

Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease

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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 poultry is listed in Annex II of the Treaty and whereas the marketing of poultry constitutes an important source of revenue for the agricultural population;

Whereas, it is necessary to establish at Community level the control measures to be taken in the event of an outbreak of Newcastle disease in order to ensure development of the poultry sector and contribute to the protection of animal health in the Community;

Whereas minimum Community control measures should furthermore be provided for against Newcastle disease to apply to certain other species;

Whereas an outbreak of Newcastle disease can quickly take on epizootic proportions, causing mortality and disturbances on a scale liable to reduce sharply the profitability of farming or poultry as a whole;

Whereas action must be taken as soon as the presence of the disease is suspected so that immediate and effective control measures can be implemented when its presence is confirmed; whereas such measures must be modulated by the competent authorities to take account of whether or not a country carries out a prophylactic vaccination programme in all or part of its territory;

Whereas it is necessary to prevent any spread of the disease as soon as an outbreak occurs, by carefully monitoring movements of animals and the use of products liable to be contaminated, and, where appropriate, by vaccination;

Whereas diagnosis of the disease must be carried out under the auspices of responsible national laboratories, the coordination of which must be ensured by a Community reference laboratory;

Whereas it is necessary to make provision for the Member States which vaccinate to draw up vaccination plans and to inform the Commission and other Member States about those plans;

Whereas Article 4 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field(4) applies in the event of the occurrence of Newcastle disease;

Whereas it is appropriate to confer upon the Commission the task of taking the necessary applicatory measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Without prejudice to the Community provisions governing intra-Community trade, this Directive defines the Community control measures to be applied in the event of an outbreak of Newcastle disease in:

- (a) poultry;
- (b) racing pigeons and other birds kept in captivity.

This Directive shall not apply where Newcastle disease is detected in wild birds living freely; however, in that case, the Member State concerned shall inform the Commission of any measure it takes.

Article 2

For the purpose of this Directive, the definitions given in Article 2 of Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs(5) shall apply as appropriate.

The following definitions shall also apply:

(a) 'infected poultry' means any poultry:

- in which the presence of Newcastle disease has been officially confirmed following an examination by an approved laboratory, or

- in the case of second and subsequent outbreaks in which clinical symptoms or post-mortem lesions consistent with Newcastle disease are present;

(b) 'poultry suspected of being infected' means any poultry showing clinical signs or post-mortem lesions which are such that the presence of Newcastle disease may reasonably be suspected;

(c) 'poultry suspected of being contaminated' means any poultry which may have been directly or indirectly exposed to the Newcastle-disease virus;

(d) 'swill' means waste from kitchens, restaurants or, where appropriate, from industries using meat;

(e) 'competent authority' means the competent authority within the meaning of Article 2 (6) of Directive 90/425/EEC(6) ;

(f) 'official veterinarian' means the veterinarian designated by the competent authority;

(g) 'racing pigeon' means any pigeon transported or intended for transport from its pigeon house to be released so that it may freely fly back to its pigeon house or to any other destination;

(h) 'pigeon house' means any installation used for keeping or breeding racing pigeons.

Article 3

Member States shall ensure that there is compulsory and immediate notification of the suspected presence of Newcastle disease to the competent authority.

Article 4

1. When poultry in a holding are suspected of being infected or contaminated with Newcastle disease, Member States shall ensure that the official veterinarian immediately activates official investigation arrangements to confirm or rule out the presence of the disease and, in particular, must take or have taken the samples necessary for laboratory examination.

2. As soon as the suspected infection is notified, the competent authority shall have the holding placed under official surveillance and shall in particular require that:

(a) a record be made of all categories of poultry on the holding showing in respect of each of the categories the numbers of poultry which have died, which show clinical signs, and which show no signs. The record shall be kept up-to-date to include birds born or dying during the period in which there is a suspicion. The data in the record shall be kept up-to-date and be produced on request, and may be checked at each visit;

(b) all poultry on the holding are kept in their living quarters or confined in some other place where they can be isolated and without contact with other poultry;

(c) no poultry enter or leave the holding;

(d) all movement

- of persons, other animals and vehicles to or from the holding,

- of poultry meat or carcasses, or of animal feed, implements, waste, droppings, manure litter or anything liable to transmit Newcastle disease be subject to authorization by the competent authority;

(e) no eggs shall leave the holding with the exception of eggs sent directly to an establishment approved for the manufacture and/or processing of egg products under Article 6 (1) of Directive

89/437/EEC(7) , and transported under an authorization which has been granted by the competent authority. Such authorization must meet the requirements laid down in Annex 1;

(f) appropriate means of disinfection be installed at the entrances and exits of buildings housing poultry and of the holding itself;

(g) an epizootiological inquiry be carried out in accordance with Article 7.

3. Until such time as the official measures laid down in paragraph 2 are enforced, the owner or keeper of any poultry in which disease is suspected shall take all reasonable action to ensure compliance with paragraph 2, except for (g) thereof.

4. The competent authority may apply any of the measures provided for in paragraph 2 to other holdings should their location, their configuration or contacts with the holding where the disease is suspected give reason to suspect possible contamination.

5. The measures referred to in paragraphs 1 and 2 shall not be withdrawn until the suspicion of Newcastle disease has been ruled out by the official veterinarian.

