II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 3 March 1992

laying down the general conditions to be complied with for the import of certain raw materials for the pharmaceutical processing industry, coming from third countries, which appear on the list established by Council Decision 79/542/EEC

(92/183/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries (1), as last amended by Directive 91/688/EEC (2), and in particular Article 16 (2) thereof,

Whereas Directive 72/462/EEC allows Member States to authorize until 31 December 1986 imports of glands and organs, including blood, as raw materials for the pharmaceutical processing industry coming from third countries which appear on the list of third countries, drawn up in Council Decision 79/542/EEC (3), as last amended by Commission Decision 92/14/EEC (4);

Whereas Directive 72/462/EEC provides for general conditions to be laid down for the said imports;

Whereas Member States may be authorized to import the raw material from third countries appearing on the third-country list without taking into account restrictions contained in that list regarding species of animals and fresh meat by reason of the treatment of the raw material after import;

Whereas, however, glands and organs, for use as raw materials for the pharmaceutical industry, have to be considered as low-risk material as defined by Council Directive 90/667/EEC (5); whereas that Directive provides for registration of pharmaceutical plants using such products as raw materials;

Whereas the general conditions and certification to be complied with for such imports shall ensure that the raw material will be used only for the specified purpose, thus preventing the risk of contaminating herds inside the Community; whereas such assurance can be achieved in a satisfactory way only if the consignments of the raw material are monitored closely;

Whereas Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (6), as amended by Directive 91/496/EEC (7), allows for immediate notification to the veterinary authorities of the destination of consignments of certain animal products with an increased risk hazard as regards animal health;

(1) OJ No L 302, 31. 12. 1972, p. 28.
(2) OJ No L 377, 31. 12. 1991, p. 18.
(3) OJ No L 146, 14. 6. 1979, p. 15.
(4) OJ No L 8, 14. 1. 1992, p. 12.
(5) OJ No L 363, 27. 12. 1990, p. 51.
(6) OJ No L 373, 31. 12. 1990, p. 1.
(7) OJ No L 268, 24. 9. 1991, p. 56.

Whereas such monitoring can be achieved by *Shift* utilizing the notification procedure as laid down by *Animo* created by Commission Decision 91/398/EEC (1);

Whereas the establishment of such general conditions constitutes no more than a first step in the setting up of arrangements for imports of raw materials from third countries; whereas, at this stage, imports of blood which has undergone a treatment to remove any component should be excluded from the scope of this Decision;

Whereas this Decision is without prejudice to the conditions laid down in Commission Decision 89/18/EEC (2) for importation from third countries of fresh meat for purposes other than human consumption, which is not intended for the pharmaceutical industry;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of this Decision:

(a) 'third-country list' means the list of third countries from which Member States authorize imports of bovine animals and swine and fresh meat stablished by Decision 79/542/EEC;

(b) 'raw material' means glands and organs, including intestinal mucosa and blood, used as raw materials for the pharmaceutical processing industry, and which have not undergone any treatment except cold treatment;

(c) 'blood' means whole blood which has not undergone any treatment to remove any components.

Article 2

1. Notwithstanding the restrictions regarding species of animals authorized in the third-country list in respect of certain third countries, Member States may authorize the importation of raw material from those third countries presenting the guarantees laid down in the accompanying animal health certificate corresponding with the specimen given in the Annex.

The abovementioned authorization shall be notified to the competent authorities of Member States through which the raw material must pass.

2. The authorization, provided for in paragraph 1, can be given only to importers specially approved for this purpose by the Member States. Member States shall immediately inform the Commission of such approvals and of the conditions under which these have been given.

3. At arrival at the border inspection post the raw material has to be accompanied by a duly completed and undersigned animal health certificate corresponding with the specimen given in the Annex.

4. After import the raw material must be consigned directly to a registered pharmaceutical processing establishment which is under continuous veterinary supervision and which has given a guarantee that the raw material will be used only for the specified purpose and that it will not leave the establishment in its original state, except in case of necessity where it is consigned to a destruction plant under the control of an official veterinarian.

5. By way of exception to paragraph 4 the imported raw material may be sorted and stored by establishments which are specially approved for this purpose by the Member States shall inform the Commission of such approvals and of the conditions under which these have been given. In any case, the following conditions shall be met:

(a) the sorting of the raw material must be done in a way that any risk of introduction of animal diseases can be avoided;

(b) the storage of the imported raw materials in the establishment must not be longer than 12 months;

(c) at all times during sorting or storage, the raw material may not be in contact with fresh meat which is not covered by this Decision, by Decision 89/18/EEC of by Directive 90/667/EEC;

(d) records kept at the establishment must allow complete monitoring of each consignment and parts thereof;

(e) the original certificate or an authenticated copy of it must be kept at the disposal of the official veterinarian for at least 12 months;

(f) the establishment must have not other activities than importing, collecting, sorting, storing and dispatching of raw materials covered by this Decision, by Decision 89/18/EEC or by Article 5 (3) of Directive 90/667/EEC;

(g) the establishment shall be under the continuous supervision of the veterinary authorities and be inspected frequently by them.

