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II

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COUNCIL

COUNCIL DIRECTIVE

of 11 December 1991

amending Directive 80/217/EEC introducing Community measures for the control of classical swine-fever

(91/685/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas Directive 80/217/EEC ⁽⁴⁾, as last amended by Directive 87/486/EEC ⁽⁵⁾, introduced Community measures for the control of classical swine-fever;

Whereas, during the period covered by Directive 80/217/EEC, this disease has, owing to the measures adopted to combat it, been eradicated in most Member States; whereas, however, certain serious difficulties have been experienced in eradicating the disease in areas with a high density of pigs and in areas containing wild boar;

Whereas, in view of the evolution of the disease, the availability of improved diagnostic methods and the completion of the internal market for 1 January 1993, it is necessary to amend the control measures already taken at Community level to control classical swine-fever;

Whereas these amendments relate to the cleaning and disinfection of infected farms, disease in wild boar, the use of crisis units, movement controls in protection and surveillance zones, emergency vaccination and diagnostic procedures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 80/217/EEC is hereby amended as follows:

1. Article 2 shall be replaced by the following:

'Article 2

For the purposes of this Directive the following definitions shall apply:

- (a) 'pig': any animal of the Suidae family;
- (b) 'breeding pig': a pig intended or used for reproduction with a view to multiplication of the species;
- (c) 'fattening pig': a pig fattened and intended for slaughter at the end of the fattening period with a view to meat production;

⁽¹⁾ OJ No C 226, 31. 8. 1991, p. 6.

⁽²⁾ OJ No C 326, 16. 12. 1991.

⁽³⁾ Opinion delivered on 28 November 1991 (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 47, 21. 2. 1980, p. 11.

⁽⁵⁾ OJ No L 280, 3. 10. 1987, p. 21.

- (d) 'slaughter pig': a pig which is intended for slaughter without undue delay in a slaughterhouse;
- (e) 'feral pig': a pig which is not kept or bred in a holding;
- (f) 'holding': a holding within the meaning of Article 2 (4) of Directive 90/425/EEC (*), as last amended by Directive 91/174/EEC (**);
- (g) 'pig suspected of being infected with classical swine-fever': any pig exhibiting clinical symptoms or showing post-mortem lesions or reactions to laboratory tests carried out according to Article 11, indicating the possible presence of classical swine-fever;
- (h) 'pig infected with classical swine-fever': any pig
 - in which clinical symptoms or post-mortem lesions of classical swine-fever have been officially confirmed, or
 - in which the presence of this disease has been officially confirmed as the result of a laboratory examination carried out in accordance with Article 11;
- (i) 'owner or keeper': any person or persons, either natural or legal, having ownership of the pigs, or charged with keeping the said animals, whether or not for financial reward;
- (j) 'competent authority': the competent authority within the meaning of Article 2 (6) of Directive 90/425/EEC;
- (k) 'official veterinarian': the veterinarian appointed by the competent authority;
- (l) 'rendering': the processing of high-risk material in accordance with Directive 90/667/EEC (1)
- (m) 'swill': waste from kitchens, restaurants or, as the case may be, from industries using meat.'

(*) OJ No L 224, 18. 8. 1990, p. 29.

(**) OJ No L 85, 5. 4. 1991, p. 37.

(1) OJ No L 363, 27. 12. 1990, p. 51.

2. in Article 5:

- (a) the following shall be added to the seventh indent of paragraph 1:

'The reintroduction of pigs shall take account of the type of farming practised on the holding concerned and must conform to one of the following procedures:

1. as regards open-air pig holdings:

the reintroduction of pigs shall start with the introduction of sentinel piglets which have

been checked and found negative for the presence of antibodies against classical swine-fever virus. The sentinel piglets shall be placed, in accordance with the requirements of the competent authority, throughout the infected holding and be rechecked, 21 and 42 days after having been placed on the holding, for the presence of antibodies.

If none of the piglets has developed antibodies against classical swine-fever virus and as soon as the results of the second test are available, with a negative result, full re-population may take place;

- 2. for all other forms of rearing, the reintroduction of pigs shall take place either in accordance with the measures provided for in paragraph 1 or with the following provisions:

- the reintroduction of piglets shall be based on total repopulation, provided that:
 - all the pigs arrive within a period of eight days and come from holdings situated outside the restriction zone,
 - no pig may leave the holding for a period of 60 days after the arrival of the last pigs,
 - the repopulated herd is subjected to a serological examination in accordance with Annexes I and IV. That examination may be carried out at the earliest 30 days after the arrival of the last pigs.';

- (b) paragraph 2 shall be replaced by the following text:

'2. The competent authority may apply the measures provided for in paragraph 1 to other holdings where pigs may have become infected as a result of their location and direct or indirect contact with the infected holding.';

- 3. the following Article shall be inserted:

'Article 6a

1. Immediately after the competent authority of a Member State has information that feral pigs are suspected of being infected, it shall take all appropriate measures to confirm the presence of the disease, by giving information to the owners or keepers of pigs and to hunters, and by investigations of all feral pigs shot or found dead, including laboratory testing.

2. As soon as confirmation of infection in feral pigs has taken place, the competent authority of a Member

State shall immediately place under official surveillance holdings in the defined infected area and shall in particular order that:

- (a) an official census be carried out of all categories of pigs on all holdings; the census must be kept up to date by the owner or keeper; the information in the census must be produced on request and may be checked at each inspection.

However, as regards open-air pig holdings, the first census carried out may be done on the basis of an estimate;

- (b) all pigs on the holding be kept in their living quarters or some other place where they can be isolated from feral pigs. The feral pigs must not have access to any material which may subsequently come in contact with the pigs on the holding;
- (c) no pigs enter or leave the holding save where authorized by the competent authority having regard to the epidemiological situation;
- (d) appropriate means of disinfection be used at the entrances and exits of buildings housing pigs and of the holding itself;
- (e) all dead or diseased pigs with classical swine-fever symptoms on a holding be tested for the presence of classical swine-fever;
- (f) no part of any feral pig (whether shot or found dead) shall be brought into a holding.

3. Without prejudice to the measures laid down in paragraph 2, Member States shall submit to the Commission at the earliest opportunity a written plan of the measures taken to eradicate the disease in an area defined as infected and the measures applied on the holdings in that area.

The Commission shall examine the plan in order to determine whether it permits the desired objective to be attained and shall approve the plan, if necessary with amendments, in accordance with the procedure laid down in Article 16.

The plan may subsequently be amended or supplemented, in accordance with the same procedure, to take account of developments in the situation.

4. After the measures provided for in the plan mentioned in paragraph 3 have been approved, they shall replace the initial measures referred to in paragraph 2, on a date which shall be decided upon when approval is given.

5. The plan mentioned in paragraph 3 shall contain information on:

- (a) a defined infected area within the territory of the Member State referred to in paragraph 2. When defining the infected area, the competent authority shall take into account:
 - (i) the geographical distribution of the disease;
 - (ii) the feral pig population in the area;
 - (iii) the existence of major natural or man-made obstacles to movements of feral pigs;
- (b) the approximate number of groups of feral pigs and their size in the defined area;
- (c) specific efforts made to determine the extent of the infection in the feral pig population, by investigation of feral pigs shot by hunters or found dead, and by laboratory testing;
- (d) the organization of close cooperation between biologists, hunters, hunting organizations, the wildlife services and veterinary services (animal health and public health);
- (e) the reduction of the feral pig population and the issuing of hunting permits; the requirements to be complied with by hunters in order to avoid any spread of the disease; the period adopted for reduction of the feral pig population shall consist of an initial eradication period to be followed by a surveillance period;
- (f) the method of removal of feral pigs found dead or shot. In the first phase (eradication period) the removal shall be based on destruction under supervision of the competent authority. In the second phase (surveillance period) the removal shall be in accordance with the requirements laid down by the competent authority;
- (g) the epizootiological enquiry which is carried out on each feral pig (shot or found dead). This enquiry must include the completion of a questionnaire which supplies information about:
 - the geographical area where the animal was found dead or shot,
 - the date on which the animal was found dead or shot,
 - the person who found or shot the animal,
 - the age and sex of the pig,
 - if shot: symptoms before shooting,
 - if found dead: the state of the carcass,
 - laboratory findings;
- (h) disease-prevention measures applicable to the holdings situated in the defined infected area, including the transport and movement of animals within, from and to the area;

- (i) the criteria to be applied for lifting the measures taken to eradicate the disease in the defined area and the measures applied to holdings in the area.';

4. the following Article is inserted:

'Article 7a

In order to provide full coordination of all measures necessary to ensure eradication of classical swine-fever as quickly as possible and for the purpose of carrying out the epizootiological enquiry, a crisis unit shall be established.

The general rules concerning national crisis units and the Community crisis unit shall be adopted by the Council acting on a proposal from the Commission.';

5. the second subparagraph of Article 8 (2) shall be replaced by the following:

'Where an authorization has been given to remove pigs for slaughter, the competent authority concerned shall ensure that the conditions for removal and slaughtering of pigs fulfil the requirements laid down in Article 9 (4) (f) (i) and that the meat of the said pigs complies with the conditions laid down in Article 9 (4) (g).';

6. Article 9 shall be replaced by the following:

'Article 9

1. Immediately after the diagnosis of classical swine-fever has been officially confirmed in pigs on a holding, the competent authority shall establish a protection zone with a radius of at least three kilometres around the outbreak site, which shall itself be included in a surveillance zone of a radius of at least 10 kilometres.

2. When establishing zones, the competent authority must take account of:

- (a) the results of the epidemiological studies carried out in accordance with Article 7;
- (b) the available serological evidence;
- (c) the geographical situation, particularly natural boundaries;
- (d) the location and proximity of holdings;
- (e) patterns of trade in breeding and slaughter pigs and the availability of slaughterhouses;
- (f) the facilities for checking and the nature of the checks employed, whether or not slaughter is carried out on the infected premises.

3. If a zone includes parts of the territory of several Member States, the competent authorities of the Member States concerned shall collaborate to establish the zone.

4. The following measures shall be applied in the protection zone:

- (a) a census of all the holdings shall be made as soon as possible; after the establishment of the protection zone these holdings shall be visited by an official veterinarian within not more than seven days;
- (b) the movement and transport of pigs on public or private roads shall be prohibited. This prohibition shall not apply to the transit of pigs by road or rail without unloading or stopping. However, in accordance with the procedure may be granted for slaughter pigs coming from outside the protection zone and on their way to a slaughterhouse situated in the said zone;
- (c) trucks and other vehicles and equipment, which are used to transport pigs or other livestock or material which may be contaminated (e.g. feedingstuff, manure, slurry, etc.) and which are used within the protection zone, shall not leave:
 - (i) a holding situated within the protection zone,
 - (ii) the protection zone,
 - (iii) a slaughterhouse,

without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority. Those procedures shall provide in particular that no truck or vehicle which has been used in the transport of pigs may leave the zone without being inspected by the competent authority;

- (d) no other species of animal may enter or leave a holding without the authorization of the competent authority;
- (e) all dead or diseased pigs on a holding shall be notified to the competent authority, which shall carry out any investigations necessary to establish the presence of classical swine-fever;
- (f) pigs may not be removed from a holding in which they are kept for 21 days after the completion of the preliminary cleaning and disinfection of the infected holdings as provided for in Article 10; after 21 days, authorization may be given to remove pigs from the said holding:
 - (i) directly to a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone, provided that:
 - an inspection of all the pigs on the holding has been carried out,
 - a clinical examination of the pigs to be moved for slaughter, including the taking of the body temperature of a proportion thereof, has been carried out,

- each pig has been marked by ear marking,
- the pigs are transported in vehicles sealed by the competent authority.

The competent authority responsible for the slaughterhouse shall be informed of the intention to send pigs to it.

On arrival at the slaughterhouse these pigs shall be kept and slaughtered separately from other pigs. The vehicle and equipment which have been involved in the transport of the pigs shall immediately be cleaned and disinfected.

During ante and post-mortem inspection carried out at the designated slaughterhouse, the competent authority shall take into account any signs relating to the presence of the classical swine-fever virus,

- (ii) under exceptional circumstances, directly to other premises located within the protection zone provided that:
 - an inspection of all the pigs on the holdings has been carried out,
 - a clinical examination of the pigs to be moved, including the taking of the body temperature of a proportion thereof, has been carried out,
 - each pig has been marked by ear marking;
- (g) fresh meat from the pigs referred to in paragraph 4 (f) shall be marked in accordance with the Annex to Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (*), and subsequently treated in accordance with the rules laid down in Article 4 (1) of Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products (**). This must be done at an establishment designated by the competent authority.

The meat shall be sent to the said establishment on condition that the consignment is sealed before departure and remains sealed throughout the transport.

However, at the request of a Member State, accompanied by appropriate justification and in accordance with the procedure laid down in Article 16, specific solutions may be adopted, in particular with respect to the marking of meat and its subsequent use, and the destination of the processed products.

(*) OJ No L 302, 31. 12. 1972, p. 24. Directive last amended by Directive 89/662/EEC (OJ No L 395, 30. 12. 1989, p. 13).

(**) OJ No L 47, 21. 2. 1980, p. 4. Directive last amended by Directive 89/662/EEC.

5. The measures in the protection zone shall continue to be applied at least until:

- (a) all measures laid down in Article 10 have been carried out;
- (b) pigs on all holdings have undergone:
 - (i) a clinical examination which has revealed that they have no signs of disease suggesting classical swine-fever, and
 - (ii) a serological examination in accordance with Annexes I and IV without the detection of antibodies to the classical swine-fever virus.

The examination referred to in (i) and (ii) shall not take place before 30 days have elapsed after the completion of preliminary cleaning and disinfection measures on the infected holding.

6. The following measures shall be applied in the surveillance zone:

- (a) a census shall be taken of all pig holdings;
- (b) the movement and transport of pigs on public or private roads, excluding the service roads of holdings, shall be prohibited, unless approved by the competent authority. This prohibition shall not apply to the transit of pigs by road or rail, without unloading or stopping;
- (c) trucks and other vehicles and equipment which are used to transport pigs or other livestock or material which may be contaminated (e.g. feedingstuff, manure, slurry, etc.) and which are used within the surveillance zone, shall not leave the zone without having been cleaned or disinfected in accordance with the procedures laid down by the competent authority;
- (d) no other species of animal may enter or leave a holding during the first seven days after establishment of the zone without the authorization of the competent authority;
- (e) all dead or diseased pigs on a holding shall be reported to the competent authority, which shall carry out any investigations necessary to establish the presence of classical swine-fever;
- (f) pigs may not be removed from a holding on which they are kept for seven days after the completion of the preliminary cleaning and disinfection of the infected holding provided for in Article 10; after seven days authorization may be given to remove pigs from the said holding:
 - (i) directly to a slaughterhouse, designated by the competent authority, preferably within the protection or surveillance zone, provided that:
 - an inspection of all the pigs on the holding has been carried out,

- a clinical examination of the pigs to be moved for slaughter, including the taking of the body temperature of a proportion thereof, has been carried out,
- each pig has been marked by ear marking,
- the pigs are transported in vehicles which are sealed by the competent authority.

The competent authority responsible for the slaughterhouse shall be informed of the intention to send pigs to it.

On arrival at the slaughterhouse these pigs shall be kept and slaughtered separately from other pigs.

During ante and post-mortem inspection carried out at the designated slaughterhouse, the competent authority shall take into account any signs relating to the presence of the classical swine-fever virus;

- (ii) under exceptional circumstances, directly to other premises located within the protection zone, provided that:
- an inspection of all the pigs on the holding has been carried out,
 - a clinical examination of the pigs to be moved, including the taking of the body temperature of a proportion thereof, has been carried out,
 - each pig has been marked by ear marking.

Trucks and other vehicles and equipment used for the transport of these pigs must be cleaned and disinfected after each transport operation;

- (g) fresh meat derived from the pigs referred to in paragraph 6 (f) shall be marked as described in the Annex to Directive 72/461/EEC and subsequently treated in accordance with the rules laid down in Article 4 (1) of Directive 80/215/EEC. This shall be done at an establishment designated by the competent authority.