Article 5

1. Once the presence of Newcastle disease in poultry has been officially confirmed on a holding, the Member States shall ensure that the competent authority requires, in addition to the measures listed in Article 4 (2), the following measures to be undertaken:

(a) all poultry on the holding shall without delay be killed on the spot. The poultry which have died or been killed and all eggs shall be destroyed. These operations shall be carried out in a way which minimizes the risk of spreading disease;

(b) any substance or waste, such as animal feed, litter or manures liable to be contaminated, shall be destroyed or treated appropriately. This treatment, carried out in accordance with the instructions of the official veterinarian, shall ensure the destruction of any Newcastle-disease virus present;

(c) where poultry from the holding have been slaughtered during the presumed incubation period of disease the meat from those poultry shall wherever possible be traced and destroyed;

(d) hatching eggs laid during the presumed incubation period which have been moved from the holding shall be traced and destroyed; but poultry which have already hatched from the eggs shall be placed under official surveillance; table eggs laid during the presumed incubation period which have been moved from the holding shall wherever possible be traced and destroyed, unless they have previously been properly disinfected;

(e) after carrying out operations listed under (a) and (b), the buildings used for housing poultry, their surroundings, the vehicles used for transport and all equipment likely to be contaminated shall be cleaned and disinfected in accordance with the provisions of Article 11;

(f) no poultry shall be reintroduced to the holding until at least 21 days after completion of operations provided for under (e);

(g) an epizootiological inquiry shall be carried out in accordance with Article 7.

2. The competent authority may extend the measures provided for in paragraph 1 to other neighbouring holdings should their location, their configuration, or contact with the holding where the disease has been confirmed give reason to suspect possible contamination.

3. Where a strain of Newcastle-disease virus with an ICPI (intracerebral pathogenicity index) greater than 0,7 and lower than 1,2 is isolated in a flock of poultry that presents no clinical signs of Newcastle disease and it has been demonstrated by the Community reference laboratory referred to in Article 15 that the virus isolate in question derives from an attenuated live Newcastle-disease vaccine, the competent authority may grant a derogation from the requirements under (a) to (f), of paragraph 1, provided that the holding concerned is placed under official surveillance for 30 days and must require in particular that:

- the provisions of Article 4 (2) (a), (b), (d), (e) and (f) are applied,

- no poultry may leave the holding except to be taken directly to a slaughterhouse designated by the competent authority.

The competent authority responsible for this slaughterhouse must be informed of the intention to send poultry there for slaughter and as soon as the poultry arrive at the slaughterhouse they shall be kept and slaughtered separately from other poultry.

4. Fresh meat from the poultry referred to in paragraph (3) of this Article must carry the health mark provided for in Article 5 (1) of Directive 91/494/EEC.

5. The provisions laid down in paragraph 3 shall be subject to a review taking into account developments in scientific research with a view to adopting harmonized rules for the use of Newcastle-disease vaccines in the Community.

Article 6

In the case of holdings which consist of two or more separate flocks, the competent authority may, in accordance with criteria set by the Commission under the procedure laid down in Article 25, grant a derogation from the requirements of

Article 5

(1), for healthy flocks of a holding which is infected, provided that the official veterinarian has confirmed that the operations carried out there are such that the flocks are completely separate as regards housing, keeping and feeding, so that the virus cannot spread from one flock to another.

Article 7

1. The epizootiological inquiry shall deal with:

- the length of time during which Newcastle disease may have existed on the holding or in the pigeon house;
- the possible origin of the Newcastle disease on the holding or in the pigeon house and the identification of other holdings or pigeon houses in which there are poultry, pigeons or other birds kept in captivity which may have become infected or contaminated from the same source;
- the movement of persons, poultry, pigeons or other birds kept in captivity or other animals, vehicles, eggs, meat and carcasses and any implement or substance likely to have carried Newcastle-disease virus to or from the holding or pigeon house in question.

2. In order to provide full coordination of all measures necessary to ensure eradication of Newcastle disease as quickly as possible and for the purpose of carrying out the epizootiological inquiry, a crisis unit shall be established.

The general rules concerning national crisis units and Community crisis units will be laid down by the Council, acting by a qualified majority proposal from the Commission.

Article 8

1. Where the official veterinarian has reason to suspect that poultry on any holding may have been contaminated as a result of the movement of persons, animals or vehicles or in any other way, that holdings shall be placed under official control in accordance with paragraph 2.

2. The purpose of the official control shall be to detect immediately any suspicion of Newcastle disease, count the poultry and monitor their movements and, where appropriate, to take the action provided for in paragraph 3.

3. When a holding is subject to official control under paragraphs 1 and 2, the competent authority shall prohibit removal of poultry from the holding other than for transport directly to a slaughterhouse under official supervision for the purpose of immediate slaughter. Before granting such authorization, the official veterinarian must have carried out a clinical examination of all the poultry to exclude presence of Newcastle disease on the holding. The movement restrictions referred to in this

Article shall be imposed for a period of 21 days from the latest date of potential contamination; however, such restrictions must apply for a period of at least seven days.

4. Where it considers that conditions permit, the competent authority may limit the measures provided for in this Article to a part of the holding and to the poultry contained therein, provided that the poultry there have been housed, kept and fed completely separately by separate staff.

5. Where the official veterinarian has reason to suspect racing pigeons or any pigeon house of being contaminated by the Newcastle-disease virus, he shall take all appropriate steps to ensure that the pigeon house is subject to restrictions, including a ban on all movement of racing pigeons outside the pigeon house for 21 days.

Article 9

1. Once the diagnosis of Newcastle disease has been officially confirmed in poultry, the Member States shall ensure that the competent authority establishes around the infected holding a protection zone based on a minimum radius of three kilometres, itself contained in a surveillance zone based on a minimum radius of 10 kilometres. The establishment of the zones must take account of geographical, administrative, ecological and epizootiological factors relating to Newcastle disease, and of monitoring facilities.

