that these requirements have been met.

When the country where the supplier is established does not issue documents testifying to non-bankruptcy, these can be replaced by a declaration made by the person concerned under oath, in the said country, before a legal or administrative authority, a lawyer or a qualified professional organization.

The documents drawn up in accordance with the two foregoing paragraphs must not be dated more than three months earlier than the date on which they are submitted. Member States shall inform one another of the authorities and organizations qualified to issue them, at the same time informing the Commission, within the time-limit laid down in Article 6 (1 a).

Article 5

1. Every Member State shall remove any restriction which places suppliers of services who are nationals of other Member States in a less advantageous position than its own nationals, by prohibiting or hindering the said

suppliers from pursuing their professional activities in its territory, whether the said restriction arises from

a) a law or regulation, or an explicitly discriminatory administrative practice;

b) from a law or regulation or an administrative practice which, although not explicitly discriminatory, does in fact hinder mainly or exclusively the activities of non-nationals.

2. The restrictions to be removed are principally those contained in provisions which forbid or limit the supply of services by beneficiaries in the following ways:

a) *In the Federal Republic of Germany:* by making it necessary to have a "Reisegewerbekarte" before paying exploratory visits to individuals with a view to obtaining orders (Gew.O. of 5 February 1960 para. 55 d; regulation of 30 November 1960);

By making the issue of the said "Reisegewerbekarte" subject to economic needs ("Bedürfnisprüfung"), and the geographical limitations imposed by this document (Gew.O. of 5 February 1960 para. 55 d; regulation of 30 November 1960);

b) *In Belgium:* by the need to possess a foreigner's work permit (Royal decree No. 62 of 16 November 1939; ministerial order of 17 December 1945);

c) *In France:* by the need to possess a foreign trader's card (decree-law of 12 November 1938; decree of 2 February 1939; law of 8 October 1940; law of 10 April 1954; decree No. 59-852 of 9 July 1959).

By the need to be of French nationality to obtain a licence to perform artificial insemination (order of 24 April 1948 — Art. 17).

3. The Member States shall in particular ensure that:

a) Work done in their territory by beneficiaries of the directive shall be eligible, as if it were carried out by their own nationals, for:

i) the granting of various forms of credit, assistance and subsidies provided for this purpose;

ii) benefit from the usual tax reliefs, notably in respect of purchase of fuel used in the supply of services;

b) The beneficiaries shall be able, on the same terms as nationals, to make contracts in private or public law with individuals or companies to supply their professional services, especially in connection with programmes for improving agricultural structures, to submit tenders and participate as joint contractors or sub-contractors;

c) In cases where provisions in force in their territory require certain types of work, especially those involving the use of dangerous toxic products, to be carried out by an approved contractor, the beneficiaries shall be able to apply for and obtain this approval with no more difficulty than their own nationals.

Article 6

1. The Member States shall take the necessary measures to comply with the present directive within the following time-limits:

a) For the supply of services included under Article 2(1) a) to b) inclusive: six months from the date of notification:

a) "*Technical assistance*":

Advice and information on all sectors of agricultural and horticultural activity, whether individual or collective, in particular with regard to:

- i) methods of agricultural and horticultural production;
- ii) methods (on the farm, market garden or establishment) of preparation, treatment and marketing of agricultural and horticultural products;
- iii) the acquisition and use of means of production;
- iv) the acquisition, installation and utilization of items of capital investment;
- v) the organization of the farm and work on it, agricultural accountancy and in general everything regarding the management of the farm;
- vi) domestic economy;
- vii) training of personnel;
- viii) agricultural co-operation (co-operatives), association and vertical integration;
- ix) improvement of land and structures (for example, the prevention of erosion, drainage and irrigation, consolidation of holdings, extension and re-establishment of agricultural undertakings, cultivation of new land);

b) "*The destruction of weeds and vermin, spraying of plants and soil*":

All kinds of work carried out manually or by machine, by land vehicles or aircraft, designed to destroy or prevent from appearing by

b) For the supply of services included under Article 2(1) i); before the end of the first year of the third stage of the transition period.

2. Member States shall inform the Commission immediately of the measures they have taken.

Article 7

The present directive is addressed to the Member States.

ANNEX

Activities to be included under a) to i) of Article 2(1)

physical, chemical or biological treatment weeds, parasites of every kind on plants and animals and their products, and harmful creatures or agents found in the earth, in water, in the air, in buildings and on stored products;

c) "*Pruning trees*":

Pruning trees, shrubs and similar plants (for example, vines and osiers), whether done manually or by mechanical means;

d) "*Picking, packing and packaging*":

All work done by hand or mechanically connected with:

- i) Gathering the products of fruit, market garden and other horticultural cultivation, and special crops (for example, grapes, hops, tobacco, olives, flower bulbs, and medicinal and condimental herbs);
- ii) Picking, cleaning, drying, storing, packaging and labelling the above-mentioned products;

e) "*The operation of irrigation systems*":

All operations involving the use of spraying and watering equipment, and other forms of water supply for agricultural and horticultural production;

f) "*Hiring agricultural machinery*":

Making available by contract and against payment, for a long or short period, various implements and machinery used in agricul-

tural and horticultural work prior to, during and after the growing stage, including tractors and trailers for agricultural use:

g) *"The care and dressing of soil or crops"*:

Any operation concerned with making land fit for cultivation or improving it, as well as working the land before, during and after the growing period, done manually or by mechanical means, in particular:

Lifting stumps, ploughing uncultivated land, fallow land and grassland, sub-oil work, terracing, grading, removing stones, filling in holes;

Deep ploughing, rotary hoe operation;

Use of all forms of fertilizers, manure and other soil-improvement materials;

Preparation of topsoil for sowing and planting; sowing and planting;

Hoeing, second dressing, earthing up, rolling;

h) *"Harvesting, threshing, pressing and gathering whether done by and or by mechanical means"*:

All work done manually or by mechanical means consisting in harvesting and processing, on the farm, products of cultivable lands and grassland (harvesting the products of fruit and market garden horticultural and special

cultivation being included in paragraph d), in particular:

i) Harvesting and threshing (combine harvesting, threshing in the field or in the barn), of grasses, leguminosae and cruciferae;

ii) Uprooting and gathering up hoed weeds, lifting and treating flax;

iii) Chopping, gathering and baling straw;

iv) All work in connection with preparing and the conservation of green fodder, succulent feeds and roughage, such as cutting, chopping, tearing up and gathering green fodder, drying in field, in stocks or artificially; steaming and silage;

v) Any operations involving pneumatic or mechanical elevators, loaders and unloaders;

vi) Picking, cleaning, drying, storing, packaging and labelling the above-named products;

i) *"Services not included in the above list"*:

Any services for agriculture and horticulture not included in the above paragraphs, performed manually or by mechanical means, in particular:

i) Work connected with stock-raising, such as artificial insemination, milking, cleaning stables, sheep shearing;

ii) Certain special work such as the maintenance of hothouses and cold frames.

Proposal for a Council directive on the marketing of beet seed

(Submitted by the Commission to the Council on 3 March 1964)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof:

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Whereas the growing of sugar and fodder beet, hereinafter referred to as beet, is a highly important agricultural activity in the European Economic Community;

Whereas satisfactory results in beet growing depend to a great extent on the use of appropriate seed; whereas for some time certain Member States have accordingly allowed only

high quality sugar or fodder beet seed to be sold; whereas they have benefited from a systematic selection of plants over decades, which has developed comparatively stable and homogeneous varieties, presenting substantial advantages as to yields, reliability of performance and suitability for the grower's purpose;

Whereas an even greater increase in productivity in beet growing in the European Economic Community will be obtained if the Member apply strict and uniform rules governing the types and varieties which may be offered for sale;

Whereas, however, limitation to certain types or varieties is only warranted in so far as there is at the same time an assurance that the user does in fact receive seeds of these types or varieties;

Whereas for this purpose certain Member States apply certification systems whereby the identity and purity of the types or varieties are guaranteed by official testing and inspection;

Whereas there are already in existence international systems of this nature, for maize seed (United Nations Food and Agriculture Organization), and for herbage seed (Organization for Economic Co-operation and Development);

Whereas a standardized system of certification is to be established by the European Economic Community, based on experience gained in applying the above-mentioned systems;

Whereas the rules thereof must normally be applicable to sales on domestic markets as well as in trade between the Member States so as to obviate disparities between domestic and Community systems;

Whereas beet seed may normally be offered for sale only if it has been officially examined and certified as basic seed or certified seed according to the rules of the certification system; and whereas the technical terms "basic seed" and "certified seed" are drawn from existing international terminology: already in existence;

Whereas the Community regulations are not applicable to seed that is shown to be intended for export to countries outside the Community;

Whereas, in order to improve not only the genetic value but the standard of external quality of beet seed in the European Economic Community, certain minimum requirements concerning specific purity and germination power must be laid down, and certain tolerances for moisture content; and whereas these are based on the standards already widely applied in the sugar beet trade in accordance with recommendations made by the International Institute of Sugar Beet Researches.

Whereas, for purposes of identification, Community rules must be established concerning packaging, sampling, sealing and making; and whereas labels must supply the particulars needed by official inspectors and by farmers, and must indicate that the seed has been certified by Community authorities;

Whereas in order to ensure that all beet seed offered for sale satisfies the requirements concerning quality and identification the Member States must make the necessary arrangements for inspection;

Whereas seed fulfilling all requirements must not be subject — save as provided in Article 36 of the Treaty — to marketing restrictions other than those laid down or permitted by Community rules;

Whereas during a preliminary stage — and pending the establishment of a general cata-

logue of types or varieties — the restrictions allowed should include in particular the right of Member States to restrict sales to types or varieties which can profitably be grown in their territory;

Whereas it is necessary on certain conditions to recognize that seed reproduced in another country from basic seed certified in a Member State is equivalent to seed reproduced in the said Member State;

Whereas other beet seed produced in non-member countries may only be offered for sale within the European Economic Community if it affords the user the same guarantees as seed produced and officially examined, certified, marked and sealed within the Community; and whereas, to obviate divergences in decisions on this matter between Member States, the Commission must be empowered to decide whether these conditions are fulfilled in the various non-member countries, and will take the necessary measures having due regard to arrangements in the non-member countries concerned;

Whereas at times when difficulties experienced over the supply of certified seed of the various categories, the Commission must be empowered to authorize provisionally the sale of grades fulfilling less strict requirements;

Whereas, in order to harmonize the technical certification methods of the different Member States, and to make it possible in the future to compare seed certified within the European Economic Community with seed from non-member countries, it is desirable to set up growth trial stations for the annual post-control of certified seed,

Has issued the following directive:

Article 1

The present directive is concerned with beet seed commercialized within the Community.

Article 2

The following definitions shall apply:

a) *Beets* are sugar and fodder beets of the species *Beta vulgaris* L.

b) *Basic seed*: seed

i) which has been produced on the responsibility of the breeder according to strict rules of selection as regards the type or variety;

ii) which is intended for the production of certified seed;

iii) which fulfils, save as provided in Article 4, the conditions set out in Annex I for basic seed, and

iv) in respect of which the fulfilment of these conditions has been established by official examination.

c) Certified seed: seed —

i) of direct descent from basic seed;

ii) which is intended for beet growing;

iii) which fulfils, save as provided in Article 4 b), the conditions set out in Annex I for certified seed; and

iv) in respect of the fulfilment of these conditions has been established by official examination.

d) Official measures: measures taken —

i) by the authorities of a Member State, or

ii) under the responsibility of that State by public or private corporations, or

iii) for ancillary activities, also under the supervision of the said State, by persons who have taken a professional oath, provided that such persons have no interest in the outcome of such measures.

Article 3

1. The Member States shall stipulate that only beet seed officially stated to be basic or certified seed may be commercialized.

2. The Member States may make exceptions to paragraph 1 for:

a) selected seed of generations prior to the basic seed;

b) experimental or scientific purposes;

c) selection work.

