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Legislation

Contents

I *Acts whose publication is obligatory*

.....

II *Acts whose publication is not obligatory*

Council

90/679/EEC:

- ★ Council Directive of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) 1

90/680/EEC:

- ★ Council Decision of 26 November 1990 on the conclusion of the Agreement in the form of an exchange of letters between the European Economic Community and the Principality of Andorra 13

Agreement in the form of an exchange of letters between the European Economic Community and the Principality of Andorra 14

Agreement between the European Economic Community and the Principality of Andorra 16

- ★ Information concerning the date of entry into force of the Agreement in the form of an Exchange of Letters between the European Economic Community and the Principality of Andorra, signed in Luxembourg on 28 June 1990 33

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 26 November 1990

on the protection of workers from risks related to exposure to biological agents at work
(seventh individual Directive within the meaning of Article 16 (1) of Directive
89/391/EEC)

(90/679/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 118a thereof,

Having regard to the proposal from the Commission ⁽¹⁾, drawn up after consulting the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament ⁽²⁾

Having regard to the Opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 118a of the Treaty provides that the Council shall adopt, by means of Directives, minimum requirements in order to encourage improvements, especially in the working environment, so as to guarantee better protection of the health and safety of workers;

Whereas that Article provides that such Directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings;

Whereas the Council Resolution of 27 February 1984 on a second action programme of the European Communities on safety and health at work ⁽⁴⁾ provides for the development of

protective measures for workers exposed to dangerous agents;

Whereas the communication from the Commission on its programme concerning safety, hygiene and health at work ⁽⁵⁾ provides for the adoption of Directives to guarantee the safety and health of workers;

Whereas compliance with the minimum requirements designed to guarantee a better standard of safety and health as regards the protection of workers from the risks related to exposure to biological agents at work is essential to ensure the safety and health of workers;

Whereas this Directive is an individual Directive within the meaning of Article 16 (1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽⁶⁾; whereas the provisions of that Directive are therefore fully applicable to the exposure of workers to biological agents, without prejudice to more stringent and/or specific provisions contained in the present Directive;

Whereas more precise knowledge of the risks involved in exposure to biological agents at work can be obtained through the keeping of records;

Whereas employers must keep abreast of new developments in technology with a view to improving the protection of workers' health and safety;

⁽¹⁾ OJ No C 150, 8. 6. 1988, p. 6.

⁽²⁾ OJ No C 158, 26. 6. 1989, p. 92.

⁽³⁾ OJ No C 56, 6. 3. 1989, p. 38.

⁽⁴⁾ OJ No C 67, 8. 3. 1984, p. 2.

⁽⁵⁾ OJ No C 28, 3. 2. 1988, p. 1.

⁽⁶⁾ OJ No L 183, 29. 6. 1989, p. 1.

Whereas preventive measures should be taken for the protection of the health and safety of workers exposed to biological agents;

Whereas this Directive constitutes a practical aspect of the realization of the social dimension of the internal market;

Whereas, pursuant to Decision 74/325/EEC⁽¹⁾, the Advisory Committee on Safety, Hygiene and Health Protection at Work is consulted by the Commission on the drafting of proposals in this field,

HAS ADOPTED THIS DIRECTIVE:

SECTION I

GENERAL PROVISIONS

Article 1

Objective

1. This Directive, which is the seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC, has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work.

It lays down particular minimum provisions in this area.

2. Directive 89/391/EEC shall apply fully to the whole area referred to in paragraph 1, without prejudice to more stringent and/or specific provisions contained in this Directive.

3. This Directive shall apply without prejudice to the provisions of Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms⁽²⁾ and of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms⁽³⁾.

Article 2

Definitions

For the purpose of this Directive:

(a) 'biological agents' shall mean micro-organisms, including those which have been genetically modified,

⁽¹⁾ OJ No L 185, 9. 7. 1974, p. 15.

⁽²⁾ OJ No L 117, 3. 5. 1990, p. 1.

⁽³⁾ OJ No L 117, 3. 5. 1990, p. 15.

cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity;

(b) 'micro-organism' shall mean a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material;

(c) 'cell culture' shall mean the in-vitro growth of cells derived from multicellular organisms;

(d) 'biological agents' shall be classified into four risk groups, according to their level of risk of infection:

1. group 1 biological agent means one that is unlikely to cause human disease;

2. group 2 biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;

3. group 3 biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available;

4. group 4 biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

Article 3

Scope — Determination and assessment of risks

1. This Directive shall apply to activities in which workers are or are potentially exposed to biological agents as a result of their work.

2. (a) In the case of any activity likely to involve a risk of exposure to biological agents, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

(b) In the case of activities involving exposure to several groups of biological agents, the risk shall be assessed on the basis of the danger presented by all hazardous biological agents present.

(c) The assessment must be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to biological agents.

(d) The employer must supply the competent authorities, at their request, with the information used for making the assessment.

3. The assessment referred to in paragraph 2 shall be conducted on the basis of all available information including:

- classification of biological agents which are or may be a hazard to human health, as referred to in Article 18;
- recommendations from a competent authority which indicate that the biological agent should be controlled in order to protect workers' health when workers are or may be exposed to such a biological agent as a result of their work;
- information on diseases which may be contracted as a result of the work of the workers;
- potential allergenic or toxigenic effects as a result of the work of the workers;
- knowledge of a disease from which a worker is found to be suffering and which has a direct connection with his work.

Article 4

Application of the various Articles in relation to assessment of risks

1. If the results of the assessment referred to in Article 3 show that the exposure and/or potential exposure is to a group 1 biological agent, with no identifiable health risk to workers, Articles 5 to 17 and Article 19 shall not apply.

However, point 1 of Annex VI should be observed.

2. If the results of the assessment referred to in Article 3 show that the activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers being exposed to a biological agent, as in the course of the activities for which an indicative list is given in Annex I, Articles 5, 7, 8, 10, 11, 12, 13 and 14 shall apply unless the results of the assessment referred to in Article 3 show them to be unnecessary.

SECTION II

EMPLOYERS' OBLIGATIONS

Article 5

Replacement

The employer shall avoid the use of a harmful biological agent if the nature of the activity so permits, by replacing it with a biological agent which, under its conditions of use, is not dangerous or is less dangerous to workers' health, as the case may be, in the present state of knowledge.

Article 6

Reduction of risks

1. Where the results of the assessment referred to in Article 3 reveal a risk to workers' health or safety, workers' exposure must be prevented.

2. Where this is not technically practicable, having regard to the activity and the risk assessment referred to in Article 3, the risk of exposure must be reduced to as low a level as necessary in order to protect adequately the health and safety of the workers concerned, in particular by the following measures which are to be applied in the light of the results of the assessment referred to in Article 3:

- (a) keeping as low as possible the number of workers exposed or likely to be exposed;
- (b) design of work processes and engineering control measures so as to avoid or minimize the release of biological agents into the place of work;
- (c) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
- (d) hygiene measures compatible with the aim of the prevention or reduction of the accidental transfer or release of a biological agent from the workplace;
- (e) use of the biohazard sign depicted in Annex II and other relevant warning signs;
- (f) drawing up plans to deal with accidents involving biological agents;
- (g) testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;

- (h) means for safe collection, storage and disposal of waste by workers, including the use of secure and identifiable containers, after suitable treatment where appropriate;
- (i) arrangements for the safe handling and transport of biological agents within the workplace.

