

Official Journal

of the European Communities

Volume 20 No L 295
18 November 1977

English Edition

Legislation

Contents

I *Acts whose publication is obligatory*

.....

II *Acts whose publication is not obligatory*

Council

77/712/EEC:

- ★ Council recommendation of 25 October 1977 on the regulating of space heating, the production of domestic hot water and the metering of heat in new buildings .. 1

77/713/EEC:

- ★ Council recommendation of 25 October 1977 on the rational use of energy in industrial undertakings 3

77/714/EEC:

- ★ Council recommendation of 25 October 1977 on the creation in the Member States of advisory bodies or committees to promote combined heat and power production and the exploitation of residual heat 5

77/715/EEC:

- ★ Council Decision of 28 October 1977 on the conclusion of the European Agreement on the exchange of tissue-typing reagents and the Additional Protocol thereto 7

European Agreement on the exchange of tissue-typing reagents 8

Additional Protocol to the European Agreement on the exchange of tissue-typing reagents 15

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL RECOMMENDATION

of 25 October 1977

on the regulating of space heating, the production of domestic hot water and the metering of heat in new buildings

(77/712/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the draft from the Commission,

Whereas, in its resolution of 17 September 1974 concerning a new energy-policy strategy for the Community ⁽¹⁾, the Council approved the objective of reduction of the rate of growth of internal consumption by measures for using energy rationally and economically without jeopardizing social and economic growth objectives;

Whereas improvements in the rational use of energy are generally beneficial to the environment;

Whereas, in its resolution of 17 December 1974 on a Community action programme on the rational utilization of energy ⁽²⁾, the Council noted that, in its communication to the Council entitled 'Rational Utilization of Energy', the Commission had drawn up a Community action programme in this field;

Whereas the Council recommendation of 4 May 1976 ⁽³⁾ related to the heating systems of existing buildings; whereas it is advisable to obtain energy savings as soon as possible for the heating systems of new buildings;

Whereas this objective can be achieved in buildings with collective heating systems only if the occupants are able to regulate their own energy consumption;

Whereas collective systems for space heating and production of domestic hot water of new buildings with several occupants should be fitted with the means for apportioning the heating costs among the various occupants on the basis of the amount of heat supplied;

Whereas the measures recommended are such as to produce sufficiently large savings in energy while ensuring that the required investments are economically worthwhile,

HEREBY RECOMMENDS TO THE MEMBER STATES:

that they adopt any laws, regulations or administrative measures necessary to ensure that:

⁽¹⁾ OJ No C 153, 9. 7. 1975, p. 1.

⁽²⁾ OJ No C 153, 9. 7. 1975, p. 5.

⁽³⁾ OJ No L 140, 28. 5. 1976, p. 12.

1. in new buildings used as offices, public buildings and buildings which are not occupied all the time
 - 1.1. all heating systems are fitted with an automatic programming and regulating device which will produce the desired temperature curve for the premises served;
 - 1.2. when heat generators are operating, the temperature during occupation of premises for which a given occupant is accountable does not exceed 20 °C on average and does not exceed 22 °C in any one room;
2. in new residential accommodation
 - 2.1. the individual heating system, whether centralized or independent, is controlled by one or more automatic devices which regulate the supply of heat to the dwellings according to the outside or inside temperature or both;
 - 2.2. the heat supply to collective heating systems is regulated according to the outside and inside temperatures;
 - 2.3. a device is fitted so that the heating level may be reduced during the night and when the buildings are empty;
3. for the production of domestic hot water in new buildings
 - 3.1. the temperature of hot water at the entry to the common circuit does not exceed 60 °C and is capable of regulation below this maximum. The flow rate in the common circuit is as low as possible but always permitting rapid and sufficient supply at the drawing points; that dead legs are as short as possible;
 - 3.2. when the power required for the production of domestic hot water and heating for the premises is provided by a multiple generator system, the production of domestic hot water during non-heating periods shall be ensured by one or more generators whose load capacity shall not exceed the requirements of the domestic hot water supply;
4. for heat metering in new buildings

each dwelling heated by a collective installation is fitted from the outset with the means of metering and/or directly or indirectly attributing the amount of heat and/or hot water supplied by this collective heating system, to permit the fair apportionment of the corresponding charges among the occupants of the building;
5. for the information of the Community

the Member States regularly inform the Commission of the measures taken in the field covered by this recommendation and of the results obtained or anticipated from the measures.