2. The measures applied in the protection zone shall include:

- (a) the identification of all holdings having poultry within the zone;
- (b) periodic visits to all the holdings having poultry, a clinical examination of those poultry including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept;
- (c) the keeping of all poultry in their living quarters or some other place where they can be isolated;
- (d) the use of appropriate means of disinfection at the entrances and exits of the holding;
- (e) the control of movements of persons handling poultry, poultry carcasses and eggs and vehicles carrying poultry, carcasses and eggs within the zone; in general, transport of poultry shall be prohibited, except for transit by major highways or railways;
- (f) a prohibition on removing poultry and hatching eggs from the holding on which they are kept unless the competent authority has authorized the transport;
- (i) of poultry for immediate slaughter to a slaughterhouse preferably located in the infected area or, if that is not possible, to a slaughterhouse designated by the competent authority outside the infected area. The special health mark provided for in

Article 5

(1) of Directive 91/494/EEC(8) must be applied to this poultry meat;

(ii) of day-old chicks or ready-to-lay pullets to a holding within the surveillance zone at which there are no other poultry. However, the Member States, that are not in a position to be able to provide transport of day-old chicks or ready-to-lay pullets to a holding situated within the surveillance zone, shall be authorized, in accordance with the procedure laid down in Article 25, to have the said chicks and pullets transported to a holding outside the surveillance zone. The holdings referred to above must be placed under official control in accordance with Article 8 (2);

(iii) of hatching eggs to a hatchery designated by the competent authority; before dispatch, eggs and their packing must be disinfected.

Movements allowed in (i), (ii) and (iii) shall be directly executed, under official control. They shall be authorized only after the official veterinarian has carried out a health inspection of the holding. The means of transport used must be cleaned and disinfected before and after use;

- (g) a prohibition on removing or spreading used litter or poultry manure without authorization;
- (h) the prohibition of fairs, markets, shows or other gatherings of poultry or other birds.

3. The measures applied in the protection zone shall be maintained for at least 21 days after the carrying out of preliminary cleaning and disinfection operations on the infected holding in accordance with Article 11. The protection zone shall thereafter be part of the surveillance zone.

4. The measures applied in the surveillance zone shall include:

- (a) the identification of all holdings having poultry within the zone;
- (b) the control of poultry and hatching egg movement within the zone;
- (c) a prohibition on the movement of poultry out of the zone during the first 15 days, except for movement directly to a slaughterhouse outside the surveillance zone designated by the

competent authority. The special health mark provided for in Article 5 of Directive 91/494/EEC must be applied to this poultry meat;

(d) a prohibition on the movement of hatching eggs out of the surveillance zone unless to a hatchery designated by the competent authority. Before dispatch the eggs and their packing must be disinfected;

(e) a prohibition on the movement of used litter or poultry manure out of the zone;

(f) a prohibition of fairs, markets, shows or other gatherings of poultry and other birds;

(g) without prejudice to the provisions of (a) and (b), the prohibition of transport of poultry except for transit by major highways or railways.

5. The measures applied in the surveillance zone shall be maintained for at least 30 days after the carrying out of preliminary cleaning and disinfection operations on the infected holding in accordance with Article 11.

6. Where the zones are situated in the territory of more than one Member State, the competent authorities of the Member States concerned shall cooperate in establishing the areas described in paragraph 1. However, if necessary, the protection zone and the surveillance zone shall be established by the procedure provided for in Article 25.

7. Where the epizootiological enquiry referred to in Article 7 confirms that the outbreak is due to an infection where there is no evidence of lateral spread, the size and duration of the protection and surveillance zones may be reduced under the procedure laid down in Article 25.

Article 10

Member States shall ensure that:

(a) the competent authority determines the arrangements allowing them to trace the movement of eggs, poultry and birds kept in captivity;

(b) the owner or keeper of poultry and/or racing pigeons and/or birds kept in captivity is required to supply the competent authority, in response to any request by that authority, with information concerning poultry and eggs entering or leaving his holding, as well as information on the races or shows in which the racing pigeons have taken part;

(c) all persons engaged in the transport or marketing of poultry, eggs, racing pigeons and birds kept in captivity are able to supply the competent authority with information concerning the movements of poultry, eggs, racing pigeons and birds kept in captivity which they have transported or marketed and to furnish all the details concerning such information.

Article 11

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) instructions given by the official veterinarian;

(ii) the procedure for cleaning and disinfecting an infected holding, as laid down in Annex II.

Article 12

Collection of samples and laboratory testing to detect the presence of Newcastle-disease virus shall be carried out in accordance with Annex III.

Article 13

Member States shall ensure that the competent authority takes all the necessary measures for persons established in the protection and surveillance zones to be informed of the restrictions in force and make all necessary arrangements for the appropriate implementation of the measures in question.

Article 14

1. Member States shall ensure that, in each Member State there is designated:

(a) a national laboratory at which facilities and expert personnel shall be maintained to permit full antigenic and biological typing of Newcastle-disease virus at all times and to confirm results obtained in regional diagnostic laboratories;

(b) a national laboratory at which reagents for use in regional laboratories are tested;

(c) a national institute or laboratory at which vaccines allowed for prophylactic use in the country or stock-piled for emergency use may be tested for efficacy, potency and purity.

2. The national laboratories listed in Annex IV shall be responsible for coordinating standards and methods of diagnosis, use of reagents and testing of vaccines.

3. The national laboratories listed in Annex IV shall be responsible for coordinating the standards and diagnostic methods laid down in each Newcastle-disease diagnostic laboratory within the Member State. To this end:

(a) they may provide diagnostic reagents to national laboratories;

(b) they shall control the quality of all diagnostic reagents used in that Member State;

(c) they shall arrange comparative tests periodically;

(d) they shall hold isolates of Newcastle-disease virus from cases confirmed in that Member State;

(e) they shall ensure the confirmation of positive results obtained in regional diagnostic laboratories.

4. The national laboratories listed in Annex IV shall liaise with the Community reference laboratory referred to in Article 15.

Article 15

The Community reference laboratory for Newcastle disease is mentioned in Annex V. Without prejudice to the provisions of Decision 90/424/EEC(9) , and in particular Article 28 thereof, the powers and duties of the laboratory shall be those appearing in the said Annex.