Article 7

Information for the competent authority

1. Where the results of the assessment referred to in Article 3 reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

- the results of the assessment;
- the activities in which workers have been exposed or may have been exposed to biological agents;
- the number of workers exposed;
- the name and capabilities of the person responsible for safety and health at work;
- the protective and preventive measures taken, including working procedures and methods;
- an emergency plan for the protection of workers from exposure to a group 3 or a group 4 biological agent which might result from a loss of physical containment.

2. Employers shall inform forthwith the competent authority of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness.

3. The list referred to in Article 11 and the medical record referred to in Article 14 shall be made available to the competent authority in cases where the undertaking ceases activity, in accordance with national laws and/or practice.

Article 8

Hygiene and individual protection

1. Employers shall be obliged, in the case of all activities for which there is a risk to the health or safety of workers due to work with biological agents, to take appropriate measures to ensure that:

- (a) workers do not eat or drink in working areas where there is a risk of contamination by biological agents;
- (b) workers are provided with appropriate protective clothing or other appropriate special clothing;
- (c) workers are provided with appropriate and adequate washing and toilet facilities, which may include eye washes and/or skin antiseptics;
- (d) any necessary protective equipment is:
 - properly stored in a well-defined place;
 - checked and cleaned if possible before, and in any case after, each use;
 - is repaired, where defective, or is replaced before further use;
- (e) procedures are specified for taking, handling and processing samples of human or animal origin.

2. (a) Working clothes and protective equipment, including protective clothing referred to in paragraph 1, which may be contaminated by biological agents, must be removed on leaving the working area and, before taking the measures referred to in subparagraph (b), kept separately from other clothing.

(b) The employer must ensure that such clothing and protective equipment is decontaminated and cleaned or, if necessary, destroyed.

3. Workers may not be charged for the cost of the measures referred to in paragraphs 1 and 2.

Article 9

Information and training of workers

1. Appropriate measures shall be taken by the employer to ensure that workers and/or any workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

- (a) potential risks to health;
- (b) precautions to be taken to prevent exposure;
- (c) hygiene requirements;
- (d) wearing and use of protective equipment and clothing;

- (e) steps to be taken by workers in the case of incidents and to prevent incidents.

2. The training shall be:

- given at the beginning of work involving contact with biological agents,
- adapted to take account of new or changed risks, and
- repeated periodically if necessary.

Article 10

Worker information in particular cases

1. Employers shall provide written instructions at the workplace and, if appropriate, display notices which shall, as a minimum, include the procedure to be followed in the case of:

- a serious accident or incident involving the handling of a biological agent;
- handling a group 4 biological agent.

2. Workers shall immediately report any accident or incident involving the handling of a biological agent to the person in charge or to the person responsible for safety and health at work.

3. Employers shall inform forthwith the workers and/or any workers' representatives of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness.

In addition, employers shall inform the workers and/or any workers' representatives in the undertaking or establishment as quickly as possible when a serious accident or incident occurs, of the causes thereof, and of the measures taken or to be taken to rectify the situation.

4. Each worker shall have access to the information on the list referred to in Article 11 which relates to him personally.

5. Workers and/or any workers' representatives in the undertaking or establishment shall have access to anonymous collective information.

6. Employers shall provide workers and/or their representatives, at their request, with the information provided for in Article 7 (1).

Article 11

List of exposed workers

1. Employers shall keep a list of workers exposed to group 3 and/or group 4 biological agents, indicating the type of work done and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures, accidents and incidents, as appropriate.

2. The list referred to in paragraph 1 shall be kept for at least 10 years following the end of exposure, in accordance with national laws and/or practice.

In the case of those exposures which may result in infections:

- with biological agents known to be capable of establishing persistent or latent infections,
- that, in the light of present knowledge, are undiagnosable until illness develops many years later,
- that have particularly long incubation periods before illness develops,
- that result in illnesses which recrudescence at times over a long period despite treatment, or
- that may have serious long-term sequelae,

the list shall be kept for an appropriately longer time up to 40 years following the last known exposure.

3. The doctor referred to in Article 14 and/or the competent authority for health and safety at work, and any other person responsible for health and safety at work, shall have access to the list referred to in paragraph 1.

Article 12

Consultation and participation of workers

Consultation and participation of workers and/or their representatives in connection with matters covered by this Directive including the Annexes shall take place in accordance with Article 11 of Directive 89/391/EEC.

Article 13

Notification to the competent authority

1. Prior notification shall be made to the competent authority of the use for the first time of:

- group 2 biological agents,

- group 3 biological agents,
- group 4 biological agents.

The notification shall be made at least 30 days before the commencement of the work.

Subject to paragraph 2, prior notification shall also be made of the use for the first time of each subsequent group 4 biological agent and of any subsequent new group 3 biological agent where the employer himself provisionally classifies that biological agent.

2. Laboratories providing a diagnostic service in relation to group 4 biological agents shall be required only to make an initial notification of their intention.

3. Renotification must take place in any case where there are substantial changes of importance to safety or health at work to processes and/or procedures which render the notification out of date.

4. The notification referred to in this Article shall include:

- (a) the name and address of the undertaking and/or establishment;
- (b) the name and capabilities of the person responsible for safety and health at work;
- (c) the results of the assessment referred to in Article 3;
- (d) the species of the biological agent;
- (e) the protection and preventive measures that are envisaged.

SECTION III

MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

1. The Member States shall establish, in accordance with national laws and practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3 reveal a risk to health or safety.

2. The arrangements referred to in paragraph 1 shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:

- prior to exposure,

- at regular intervals thereafter.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

3. The assessment referred to in Article 3 should identify those workers for whom special protective measures may be required.

When necessary, effective vaccines should be made available for those workers who are not already immune to the biological agent to which they are exposed or are likely to be exposed.

If a worker is found to be suffering from an infection and/or illness which is suspected to be the result of exposure, the doctor or authority responsible for health surveillance of workers shall offer such surveillance to other workers who have been similarly exposed.

In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3.

4. In cases where health surveillance is carried out, an individual medical record shall be kept for at least 10 years following the end of exposure, in accordance with national laws and practice.

In the special cases referred to in Article 11 (2) second subparagraph, an individual medical record shall be kept for an appropriately longer time up to 40 years following the last known exposure.

5. The doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual worker.

6. Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

7. In accordance with national laws and/or practice:

- workers shall have access to the results of the health surveillance which concern them, and
- the workers concerned or the employer may request a review of the results of the health surveillance.

8. Practical recommendations for the health surveillance of workers are given in Annex IV.

9. All cases of diseases or death identified in accordance with national laws and/or practice as resulting from occupational exposure to biological agents shall be notified to the competent authority.

*Article 15***Health and veterinary care facilities other than diagnostic laboratories**

1. For the purpose of the assessment referred to in Article 3, particular attention should be paid to:

- (a) uncertainties about the presence of biological agents in human patients or animals and the materials and specimens taken from them;
- (b) the hazard represented by biological agents known or suspected to be present in human patients or animals and materials and specimens taken from them;
- (c) the risks posed by the nature of the work.

2. Appropriate measures shall be taken in health and veterinary care facilities in order to protect the health and safety of the workers concerned.

The measures to be taken shall include in particular:

- (a) specifying appropriate decontamination and disinfection procedures, and
- (b) implementing procedures enabling contaminated waste to be handled and disposed of without risk.