Done at Luxembourg, 25 October 1977.

For the Council

The President

W. CLAES

COUNCIL RECOMMENDATION

of 25 October 1977

on the rational use of energy in industrial undertakings

(77/713/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

appointing an energy management officer, should be extended;

Having regard to the Treaty establishing the European Economic Community,

Whereas the bodies referred to above should monitor the progress achieved by the undertakings in realizing their energy-saving programmes;

Having regard to the draft from the Commission,

Whereas in its resolution of 17 September 1974 concerning a new energy-policy strategy for the Community ⁽¹⁾ the Council approved the objective of reduction of the rate of growth of internal consumption by measures for using energy rationally and economically without jeopardizing social and economic growth objectives;

Whereas since one of the most profitable exercises at Community level is the systematic and regular exchange of information on energy-saving processes between Community undertakings and in particular small- and medium-sized undertakings, professional organizations should collate information from energy management officers on experience gained and difficulties encountered in order to disseminate this information; whereas these same organizations should also periodically organize meetings or seminars to exchange details of their members' experiences,

Whereas improvements in the rational use of energy are generally beneficial to the environment;

Whereas in its resolution of 17 December 1974 on a Community action programme on the rational utilization of energy ⁽²⁾ the Council noted that, in its communication to the Council entitled 'Rational Utilization of Energy', the Commission had drawn up a Community action programme in this field;

HEREBY RECOMMENDS TO THE MEMBER STATES:

Whereas the industrial sector also lends itself to the more efficient utilization of energy, in keeping with its economic objectives; whereas this possibility varies according to the size, location, production processes and products of the undertaking;

1. that they take the necessary measures to mount campaigns to provide information and increase awareness, and to encourage, in accordance with Article 92 *et seq.* of the Treaty, the achievement of energy savings; and, to this end, to set up, in so far as they do not already exist and along the lines of the initiatives already taken by some Member States, one or more public or approved bodies or departments with particular responsibility for these tasks;

Whereas it is desirable to inform, increase the awareness of and encourage undertakings, in accordance with Article 92 *et seq.* of the Treaty, in their efforts to save energy; whereas the initiatives already taken by some Member States to set up public or approved bodies charged with these tasks should be extended;

2. that they invite sectoral and general professional organizations as well as technical and scientific associations and consultancy services to arrange periodically for meetings and seminars, to exchange details of experience at national level, and possibly at Community level, in order to ensure the widest and most rapid dissemination of information possible;

Whereas the practice already adopted by some undertakings, in particular the large energy-intensive ones, of

3. that they encourage industrial undertakings:

— to set up an energy department within their organization, if they have not already done so, or call in an outside expert.

⁽¹⁾ OJ No C 153, 9. 7. 1975, p. 1.

⁽²⁾ OJ No C 153, 9. 7. 1975, p. 5.

The duties and tasks of such departments or persons could be along the lines of those proposed as a guide in the Annex to this recommendation;

- if they are required to prepare an annual report, to devote a chapter of it to their energy consumption, also including any energy-saving measures taken or planned and the results obtained;

4. that they collate, as efficiently as possible, all useful information concerning the results of the energy-

saving measures taken by the industrial undertakings mentioned in 3;

5. that they inform the Commission regularly of the measures taken in the field covered by this recommendation and of the results obtained or anticipated from the measures.

Done at Luxembourg, 25 October 1977.