Article 16

1. Member States shall ensure that:

(a) vaccination against Newcastle disease with vaccines authorized by the competent authority may be used for a prophylactic purpose or to supplement the control measures carried out when the disease appears;

(b) the only vaccines allowed are those which have received a marketing authorization from the competent authority of the Member State in which the vaccine is used.

2. Further criteria for using vaccines against Newcastle disease may be established in accordance with the procedure laid down in Article 25.

Article 17

1. A Member State in which voluntary or compulsory prophylactic vaccination against Newcastle disease is carried out shall inform the Commission and the other Member States.

2. The information given in accordance with paragraph 1 must specify:

- the characteristics and composition of the vaccine to be used;
- the procedures for supervision of the distribution, storage and use of vaccines;
- the species and categories of poultry which may or shall be subject to vaccination;
- the areas in which vaccination may or shall be carried out;
- the reasons for which vaccination is carried out.

3. Member States may provide for the establishment of a vaccination programme for racing pigeons. Where this is the case, they must notify the Commission. Without prejudice to such a programme, the Member States shall ensure that the organizers of races and shows take the necessary steps so that only racing pigeons which have been vaccinated against Newcastle disease may be entered in races and shows.

4. The detailed rules for applying this Article, in particular with respect to the criteria to be adopted, and any derogations that may be granted taking into account the health status of the Member States shall be fixed in accordance with the procedure laid down in Article 25.

Article 18

1. Member States shall ensure that, when Newcastle disease has been confirmed, the competent authority, in order to supplement the other control measures provided for in this Regulation, is able to specify a territorial area and period in which the prompt and systematic vaccination (emergency vaccination) of designated species of poultry shall be carried out under official control. A Member State applying emergency vaccination shall inform the Commission and other Member States within the framework of the standing veterinary committee, set up by Decision 68/361/EEC(10) , about the Newcastle-disease situation and emergency vaccination programme.

2. In the case referred to in paragraph 1, the vaccination or re-vaccination of poultry on the holding subject to the restrictions referred to in Article 4 is prohibited.

3. In the case referred to in paragraph 1:

(a) the designated species of poultry shall be vaccinated as soon as possible;

(b) all poultry of designated species born on or transferred to a holding inside the vaccination area must be or have been vaccinated;

(c) throughout the vaccination operation provided for in paragraph 1 all poultry of designated species kept on holdings inside the vaccination area must remain there except:

- day-old chicks moved to a holding inside the vaccination area where they shall be vaccinated;

- poultry moved direct to a slaughterhouse for immediate slaughter. If the slaughterhouse is located outside the vaccination area the movement of poultry shall be permitted only after the official veterinarian has carried out a health inspection of the holding;

(d) when the vaccination operations provided for in (a) have been completed movements out of the vaccination area may be authorized for:

- day-old chicks intended for meat production may be moved to a holding where they shall be vaccinated; the holding in question must be kept under surveillance until the poultry which have been moved have been slaughtered;

- poultry vaccinated more than 21 days previously and intended for immediate slaughter;

- hatching eggs which originate from breeding poultry vaccinated at least 21 days previously; the eggs and their packing must be disinfected before movement.

4. The measures provided for in (b) and (d) of paragraph 3 shall be applied for a period of three months following completion of vaccination operations provided for in paragraph 1; they may be extended for one or more additional periods of three months.

5. By way of derogation from (a) and (b) of paragraph 3, the competent authorities may exempt certain flocks of particular scientific value from systematic vaccination, provided that all necessary steps are taken by the competent authority to ensure protection of their health and to subject them to periodic serological checks.

6. The Commission shall follow the development of the disease situation and if necessary it may, in accordance with the procedure laid down in Article 25, take a decision in particular in relation to control of movement and vaccination.

Article 19

1. Where carrier pigeons or birds kept in captivity are suspected of being infected with Newcastle disease, Member States shall ensure that the official veterinarian immediately starts the official investigation procedures for confirming or notifying the presence of the disease; in particular, he shall take adequate samples for laboratory examination or see that they are taken.

2. As soon as it has been notified of the suspicion, the competent authority shall place the holding or pigeon house under official surveillance and order that no pigeon or bird kept in captivity, and nothing likely to transmit Newcastle disease, may leave the pigeon house or holding.

3. The measures provided for in paragraphs 1 and 2 shall not be withdrawn until the suspicion of Newcastle disease has been ruled out by the official veterinarian.

4. As soon as the presence of Newcastle disease has been officially confirmed, the competent authority shall, inter alia, order:

(a) application of the control and eradication measures provided for in Article 5 (1) (a), (b), (e) and (f) to the carrier pigeons or birds kept in captivity and pigeon houses infected with Newcastle disease; or

(b) at least

(i) a ban on movement of the pigeons or birds kept in captivity outside the pigeon house or holding for at least 60 days after the clinical signs of Newcastle disease have disappeared;

(ii) destruction or treatment of any matter or waste likely to be contaminated. Treatment must guarantee the destruction of any Newcastle-disease virus present and all waste that has accumulated during the 60-day period referred to in (i);

(c) an epizootiological inquiry in accordance with Article 7.

5. To the extent that it is required for the proper application of the provisions laid down in this Article, the Member States shall furnish to the Commission, within the Standing Veterinary Committee, information on the situation of the disease and the control measures applied in accordance with the model appearing in Annex VI.

Article 20

1. The use of swill originating from means of international transport, such as ships, land vehicles or aircraft, shall be prohibited for the feeding of poultry; such swill shall be collected and destroyed under official supervision.

2. The use of swill other than as defined in paragraph 1, or poultry scraps, may be authorized for the feeding of poultry only after a heat-treatment in appropriate facilities ensuring that the disease is not transmitted and the Newcastle-disease virus is destroyed.