3. In isolation facilities where there are human patients or animals who are, or who are suspected of being, infected with group 3 or group 4 biological agents, containment measures shall be selected from those in Annex V column A, in order to minimize the risk of infection.

*Article 16***Special measures for industrial processes, laboratories and animal rooms**

1. The following measures must be taken in laboratories, including diagnostic laboratories, and in rooms for laboratory animals which have been deliberately infected with group 2, 3 or 4 biological agents or which are or are suspected to be carriers of such agents:

- (a) Laboratories carrying out work which involves the handling of group 2, 3 or 4 biological agents for research, development, teaching or diagnostic purposes shall determine the containment measures in accordance with Annex V, in order to minimize the risk of infection.
- (b) Following the assessment referred to in Article 3, measures shall be determined in accordance with Annex V, after fixing the physical containment level

required for the biological agents according to the degree of risk.

Activities involving the handling of a biological agent must be carried out:

- only in working areas corresponding to at least containment level 2, for a group 2 biological agent;
 - only in working areas corresponding to at least containment level 3, for a group 3 biological agent;
 - only in working areas corresponding to at least containment level 4, for a group 4 biological agent.
- (c) Laboratories handling materials in respect of which there exist uncertainties about the presence of biological agents which may cause human disease but which do not have as their aim working with biological agents as such (i.e. cultivating or concentrating them) should adopt containment level 2 at least. Containment levels 3 or 4 must be used, when appropriate, where it is known or it is suspected that they are necessary, except where guidelines provided by the competent national authorities show that, in certain cases, a lower containment level is appropriate.

2. The following measures concerning industrial processes using group 2, 3 or 4 biological agents must be taken:

- (a) The containment principles set out in the second subparagraph of paragraph 1 (b) should also apply to industrial processes on the basis of the practical measures and appropriate procedures given in Annex VI.
- (b) In accordance with the assessment of the risk linked to the use of group 2, 3 or 4 biological agents, the competent authorities may decide on appropriate measures which must be applied to the industrial use of such biological agents.
- (c) For all activities covered by this Article where it has not been possible to carry out a conclusive assessment of a biological agent but concerning which it appears that the use envisaged might involve a serious health risk for workers, activities may only be carried out in workplaces where the containment level corresponds at least to level 3.

*Article 17***Use of data**

The Commission shall have access to the use made by the competent national authorities of the information referred to in Article 14 (9).

*Article 18***Classification of biological agents**

1. In accordance with the procedure laid down in Article 118a of the Treaty, the Council shall adopt within six months of the date of implementation given in Article 20 (1) a first list of group 2, group 3 and group 4 biological agents for Annex III.
2. Community classification shall be on the basis of the definitions in Article 2 (d) points 2 to 4 (groups 2 to 4).
3. Pending Community classification Member States shall classify biological agents that are or may be a hazard to human health on the basis of the definition in Article 2 (d) points 2 to 4 (groups 2 to 4).
4. If the biological agent to be assessed cannot be classified clearly in one of the groups defined in Article 2 (d), it must be classified in the highest risk group among the alternatives.

*Article 19***Annexes**

Purely technical adjustments to the Annexes in the light of technical progress, changes in international regulations or

specifications and new findings in the field of biological agents shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

*Article 20***Final provisions**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than three years after the notification of this Directive ⁽¹⁾. They shall forthwith inform the Commission thereof.

However, in the case of the Portuguese Republic, the time limit referred to in the first subparagraph shall be five years.

2. Member States shall communicate to the Commission the provisions of national law already adopted or which they adopt in the field governed by this Directive.

Article 21

This Directive is addressed to the Member States.

Done at Brussels, 26 November 1990.

For the Council

The President

C. DONAT CATTIN

⁽¹⁾ This Directive was notified to the Member States on 29 November 1990.

*ANNEX I***INDICATIVE LIST OF ACTIVITIES****(Article 4 (2))**

1. Work in food production plants.
2. Work in agriculture.
3. Work activities where there is contact with animals and/or products of animal origin.
4. Work in health care, including isolation and post mortem units.
5. Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
6. Work in refuse disposal plants.
7. Work in sewage purification installations.

*ANNEX II***BIOHAZARD SIGN****(Article 6 (2) (e))**

*ANNEX III***COMMUNITY CLASSIFICATION****(Articles 18 and 2 (d))**

for the record

ANNEX IV

PRACTICAL RECOMMENDATIONS FOR THE HEALTH SURVEILLANCE OF WORKERS

(Article 14 (8))

1. The doctor and/or the authority responsible for the health surveillance of workers exposed to biological agents must be familiar with the exposure conditions or circumstances of each worker.
2. Health surveillance of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:
 - keeping records of a worker's medical and occupational history;
 - a personalized assessment of the workers' state of health;
 - where appropriate, biological monitoring, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

ANNEX V

INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS

(Articles 15 (3) and 16 (1) (a) and (b))

Preliminary note

The measures contained in this Annex shall be applied according to the nature of the activities, the assessment of risk to workers, and the nature of the biological agent concerned.

A. Containment measures	B. Containment levels		
	2	3	4
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. Input air and extract air to the workplace are to be filtered using (HEPA) or likewise	No	Yes, on extract air	Yes, on input and extract air
3. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock
4. The workplace is to be sealable to permit disinfection	No	Recommended	Yes
5. Specified disinfection procedures	Yes	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
7. Efficient vector control e.g. rodents and insects	Recommended	Yes	Yes
8. Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
10. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
11. An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes
12. A laboratory is to contain own equipment	No	Recommended	Yes
13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment	Where appropriate	Yes where infection is by airborne route	Yes
14. Incinerator for disposal of animal carcasses	Recommended	Yes (available)	Yes, on site

ANNEX VI

CONTAINMENT FOR INDUSTRIAL PROCESSES

(Article 4 (1) and Article 16 (2) (a))

Group 1 biological agents

For work with group 1 biological agents including life attenuated vaccines, the principles of good occupational safety and hygiene should be observed.

Group 2, 3 and 4 biological agents

It may be appropriate to select and combine containment requirements from different categories below on the basis of a risk assessment related to any particular process or part of a process.

Containment measures	Containment levels		
	2	3	4
1. Viable organisms should be handled in a system which physically separates the process from the environment	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimize release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system, should be performed so as to:	Minimize release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimize release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via an airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) The controlled area should be adequately ventilated to minimize air contamination	Optional	Optional	Yes
(h) The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
(l) Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

COUNCIL DECISION

of 26 November 1990

on the conclusion of the Agreement in the form of an exchange of letters between the European Economic Community and the Principality of Andorra

(90/680/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS DECIDED AS FOLLOWS:

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 99 and 113 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾.

Whereas the national arrangements currently in force in trade relations between the European Community and the Principality of Andorra should be replaced by a Community system;

Whereas, owing to geographical, historical and socioeconomic factors, special arrangements should be granted to the Principality of Andorra with regard to exemptions from import duties, turnover taxes and excise duties applicable to goods contained in the personal luggage of travellers;

Whereas the Agreement in the form of an exchange of letters negotiated between the European Economic Community and the Principality of Andorra was signed in Luxembourg on 28 June 1990; whereas it should be approved,

Article 1

The Agreement in the form of an exchange of letters between the European Economic Community and the Principality of Andorra, and the Agreement and Declarations attached thereto, is hereby approved on behalf of the Community.