The meat shall be sent to the said establishment on condition that the consignment is sealed before departure and remains sealed throughout the transport.

However, at the request of a Member State, accompanied by appropriate justification and in accordance with the procedure laid down in Article 16, specific solutions may be adopted, in particular with respect to the marking of meat and its subsequent use, and the destination of the processed products.

7. The measures in the surveillance zone shall continue to be applied at least until:

- (a) all measures laid down in Article 10 have been carried out;

- (b) the pigs on all holdings have undergone a clinical examination and have been found to have no signs of disease suggesting classical swine-fever;

- (c) a serological examination has been carried out by representative sampling of the holdings, to be determined in accordance with the procedure laid down in Article 16 and such sampling has failed to reveal any antibodies to the classical swine-fever virus.

The examinations referred to in (b) and (c) may not take place before 15 days have elapsed after completion of preliminary cleaning and disinfection measures on the infected holding.

8. By derogation from paragraphs 4 (f) and 6 (f), the competent authority may authorize that pigs be moved from the holding to be transported to a rendering plant for rendering or to a place where the pigs are slaughtered in order to be burned or buried. These animals shall be tested at random for the presence of the classical swine-fever virus. The criteria laid down in Annex IV with regard to the collection of blood samples shall be taken into account during such random testing.

All necessary precautions shall be taken to avoid the risk of spreading the virus during such transport, in particular by cleaning and disinfecting the truck after the transport.

9. Where the prohibitions provided for in paragraphs 4 (f) and 6 (f) are maintained beyond 30 days because of an outbreak of further cases of the disease and as a result problems arise in keeping the pigs, the competent authority may, following a reasoned application by the owner, authorize removal of pigs from a holding within the protection or surveillance zone, as the case may be, provided that:

- (a) the official veterinarian has verified the facts;
- (b) an inspection of all pigs on the holding has been carried out;
- (c) a clinical examination of the pigs to be moved, including the taking of the body temperature of a proportion thereof, has been carried out;
- (d) each pig has been marked by ear marking;
- (e) the holding of destination is located in the protection zone or within the surveillance zone.

Es All necessary precautions shall be taken to avoid the risk of spreading the virus during such transport, in particular by cleaning and disinfecting the truck after the transport.

10. The competent authority shall take all necessary measures, including the use of prominent signs and warning notices and use of media resources, such as the press and television, to ensure that all persons in

the protection and surveillance zones are fully aware of the restrictions in force, and shall take such measures as they consider appropriate to ensure the adequate enforcement of these measures.';

7. Article 10 shall be replaced by the following:

'Article 10

Member States shall ensure that:

- (a) the disinfectants to be used and their concentrations are officially approved by the competent authority;
- (b) the cleaning and disinfection operations are carried out under official supervision in accordance with:
 - (i) the instructions given by the official veterinarian; and
 - (ii) the procedure for cleaning and disinfecting an infected holding as laid down in Annex V.';

8. the following Article shall be inserted:

'Article 10a

Should classical swine-fever be confirmed in a slaughterhouse, the competent authority shall ensure that:

- (a) all pigs in the slaughterhouse are slaughtered without delay;
- (b) the carcasses and offal of infected and contaminated pigs are destroyed under official supervision in such a way as to avoid the risk of classical swine-fever virus spreading;
- (c) cleaning and disinfection of buildings and equipment, including vehicles, take place under the supervision of the official veterinarian in accordance with instructions laid down by the competent authority;
- (d) an epidemiological enquiry is carried out in accordance with Article 7;
- (e) no pigs are reintroduced for slaughter until at least 24 hours after completion of the cleaning and disinfection operations carried out in accordance with (c).';

9. Article 14 shall be replaced by the following:

'Article 14

1. Member States shall ensure that:

- (a) the use of classical swine-fever vaccines is prohibited;
- (b) the manipulation of classical swine-fever virus for research, diagnosis or manufacture of vaccines shall be carried out only in approved establishments and laboratories;

- (c) the storage, supply, distribution and sale of classical swine-fever vaccines in the territory of the Community are carried out under official control.

2. Notwithstanding paragraph 1 concerning the use of classical swine-fever vaccine, it may be decided, when classical swine-fever has been confirmed and threatens to spread, that emergency vaccination may be introduced. In this case, the Member State concerned shall submit to the Commission an emergency vaccination plan which shall include information on:

- (a) the disease situation which has resulted in the request for emergency vaccination;
- (b) the extent of geographical area in which emergency vaccination is to be carried out;
- (c) categories of pigs and the approximate number of pigs to be vaccinated;
- (d) the vaccine to be used;
- (e) the duration of the vaccination campaign;
- (f) the identification and registration of the vaccinated animals;
- (g) measures for the movement of pigs and their products;
- (h) other matters appropriate to the emergency situation.

The Commission shall immediately examine the plan in collaboration with the Member State concerned. In accordance with the procedure laid down in Article 16, the emergency vaccination plan may be approved or amendments and additions may be requested before approval is given, especially where marking is concerned.

3. Any Member State which carries out emergency vaccination shall ensure that:

- no live pigs leave the vaccination area except for immediate slaughter in a slaughterhouse designated by the competent authority and situated within the vaccination area or close to that area;
- all fresh pig meat produced from pigs vaccinated during the emergency vaccination bears the stamp provided for in Article 5a of Directive 72/461/EEC and is stored and transported separately from meat not bearing the said stamp.

4. Paragraph 3 shall apply during the emergency vaccination period and for a minimum of six months following completion of the vaccination operations in the affected area.

In accordance with the procedure laid down in Article 16 and before the end of the said six-month period, measures shall be taken to ban:

- (a) sero-positive pigs from leaving the holding where they are kept, except for immediate slaughter;

- (b) piglets of sero-positive sows from leaving their holding of origin unless being transported to:
- a slaughterhouse for immediate slaughter,
 - a holding designated by the competent authority, from which they are to be sent directly to the slaughterhouse,
 - a holding after obtaining a negative result from a serological test for antibodies against the classical swine-fever virus.

5. If necessary, the Commission shall adopt rules relating to the production, packaging, distribution and state of the stocks of classical swine-fever vaccines in the Community.';

10. Article 14a shall be replaced by the following:

'Article 14a

Veterinary experts from the Commission may, in collaboration with the authorities of the Member State concerned and, in so far as is necessary to ensure uniform application of this Directive, make on-the-spot checks; the Commission shall inform the Member States of the results of such checks.

A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties.

The general provisions for implementing this Article shall be determined in accordance with the procedure laid down in Article 16.';

11. The following Article shall be inserted:

'Article 14b

1. Each Member State shall draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of classical swine-fever.

12. Annex I shall be replaced by the following:

'ANNEX I

DIAGNOSTIC PROCEDURES FOR THE CONFIRMATION OF DIFFERENTIAL DIAGNOSIS OF CLASSICAL SWINE-FEVER

Notwithstanding the period required for antibodies to develop, the following guidelines, standards and minimum criteria are laid down for the diagnostic procedures of classical swine-fever (CSF).

A. COLLECTION OF MATERIALS FOR DIAGNOSIS

1. For virus isolation and antigen detection, tonsil and spleen tissues are considered essential. Preferably at least two other lymphatic tissues should be collected, such as the retropharyngeal, parotid, mandibular or mesenteric lymph nodes together with ileum or kidney. Each sample of the tissue should be placed in a separate sealed plastic bag and labelled. The samples should be transported and stored in leak-proof containers. They should not be frozen but kept cool at refrigerator temperature and tested without delay.

This plan should allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak. It must give a precise indication of the vaccine requirements which each Member State concerned considers it needs in the event of emergency vaccination.

2. The criteria to be applied *mutatis mutandis* for drawing up the contingency plan shall be those laid down in Commission Decision 91/42/EEC of 8 January 1991 laying down the criteria to be applied when drawing up contingency plans for the control of foot and mouth disease in application of Article 5 of Council Decision 90/423/EEC (*).

The Commission may, in accordance with Article 16, amend or supplement those criteria taking into account the specific nature of classical swine-fever.

3. Plans drawn up in accordance with the criteria provided for in paragraph 2 shall be submitted to the Commission not later than 1 January 1993.

4. The Commission shall examine the plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that they are compatible with those of the other Member States.

The Commission shall approve the plans, if necessary amended, in accordance with the procedure laid down in Article 16.

The plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation.

(*) OJ No L 23, 29. 1. 1991, p. 29.'

2. Blood samples for virus isolation from leucocytes should be collected from pigs showing signs of fever or other signs of disease. EDTA or heparin should be used as anticoagulants. The samples must be kept cool at refrigerator temperature and submitted to laboratory testing without delay.
3. Blood samples for the detection of antibody as an aid to diagnosis of clinical outbreaks and for the purposes of surveillance should be taken from animals which have recovered from suspect infection and from pigs known to have been in contact with infected or suspect cases. In such suspect holdings, all of the first 20 suspect or in-contact animals, and 25 % of any additional animals, should be sampled. In order to ensure a high probability of detection of antibody, samples should be collected from each unit of the holding at this level.

B. THE LABORATORY DIAGNOSIS OF CLASSICAL SWINE-FEVER

The principal basis for the laboratory diagnosis of CSF shall be the demonstration of viral antigen, virus or antibodies in organs or tissue fluids.

In the case of inconclusive results, the tests shall be repeated on the same samples. Additional samples should be collected from the same source if clinical suspicion continues.

Serological tests for the detection of antibodies may be used as an adjunct to diagnosis in cases of suspect CSF. If the demonstration of viral antigen or virus isolation has not been successful on material derived from animals giving rise to suspicion of CSF or with material from holdings which have had contact with cases of CSF, tests for the detection of antibody shall be applied to blood samples from animals which are no longer suspect and from those suspected of having been in contact with the disease.

1. Demonstration of viral antigen

For the demonstration of viral antigen in organ tissues, a direct immune labelling system should be used on thin cryostat sections (up to five microns) of tonsils and tissues of other organs as specified in A (1). The diagnostic reagent must be a pestivirus-specific polyclonal antiserum to CSF virus, labelled with a fluorochrome, enzyme or biotin, according to the following criteria:

- (a) hyperimmune serum shall be prepared from pigs which are free from infections or the serum of which is free from any antibody which could affect the specificity or quality of the reactions;
- (b) labelled immunoglobulin prepared from CSF hyperimmune pig serum as specified under (a) shall have a minimum working titre of 1/20 as determined in CSF virus infected cell cultures and confirmed by check tests on tissue sections. The working dilution of the conjugate shall combine a maximum of signal with a minimum of background staining.

Any sample showing specific cytoplasmic reaction shall be considered positive for pestivirus. In such cases, further tests must be carried out as described in B (3).

2. Virus isolation and identification in cell cultures

- (a) Virus isolation from tissue samples is performed on susceptible cell cultures of PK15 or other equally susceptible cell lines. Organ suspension from a suspected animal should be inoculated at a dilution of 1/10.
- (b) Virus isolation from blood samples, collected and handled as indicated in paragraph A (2), is performed by the inoculation of cell cultures with buffy coat suspension reconstituted to the original blood volume.
- (c) For detection of viral antigen in the cytoplasm of inoculates, such cell cultures shall be treated with labelled polyclonal antiserum. The staining should be applied at intervals from 24 to 72 hours from the time of inoculation.
- (d) Positive cultures should be subject to differential diagnostic tests as specified in B (3). Negative results after the first cell culture passage may require second or even more passages in order to isolate the virus.

3. Monoclonal antibody typing of pestivirus isolates

- (a) Duplicates of tissue cryostat sections or cell cultures which give positive reactions with polyclonal antiserum as described in B (1) and (2) shall be further examined by labelled monoclonal antibodies to distinguish the CSF virus from the bovine virus diarrhoea (BVD) or border disease (BD) viruses.

(b) Only monoclonals which have been officially recommended by the Community Reference Laboratory for Classical Swine-Fever should be used.

(c) The monoclonals should be grouped into four panels according to the following criteria:

Panel number	Reactivity
1	All pestiviruses
2	All CSF viruses
3	CSF vaccine strains
4	All BVD/BD viruses

Each panel may be represented by either a single monoclonal or a mixture of the competent monoclonal antibodies, provided that the spectrum of reactivity corresponds to that given above.

(d) The interpretation of the reaction patterns is summarized as follows:

Panel	Interpretation
1 2 3 4	
+ + - -	CSF confirmed
+ + + -	CSF vaccine strain
+ - - +	BVD/BD virus
+ - - -	} Virus unclassified, further tests required
+ + - +	
+ + + +	
- - - -	

C. DETECTION OF ANTIBODIES TO CLASSICAL SWINE-FEVER VIRUS

The detection of CSF virus antibodies in blood samples is carried out to assist in the diagnosis of swine-fever in holdings containing pigs showing clinical signs of the disease or in pigs believed to have had contact with infected pigs. It may also be carried out for the purpose of surveillance or for surveys in herds of unknown status.

For these purposes, blood samples should be subjected to an approved test.

The following tests are approved for use and must be carried out with the inclusion of positive and negative serum controls.

The virus strains to be used for serological tests should be agreed at a meeting of the National Swine Fever Laboratories (NSFL), and issued as required by the Community Reference Laboratory for Classical Swine Fever to the NSFL, upon request.

All test procedures used must be shown to give satisfactory results with CSF reference sera supplied by the Community Reference Laboratory for Classical Swine-Fever.

1. The virus-neutralization test

This test is based on the determination of the neutralizing 50 % endpoint. Cultures are inoculated with mixtures of diluted serum and a constant amount of virus after a specified incubation period at 37°C. The results are based on the absence of any viral replication detectable by an immune labelling system. Either neutralization-immunofluorescence (NIF) or the neutralizing peroxidase-linked antibody (NPL) assays must be used. Detailed protocols will be supplied by the EC Reference Laboratory for CSF as required.

For screening purposes, the sera are initially diluted 1/10. When a full titration is necessary two-fold dilutions of serum starting at 1/10 are prepared. Each dilution is mixed with an equal volume of virus suspension containing $100 (\pm 0,5 \log_{10})$ infectious doses (TCID₅₀). At least two cultures are used for each dilution. After an appropriate incubation period the cell cultures are fixed and viral antigen is detected by an immune labelling system. The results are expressed as the reciprocal of the initial serum dilution at which half the inoculated cell cultures fail to show any specific labelling. A point between two dilution levels is estimated.

2. The enzyme-linked immunosorbent assay (Elisa)

Competitive, blocking and indirect techniques may be used on any suitable support.

It is recommended that the tests used should minimize cross-reactions with BVDV and other pestiviruses. However, the test system must ensure identification of all CSF infections, and at all stages of the immune response to infection.

Antigen

The antigen should be derived from or correspond to viral proteins of one of the recommended CSF virus strains. Cells used to prepare antigen should be free of any other pestivirus infection.

Antisera

Polyclonal antisera for competitive or blocking assays should be raised in pigs or rabbits by infection with one of the recommended CSF virus strains or with the lapinized C strain. Monoclonal antibodies should be directed against or correspond to an immunodominant viral protein of CSF virus. Indirect assay should use an anti-porcine immunoglobulin reagent which detects both IgG and IgM.

The sensitivity of the Elisa should be high enough to score positive any serum reacting in the neutralization test and also reference positive sera as issued by the Community Reference Laboratory for CSF.

The Elisa procedure may be used only with serum or plasma samples derived from individual pigs.

If the Elisa procedure used is not CSF-specific, positive samples should be further examined by differential tests, as specified in section E.

D. EVALUATION OF THE RESULTS OF LABORATORY TESTING

1. The demonstration of CSF virus antigen in organ tissues or cell cultures after virus isolation from tissue samples following the techniques defined in B (1), (2) and (3) shall form the basis of confirmation of the presence of the disease, except in the case of a reaction demonstrated to be due to vaccinal virus specified according to B (3). The demonstration of BVD/BD antigen according to B (3) shall rule out suspicion of CSF provided that there are no other grounds for such suspicion.