For the Council

The President

W. CLAES

ANNEX

Suggested duties and tasks of the energy management officer in industrial undertakings

1. In keeping with the economic objectives of their undertaking, the functions of the energy management departments or officers could be focused on the following tasks:

- (i) *Within the undertaking*

deciding on the appropriate ways and means of carrying out the energy-saving programme which the undertaking has devised and in particular:

- keeping a permanent check that the undertaking is not wasting energy,
- suggesting ways in which industrial equipment and processes might be modified to bring about a more rational use of energy; in this respect any investment in new or additional equipment or processes should be the subject of energy appraisals as well as financial ones,
- establishing channels of communication between the various sections or departments and with office staff and manual workers and making them aware of the aims of energy saving.

- (ii) *Outside the undertaking*

maintaining contact with other industrial sectors concerned so that their undertaking may draw on the experience gained elsewhere.

2. To enable it to discharge these duties effectively, the energy management department should be responsible directly to the decision-making bodies of its undertaking.
-

COUNCIL RECOMMENDATION

of 25 October 1977

on the creation in the Member States of advisory bodies or committees to promote combined heat and power production and the exploitation of residual heat

(77/714/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Whereas the search for solutions at local and regional level is facilitated by an exchange of information and cooperation at national and Community level,

Having regard to the Treaty establishing the European Economic Community,

HEREBY RECOMMENDS TO THE MEMBER STATES:

Having regard to the draft from the Commission,

Whereas in its resolution of 17 September 1974 concerning a new energy-policy strategy for the Community ⁽¹⁾ the Council approved the objective of reduction of the rate of growth of internal consumption by measures for using energy rationally and economically without jeopardizing social and economic growth objectives;

Whereas improvements in the rational use of energy are generally beneficial to the environment;

Whereas in its resolution of 17 December 1974 on a Community action programme on the rational utilization of energy ⁽²⁾ the Council noted that, in its communication to the Council entitled 'Rational Utilization of Energy', the Commission had drawn up a Community action programme in this field;

Whereas a more rational use of energy can be obtained by greater use of combined heat and power production and the exploitation of residual heat in industry, electricity generating and remote heat supply systems;

Whereas implementation of this technique requires the solution of a number of complex problems of an economic, technical, administrative and legislative nature;

Whereas the solution of these problems depends to a large extent on local, regional and national factors;

1. that they create one or more advisory bodies or committees, in so far as these do not already exist, to be responsible for giving an opinion on all measures likely to lead to increased efficiency in the supply of heat for industry and to promote the use of remote heat supply systems, in particular by:

- concentrating heat production and making greater use of combined heat and power production;
- greater thermal efficiency of power stations by exploitation of their residual heat;
- improved efficiency of heat conduits and associated distribution installations in industrial establishments and in district heating systems, while taking into account the service life of the conduits;

2. that to this end they invite the advisory bodies or Committees to consider the following measures:

- broadening of cooperation between electrical utilities and heat-consuming industries;
- identification and abolition of legal, administrative and price obstacles to the development of combined heat and power production to supply industry;
- reservation of sites on which industrial complexes and combined heat and power stations can be built side by side;
- encouragement, in accordance with Article 92 *et seq.* of the Treaty, of combined heat and power production and of the transport of heat;

⁽¹⁾ OJ No C 153, 9. 7. 1975, p. 1.

⁽²⁾ OJ No C 153, 9. 7. 1975, p. 5.

- provision of better information to small- and medium-sized industrial undertakings;
 - drawing up statements of heat requirements;
3. that they encourage the advisory bodies or Committees to have regular exchanges of experience and to cooperate at Community level through procedures organized by the Commission;
4. that they instigate and promote technical and economic studies with the aim of identifying new economically viable remote heat supplies and that
- they promote the development, where justifiable, of existing district heating and industrial heat supply systems;
5. that they inform the Commission regularly of the measures taken in the field covered by this recommendation and of the results obtained or anticipated from the measures.

Done at Luxembourg, 25 October 1977.