Article 4

The Member States may at their discretion allow:

a) that beet seed not fulfilling the requirements of Annex I regarding germination may be officially certified and commercialized as basic seed; in such case the supplier shall guarantee a certain germination, which shall be indicated at the time of sale on a special label bearing his name and address and the lot reference number;

b) that beet seed in respect of which the official testing for fulfilment of the requirements set out in Annex I with regard to germination has not been completed may, in

order to supply seed rapidly to wholesalers, be officially certified as basic or certified seed and commercialized as such; in order to obtain certification the results of a provisional test must be submitted and the name and address of the wholesaler must be indicated; in such case the supplier shall guarantee the germination established by the provisional test, which on commercializing he shall indicate on a special label bearing his name and address and the lot reference number.

Article 5

The Member States may at their discretion lay down, as well as the conditions set out in Annex I, additional or stricter conditions for certification.

Article 6

1. Each Member State shall establish a list of the types or varieties of beet eligible for certification in its territory; the list shall indicate the main morphological and physiological characters by which the types or varieties are distinguished.

2. A type or variety shall be approved for certification only if it has been shown after official or officially supervised growth trials over three successive years that the type or variety is sufficiently homogeneous and stable.

3. A regular official check shall be made of the types or varieties accepted. If it appears from growth trials carried out over several years that any condition of approval for certification is no longer fulfilled, the approval shall be withdrawn and the type or variety deleted from the list. In the case of a change in any of the secondary characteristics of a type or variety, its description in the list shall immediately be altered.

4. The list and any changes made in it shall be immediately transmitted to the Commission, which shall inform the other Member States thereof.

Article 7

1. The Member States shall stipulate that samples taken in the process of testing types and varieties and the examination of seed for certification shall be taken officially by suitable methods.

2. Samples taken in the course of examination of seed for certification shall be taken from homogeneous lots; the maximum weight of a lot and the minimum weight of a sample are stipulated in Annex II.

Article 8

The Member States shall stipulate that certified polyploid beet seed commercialized shall contain not more than 40% of diploid seeds.

Article 9

1. The Member States shall stipulate that basic and certified beet seed shall be commercialized only in homogeneous lots in closed packages, sealed and marked as specified in Articles 10 and 11, except as may be otherwise provided by the Council of Ministers or the Commission regarding mixtures of seeds.

2. The Member States may at their discretion make exceptions to paragraph 1 for the sale of small quantities to final users.

Article 10

1. The Member States shall stipulate that packages of basic and certified beet seed shall be officially closed in such a way that when the package is opened the seal is damaged and cannot be replaced.

2. A second closure shall only be effected under official auspices. In such case, the second closure, with the date and the name of the department by which it was effected, shall be indicated on the label as provided in Article 11(1); where a new label is used, the particulars given on the previous label shall be reproduced.

Article 11

The Member States shall stipulate that basic and certified beet seed packages:

a) shall bear on the outside an official label of the form prescribed in Annex III in one of the official Community languages; it shall be secured by the official seal; the label shall be white for basic seed and blue for certified seed; for trade between Member States the label shall give the date of the official closure: where basic seed does not fulfil the requirements set out in Annex I regarding germination (Article 4 a), this shall be stated on the label;

b) shall contain an official notice of the same colour and giving the same particulars as the label; this notice may be dispensed with in the case of small packages or if the method of packaging makes its insertion impossible.

2. The Member States may at their discretion stipulate that labels must in all cases show the date of official sealing.

Article 12

The Member States may at their discretion stipulate that packages of basic or certified beet seed shall in cases additional to those specified in Article 4 be accompanied by a special supplier's label.

Article 13

The Member States shall stipulate that any chemical treatment of basic or certified beet seed shall be mentioned either on the official label or on the supplier's label.

Article 14

1. The Member States shall ensure that basic and certified beet seed which has been officially certified, marked and sealed in accordance with the rules of the present directive shall be subject to no marketing restrictions in respect of their characteristics, official testing, minimum marking and sealing other than those laid down or permitted by the present directive.

2. Pending the establishment of a Community catalogue of types or varieties, the Member States may restrict the marketing of beet seed to types or varieties contained in a national list of those which can profitably be grown in their territory; the conditions for inclusion in the list shall be the same for types and varieties from other Member States as for national types and varieties.

Article 15

1. The Member States shall stipulate that beet seed which is of direct descent from basic seed certified in a Member State and is produced in another Member State or in a non-member country shall be considered as equivalent to certified seed raised in the State producing the basic seed, provided that it has been subjected to crop inspection at the place where it was produced under the conditions set out in Annex I, section A, and that it has been packaged in the State producing the basic seed where it has been found, on official examination, to satisfy the conditions laid down in Annex I, section B, for certified seed.

2. When a package of certified beet seed contains, in accordance with paragraph 1, seed harvested in non-member countries, these countries shall be named on the official label.

Article 16

The Commission shall determine, by decision at the request of one or more Member States

and after consultation with the other Member States:

a) whether the crop inspection carried out in a non-member country satisfies the conditions laid down in Annex I, section A and referred to in Article 15(1) above;

b) that beet seed grown in a non-member country offering the same assurances to the user as regards its characteristics and the measures taken to examine, identify and test it is equivalent to basic or certified seed officially certified, marked and sealed in accordance with the rules of the present directive.

Article 17

1. If in one or more Member States there should be temporary difficulties over the general supply of basic or certified beet seed and these difficulties cannot be resolved within the Community, the Commission shall issue a directive, at the request of at least one of the Member States concerned and after consulting the other Member States, authorizing one or more Member States to allow the sale, for a specified period, of seed of a grade fulfilling less strict requirements.

2. If the grade of seed is of a specified type or variety the colour of the official label shall be the same that prescribed for the corresponding category; in all other cases it shall be dark yellow. In every case the label shall indicate that the seed is of a grade fulfilling less strict requirements.

Article 18

The present directive shall not apply to beet seed that is shown to be intended for export to non-member countries.

Article 19

Member States shall make appropriate arrangements for the official checking of beet seed commercialized, at least by the testing of samples for conformity with the conditions laid down in the present directive.

Article 20

1. Community growth trial stations shall be set up on Community territory; here annual post-controls shall be made of samples of certified beet seed; the trial grounds shall be open to inspection by a committee of experts from Member States.

2. During the preliminary stage, comparative tests shall be made with a view to harmonizing technical methods of certification. When this has been done, comparative tests shall be the subject of an annual progress report transmitted confidentially to the Commission and the Member States. The Commission shall decide, after consulting the Member States, the date from which this report shall be made.

3. After consulting the Member States, the Commission shall make the necessary arrangements for carrying out comparative tests. Provision may be made for beet seed produced in non-member countries to be included in these tests.

Article 21

The provisions of the present directive shall be without prejudice to regulations designed to protect the life and health of human beings or animals or to preserve plant life.

Article 22

1. The Member States shall introduce the necessary laws and regulations to conform with the provisions of Article 14(1) by 1 May 1966 and with the other provisions of the present directive and its annexes by 1 May 1968 at latest. They shall inform the Commission thereof immediately.

2. The Member States shall inform the Commission, in time for it to submit comments, of any further draft of laws or regulations they may contemplate adopting in the matters covered by the present directive.

Article 23

The present directive is addressed to the Member States.

ANNEX I

Conditions for certification

A. Conditions relating to the trial crop

1. The crop shall have sufficient identity and purity of type or variety.

2. The breeder shall submit for testing by the certification service all generations of seed of a type or variety.

3. There shall be at least one official crop inspection, and in the case of basic seed at least two such inspections: one of the shoes and the other of the seed boxes.

4. The cultivable condition of the trial ground and the stage of growth reached shall be such

as to make possible an adequate check on the identity and purity of the type or variety.

5. The minimum distances between trial crops and neighbouring crops, where there is no adequate protection from external pollination, shall be as follows:

	For basic seed	For certified seed
a) Sugar beet away from other types and varieties of sugar beet	500 m	300 m
sugar beet from other sub-species of <i>Beta vulgaris</i>	1 000 m	600 m
b) Fodder beet away from other types and varieties of fodder beet	500 m	300 m
fodder beet from other sub-species of <i>Beta vulgaris</i>	1 000 m	600 m

B. Conditions relating to the seed

1. The seed shall have sufficient identity and purity of type or variety.

2. The presence of diseases which reduce the utilization value of seed shall as far as possible be avoided.

3. Seed shall further satisfy the following conditions:

	Minimum specific purity (% of weight)	Minimum germination (% of pure glomerules or seeds)	Maximum moisture content (% of weight)
<i>Sugar beet</i>			
Diploid	97	73	15
Polyploid	97	68	15
<i>Fodder beet</i>			
Diploid	97	73	15
Polyploid	97	68	15

The percentage by weight of seeds of other plants shall not exceed 0.3, no more than 0.1 of which shall consist of weed seeds.

To check for fulfilment of these requirements at least 200 grammes of the sample shall be examined.

ANNEX II

Maximum weight of a lot: 20 t.

Minimum weight of a sample: 300 g.

ANNEX III

Label

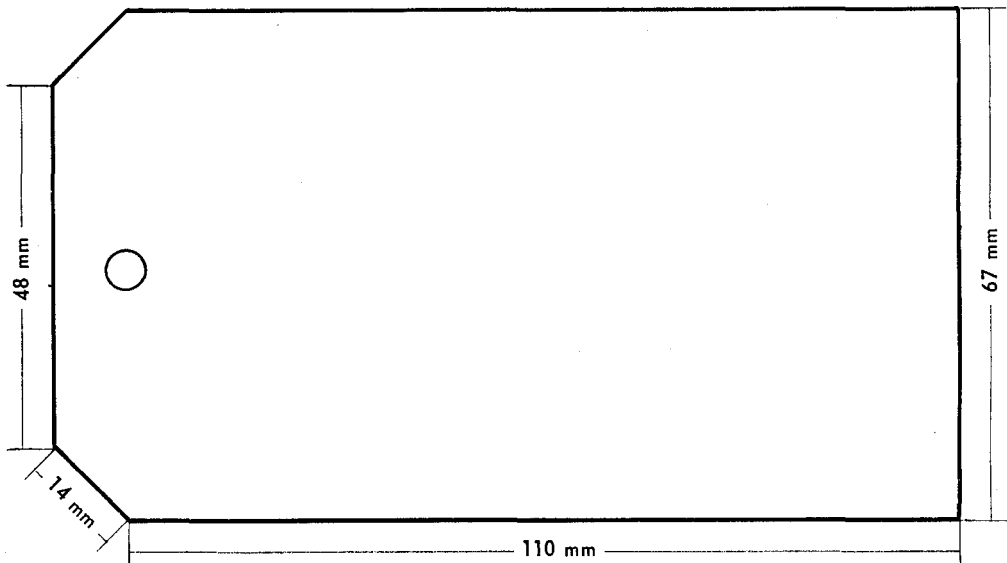
A. Particulars to be supplied:

1. The words "Beet seed certified in accordance with EEC regulations".
2. Certifying department and Member State.
3. Lot reference number.
4. Species.