Following unusual or unexpected results of monoclonal typing according to B (3), pestivirus isolates shall be considered unclassified and the herd of origin regarded as suspect pending further testing. This may include submission of the virus to a reference laboratory for characterization and serological investigations on the herd of origin.

2. Following the detection of antibody reactive with CSF virus, the herd of origin shall be regarded as suspect.
 - (a) In order to rule out the suspicion of CSF raised by the detection of antibody, the test described in Section E shall be used to distinguish between CSF-reactive antibody which may have been induced by other pestiviruses and such antibody due to CSF virus itself. All original samples shall be retested by the differential test.
 - (b) If suspicion cannot be ruled out on the first differential test, a further test shall be carried out at least 30 days later to follow up the possible spread of infection. All of the first 20 animals on the suspect holding shall be sampled, and 25 % of any additional animals.

3. Interpretation of serological results

A virus neutralization titre of $\geq 1/10$ in any pig, together with clinical or epizootiological evidence giving rise to suspicion of disease, shall constitute a positive diagnosis. A titre of $\geq 1/10$ in any pig without clinical or epizootiological evidence gives rise to suspicion of disease and should be followed by differential diagnostic procedures.

The same criteria should be applied for any pig giving a positive Elisa result.

E. SEROLOGICAL PROCEDURES FOR THE DIFFERENTIAL DIAGNOSIS BETWEEN CLASSICAL SWINE-FEVER AND OTHER PESTIVIRUSES

1. Tests for the differential diagnosis of CSF and other pestivirus infections are based on parallel testing of the sera with both CSF and BVD/BD virus strains, using fully comparable methods.

The CSF and BVD/BD virus strains for use should have been officially approved (see section C). To rule out the suspicion of CSF raised by the detection of antibody, blood samples should be examined by comparative end-point titrations for neutralizing antibody against CSF virus and BVD/BD virus.

In blocking Elisa, a comparison of percentage blocking with CSF and BVD/BD antigens may be used.

2. The results of the comparative serological tests using reference strains of CSF and other pestiviruses shall be interpreted as follows:

- (a) if the comparative tests show that more than one pig has antibody to CSF virus with no antibody to other pestiviruses, the test result is considered positive for CSF;
- (b) if the comparative tests show that the titres to CSF virus are equal to or higher than the titres to other pestiviruses in more than one of the pigs, there shall be suspicion of CSF and differentiation shall proceed as follows:
 - those pigs which show neutralizing titres against CSF virus which are higher than or equal to the titres against other pestiviruses shall be slaughtered. Their tissues and, if pregnant, their foetuses, shall be subjected to examination for CSF antigen or virus, following the procedure defined in B (1), (2) or (3),
 - if CSF virus antigen or virus is detected, CSF shall be confirmed,
 - if the examination defined in the second indent fails to reveal the presence of CSF antigen or virus, the holding shall be considered as suspect until a further set of blood samples collected at least 30 days later has been subjected to further comparative tests,
 - if these subsequent comparative tests show all animals to have significantly (four-fold or greater) higher titres against BVD/BD virus than against CSF virus, suspicion shall be ruled out,
 - if one or more animals show a titre against CSF virus which is equal to, or higher than, its titre to BVD/BD virus, the result shall be considered positive for CSF;
- (c) if the BVD/BD titres are such as not to exclude the possibility of CSF, the holding shall be considered as suspect and be retested after at least 30 days.

F. THE DIFFERENTIAL DIAGNOSIS OF AFRICAL SWINE-FEVER (ASF)

ASF cannot be differentiated from classical swine-fever by either clinical or post-mortem examinations and both of these diseases should be considered in the differential diagnosis of any acute febrile haemorrhagic syndrome of pigs.

Laboratory tests are essential to distinguish between the two diseases. A positive diagnosis in an ASF-free country should be based on the isolation and identification of ASF virus.

The principal basis for the laboratory diagnosis of ASF shall be the demonstration of virus, viral antigen or antibodies in organs and tissue fluids.

In the case of inconclusive or negative results of at least two tests on samples from animals giving rise to suspicion of ASF or with material from holdings which had contracts with cases of ASF, additional material should be collected in the same holding and from animals which have been in contact with the disease.

1. Demonstration of viral antigen

For the demonstration of viral antigen, the direct immunofluorescence technique or other suitable techniques shall be applied to thin cryostat sections of organ tissues or smears, or on sediments from leucocyte cultures. The procedures used are similar to those described for CSF, except that ASF-specific reagents are used.

2. Virus isolation and identification

(a) *Haemadsorption (HAD) test*

The HAD test is carried out by inoculating either 10 % tissue suspensions or blood collected in the field from suspect pigs into primary pig leucocyte cultures or by preparing leucocyte cultures from the blood of febrile pigs inoculated at the laboratory or collected in the field. Haemadsorption consists of the attachment of large numbers of pig erythrocytes to the surface of infected cells and confirm ASF diagnosis.

(b) *Pig inoculation*

A pool is made with aliquote for each 10 % tissue suspension and 2 ml inoculated intramuscularly into each of four pigs: two of these should be vaccinated against CSF and two unvaccinated. Pigs should be examined daily for increase of rectal temperature and onset of clinical signs for 21 days. If fever develops, blood samples should be collected for preparation of leucocyte cultures for the HAD test (autorosette and inoculation of primary pig leucocyte cultures). If no clinical signs develop, blood should be taken for detection of antibodies after the 21 day observation period.

G. DETECTION OF ANTIBODIES INDUCED BY ASF-VIRUS IN BLOOD SAMPLES AND TISSUE FLUIDS

The detection of antibodies in samples of serum or tissue fluid is carried out to assist in the diagnosis of ASF in holdings containing pigs showing clinical signs suspicious of disease or in pigs believed to have had contact with ASF-infected pigs. It may also be carried out for the purpose of surveillance or for surveys in herds of unknown status.

For these purposes, samples should be subjected to an approved test.

The following are approved for use and must be carried out with the inclusion of appropriate positive and negative serum controls.

(a) Indirect immunofluorescence (IIF) test;

(b) Elisa²;

12. The following Annexes shall be added after Annex III:

'ANNEX IV

SEROLOGICAL SCREENING OF PIGS IN THE PROTECTION ZONE AND SURVEILLANCE ZONE FOR DETECTION OF ANTIBODIES AGAINST CLASSICAL SWINE-FEVER VIRUS

The programme for serological screening shall take into account the transmission of classical swine-fever and the way pigs are kept, e.g. a reference to whether pigs are kept in groups or not.

1. Serological screening of pigs kept in a group

A group is two or more pigs kept in direct contact.

Sampling of groups

- If 20 or fewer than 20 pigs in a group:
 - two pigs. Where the group consists of a sow with piglet, only the sow shall be sampled,
- if more than 20:
 - two pigs + 5 % of the remainder.

All groups shall be sampled.

2. Serological screening of pigs kept individually; this includes pigs kept in close proximity to each other but having no direct contact, e.g. tethered sows.

Sampling procedure

Number of pigs	Pigs to be tested
fewer than 20	all
20 — 100	20 + 20 % of the remainder
more than 100	20 + 10 % of the remainder (at least 36);

ANNEX V

PROCEDURE FOR CLEANING AND DISINFECTING AN INFECTED HOLDING

I. PRELIMINARY CLEANING AND DISINFECTION

- (a) As soon as the carcasses of the pigs have been removed for disposal, those parts of the premises in which the pigs were housed and any parts of other buildings, yards etc. contaminated during slaughter or post-mortem examination should be sprayed with disinfectants approved for use in accordance with Article 10.
- (b) Any tissue or blood which may have been spilled during slaughter or post-mortem or gross contamination of buildings, yards, utensils etc. should be carefully collected and disposed of with the carcasses.
- (c) The used disinfectant shall remain on the surface for at least 24 hours.

II. FINAL CLEANING AND DISINFECTION

- (a) Grease and dirt should be removed from all surfaces by the application of a degreasing agent and washed with cold water.
- (b) After washing with cold water as described in (a), further spraying with disinfectant should be applied.
- (c) After seven days the premises should be treated with a degreasing agent, rinsed with cold water, sprayed with disinfectant and rinsed again with cold water.
- (d) Manure and used bedding should be stacked to heat, sprayed with disinfectant and left for 42 days. Slurry should normally be stored for 42 days after the last addition of infective material. This period may be extended if the slurry has been heavily contaminated.'

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1992. They shall forthwith inform the Commission thereof.

When the above measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 11 December 1991.

For the Council

The President

P. BUKMAN

COUNCIL DECISION

of 11 December 1991

amending Directive 80/1095/EEC and Decision 80/1096/EEC as regards certain measures relating to classical swine-fever

(91/686/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas Directive 80/1095/EEC ⁽⁴⁾, as last amended by Directive 87/487/EEC ⁽⁵⁾, lays down conditions designed to render and keep the territory of the Community free from classical swine-fever;

Whereas Decision 80/1096/EEC ⁽⁶⁾, as last amended by Decision 87/488/EEC ⁽⁷⁾, introduced Community financial measures for the eradication of classical swine-fever;

Whereas the measures applied to eradicate classical swine-fever have gradually improved the health status of the pig population in the territory of the Community; whereas it has been possible, due to this improved status, to recognize certain areas (regions or Member States) as officially swine-fever-free or swine-fever-free;

Whereas one of the given objectives, namely to keep the territory of the Community free from classical swine-fever,

has been attained in large areas; whereas it is necessary to take this situation into account and consequently amend Directive 80/1095/EEC and Directive 80/1096/EEC,

HAS ADOPTED THIS DECISION:

Article 1

In Article 12 (2) of Directive 80/1095/EEC the date '1 July 1993' shall be replaced by '1 July 1992'.

Article 2

The following sentence shall be added to Article 2 (1) of Decision 80/1096/EEC: 'However, participation by the Community shall be limited to measures carried out before 1 July 1992.'

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 11 December 1991.

For the Council

The President

P. BUKMAN

⁽¹⁾ OJ No C 226, 31. 8. 1991, p. 19.

⁽²⁾ OJ No C 326, 16. 12. 1991.

⁽³⁾ Opinion delivered on 28 November (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 325, 1. 12. 1980, p. 1.

⁽⁵⁾ OJ No L 280, 3. 10. 1987, p. 24.

⁽⁶⁾ OJ No L 325, 1. 12. 1980, p. 5.

⁽⁷⁾ OJ No L 280, 3. 10. 1987, p. 26.

COUNCIL DIRECTIVE

of 11 December 1991

amending Directives 64/432/EEC, 72/461/EEC and 80/215/EEC as regards certain measures relating to swine-fever

(91/687/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas Council Decision 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine ⁽⁴⁾, as last amended by Directive 91/499/EEC ⁽⁵⁾, defines in particular the conditions which must be satisfied, as regards swine-fever, by live pigs intended for intra-Community trade;

Whereas Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat ⁽⁶⁾, as last amended by Directive 91/266/EEC ⁽⁷⁾, defines the conditions which must be satisfied as regards classical swine-fever by fresh pigmeat intended for intra-Community trade;

Whereas Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products ⁽⁸⁾, as last amended by Directive 89/662/EEC ⁽⁹⁾, defines in particular the conditions which must be satisfied as regards classical swine-fever for meat products intended for intra-Community trade;

Whereas the measures applied to eradicate classical swine-fever have gradually improved the health status of the pig population in the territory of the Community;

Whereas one of the given objectives, namely to keep the territory of the Community free from classical swine-fever, has been attained in large areas and it is necessary to take this situation into account and consequently to amend Directives 64/432/EEC, 72/461/EEC and 80/215/EEC;

Whereas, in this context, it is appropriate not to extend the type of guarantees laid down in Article 4b of Directive 64/432/EEC and in Article 13a of Directive 72/461/EEC, and to discontinue the measures laid down in Article 10 of Directive 80/215/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 64/432/EEC is hereby amended as follows:

(1) in Article 2:

- (a) the words 'swine-fever' in point (j) of (ii) shall be deleted;
- (b) points (p), (q) and (r) shall be deleted;

(2) in Article 3:

- (a) the words 'swine-fever' in the introductory words of paragraph 2 (b) shall be deleted;
- (b) the words 'swine-fever' in paragraph 2 (b) (i) shall be deleted;
- (c) paragraph 2 (b) (ii) shall be deleted;
- (d) the words 'swine-fever' in paragraph 2 (c) (ii) shall be deleted;
- (e) the first sentence of paragraph 4 shall be replaced by the following:
'4. Swine for breeding and production must, moreover, come from brucellosis-free stock.'

(3) in Article 4b, '31 December 1991' shall be replaced by '1 July 1992';

⁽¹⁾ OJ No C 226, 3. 8. 1991, p. 20.

⁽²⁾ OJ No C 326, 16. 12. 1991.

⁽³⁾ Opinion delivered on 28 November 1991 (not yet published in the Official Journal).

⁽⁴⁾ OJ No 121, 29. 7. 1964, p. 1977/64.

⁽⁵⁾ OJ No L 268, 24. 9. 1991, p. 107.

⁽⁶⁾ OJ No L 302, 31. 12. 1972, p. 28.

⁽⁷⁾ OJ No L 134, 29. 5. 1991, p. 45.

⁽⁸⁾ OJ No L 47, 21. 2. 1980, p. 4.

⁽⁹⁾ OJ No L 395, 30. 12. 1989, p. 13.

- (4) with effect from 1 July 1992, Article 4b shall be replaced by the following:

'Article 4b

In addition to the measures provided for in this Directive concerning classical swine-fever, each Member State shall ensure that pigs sent from its territory to that of another Member State shall not come from a holding or an area which is subject to restrictions for classical swine-fever in conformity with Council Decision 80/217/EEC of 22 January 1980 introducing Community measures for the control of classical swine-fever (*).

(*) OJ No L 47, 21. 2. 1980, p. 11.;

- (5) in Annex F, Form III, V, point (c) shall be deleted. Points '(d), (e), (f), and (g)' shall become '(c), (d), (e) and (f)'.

Article 2

Directive 72/461/EEC is hereby amended as follows:

- (1) in the first subparagraph of Article 13 a (3), '31 December 1991' shall be replaced by '1 July 1992';
- (2) in Article 3, the following point shall be added:
- '(e) The meat shall not be subject of animal health restrictive measures pursuant to the provisions of Council Directive 80/217/EEC of 22 January 1980 introducing Community measures for the control of classical swine-fever (*).

(*) OJ No L 47, 21. 2. 1980, p. 11.'

Article 3

Article 10 of Directive 80/215/EEC shall be deleted.

Article 4

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 1 (3) and Article 2 (1) of this Directive not later than 1 January 1992 and, as regards compliance with the remaining provisions thereof, not later than 1 July 1992. They shall forthwith inform the Commission thereof.

When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 11 December 1991.

For the Council

The President

P. BUKMAN

COUNCIL DIRECTIVE

of 11 December 1991

amending Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries

(91/688/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas Directive 72/462/EEC ⁽⁴⁾, as last amended by Directive 91/266/EEC ⁽⁵⁾, defines in particular the conditions which must be satisfied as regards classical swine-fever upon importation of live pigs, fresh pig meat and meat products from third countries;

Whereas, given that the health situation within the Community in respect of classical swine-fever has improved, and systematic vaccination against the disease has been discontinued, it is appropriate to amend the conditions laid down for importation of live pigs, fresh pig meat and meat products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 72/462/EEC is hereby amended as follows:

1. the following paragraphs shall be added to Article 6:

- '4. In respect of classical swine-fever, pigs must come from the territory of a third country which:
- has been free from classical swine-fever for at least 12 months,
 - has not permitted vaccination for the preceding 12 months,

— does not allow on its territory pigs which have been vaccinated less than 12 months previously.

5. By way of derogation from paragraph 4, it may be decided, in accordance with the procedure laid down in Article 29, to authorize the importation of pigs coming from a part of the territory of a third country provided that vaccination against classical swine-fever is prohibited throughout the entire territory of that country and that the part of the territory of the third country concerned fulfils the conditions laid down in paragraph 4.