For the Council

The President

W. CLAES

COUNCIL DECISION

of 28 October 1977

on the conclusion of the European Agreement on the exchange of tissue-typing reagents and the Additional Protocol thereto

(77/715/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS DECIDED AS FOLLOWS:

Having regard to the Treaty establishing the European Economic Community,

Having regard to the recommendation from the Commission,

Whereas the European Agreement on the exchange of tissue-typing reagents, drawn up on the initiative of the Council of Europe, provides in Article 5 (1) that the Contracting Parties shall take all necessary measures to exempt from all import duties the tissue-typing reagents placed at their disposal by the other Parties;

Whereas any derogation from the Common Customs Tariff, whether of an autonomous or conventional nature, falls within the exclusive competence of the Community;

Whereas the addition to the said Agreement of an Additional Protocol enabling the European Economic Community to become a Contracting Party to the said Agreement enables the Community to exercise that competence;

Whereas that Agreement and the Additional Protocol thereto should therefore be concluded,

Article 1

The European Agreement on the exchange of tissue-typing reagents and the additional Protocol thereto are hereby approved on behalf of the Community.

The texts of the Agreement and the Additional Protocol are annexed hereto.

Article 2

The President of the Council is hereby authorized to designate the persons empowered to sign the Agreement and the Additional Protocol and to confer upon them the necessary powers to bind the Community.

Done at Luxembourg, 28 October 1977.

*For the Council**The President*

G. SPITAELS

EUROPEAN AGREEMENT ON THE EXCHANGE OF TISSUE-TYPING REAGENTS

THE MEMBER STATES OF THE COUNCIL OF EUROPE,
SIGNATORY HERETO,

purposes and shall be delivered only to laboratories designated by the Governments concerned in accordance with Article 6 of this Agreement.

Considering that tissue-typing reagents are not available in unlimited quantities;

Considering that it is highly desirable that Member States, in a spirit of European solidarity, should assist one another in the supply of these tissue-typing reagents, should the need arise;

Considering that such mutual assistance is only possible if the character and use of such tissue-typing reagents are subject to rules to be laid down jointly by the Member States and if the necessary import facilities and exemptions are granted,

HAVE AGREED AS FOLLOWS:

Article 1

1. For the purposes of this Agreement, the expression 'tissue-typing reagents' refers to reagents of human, animal, plant and other origin, used for the determination of tissue-typing.
2. The provisions of Articles 2 to 6 of this Agreement shall also apply to cells of known antigenic composition to be used for the investigation of typing reagents.

Article 2

The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make tissue-typing reagents available to other Parties who are in need of them and to charge only those costs of collection, processing and carriage of such substances and the cost (if any) of their purchase.

Article 3

Tissue-typing reagents shall be made available to the other Contracting Parties subject to the condition that no profit is made on them, and that they shall be used solely for medical and scientific, i.e. non-commercial,

Article 4

1. The contracting parties shall certify that the provisions as laid down in the Protocol to this Agreement have been observed.
2. They shall also comply with any rules to which they have subscribed with regard to international standardization in this field.
3. All consignments of tissue-typing reagents shall be accompanied by a certificate to the effect that they were prepared in accordance with the specifications in the Protocol. This certificate shall be based on the model to be found in the Annex to the Protocol.
4. The Protocol and its Annex constitute an administrative arrangement and may be amended or supplemented by the Governments of the Parties to this Agreement.

Article 5

1. The Contracting Parties shall take all necessary measures to exempt from all import duties the tissue-typing reagents placed at their disposal by the other Parties.
2. They shall also take all necessary measures to provide for the speedy delivery of these substances, by the most direct route, to the consignees referred to in Article 3 of this Agreement.

Article 6

The Contracting Parties shall forward to one another, through the Secretary-General of the Council of Europe, a list of the national and/or regional reference laboratories empowered to issue certificates as provided in Article 4 of the Agreement and to distribute imported tissue-typing reagents.

Article 7

1. This Agreement shall be open to signature by the Member States of the Council of Europe, who may become parties to it either by:

- (a) signature without reservation in respect of ratification or acceptance, or
- (b) signature with reservation in respect of ratification or acceptance, followed by ratification or acceptance.

2. Instruments of ratification or acceptance shall be deposited with the Secretary-General of the Council of Europe.

Article 8

1. This Agreement shall enter into force one month after the date on which three Member States of the Council shall have become Parties to the Agreement, in accordance with the provisions of Article 7.