The texts of the acts referred to in the first subparagraph are attached to this Decision.

Article 2

The President of the Council shall give, on behalf of the Community, the notification provided for in Article 24 of the Agreement ⁽²⁾.

Done at Brussels, 26 November 1990.

For the Council

The President

C. DONAT CATTIN

⁽¹⁾ Opinion delivered on 23 November 1990 (not yet published in the Official Journal).

⁽²⁾ See page 33 of this Official Journal.

AGREEMENT

in the form of an exchange of letters between the European Economic Community and the Principality of Andorra

A. Letter from the Principality of Andorra

Luxembourg, 28 June 1990

Gentlemen,

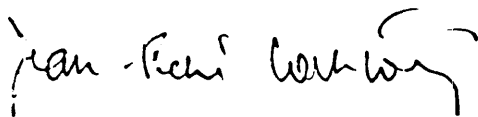
Please find attached the text of the Agreement between the Principality of Andorra and the European Economic Community. We have the honour to confirm that the Principality of Andorra accepts the Agreement.

We should be grateful if you would kindly confirm that the European Economic Community accepts the Agreement. The Agreement between the Principality of Andorra and the European Economic Community shall thereby be concluded, as set out in the attached text.

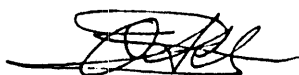
Please accept, Gentlemen, the assurance of our highest consideration.

*For the President of the French Republic
Co-Prince of Andorra*

*For the Bishop of Urgel
Co-Prince of Andorra*



For the Government of Andorra



B. Letter from the Community

Luxembourg, 28 June 1990

Gentlemen,

We acknowledge receipt of your letter accepting the Agreement between the Principality of Andorra and the European Economic Community. Your letter reads as follows:

'Please find attached the text of the Agreement between the Principality of Andorra and the European Economic Community. We have the honour to confirm that the Principality of Andorra accepts the Agreement.

We should be grateful if you would kindly confirm that the European Economic Community accepts the Agreement. The Agreement between the Principality of Andorra and the European Economic Community shall thereby be concluded, as set out in the attached text.'

We have the honour to confirm that the Community accepts the Agreement between the Principality of Andorra and the European Economic Community. Acceptance of the Agreement by the Community will take place following completion of the necessary internal procedures and will be notified to you in accordance with Article 24 (2) of the Agreement.

Please accept, Gentlemen, the assurance of our highest consideration.

*On behalf of
the Council of the European Communities*

Máire Geaghegan - O'Leary

AGREEMENT

between the European Economic Community and the Principality of Andorra

THE PRINCIPALITY OF ANDORRA

and

THE EUROPEAN ECONOMIC COMMUNITY,

DESIROUS of introducing, in respect of their trade relations, arrangements to take the place of national arrangements currently in force and respecting the specific situation of the Principality of Andorra,

CONSIDERING THAT, owing to geographical, historical and social and economic factors, Andorra's exceptional situation justifies special arrangements, particularly as regards exemption from import duties, turnover tax and excise duties collected on goods imported by travellers from Andorra into the Community,

HAVE AGREED AS FOLLOWS:

Article 1

Trade between the European Economic Community, on the one hand, and the Principality of Andorra, on the other, shall be governed by the provisions set out below.

TITLE I

Customs Union

Article 2

A customs union shall be established between the European Economic Community and Andorra for the products covered by Chapters 25 to 97 of the Harmonized System in accordance with the procedure and conditions set out under this Title.

Article 3

1. The provisions of this Title shall apply to:

- (a) goods produced in the Community or in the Principality of Andorra, including those obtained wholly or in part from products which come from third countries and are in free circulation in the Community or in the Principality of Andorra;
- (b) goods which come from third countries and are in free circulation in the Community or in the Principality of Andorra.

2. Products coming from third countries shall be considered to be in free circulation in the Community or in the Principality of Andorra if the import formalities have been complied with and any customs duties or charges having equivalent effect which are payable have been levied, and there has been no total or partial drawback of such duties or charges in respect of the said products.

Article 4

The provisions of this Title shall also apply to goods obtained in the Community or in the Principality of Andorra, in the manufacture of which were used products coming from third countries and not in free circulation either in the Community or in the Principality of Andorra. These provisions shall, however, apply to those goods only if the exporting Contracting Party levies the customs duties laid down in the Community for third country products used in their manufacture.

Article 5

The Contracting Parties shall refrain from introducing between themselves any new customs duties on imports or exports or charges having equivalent effect, and from increasing those already applied in their trade with each other on 1 January 1989.

Article 6

1. Customs duties on imports and charges having equivalent effect in force between the Community and the Principality of Andorra shall be abolished in accordance with paragraphs 2 and 3.

2. On 1 January 1991, the Principality of Andorra shall abolish customs duties and charges having equivalent effect on imports from the Community.

3. (a) From 1 January 1991 the Community, with the exception of the Kingdom of Spain and the Portuguese Republic, shall abolish customs duties and charges having equivalent effect on imports from the Principality of Andorra.

(b) From 1 January 1991 the Kingdom of Spain and the Portuguese Republic shall apply the same customs

duties in respect of the Principality of Andorra as they apply in respect of the Community as constituted on 31 December 1985.

- (c) In the case of processed agricultural products covered by Chapters 25 to 97 of the Harmonized System and referred to in Regulation (EEC) No 3033/80, subparagraphs (a) and (b) shall apply to customs duties constituting the fixed component of the charge on imports of those products into the Community from the Principality of Andorra, while the variable component provided for in the Regulation shall continue to apply.
- (d) By way of derogation from subparagraphs (a), (b) and (c), imports covered by the provisions relating to tax relief for travellers referred to in Article 13 shall be exempt from customs duties from 1 January 1991.

Article 7

1. For products covered by the customs union, the Principality of Andorra shall adopt, with effect from 1 January 1991:

- the provisions on import formalities applied by the Community to third countries,
- the laws, regulations and administrative provisions applicable to customs matters in the Community and necessary for the proper functioning of the customs union.

The provisions referred to in the first and second indents shall be those currently applicable in the Community.

2. The provisions referred to in the second indent of paragraph 1 shall be determined by the Joint Committee provided for in Article 17.

Article 8

- 1. (a) Over a period of five years, and beyond that period if no agreement can be reached in accordance with (b), the Principality of Andorra shall authorize the Community, acting on behalf of and for the Principality of Andorra, to enter goods sent from third countries to the Principality of Andorra for free circulation. Entry into free circulation will be effected by the Community customs offices listed in Annex I.
- (b) At the end of this period, and under Article 20, the Principality of Andorra may exercise right of entry into free circulation for its goods, following agreement by the Contracting Parties.

2. Where import duties are payable on goods pursuant to paragraph 1, these duties shall be levied on behalf of the Principality of Andorra. The Principality of Andorra shall undertake not to refund these sums directly or indirectly to the parties concerned.

3. The Joint Committee provided for in Article 17 shall determine:

- (a) possible changes to the list of the Community customs offices competent to clear the goods referred to in paragraph 1 and the procedure for forwarding the said goods to the Principality of Andorra referred to in paragraph 1;
- (b) the arrangements for assigning to the Andorran Exchequer the amounts collected in accordance with paragraph 2, and the percentage to be deducted by the Community to cover administrative costs in accordance with the relevant regulations in force within the Community;
- (c) any other arrangements necessary for the proper implementation of this Article.