6. By way of derogation from paragraph 4, in the event of classical swine-fever occurring in a third country which fulfils the conditions of paragraph 4, it may be decided, in accordance with the procedure laid down in Article 29, that the period of 12 months referred to in the first indent of paragraph 4 may be reduced to six months if:

- (a) an outbreak or a number of epizootiologically interrelated outbreaks occur within a geographical limited area; and
- (b) the outbreak or outbreaks have been stamped out, within a period of three months and without recourse to vaccination.'

2. the following subparagraph shall be added to Article 14 (2):

- '(c) in which no classical swine-fever has been detected for at least the preceding 12 months, vaccination against classical swine-fever has not been authorized for at least the preceding 12 months and no pigs have been vaccinated against classical swine-fever in the preceding 12 months.'

3. the following sentence shall be added to Article 15:

- 'In accordance with the procedure laid down in Article 29, it may be decided to derogate from Article 14 (2) (c).'

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1992. They shall forthwith inform the Commission thereof.

When these measures are adopted by the Member States, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official

⁽¹⁾ OJ No C 226, 31. 8. 1991, p. 21.

⁽²⁾ OJ No C 326, 16. 12. 1991.

⁽³⁾ Opinion delivered on 28 November 1991 (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 302, 31. 12. 1972, p. 28.

⁽⁵⁾ OJ No L 134, 29. 5. 1991, p. 45.

publication. The procedure for such reference shall be adopted by Member States.

Done at Brussels, 11 December 1991.

Article 3

This Directive is addressed to the Member States.

For the Council

The President

P. BUKMAN

COUNCIL DIRECTIVE

of 12 December 1991

on hazardous waste

(91/689/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 103s thereof,

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste ⁽⁴⁾, established Community rules on the disposal of dangerous waste; whereas in order to take account of experience gained in the implementation of that Directive by the Member States, it is necessary to amend the rules and to replace Directive 78/319/EEC by this Directive;

Whereas the Council resolution of 7 May 1990 on waste policy ⁽⁵⁾ and the action programme of the European Communities on the environment, which was the subject of the resolution of the Council of the European Communities and of the representatives of the Government of the Member States, meeting within the Council, of 19 October 1987 on the continuation and implementation of a European Community policy and action programme on the environment (1987 to 1992) ⁽⁶⁾, envisage Community measures to improve the conditions under which hazardous wastes are disposed of and managed;

Whereas the general rules applying to waste management which are laid down by Council Directive 75/442/EEC of 15 July 1975 on waste ⁽⁷⁾, as amended by Directive 91/156/EEC ⁽⁸⁾, also apply to the management of hazardous waste;

Whereas the correct management of hazardous waste necessitates additional, more stringent rules to take account of the special nature of such waste;

Whereas it is necessary, in order to improve the effectiveness of the management of hazardous waste in the Community, to use a precise and uniform definition of hazardous waste based on experience;

Whereas it is necessary to ensure that disposal and recovery of hazardous waste is monitored in the fullest manner possible;

Whereas it must be possible rapidly to adapt the provisions of this Directive to scientific and technical progress; whereas the Committee set up by Directive 75/442/EEC must also be empowered to adapt the provisions of this Directive to such progress,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The object of this Directive, drawn up pursuant to Article 2 (2) of Directive 75/442/EEC, is to approximate the laws of the Member States on the controlled management of hazardous waste.

2. Subject of this Directive, Directive 75/442/EEC shall apply to hazardous waste.

3. The definition of 'waste' and of the other terms used in this Directive shall be those in Directive 75/442/EEC.

4. For the purpose of this Directive 'hazardous waste' means:

— wastes featuring on a list to be drawn up in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC on the basis of Annexes I and II to this Directive, not later than six months before the date of implementation of this Directive. These wastes must have one or more of the properties listed in Annex III. The list shall take into account the origin and composition of the waste and, where necessary, limit

⁽¹⁾ OJ No C 295, 19. 11. 1988, p. 8, and OJ No C 42, 22. 2. 1990, p. 19.

⁽²⁾ OJ No C 158, 26. 6. 1989, p. 238.

⁽³⁾ OJ No C 56, 6. 3. 1989, p. 2.

⁽⁴⁾ OJ No L 84, 31. 3. 1978, p. 43.

⁽⁵⁾ OJ No C 122, 18. 5. 1990, p. 2.

⁽⁶⁾ OJ No C 328, 7. 12. 1987, p. 1.

⁽⁷⁾ OJ No L 194, 25. 7. 1975, p. 39.

⁽⁸⁾ OJ No L 78, 26. 3. 1991, p. 32.

values of concentration. This list shall be periodically reviewed and if necessary by the same procedure,

- any other waste which is considered by a Member State to display any of the properties listed in Annex III. Such cases shall be notified to the Commission and reviewed in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC with a view to adaptation of the list.

5. Domestic waste shall be exempted from the provisions of this Directive. The Council shall establish, upon a proposal from the Commission, specific rules taking into consideration the particular nature of domestic waste not later than the end of 1992.

Article 2

1. Member States shall take the necessary measures to require that on every site where tipping (discharge) of hazardous waste takes place the waste is recorded and identified.

2. Member States shall take the necessary measures to require that establishment and undertaking which dispose of, recover, collect or transport hazardous waste do not mix different categories of hazardous waste or mix hazardous waste with non-hazardous waste.

3. By way of derogation from paragraph 2, the mixing of hazardous waste with other hazardous waste or with other waste, substances or materials may be permitted only where the conditions laid down in Article 4 of Directive 75/442/EEC are complied with and in particular for the purpose of improving safety during disposal or recovery. Such an operation shall be subject to the permit requirement imposed in Articles 9, 10 and 11 of Directive 75/442/EEC.

4. Where waste is already mixed with other waste, substances or materials, separation must be effected, where technically and economically feasible, and where necessary in order to comply with Article 4 of Directive 75/442/EEC.

Article 3

1. The derogation referred to in Article 11 (1) (a) of Directive 75/442/EEC from the permit requirement for establishments or undertakings which carry out their own waste disposal shall not apply to hazardous waste covered by this Directive.

2. In accordance with Article 11 (1) (b) of Directive 75/442/EEC, a Member State may waive Article 10 of that Directive for establishments or undertakings which recover waste covered by this Directive:

- if the Member State adopts general rules listing the type and quantity of waste and laying down specific conditions (limit values for the content of hazardous substances in the waste, emission limit values, type of activity) and other necessary requirements for carrying out different forms of recovery, and
- if the types or quantities of waste and methods of recovery are such that the conditions laid down in Article 4 of Directive 75/442/EEC are complied with.

3. The establishments or undertakings referred to in paragraph 2 shall be registered with the competent authorities.

4. If a Member State intends to make use of the provisions of paragraph 2, the rules referred to in that paragraph shall be sent to the Commission not later than three months prior to their coming into force. The Commission shall consult the Member States. In the light of these consultations the Commission shall propose that the rules be finally agreed upon in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC.

Article 4

1. Article 13 of Directive 75/442/EEC shall also apply to producers of hazardous waste.

2. Article 14 of Directive 75/442/EEC shall also apply to producers of hazardous waste and to all establishments and undertakings transporting hazardous waste.

3. The records referred to in Article 14 of Directive 75/442/EEC must be preserved for at least three years except in the case of establishments and undertakings transporting hazardous waste which must keep such records for at least 12 months. Documentary evidence that the management operations have been carried out must be supplied at the request of the competent authorities or of a previous holder.

Article 5

1. Member States shall take the necessary measures to ensure that, in the course of collection, transport and temporary storage, waste is properly packaged and labelled in accordance with the international and Community standards in force.

2. In the case of hazardous waste, inspections concerning collection and transport operations made on the basis of Article 13 of Directive 75/442/EEC shall cover more particularly the origin and destination of such waste.

3. Where hazardous waste is transferred, it shall be accompanied by an identification form containing the details specified in Section A of Annex I to Council Directive 84/631/EEC of 6 December 1984 on the

supervision and control within the European Community of the transfrontier shipment of hazardous waste ⁽¹⁾, as last amended by Directive 86/279/EEC ⁽²⁾.

Article 6

1. As provided in Article 7 of Directive 75/442/EEC, the competent authorities shall draw up, either separately or in the framework of their general waste management plans, plans for the management of hazardous waste and shall make these plans public.

2. The Commission shall compare these plans, and in particular the methods of disposal and recovery. It shall make this information available to the competent authorities of the Member States which ask for it.

Article 7

In cases of emergency or grave danger, Member States shall take all necessary steps, including, where appropriate, temporary derogations from this Directive, to ensure that hazardous waste is so dealt with as not to constitute a threat to the population or the environment. The Member State shall inform the Commission of any such derogations.

Article 8

1. In the context of the report provided for in Article 16 (1) of Directive 75/442/EEC, and on the basis of a questionnaire drawn up in accordance with that Article, the Member States shall send the Commission a report on the implementation of this Directive.

2. In addition to the consolidated report referred to in Article 16 (2) of Directive 75/442/EEC, the Commission shall report to the European Parliament and the Council every three years on the implementation of this Directive.

3. In addition, by 12 December 1994, the Member States shall send the Commission the following information for every establishment or undertaking which carries out disposal and/or recovery of hazardous waste principally on behalf of third parties and which is likely to form part of the integrated network referred to in Article of Directive 75/442/EEC:

- name and address,
- the method used to treat waste,
- the types and quantities of waste which can be treated.

Once a year, Member States shall inform the Commission of any changes in this information.

The Commission shall make this information available on request to the competent authorities in the Member States.

The format in which this information will be supplied to the Commission shall be agreed upon in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC.

Article 9

The amendments necessary for adapting the Annexes to this Directive to scientific and technical progress and for revising the list of wastes referred to in Article 1 (4) shall be adopted in accordance with the procedure laid down in Article 18 of Directive 74/442/EEC.

Article 10

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 12 December 1993. They shall forthwith inform the Commission thereof.

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

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

Article 11

Directive 78/319/EEC is hereby repealed with effect from 12 December 1993.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 12 December 1991.

For the Council
The President
J.G.M. ALDERS

(1) OJ No L 326, 13. 12. 1984, p. 31.

(2) OJ No L 181, 4. 7. 1986, p. 13.

ANNEX I

CATEGORIES OR GENERIC TYPES OF HAZARDOUS WASTE LISTED ACCORDING TO THEIR NATURE OR THE ACTIVITY WHICH GENERATED THEM (*) (WASTE MAY BE LIQUID, SLUDGE OR SOLID IN FORM)

ANNEX I.A.

Wastes displaying any of the properties listed in Annex III and which consist of:

1. anatomical substances; hospital and other clinical wastes;
2. pharmaceuticals, medicines and veterinary compounds;
3. wood preservatives;
4. biocides and phyto-pharmaceutical substances;
5. residue from substances employed as solvents;
6. halogenated organic substances not employed as solvents excluding inert polymerized materials;
7. tempering salts containing cyanides;
8. mineral oils and oily substances (e.g. cutting sludges, etc.);
9. oil/water, hydrocarbon/water mixtures, emulsions;
10. substances containing PCBs and/or PCTs (e.g. dielectrics etc.);
11. tarry materials arising from refining, distillation and any pyrolytic treatment (e.g. still bottoms, etc.);
12. inks, dyes, pigments, paints, lacquers, varnishes;
13. resins, latex, plasticizers, glues/adhesives;
14. chemical substances arising from research and development or teaching activities which are not identified and/or are new and whose effects on man and/or the environment are not known (e.g. laboratory residues, etc.);
15. pyrotechnics and other explosive materials;
16. photographic chemicals and processing materials;
17. any material contaminated with any congener of polychlorinated dibenzo-furan;
18. any material contaminated with any congener of polychlorinated dibenzo-p-dioxin.

ANNEX I.B.

Wastes which contain any of the constituents listed in Annex II and having any of the properties listed in Annex III and consisting of:

19. animal or vegetable soaps, fats, waxes;
20. non-halogenated organic substances not employed as solvents;
21. inorganic substances without metals or metal compounds;
22. ashes and/or cinders;
23. soil, sand, clay including dredging spoils;
24. non-cyanidic tempering salts;
25. metallic dust, powder;
26. spent catalyst materials;
27. liquids or sludges containing metals or metal compounds;

(*) Certain duplications of entries found in Annex II are intentional.

28. residue from pollution control operations (e.g. baghouse dusts, etc.) except (29), (30) and (33);
 29. scrubber sludges;
 30. sludges from water purification plants;
 31. decarbonization residue;
 32. ion-exchange column residue;
 33. sewage sludges, untreated or unsuitable for use in agriculture;
 34. residue from cleaning of tanks and/or equipment;
 35. contaminated equipment;
 36. contaminated containers (e.g. packaging, gas cylinders, etc.) whose contents included one or more of the constituents listed in Annex II;
 37. batteries and other electrical cells;
 38. vegetable oils;
 39. materials resulting from selective waste collections from households and which exhibit any of the characteristics listed in Annex III;
 40. any other wastes which contain any of the constituents listed in Annex II and any of the properties listed in Annex III.
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ANNEX II

CONSTITUENTS OF THE WASTES IN ANNEX I.B. WHICH RENDER THEM HAZARDOUS WHEN THEY HAVE THE PROPERTIES DESCRIBED IN ANNEX III (*)

Wastes having as constituents:

- C1 beryllium; beryllium compounds;
- C2 vanadium compounds;
- C3 chromium (VI) compounds;
- C4 cobalt compounds;
- C5 nickel compounds;
- C6 copper compounds;
- C7 zinc compounds;
- C8 arsenic; arsenic compounds;
- C9 selenium; selenium compounds;
- C10 silver compounds;
- C11 cadmium; cadmium compounds;
- C12 tin compounds;
- C13 antimony; antimony compounds;
- C14 tellurium; tellurium compounds;
- C15 barium compounds; excluding barium sulfate;
- C16 mercury; mercury compounds;
- C17 thallium; thallium compounds;
- C18 lead; lead compounds;
- C19 inorganic sulphides;
- C20 inorganic fluorine compounds, excluding calcium fluoride;
- C21 inorganic cyanides;
- C22 the following alkaline or alkaline earth metals: lithium, sodium, potassium, calcium, magnesium in uncombined form;
- C23 acidic solutions or acids in solid form;
- C24 basic solutions or bases in solid form;
- C25 asbestos (dust and fibres);
- C26 phosphorus: phosphorus compounds, excluding mineral phosphates;
- C27 metal carbonyls;
- C28 peroxides;
- C29 chlorates;
- C30 perchlorates;
- C31 azides;
- C32 PCBs and/or PCTs;
- C33 pharmaceutical or veterinary compounds;
- C34 biocides and phyto-pharmaceutical substances (e.g. pesticides, etc.);
- C35 infectious substances;
- C36 creosotes;
- C37 isocyanates; thiocyanates;
- C38 organic cyanides (e.g. nitriles, etc.);
- C39 phenols; phenol compounds;
- C40 halogenated solvents;
- C41 organic solvents, excluding halogenated solvents;
- C42 organohalogen compounds, excluding inert polymerized materials and other substances referred to in this Annex;
- C43 aromatic compounds; polycyclic and heterocyclic organic compounds;
- C44 aliphatic amines;
- C45 aromatic amines
- C46 ethers;
- C47 substances of an explosive character, excluding those listed elsewhere in this Annex;
- C48 sulphur organic compounds;
- C49 any congener of polychlorinated dibenzo-furan;
- C50 any congener of polychlorinated dibenzo-p-dioxin;
- C51 hydrocarbons and their oxygen; nitrogen and/or sulphur compounds not otherwise taken into account in this Annex.

(*) Certain duplications of generic types of hazardous wastes listed in Annex I are intentional.