3. If necessary, the Commission shall, in accordance with the procedure laid down in Article 25, lay down the detailed rules for the implementation of paragraph 2.

Article 21

1. Each Member State shall draw up a contingency plan, specifying the national measures to be implemented in the event of an outbreak of Newcastle disease.

This plan must 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 deems necessary for emergency vaccination.

2. The criteria to be applied for drawing up the plan are laid down in Annex VII.

3. Plans drawn up in accordance with the criteria listed in Annex VII shall be submitted to the Commission not later than six months after this Directive is brought into application.

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 25.

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

Article 22

Commission experts may, in collaboration with the competent authorities, and insofar as is necessary to ensure uniform application of this Directive, make on-the-spot checks. In order to do this, they may check a representative percentage of establishments to see whether the competent authorities are checking that these establishments are fulfilling the requirements of

this Directive. The Commission shall inform the Member States of the result of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the 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 25.

Article 23

The detailed conditions governing the Community's financial contribution to the measures connected with the application of this Directive are laid down in Decision 90/424/EEC.

Article 24

The Annexes shall be amended, as and when required, by the Council acting by a qualified majority acting on a proposal from the Commission, in particular in order to take into account developments in research and in diagnostic procedures.

Article 25

1. Where the procedure laid down in this Article is to be followed, the Standing Veterinary Committee, set up by Decision 68/361/EEC, hereinafter referred to as 'the Committee', shall be informed without delay by its Chairman either on his own initiative or at the request of the representative of a Member State.

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 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.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 26

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

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.

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

Article 27

This Directive is addressed to the Member States.

Done at Brussels, 14 July 1992

For the Council The President J. GUMMER

(1) OJ No C 146, 5. 6. 1991, p. 12.

(2) OJ No C 280, 28. 10. 1991, p. 174.

(3) OJ No C 339, 31. 12. 1991, p. 14.

(4) OJ No L 224, 18. 8. 1990, p. 19; amended by Decision 91/133/EEC (OJ No L 66, 13. 3. 1991, p.18).

(5) OJ No L 303, 31. 10. 1990, p. 6; as last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

(6) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ No L 224, 18. 8. 1990, p. 29); as last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

(7) Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products (OJ No L 272, 22. 7. 1989, p. 87); as amended by Directive 89/662/EEC (OJ No L 395, 30. 12. 1989, p. 13).

(8) Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (OJ No L 268, 24. 9. 1991, p. 35).

(9) OJ No L 224, 18. 8. 1990, p. 19.

(10) OJ No L 255, 18. 10. 1968, p. 23.

ANNEX I

AUTHORIZATION TO REMOVE EGGS FROM A HOLDING SUBJECT TO THE CONDITIONS OF ARTICLE 4 (2) (e) OF THIS DIRECTIVE The authorization issued by the competent authority to transport eggs from a suspect holding subject to the provisions of Article 4 (2) (e) to an establishment approved for the manufacture and processing of egg products in accordance with the provisions of Article 6 (1) of Directive 89/437/EEC, hereinafter called the designated establishment, must meet the following conditions:

1. in order to be allowed to be removed from a suspect undertaking, eggs must:

(a) comply with the requirements laid down in Chapter IV of the Annex to Directive 89/437/EEC;

(b) be sent directly from the suspect undertaking to the designated establishment; each consignment must be sealed before dispatch by the official veterinarian of the suspect holding and must remain sealed throughout transport to the designated establishment;

2. the official veterinarian of the suspect undertaking shall inform the competent authority of the designated establishment of his intention of sending eggs to it;

3. the competent authority responsible for the designated establishment shall ensure that:

(a) eggs referred to in 1 (b) will be kept isolated from other eggs from the time they arrive until they are processed;

(b) the shells of such eggs shall be regarded as high-risk material in accordance with Article 2 (2) of Directive 90/667/EEC (1) and shall be dealt with in accordance with the requirements of Chapter II of that Directive;

(c) the packaging material, the vehicles used to transport eggs referred to in 1 (b) and all premises with which the eggs come into contact are cleaned and disinfected in such a way as to destroy all Newcastle disease virus;

(d) the official veterinarian of the suspect holding shall be informed of all consignments of processed eggs.

(1) Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the elimination and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin, and amending Directive 90/425/EEC (OJ No L 363, 27. 12. 1990, p. 51).

ANNEX II

PROCEDURE FOR CLEANING AND DISINFECTING AN INFECTED HOLDING I. Preliminary cleaning and disinfecting

(a) As soon as the carcasses of the poultry have been removed for disposal, those parts of the premises in which the poultry was 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 11 of this Directive.

(b) Any tissue of poultry or eggs which could have contaminated buildings, yards, utensils etc. should be carefully collected and disposed of with the carcasses.

(c) The used disinfectant must 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 water.

(b) After washing with 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 water.

(d) Used litter and manure must be treated by a method capable of killing the virus. This method must comprise at least one of the following practices:

(i) incineration or steam treatment at a temperature of 70 °C;

(ii) burying deep enough to prevent access by vermin and wild birds;

(iii) stacking and dampening (if necessary to facilitate fermentation), covering to keep in the heat so that a temperature of 20 °C is attained and leaving covered for 42 days so as to prevent access by vermin and wild birds.

ANNEX III

DIAGNOSTIC PROCEDURES FOR THE CONFIRMATION AND DIFFERENTIAL DIAGNOSIS OF NEWCASTLE DISEASE The following procedures for the isolation and characterization of Newcastle-disease viruses should be regarded as guidelines and the minima to be applied in the diagnosis of the disease.