(1) OJ No L 221, 9. 8. 1991, p. 30.
(2) OJ No L 8, 11. 1. 1989, p. 17.

Veterinary experts of the Commission may carry out on-the-spot inspections in establishments which are approved according to this paragraph. In such cases these inspections shall be carried out in accordance with Article 12 of Directive 90/667/EEC.

6. In addition to paragraphs 3, 4 and 5, the following conditions shall be met:

(a) on dispatch to the Community territory, the raw material must be enclosed in leak-proof and duly sealed containers. The containers and the accompanying documents must be marked: 'Use restricted to the manufacture of pharmaceuticals'. The containers and the accompanying documents shall bear the name and address of the consignee;

(b) the raw material must be transported from the point of arrival in Community territory in containers or means of transport which are leak-proof and duly sealed;

(c) on arrival in the territory of the Community and before dispatch of the raw material to the registered processing establishment or to an establishment approved in accordance with paragraph 5, prior notification of intending dispatch must be made by *Animo* message or, when this is not possible, by telex or by telefax to the local official veterinarian at the local health unite; the same provision applies for dispatch from the establishment approved in accordance with paragraph 5 to one or more registered pharmaceutical plants of destination;

(d) the health certificate or an authenticated copy thereof must accompany the goods until arrival; in the case of application of paragraph 5 the local official veterinarian must provide for as many authenticated copies as needed to accompany each subconsignment to its destination;

(e) after arrival, the raw material shall be treated in such a way as to prevent contamination of indigenous herds;

(f) the vehicles and containers or any other means of transport referred to in point (b) and all equipment and utensils which come into contact with the raw material shall be cleansed and disinfected and all packagings shall be destroyed in an incinerator. If incineration of the packaging is not possible on site then suitable arrangements must be made for incineration of this material as near as possible to the plan provided this is agreed and monitored by the veterinarian authorities.

7. Member States shall notify to the Commisison a list of approved importers, establishments refered to in paragraph 5 and registered pharmaceutical processing establishments. This list shall contain the name, address and registration number of these importers and establishments.

Article 3

This Decision shall apply from 1 July 1992.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 3 March 1992.

For the Commission

Ray MAC SHARRY

Member of the Commission

ANNEX

ANIMAL HEALTH CERTIFICATE

for raw material intended for consignment to the European Economic Community for pharmaceutical processing

Country of destination : .....

Exporting country : .....

Competent Ministry : .....

Competent issuing authority : .....

References (1) : .....

I. Identification of raw material

Nature or raw material : .....

Nature of packaging : .....

Number of packages : .....

Net weight : .....

II. Origin of raw material

Address(es) of the establishment(s) controlled by the responsible veterinary authorities :

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.....

III. Destination of raw material

The raw material will be sent from : .....
(place of loading)

to : .....
(country and place of destination)

by the following means of transport (2) : .....

Name and address of consignor : .....

.....

.....

Name and address of consignee : .....

.....

.....

(1) Optional.
(2) Indicate means of transport and registration marks, flight number or registered name, as appropriate.

IV. **Attestation of health**

I, the undersigned, official veterinarian, certify that :

1. the raw material described above is obtained from :

   (a) animals which have remained on the territory of ..... (3) for at least three months before being slaughtered or since birth in the case of animals less than three months old ;

   (b) animals which come from holdings in which there has been no outbreak of rinderpest, foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease or porcine entero-viral encephalomyelitis (Teschen disease) in the previous 60 days and around which, within a radius of 25 km, there has been no case of any of the abovementioned diseases for at least 30 days ;

   (c) an establishment or establishments in which no case of one of the diseases referred to in 1 (b) has been detected for at least 30 days.

2. The raw material described above has not been obtained from animals which :

   (a) have died on the holdings, including stillborn and unborn animals ;

   (b) have been killed either on the holding or at any other place, in order to eradicate epizootic diseases ;

   (c) show, during inspection at slaughter, signs or evidence of diseases communicable to humans and which are for that reason, or due to the presence of residues, excluded from human consumption.

3. The raw material has been handled so as to avoid recontamination

Done at ..... on .....

Seal

.....

(signature of official veterinarian)

.....

(name in capital letters,
qualifications and title)

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(1) Name of the exporting country.