*Annex III***PROPERTIES OF WASTES WHICH RENDER THEM HAZARDOUS**

- H1 'Explosive': substances and preparations which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene.
- H2 'Oxidizing': substances and preparations which exhibit highly exothermic reactions when in contact with other substances, particularly flammable substances.
- H3-A 'Highly flammable':
- liquid substances and preparations having a flash point below 21 °C (including extremely flammable liquids), or
 - substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
 - solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
 - gaseous substances and preparations which are flammable in air at normal pressure, or
 - substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities.
- H3-B 'Flammable': liquid substances and preparations having a flash point equal to or greater than 21 °C and less than or equal to 55 °C.
- H4 'Irritant': non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation.
- H5 'harmful': substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve limited health risks.
- H6 'Toxic': substances and preparations (including very toxic substances and preparations) which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks and even death.
- H7 'Carcinogenic': substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.
- H8 'Corrosive': substances and preparations which may destroy living tissue on contacts.
- H9 'Infectious': substances containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms.
- H10 'Teratogenic': substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce non-hereditary congenital malformations or increase their incidence.
- H11 'Mutagenic': substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce hereditary genetic defects or increase their incidence.
- H12 Substances and preparations which release toxic or very toxic gases in contact with water, air or an acid.
- H13 Substances and preparations capable by any means, after disposal, of yielding another substance, e.g. a leachate, which possesses any of the characteristics listed above.
- H14 'Ecotoxic': substances and preparations which present or may present immediate or delayed risks for one or more sectors of the environment.

Notes

1. Attribution of the hazard properties 'toxic' (and 'very toxic'), 'harmful', 'corrosive' and 'irritant' is made on the basis of the criteria laid down by Annex VI, part I A and part II B, of Council Directive 67/548/EEC of 27 June 1967 of the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽¹⁾, in the version as amended by Council Directive 79/831/EEC ⁽²⁾.

⁽¹⁾ OJ No L 196, 16. 8. 1967, p. 1.

⁽²⁾ OJ No L 259, 15. 10. 1979, p. 10.

2. With regard to attribution of the properties 'carcinogenic', 'teratogenic' and 'mutagenic', and reflecting the most recent findings, additional criteria are contained in the Guide to the classification and labelling of dangerous substances and preparations of Annex VI (part II D) to Directive 67/548/EEC in the version as amended by Commission Directive 83/467/EEC ⁽¹⁾.

Test methods

The test methods serve to give specific meaning to the definitions given in Annex III.

The methods to be used are those described in Annex V to Directive 67/548/EEC, in the version as amended by Commission Directive 84/449/EEC ⁽²⁾, or by subsequent Commission Directives adapting Directive 67/548/EEC to technical progress. These methods are themselves based on the work and recommendations of the competent international bodies, in particular the OECD.

⁽¹⁾ OJ No L 257, 16. 9. 1983, p. 1.

⁽²⁾ OJ No L 251, 19. 9. 1984, p. 1.

COUNCIL DECISION

of 12 December 1991

concerning the conclusion of the amendment to the Montreal Protocol on substances that deplete the ozone layer as adopted in June 1990 in London by the Parties to the Protocol

(91/690/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130s thereof,

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas it has been established that continued emissions of ozone-depleting substances at current levels cause significant damage to the ozone layer; whereas there is an international consensus that significant reductions in both production and consumption of such substances are necessary; whereas Decisions 80/372/EEC ⁽⁴⁾ and 82/795/EEC ⁽⁵⁾ provide controls which are of limited effect and which cover only two such substances (CFC 11 and CFC 12);

Whereas the Community together with all of its Member States have signed the Vienna Convention for the protection of the ozone layer, hereinafter referred as the 'Vienna Convention';

Whereas a Protocol supplementary to the Vienna Convention, the Montreal Protocol on substances that deplete the ozone layer, hereinafter referred to as the 'Montreal Protocol', was negotiated and adopted on 16 September 1987; whereas the Protocol has been signed by the Community and by all of its Member States;

Whereas the Community, in view of its responsibilities for the environment and trade, has approved, by Decision 88/540/EEC ⁽⁶⁾, the Vienna Convention and the Montreal Protocol;

Whereas the most recent scientific evidence indicates that for the adequate protection of the ozone layer a higher degree of control of chlorofluorocarbons and halons is required than that provided by the Montreal Protocol; whereas the same evidence indicates that additional controls should be placed on all other fully halogenated chlorofluorocarbons, carbon tetrachloride and 1,1,1-trichloroethane;

Whereas an amendment and an adjustment to the Montreal Protocol implementing these controls were adopted in London in June 1990 and only the amendment needs to be approved;

Whereas it is necessary for the protection, promotion and improvement of the environment to bring into force the amendment to the Montreal Protocol, which is based on the principle of preventive action to avoid further damage to the ozone layer and on the scientific and technical data which were available at the time of its adoption;

Whereas, to that end, the Community should approve the said amendment;

Whereas it is, in particular, necessary for the Community to approve the amendment to the Montreal Protocol because some of its provisions can be carried out only if the Community and all its Member States approve it;

Whereas, in order for all the obligations under the amendment to be appropriately carried out, it is necessary that all Member States should approve it;

Whereas all Member States should conclude as rapidly as possible their procedures for ratification of the said amendment, with a view to permit the deposit, as far as possible simultaneously, of the instruments of approval, acceptance or ratification by the Community and the Member States,

HAS ADOPTED THIS DECISION:

Article 1

The amendment to the Montreal Protocol on substances that deplete the ozone layer is hereby approved on behalf of the Community.

(1) OJ No C 11, 17. 1. 1991, p. 19.

(2) OJ No C 280, 28. 10. 1991, p. 29.

(3) OJ No C 120, 6. 5. 1991, p. 14.

(4) OJ No L 90, 3. 4. 1980, p. 45.

(5) OJ No L 329, 25. 11. 1982, p. 29.

(6) OJ No L 297, 31. 10. 1988, p. 8.

The text of the amendment is attached to this Decision.

The original Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic.

Article 2

The President of the Council shall deposit the act of approval of the amendment to the Montreal Protocol on behalf of the Community with the Secretary-General of the United Nations in accordance with Article 13 of the Vienna Convention, as read in conjunction with Article 2 of the amendment to the Montreal Protocol.

Article 3

Member States shall take the necessary steps to permit the deposit, as far as possible simultaneously, before 31 December 1991 of the instruments of ratification, acceptance or approval of the amendment to the Montreal Protocol by the Community and the Member States.

Member States will inform the Commission, if possible before 15 December 1991, of their decision to ratify or of the prospective date of finalization of their ratification procedures. The Commission, in cooperation with Member States, shall arrange for the Community and those Member States which are ready, a date for the simultaneous deposit of the instruments which shall if possible be before 31 December 1991.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 12 December 1991.

For the Council

The President

J. G. M. ALDERS

AMENDMENT TO THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEplete THE OZONE LAYER

Article 1: AMENDMENT

A. Preambular paragraphs

1. The sixth preambular paragraph of the Protocol shall be replaced by the following:

'DETERMINED to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations and bearing in mind the developmental needs of developing countries,'.

2. The seventh paragraph of the Protocol shall be replaced by the following:

'ACKNOWLEDGING that special provision is required to meet the needs of developing countries, including the provision of additional financial resources and access to relevant technologies, bearing in mind that the magnitude of funds necessary is predictable, and the funds can be expected to make a substantial difference in the world's ability to address the scientifically established problem of ozone depletion and its harmful effects,'.

3. The ninth preambular paragraph of the Protocol shall be replaced by the following:

'CONSIDERING the importance of promoting international cooperation in the research, development and transfer of alternative technologies relating to the control and reduction of emissions of substances that deplete the ozone layer, bearing in mind in particular the needs of developing countries,'.

B. Article 1: Definitions

1. Paragraph 4 of Article 1 of the Protocol shall be replaced by the following paragraph:

'4. 'Controlled substance' means a substance in Annex A or in Annex B to this Protocol, whether existing alone or in a mixture. It includes the isomers of any such substance, except as specified in the relevant Annex, but excludes any controlled substance or mixture which is in a manufactured product other than a container used for the transportation or storage of that substance.'

2. Paragraph 5 of Article 1 of the Protocol shall be replaced by the following paragraph:

'5. 'Production' means the amount of controlled substance produced, minus the amount destroyed by technologies to be approved by the Parties and minus the amount entirely used as feedstock in the manufacture of other chemicals. The amount recycled and reused is not to be considered as 'production'.'

3. The following paragraph shall be added to Article 1 of the Protocol:

'9. 'Transitional substance' means a substance in Annex C to this Protocol, whether existing alone or in a mixture. It includes the isomers of any such substance, except as may be specified in Annex C, but excludes any transitional substance or mixture which is in a manufactured product other than a container used for the transportation or storage of that substance.'

C. Article 2, paragraph 5

Paragraph 5 of Article 2 of the Protocol shall be replaced by the following paragraph:

'5. Any Party may, for any one or more control periods, transfer to another Party any portion of its calculated level of production set out in Articles 2 A to 2 E, provided that the total combined calculated levels of production of the Parties concerned for any group of controlled substances do not exceed the production limits set out in those Articles for that group. Such transfer of production shall be notified to the secretariat by each of the Parties concerned, stating the terms of such transfer and the period for which it is to apply.'

D. Article 2, paragraph 6

The following words shall be inserted in paragraph 6 of Article 2 before the words 'controlled substances' the first time they occur:

'Annex A or Annex B'.

E. Article 2, paragraph 8 (a)

The following words shall be added after the words 'this Article' wherever they appear in paragraph 8 (a) of Article 2 of the Protocol:

'and Articles 2 A to 2 E'.

F. Article 2, paragraph 9 (a) (i)

The following words shall be added after 'Annex A' in paragraph 9 (a) (i) of Article 2 of the Protocol:

'and/or Annex B'.

G. Article 2, paragraph 9 (a) (ii)

The following words shall be deleted from paragraph 9 (a) (ii) of Article 2 of the Protocol:

'from 1986 levels'.

H. Article 2, paragraph 9 (c)

The following words shall be deleted from paragraph 9 (c) of Article 2 of the Protocol:

'representing at least 50 % of the total consumption of the controlled substances of the Parties';

and replaced by:

'representing a majority of the Parties operating under paragraph 1 of Article 5 present and voting and a majority of the Parties not so operating present and voting'.

I. Article 2, paragraph 10 (b)

Paragraph 10 (b) of Article 2 of the Protocol shall be deleted, and paragraph 10 (a) of Article 2 shall become paragraph 10.

J. Article 2, paragraph 11

The following words shall be added after the words 'this Article' wherever they occur in paragraph 11 of Article 2 of the Protocol:

'and Articles 2 A to 2 E'.

K. Article 2 C: Other fully halogenated CFCs

The following paragraphs shall be added to the Protocol as Article 2 C:

'Article 2 C

Other fully halogenated CFCs

1. Each Party shall ensure that for the 12-month period commencing on 1 January 1993, and in each 12-month period thereafter, its calculated level of consumption of the controlled substances in Group I of Annex B does not exceed, annually, 80 % of its calculated level of consumption in 1989. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed, annually, 80 % of its calculated level of production in 1989. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 10 % of its calculated level of production in 1989.
2. Each Party shall ensure that for the 12-month period commencing on 1 January 1997, and in each 12-month period thereafter, its calculated level of consumption of the controlled substances in Group I of Annex B does not exceed, annually, 15 % of its calculated level of consumption in 1989. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed, annually, 15 % of its calculated level of production in 1989. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 10 % of its calculated level of production in 1989.
3. Each Party shall ensure that for the 12-month period commencing on 1 January 2000, and in each 12-month period thereafter, its calculated level of consumption of the controlled substances in Group I of Annex B does not exceed zero. Each Party producing one or more of these substances shall, for the same periods, ensure that its calculated level of production of the substances does not exceed zero. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 15 % of its calculated level of production in 1989.'

L. Article 2 D: Carbon tetrachloride

The following paragraphs shall be added to the Protocol as Article 2 D:

'Article 2 D

Carbon tetrachloride

1. Each Party shall ensure that for the 12-month period commencing on 1 January 1995, and in each 12-month period thereafter, its calculated level of consumption of the controlled substance in Group II of Annex B does not exceed, annually 15 % of its calculated level of consumption in 1989. Each Party producing the substance shall, for the same periods, ensure that its calculated level of production of the substances does not exceed, annually 15 % of its calculated level of production in 1989. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 10 % of its calculated level of production in 1989.
2. Each Party shall ensure that for the 12-month period commencing on 1 January 2000, and in each 12-month period thereafter, its calculated level of consumption of the controlled substance in Group II of Annex B does not exceed zero. Each Party producing the substance shall, for the same periods, ensure that its calculated level of production of the substance does

not exceed zero. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 15 % of its calculated level of production in 1989.'

M. Article 2 E: 1,1,1-trichlorethane (methyl chloroform)

The following paragraphs shall be added to the Protocol as Article 2 E:

'Article 2 E

1,1,1-trichlorethane (methyl chloroform)

1. Each Party shall ensure that for the 12-month period commencing on 1 January 1993, and in each 12-month period thereafter, its calculated level of consumption of the controlled substances in Group III of Annex B does not exceed, annually its calculated level of consumption in 1989. Each Party producing the substance shall, for the same periods, ensure that its calculated level of production of the substance does not exceed, annually, its calculated level of production in 1989. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 10 % of its calculated level of production in 1989.

2. Each Party shall ensure that for the 12-month period commencing on 1 January 1995, and in each 12-month period thereafter, its calculated level of consumption of the controlled substance in Group III of Annex B does not exceed, annually 70 % of its calculated level of consumption in 1989. Each Party producing the substance shall, for the same periods, ensure that its calculated level of production of the substance does not exceed, annually, 70 % of its calculated level of consumption in 1989. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 10 % of its calculated level of production in 1989.

3. Each Party shall ensure that for the 12-month period commencing on 1 January 2000, and in each 12-month period thereafter, its calculated level of consumption of the controlled substance in Group III of Annex B does not exceed, annually, 30 % of its calculated level of consumption in 1989. Each Party producing the substance shall, for the same periods, ensure that its calculated level of production of the substance does not exceed, annually, 30 % of its calculated level of production in 1989. However, in order to satisfy the basic domestic needs of Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 10 % of its calculated level of production in 1989.

4. Each Party shall ensure that for the 12-month period commencing on 1 January 2005, and in each 12-month period thereafter, its calculated level of consumption of the controlled substance in Group III of Annex B does not exceed zero. Each Party producing the substance shall, for the same periods, ensure that its calculated level of production of the substance does not exceed zero. However, in order to satisfy the basic domestic needs of the Parties operating under paragraph 1 of Article 5, its calculated level of production may exceed that limit by up to 15 % of its calculated level of production in 1989.

5. The Parties shall review, in 1992, the feasibility of a more rapid schedule of reductions than that set out in this Article.'

N. Article 3: Calculation of control levels

1. The following shall be added after 'Article 2' in Article 3 of the Protocol:

'2 A to 2 E'.

2. The following words shall be added after 'Annex A' each time it appears in Article 3 of the Protocol:

'or Annex B'.

O. Article 4: Control of trade with non-Parties**1. Paragraphs 1 to 5 of Article 4 shall be replaced by the following paragraphs:**

'1. As of 1 January 1990, each Party shall ban the import of the controlled substances in Annex A from any State not party to this Protocol.

1 (a). Within one year of the date of the entry into force of this paragraph, each Party shall ban the import of the controlled substances in Annex B from any State not party to this Protocol.

2. As of 1 January 1993, each Party shall ban the export of any controlled substances in Annex A to any State not party to this Protocol.

2 (a). Commencing one year after the date of entry into force of this paragraph, each Party shall ban the export of any controlled substances in Annex B to any State not party to this Protocol.

3. By 1 January 1992, the Parties shall, following the procedures in Article 10 of the Convention, elaborate in an annex a list of products containing controlled substances in Annex A. Parties that have not objected to the annex in accordance with those procedures shall ban, within one year of the annex having become effective, the import of those products from any State not party to this Protocol.

3 (a). Within three years of the date of the entry into force of this paragraph, the Parties shall, following the procedures in Article 10 of the Convention, elaborate in an annex a list of products containing controlled substances in Annex B. Parties that have not objected to the annex in accordance with those procedures shall ban, within one year of the annex having become effective, the import of those products from any State not party to this Protocol.