5. Type or variety.

6. Category.
7. Declared net or gross weight.
8. For polyploid seed mention "Polyploid".

B. Dimensions.



Proposal for a Council directive on the marketing of herbage seed

(Submitted by the Commission to the Council on 3 March 1964)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community and in particular Article 43 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Whereas herbage growing is a highly important agricultural activity in the European Economic Community;

Whereas satisfactory results in the herbage growing depend to a great extent on the use of appropriate seed; whereas for some time certain Member States have accordingly allowed only high-quality herbage seed to be sold; and whereas they have benefited from a systematic plant breeding over decades, which has developed stable and homogeneous varieties presenting substantial advantages, as to yields, reliability of performance and suitability for the grower's purpose;

Whereas it will only be possible to increase productivity in herbage growing within the European Economic Community if the Mem-

ber States apply strict and uniform rules governing the varieties of seed which may be commercialized:

Whereas, however, limitation to certain varieties is only warranted if the farmer can be assured of an adequate supply of the selected seed;

Whereas for this purpose certain Member States apply certification systems whereby the identity and purity of the varieties are guaranteed by official testing and inspection;

Whereas there already exists an international system of this kind; and whereas the Organization for Economic Co-operation and Development has introduced a scheme for the varietal certification of herbage seed moving in international trade;

Whereas a standardized certification system should be set up for the European Economic Community, based on experience of applying the OECD system and similar national systems;

Whereas the regulations of the system should normally be applicable to sales on domestic markets as well as in trade between the Member States so as to obviate disparities between domestic and Community systems;

Whereas herbage seed may normally be offered for sale only if it has been officially examined and certified as basic or certified seed, or, for certain genera or species, officially examined as commercial seed, according to the rules of the certification system; and whereas the technical terms "basic seed" and "certified seed" are drawn from existing international terminology;

Whereas commercial seed is approved because up to now there do not exist for all the genera and species of herbage plants of importance to agriculture sufficient varieties or an adequate supply of the existing varieties to meet Community needs; whereas, therefore, in the case of certain genera and species, for the time being herbage seed which does not belong to a particular variety but which fulfils the other requirements of the system must be accepted;

Whereas herbage seed not commercialized, having little economic importance, should be exempt from Community rules, though the Member States may still at their discretion apply special rules to it;

Whereas the Community regulations are not applicable to seed that is shown to be intended for export to non-member countries;

Whereas, in order to improve the genetic value and the standard of external quality of

herbage seed within the European Economic Community, minimum requirements for technical purity and germination must be laid down;

Whereas for purposes of identification, Community regulations governing packaging, sampling, sealing and marking must be introduced; and whereas the labels must supply the particulars needed by official inspectors and by farmers; and, for the various categories of certified seed, must indicate that the seed has been certified by Community authorities;

Whereas certain farmers in some Member States need herbage seed containing a mixture of several species of plant; and whereas in view of this need Member States must be authorized to approve such mixtures subject to certain conditions;

Whereas in order to ensure that quality requirements and those concerning identity are in every case fulfilled when the seed is placed on sale, the Member States must make appropriate arrangements for checking and inspection;

Whereas seed fulfilling all the requirements may not be subject — save as provided by Article 36 of the Treaty — to marketing restrictions other than those laid down or permitted by Community rules;

Whereas during the preliminary stage — and pending the establishment of a common catalogue of varieties — these restrictions will in particular include the Member States' right to confine the marketing of certified seed to varieties which can profitably be grown in their territory;

Whereas it is necessary on certain conditions to recognize that seed reproduced in another country from basic seed certified in a Member State is equivalent to seed reproduced in the said Member State;

Whereas other herbage seed grown in non-member countries may only be offered for sale in the European Economic Community if it affords the user the same guarantee as seed grown and officially examined, certified, labelled and sealed within the Community or officially examined, labelled and sealed as commercial seed within the Community; and whereas, in order to obviate divergences in decisions on this matter between Member States, the Commission must be empowered to decide whether these conditions are fulfilled in the various non-member countries, and will take the necessary measures having due regard to arrangements in the non-member countries concerned;

Whereas, at times when difficulties are experienced over the supply of certified seed of the various categories or commercial seed, the

Commission must be empowered to authorize provisionally the sale of categories fulfilling less strict requirements;

Whereas in order to harmonize the technical certification procedures of Member States, and to make it possible in the future to compare seed certified within the European Economic Community and seed from non-member countries, Community growth trial plots should be set up in the Member States for an annual post-control of certified seed of the various categories,

Has issued the present directive:

i) *Gramineae*

Agrostis spec.
Alopecurus pratensis L.
Arrhenatherum elatius (L.)
J. & C. Presl
Dactylis glomerata L.
Festuca arundinacea Schreb.
Festuca ovina L.
Festuca pratensis Huds.
Festuca rubra L.
Lolium spec.
Phleum pratense L.
Poa spec.
Trisetum flavescens (L.)
Pal. Beauv.

ii) *Leguminosae*

Lotus corniculatus L.
Lupinus spec.
Medicago lupulina L.
Medicago sativa L.
Medicago varia Martyn
Onobrychis sativa L.
Pisum arvense L.
Trifolium hybridum L.
Trifolium incarnatum L.
Trifolium pratense L.
Trifolium repens L.
Vicia spec.

Article 1

The present directive is concerned with herbage seed commercialized within the Community.

Article 2

The following definitions shall apply:

a) *Herbage plants:*

Plants of the following genera and species, in so far as they are not legumes:

Herbage plants

Bent grass
Meadow foxtail
False oats

Orchard grass
Reed fescue
Sheep's fescue
Meadow fescue
Red fescue
Ryegrass
Timothy
Meadow grass
Yellow oats

Legumes

Bird's foot trefoil
Lupin
Black medick
Lucerne
Lucerne
Sainfoin
Field pea
Hybrid clover
Crimson clover
Red clover
White clover
Vetch, horse bean.

b) Basic seed:

i) Seed of selected varieties:

Seed —

aa) produced on the responsibility of the breeder in accordance with generally accepted practices for the maintaining of the variety;

bb) intended for the production of certified seed;

cc) fulfilling — save as provided by Article 4 — the conditions laid down in Annexes I and II for basic seed, and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

ii) Local race seed:

Seed —

aa) produced under official supervision from stock materials officially approved as local varieties and grown on one or more establishments in an adequately defined area;

bb) intended for the production of certified seed;

cc) fulfilling — save as provided by Article 4 — the conditions laid down in Annexes I and II for basic seed, and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

c) Certified seed:

Seed —

aa) of direct descent from basic or certified seed of one variety;

bb) intended for the production of certified seed or of fodder;

cc) fulfilling — save as provided by Article 4 — the conditions laid down in Annexes I and II for certified seed, and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

d) Commercial seed

Seed —

aa) true to the species;

bb) fulfilling — save as provided by Article 4 — the conditions laid down in Annex II for commercial seed, and

cc) in respect of which the fulfilment of these conditions has been established by official examination.

e) Official measures

Measures which are taken:

aa) by the authorities of a Member State, or

bb) under the responsibility of the said State by public or private corporations, or

cc) for ancillary activities, also under the supervision of the said State, by persons who have taken a professional oath, provided that they have no interest in the outcome of such measures.

Article 3

1. The Member States shall order that seed of:

Dactylis glomerata L.

Festuca arundinaca Schreb.

Festuca pratensis Huds.

Festuca rubra L.

Lolium spec.

Phleum pratense L.

Medicago sativa L.

Medicago varia Martyn

Pisum arvense L. and

Trifolium repens L.

shall only be commercialized if it is basic seed or certified seed, officially certified as such.

2. Member States shall order that seed of genera and species of herbage plants other than those listed in paragraph 1 shall only be commercialized if it is officially certified basic seed or certified seed or commercial seed.

3. The Commission may, after consulting the Member States, issue a directive that seed of genera and species of herbage plants other than those listed in paragraph 1 shall from specified dates onwards be commercialized only if it is officially certified basic seeds or certified seed.

4. The Member States may at their discretion make exceptions to paragraphs 1 and 2 for:

a) selected seed from generations prior to the basic seed;

b) experimental or scientific purposes;

c) selection work.

Article 4

The Member States may at their discretion allow:

a) that herbage seed not fulfilling the requirements of Annex II regarding germination be officially certified and commercialized —

i) as basic seed;

ii) in the case of trifolium pratense, also as certified seed designated for the production of other certified seed; in such case the supplier shall guarantee a certain germination, which shall be indicated when seed is commercialized on a special label bearing his name and address and the lot reference number;

b) that herbage seed in respect of which the official testing for germination provided for in Annex II has not been completed, may, in order to supply seed rapidly to wholesalers, be officially certified as basic seed or described as certified seed, or approved as commercial seed and commercialized as such; in order to obtain certification or approval the results of a provisional test and the name and address of the wholesaler must be indicated; in such case the supplier must guarantee the germination established by the provisional test, which on marketing he shall indicate on a special label, bearing his name and address and the lot reference number.

Article 5

The Member States may at their discretion, lay down as well as the conditions set out in Annexes I and II, additional or stricter conditions for certification.

Article 6

1. Each Member State shall draw up a list of the varieties of herbage plants eligible for certification in its territory; the list shall state the main morphological or physiological characters by which the varieties are distinguished, and the maximum number of generations from basic seed accepted in certifying each variety.

2. A variety shall be approved for certification only if it has been shown by official or officially supervised growth trials to be sufficiently stable and homogeneous.

3. A regular official check shall be made of the varieties approved for certification if any condition of approval is no longer fulfilled, the approval shall be withdrawn and the variety deleted from the list.

4. The list and any changes made in it shall be immediately notified to the Commission, which shall inform the other Member States thereof.

Article 7

1. The Member States shall stipulate that samples in the process of testing varieties, in the examination of seed for certification or in the examination of commercial seed shall be taken officially by suitable methods.

2. Samples in the examination of seeds for certification and the examination of commercial seed shall be taken from a homogeneous lot. The maximum weight of a lot and the minimum weight of a sample are stipulated in Annex III.

Article 8

1. The Member States shall stipulate that basic, certified and commercial herbage seed shall be commercialized only in homogeneous lots and in closed packages, sealed and labelled as specified in Articles 9 and 10.

2. The Member States may at their discretion make exceptions to paragraph 1 for the sale of small quantities to final users.

Article 9

1. The Member States shall stipulate that packages of basic, certified and commercial herbage seed shall be officially closed in such a way that when the package is opened the seal is damaged and cannot be replaced.

2. A new closure shall be effected only under official auspices. In such case the second closure, with the date and the name of the department by which it was effected, shall be indicated on the label provided for in Article 10(1): where a new label is used, the particulars given on the previous label shall be reproduced.

Article 10

1. The Member States shall stipulate that packages containing basic, certified and commercial herbage seed shall:

a) bear on the outside an official label of the form prescribed in Annex IV, in one of the official languages of the Community. It shall be secured by the official seal; the colour shall be white for basic seed, blue for certified seed of direct descent from basic seed, red for certified seed of subsequent generations from basic seed, and dark yellow for commercial seed; for trade between Mem-

ber States the label shall bear the date of the official sealing; where basic seed or certified seed does not fulfil the requirements of Annex II regarding germination (Article 4 a), this shall be stated on the label;

b) contain an official notice of the same colour and giving the same particulars as the label; this notice may be dispensed with in the case of small packages or if the method of packaging makes its insertion impossible.

2. The Member States may at their discretion stipulate that labels must in all cases show the date of official sealing.

Article 11

The Member States may at their discretion stipulate that packages of basic, certified or commercial herbage seed shall be accompanied by a special supplier's label in cases additional to those specified in Article 4.

Article 12

The Member States shall stipulate that any chemical treatment of basic, certified or commercial herbage seed shall be mentioned either on the official label or on the supplier's label.

Article 13

1. The Member States may at their discretion allow the offer for sale of herbage seed in mixtures of different genera or species, or with the admixture of seeds of plants which are not herbage plants within the meaning of the present directive, provided that the various constituents of the mixture complied, before mixing, with such conditions for marketing as may be applicable to them under provisions made by the Council of Ministers or the Commission.

2. Articles 8, 9 and 11 and also Article 10 shall apply by analogy, except that in this case the label shall be green and the dimensions given in Annex IV shall be minimum dimensions.

Article 14

1. The Member States shall ensure that basic and certified herbage seed which has been officially certified, labelled and sealed according to the rules of the present directive, and also commercial herbage seed which has been similarly marked and sealed, shall be subject to no marketing restrictions in respect of their characteristics, official testing, minimum marking and sealing other than those laid down or permitted by the present directive.

2. The Member States may at their discretion:

a) stipulate, in so far as this has not been covered by a Commission directive issued in accordance with Article 3(3), that seeds of genera and species of herbage plants other than those listed in Article 3(1) shall after specified dates be commercialized only if they are officially certified as basic or certified seed;

b) stipulate the maximum moisture content allowed in seed commercialized;

c) restrict the marketing of certified herbage seed to seed of direct descent from basic seed;

d) pending the establishment of a Community catalogue of varieties, restrict the marketing of herbage seed, in so far as it is limited to basic and certified seed, to seeds of varieties contained in a national list of those which can profitably be grown in their territory; the conditions for inclusion in this list shall be the same for varieties from other Member States as for national varieties.

Article 15

1. The Member States shall stipulate that herbage seed which is of direct descent from basic seed certified in a Member State and is produced in another Member State or in a non-member country shall be considered as equivalent to certified seed of direct descent from basic seed raised in the State producing the basic seed, provided that it has been subjected to a crop inspection at the place where it was produced under the conditions set out in Annex I, and that it has been cleaned in the State producing the basic seed, where it has been found, on official examination, to satisfy the conditions laid down in Annex II for certified seed.

