

EUROPEAN COMMUNITIES (ZOOSES) REGULATIONS 1996

I, Ivan Yates, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972) and for the purpose of giving effect to Council Directive No. 92/117/EEC (1) of 17 December 1992 hereby make the following Regulations:

(1) O.J. No. L62 of 15.3.1993, P.38.

Part I Preliminary

REG 1

Title and Commencement

1. (1) These Regulations may be cited as the European Communities (Zoonoses) Regulations, 1996.

(2) These Regulations shall come into operation on the eighth day of January, 1996.

REG 2

Interpretation

2. (1) In these Regulations, except where the context otherwise requires—

"approved egg supply farm" means an egg supply farm for the time being approved under the Poultry Hatcheries Act, 1947 (No. 49 of 1947);

"approved laboratory" means a laboratory approved in writing by the Minister to test and analyse samples for salmonella in accordance with the provisions of these Regulations;

"authorised officer" means a person authorised in writing by the Minister to exercise for the purposes of these Regulations and the Council Directive the powers conferred on an authorised officer by these Regulations;

"breeding flock" means any flock of birds consisting of at least 250 birds of the species *Gallus gallus* which are kept or reared on a single holding for the production of hatching eggs;

"chicks" means poultry less than 72 hours old which have not been fed;

"the Council Directive" means Council Directive No. 92/117/EEC of 17 December 1992;

"domestic fowl" means birds of the species *Gallus gallus*;

"egg supply farm" means any premises where eggs are produced for hatching;

"licensed poultry hatchery" means a poultry hatchery for the time being licensed under the Poultry Hatcheries Act, 1947 (No. 49 of 1947);

"official veterinarian" has the meaning assigned in Article 2.7 of Annex B to Directive No. 92/116/EEC (2) of 17 December 1992;

(2) O.J. No. L62 of 15.3.1993, P.1.

"poultry" means birds of any of the following species, domestic fowl, ducks, geese, turkeys, guinea fowl and pheasants;

"poultry hatchery" means any premises for the hatching of eggs by

artificial means;

"premises" includes any land and any buildings, structures or private dwellings;

"the Minister" means the Minister for Agriculture, Food and Forestry.

(2) In these Regulations—

(a) a reference to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other provision is intended;

(b) a reference to a Schedule is to a Schedule to these Regulations;

(c) a reference to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(3) A word or expression that is used in these Regulations and is also used in the Council Directive has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Council Directive.

REG 3

General Conditions and Exemption

3. (1) The owner or person in charge of an establishment approved by the Minister in accordance with Council Directives Nos. 64/433/EEC (3), 71/118/EEC (4) or the European Communities (Meat Products and Other Products of Animal Origin) Regulations, 1995 (S.I. No. 126 of 1995) shall provide all information and take or have taken any samples required by the Minister to detect the presence of the zoonoses listed in Paragraph I of the First Schedule.

(3) Updated by Council Directive No. 91/497/EEC-O.J. No. L268 of 24.9.1991, P.69.

(4) Updated by Council Directive No. 92/116/EEC-O.J. No. L62 of 15.3.1993, P.1.

(2) Subject to the provisions of paragraph (3), the owner or person in charge of an approved egg supply farm or a licenced poultry hatchery shall provide all information and carry out or have carried out sampling as required by these Regulations.

(3) The provisions of these Regulations shall not apply in the case of a breeding flock which is kept solely for the production of hatching eggs for use in the manufacture of vaccines or for research or other scientific purposes.

Part II

Requirements for Establishments, Supply Farms and Hatcheries

REG 4

Requirements for Meat Establishments

4. (1) The Minister may lay down the requirements, including the frequency of examination, sampling, identification and the keeping of records, for determining the presence of the zoonoses listed in Paragraph I of the First Schedule for establishments approved by the Minister in accordance with Council Directives 64/433/EEC or 71/118/EEC or the European Communities (Meat Products and Other

Products of Animal Origin) Regulations, 1995 (S.I. No. 126 of 1995).

(2) The owner or person in charge of an establishment approved by the Minister in accordance with the Council Directives 64/433/EEC, 71/118/EEC or the European Communities (Meat Products and Other Products of Animal Origin) Regulations, 1995 (S.I. No. 126 of 1995) shall ensure that the requirements laid down by the Minister in paragraph (1) are complied with.