2. As regards any Member State who shall subsequently sign the Agreement without reservation in respect of ratification or acceptance or who shall ratify or accept it, the Agreement shall enter into force one month after the date of such signature or after the date of deposit of the instrument of ratification or acceptance.

Article 9

1. After the entry into force of this Agreement, the Committee of Ministers of the Council of Europe may invite any non-member State to accede thereto.

2. Such accession shall be effected by depositing with the Secretary-General of the Council of Europe an instrument of accession which shall take effect one month after the date of its deposit.

Article 10

1. Any Contracting Party may at the time of signature or when depositing its instrument of ratification, acceptance or accession, specify the territory or territories to which this Agreement shall apply.

2. Any Contracting Party may, when depositing its instrument of ratification, acceptance or accession or at any later date, by declaration addressed to the Sec-

retary-General of the Council of Europe, extend this Agreement to any other territory or territories specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorized to give undertakings.

3. Any declaration made in pursuance of the preceding paragraph may, in respect of any territory mentioned in such declaration, be withdrawn according to the procedure laid down in Article 11 of this Agreement.

Article 11

1. Any Contracting Party may, in so far as it is concerned, denounce this Agreement by means of a notification addressed to the Secretary-General of the Council of Europe.

2. Such denunciation shall take effect six months after the date of receipt by the Secretary-General of such notification.

Article 12

The Secretary-General of the Council of Europe shall notify the Member States of the Council and any State which has acceded to this Agreement, of:

- (a) any signature without reservation in respect of ratification or acceptance;
- (b) any signature with reservation in respect of ratification or acceptance;
- (c) the deposit of any instrument of ratification, acceptance or accession;
- (d) any date of entry into force of this Agreement in accordance with Article 8 thereof;
- (e) any declaration received in pursuance of the provisions of paragraphs 2 and 3 of Article 10;
- (f) any notification received in pursuance of the provisions of Article 11 and the date on which denunciation takes effect;
- (g) any amendment of or supplement to the Protocol and its Annex under Article 4 (4) of this Agreement.

In witness whereof the undersigned, being duly authorized thereto, having signed this Agreement.

Done at Strasbourg, this 17th day of September 1974, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary-General of the Council of Europe shall transmit certified copies to each of the signatory and acceding States.

PROTOCOL TO THE AGREEMENT

GENERAL PROVISIONS

1. Specificity

A. Tissue-typing reagents to be used in cytotoxic techniques on lymphocytes

These reagents must, when used according to the technique recommended by the producer, react with all lymphocytes known to contain the antigen(s) corresponding to the specificity (specificities) mentioned on the label. They must not react with any cell known not to contain this antigen (these antigens).

When these reagents are used according to the technique recommended by the producer there must be no evidence of any interfering serological phenomena such as:

- (a) prozone effect;
- (b) anticomplementarity.

B. Tissue-typing reagents for use in a complement fixation technique on platelets

These reagents must, when used according to the technique recommended by the producer, give complement fixation with all platelets known to contain the antigen(s) corresponding to the specificity (specificities) mentioned on the label. They must not give complement fixation with any platelets known not to contain this antigen (these antigens).

When these reagents are used according to the technique recommended by the producer there must be no evidence of any interfering serological phenomena such as:

- (a) prozone effect;
- (b) anticomplementarity.

2. Potency

A. Tissue-typing reagents to be used in cytotoxic techniques on lymphocytes

The titre of such a reagent is determined by making successive twofold dilutions of the reagent under study in inactivated AB serum from a donor negative for the antigen(s) corresponding to the antibody

(antibodies) in the reagent who should also not have been immunized against tissue antigens by transfusion, pregnancy or other means. Each dilution is then tested with lymphocytes known to contain the corresponding antigen(s) in the reagent, using the technique recommended by the producer. The titre is the reciprocal of the figure representing the highest serum dilution in which a significantly positive reaction occurs, the dilution being calculated without the inclusion of the volume of the corpuscular suspension or any other additive in the total volume.