2. Where a package of certified herbage seed contains, in accordance with paragraph 1, seed produced in other States, these States shall be named on the official label.

Article 16

The Commission shall determine, by decision, at the request of one or more Member States and after consultation with the other Member States:

a) whether the crop inspection of the growing plants carried out in non-member countries complies with the conditions laid down in Annex I and referred to in Article 15(1) above;

b) that herbage seed produced in a non-member country and offering the same guarantees to the user as regards its characteristics and the measures taken to examine, identify and test it is equivalent to basic or

certified herbage seed officially certified, labelled and sealed in accordance with the rules set out in the present directive or to commercial herbage seed similarly labelled and sealed.

Article 17

1. If in one or more Member States there should be temporary difficulties over the general supply of basic seed, certified seed or commercial seed approved for marketing, and these difficulties cannot be resolved within the Community, the Commission shall issue a directive, at the request of at least one of the Member States concerned and after consulting the other Member States, authorizing one or more Member States to allow the marketing, for a specified period, of seed of a grade fulfilling less strict requirements.

2. Where a grade of seed of one in a variety is concerned, the official label must be the same as that prescribed for the corresponding category of seed of varieties; in all other cases, that prescribed for commercial seed. In all cases the label shall state that the seed is of a grade fulfilling less strict requirements.

Article 18

The present directive shall not apply to herbage seed that is shown to be intended for export to non-member countries.

Article 19

The Member States shall make appropriate arrangements for official checking of seed commercialized, at least by the testing of samples, for conformity with the conditions laid down in the present directive.

Article 20

1. Community trial plots shall be set up on Community territory; here annual post-controls shall be made of samples of basic

and certified herbage seed; the trial plots shall be open to inspection by a committee of experts from Member States.

2. During the preliminary stage, comparative tests shall be made with a view to harmonizing technical methods of certification. When this has been done, comparative tests shall be the subject of an annual progress report transmitted confidentially to the Commission and the Member States. The Commission shall decide after consulting the Member States the date from which this report shall be made.

3. After consulting the Member States, the Commission shall make the necessary arrangements for carrying out comparative tests. Provision may be made for herbage seed produced in non-member countries to be included in these tests.

Article 21

The provisions of the present directive shall be without prejudice to regulations designed to protect the life and health of human beings and animals or to preserve plant life.

Article 22

1. The Member States shall introduce the necessary laws and regulations to conform with Article 14(1) by 1 May 1966 and with the other provisions of the present directive and its annexes by 1 May 1968 at latest. They shall inform the Commission thereof.

2. The Member States shall inform the Commission, in time for it to submit comments, of any further draft laws or regulations they may contemplate adopting in the matters covered by the present directive.

Article 23

The present directive is addressed to the Member States.

ANNEX I

Certification conditions relating to the crop

1. The crop shall display adequate varietal identity and purity.

2. At least one official crop inspection plants shall be made before each harvest.

3. The cultivable condition of the production ground and the stage of growth reached shall

be such as to allow of an adequate check on varietal identity and purity.

4. The production ground shall not in the past have been used for types of cultivation which are incompatible with the production of seed of the species and variety being grown.

5. For cross-fertilizing species, where there is no adequate protection from external pollination, the minimum distance from neighbouring fields growing other varieties of the same species, from fields growing the same variety in a state of serious deterioration, and

from fields of related species capable of producing cross-fertilization shall be:

for basic seed	200 metres
for certified seed	100 metres

ANNEX II

Certification conditions relating to the seed

I. Certified seed

1. The seed shall have sufficient varietal identity and purity.

2. The presence of diseases affecting the utili-

zation value of seed shall as far as possible be avoided.

3. The seed shall also satisfy the following conditions:

Species	Minimum specific purity (% by weight)	Maximum content of weed seed (% by weight)	Minimum germination (% of pure seed)
<i>A. Gramineae</i>			
<i>Agrostis alba</i>	90	1	80
<i>Agrostis al. spec.</i>	90	1	75
<i>Alopecurus pratensis</i> L.	75	1.5	70
<i>Arrhenatherum elatius</i> (L.) J.D. Presl	90	1	80
<i>Dactylis glomerata</i> L.	90	1	80
<i>Festuca arundinacea</i> Schreb.	95	1	80
<i>Festuca ovina</i> L.	85	1	75
<i>Festuca pratensis</i> Huds.	95	1	80
<i>Festuca rubra</i> L.	90	1	75
<i>Lolium multiflorum</i>	96	1	75
<i>Lolium al. spec.</i>	96	1	80
<i>Phleum pratense</i> L.	95	0.5	80
<i>Poa spec.</i>	85	1	75
<i>Trisetum flavescens</i> (L.) } Pal. Beauv.	75	1	70

Species	Minimum specific purity (% by weight)	Maximum content of weed seed (% by weight)	Minimum germination (% of pure seed)	Maximum content of hard seeds (% of pure seed)
<i>B. Leguminosae</i>				
<i>Lotus corniculatus</i> L.	95	0.8	75	40
<i>Lupinus spec.</i>	98	0.1	80	20
<i>Medicago lupulina</i> L.	97	0.8	80	20
<i>Medicago sativa</i> L.	97	0.5	80	40
<i>Medicago varia</i> Martyn	97	0.5	80	40
<i>Onobrychis sativa</i> L.	95	1.5	75	20
<i>Pisum arvense</i> L.	97	0.1	80	—
<i>Trifolium hybridum</i> L.	97	0.5	80	20
<i>Trifolium incarnatum</i> L.	97	0.5	80	20
<i>Trifolium pratense</i> L.	97	0.5	80	20
<i>Trifolium repens</i> var. <i>giganteum</i>	97	0.5	80	40
<i>Trifolium repens</i> L.	97	0.8	80	20
<i>Vicia faba</i>	97	0.1	85	20
<i>Vicia al. spec.</i>	97	0.5	85	20

Notes

i) Up to the percentage indicated, hard seeds are considered as seeds capable of germinating.

ii) Seed shall be free from *Avena fatua* and *Cuscuta*; however, one seed of *Avena fatua* or *Cuscuta* in a sample of 100 grammes shall not be considered as an impurity provided a second 100-gramme sample is free from *Avena fatua* or *Cuscuta*.

iii) The percentage by weight of *Alopecurus agrostis* shall not exceed 0.2.

iv) The percentage by weight of seed of other cultivated plants shall not exceed 1: for *Poa spec.*, 1% of seed of other species of *Poa* shall not be considered as an impurity.

Exceptional rules for *Lupinus spec.*:

The percentage by number of seed of another colour shall not exceed 1. The percentage by number of bitter seeds in sweet varieties of lupin shall not exceed:

Three for certified seed of direct descent from basic seed;

Five for certified seed of subsequent generations form basic seed.

II. Basic seeds

Except as otherwise provided below, the conditions laid down under I above shall apply to basic seed:

1. The percentage by weight of seed of other plants shall not exceed 0.2, in which a percentage of seed of other cultivated plants and weed seed of 0.1 in each case shall be permissible;

2. The number of seeds of *Alopecurus Agrostis* shall not exceed 10 in a sample of 100 grammes;

3. *Lupinus spec.*: the percentage by number of bitter seeds in sweet lupin varieties shall not exceed 1.

III. Commercial seed

Except as otherwise provided below, the conditions laid down under I (2 and 3) above shall apply to commercial seed:

1. The percentage by weight of seeds of other cultivated plants shall not exceed 3.

2. *Poa spec*: Pure seeds of other species of *Poa* up to 3% shall not be considered an impurity.

3. *Vicia spec*: 6% of seed of *Vicia pannon-*

ica, Vicia villosa and related species shall not be considered an impurity.

4. *Lupinus*: The percentage by number of bitter seeds in sweet lupin varieties shall not exceed 5.

ANNEX III

	Maximum weight of a lot	Minimum weight of a sample
1. Seed of the same size as wheat seed or larger	20 tons	500 grammes
2. Seed smaller than wheat seed	10 tons	250 grammes

ANNEX IV

Label

A. Particulars to be supplied

a) For basic and certified seed

1. The words "Herbage seed certified in accordance with EEC regulations".

2. Certifying authority and Member State.

3. Lot reference number.

4. Species.

5. Variety.

6. Category.

7. Declared or gross weight.

8. For certified seed of the second or subsequent generations from basic seed: the number of generations from basic seed.

9. For certified land race seed: the region where produced.

b) For commercial seed

1. The words "Commercial herbage seed (not certified as to variety)".

2. Inspection service and Member State.

3. Lot reference number.

4. Species.

5. Region where produced.

6. Declared net or gross weight.

c) For mixtures of seed

1. The words "Seed mixtures for ... (use for which intended)".

2. Department which sealed the package and Member State.

3. Lot reference number.

4. Species, categories and varieties or production regions of the component seeds and their proportion by weight.

5. Declared net or gross weight.

B. Dimensions

(See page 24)

Proposal for a Council directive on the marketing of cereal seed

(Submitted by the Commission to the Council)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Whereas cereal growing is a highly important agricultural activity in the European Economic Community;

Whereas satisfactory results in cereal growing depend to a large extent on the use of appropriate seed; whereas for some time certain Member States have allowed only high-quality cereal seed to be sold; whereas they have benefited from a systematic selection of plants over decades, which has developed comparatively stable and homogeneous varieties presenting substantial advantages as to yields, reliability of performance and suitability for the grower's purpose;

Whereas an even greater improvement of productivity in cereal growing in the European Economic Community will be obtained if the Member States apply strict and uniform rules governing the varieties which may be offered for sale;

Whereas, however, limitation to certain varieties is only warranted in so far as there is at the same time an assurance that the user does in fact receive seed of these varieties;

Whereas for this purpose certain Member States apply certification systems whereby the identity and the purity of the varieties are guaranteed by official testing and inspection;

Whereas there are already in existence international systems of this nature at international level; whereas the United Nations Food and Agriculture Organization has recommended minimum standards for the certification of maize seed in European and mediterranean countries; and whereas the Organization for Economic Co-operation and Development has established a system for the varietal certification of herbage seed intended for international trade;

Whereas a standardized system of certification is to be established by the European Economic Community, based on experience gained in applying the above-mentioned systems;

Whereas the rules thereof must normally be applicable to sales on domestic markets as well

as in trade between the Member States, so as to obviate disparities between domestic and Community systems;

Whereas cereal seed may normally be offered for sale only if it has been officially examined and certified as basic or certified seed according to the rules of the certification scheme; and whereas the technical terms "basic seed" and "certified seed" are drawn from existing international terminology;

Whereas cereal seed not offered for sale, having little economic importance, should be exempt from Community rules, though the Member States may still at their discretion apply special rules to it;

Whereas the Community regulations are not applicable to seed that is shown to be intended for export to non-member countries;

Whereas, in order to improve the genetic value and the standard of external quality of cereal seed within the European Economic Community, minimum requirements must be laid down for technical purity, germination power and freedom from disease;

Whereas, for purposes of identification, Community regulations governing packaging, sampling, sealing and marking must be introduced; and whereas the labels must supply the particulars needed by official inspectors and by farmers, and must indicate that the seed has been certified by Community authorities;

Whereas, in order to ensure that quality requirements and those concerning identity are in every case fulfilled when the seed is placed on sale, the Member States must make appropriate arrangements for checking and inspection;

Whereas seed fulfilling all these requirements may not be subject — save as provided by Article 36 of the Treaty — to marketing restrictions other than those laid down or permitted by Community rules; and whereas even Article 36 of the Treaty does not justify additional marketing restrictions in so far as Community rules stipulate tolerances for noxious organisms;

Whereas, during the preliminary stage — and pending the establishment of a common catalogue of varieties — the restrictions allowed will in particular include the Member States' right to confine the marketing of seed to varieties which can profitably be grown in their territory;

Whereas it is necessary on certain conditions to recognize that seed reproduced in another country from basic seed certified in a Member State is equivalent to seed reproduced in the said Member State:

Whereas other cereal seed grown in non-member countries may only be commercialized within the European Economic Community if it affords the user the same guarantee as seed grown and officially examined, certified, marked and sealed within the Community; and whereas in order to obviate divergences in decisions on this matter between Member States, the Commission must be empowered to decide whether these conditions are fulfilled in the various non-member countries, and will take the necessary measures having due regard to arrangements in the non-member countries concerned;

Whereas at times when difficulties are experienced over the supply of certified seed of the various categories, the Commission must be empowered to authorize provisionally the sale of grades fulfilling less strict requirements;

Whereas, in order to harmonize the technical certification procedures of Member States, and to make it possible in the future to compare seed certified within the European Economic Community with seed from non-member countries, Community growth trial stations should be set up in the Member States for an annual post-control of certified seed of the various categories,

Has issued the present directive:

Article 1

The present directive is concerned with all cereal seed commercialized within the European Economic Community.