4. By 1 January 1994, the Parties shall determine the feasibility of banning or restricting, from States not party to this Protocol, the import of products produced with, but not containing, controlled substances in Annex A. If determined feasible, the Parties shall, following the procedures in Article 10 of the Convention, elaborate in an annex a list of such products. Parties that have not objected to the annex in accordance with those procedures shall ban, within one year of the annex having become effective, the import of those products from any State not party to this Protocol.

4 (a). Within five years of the date of the entry into force of this paragraph, the Parties shall determine the feasibility of banning or restricting, from States not party to this Protocol, the import of products produced with, but not containing, controlled substances in Annex B. If determined feasible, the Parties shall, following the procedures in Article 10 of the Convention, elaborate in an annex a list of such products. Parties that have not objected to the annex in accordance with those procedures shall ban or restrict, within one year of the annex having become effective, the import of those products from any State not party to this Protocol.

5. Each Party undertakes to the fullest practicable extent to discourage the export to any State not party to this Protocol of technology for producing and for utilizing controlled substances.'

2. Paragraph 8 of Article 4 of the Protocol shall be replaced by the following paragraph:

'8. Notwithstanding the provisions of this Article, imports referred to in paragraph 1, 1 (a), 3, 3 (a), 4 and 4 (a) and exports referred to in paragraph 2 and 2 *bis*, may be permitted from, or to, any State not party to this Protocol, if that State is determined by a meeting of the Parties to be in full compliance with Article 2, Articles 2 A, 2 E, and this Article and have submitted data to that effect as specified in Article 7.'

3. The following paragraph shall be added to Article 4 of the Protocol as paragraph 9:

'9. For the purposes of this Article, the term "State not party to this Protocol" shall include, with respect to a particular controlled substance, a State or regional economic integration

organization that has not agreed to be bound by the control measures in effect for that substance.'

P. Article 5: Special situation of developing countries

Article 5 of the Protocol shall be replaced by the following:

'1. Any Party that is a developing country and whose annual calculated level of consumption of the controlled substances in Annex A is less than 0,3 kilograms per capita on the date of the entry into force of the Protocol for it, or any time thereafter until 1 January 1999, shall in order to meet its basic domestic needs, be entitled to delay for 10 years its compliance with the control measures set out in Articles 2 A to 2 E.

2. However, any Party operating under paragraph 1 of this Article shall exceed neither an annual calculated level of consumption of the controlled substances in Annex A of 0,3 kilograms per capita nor an annual calculated level of consumption of the controlled substances of Annex B of 0,2 kilograms per capita.

3. When implementing the control measures set out in Articles 2 A to 2 E, any Party operating under paragraph 1 of this Article shall be entitled to use:

(a) for controlled substances under Annex A, either the average of its annual calculated level of consumption for the period 1995 to 1997 inclusive or a calculated level of consumption of 0,3 kilograms per capita, whichever is the lower, as the basis for determining its compliance with the control measures;

(b) for controlled substances under Annex B, the average of its annual calculated level of consumption for the period 1998 to 2000 inclusive or a calculated level of consumption of 0,2 kilograms per capita, whichever is the lower, as the basis for determining its compliance with the control measures.

4. If a Party operating under paragraph 1 of this Article, at any time before the control measures obligations in Article 2 A to 2 E become applicable to it, finds itself unable to obtain an adequate supply of controlled substances, it may notify this to the Secretariat. The Secretariat shall forthwith transmit a copy of such notification to the Parties, which shall consider the matter at their next meeting, and decide upon appropriate action to be taken.

5. Developing the capacity to fulfil the obligations of the Parties operating under paragraph 1 of this Article to comply with the control measures set out in Articles 2 A to 2 E and their implementation by those same Parties will depend upon the effective implementation of the financial cooperation as provided by Article 10 and transfer of technology as provided by Article 10 A.

6. Any Party operating under paragraph 1 of this Article may, at any time, notify the Secretariat in writing that, having taken all practicable steps it is unable to implement any or all of the obligations laid down in Articles 2 A to 2 E due to the inadequate implementation of Articles 10 and 10 A. The Secretariat shall forthwith transmit a copy of the notification to the Parties, which shall consider the matter at their next meeting, giving due recognition to paragraph 5 of this Article and shall decide upon appropriate action to be taken.

7. During the period between notification and the meeting of the Parties at which the appropriate action referred to in paragraph 6 above is to be decided, or for a further period if the meeting of the Parties so decides, the non-compliance procedures referred to in Article 8 shall not be invoked against the notifying Party.

8. A meeting of the Parties shall review, not later than 1995, the situation of the Parties operating under paragraph 1 of this Article, including the effective implementation of financial cooperation and transfer of technology to them, and adopt such revisions that may be deemed necessary regarding the schedule of control measures applicable to those Parties.

9. Decisions of the Parties referred to in paragraphs 4, 6 and 7 of this Article shall be taken according to the same procedure applied to decision-making under Article 10.'

Q. Article 6: Assessment and review of control measures

The following words shall be added after 'Article 2' in Article 6 of the Protocol:

'Articles 2 A to 2 E, and the situation regarding production, imports and exports of the transitional substances in Group I of Annex C'.

R. Article 7: Reporting of data

Article 7 of the Protocol shall be replaced by the following:

'1. Each Party shall provide to the Secretariat, within three months of becoming a Party, statistical data on its production, imports and exports of each of the controlled substances in Annex A for the year 1986, or the best possible estimates of such data where actual data are not available.

2. Each Party shall provide to the Secretariat statistical data on its production, imports and exports of each of the controlled substances in Annex B and each of the transitional substances in Group I of Annex C, for the year 1989, or the best possible estimates of such data where actual data are not available, not later than three months after the data when the provisions set out in the Protocol with regard to the substances in Annex B enter into force for that Party.

3. Each Party shall provide statistical data to the Secretariat on its annual production (as defined in paragraph 5 of Article 1), and separately:

- amounts used for feedstocks,
- amounts destroyed by technologies approved by the Parties,
- imports and exports to Parties and non-Parties respectively,

of each of the controlled substances listed in Annexes A and B as well as of the transitional substances in Group I of Annex C, for the year during which provisions concerning the substances in Annex B entered into force for that Party and for each year thereafter. Data shall be forwarded not later than nine months after the end of the year to which the data relate.

4. For Parties operating under the provisions of paragraph 8 (a) of Article 2, the requirements in paragraph 1, 2 and 3 of this Article in respect of statistical data on imports and exports shall be satisfied if the regional economic integration organization concerned provides data on imports and exports between the organization and States that are not members of that organization.'

S. Article 9: Research, development, public awareness and exchange of information

Paragraph 1 (a) of Article 9 of the Protocol shall be replaced by the following:

'(a) Best technologies for improving the containment, recovery, recycling, or destruction of controlled and transitional substances or otherwise reducing their emissions;'

T. Article 10: Financial mechanism

Article 10 of the Protocol shall be replaced by the following:

*Article 10***Financial Mechanism**

1. The Parties shall establish a mechanism for the purposes of providing financial and technical cooperation, including the transfer of technologies, to Parties operating under paragraph 1 of Article 5 of this Protocol to enable their compliance with the control measures set out in Articles 2 A to 2 E of the Protocol. The mechanism, contributions to which shall be additional to other financial transfers to Parties operating under that paragraph, shall meet all agreed incremental costs of such Parties in order to enable their compliance with the control measures of the Protocol. An indicative list of the categories of incremental costs shall be decided by the meeting of the Parties.

2. The mechanism established under paragraph 1 shall include a multilateral fund. It may also include other means of multilateral, regional and bilateral cooperation.

3. The multilateral fund shall:

(a) meet, on a grant or concessional basis as appropriate, and according to criteria to be decided upon by the Parties, the agreed incremental costs;

(b) finance clearing-house functions to:

(i) assist Parties operating under paragraph 1 of Article 5, through country-specific studies and other technical cooperation, to identify their needs for cooperation,

(ii) facilitate technical cooperation to meet these identified needs,

(iii) distribute, as provided for in Article 9, information and relevant materials, and hold workshops, training sessions, and other related activities, for the benefit of Parties that are developing countries, and

(iv) facilitate and monitor other multilateral, regional and bilateral cooperation available to Parties that are developing countries;

(c) finance the secretarial services of the multilateral fund and related support costs.

4. The multilateral fund shall operate under the authority of the Parties who shall decide on its overall policies.

5. The Parties shall establish an Executive Committee to develop and monitor the implementation of specific operational policies, guidelines and administrative arrangements, including the disbursement of resources, for the purpose of achieving the objectives of the multilateral fund. The Executive Committee shall discharge its tasks and responsibilities, specified in its terms of reference as agreed by the Parties, with the cooperation and assistance of the International Bank for Reconstruction and Development (World Bank), the United Nations Environment Programme, the United Nations Development Programme or other appropriate agencies depending on their respective areas of expertise. The members of the Executive Committee, which shall be selected on the basis of a balanced representation of the Parties operating under paragraph 1 of Article 5 and of the Parties not so operating, shall be endorsed by the Parties.

6. The multilateral fund shall be financed by contributions from Parties not operating under paragraph 1 of Article 5 in convertible currency or, in certain circumstances, in kind and/or in national currency, on the basis of the United Nations scale of assessments. Contributions by other Parties shall be encouraged. Bilateral and, in particular cases agreed by a decision of the Parties, regional cooperation may, up to a percentage and consistent with any criteria to be specified by decision of the Parties, be considered as a contribution to the multilateral fund, provided that such cooperation, as a minimum:

(a) strictly relates to compliance with the provisions of this Protocol;

- (b) provides additional resources; and
- (c) meets agreed incremental costs.

7. The Parties shall decide upon the programme budget of the multilateral fund for each fiscal period and upon the percentage of contributions of the individual Parties thereto.

8. Resources under the multilateral fund shall be disbursed with the concurrence of the beneficiary Party.

9. Decisions by the Parties under this Article shall be taken by consensus whenever possible. If all efforts at consensus have been exhausted and no agreement reached, decisions shall be adopted by a two-thirds majority vote of the Parties present and voting, representing a majority of the Parties operating under paragraph 1 of Article 5 present and voting and a majority of the Parties not so operating present and voting.

10. The financial mechanism set out in this Article is without prejudice to any future arrangements that may be developed with respect to other environmental issues.'

U. Article 10 A: Transfer of technology

The following Article shall be added to the Protocol as Article 10 A:

'Article 10 A:

Transfer of technology

Each Party shall take every practicable step, consistent with the programmes supported by the financial mechanism, to ensure:

- (a) that the best available, environmentally safe substitutes and related technologies are expeditiously transferred to Parties operating under paragraph 1 of Article 5; and
- (b) that the transfers referred to in subparagraph (a) occur under fair and most favourable conditions.'

V. Article 11: Meetings of the Parties

Paragraph 4 (g) of Article 11 of the Protocol shall be replaced by the following:

- '(g) assess, in accordance with Article 6, the control measures and the situation regarding transitional substances;'

W. Article 17: Parties joining after entry into force

The following words shall be added after 'as well as under' in Article 17:

'Articles 2 A to 2 E, and'.

X. Article 19: Withdrawal

Article 19 of the Protocol shall be replaced by the following paragraph:

'Any Party may withdraw from this Protocol by giving written notification to the depositary at any time after four years of assuming the obligations specified in paragraph 1 of Article 2 A. Any such withdrawal shall take effect upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notifications of the withdrawal.'

Y. Annexes

The following annexes shall be added to the Protocol:

Annex B
CONTROLLED SUBSTANCES

Group	Substance	Ozone-depleting potential
Group I		
CF ₃ Cl	(CFC-13)	1,0
C ₂ FCl ₅	(CFC-111)	1,0
C ₂ F ₂ Cl ₄	(CFC-112)	1,0
C ₃ FCl ₇	(CFC-211)	1,0
C ₃ F ₂ Cl ₆	(CFC-212)	1,0
C ₃ F ₃ Cl ₅	(CFC-213)	1,0
C ₃ F ₄ Cl ₄	(CFC-214)	1,0
C ₃ F ₅ Cl ₃	(CFC-215)	1,0
C ₃ F ₆ Cl ₂	(CFC-216)	1,0
C ₃ F ₇ Cl	(CFC-217)	1,0
Group II		
CCl ₄	Carbon tetrachloride	1,1
Group III		
C ₂ H ₃ Cl ₃ (*)	1,1,1-trichloroethane (methyl chloroform)	0,1

(*) This formula does not refer to 1,2,2-trichloroethane.

Annex C
TRANSITIONAL SUBSTANCES

Group	Substance
Group I	
CHFCl ₂	(HCFC-21)
CHF ₂ Cl	(HCFC-22)
CH ₂ FCl	(HCFC-31)
C ₂ HFCl ₄	(HCFC-121)
C ₂ HF ₂ Cl ₃	(HCFC-122)
C ₂ HF ₃ Cl ₂	(HCFC-123)
C ₂ HF ₄ Cl	(HCFC-124)
C ₂ H ₂ FCl ₃	(HCFC-131)
C ₂ H ₂ F ₂ Cl ₂	(HCFC-132)
C ₂ H ₂ F ₃ Cl	(HCFC-133)
C ₂ H ₃ FCl ₂	(HCFC-141)
C ₂ H ₃ F ₂ Cl	(HCFC-142)
C ₂ H ₄ FCl	(HCFC-151)
C ₃ HFCl ₆	(HCFC-221)
C ₃ HF ₂ Cl ₅	(HCFC-222)
C ₃ HF ₃ Cl ₄	(HCFC-223)
C ₃ HF ₄ Cl ₃	(HCFC-224)
C ₃ HF ₅ Cl ₂	(HCFC-225)
C ₃ HF ₆ Cl	(HCFC-226)
C ₃ H ₂ FCl ₅	(HCFC-231)
C ₃ H ₂ F ₂ Cl ₄	(HCFC-232)
C ₃ H ₂ F ₃ Cl ₃	(HCFC-233)
C ₃ H ₂ F ₄ Cl ₂	(HCFC-234)
C ₃ H ₂ F ₅ Cl	(HCFC-235)
C ₃ H ₃ FCl ₄	(HCFC-241)
C ₃ H ₃ F ₂ Cl ₃	(HCFC-242)
C ₃ H ₃ F ₃ Cl ₂	(HCFC-243)
C ₃ H ₃ F ₄ Cl	(HCFC-244)
C ₃ H ₄ FCl ₃	(HCFC-251)
C ₃ H ₄ F ₂ Cl ₂	(HCFC-252)
C ₃ H ₄ F ₃ Cl	(HCFC-253)
C ₃ H ₅ FCl ₂	(HCFC-261)
C ₃ H ₅ F ₂ Cl	(HCFC-262)
C ₃ H ₆ FCl	(HCFC-271)

Article 2: ENTRY INTO FORCE

1. This amendment shall enter into force on 1 January 1992, provided that at least 20 instruments of ratification, acceptance or approval of the amendment have been deposited by States or regional economic integration organizations that are Parties to the Montreal Protocol on substances that deplete the ozone layer. In the event that this condition has not been fulfilled by that date, the amendment shall enter into force on the 90th day following the date on which it has been fulfilled.
2. For the purposes of paragraph 1, any such instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.
3. After the entry into force to this amendment as provided under paragraph 1, it shall enter into force for any other Party to the Protocol on the 90th day following the date of deposit of its instrument of ratification, acceptance or approval.