Article 9

Quantitative restrictions on imports and exports and all measures having equivalent effect between the Community and the Principality of Andorra shall be prohibited from 1 January 1991.

Article 10

1. Should either Contracting Party consider that disparities arising from the other Party's application, in respect of imports from third countries, of customs duties, quantitative restrictions or any measures having equivalent effect, or of any other measure of commercial policy, threaten to deflect trade or to cause economic difficulties in its territory, it may bring the matter before the Joint Committee, which shall, if necessary, recommend appropriate methods for avoiding any harm liable to result therefrom.

2. Where deflections occur or economic difficulties arise and the Party concerned considers that they call for immediate action, that Party may itself take the necessary surveillance or protection measures, notifying the Joint Committee without delay; the Joint Committee may recommend that the said measures be amended or abolished.

3. In the choice of such measures, preference shall be given to those which least disturb the operation of the customs union and, in particular, the normal development of trade.

TITLE II

Arrangements for products not covered by the customs union

Article 11

1. Products covered by Chapters 1 to 24 of the Harmonized System which originate in the Principality of Andorra shall be exempt from import duties when imported into the Community.

2. Rules of origin and methods of administrative cooperation are set out in the Appendix.

Article 12

1. The arrangements applied to goods from third countries imported into the Principality of Andorra shall not be more favourable than those applied to imports of Community goods.

2. Products covered by headings No 24.02 and 24.03 of the Harmonized System which are manufactured in the Community from raw tobacco and which meet the conditions of Article 3 (1) shall be eligible, when imported into the Principality of Andorra, for a preferential rate corresponding to 60 % of the rate applied in the Principality of Andorra for the same products *vis-à-vis* third countries.

TITLE III

Common provisions

Article 13

1. Exemptions from import duties, turnover tax and excise duties levied on imports by travellers between the Contracting Parties and applicable to goods contained in the personal luggage of travellers coming from one of the Contracting Parties shall be those currently applicable in the Community in respect of third countries, provided imports of those goods are strictly non-commercial.

2. With regard to the products covered by Title II of this Agreement and listed below, the exemptions referred to in paragraph 1 shall be granted within the following quantitative limits for each traveller entering the Community from the Principality of Andorra:

— milk powder	2,5 Kilograms
— condensed milk	3 Kilograms
— fresh milk	6 Kilograms
— butter	1 Kilograms
— cheese	4 Kilograms
— sugar and confectionery	5 Kilograms
— meat	5 Kilograms.

3. By way of derogation from the provisions of paragraph 1 and provided that the goods have been acquired under the domestic market conditions of one of the Contracting Parties and meet the above conditions:

- the total value of the exemptions applicable to goods covered by Title I shall be set per person at three times the value of the exemption granted by the Community to travellers from third countries,
- the following quantitative limits shall apply to the goods listed below:

(a) Tobacco products

cigarettes	300 items
or	
cigarillos	150 items
(cigars weighing no more than 3 g each)	
or	
cigars	75 items
or	
smoking tobacco	400 grams

(b) Alcohol and alcoholic beverages

- distilled beverages and spirituous beverages having an alcoholic strength by volume of more than 22 % vol; undenatured ethyl alcohol of 80 % vol or more, 1,5 litres total
- or
- spirituous distilled beverages, aperitifs based on wine or alcohol, taffia, sake or similar beverages with an alcoholic strength by volume not exceeding 22 % vol, sparkling wine, dessert wine 3 litres total
- and
- still wine 5 litres total

(c) Perfume

and	75 gram
toilet water	$\frac{3}{8}$ litres

(d) Coffee

or	1 000 grams
extracts and essences of coffee	400 grams

(e) Tea

or	200 grams
extracts and essences of tea	80 gram

4. Within the quantitative limits laid down in the second indent of paragraph 3, the value of the goods listed therein shall not be taken into consideration for determining the exemptions referred to in paragraph 1.

Article 14

The Contracting Parties shall refrain from any domestic tax measure or practice leading directly or indirectly to discrimination between the products of one Contracting Party and similar products from the other Contracting Party.

Products sent to the territory of one of the Contracting Parties shall not be eligible for a refund of domestic charges which is higher than the charges which have been levied directly or indirectly.

Article 15

1. In addition to the cooperation provided for in Articles 11 (2) and 17 (8), the administrative authorities of the Contracting Parties responsible for implementing the provisions of this Agreement shall assist each other in other cases so as to ensure compliance with the provisions.

2. Arrangements for the application of paragraph 1 shall be determined by the Joint Committee referred to in Article 17.

Article 16

The Agreement shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, the protection of industrial or commercial property or controls relating to gold and silver. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties.

Article 17

1. A Joint Committee shall be set up with responsibility for administering this Agreement and ensuring that it is properly implemented. To that end, it shall formulate recommendations. It shall take decisions in the cases provided for in the Agreement. The decisions shall be executed by the Contracting Parties in accordance with their own regulations.

2. With a view to the proper performance of this Agreement, the Contracting Parties shall carry out exchanges of information and, at the request of either party, shall consult together in the Joint Committee.

3. The Joint Committee shall draw up its own rules of procedure.

4. The Joint Committee shall be composed, on the one hand, of representatives of the Community and, on the other, of representatives of the Principality of Andorra.

5. The Joint Committee shall take decisions by common accord.

6. The Joint Committee shall be chaired by each of the Contracting Parties in turn in accordance with the arrangements to be laid down in its rules of procedure.

7. The Joint Committee shall meet at the request of either of the Contracting Parties, to be lodged at least one month before the date of the intended meeting. Where the Joint

Committee is convened under Article 10, it shall meet within eight working days from the date on which the request is lodged.

8. In accordance with the procedure laid down in paragraph 1, the Joint Committee shall determine methods of administrative cooperation for the purposes of applying Articles 3 and 4, taking as a basis the methods adopted by the Community in respect of trade between the Member States; it may also amend provisions in the Appendix, referred to in Article 11.

Article 18

1. Any disputes arising between the Contracting Parties over the interpretation of the Agreement shall be put before the Joint Committee.

2. If the Joint Committee does not succeed in settling the dispute at its next meeting, each Party may notify the other of the designation of an arbitrator; the other Party shall then be required to designate a second arbitrator within two months.

The Joint Committee shall designate a third arbitrator.

The arbitrator's decisions shall be taken by a majority vote.

Each Party involved in the dispute shall be required to take the measures needed to ensure the application of the arbitrator's decision.

Article 19

In trade covered by this Agreement:

- the arrangements applied by the Principality of Andorra *vis-à-vis* the Community may not give rise to any discrimination between the Member States, their nationals or their companies,
- the arrangements applied by the Community *vis-à-vis* the Principality of Andorra may not give rise to any discrimination between Andorran nationals or companies.

TITLE IV

General and final provisions

Article 20

This Agreement is concluded for an unlimited duration. Within five years of its entry into force, the two Parties shall begin consultations to examine the results of its application and, if necessary, to open negotiations on its amendment in the light of that examination.

Article 21

Either Contracting Party may denounce this Agreement by notifying the other Contracting Party in writing. In that case, the Agreement shall cease to have effect six months after the date of such notification.

Article 22

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Economic Community is applied and under the conditions laid down in that Treaty and, on the other, to the territory of the Principality of Andorra.