Article 2

1. The following definitions shall apply:

a) Cereals:

plants of the following species:

<i>Avena sativa</i> L.	Oats
<i>Hordeum distichum</i> L.	Two-rowed-barley
<i>Hordeum polystichum</i> L.	Winter barley
<i>Oryza sativa</i> L.	Rice
<i>Secale cereale</i> L.	Rye
<i>Triticum aestivum</i> L.	Soft wheat
<i>Triticum durum</i> L.	Durum wheat
<i>Triticum spelta</i> L.	Spelt (German wheat)
<i>Zea maïs</i> L.	Maize.

b) Inbred varieties and clones of maize:

aa) Open pollination variety: a sufficiently homogeneous and stable variety;

bb) Inbred clone: A sufficiently homogeneous and stable clone obtained either by artificial self-fertilization accompanied by selection over at least five successive generations, or by equivalent operations;

cc) Single hybrid: Direct descent of a cross specified by the breeder between two inbred clones;

dd) Double hybrid: Direct descent of a cross specified by the breeder between two single hybrids;

ee) Three-way hybrid: Direct descent of a cross specified by the breeder between an inbred clone and a single hybrid;

ff) "Top-cross hybrid": Direct descent of a cross specified by the breeder between an inbred clone or a single hybrid and an open pollination variety;

gg) Intervarietal hybrid: Direct descent of a cross specified by the breeder between plants from basic seed of two open pollination varieties.

c) Basic seed (oats, barley, rice, wheat, spelt, rye):

Seed —

aa) produced on the responsibility of the breeder in accordance with the rules of conservative selection as regards variety;

bb) intended for the production of certified seed of direct descent or second generation;

cc) fulfilling — save as provided by Article 4(1) — the conditions laid down in Annexes I and II for basic seed; and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

d) Basic seed (maize):

i) Open pollination varieties:

Seed —

aa) produced on the responsibility of the breeder in accordance with the rules of conservative selection as regards variety;

bb) intended for the production of certified seed of the said variety, of "Top-cross" hybrids or inter-varietal hybrids;

cc) fulfilling — save as provided by Article 4 — the conditions laid down in Annexes I and II for basic seed; and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

ii) *Inbred clones:*

Seed —

aa) fulfilling — save as provided by Article 4 — the conditions laid down in Annexes I and II for basic seed; and

bb) in respect of which the fulfilment of these conditions has been established by official examination.

iii) *Single hybrids:*

Seed —

aa) intended for the production of double hybrids, three-way hybrids or "Top-cross" hybrids;

bb) fulfilling — save as provided by Article 4 — the conditions laid down in Annexes I and II for basic seed; and

cc) in respect of which the fulfilment of these conditions has been established by official examination.

e) *Certified seed (rye, maize):*

Seed —

aa) of direct descent from basic seed;

bb) intended for purposes other than the production of cereal seed;

cc) fulfilling — save as provided by Article 4 (1 b and 2) — the conditions laid down in Annexes I and II for certified seed; and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

f) *Certified seed of direct descent (oats, barley, rice, wheat and spelt):*

Seed —

aa) of direct descent from basic seed of one variety;

bb) intended either for the production of certified seed of the second generation or for purposes other than the production of cereal seed;

cc) fulfilling — save as provided by Article 4 (1 b) — the conditions laid down in Annexes I and II for certified seed of the first generation; and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

g) *Certified seed of the second generation (oats, barley, rice, spelt and wheat):*

Seed —

aa) of direct descent from basic seed or certified seed of direct descent of a variety;

bb) intended for purposes other than the production of cereal seed;

cc) fulfilling — save as provided by Article 4 (1 b) — the conditions laid down in Annexes I and II for certified seed of the second generation; and

dd) in respect of which the fulfilment of these conditions has been established by official examination.

b) *Official measures:*

Measures which are taken:

aa) by the authorities of a Member State, or

bb) under the responsibility of that State by public or private corporations, or

cc) for ancillary activities, also under the supervision of the said State, by persons who have taken a professional oath, provided that they have no interest in the outcome of such measures.

2. The Member States may at their discretion include several generations in the category of basic seed and to subdivide that category by generations.

Article 3

1. The Member States shall stipulate that cereal seed shall only be commercialized if officially designated basic seed or certified seed of direct descent or second generation.

2. The Member States shall stipulate a maximum moisture content for any kind of basic or certified seed at the time of certification and commercialization.

3. The Member States may at their discretion make exceptions to paragraphs 1 and 2 for:

- a) selected seed from generations prior to the basic seed;
- b) experimental or scientific purposes;
- c) selection work.

Article 4

1. The Member States may at their discretion allow:

a) that cereal seed not fulfilling the requirements of Annex II regarding germination may be officially certified and commercialized as basic seed: in such case the supplier shall guarantee a certain germination, which shall be indicated when seed is commercialized on a special label bearing his name and address and the lot reference number;

b) that cereal seed in respect of which the official testing for germination provided for in Annex II has not been completed, may, in order to supply seed rapidly to wholesalers, be officially certified as basic seed or described as certified seed of direct descent or second generation respectively, and commercialized as such; in order to obtain certification the results of a provisional test and the name and address of the wholesaler must be indicated; the supplier must guarantee the germination established by the provisional test, which he shall indicate on a special label with his name and address and the lot reference number.

2. The Member States may, in respect of Zea mays L. seed, reduce the minimum germination laid down in Annex II to 85% of the pure seed.

Article 5

The Member States may at their discretion lay down, as well as the conditions set out in Annexes I and II, additional or stricter conditions for certification.

Article 6

1. Each Member State shall draw up a list of the varieties of cereals and inbred maize clones eligible for certification in its territory.

2. A variety shall be accepted for certification only if it has been established by official inspections or inspections under official aus-

pices of trial crops over two successive years, and for rye and open pollination varieties of maize, three successive years:

a) in the case of oats, barley, rice, wheat and spelt, that the variety is sufficiently homogeneous and stable; the list shall state the morphological and physiological characters by which the variety is identified;

b) in the case of rye and open pollination varieties of maize, that the variety is sufficiently homogeneous and stable; the list shall state the main morphological and physiological characters by which it is distinguished from other varieties;

c) in the case of hybrid varieties of maize, that the basic inbred clones are sufficiently homogeneous and stable and that the hybrid is produced from crosses specified by the breeder; the list shall state the morphological and physiological characters by which the variety is identified.

3. The Member States shall stipulate that descriptions of inbred clones of maize shall be confidential.

4. A regular official check shall be made of the varieties and inbred clones of maize approved for certification. If any condition of approval is no longer fulfilled, the approval shall be withdrawn and the variety or inbred clone of maize deleted from the list. In the case of a change in any of the secondary characters of a variety of rye or an open-pollination variety of maize, its description in the list shall immediately be altered.

5. The list and any changes made in it shall be immediately notified to the Commission, which shall inform the other Member States thereof.

Article 7

1. The Member States shall stipulate that samples in the process of checking varieties and inbred clones of maize and in the examination of seed for certification shall be taken officially by suitable methods.

2. Samples in examination for certification shall be taken from a homogeneous lot. The maximum weight of a lot and minimum weight of a sample are stipulated in Annex III.

Article 8

1. The Member States shall stipulate that basic and certified cereal seed of whatsoever kind shall be commercialized only in homo-

geneous lots and in closed packages, sealed and marked as specified in Articles 9 and 10, except as may be otherwise provided by the Council of Ministers or the Commission.

2. The Member States may at their discretion make exceptions to paragraph 1 for the sale of small quantities to final users.

Article 9

1. The Member States shall stipulate that packages of basic or certified cereal seed of whatsoever kind shall be officially closed in such a way that when the package is opened the seal is damaged and cannot be replaced.

2. A new closure shall be effected only under official auspices. In such case the second closure, with the date and the name of the department by which it was effected, shall be indicated on the label provided for in Article 10(1); where a new label is used the particulars given on the previous label shall be reproduced.

Article 10

1. The Member States shall stipulate that packages of basic and certified cereal seed of whatsoever kind shall:

a) bear, on the outside, an official label of the form prescribed in Annex IV, in one of the official languages of the Community; it shall be secured by the official seal; the colour shall be white for basic seed, blue for certified seed and seed certified as being of direct descent; red for seed certified as being of the second generation; for trade between Member States, the label shall bear the date of the official sealing; for basic seed of *Zea mays* L. which does not fulfil the requirements laid down in Annex II regarding germination (Article 4, 1 a and 2), this shall be stated on the label;

b) contain an official notice of the same colour and giving the same particulars as the label this notice may be dispensed with in the case of small packages or if the method of packaging makes its insertion impossible.

2. The Member States may at their discretion stipulate that the label must in all cases show the date of official sealing.

Article 11

The Member States may at their discretion stipulate that packages of basic or certified cereal seed of whatsoever kind shall be accompanied by a special supplier's label in cases additional to those specified in Article 4.

Article 12

The Member States shall stipulate that any chemical treatment of basic or certified cereal seed of whatsoever kind shall be mentioned either on the official label or on the supplier's label.

Article 13

1. The Member States shall ensure that basic and certified cereal seed of whatsoever kind which has been officially certified, marked and sealed according to the rules of the present directive shall be subject to no marketing restrictions in respect of their characteristics, official testing, minimum marking and sealing other than those laid down or permitted by the present directive.

2. The Member States may at their discretion:

a) restrict the marketing of certified oat, barley, rice, or spelt seed to seed of direct descent;

b) pending the establishment of a Community catalogue of varieties or inbred clones of maize, restrict the marketing of cereal seed to varieties or inbred clones of maize contained in a national list of varieties and clones which can profitably be grown in their territory; the conditions for inclusion in this list shall be the same for varieties and for inbred clones of maize from other member countries as for national varieties and national inbred clones of maize.

Article 14

1. The Member States shall stipulate that cereal seed which is of direct descent from basic seed certified in a Member State and is produced in another Member State or in a non-member country shall be considered as equivalent to certified seed or seed certified as being of direct descent or second gene-

ration raised in the State producing the basic seed, provided that it has been subjected to a crop inspection at the place where it was produced under the conditions set out in Annex I, and that it has been packaged in the State producing the basic seed, where it has been found, on official examination, to satisfy with the conditions laid down in Annex II for certified seed, or seed certified as being of direct descent or second generation.

2. Where a package of certified seed of cereals of whatsoever kind contains, in accordance with paragraph 1, seed produced in other States, these States shall be named on the official label.

Article 15

The Commission shall determine, by decision, at the request of one or more Member States and after consultation with the other Member States:

a) whether the crop inspection carried out in a non-member country complies with the conditions laid down in Annex I and referred to in Article 14(1) above;

b) that cereal seed produced in a non-member country and offering the same assurances to the user as regards its characteristics and the measures taken to examine, identify and test it shall be equivalent to basic seed, certified seed or seed certified as being of direct descent or second generation, marked and sealed in accordance with the rules set out in the present directive.

Article 16

1. If in one or more Member States there should be temporary difficulties over the general supply of basic or certified seed of cereals of any kind, and these difficulties cannot be resolved within the Community, the Commission shall issue a directive, at the request of at least one of the Member States concerned and after consulting the other Member States, authorizing one or more Member States to allow the sale, for a specified period, of seed of a grade fulfilling less strict requirements.

Article 17

The present directive shall not apply to cereal seed that is shown to be intended for export to non-member countries.