The virus responsible for Newcastle disease is the prototype virus of the Paramyxoviridae. At present, there are nine serologically distinguishable groups of Avian Paramyxoviruses, which have been designated PMV-1 to PMV-9. All Newcastle disease viruses are placed in the PMV-1 group. For the purpose of the diagnostic procedures for the confirmation and differential diagnosis of Newcastle disease the following definition shall apply:

'Newcastle disease' means an infection of poultry caused by any avian strain of the paramyxovirus 1 with an intracerebral pathogenicity index (ICPI) in day-old chicks greater than 0,7.

CHAPTER 1 Sampling and treatment of samples 1. Samples

Cloacal swabs (or faeces) and tracheal swabs from sick birds; faeces or intestinal contents, brain tissue, trachea, lungs, liver, spleen and other obviously affected organs from recently dead birds.

2. Treatment of samples

The organs and tissues listed in paragraph 1 may be pooled, but separate treatment of faecal material is essential. Swabs should be placed in sufficient antibiotic medium to ensure full immersion. Faeces samples and organs should be homogenized (in an enclosed blender or using a pestle and mortar and sterile sand) in antibiotic medium and made to 10-20 % w/v suspensions in the medium. The suspensions should be left for about two hours at ambient temperature (or longer periods at 4 °C) and then clarified by centrifugation (e.g. 800 to 1 000 g for 10 minutes).

3. Antibiotic medium

Different laboratories have used various formulations of antibiotic medium with success and laboratories referred to in Annex II will be able to offer advice for a particular country. High concentrations of antibiotics are required for faeces samples and a typical mixture is: 10 000 units/ml penicillin, 10 mg/ml streptomycin, 0,25 mg/ml gentamycin and 5 000 units/ml mycostatin in phosphate buffered saline (PBS) These levels can be reduced up to five-fold for tissues and tracheal swabs. For control of Chlamydia organisms, 50 mg/ml oxytetracycline may

be added. It is imperative when making the medium that the pH is checked after the addition of the antibiotics and readjusted to pH 7,0-7,4.

CHAPTER 2 Virus isolation Virus isolation in embryonated fowls' eggs

The clarified supernatant fluid should be inoculated in 0,1-0,2 ml amounts into the allantoic cavity of each of a minimum of four embryonated, fowls' eggs which have been incubated for 8 to 10 days. Ideally, these eggs should be obtained from a specific pathogen-free flock, but when this is impracticable it is acceptable to use eggs obtained from a flock shown to be free of antibodies to Newcastle-disease virus. The inoculated eggs are held at 37 °C and candled daily. Eggs with dead or dying embryos as they arise, and all remaining eggs six days after inoculation should be chilled to 4 °C and the allantoic-amniotic fluids tested for haemagglutination activity. If no haemagglutination is detected the above procedure is repeated using undiluted allantoic/amniotic fluid as inoculum.

When haemagglutination is detected the presence of bacteria should be excluded by culture. If bacteria are present the fluids may be passed through a 450 nm membrane filter, further antibiotics added and inoculated into embryonated eggs as above.

CHAPTER 3 Differential diagnosis 1. Preliminary differentiation

It is intended that all haemagglutinating viruses should be submitted to the national laboratory referred to in Annex II for full identification, characterization and pathogenicity tests. However, it is important that interim control measures for Newcastle disease aimed at limiting the spread of the virus should be implemented as soon as possible and regional laboratories should be able to identify the presence of Newcastle disease virus. The haemagglutinating fluids should, therefore, be used in an haemagglutination inhibition test as described in Chapters 5 and 6. Positive inhibition 1. e. 24, or more, with the Newcastle disease virus specific polyclonal antiserum of titre known to be at least 29 would serve as preliminary identification enabling the imposition of interim control measures.

2. Confirmatory identification

The national laboratory should undertake full differential diagnosis of any haemagglutinating agent. Confirmation of Newcastle-disease virus would again be by inhibition in haemagglutination inhibition tests with monospecific chicken antisera. Intracerebral pathogenicity index tests as described in Chapter 7 should be carried out on all positive isolates. Pathogenicity indices of greater than 0,7 indicate the presence of virus requiring the full implementation of control measures.

Recent developments in typing Newcastle-disease viruses, particularly monoclonal antibody techniques, has enabled grouping of the strains and isolates. In particular, some monoclonal antibodies are available which are specific for the vaccinal strains used on the territory of the Community and can be employed in simple haemagglutination inhibition tests.

Since live vaccine strains may often be isolated from sampled poultry the advantage of their rapid identification at the national laboratory referred to in Annex II is obvious. Such monoclonal antibodies should be obtained by the Community reference laboratory as referred to in Article 14 and supplied to the national laboratories to enable confirmation of the isolation of vaccinal viruses.

The national laboratories should submit all haemagglutinating agents to the Community reference laboratory.

3. Further typing and characterization of isolates

The Community reference laboratory should receive all haemagglutinating viruses from the national laboratories for further antigenic and genetic studies to enable a greater understanding of the epizootiology of the disease(s) within the Community in keeping with the functions and duties of the reference laboratory.

CHAPTER 4 Rapid tests for detection of Newcastle-disease virus and antibodies Rapid tests for the detection of Newcastle disease virus in vaccinated birds and the detection of antibodies in unvaccinated birds are outlined below:

1. Detection of Newcastle disease virus

Several rapid test that directly detect Newcastle-disease antigens have been employed in the diagnosis of infections in vaccinated birds. Those most commonly used to date are fluorescent antibody tests on longitudinal sections of the trachea and peroxidase antibody tests on the brain. There seems no reason to doubt that other direct antigen detection tests could be applied to Newcastle-disease virus infections.

The drawback to such tests is that it is impracticable to examine all the potential sites of replication of Newcastle-disease virus in the vaccinated birds. So that, for example, absence of evidence of virus in the trachea does not preclude virus replication in the gut. No direct detection method is recommended for routine use in the diagnosis of Newcastle disease, although in specific circumstances such tests may have a useful role.