Article 23

Annexes I and II and the Appendix to this Agreement shall form an integral part thereof.

Article 24

1. This Agreement shall enter into force on 1 July 1990, on condition that the Contracting Parties have notified each other before that date of the completion of the procedures necessary to that effect.

2. After the date provided for in paragraph 1, this Agreement shall enter into force on the first day of the second month following notification.

3. If paragraph 2 applies, the date 1 January 1991 contained in various provisions of this Agreement shall be replaced by the date 1 July 1991.

Article 25

The provisions of this Agreement shall replace those applied by the Community, and in particular by France and Spain, prior to the Agreement's entry into force, under the 1967 Exchange of Letters with the Principality of Andorra.

Article 26

This Agreement is drawn up in two originals in the Danish, Dutch, English, French, German, Greek, Italian, Portuguese, Spanish and Catalan languages, each text being equally authentic.

*ANNEX I**List of customs offices referred to in Article 8 (1)*

- TOULOUSE PORTET
 - L'HOSPITALET-PAS DE LA CASE
 - LA TOUR DE CAROL
 - PERPIGNAN
 - MADRID
 - BARCELONA
 - ALGECIRAS
 - TUY
 - FARGA DE MOLES
-

ANNEX II

As regards the provisions of trade policy adopted by the Principality of Andorra under the Agreement, and in order that imports of the products consumed in Andorra should not be affected by these provisions, derogations may be decided by the Joint Committee at the request of the Principality of Andorra; these derogations may include aspects of common commercial policy which do not apply to all the Member States of the Community.

The Commission shall communicate to the Andorran authorities any relevant information concerning the arrangements applicable to the Community's external trade.

Statement by the Community concerning agricultural and processed agricultural products

This Agreement shall not affect the Community's refund arrangements for exports of Community agricultural products or processed agricultural products.

Joint Statement

In so far as provisions of this Agreement, such as, in particular, the provisions governing customs duties, charges having equivalent effect, quantitative restrictions, measures having equivalent effect, prohibitions on imports, exports or goods in transit, are similar to the provisions of the Treaty establishing the European Economic Community, the Contracting Parties' representatives within the Joint Committee shall undertake to interpret the former, within the scope of this Agreement, in the same way as the latter are interpreted in trade within the European Economic Community.

Statement by the Principality of Andorra

The Principality of Andorra undertakes not to operate any discrimination as regards import duties and taxes levied on whisky, absinth and aniseed-based aperitifs, on the one hand, and other alcoholic beverages and aperitifs, on the other hand.

Joint Statement

The Joint Committee shall examine, and endeavour to find a solution to, any problems which arise in trade between the Contracting Parties as regards the monitoring and certification of technical standards.

APPENDIX

concerning the definition of 'originating products' and methods of administrative cooperation

TITLE I

DEFINITION OF THE CONCEPT OF ORIGINATING PRODUCTS

Article 1

For the purpose of implementing the provisions of Article 11 (1) of the Agreement, the following shall be regarded as products originating in the Principality of Andorra:

- (a) vegetable products which are harvested in the Principality of Andorra;
- (b) live animals born and raised in the Principality of Andorra;
- (c) products obtained from live animals born and raised in the Principality of Andorra;
- (d) products from hunting or fishing in the Principality of Andorra;
- (e) products obtained in the Principality of Andorra by working or processing products referred to in points (a) to (d), even if other products have been used in their manufacture, provided that the products which were not obtained in the Principality of Andorra play only a subsidiary part in manufacture.

TITLE II

ARRANGEMENTS FOR ADMINISTRATIVE COOPERATION

Article 2

1. Originating products within the meaning of this Appendix shall when imported into the Community be covered by the Agreement on presentation of:

- (a) an EUR. 1 movement certificate, hereinafter referred to as an 'EUR. 1 certificate'. A specimen of the EUR. 1 certificate is given in Annex 2 to this Appendix;
- (b) an invoice bearing the exporter's declaration as given in Annex 3 to this Appendix, made out by any exporter for any consignment of one or more packages containing originating products whose total value does not exceed ECU 2 820.

2. The following originating products within the meaning of this Appendix shall when imported into the Community be covered by the Agreement without it being necessary to present either of the documents referred to in paragraph 1:

- (a) goods sent as small packages from private persons to private persons, whose total value does not exceed ECU 200;

- (b) goods forming part of travellers' personal luggage whose value does not exceed ECU 565.

These provisions shall apply only provided that such goods are not imported by way of trade and have been declared as meeting the conditions required for the application of the Agreement, and where there is no doubt as to the veracity of such declaration.

Imports which are occasional and consist solely of goods for the personal use of the recipients or travellers shall not be considered as imports by way of trade if it is evident from the nature and quantity of the goods that no commercial purpose is in view.

3. Up to and including 30 April 1991 the ecu to be used in terms of any given national currency shall be the equivalent in that national currency of the ecu as at 3 October 1988. For each successive period of two years thereafter it shall be the equivalent in that national currency of the ecu as at the first working day in October in the year immediately preceding the two-year period.

4. Amounts in the national currency of the exporting State equivalent to the amounts expressed in ecus shall be fixed by the exporting State and communicated to the other parties. When these amounts are greater than the corresponding amounts fixed by the importing State, the importing State shall accept them if the goods are invoiced in the currency of the exporting State.

If the goods are invoiced in the currency of another Member State of the Community, the importing State shall recognize the amount notified by the State concerned.

Article 3

1. An EUR. 1 certificate shall be issued by the Andorran customs authorities when the goods to which it relates are exported. It shall be made available to the exporter as soon as actual exportation has been effected or ensured.

2. The EUR. 1 certificate shall be issued by the Andorran customs authorities if the goods to be exported can be considered as products originating in the Principality of Andorra within the meaning of Article 1 of this Appendix.

3. An EUR. 1 certificate may be issued only where it can serve as the documentary evidence required for the purpose of implementing the preferential arrangements provided for by the Agreement.

The date of issue of the EUR. 1 certificate must be indicated in the part of the certificate reserved for the customs authorities.

4. In exceptional circumstances an EUR. 1 certificate may also be issued after exportation of the goods to which it relates if it was not issued at the time of exportation because of errors or involuntary omissions or special circumstances.

Certificates issued retrospectively must be endorsed with one of the following phrases:

'EXPEDIDO A POSTERIORI', 'UDSTEDT EETERFØLGENDE', 'NACHTRÄGLICH AUSGESTELLT', 'ΕΚΔΟΘΕΝ ΕΚ ΤΩΝ ΥΣΤΕΡΙΩΝ', 'ISSUED RETROSPECTIVELY', 'DELIVRE A POSTERIORI', 'RILASCIATO A POSTERIORI', 'AFGEGEVEN A POSTERIORI', 'EMITIDO A POSTERIORI', 'EMES A POSTERIORI'.

5. In the event of the theft, loss or destruction of an EUR. 1 certificate, the exporter may apply to the Andorran customs authorities which issued it for a duplicate made out on the basis of the export documents in their possession. The duplicate issued in this way must be endorsed with one of the following:

'DUPLICADO', 'DUPLIKAT', 'DUPLIKAT', 'ΑΝΤΙΓΡΑΦΟ', 'DUPLICATE', 'DUPLICATO', 'DUPLICAAT', 'SEGUNDA VIA', 'DUPLICAT'.

The duplicate, which must bear the date of issue of the original EUR. 1 certificate, shall take effect as from that date.