COUNCIL DECISION

of 12 December 1991

adopting a programme for the establishment of an internal information services market

(91/691/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas, by virtue of the economic importance of information, the creation of an internal information services market occupies an essential place in the strengthening of the internal market between now and the end of 1992;

Whereas the initial results of the implementation of the plan of action for setting up an information service market adopted by Council Decision 88/524/EEC ⁽⁴⁾ indicate that a further programme is necessary;

Whereas there are numerous legal, administrative, fiscal and technical barriers to the development of an internal information market which are hindering the setting up of new services and in some cases causing distortions of competition;

Whereas the development of information resources and information-based services requires the application of new technologies in European cooperation;

Whereas the Community has a competitive position which is strong in some sectors of the information market but needs to be strengthened in others, without creating distortions of competition;

Whereas the need for simplification of procedures as well as harmonization in the field of database access should undergo priority scrutiny;

Whereas the needs and legitimate demands of users of information services, particularly in small and

medium-sized enterprises (SMEs) and in the less favoured regions of the Community, merit special attention;

Whereas there should be adequate means of informing SMEs of the programme and encouraging them to take part in it;

Whereas the different rates of development in the provision and use of information services in the Member States deserve special attention, having regard to the internal cohesion of the Community and the working of the internal market;

Whereas that part of the amount estimated as necessary which is intended to finance pilot and demonstration projects may be used, in particular, to attract possible additional sources of funding from the partners concerned, thereby having a multiplier effect on the development of the European information services market;

Whereas any information market policy must be complementary to other ongoing Community initiatives, notably in the field for telecommunications;

Whereas provision should be made for a four-year programme;

Whereas the funds estimated as necessary for the implementation of the programme amount to ECU 64 million; whereas the funds estimated as necessary for the period 1991/92, within the current financial perspective, amount to ECU 21,6 million;

Whereas the amounts to be committed for financing the programme after financial year 1992 should be included in the Community financial framework in force;

Whereas the Treaty does not provide, for the adoption of this Decision, powers other than those laid down in Article 235 thereof,

HAS DECIDED AS FOLLOWS:

Article 1

A programme is hereby set up with the following objectives:

⁽¹⁾ OJ Nr. C 53, 28. 2. 1991, p. 65.

⁽²⁾ OJ Nr. C 240, 16. 9. 1991, p. 220.

⁽³⁾ OJ Nr. C 159, 17. 6. 1991, p. 16.

⁽⁴⁾ OJ Nr. L 288, 21. 10. 1988, p. 39.

- to establish an internal information service market,
- to identify the strength and weaknesses of existing information services in the Community and to stimulate and reinforce the competitive capability of European suppliers of information services,
- to promote the use of advanced information services,
- to reinforce European cooperation in order to achieve a Community information services policy, paying particular attention to SMEs, the differences between the various regions and the development lag of the favoured regions in the Community,
- to make use of the results supplied by other Community or national programmes with a view to strengthening the information services market.

Article 2

In order to attain the objectives referred to in Article 1, the following measures shall be undertaken under the responsibility of the Commission, in accordance with the action lines in Annex I and the detailed implementing arrangements set out in Annex II:

- improving the understanding of the internal information market,
- overcoming legal, administrative and technical barriers,
- increasing user-friendliness and improving information literacy,
- supporting strategic information initiatives.

None of these measures shall duplicate the work carried out in these areas under Community or national programmes.

Article 3

1. The programme shall cover a period of four years.
2. The amount estimated as necessary for the execution of the programme amounts to ECU 64 million, of which ECU 21,6 million are for the period 1991/92 under the 1988 to 1992 financial perspective. The amount required for the subsequent period of application of the programme shall be included in the Community financial framework in force.
3. The budgetary authority shall determine the appropriations available for each financial year with reference to the principles of sound management referred to in Article 2 of the Financial Regulation applicable to the general budget of the European Communities.

4. The Community's financial contribution to each line of action shall on a shared-cost basis normally be 50 %.

Article 4

1. The Commission shall be responsible for implementing the programme. It shall be assisted by a committee of an advisory nature composed of the representative of the Member States and chaired by the representative of the Commission.
2. The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.
3. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.
4. The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 5

1. Notwithstanding Article 4, the procedure described in paragraphs 2 and 3 below shall apply to preparation of the annual work programmes for carrying out the action lines referred to in Annex I, to the breakdown of budgetary expenditure, to the implementation of a more flexible funding scheme than calls for proposals, to the consideration, in exceptional cases, of unsolicited proposals for projects, to support for projects under action line 3 in Annex I and to strategic information initiatives involving a Community financial contribution in excess of ECU 500 000.
2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Articles 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
3. The Commission shall adopt measures which shall apply immediately. However, if these measures are not in accordance with the opinion of the committee, they shall be communicated by the Commission to the Council forthwith. In that event, the Commission shall defer application of the measures which it has decided for a period of three months from the date of such communication.

The Council, acting by a qualified majority, may take a different decision within the time limit referred to in the foregoing subparagraph.

Article 6

At mid-term and at the end of the programme, the Commission shall submit to the European Parliament and to the Council, once the committee referred to in Article 4 has examined it, an evaluation report drawn up by independent experts on the results obtained in implementing the action lines referred to in Article 2 and may present, on the basis of these results, proposals for adjusting the orientation of the programme. The annual report of the European Information Market Observatory (IMO) and the regular reports by the Legal Advisory Board shall also be submitted to the European Parliament, the Council and the Economic and Social Committee.

Article 7

1. The Commission is hereby authorized to negotiate agreements with third countries taking part in the

development of the information services market with a view to associating them wholly or partially with the programme. The negotiation of these agreements shall be based on the criterion of mutual advantage.

2. Before entering into the negotiations referred to in paragraph 1, the Commission shall inform the Council of its intention to negotiate and of the terms of reference of the negotiations. The Commission shall take account of the Council's opinion.

Article 8

This Decision shall take effect on the day of its adoption.

Done at Brussels, 12 December 1991.

For the Council

The President

J.G.M. ALDERS

ANNEX I

ACTION LINES UNDER IMPACT 2

Action Line 1: Improving the understanding of the information market

- 1.1. The European Information Market Observatory (IMO) will continue and extend the scope of its activities for the identification of the Community's competitive strengths and weaknesses in the sector in order to keep Community institutions and Member States informed in drawing up their policy. During the initial phase of Impact, the IMO focused its investigations on the supply of database services. It will enlarge the scope of its investigations to neighbouring publishing markets with particular attention to the market for business and trade press and scientific, technical and medical publishing. The IMO will give greater focus to user surveys in order to gain better knowledge of the means by which users obtain access to the professional information they need, and identify gaps which requires Community initiatives.
- 1.2. The IMO will keep a permanent inventory of existing market data sources. It will primarily rely on these sources to purchase the data it needs for its investigations. It will launch or stimulate additional surveys when the data required are not available, incomplete or unreliable. It will also carry out sectoral investigations in order to identify those sectors of the information market which are inadequately served or progressing slowly, although they are of strategic importance for the Community. Following the initial methodological workshop organized in 1989 in cooperation with Eurostat, the IMO will support the long-term methodological efforts required for the creation of a conceptual framework that will allow the inclusion of the information services sector in official statistics. In addition, the IMO will encourage further work in information sciences and the economics of information to stimulate the development of the models and forecasting to stimulate the development of the models and forecasting tools which are required for the prognosis of information market trends and the assessment of their impact on the rest of the economy.
- 1.3. The intention of the IMO is to supplement the efforts of Member States, companies and other organizations interested in the development of the information market. The activities of the IMO will therefore be undertaken in conjunction with, and not supplant, the efforts of Member States, private sector companies and other organizations. The IMO will strengthen its network of national correspondents and improve links with existing European and national associations in the information market. It will cooperate with these associations and relevant research organizations on shared-cost projects. In order to improve its documentation on the world market for information services, the IMO will seek to exchange information with appropriate non-Community organizations such as the Japan Database Promotion Center and the American Information Industry Association.
- 1.4. The results of the IMO analysis will be widely disseminated to users and industry through dissemination agreements with representative associations and specialized publisher. Each year, the IMO will prepare a report to the European Parliament and the Council on the main changes which have occurred on the information market.

Action Line 2: Overcoming legal and administrative barriers

- 2.1. The actions which will be undertaken within the framework of Impact 2 will contribute to strengthening the synergy of work being carried out on legal problems of a horizontal nature (e.g. protection of privacy, responsibility, intellectual property, proof and authentication of electronic signatures) and to proposing Community initiatives specific to certain segments of the information services market.
- 2.2. The first category of work will contribute to the improvement of the coordination of sectoral initiatives on legal problems of a horizontal nature being undertaken within the framework of different programmes. With this in view, the Commission will reinforce the expertise and documentary resources it has acquired with the help of the Legal Advisory Board (LAB) in order to provide Member States and Community institutions with easier access to reference documents and to information on current work in the area. To this effect, the Commission will examine the possibility of encouraging the development of a specialized database. It will seek the expertise of LAB in preparing legal initiatives linked to new technologies. In parallel, it will continue and strengthen its cooperation with the Council of Europe and OECD in areas of common interest.

- 2.3. The second category of work will concentrate on the contribution to the preparation of initiatives specific to certain segments of the information market. The Commission will examine the legal problems raised by the implementation of the guidelines designed to strengthen the synergy between the public sector and the private sector in the information market; it will draw up proposals for harmonizing the rules on the marketing of data files held by public and quasi-public bodies. It will encourage the drawing up of European codes of conduct and monitor the application of data privacy, protection in relation to the marketing of certain database services, such as mailing lists and databanks on credit and solvency. It will draw up Community guidelines to harmonize the conditions for opening up electric information services to the public and to provide the framework for contractual arrangements between the various market actors in areas such as editorial liability, service quality control, confidentiality, database usage and, in particular, publishers' rights.
- 2.4. The composition of LAB will be modified by the Commission so as to make better provision for the participation in its work of public authorities and of relevant market actors as a complement to the participation of independent legal experts specialized in the various topics for examination.
- 2.5. The Commission will implement an active policy of disseminating the results of LAB's work, in conjunction with specialized publishers, in order better to inform the actors of their rights and obligations

Action Line 3: Increasing user-friendliness and improving information literacy

- 3.1. As a complement to current efforts for Open Systems Interconnection (OSI), the Commission will promote development of open information interchange standards in cooperation with existing standardization structures such as EWOS, ETSI and CEN/Cenelec. The demonstration and efficient application of information standards or industry norms for the encoding and structuring of information will be supported. Incentives will be provided to the acting parties to complete and extend existing information standards. The Commission will support demonstration projects to promote the application of information standards and to demonstrate their benefits. This will include in particular standards like the Standardized General Markup Language (SGML) and Office Document Architecture (ODA). The use of information standards in public sector information products will be promoted.
- 3.2. The development of generic interfaces providing flexible and economic solutions to access a large spectrum of information services will be encouraged. This will cover multimedia and European-wide access. The integration of multilingual facilities or icons and graphics in information services, the development of controlled vocabulary and natural language retrieval methods will be supported to facilitate access by untrained users. Incentives to extend existing natural language interfaces to other Community languages will be provided to support the Community's cohesion. Efforts will be undertaken to encourage the application in information services of research results in areas such as expert systems, human-computer interface and natural language processing. An umbrella project for testing the viability of European business Kiosk facilities that will provide SMEs with easy access to professional audiotex, videotex and Ascii information services will be developed. Integrated application of different types of information using sound, graphics, text and images will be stimulated.
- 3.3. To promote information literacy among professional people, the Commission will rely primarily on multipliers in the information service market and on certain groups of end-users. These multipliers include educational institutions, professional associations, national focal points, gateway operators and the specialized press.

Actions aimed at supporting the multipliers, experts and end-users will comprise: development of appropriate tools, such as documentation, multi-media shows, videos, in all Community languages; organization of conferences; seminars, workshops, information days, press conferences; participation in exhibitions, maintenance of existing directories and extension by new information products; publication of a regular newsletter giving information on Community initiatives; presence in information distribution networks of database inventories etc.; providing a central help desk for users of information services, including a free phone enquiry service; operation of the multilingual host service ECHO (European Commission Host Organization) which will continue to support more particularly new users of electronic information services and will act as an instrument for transferring know-how to the market place in accordance with the guidelines for the improvement of the synergy between the public and the private sectors in the information market.

- 3.4. Training actions will address all kinds of information handlers within the information chain covering: database production, host service operation, multimedia dissemination of information and use of information. Support will be given to training intermediaries and professionals in the use of electronic information both on-line, with special attention being given to less favoured regions. Actions will also include training of future trainers in different regions, economic sectors and companies. Close collaboration with national and local authorities and other programmes (e.g. STAR, Delta) will be sought.

Action Line 4: Supporting strategic information initiatives

- 4.1. The provision of electronic scientific and technical information services (STI) — a basic resource for the European research community and for industrial progress — will be stimulated and strengthened. The Commission will build on recent initiatives in the area of biotechnology information and engineering materials data systems by creating a European cooperative network for biotechnology information and the further development of material data services. These initiatives will aim at improving the availability, quality and accessibility of European STI services through the creation of appropriate tools and structure which will foster the integration of existing systems and services and a more efficient sharing of resources.
- 4.2. Information services development in strategically important market sectors will be stimulated and facilities for cooperation made available. Where necessary, the creation of embryonic structures will be supported. In particular, information services which are relevant to Community policies on internal market operations will be stimulated. Harmonization efforts will be undertaken in new sectors in which spontaneous, but uncoordinated developments take place, in order to stimulate cooperation and networking. The areas of patent information, information on standards, tourism and transport information, cultural information, environment and health information, and the standardized production of digitized basic geographical maps have been identified as sectors for Community action.
- 4.3. The strategic information projects may be extended and/or reviewed in the course of programme implementation on the basis of requirements identified by the IMO, the results obtained at the mid-term review of this programme, and close consultation with the information industry and the programme's advisory body. The priority areas which had been identified for pilot/demonstration projects under the previous Impact programme, but not yet developed, will be reviewed and action undertaken, if market needs are confirmed.
- 4.4. Commercial ventures for the development of information products and services on the basis of European partnership, e.g. European Economic Interest Grouping (EEIG), will be stimulated by reducing the financial burden involved in international cooperation. This will be applied in particular to small and medium-sized enterprises (SMEs). A support scheme will be provided for the preparation of international projects, for joint ventures agreed by partners from different Member States and for the transfer of know-how from advanced to less favoured regions of the Community. Closer cooperation between European and national trade or professional organizations will be supported, as well as the involvement of national focal points in order to promote strategic projects and the creation of an internal market for information.
- 4.5. The Commission will explore the possible linking of relevant organization in the Member States into a networked media laboratory to develop a European expertise in information product prototype development for multimedia information product prototype development for multimedia information services products, for promoting the exchange of experience and the transfer of know-how, and for achieving synergy between publishers and system suppliers.
- 4.6. The taking off the information market in less favoured regions depends on strategic information projects with catalytic effects. Adequate national/regional initiatives will be encouraged through Community support to projects with a multiplier effect and elements of reproducibility in other geographical areas.
- 4.7. Shared-cost projects will be one of the Commission's main instruments for boosting the strategic information initiatives. In some market sectors, pilot and demonstration projects will be required to demonstrate new developments on a sufficiently wide scale and to achieve a catalytic effect on the development of European information services which otherwise would remain inadequate in size, coverage and scope. These projects will be defined in collaboration with users and/or industry.

ANNEX II

THE ARRANGEMENTS FOR IMPLEMENTING THE PROGRAMME

1. The Commission will implement the programme in accordance with the technical content specified in Annex I.
2. The number of shared-cost projects for horizontal activities, in particular for work carried out by the IMO, will be increased. Procedures for the implementation of vertical measures will be simplified in order to accommodate the interests of all kinds of market operators and to increase and facilitate their participation in the programme.
3. With reference to Article 7 of the Decision, the Commission states that natural or legal persons from countries which have concluded agreements for cooperation under the programme may, on the basis of the criterion of mutual benefit, participate in projects in the framework of the programme. They shall not, however, benefit from the financial contribution of the Community and will contribute to general administrative costs.
4. The selection of pilot and demonstration projects will normally be based on the usual procedure of calls for proposals published in the *Official Journal of the European Communities*. The objectives will be defined by workplans developed in close consultation with the information services market operators and the committee referred to in Article 4 of the Decision.

The main criterion for supporting projects through calls for proposals will be their potential for expanding the information market without distorting it. Special add-on incentives will be provided to encourage participation by SMEs and less favoured regions, as well as for the transfer of know-how.