2. Detection of antibodies in unvaccinated birds

The majority of laboratories involved in Newcastle disease diagnosis are familiar with the haemagglutination inhibition test and the recommendation described below relate to this test for the measurement of antibodies to the virus. However, enzyme-linked immunosorbent assays (Elisa) may be successfully used to detect antibodies to the virus. It is suggested that if there is a wish to employ an Elisa test at regional laboratory level the test should be monitored by the national laboratory referred to in Annex II.

(a) Samples

Blood samples should be taken from all birds if the flock size is less than 20 and from 20 birds from larger flocks (this will give a 99 % probability of detecting at least one positive serum if 25 % or more of the flock is positive, regardless of flock size). The blood should be allowed to clot and serum removed for testing.

(b) Examination for antibodies

Individual serum samples should be tested for their ability to inhibit Newcastle disease virus haemagglutinating antigen in standard haemagglutination inhibition tests as defined in Chapter 6.

There is some debate as to whether 4 or 8 haemagglutinin units should be used for the HI test. It would appear that either is valid and the choice should be left to the discretion of the national laboratories. However, the antigen used will affect the level at which a serum is considered positive: for 4 HAU a positive serum is any showing a titre of 24 or greater and for 8 HAU a positive serum is any showing a titre of 23 or greater.

CHAPTER 5 Haemagglutination (HA) test Reagents

1. Isotonic saline buffered with phosphate (PBS) (0,05 M) to pH 7,0-7,4.
2. Red blood cells (RBC) taken and pooled from a minimum of three specific pathogen free chickens (if not available blood may be taken from birds regularly monitored and shown to be free of NDV antibodies) into an equal volume of Alsever's solution. Cells should be washed three times in PBS before use. For the test a 1 % suspension (packed cell v/v) in PBS is recommended.
3. NDV strain Ulster 2C is recommended for use as standard antigen.

Procedure

- (a) Dispense 0,025 ml PBS into each well of a plastic microtitre plate (V-bottomed wells should be used).
- (b) Place 0,025 ml of virus suspension (i.e. allantoic fluid) in the first well.
- (c) Use a microtitration diluter to make two-fold dilutions (1:2 to 1:4096) of virus across the plate.
- (d) Dispense a further 0,025 ml of PBS to each well.
- (e) Add 0,025 ml of 1 % red blood cells to each well.
- (f) Mix by tapping gently and place at 4 °C.
- (g) Plates are read 30 - 40 minutes later when controls are settled. Reading is done by tilting the plate and observing the presence or absence of tear-shaped streaming of the RBCs. Wells with no HA should flow at the same rate as the control cells with no virus.

(h) The HA titre is the highest dilution that causes agglutination of the RBCs. That dilution may be regarded as containing one HA unit (HAU). A more accurate method for determining the HA titre is to do HA tests on virus from a close range of initial dilutions i.e. 1:3, 1:4, 1:5, 1:6 etc. This is recommended for the accurate preparation of antigen for haemagglutination inhibition tests (see Chapter 6).

CHAPTER 6 Haemagglutination inhibition (HI) test Reagents (see Chapter 5)

- (a) Phosphate buffered saline (PBS)
- (b) Virus-containing allantoic fluid diluted with PBS to contain 4 or 8 HAU per 0,025 ml.
- (c) 1 % chicken RBCs.
- (d) Negative control chicken serum.
- (e) Positive control serum.

Procedure

- (a) Dispense 0,025 ml PBS into all wells of a plastic microtitre plate (with V-bottomed wells).
- (b) Place 0,025 ml of serum into first well of plate.
- (c) Use microtitration diluter to make two-fold dilutions of serum across plate.
- (d) Add 0,025 ml of diluted allantoic fluid containing 4 or 8 HAU.
- (e) Mix by tapping and place plate at 4 °C for a minimum of 60 minutes or room temperature for a minimum of 30 minutes.
- (f) Add 0,025 ml 1 % RBCs to all wells.
- (g) Mix by gentle tapping and place at 4 °C.
- (h) Plates are read after 30-40 minutes when control RBCs are settled. This is done by tilting and observing the presence or absence of tear-shaped streaming at the same rate as control wells containing RBCs (0,025 ml) and PBCs (0,05 ml) only.
- (i) The HI titre is the highest dilution of antiserum causing complete inhibition of 4 or 8 units of virus (an HA titration to confirm the presence of the required HAU should be included in each test).
- (j) The validity of the results is dependent on obtaining a titre of less than 23 for 4 HAU or 22 for 8 HAU with the negative control serum and a titre of within one dilution of the known titre of the positive control serum.

CHAPTER 7 Intracerebral pathogenicity index test 1. Infective freshly harvested allantoic fluid (HA titre must be greater than 24 is diluted 1:10 in sterile isotonic saline (anti-bodies must not be used).

2. 0,05 ml of the diluted virus is injected intracerebrally into each of 10 one-day old chicks (i.e. 24 hours; 40 hours after hatching). The chicks should be hatched from eggs obtained from a specific pathogen-free flock.

3. The birds are examined at intervals of 24 hours for eight days.

4. At each observation each bird is scored: 0 = normal; 1 = sick; 2 = dead.

5. The index is calculated as shown in the following example:

Clinical signs

Day after inoculation

(number of birds)

12345678TotalScore

normal 10 4 0 0 0 0 0 0 14 × 0 = 0

sick 0 6 10 4 0 0 0 0 20 × 1 = 20

dead 0 0 0 6 10 10 10 10 46 × 2 = 92

Total = 112

Index is a mean score per bird per observation = $112/80 = 1,4$

CHAPTER 8 Assessment of plaque-forming ability 1. It is usually best to use a dilution range of virus to ensure that an optimum number of plaques are present on the plate. Ten-fold dilutions up to 10⁻⁷ in PBS should be sufficient.