B. Tissue-typing reagents for use in a complement fixation technique on platelets

The titre of such a reagent is determined by making successive twofold dilutions of the reagent under study in 10% inactivated AB serum in Veronal buffer. Each serum is then tested with platelets known to contain the antigen homologous to the antibodies in the reagent, using the technique recommended by the producer. The titre is the reciprocal of the figure representing the highest serum dilution in which a significantly positive reaction occurs, the dilution being calculated without the inclusion of the volume of the corpuscular suspension or any other additive in the total volume.

Further provisions, for tissue-typing reagents to be used in cytotoxic techniques on lymphocytes as well as for reagents to be used in a complement fixation technique on platelets:

3. Preservation

Tissue-typing reagents may be preserved in the liquid or in the dried state. Liquid reagents shall be kept at a temperature not above -70°C , dried reagents at a temperature not above $+4^{\circ}\text{C}$.

Thawing and refreezing of the reagents during the period of storage must be avoided as much as possible.

Dried reagents shall be kept in an atmosphere of inert gas or *in vacuo* in the container in which they were dried and which shall be closed so as to exclude moisture. A dried reagent must not lose more than 0.5% of its weight when tested by further drying over phosphorous pentoxide at a pressure not exceeding 0.02 mm of mercury for 24 hours.

Reagents shall be prepared with aseptic precautions and shall be free from bacterial contamination. In order to prevent bacterial growth the producer may decide that an antiseptic and/or antibiotic shall be added to the reagent. In such cases the reagent must still fulfil the requirements for specificity and potency in the presence of the added substance.

The above also applies to any other additives such as anticoagulants. Reagents, after thawing or after reconstitution, should be transparent and should not contain any sediment, gel or visible particles.

4. Stability and expiry date

Each reagent, when kept under the appropriate conditions of storage, should retain the requisite properties for at least one year.

The expiry date of a reagent in the liquid state as given on the label shall be not more than one year from the date of the last satisfactory potency test. The expiry date can be extended for further periods of one year by repetition of potency tests.

The expiry date of reagents in the dried form as given on the label shall be in accordance with evidence obtained from experiments on stability.

5. Dispensing and volume

Tissue-typing reagents shall be dispensed in such a way and in such volumes that the reagent in one container is sufficient for the performance of tests with positive and negative control corpuscles in addition to the performance of tests with the unknown corpuscles.

The volume in one container shall be such that the contents can, if necessary, be used for the performance of the appropriate tests for potency as described in this Protocol.

6. Records and samples

Written records shall be kept by the producing laboratory of all steps in the production and control of blood-grouping reagents. Adequate samples of all reagents issued shall be retained by the laboratory, until it can be reasonably assumed that the batch is no longer in use.

7. Shipment

Frozen reagents must be shipped in such fashion that they remain frozen until arrival. Care must be taken to protect reagents against inactivation by the entry of CO₂. Dried reagents may be shipped at ambient temperatures.

8. Labels, leaflets and certificates

Two labels, one printed in English and one in French, in black on white paper, shall be affixed to each final container and shall contain the following information:

- (a) name and address of producer;
- (b) name of the reagent as it appears in the heading of the relevant specification;
- (c) name and amount of antiseptic and/or antibiotic, if present, or indication of absence;
- (d) the volume or, where the reagent is dried, the volume and composition of the fluid needed for reconstitution;
- (e) expiry date;
- (f) batch number;
- (g) conditions of storage;
- (h) results of the test for HB-Ag.

