ANNEX IV

Detailed conditions for *Trichinella*-free holdings and regions with a negligible *Trichinella* risk For the purpose of this Annex,

'controlled housing conditions in integrated production systems' means a type of animal husbandry where swine are kept at all times under conditions controlled by the food business operator with regard to feeding and housing.

CHAPTER I

OBLIGATIONS ON FOOD BUSINESS OPERATORS

- A. The following requirements must be met by food business operators to obtain official recognition of holdings as free from *Trichinella*:
- (a) the operator must have taken all practical precautions with regard to building construction and maintenance in order to prevent rodents, any other kind of mammals and large carnivorous birds from having access to buildings where animals are kept;
- (b) the operator must apply a pest-control programme, in particular for rodents, effectively to prevent infestation of pigs. The operator must keep records of the programme to the satisfaction of the competent authority;
- (c) the operator must ensure that all feed has been obtained from a facility that produces feed in accordance with the principles described in Regulation (EC) No 183/2005 of the European Parliament of 12 January 2005 and of the Council laying down requirements for feed hygiene⁽¹⁾;
- (d) the operator must store feed intended for *Trichinella* susceptible species in closed silos or other containers that are impenetrable to rodents. All other feed supplies must be heat-treated or produced and stored to the satisfaction of the competent authority;
- (e) the operator must ensure that dead animals are collected for disposal by sanitary means within 24 hours of death. However, dead piglets may be collected and stored on the holding in a properly closed container pending disposal;
- (f) if a rubbish dump is located in the neighbourhood of the holding, the operator must inform the competent authority. Subsequently, the competent authority must assess the risks involved and decide whether the holding is to be recognised as free from *Trichinella*;
- (g) the operator must ensure that piglets coming onto the holding from outside and pigs purchased are born and bred under controlled housing conditions in integrated production systems;
- (h) the operator must ensure that pigs are identified so each animal can be traced back to the holding;
- (i) the operator may introduce new animals, onto the holding only if they:
 - (i) come from in holdings officially recognised as free from *Trichinella*; or

- (ii) are accompanied by a certificate authenticated by the competent authority in the exporting country stating that the animal comes from a holding recognised as free from *Trichinella*; or
- (iii) are kept in isolation until the results of a serological test approved by the Community reference laboratory prove to be negative. Serological sampling must commence only after the animals have been on the holding for four weeks;
- (j) the operator shall ensure that no pigs intended for slaughter have had outdoor access during the entire production period;
- (k) outdoor access during the first few weeks of life before weaning shall be permitted if all the following conditions are met:
 - (i) no *Trichinella* infestations have been diagnosed in domestic animals in the country in the past 10 years;
 - (ii) an annual surveillance programme exists for wildlife susceptible to *Trichinella*. The programme shall be risk-based and shall be conducted in an area epidemiologically related to the geographical location of the *Trichinella*-free farms. The programme shall test the relevant indicator species on the basis of previous findings. The results shall show a prevalence of *Trichinella* in indicator animals below 0,5 %;
 - (iii) when outdoors, the animals shall be in properly fenced areas;
 - (iv) the monitoring program referred to in Article 11 shall be in place and monitoring shall be more frequent on the holdings involved;
 - (v) all sows and boars kept for breeding purposes on the holding shall be systematically sampled at slaughter for examination using the reference method of detection described in Chapter I of Annex I or one of the equivalent methods described in Chapter II of Annex I, and
 - (vi) steps shall be taken to prevent access by large carnivorous and omnivorous birds (e.g. crows, birds of prey).
- B. Food business operators of holdings recognised as free from *Trichinella* shall inform the competent authority where any of the requirements in point A is no longer fulfilled or where any other change has occurred that might affect the *Trichinella*-free status of the holding.

CHAPTER II

OBLIGATIONS ON THE COMPETENT AUTHORITIES

- A. The competent authorities in Member States where *Trichinella* has been detected in domestic swine in the last 10 years may recognise a holding as free from *Trichinella* provided that:
- (a) at least two control visits are made in the 12 months preceding recognition of the holding to verify compliance with the requirements of Chapter I(A) of Annex IV; and

- (b) all pigs sent for slaughter during the 24 months preceding recognition or a longer time period if the competent authority decides it to be necessary have been tested to ensure to the satisfaction of the competent authority that a sufficient number of animals from the holding have been tested using one of the parasite detection methods described in Chapters I and II of Annex I; and
- (c) the results of the tests have been negative; and
- (d) a risk-based wildlife monitoring programme has been put in place in those areas where wildlife and holdings applying for *Trichinella*-free status coexist; the monitoring programme optimises parasite detection by applying the most suitable indicator animal and detection technique, by sampling as wide a number of animals and taking as large a meat sample as is feasible; parasites detected in wildlife are identified at species level in a Community or national reference laboratory; the Community reference laboratory can assist by preparing a standardised protocol for a wildlife monitoring programme. Historical data may be used for the fulfilment of the requirements listed in this part.
- B. The competent authorities in Member States where *Trichinella* has not been detected in domestic swine in the last 10 years may recognise a holding as free from *Trichinella* provided that,

the requirement in part A(d) above has been fulfilled.

- C. The competent authority may decide to recognise a category of holdings as free from *Trichinella* where all of the following conditions are met:
- (a) all the requirements set out in Chapter I(A) of Annex IV are met, with the exception of point (k), which does not apply; and
- (b) no autochthonous *Trichinella* infestations in domestic animals have been detected in the country in the past 10 years, during which time continuous testing has been conducted on slaughtered swine population such as to provide at least 95 % confidence that where the prevalence of *Trichinella* exceeds 0,0001 %, any infestations will be detected; and
- (c) a clear description must be available of the category of holdings, the type of farming and the type of animals involved; and
- (d) a risk-based monitoring programme for wildlife has been established in accordance with Chapter II(A)(d) of Annex IV.
- D. In addition to the requirements laid out in Annex IV to Directive 2003/99/EC, the initial report and the subsequent annual reports to the Commission shall contain the following information:
- (a) the number of cases (imported and autochthonous) of *Trichinella* in humans, including epidemiological data;
- (b) the results of testing for *Trichinella* in domestic swine not raised under controlled housing conditions in integrated production systems; the results must include the age and sex of affected animals, the type of management system, the type of diagnostic method used, the degree of infestation (if known), and any relevant additional information;
- (c) the results of testing for *Trichinella* in breeding sows and boars; the results must include the information mentioned under (b);

- (d) the results of testing for *Trichinella* in carcases of wild boar, horses, game and any indicator animals;
- (e) the results of serological tests as referred to in Article 11 once a suitable test has been validated by the Community reference laboratory;
- (f) other cases where *Trichinella* is suspected, either imported or autochthonous, and all relevant laboratory results;
- (g) details of all positive results and the *Trichinella* species verification by the Community or national reference laboratory;
- (h) the data are to be submitted in the format and according to the timetable determined by EFSA for the reporting of zoonoses.
- (i) for reports concerning *Trichinella*-free holdings or category of holdings: information on the number of *Trichinella*-free holdings and summary results of inspections of *Trichinella*-free holdings, including information on farmer compliance;
- (j) for reports concerning a region with negligible risk, information is to be submitted on:
 - (i) the monitoring programme implemented according to Article 11, or equivalent information;
 - (ii) the risk-based wildlife monitoring programmes implemented according to part A(d) above, or equivalent information.

(1) OJ L 35, 8.2.2005, p. 1.