Article 18

The Member States shall make appropriate arrangements for the official checking of seed commercialized, at least by the testing of samples, for conformity with the conditions laid down in the present directive.

Article 19

1. Community growth trial stations shall be set up on Community territory; here annual post-controls shall be made of samples of basic and certified cereal seed; the field grounds shall be open to inspection by a committee of experts from Member States.

2. During the preliminary stage, comparative tests shall be made with a view to harmonizing methods of certification. When this has been done, comparative tests shall be the subject of an annual progress report transmitted confidentially to the Commission and the Member States. The Commission shall decide after consulting the Member States the date from which this report shall be made.

3. After consulting the Member States, the Commission shall make the necessary arrangements for carrying out comparative tests. Provision may be made for cereal seed produced in non-member countries to be included in these tests.

Article 20

Subject to the tolerances laid down in Annex I(5) and Annex II(2), regarding the presence of noxious organisms, the provisions of the present directive shall be without prejudice to regulations designed to protect the life and health of human beings and animals or to preserve plant life.

Article 21

1. The Member States shall introduce the necessary laws and regulations to conform with Article 13(1) by 1 May 1966, and with the other provisions of the present directive and its annexes by 1 May 1968 at latest. They shall inform the Commission thereof immediately.

2. The Member States shall inform the Commission, in time for it to submit comments, of any further draft laws or regulations they may contemplate adopting in the matters covered by the present directive.

Article 22

The present directive is addressed to the Member States.

ANNEX I

Conditions for certification

A. *Conditions relating to the trial crop*

1. The crop shall display sufficient varietal identity and purity. This conditions applies by analogy to inbred clones of maize.

2. The following minimum numbers of official crop inspections must be carried out:

a) for oats, barley, rice, wheat, spelt and rye: 1

b) for maize, during the flowering season:

i) open pollination varieties: 1

ii) for the production of certified seed of hybrid varieties: 3

iii) for the production of basic seed of simple hybrids: 4

iv) inbred clones: 4.

3. The cultivable condition of the trial ground and the stage of growth reached shall be such as to make possible an adequate check on varietal identity and purity and health standard; in the case of maize, checks on the identity and purity of inbred clones; and in the production of seed of hybrid varieties, the removal of tassels.

4. In the case of rye and maize, where there is no adequate protection from external pollination, the minimum distances from neighbouring crops of other varieties or inbred clones of the same species, or from crops of the same variety or inbred clone which does not reach the standards of purity for the production of basic seed of the same category, shall be:

	basic seed	certified seed
For maize	200 metres	200 metres
For rye	300 metres	250 metres

5. In crop inspections of oats, barley, wheat and spelt, the following shall be the tolerance for each of the 100 sq. metre plots examined:

for basic seed: 1 plant infected with *Ustilaginae*

for all types of certified seed: 5 plants infected with *Ustilaginae*

Neighbouring crops within a radius of 80 metres shall not show a much higher proportion of infected plants.

6. Special requirements for maize:

a) the percentage by number of plants showing aberrations from type shall not exceed:

i) for basic seed: 0.1

ii) for the production of certified seed of hybrid varieties: 0.2

iii) for the production of seed of open pollination varieties: 0.5.

b) Removal of tassels: for the production of seed of hybrid varieties the percentage of female parent plants having discharged pollen shall not be found to exceed 1% at any one inspection nor 2% as a total for all inspections.

c) For the production of seed of hybrid varieties, the flowering of parent plants must coincide sufficiently closely.

ANNEX II

Conditions relating to the seed

1. The seed shall have sufficient varietal identity and purity. This condition applies by analogy to inbred clones of maize.
2. The presence of diseases affecting the utilization value of seed shall as far as possible be avoided. In 500 grammes the tolerance is 1 stub of ergot or specks of ergot for basic seed, and 2 stubs for all types of certified seed.
3. The seed shall reach the following standards:

Species	Category	Minimum technical purity (% of seeds)	Minimum germination (% of pure seed)	Minimum specific purity (% by weight)	Maximum content of seed of other species of plants (number of seeds per 500 grammes)		
					Total	Other species of cereals	Other species of plants
a) Oats Barley Wheat Spelt	i) Basic seed	99.9	85	98	4	1	3, including 1 <i>Raphanus raphanistrum</i> or <i>Agrostemma githago</i> , 0 <i>Avena fatua</i> , <i>Avena sterilis</i> , <i>Avena ludoviciana</i> or <i>Lolium temulentum</i>
	ii) Certified seed of direct descent	99.7	95	98	10	5	7, including 3 <i>Raphanus raphanistrum</i> or <i>Agrostemma githago</i> , 0 <i>Avena fatua</i> , <i>Avena sterilis</i> , <i>Avena ludoviciana</i> or <i>Lolium temulentum</i>
	iii) Certified seed of the second generation	99.5	85	98	10	5	ditto.

b) Rice	i) Basic seed	99.9	80	98	4	1 red seed	1 Panicum
	ii) Certified seed of direct descent	99.7	80	98	10	2 red seeds	3 Panicum
	iii) Certified seed of the second generation	99.5	80	98	10	2 red seeds	3 Panicum
c) Rye	i) Basic seed	99.5	85	98	4	1	3, including 1 Raphanus raphanistrum or Agrostemma githago, 0 Avena fatua, Avena sterilis, Avena ludoviciana or Lolium temulentum
	ii) Certified seed	99	85	98	10	5	7, including 3 Raphanus raphanistrum or Agrostemma githago, 0 Avena fatua, Avena sterilis Avena ludoviciana or Lolium temulentum
d) Maize	i) Basic seed	99.9	90	98	0		
	ii) Certified seed of hybrid varieties	99.8	90	98	0		
	iii) Certified seed of open pollination varieties	99.5	90	98	0		

ANNEX III

Maximum weight of lot: 20 tons

Minimum weight of sample: 1 kg.; 250 grammes for inbred clones of maize.

ANNEX IV

Label

A. Particulars to be supplied

1. The words "Cereal seed certified in accordance with EEC regulations".
2. Certifying department and Member State.
3. Lot reference number.
4. Species.
5. Variety of inbred clone of maize.

6. Category.

7. Declared net or gross weight.
8. For hybrid varieties of maize: the word "Hybrid".

B. Dimensions

(See page 24).

Proposal for a Council directive on the marketing of seed potatoes

(Submitted by the Commission to the Council)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community and in particular Article 43 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Whereas potato growing is a highly important agricultural activity in the European Economic Community;

Whereas satisfactory results in potato growing depend to a great extent on the use of appropriate seed; whereas for some time certain Member States have accordingly allowed only high-quality seed potatoes to be sold; whereas they have benefited from a systematic selection of plants over decades, which has developed stable and homogeneous varieties presenting substantial advantages as to yields, reliability of performance and suitability for the grower's purpose:

Whereas an even greater improvement of productivity in potato growing in the European Economic Community will be obtained if the Member States apply strict and uniform rules governing the varieties which may be commercialized, notably with respect to their resistance to disease;

Whereas, however, limitation to certain varieties is only warranted in so far as there is at the same time an assurance that the user does in fact receive seed potatoes of those varieties;

Whereas for this purpose certain Member States apply certification systems whereby the identity and the purity of the varieties and their resistance to disease are guaranteed by official testing and inspection;

Whereas definitive recommendations for such a system are now being prepared by the Economic Commission for Europe with a view to standardizing the commercial quality of seed potatoes entering into international trade; whereas these recommendations refer in particular to the resistances to disease of the pro-

geny; whereas they consequently provide one of the fundamental bases for a unified certification system in the European Economic Community;

Whereas EEC rules must normally be applicable to sales on domestic markets as well as in trade between the Member States, so as to obviate disparities between domestic and Community systems;

Whereas seed potatoes should normally only be offered for sale if they have been officially examined and certified as "basic seed" or "certified seed" according to the rules of the certification system; whereas the technical terms "basic seed" and "certified seed" are drawn from existing international terminology;

Whereas seed potatoes not offered for sale, having little economic importance, should be exempt from Community rules, though the Member States may still at their discretion apply special rules to them;

Whereas, moreover, Community rules should not apply to seed potatoes of which it is established that they are intended for export to non-member countries;

Whereas in order to improve the external characteristics of seed potatoes in the European Economic Community as well as their genetic value and resistance to disease, strict tolerances must be laid down with respect to certain blemishes and diseases;

Whereas for purposes of identification, Community rules must be established concerning packaging, sealing and labelling; whereas labels must supply the particulars needed by official inspectors and by farmers and must indicate that the seed potatoes have been certified by Community authorities;

Whereas in order to ensure that all seed potatoes offered for sale satisfy the requirements concerning quality and identification the Member States must make the necessary arrangements for inspection:

Whereas seed potatoes fulfilling all requirements must not be subject, save as provided in Article 36 of the Treaty, to marketing restrictions other than those laid down or permitted by Community rules;

Whereas even Article 36 of the Treaty does not justify additional marketing restrictions, in so far as Community rules stipulate tolerances for diseases, noxious organisms and carriers of such organisms; whereas during a preliminary stage — and pending the establishment of a common catalogue of varieties — the restrictions allowed should include in particular the right of Member States to confine sales to varieties which can profitably be grown on their territories;

Whereas seed potatoes grown in non-member countries may only be offered commercialized in the European Economic Community if they afford users the same guarantees as seed potatoes grown and officially inspected, certified, labelled and sealed within the Community; whereas to obviate divergences in decisions on this matter between Member States the Commission must be empowered to decide whether these conditions are fulfilled in the various non-member countries, and will take the necessary measures having due regard to arrangements in the non-member countries concerned;

Whereas at times when difficulties are experienced over the supply of certified seed potatoes of the various categories, the Commission must be empowered to authorize provisionally grades fulfilling less strict requirements;

Whereas in order to ensure that all seed potatoes certified in the Member States fulfil the established requirements and in order to enable comparisons to be made in future between these seed potatoes and those imported from non-member countries, it is desirable to establish growth trial stations in the Member States for annual testing of certified seeds of the different categories; whereas the Member States must have power to prohibit wholly or partly sales of seed potatoes from other Member States when comparative tests over several years have failed to show satisfactory results in respect of all or some varieties,

Has issued the present directive:

Article 1

The present directive concerns seed potatoes marketed within the Community.

Article 2

a) The following shall be deemed to be basic seed potatoes:

Potato tubers which:

- i)* have been produced in accordance with the rules of conservative selection with respect to variety and healthiness;
- ii)* are intended for the production of certified seed potatoes;
- iii)* fulfil the conditions set out in Annexes I and II for basic seed potatoes and
- iv)* have been officially checked for fulfilment of these conditions;

b) The following shall be deemed to be certified seed potatoes:

Potato tubers which:

i) are of direct descent from basic seed potatoes or certified seed potatoes of one variety;

ii) are intended in particular for the growing of potatoes other than seed potatoes;

iii) fulfil the conditions set out in Annexes I and II for certified seed potatoes; and

iv) have been checked for fulfilment of these conditions by official inspection.

c) The following shall be deemed to be official measures:

Measures taken:

i) by the authorities of a Member State; or
ii) under the responsibility of that State by public or private corporations; or

iii) for ancillary activities, also under the supervision of that State, by persons who have taken a professional oath, provided that they have no interest in the outcome of such measures.

Article 3

1. The Member States shall stipulate that seed potatoes may only be commercialized if they are officially stated to be basic seed potatoes or certified seed potatoes. Seed potatoes not fulfilling when commercialized the conditions set out in Annex II may be put aside and subjected to a further official inspection.

2. The Member States may at their discretion:

a) create within the seed potato categories provided for in Article 2 grades subject to different standards;

b) provide for exceptions to paragraph 1 for:

i) selected seed of generations prior to the basic seed potatoes;

ii) experimental or scientific purposes;

iii) selection work.

Article 4

In addition to the conditions set out in Annexes I and II, the Member States may at their discretion establish supplementary or more stringent conditions to be complied with for the issue of certificates.

Article 5

1. Each Member State shall establish a list of the potato varieties officially approved for

certification in its territory; the list shall indicate the main morphological and physiological characters by which the varieties are distinguished; long varieties shall be indicated as such; a variety shall be deemed long when on average the length of its tubers is at least twice their greatest width.