6. The endorsements referred to in paragraphs 4 and 5 shall be entered in the Remarks box on the EUR. 1 certificate.

7. For the purpose of verifying whether the conditions stated in paragraph 2 have been met, the Andorran customs authorities shall have the right to call for any documentary evidence or to carry out any check which they consider appropriate.

Article 4

1. An EUR. 1 certificate shall be issued only on application having been made in writing by the exporter or, under the exporter's responsibility, by his authorized representative, on the form of which a specimen is given in Annex 2 to this Appendix; it shall be completed in accordance with this Appendix.

2. It shall be the responsibility of the Andorran customs authorities to ensure that the form referred to in paragraph 1 is duly completed. In particular, the Andorran customs authorities shall check whether the space reserved for the description of the goods has been completed in such a manner as to exclude all possibility of fraudulent additions. To this end, the description of the goods must be given without leaving any blank lines. Where the space is not completely filled a horizontal line must be drawn below the last line of the description, the empty space being crossed through.

3. Since the EUR. 1 certificate constitutes the documentary evidence for the application of the preferential tariff provided for by the Agreement, it shall be the responsibility of the Andorran customs authorities to take any steps necessary to verify the origin of the goods and to check the other statements on the EUR. 1 certificate.

4. When a certificate is issued in accordance with Article 3 (4) of this Appendix, after the goods to which it relates have actually been exported, the exporter must in the application referred to in paragraph 1:

- indicate the place and date of consignment of the goods to which the certificate relates,
- certify that no EUR. 1 certificate was issued at the time of exportation of the goods in question, and state the reasons.

Article 5

1. EUR. 1 certificates shall be made out on the form of which a specimen is given in Annex 2. This form shall be printed in one or more of the languages in which the Agreement is drawn up. Certificates shall be made out in one of these languages and in accordance with the provisions of the domestic law of the Principality of Andorra; if they are handwritten they shall be completed in ink and in capital letters.

2. Each certificate shall measure 210 × 297 mm. A tolerance of up to plus 8 mm or minus 5 mm in the length may be allowed. The paper used must be white writing paper, sized, not containing mechanical pulp and weighing not less than 25 g/m². It shall have a printed green guilloche pattern background making any falsification by mechanical or chemical means apparent to the eye.

3. The Principality of Andorra may reserve the right to print the certificates itself or may have them printed by approved printers. In the latter case, each certificate must include a reference to such approval. Each certificate must bear the name and address of the printer or a mark by which the printer can be identified. It shall also bear a serial number, either printed or not, by which it can be identified.

Article 6

1. An EUR. 1 certificate must be submitted, within four months of the date of issue, by the Andorran customs authorities to the customs authorities of the importing State where the goods are entered in accordance with the procedures laid down by that State.

2. An EUR. 1 certificate which is submitted to the customs authorities of the importing State after the final date for presentation specified in paragraph 1 may be accepted for the purpose of applying preferential treatment, where the failure to submit the certificate by the final date set is due to reasons of *force majeure* or exceptional circumstances.

In other cases of belated presentation, the customs authorities of the importing State may accept the certificates where the goods have been submitted to them before the said final date.

3. The discovery of slight discrepancies between the statements made in the EUR. 1 certificate and those made in the documents submitted to the customs office for the purpose of carrying out the formalities for importing the goods shall not *ipso facto* render the certificate null and void if it is duly established that the certificate does correspond to the goods submitted.

Article 7

The declaration referred to in Article 2 (1) (b) shall be drawn up by the exporter in the manner specified in Annex 3 to this Appendix, in one of the languages in which the Agreement is drawn up.

It shall be typed, or printed by means of a stamp and signed by hand. The exporter must retain a copy of the invoice bearing this declaration for at least two years.

Article 8

1. The exporter or his representative shall submit with his application for an EUR. 1 certificate any appropriate supporting document proving that the goods to be exported qualify for the issue of an EUR. 1 certificate.

He shall undertake to submit, at the request of the appropriate authorities, any supplementary evidence they may require for the purpose of establishing the correctness of the originating status of the goods eligible for preferential treatment and shall undertake to agree to any inspection of his accounts and to any check on the processes of the obtaining of the above goods, carried out by the said authorities.

2. Exporters must keep for not less than two years the supporting documents referred to in paragraph 1.

3. The provisions of paragraphs 1 and 2 shall apply *mutatis mutandis* in the case of the use of the declaration referred to in Article 2 (1) (b).

Article 9

1. Goods sent from the Principality of Andorra for exhibition in another country and sold after the exhibition for importation into the Community shall benefit on importation from the provisions of the Agreement on condition that the goods meet the requirements of this Appendix entitling them to be recognized as originating in the Principality of Andorra and provided that it is shown to the satisfaction of the customs authorities that:

(a) an exporter has consigned the goods from the Principality of Andorra to the country in which the exhibition is held and has exhibited them there;

(b) the goods have been sold or otherwise disposed of by that exporter to a consignee in the Community;

(c) the goods have been consigned during the exhibition or immediately thereafter to the Community in the State in which they were sent for exhibition;

(d) the goods have not, since they were consigned for exhibition, been used for any purpose other than demonstration at an exhibition.

2. An EUR. 1 certificate must be submitted to the customs authorities in the normal manner. The name and place of the exhibition must be indicated thereon. Where necessary, additional documentary evidence of the nature of the goods and the conditions under which they have been exhibited may be required.

3. Paragraph 1 shall apply to any trade, industrial, agricultural or crafts exhibition, fair or similar public show or display which is not organized for private purposes in shops or business premises with a view to the sale of foreign goods, and during which the goods remain under customs control.

Article 10

1. In order to ensure the proper application of this Title, Member States of the Community and the Principality of Andorra shall assist each other, through their respective customs administrations, in checking the authenticity and accuracy of EUR. 1 certificates and the declarations by exporters made on invoices.

Representatives of the Commission of the European Communities may on request take part in this checking.

2. The Andorran customs authorities shall forward to the customs authorities of the Member States, via the Commission of the European Communities, specimen impressions of the stamps used in their offices for issuing EUR. 1 certificates.

3. Penalties shall be imposed on any person who, in order to enable goods to be accepted as eligible for preferential treatment, draws up, or causes to be drawn up, a document which contains incorrect particulars.

Article 11

1. Subsequent verification of EUR. 1 certificates and of exporters' declarations made on invoices shall be carried out at random or whenever the customs authorities of the importing State have reasonable doubt as to the authenticity of the document or the accuracy of the information regarding the true origin of the goods in question.

2. For the purposes of implementing the provisions of paragraph 1 the customs authorities of the importing State

shall return the EUR. 1 certificate, and the invoice if it has been submitted, or the invoice bearing the exporter's declaration or a copy of those documents, to the Andorran customs authorities, giving, where appropriate, the reasons of substance or form for an inquiry.

The customs authorities of the importing State shall forward, in support of the request for subsequent verification, any documents and information that have been obtained suggesting that the particulars given on the EUR. 1 certificate or the invoice are inaccurate.

If the customs authorities of the importing State decide to suspend the application of Article 11 pending the results of the verification, they shall offer to release the goods to the importer subject to any precautionary measures judged necessary.

3. The customs authorities of the importing State shall be informed of the results of the verification as soon as possible. The results must be such as to make it possible to determine whether the documents which are referred to in paragraph 2, and which have been returned, apply to the goods actually exported and whether these goods can in fact qualify for the application of the preferential arrangements.