Moreover, these labels or the labels of the carton enclosing several final containers, or the leaflet accompanying the containers, shall contain the following information:

- (a) full name and address of producer;
- (b) name of the reagent as it appears in the heading of the relevant specification;
- (c) the volume or, where the reagent is dried, the volume and composition of the fluid needed for reconstitution;
- (d) date of last potency test;
- (e) expiry date (if any);
- (f) batch number;
- (g) adequate description of the method of use recommended by the producer;

- | | |
|---|---|
| (h) conditions of storage of unopened ampoules and precautions to be taken after opening; | (j) statement whether the product contains or does not contain material of human origin. |
| (i) exact composition, including antiseptic and/or antibiotic if any; | Each consignment shall be accompanied by a certificate as provided in Article 4 of the Agreement and the Annex to the present Protocol. Examples of label and leaflet are attached to the present Protocol. |

SPECIFIC PROVISIONS ⁽¹⁾

⁽¹⁾ To be completed under Article 4 (4) of the European Agreement on the exchange of tissue-typing reagents.

EXAMPLE OF LABEL

COUNCIL OF EUROPE

European Agreement on the exchange of tissue-typing reagents

1. Name and address of the producer.
2. Tissue-typing reagent anti HL-A
3. 1 ml
or
To be reconstituted with 1 ml of distilled water.
4. Date of last potency test.
5. Expiry date.
6. Batch number.
7. Technique to be used: NIH Lymphocytotoxicity.
8. To be stored at — ... (temperature etc.).
9. Composition.
10. The reagent contains human serum.

This label must be attached to a container enclosing several final containers.

EXAMPLE OF LEAFLET

COUNCIL OF EUROPE

European Agreement on the exchange of tissue-typing reagents

1. National Tissue-Typing Reference Laboratory,
1 Main Street, Metropolis, Westland.
2. Tissue-typing reagent anti HL-A I.
3. N_3Na 0.1 g % solution is added.
4. 1 ml
or
To be reconstituted with 1 ml of distilled water.
5. Expiry date 5 December 1975.
6. Batch number No 7257.
7. To be stored at -70°C .
8. Result of the test for HB-Ag: negative.

This leaflet must be affixed to each final container.

ANNEX TO THE PROTOCOL

COUNCIL OF EUROPE

European Agreement on the exchange of tissue-typing reagents

CERTIFICATE

(Article 4)

NOT TO BE SEPARATED FROM THE SHIPMENT

.....19 ...
 (Place) (Date)

Number of packages Marked Batch No	The undersigned certifies that the shipment specified in the margin prepared under the responsibility of one of the bodies referred to in Article 6 of the Agreement, is in conformity with the specifications of the Protocol to the Agreement and can be delivered im- mediately to the consignee (name and place)
---	--

(Stamp) (Signature) (Title)

ADDITIONAL PROTOCOL TO THE EUROPEAN AGREEMENT ON THE EX-
CHANGE OF TISSUE-TYPING REAGENTS

THE SIGNATORY STATES TO THE EUROPEAN AGREEMENT ON THE EXCHANGE OF TISSUE-TYPING REAGENTS,

hereinafter called the 'Agreement',

Recalling the provisions of Article 5 (1) of the Agreement, whereby the Contracting Parties shall take all necessary measures to exempt from all import duties the tissue-typing reagents placed at their disposal by the other Parties;

Whereas, with regard to the Member States of the European Economic Community, the undertaking to grant such exemption falls within the competence of the said Community which possesses the necessary powers for this purpose by virtue of the Treaty establishing the Community;

Whereas, for the purposes of applying Article 5 (1) of the Agreement, the European Economic Community should therefore be a Contracting Party to the Agreement,

HAVE AGREED AS FOLLOWS:

Article 1

The European Economic Community may become a Contracting Party to the Agreement by virtue of signing that Agreement.

Article 2

This Additional Protocol shall be open for signature by the States signatory to the Agreement who may become party to the Additional Protocol by following the procedure laid down in Article 7 of the Agreement.

Article 3

No Member State may become a Contracting Party to the Agreement without at the same time becoming a Contracting Party to this Additional Protocol, which shall form an integral part of the Agreement.

Article 4

This Additional Protocol shall enter into force at the same time as the Agreement.

Article 5

The Secretary-General of the Council of Europe shall notify Member States of the Council and the European Economic Community of:

- (a) all signatures of this Additional Protocol;
- (b) the deposit of all instruments of ratification or of acceptance;
- (c) the date of entry into force of this Additional Protocol.