2. The list, together with any changes made in it, shall be immediately transmitted to the Commission, which shall inform the other Member States thereof.

Article 6

The Member States shall prohibit the marketing of seed potatoes that have been treated with products inhibiting their germination.

Article 7

1. The Member States shall stipulate that seed potatoes for marketing must be not less than 28 mm. in width and for long varieties not less than 35 mm. in width, the minimum widths of the tubers in any given consignment shall be divisible by 5; the difference between the minimum and maximum widths shall not exceed 20 mm.

2. For official checking of sizes square meshes shall be used.

3. In the case of home-grown seed potatoes the Member States may at their discretion stipulate a narrower range between the minimum and maximum sizes of the tubers in any given consignment.

Article 8

1. The Member States shall stipulate that basic seed potatoes and certified seed potatoes may only be commercialized in homogeneous consignments and in new packages, sealed and labelled according to the rules provided for in Articles 9 and 10.

2. The Member States may at their discretion provide for exceptions to paragraph 1 above for the sale of small quantities to final users.

Article 9

1. The Member States shall stipulate that the packages of basic seed potatoes and certified seed potatoes shall be officially closed in such a way that when the package is opened the seal is damaged and cannot be replaced.

2. A second closure shall be effected only under official auspices. In such case the second closure, with the date and the name

of the department by which it was effected, shall be indicated on the label provided for in Article 10(1); where a new label is used, the particulars given on the previous label shall be reproduced.

Article 10

1. The Member States shall stipulate that the packages containing basic seed potatoes and certified seed potatoes shall:

a) bear on the outside an official label as shown in Annex III in one of the official Community languages; it shall be secured by the official seal; the label shall be white for basic seed potatoes and blue for certified seed potatoes;

b) contain an official notice of the same colour and giving the same particulars as the outside label; this notice may be dispensed with in the case of small packages or if the method of packaging makes its insertion impossible.

2. The Member States may at their discretion stipulate that labels must in all cases give the date of official closing.

Article 11

The Member States may at their discretion stipulate that packages of basic or certified seed potatoes shall bear in certain cases the supplier's special label.

Article 12

The Member States shall stipulate that any chemical treatment of basic or certified seed potatoes shall be indicated either on the official label or on a supplier's label.

Article 13

1. The Member States shall ensure that basic seed potatoes and certified seed potatoes which have been officially certified, labelled and closed in accordance with the rules of the present directive shall be subject to no marketing restrictions in respect of their characteristics, their official inspection, their minimum marking or their closure other than those laid down or permitted by the present directive.

2. With regard to the marketing of seed potatoes in all or in parts of the territory of one or more Member States, the Commission shall be empowered to authorize, at the request of one or more Member States and after consulting the others, the adoption of more stringent measures than those laid down in Annex I against certain viruses which either

do not exist in these areas or which are particularly harmful to agriculture in these areas. Where there is imminent danger of the introduction or propagation of such viruses, the measures may be adopted as from the date of the request until the Commission's final ruling thereon.

3. Pending the establishment of a Community catalogue of varieties the Member States may at their discretion restrict the marketing of seed potatoes to those on a national list of varieties which can profitably be grown on their territories; the conditions for inclusion in this list shall be the same for varieties from other Member States as for national varieties.

Article 14

1. The Member States may prohibit any or all sales of seed potatoes grown in another Member State if the progeny of samples which have been taken under official auspices from basic seed potatoes or certified seed potatoes grown in that Member State and which have been planted on one or more Community trial grounds has deviated appreciably in the course of three successive years from the specifications of Annex I:

2. Any measures adopted pursuant to paragraph 1 shall be withdrawn as soon as it has been established with a sufficient degree of certainty that in future all basic seed potatoes and certified seed potatoes grown in the Member State in question will satisfy the requirements of Annex I.

3. Before measures permitted under paragraph 1 are adopted or withdrawn an expert committee to be set up and attached to the Commission shall be consulted.

4. After consulting the Member States, the Commission shall make the necessary arrangements for carrying out comparative tests. Provision may be made for seed potatoes produced in non-member countries to be included in these tests.

Article 15

The Commission shall be empowered to decide, at the request of one or more Member States and after consulting the other Member States, that seed potatoes grown in a non-member country offering the same assurances to the user as regards their characteristics and the measures taken to examine, identify and test them are equivalent to those offered by basic seed potatoes or certified seed potatoes

officially certified, packed, sealed and labelled in accordance with the rules set out in the present directive.

Article 16

1. If in one or more Member States there should be temporary difficulties over the general supply of basic seed potatoes or certified seed potatoes, and these difficulties cannot be resolved within the Community, the Commission shall issue a directive, at the request of at least one of the Member States concerned and after consulting the other Member States, authorizing one or more Member States to allow the marketing, for a specified period, of seed potatoes of a grade fulfilling less strict requirements.

2. The colour of the official label for this grade shall be the same as that prescribed for the corresponding category. The label shall indicate that the seed potatoes in question are of a grade fulfilling less strict requirements.

Article 17

The present directive shall not apply to seed potatoes which are shown to be intended for export to non-member countries.

Article 18

The Member States shall make appropriate arrangements for the official checking of

seed potatoes commercialized, at least by the testing of samples, for conformity with the conditions laid down in the present directive.

Article 19

Subject to the tolerances laid down in Annexes I and II regarding the presence of diseases, noxious organisms or carriers of such organisms, the provisions of the present directive shall be without prejudice to regulations designed to protect the life and health of human beings and animals or to preserve plant life.

Article 20

1. The Member States shall introduce the necessary laws and regulations to conform with Article 13(1) by 1 May 1966 and with the other provisions of the present directive and of its annexes by 1 May 1968 at latest. They shall inform the Commission thereof immediately.

2. The Member States shall inform the Commission, in time for it to submit comments, of any further draft laws or regulations they may contemplate adopting in the matters covered by the present directive.

Article 21

The present directive is addressed to the Member States.

ANNEX I

Conditions for certification relating to the trial crop

1. Basic seed potatoes shall satisfy the following requirements:

a) On official inspection of the trial crop, the proportion affected by blackleg must not exceed 2%;

b) The proportion, in the first crop, of plants not true to the variety must not exceed 0.25%: not more than 0.1% of plants of other varieties shall be allowed;

c) The proportion, in the first crop, of plants showings signs of mild or serious virus disease must not exceed 4%.

2. Certified seed potatoes shall satisfy the following requirements:

a) On official inspection of the trial crop, the proportion affected by blackleg must not exceed 4%;

b) The proportion, in the first crop, of plants not true to the variety must not exceed 0.5%: not more than 0.2% of plants of other varieties shall be allowed;

c) The proportion, in the first crop, of plants showing signs of severe virus disease must not exceed 10%. Light mosaics merely causing discoloration and not leaf deformation are to be ignored.

3. In assessing the progeny of a variety carrying a chronic virus, no account is to be taken of slight signs caused by the said virus.

4. The tolerances allowed under 1 c), 2 c) and 3 shall apply only where the virus diseases are caused by viruses already prevalent in Europe.

ANNEX II

Conditions for certification relating to the seed potatoes

1. The seed potatoes shall possess sufficient varietal identity and purity.
 2. The seed potatoes shall not exceed the following tolerances in respect of the defects and diseases indicated:
 - a) Presence of soil and extraneous matter: 2% by weight
 - b) Dry and wet rot (except if caused by *Synchytrium endohyeticum*, *Corynebacterium sepe-donicum* or *Pseudomonas solanacearum*): 1% by weight
 - c) External blemishes (e.g. mis-shapen or damaged tubers): 3% by weight
 - d) Common scab: tubers affected over more than one-third of their surface: 5% by weight
- Tolerance for items a) to d): 6% by weight

ANNEX III

Label

A. Particulars to be supplied

1. The words "Seed potatoes certified in accordance with EEC regulations".
2. Certifying department and Member State.
3. Producer's identification number or lot number.
4. Variety.
5. Region where grown.

6. Category and grade (if any).

7. Size.
8. Declared net weight.
9. Crop year.

B. Dimensions

(See page 24).

Proposal for a Council directive on the marketing of forestry reproductive material

(Submitted by the Commission to the Council on 3 March 1964)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof;

Having regard to the proposal Commission;

Having regard to the opinion of the European Parliament;

Whereas 21.6% of the area of the European Community is woodland; and whereas afforestation and reforestation call for increasing quantities of forestry reproductive material;

Whereas research into forest plant breeding shows that reproductive material of high genetic quality must be used in order to obtain a substantial increase in forest production and thus improve the profitability of plantations;

Whereas several Member States have applied rules for this purpose for many years; whereas the divergences among these rules constitute an obstacle to trade among the Member States; and whereas strict Community rules must be introduced, which will benefit all Member States;

Whereas in principle these rules must be applicable to trade both among the Member

States and on national markets in order to prevent any divergence between national and Community systems;

Whereas, however, such rules must take account of practical needs and must be limited in scope to forest genera and species of importance in afforestation intended for the production of wood;

Whereas these rules must also be limited for the time being to the genetic value of the reproductive material, while the external characteristics of such material will be the subject of subsequent harmonization;

Whereas the basis of selection for reproductive material in the European Economic Community is the approval of the basic material and consequently the delimitation of regions of origin; whereas the Member States must apply identical and strict rules for the approval of basic material; whereas only reproductive material derived therefrom may be commercialized; and whereas the Member States must each draw up a list of regions of origin;

Whereas forestry reproductive materials not commercialized, having little economic importance, should be exempt from Community rules, though the Member States may still at their discretion apply special rules to them;

Whereas, furthermore, the Community rules should not apply to reproductive material shown to be intended for export to non-member countries;

Whereas the identity as well as the genetic value of reproductive material commercialized must be guaranteed;

Whereas the Member States must be authorized to stipulate that reproductive material imported into their territory from other States be accompanied by an official certificate of prescribed form;

Whereas, in order to ensure that requirements as regards both genetic value and identity are complied with in every case where material is commercialized, the Member States must make provision for appropriate inspection and control;

Whereas reproductive material satisfying all requirements must not be subject to marketing restrictions other than those laid down or permitted by Community rules; and whereas the restrictions allowed should include the right of the Member States to prohibit the

marketing of forestry reproductive material that is unsuitable for use on their territory;

Whereas reproductive material from non-member countries may be commercialized within the European Economic Community only if it affords the user the same guarantee as regards identity and the genetic value of the basic material as reproductive material from Community sources; and whereas, in order to obviate divergence in decisions on this matter between Member States, the Commission will decide whether these conditions have been fulfilled in the case of each of the non-member countries and will take the necessary measures having due regard to arrangements in the non-member countries concerned,

Has issued the present directive:

Article 1

The present directive concerns the genetic value of forestry reproductive material to be sold or commercialized within the Community.

Article 2

1. The present directive shall apply to:

a) reproductive material of:

Abies alba Mill. (*Abies pectinata* D.C.)

Fagus silvatica L.

Larix

Picea abies Karst. (*Picea excelsa* Link.)

Picea sitchensis Trautv. et Mey. (*Picea menziesii* Carr.)

Pinus nigra Arn. (*Pinus Laricio* Poir.)

Pinus silvestris L.

Pinus strobus L.

Pseudotsuga taxifolia (Poir.) Britt. (*Pseudotsuga douglassii* Carr., *Pseudotsuga menziesii* (Mirb.) Franco.)

Quercus borealis Michx. (*Quercus rubra* Du Roi.)

Quercus pedunculata Ehrh. (*Quercus robur* L.)

Quercus sessiliflora Sal. (*Quercus petraea* Liebl.)

b) vegetatively propagated reproductive material of:

Populus.

2. The Member States shall be free to apply the present directive to reproductive material of other genera and species or to sexually propagated reproductive material of *Populus*, in which case less stringent requirements may be specified; no requirements of a different kind shall be imposed as regards genetic value.