When such disputes cannot be settled between the customs authorities of the importing State and the Andorran customs

authorities, or when they raise a problem of interpretation of this Appendix, they shall be submitted to the Customs Committee.

For the purpose of subsequent verification of EUR. 1 certificates, the export documents or copies of EUR. 1 certificates provided in their place must be retained for at least two years by the Andorran customs authorities.

TITLE III

FINAL PROVISIONS

Article 12

The Community and the Principality of Andorra shall each take the measures necessary for the implementation of this Appendix.

Article 13

The Annexes to this Appendix shall form an integral part thereof.

ANNEX 1

EXPLANATORY NOTES

Note 1

In order to determine whether goods originate in the Principality of Andorra, it shall not be necessary to establish whether the power and fuel, plant and equipment, machines and tools used to obtain such goods originate in third countries or not.

Note 2

In order to determine the origin of products falling within Chapters 1 to 24 of the Combined Nomenclature, no account shall be taken of any packaging.

Note 3

Products which do not make up more than 10% by quantity of those referred to in Article 1 (a) to (e) of the Appendix be regarded as 'playing a subsidiary part' in manufacture.

MOVEMENT CERTIFICATE

Annex 2

1. Exporter (Name, full address, country)		EUR. 1 No A 000.000	
		See notes overleaf before completing this form	
3. Consignee (Name, full address, country) (Optional)		2. Certificate used in preferential trade between	
		 and (Insert appropriate countries, groups of countries or territories)	
		4. Country, group of countries or territory in which the products are considered as originating	5. Country, group of countries or territory of destination
6. Transport details (Optional)		7. Remarks	
8. Item number; Markes and numbers; Number and kind of packages (!); Description of goods		9. Gross weight (kg) or other measure (litres, m ³ , etc.)	10. Invoices (Optional)
11. CUSTOMS ENDORSEMENT		12. DECLARATION BY THE EXPORTER	
Declaration certified Export document (!) Form No Customs office Issuing country or territory Date (Signature)		I, the undersigned, declare that the goods described above meet the conditions required for the issue of this certificate. Place and date (Signature)	

(*) If goods are not packed, indicate number of articles of state 'in bulk' as appropriate.

(*) Complete only where the regulations of the exporting country or territory require.

13. REQUEST FOR VERIFICATION, to:	14. RESULT OF VERIFICATION
Verification of the authenticity and accuracy of this certificate is requested. (Place and date) Stamp (Signature)	Verification carried out shows that this certificate (') ☐ was issued by the customs office indicated and that the information contained therein is accurate. ☐ does not meet the requirements as to authenticity and accuracy (see remarks appended). (Place and date) Stamp (Signature) (') Insert X in the appropriate box.

NOTES

1. Certificates must not contain erasures or words written over one another. Any alterations must be made by deleting the incorrect particulars and adding any necessary corrections. Any such alteration must be initialled by the person who completed the certificate and endorsed by the customs authorities of the issuing country or territory.
2. No spaces must be left between the items entered on the certificate and each item must be preceded by an item number. A horizontal line must be drawn immediately below the last item. Any unused space must be struck through in such a manner as to make any later additions impossible.
3. Goods must be described in accordance with commercial practice and with sufficient detail to enable them to be identified.

APPLICATION FOR A MOVEMENT CERTIFICATE

1. Exporter (Name, full address, country)	EUR. 1 No A 000.000		
	See notes overleaf before completing this form		
	2. Application for a certificate to be used in preferential trade between and (Insert appropriate countries, groups of countries or territories)		
3. Consignee (Name, full address, country) (Optional)	4. Country, group of countries or territory in which the products are considered as originating		5. Country, group of countries or territory of destination
	7. Remarks		
6. Transport details (Optional)			
8. Item number; Markes and numbers; Number and kind of packages (''); Description of goods		9. Gross weight (kg) or other measure (litres, m³, etc.)	10. Invoices (Optional)

() If goods are not packed, indicate number of articles or state 'in bulk' as appropriate.

DECLARATION BY THE EXPORTER

I, the undersigned, exporter of the goods described overleaf,

DECLARE that the goods meet the conditions required for the issue of the attached certificate;

SPECIFY as follows the circumstances which have enabled these goods to meet the above conditions:

.....
.....
.....
.....

SUBMIT the following supporting documents ⁽¹⁾:

.....
.....
.....
.....

UNDERTAKE to submit, at the request of the appropriate authorities, any supporting evidence which these authorities may require for the purpose of issuing the attached certificate, and undertake, if required, to agree to any inspection of my accounts and to any check on the processes of manufacture of the above goods, carried out by the said authorities;

REQUEST the issue of the attached certificate for these goods.

.....
(Place and date)

.....
(Signature)

⁽¹⁾ For example: import documents, movement certificates, invoices, manufacturer's declarations, etc., referring to the products used in manufacture or to the goods re-exported in the same state.

*Annex 3***DECLARATION PROVIDED FOR IN ARTICLE 2 (1) (B)**

I, the undersigned, exporter of the goods covered by this document, declare that, except where otherwise indicated (1), the goods meet the conditions laid down for obtaining originating status in preferential trade with the Community and that the country of origin of the goods is the Principality of Andorra.

.....
(place and date)

.....
(signature)

(The signature must be followed by the name of the
signatory in clear script)

(1) When an invoice also includes products not originating in the Principality of Andorra, the exporter must clearly indicate them.

Andorra, 14 December 1989

Mr J.J. Schwed

Head of Division

Head of the Delegation of the European Economic Community for the negotiations with the Principality of Andorra

Sir,

Following our negotiating meeting on 13 and 14 December, the Andorran delegation for the negotiations with the European Economic Community stated that the import duties collected on entry into free circulation operations at all the Community customs offices for goods being sent to the Principality of Andorra were collected on behalf of the Principality of Andorra and should be paid back to the Principality of Andorra. It would like the Joint Committee to examine, at its first meeting, ways and means of fully applying this principle.

Please accept, Sir, the assurance of my highest consideration.

Mr Joseph Pintat

Head of Government

Spokesman of the Delegation of the Principality of Andorra for the negotiations with the European Community

Brussels, 14 December 1989

Mr Joseph Pintat

Head of Government

Spokesman for the Delegation of the Principality of Andorra for the negotiations with the European Community

Sir,

I have the honour to acknowledge your letter of 14 December 1989 containing the Andorran Delegations's statement concerning the collection and repayment of import duties. I am able to agree to the discussion of the matter at the first Joint Committee meeting.

Please accept, Sir, the assurance of my highest consideration.

J. J. Schwed

Head of Division

Head of the Delegation of the European Economic Community for the negotiations with the Principality of Andorra

Information concerning the date of entry into force of the Agreement in the form of an Exchange of Letters between the European Economic Community and the Principality of Andorra, signed in Luxembourg on 28 June 1990 ⁽¹⁾.

The exchange of instruments of notification of completion of the procedures necessary for the entry into force of the Agreement in the form of an Exchange of Letters between the European Economic Community and the Principality of Andorra, signed in Luxembourg on 28 June 1990, having taken place on 28 November 1990, the Agreement will enter into force, in accordance with Article 24 (2) thereof, on 1 January 1991.

⁽¹⁾ See p. 14 of this Official Journal.