5. The Commission may also implement a more flexible funding scheme than the call for proposals in order to provide incentives for the creation of partnership, in particular involving SMEs and organizations in less favoured regions, or for other exploratory activities in different segments of the information services market. This scheme might be operated on a permanent basis.
6. The Commission will make provision for considering in exceptional cases unsolicited project proposals which involve a particularly promising and significant information market development, a highly innovative approach or an exceptional technology or methodology, and which cannot be submitted within the normal call for proposals procedure. The objective of avoiding market distortion will be maintained.
7. The detailed arrangements for the latter two procedures will be implemented by the management committee procedure (type IIb) and in accordance with the Commission's financial regulations. They will be published each year in the *Official Journal of the European Communities*.
8. Projects fully financed by the Commission within the framework of study and services contracts will be implemented through calls for tenders in accordance with the Commission's Financial Regulations. Transparency will be achieved by publishing the work programme and circulation it regularly to trade associations and other bodies.
9. For the implementation of the programme the Commission will also undertake activities designed to achieve the general objectives of the programme and the specific aims of each action line. Such activities will include workshops, seminars, conferences, studies, awareness campaigns, training courses, support schemes for joint ventures, assistance to national focal points and specific support for development of the information market in the less favoured regions.

COUNCIL DIRECTIVE

of 23 December 1991

standardizing and rationalizing reports on the implementation of certain Directives relating to the environment

(91/692/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130s thereof,

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

Having regard to the opinion of the European Parliament ⁽²⁾,

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

Whereas some Community Directives relating to the environment require the Member States to establish a report on the measures taken to implement them; whereas the Commission drafts a consolidated report; whereas other Community Directives relating to the environment call for no such reports;

Whereas the existing provisions on the establishment of reports stipulate different intervals between reports and set different requirements for their content;

Whereas such an obligation should be introduced to enable the Member States and the Commission alike to assess the progress made in implementing these Directives throughout the Community's territory and, at the same time, to provide the general public with a source of information on this subject;

Whereas the existing provisions should therefore be harmonized to make them more consistent and more complete on a sectoral basis;

Whereas the interval at which the Member States submit these reports to the Commission should be fixed at three years, with a one-year interval between sectors; whereas the reports are to be drawn up on the basis of a questionnaire produced by the Commission with the

assistance of a committee and sent to Member States six months before the start of the period referred to by the report; whereas the Commission is to publish a consolidated report on the sector concerned within nine months of Member States' submission of their respective reports;

Whereas, in particular, the report on the implementation of Council Directive 76/160/EEC of 8 December 1975 concerning the quality of bathing water ⁽⁴⁾, as last amended by the 1985 Act of Accession, should appear annually and in sufficient time to inform the public of the quality of bathing water for the most recent period.

Whereas the measures which need to be taken by Member States do not entail the adoption of legislation or regulations since the drawing-up of reports on the implementation of Community Directives does not at present require the adoption of such provisions by Member States,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purpose of this Directive is to rationalize and improve on a sectoral basis the provisions on the transmission of information and the publication of reports concerning certain Community Directives on the protection of the environment, without prejudice to the provisions of the first indent of Article 155 of the Treaty.

Article 2

1. The provisions listed in Annex I shall be replaced by the following:

'At intervals of three years the Member States shall send information to the Commission on the implementation of this Directive, in the form of a sectoral report which shall also cover other pertinent Community Directives. This report shall be drawn up on the basis of a questionnaire or outline drafted by the Commission in accordance with the procedure laid down in Article 6 of Directive 91/692/EEC (*). The questionnaire or outline

(1) OJ No C 214, 29. 8. 1990, p. 6.

(2) OJ No C 19, 28. 1. 1991, p. 587.

(3) OJ No C 60, 8. 3. 1991, p. 15.

(4) OJ No L 31, 5. 2. 1976, p. 1.

shall be sent to the Member States six months before the start of the period covered by the report. The report shall be sent to the Commission within nine months of the end of the three-year period covered by it.

The first report shall cover the period from 1993 to 1995 inclusive.

The Commission shall publish a Community report on the implementation of the Directive within nine months of receiving the reports from the Member States.

(*) OJ No L 377, 31. 12. 1991, p. 48.'

2. The text set out in paragraph 1 shall be inserted into the Directives listed in Annex II as there indicated.

Article 3

Article 13 of Directive 76/160/EEC shall be replaced by the following:

'Article 13

Every year, and for the first time by 31 December 1993, the Member States shall send to the Commission a report on the implementation of this Directive in the current year. The report shall be drawn up on the basis of a questionnaire or outline drafted by the Commission in accordance with the procedure laid down in Article 6 of Directive 91/692/EEC (*). The questionnaire or outline shall be sent to the Member States six months before the start of the period covered by the report. The report shall be made to the Commission before the end of the year in question.

The Commission shall publish a Community report on the implementation of the Directive within four months of receiving the reports from the Member States.

(*) OJ No L 377, 31. 12. 1991, p. 48.'

Article 4

1. The provisions listed in Annex III shall be replaced by the following:

'At intervals of three years the Member States shall send information to the Commission on the implementation of this Directive, in the form of a sectoral report which shall also cover other pertinent Community Directives. This report shall be drawn up on the basis of a questionnaire or outline drafted by the Commission in accordance with the procedure laid down in Article 6 of Directive 91/692/EEC (*). The questionnaire or outline shall be sent to the Member States six months before the start of the period covered by the report. The report shall be sent to the Commission within nine months of the end of the three-year period covered by it.

The first report shall cover the period from 1994 to 1996 inclusive.

The Commission shall publish a Community report on the implementation of the Directive within nine months of receiving the reports from the Member States.

(*) OJ No L 377, 31. 12. 1991, p. 48.'

2. The text set out in paragraph 1 shall be inserted into the Directive listed in Annex IV as there indicated.

3. The following text shall be inserted into the Directives listed in Annex V as there indicated:

'The Commission shall each year communicate to the Member States the information it has received pursuant to this Article.'

Article 5

The provisions listed in Annex VI shall be replaced by the following:

'At intervals of three years Member States shall send information to the Commission on the implementation of this Directive, in the form of a sectoral report which shall also cover other pertinent Community Directives. The report shall be drawn up on the basis of a questionnaire or outline drafted by the Commission in accordance with the procedure laid down in Article 6 of Directive 91/692/EEC (*). The questionnaire or outline shall be sent to the Member States six months before the start of the period covered by the report. The report shall be made to the Commission within nine months of the end of the three-year period covered by it.

The first report shall cover the period 1995 to 1997 inclusive.

The Commission shall publish a Community report on the implementation of the Directive within nine months of receiving the reports from the Member States.

(*) OJ No L 377, 31. 12. 1991, p. 48.'

Article 6

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representatives of the Commission.

The representative of the Commission shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the

representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt measures which shall apply immediately. However, if these measures are not in accordance with the opinion of the committee, they shall be communicated by the Commission to the Council forthwith. In that event:

- the Commission may defer applications of the measures which it has decided for a period of not more than one month from the date of such communication,
- the Council, acting by a qualified majority, may take a different decision within the time limit referred to in the first indent.

Article 7

1. The Member States shall take such measures as are needed to comply with the provisions of:

- Articles 2 and 3 by 1 January 1993 at the latest,
- Article 4 by 1 January 1994 at the latest,
- Article 5 by 1 January 1995 at the latest.

They shall immediately notify the Commission of the measures taken.

2. The existing provisions of the various Directives which have been amended by new provisions shall remain in force until the dates mentioned in the first subparagraph 1.

3. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 23 December 1991.

For the Council

The President

V. VAN ROOY

ANNEX I

Directives amended in accordance with Article 2 (1) of this Directive

- (a) Article 13 (1) of Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community ⁽¹⁾.
- (b) Article 14 of Council Directive 78/176/EEC of 20 February 1978 on waste from the titanium oxide industry ⁽²⁾, as amended by Directive 83/29/EEC ⁽³⁾.
- (c) Article 16 of Council Directive 78/659/EEC of 18 July 1978 on the quality of fresh waters needing protection or improvement in order to support fish life ⁽⁴⁾, as last amended by the 1985 Act of Accession.
- (d) Article 8 of Council Directive 79/869/EEC of 9 October 1979 concerning the methods of measurement and frequencies of sampling and analysis of surface water intended for the abstraction of drinking water in the Member States ⁽⁵⁾, as last amended by Directive 81/855/EEC ⁽⁶⁾.
- (e) Article 14 of Council Directive 79/923/EEC of 30 October 1979 on the quality required of shellfish waters ⁽⁷⁾.
- (f) Article 16 (1) of Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances ⁽⁸⁾.
- (g) Article 5 (1) and (2) (1) first subparagraph of Council Directive 82/176/EEC of 22 March 1982 on limit values and quality objectives for mercury discharges by the chlor-alkali electrolysis industry ⁽⁹⁾.
- (h) Article 5 (1) and (2) of Council Directive 83/513/EEC of 26 September 1983 on limit values and quality objectives for cadmium discharges ⁽¹⁰⁾.
- (i) Article 6 (1) of Council Directive 84/156/EEC of 8 March 1984 on limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry ⁽¹¹⁾.
- (j) Article 5 (1) and (2) of Council Directive 84/491/EEC of 9 October 1982 on limit values and quality objectives for discharges of hexachlorocyclohexane ⁽¹²⁾.
- (k) Article 6 (1) and (2) of Council Directive 86/280/EEC of 12 June 1986 on limit values and quality objectives for discharge of certain dangerous substances included in list I of the Annex to Directive 76/464/EEC ⁽¹³⁾, as last amended by Directive 90/415/EEC ⁽¹⁴⁾.

⁽¹⁾ OJ No L 129, 18. 5. 1976, p. 23.

⁽²⁾ OJ No L 54, 25. 2. 1978, p. 19.

⁽³⁾ OJ No L 32, 3. 2. 1983, p. 28.

⁽⁴⁾ OJ No L 222, 14. 8. 1978, p. 1.

⁽⁵⁾ OJ No L 271, 29. 10. 1979, p. 44.

⁽⁶⁾ OJ No L 319, 7. 11. 1981, p. 16.

⁽⁷⁾ OJ No L 281, 10. 11. 1979, p. 47.

⁽⁸⁾ OJ No L 20, 26. 1. 1980, p. 43.

⁽⁹⁾ OJ No L 81, 27. 3. 1982, p. 29.

⁽¹⁰⁾ OJ No L 291, 24. 10. 1983, p. 2.

⁽¹¹⁾ OJ No L 74, 17. 3. 1984, p. 49.

⁽¹²⁾ OJ No L 274, 17. 10. 1984, p. 11.

⁽¹³⁾ OJ No L 181, 4. 7. 1986, p. 16.

⁽¹⁴⁾ OJ No L 219, 14. 8. 1990, p. 49.

ANNEX II

Directives supplemented in accordance with Article 2 (2) of this Directive

- (a) Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States⁽¹⁾, as last amended by Directive 79/869/EEC⁽²⁾.

The text of Article 2 (1) of this Directive is incorporated as Article 9a.

- (b) Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption⁽³⁾, as last amended by Directive 81/858/EEC⁽⁴⁾.

The text of Article 2 (1) of this Directive is incorporated as Article 17a.

⁽¹⁾ OJ NO L 194, 25. 7. 1975, p. 26.

⁽²⁾ OJ NO L 271, 29. 10. 1979, p. 44.

⁽³⁾ OJ NO L 229, 30. 8. 1980, p. 11.

⁽⁴⁾ OJ NO L 319, 7. 11. 1981, p. 19.

ANNEX III

Directives amended in accordance with Article 4 (1) of this Directive

- (a) Article 8 of Council Directive 80/779/EEC of 15 July on air quality limit values and guide values for sulphur dioxide and suspended particulates⁽¹⁾, as last amended by Directive 89/427/EEC⁽²⁾.
- (b) Article 18 of Council Directive 82/501/EEC of 24 June 1982 on the major-accident hazards of certain industrial activities⁽³⁾, as last amended by Directive 88/610/EEC⁽⁴⁾.
- (c) Article 6 of Council Directive 82/884/EEC of 3 December 1982 on a limit value for lead in the air⁽⁵⁾.
- (d) Article 8 of Council Directive 85/203/EEC of 7 March 1985 on air quality standards for nitrogen dioxide⁽⁶⁾, as amended by Directive 85/580/EEC⁽⁷⁾.
- (e) Article 13 (1) of Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos⁽⁸⁾.

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 30.

⁽²⁾ OJ No L 201, 14. 7. 1989, p. 53.

⁽³⁾ OJ No L 230, 5. 8. 1982, p. 1.

⁽⁴⁾ OJ No L 336, 7. 12. 1988, p. 14.

⁽⁵⁾ OJ No L 378, 31. 12. 1982, p. 15.

⁽⁶⁾ OJ No L 87, 27. 3. 1985, p. 1.

⁽⁷⁾ OJ No L 372, 31. 12. 1985, p. 36.

⁽⁸⁾ OJ No L 85, 28. 3. 1987, p. 40.

ANNEX IV**Directives amended in accordance with Article 4 (2) of this Directive**

- (a) Council Directive 75/716/EEC of 24 November 1975 on the approximation of the laws of the Member States relating to the sulphur content of certain liquid fuels⁽¹⁾, as last amended by Directive 87/219/EEC⁽²⁾.

The text of Article 4 (2) of this Directive is incorporated in Article 7a.

- (b) Council Directive 84/360/EEC of 28 June 1984 on the combating of air pollution from industrial plants⁽³⁾.

The text of Article 4 (2) of this Directive is incorporated as Article 15a.

⁽¹⁾ OJ No L 307, 27. 11. 1975, p. 22.

⁽²⁾ OJ No L 91, 3. 4. 1987, p. 19.

⁽³⁾ OJ No L 188, 16. 7. 1984, p. 20.

ANNEX V**Directives amended in accordance with Article 4 (3) of this Directive**

- (a) Council Directive 80/779/EEC of 15 July 1980 on air quality limit values and guide values for sulphur dioxide and suspended particulates, as amended by Directive 89/427/EEC.

The text of Article 4 (3) of this Directive is incorporated as Article 7 (4).

- (b) Council Directive 82/884/EEC of 3 December 1982 on a limit value for lead in the air.

The text of Article 4 (3) of this Directive is incorporated as Article 5 (4).

- (c) Council Directive 85/203/EEC of 7 March 1985 on air quality standards for nitrogen dioxide, as amended by Directive 85/580/EEC.

The text of Article 4 (3) of this Directive is incorporated as Article 7 (4).

ANNEX VI

Directives amended in accordance with Article 5 of this Directive

- (a) Article 18 of Council Directive 74/439/EEC of 16 June 1975 on the disposal of waste oils ⁽¹⁾, as amended by Directive 87/101/EEC ⁽²⁾.
- (b) Article 12 of Council Directive 75/442/EEC of 15 July 1975 on waste ⁽³⁾, as amended by Directive 91/156/EEC ⁽⁴⁾.
- (c) Article 10 of Council Directive 76/403/EEC of 6 April 1976 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls ⁽⁵⁾.
- (d) Article 16 of Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste ⁽⁶⁾, as last amended by the 1985 Act of Accession.
- (e) Article 13 (1) of Council Directive 84/631/EEC of 6 December 1984 on the supervision and control within the European Community of the trans-frontier shipment of hazardous waste ⁽⁷⁾, as last amended by Commission Directive 87/112/EEC ⁽⁸⁾.
- (f) Article 6 of Council Directive 85/339/EEC of 27 June 1985 on containers of liquids for human consumption ⁽⁹⁾.
- (g) Article 17 of Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture ⁽¹⁰⁾.

⁽¹⁾ OJ No L 194, 25. 7. 1975, p. 23.

⁽²⁾ OJ No L 42, 12. 2. 1987, p. 43.

⁽³⁾ OJ No L 194, 25. 7. 1975, p. 39.

⁽⁴⁾ OJ No L 78, 26. 3. 1991, p. 32.

⁽⁵⁾ OJ No L 108, 26. 4. 1976, p. 41.

⁽⁶⁾ OJ No L 84, 31. 3. 1978, p. 43.

⁽⁷⁾ OJ No L 236, 13. 12. 1984, p. 31.

⁽⁸⁾ OJ No L 48, 17. 2. 1987, p. 31.

⁽⁹⁾ OJ No L 176, 6. 7. 1985, p. 18.

⁽¹⁰⁾ OJ No L 181, 4. 7. 1986, p. 6.