Article 3

Definitions

a) Reproductive material:

i) seeds: cones, infructescences, fruits and seeds intended for the production of plants;

ii) parts of plants: cuttings and scions intended for the production of plants;

iii) plants: plants raised from seeds or parts of plants or layerings produced by natural regeneration;

b) Basic material:

i) seed stands and seed orchards — for sexually propagated material;

ii) clones — for vegetatively propagated material;

c) Seed orchard:

Artificial plantation derived from reproductive material from one or more officially approved stands from a single region of origin and intended for the production of seed;

d) Region of origin:

For a given genus, species, sub-species or variety, the territory or group of territories subject to sufficiently uniform ecological conditions on which are found stands showing characters that are genetically or at least morphologically analogous and of equal value for the production of wood; the region of origin of material produced by a seed orchard is that of the basic material used in forming the said orchard;

e) Official measures:

Measures taken:

i) by the authorities of a Member State, or

ii) on the responsibility of the State by public or private corporations, or

iii) for ancillary activities, also under the supervision of that State, by persons who have taken a professional oath, provided that such persons have no interest in the outcome of such measures.

Article 4

1. The Member States shall stipulate that forestry reproductive material may only be commercialized if it is derived from officially approved basic material.

2. The Member States shall be free to make exceptions to paragraph 1 for

a) experimental or scientific purposes, or

b) selection work.

3. Paragraph 1 shall not apply to plants or parts of plants shown to be not mainly intended for the production of wood.

Article 5

The Member States shall stipulate that only material that appears to be of suitable quality for reproduction and does not show generic characters unfavourable for the production of wood shall be officially approved as basic material. The approval procedure shall follow the principles set out in Annex I.

Article 6

Each Member State shall draw up a list of officially approved basic materials for the various genera and species. The list and any amendments thereto shall be communicated promptly to the Commission, which shall notify the other Member States.

Article 7

The Member States shall define regions of origin for sexually propagated material by means of administrative or geographic boundaries and, where applicable, by altitudinal boundaries.

Article 8

1. The Member States shall stipulate that, in raising, gathering, storage and transport, forestry reproductive material shall be kept in separate lots according to the following criteria:

a) Genus and species and, where applicable, sub-species and variety;

b) Clone — for vegetatively propagated material;

c) Région of origin — for sexually propagated material;

d) Place of origin and altitude — for sexually propagated material not derived from officially approved basic material (Article 13);

e) Length of time in the nursery as seedlings or as plants transplanted one or more times — for plants.

2. Paragraph 1 shall not apply to plants or parts of plants shown to be not mainly intended for the production of wood.

Article 9

1. The Member States shall lay down that forestry reproductive material may only be commercialized in lots as specified in Article 8 and only if accompanied by a document bearing the criteria set out in Article 8, together with the botanical name of the reproductive material.

2. The Member States may at their discretion stipulate that the following additional particulars shall be furnished:

a) Designation of supplier;

b) Quantity;

c) Any treatment applied to the reproductive material;

d) Seed-test results;

e) The words "Reproductive material from a seed orchard" — for seeds from seed orchards and for plants derived therefrom.

3. Paragraph 1 shall not apply to plants or parts of plants shown to be not mainly intended for the production of wood.

Article 10

1. The Member States shall stipulate that forestry reproductive material may only be offered for sale if its identity is guaranteed by an appropriate official system from gathering until delivery to the final user.

2. Paragraph 1 shall not apply to plants or parts of plants shown to be not mainly intended for the production of wood.

Article 11

1. The Member States may at their discretion stipulate that forestry reproductive material may be imported into their territory from another state only if it is accompanied by an official certificate conforming to the model provided in Appendix II in the case of another Member State or by an equivalent certificate in the case of a non-member country stating:

a) the origin — for sexually propagated material;

b) the clonal identity — for vegetatively propagated material.

2. Paragraph 1 shall not apply to plants or parts of plants shown to be not mainly intended for the production of wood.

Article 12

1. The Member States shall ensure that forestry reproductive material is subject to no marketing restrictions in respect of the genetic value of its basic material and measures taken to guarantee its identity other than those laid down or permitted in the present directive.

2. The Member States may at their discretion take measures to prevent the yield capacity or the production of wood in their forests from being impaired as regards genetic value by reproductive material unsuited to their territories as a whole.

In so doing they shall not, subject to a strict check on this point, restrict trade in seedlings or parts of plants shown to be not mainly intended for the production of wood.

3. Where measures allowed under paragraph 2 relate to material produced in another Member State, there shall be prior consultation of the Commission and the other Member States. In urgent cases such consultation shall be confined to the Commission and the Member States concerned.

Article 13

On application by one or more Member States and after hearing the other Member States, the Commission shall determine, by decision that forestry reproductive material produced in a non-member country or forestry reproductive material derived from officially approved basic material and whose identity is guaranteed by an appropriate official system from gathering until delivery to the final user, provided that it offers the same guarantee as regards the genetic value of its basic material and the measures taken to ensure identity.

Article 14

The present directive shall not apply to forestry reproductive material shown to be intended for export to non-member countries.

Article 15

The Member States shall make appropriate arrangements for the official checking of forestry reproductive material commercialized at least by the testing samples for conformity with the conditions laid down in the present directive.

Article 16

1. The Member States shall introduce the necessary laws or regulations to conform with the provisions of the present directive and its annexes:

a) no later than 30 June 1966 for seeds and parts of plants of

Abies alba Mill.

Picea abies Karst.

Pinus silvestris L.

Pseudotsuga taxifolia Britt.,

b) no later than 30 June 1968 for seeds and parts of plants of

Larix

Picea sitchensis Trautv. et Mey.

Pinus nigra Arn.

Pinus strobus L.,

c) no later than 30 June 1970 for seeds and parts of plants of

Fagus silvatica L.

Quercus borealis Michx.

Quercus pedunculata Ehrh.

Quercus sessiliflora Sal.

Populus.

2. For seeds of conifer genera and species harvested before the dates specified in paragraph 1, the time-limits may be extended by two years.

3. For plants, the time-limits shall be extended by four years beyond the dates specified in paragraph 1 or those fixed in pursuance of paragraph 2.

4. The Member States shall notify the Commission immediately these provisions have been put into effect.

5. The Member States shall inform the Commission, in time for it to make its comments, of any further drafts of laws or regulations they may contemplate adopting in the matters covered by the present directive.

Article 17

The present directive is addressed to the Member States.

ANNEX I

Criteria for the approval of basic material

A. Stands

1. *Origin* — The basic material should, for preference, consist of indigenous stands, or introduced stands that have proved their value.

2. *Isolation* — The stands should be sufficiently isolated from poor stands of the same species or from stands of a related species or variety which can form hybrids with the species in question. This isolation is particularly important when the surrounding stands are not indigenous.

3. *Uniformity* — The stands should show a normal degree of individual variation in morphological characters.

4. *Volume production* — Volume production is an essential criterion for the acceptance of basic material. Volume production must normally be superior to the accepted mean under the same ecological conditions.

5. *Wood quality* — The quality of the wood should be taken into account and, in some cases, may become an essential criterion.

6. *Form or growth habit* — The stands must show particularly good morphological features, especially straightness of stem, favourable branching habit, small size of branches, and good natural pruning; in addition, the frequency of forking and incidence of spiral grain should be as weakly developed as possible.

7. *Resistance* — The stands should in general be free from and show resistance to dam-

aging organisms and also to severe climatic or site conditions.

8. *Age* — The stands should consist of trees of such an age that the criteria given above can be clearly judged.

9. *Effective size of the population* — The stands must consist of one or more groups of trees sufficient to make possible adequate cross-pollination. To avoid the unfavourable effects of inbreeding, stands should consist of a sufficient number of individuals on a given minimum area.

B. Seed orchards

Seed orchards should be planted so as to provide sufficient guarantee that the seeds raised there have at least the average genetic quality of the basic material from which the orchard is derived.

C. Clones

1. Points 4, 5, 6, 7 and 8 under A above shall be applicable by analogy.

2. The clones should be identifiable by their distinguishing features.

3. The utility of the clones should be supported by experience or established by sufficiently prolonged experiments.

ANNEX II

Certificate of origin ⁽¹⁾

Certificate of clonal identity ⁽¹⁾

..... No.
(country)

It is hereby certified that the forestry reproductive material described below has been controlled by the responsible authorities and that, from the declarations made and the documents presented, it complies with the following specifications:

1. Nature of produce: seed/parts of plants/plants ⁽¹⁾
2. Genus and species, sub-species, variety, clone ⁽¹⁾
 - (a) common name:
 - (b) botanical name:
3. Region of origin ⁽¹⁾:
(Place of origin and altitude) ⁽¹⁾ ⁽²⁾
4. Length of time in nursery as seedling
or transplant ⁽¹⁾
5. Quantity:
6. Number and nature of packages:
7. Marking of packages:
8. Additional information ⁽¹⁾:

..... 19.....
.....
(Stamp of responsible authority) (Signature)
.....
(Description)

⁽¹⁾ Delete the words that do not apply.
⁽²⁾ For reproductive material not derived from basic material officially approved within the European Economic Community.

Proposal for a decision instituting a standing committee on agricultural, horticultural and forestry seeds and seedlings

(Submitted by the Commission to the Council on 3 March 1964)

The Council of the European Economic Community,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof;

Having regard to the proposal of the Commission;

Having regard to the opinion of the European Parliament;

Whereas the implementation of the directives designed to promote practical and legal harmonization in the marketing of beet seed, seed potatoes, herbage seeds, cereal seeds and forestry reproductive material will entail a number of specific tasks;

Whereas one of these tasks is the application of harmonized legislative provisions, which must be carried out as uniformly as possible in all the Member States and in such a way as to leave no obstacle to this branch of trade within the European Economic Community;

Whereas by these directives certain powers and responsibilities devolve upon the Commission in connection with the issue of licences after consultation of the Member States;

Whereas it has been provided that the Member States may take certain implementing measures only after consulting the Commission and the other Member States;

Whereas, in so far as they concern agricultural seeds and seedlings, the directives provide for the institution of expert committees to render opinions on the basis of growth trials of certified seeds of all categories;

Whereas new tasks will arise from the planned harmonization of laws, notably in connection with the marketing of vegetable seeds, the establishment of a common catalogue of varieties and the external characteristics of forestry reproductive material;

Whereas all these tasks necessitate a committee of government experts, which in cases of urgency can be speedily consulted, particularly if it is necessary for the Commission to authorize a Member State to admit provisionally other categories of seeds or seedlings in poor harvest years;

Whereas in the interests of efficiency, the membership of the Committee should be

confined to one head of delegation and two other experts per Member State; whereas in view of the diversity of the products concerned, more especially as regards agricultural seeds and seedlings and forestry reproductive material, the Member States must be authorized to vary the composition of their delegations according to the subject being dealt with,

Has made the present decision:

Article 1

1. A standing committee on agricultural, horticultural and forestry seeds and seedlings, hereinafter referred to as "the Committee", shall be set up and attached to the Commission.

2. The Committee shall:

a) deal with all questions arising from the implementation or harmonized laws or regulations on seeds and seedlings;

b) advise on the preparation of measures to be adopted by the Commission under:

i) Articles 16, 17(1) and 20(2 and 3) of the Directive on the marketing of beet seed;

ii) Articles 13(2), 14(4), 15 and 16(1) of the Directive on the marketing of seed potatoes;

iii) Articles 3(3), 16, 17(1) and 18(2 and 3) of the Directive on the marketing of herbage seeds;

iv) Articles 15, 16(1) and 19(2 and 3) of the Directive on the marketing of cereal seeds;

v) Articles 12(3) and 13 of the Directive on forestry reproductive material;

c) to carry out the duties of the committees of experts referred to in:

i) Article 20(1) of the Directive on the marketing of beet seed;

ii) Article 14(3) of the Directive on the marketing of seed potatoes;

iii) Article 20(1) of the Directive on the marketing of herbage seeds;

iv) Article 19(1) of the Directive on the marketing of cereal seeds.

Article 2

The consultation of the Member States stipulated in the provisions referred to in Article 1(2 b) above shall take place within the Committee.

Article 3

The Committee shall comprise one delegate with not more than two alternates of the Government of each Member State. The delegates and alternates may be varied according to the subject under discussion.

Article 4

1. The Committee shall have as its chairman

a representative of the Commission (Directorate-General for Agriculture).

2. Secretarial services shall be provided by the Commission.

Article 5

The Committee shall draw up its own rules of procedure.

Article 6

The present decision is addressed to the Member States.

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