2. Confluent monolayers of chick embryo cells or a suitable cell line (Madin-Darby bovine kidney for example) are prepared in 5 cm diameter Petri dishes.

3. 0,2 ml of each virus dilution is added to each of two Petri dishes and the virus allowed to absorb for 30 minutes.

4. After washing three times with PBS the infected cells are overlaid with the relevant medium containing 1 % w/v agar and either 0,01 mg/ml trypsin or no trypsin. It is important that no serum is added to the overlay medium.

5. After 72 hours, incubation at 37 °C the plaques should be of sufficient size. They are best seen by removing the agar overlay and staining the cell monolayer with crystal violet (0,5 % w/v) in 25 % v/v ethanol.

6. All viruses should give clear plaques when incubated in the presence of trypsin in the overlay. When trypsin is absent from the overlay only viruses virulent for chickens will produce plaques.

ANNEX IV

LIST OF NATIONAL NEWCASTLE DISEASE LABORATORIES

BELGIUM Institut National de Recherches Vétérinaires

Groeselenberg 99

B-1180 Bruxelles

DENMARK National Veterinary Laboratory

Poultry Disease Division

Hangoevej 2

DK-8200 Aarhus N.

FEDERAL REPUBLIC Bundesforschungsanstalt fuer Viruskrankheiten der Tiere

OF GERMANY Anstaltsteil Riems (Friedrich-Loeffler-Institut)

D-O-2201 Insel Riems

FRANCE Centre national d'études vétérinaires et alimentaires, Laboratoire central de recherches agricoles et porcines

BP 53

F-22440 Ploufragan

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IRELAND Veterinary Research Laboratory

Abbotstown

Castleknock, IRL-Dublin 15

ITALY Istituto Zooprofilattico Sperimentale di Padova

Via G. Orus n. 2

I-35100 Padova

LUXEMBOURG Institut National de Recherches Vétérinaires

Groeselenberg 99

B-1180 Bruxelles

NETHERLANDS Centraal Diergeneeskundig Instituut

Vestiging Virologie

Houtribweg 39

NL-8221 RA Lelystad

PORTUGAL Laboratório Nacional de Investigaçao Veterinaria (LNIV)

Estrada de Benfica 701

1500 Lisboa

SPAIN Laboratório de Sanidad y Producción Animal

Zona Franca, Circunvalación - Tramo 6

Esquina Calle 3

E-08004 Barcelona

UNITED KINGDOM Central Veterinary Laboratory

New Haw, Weybridge

GB-Surrey KT15 3NB

ANNEX V

COMMUNITY REFERENCE LABORATORY FOR NEWCASTLE DISEASE Name of Laboratory:

Central Veterinary Laboratory

New Haw

Weybridge

Surrey KT15 3NB

United Kingdom

The functions and duties of the Community reference laboratory for Newcastle disease shall be:

1. to coordinate, in consultation with the Community Commission, the methods employed in the Member States for diagnosing Newcastle disease. Specifically by:

(a) typing, storing and supplying strains of Newcastle-disease virus for serological tests and the preparation of antisera;

(b) supplying standard sera and other reference reagents to the national reference laboratories in order to standardize the tests and reagents used in the Member States;

(c) building up and retaining a collection of Newcastle-disease virus strains and isolates;

(d) organizing periodical comparative tests of diagnostic procedures at Community level;

(e) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;

(f) characterizing isolates of Newcastle disease viruses by the most up-to-date methods available to allow greater understanding of the epizootiology of Newcastle disease;

(g) keeping abreast of developments in Newcastle disease surveillance, epizootiology and prevention throughout the world;

(h) retaining expertise on Newcastle disease virus and other pertinent viruses to enable rapid differential diagnosis;

(i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control Newcastle disease;

2. to actively assist in the diagnosis of Newcastle disease outbreaks in Member States by receiving virus isolates for confirmatory diagnosis, characterization and epizootiological studies;

3. to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonization of techniques throughout the Community.

ANNEX VI

NEWCASTLE DISEASE - RACING PIGEONS - BIRDS KEPT IN CAPTIVITY 1. Location of:

- pigeon house: .

- holding: .

2. Name(s) and address(es) of owner(s): .

.
.
3. Newcastle disease suspected

(a) date: .

(b) reason: .

(c) number of: - pigeons kept when the disease was suspected: .

- birds kept in captivity: .

4. Confirmation of Newcastle disease

(a) date: .

(b) confirmed by: .

(c) clinical signs observed at the time of confirmation: .

.
.
5. Vaccination status when the disease was suspected: .

.
.
6. Restriction of movement imposed on: .

7. Restriction of movement suspended on: .

8. Number of flocks situated within one kilometre of the pigeon house of holding referred to in point 1: .

ANNEX VII

MINIMUM CRITERIA FOR CONTINGENCY PLANS Contingency plans shall meet at least the following criteria:

1. the establishment of a crisis centre on a national level, which shall coordinate all control measures in the Member State concerned;
2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;
3. detailed information shall be given about the staff involved in control measures, their skills and their responsibilities;
4. each local disease control centre must be able to contact rapidly persons or organizations which are directly or indirectly involved in an outbreak;
5. equipment and materials shall be available to carry out the disease control measures properly;
6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination, including proposed means of disposal of carcasses;
7. training programmes shall be established to maintain and develop skills in field and administrative procedures;
8. diagnostic laboratories must have facilities for post-mortem examination, the necessary capacity for serology, histology etc., and must maintain the skills for rapid diagnosis. Arrangements must be made for rapid transportation of samples;
9. details shall be provided of the quantity of Newcastle disease vaccine estimated to be required in the event of a reinstatement of emergency vaccination;
10. provisions shall be made to ensure the legal powers necessary for the implementation of the contingency plans.