REG 5

Requirements for Supply Farms, Hatcheries and Holdings

5. The owner or person in charge of an approved egg supply farm or a licensed poultry hatchery shall ensure that—

- (a) samples are taken in such manner and at such times as are specified in Part II of Section I of the Second Schedule;
- (b) such samples are tested at a laboratory approved by the Minister in accordance with Regulation 7;
- (c) any samples sent to an approved laboratory in accordance with the provisions of these Regulations are identified in such a manner as to enable the laboratory to which they are submitted to know:
 - (i) the type of samples which were sent;
 - (ii) the date on which the samples were taken;
 - (iii) the name of the owner or person in charge of the farm or hatchery;
 - (iv) the address of the holding on which the breeding flock is kept;
 - (v) the building or house on that holding from which the samples were taken;
- (d) any samples taken in accordance with the provisions of the Second Schedule, other than those required to be taken under the supervision of an authorised officer, are dispatched, within 48 hours of being taken, to an approved laboratory for testing, at the expense of the owner of the farm or hatchery, for the presence of salmonella. Such samples shall be kept in a refrigerator at a temperature of between 1°C and 4°C if they are not so dispatched within 24 hours of being taken.

REG 6

Keeping of records

6. The owner or person in charge of an approved egg supply farm or a licensed poultry hatchery shall ensure that —

- (a) records containing the information specified in the Third Schedule are kept of any sample taken in respect of the farm or hatchery in accordance with these Regulations;
- (b) a record of the result of any test carried out on a sample in accordance with Regulation 5 is kept;
- (c) such records are retained for a period of 2 years from the date on which the sample was taken or from the date of the test;
- (d) such records are produced to an authorised officer on such a demand being made by such officer at any reasonable time during that period and that a copy or extract from such records may be taken.

Part III

Requirements for Approved Laboratories

REG 7

Conditions of Registration for Private Laboratories

7. (1) No person may use a private laboratory for the testing of samples taken under these Regulations unless that laboratory has been registered by the Minister in accordance with this Regulation.
- (2) The Minister shall establish and maintain a register (referred to subsequently in this Regulation as "the register") of laboratories which have been approved by him to carry out the testing of samples taken in accordance with the provisions of these Regulations.
- (3) An application for registration in the register shall be made in such form as the Minister may specify.
- (4) The owner or person in charge of a laboratory applying for registration in the register shall furnish the Minister with such information as he may reasonably require for the purposes of his functions under these Regulations and shall ensure that the laboratory complies with the approval conditions for registration laid down in the Fourth Schedule.
- (5) The register may be established and maintained in a form that is not legible if it is capable of being converted into a legible form.
- (6) A certificate purported to be signed by a person authorised by the Minister in that behalf and to certify that on a specified day or days or during the whole of a specified period a particular laboratory did not stand registered in the register or that on a specified day the laboratory's registration had been revoked shall, without proof of the signature of the person purporting to sign the certificate or that he was so authorised by the Minister, be evidence, unless the contrary is shown, of the matters stated in the certificate.
- (7) The Minister may, if he is satisfied that the provisions of these Regulations and of the Council Directive are not being complied with by a laboratory registered in the register or will not be complied with by an applicant for such registration, revoke or suspend the registration or refuse to register the laboratory in the register.
- (8) Where the Minister proposes to revoke or suspend a registration, or to refuse to register a laboratory, in the register, he shall —
 - (a) notify the person concerned in writing of the proposal and of the reasons therefor,
 - (b) notify the person in writing that he, or a person acting on his behalf, may make representations to the Minister in relation to the proposal within 14 days of the issue by him of the notification, and
 - (c) consider any such representations duly made before deciding whether to proceed with the proposal or not.
- (9) Where a registration is suspended or revoked, the Minister may issue a notice in writing requiring the owner or person in charge of the laboratory to cease the testing of samples under these Regulations from a date specified in that notice.
- (10) Where the Minister suspends or revokes a registration, the

person who held the registration or the owner or person in charge of the laboratory, as the case may be, shall not test the samples taken under these Regulations subsequent to the date of revocation or suspension, as the case may be, except with the approval of the Minister.

(11) The Minister may restore a registration, if the registration has been suspended in accordance with paragraph (7), in instances where —

(a) the owner or person in charge of the laboratory demonstrates to the satisfaction of the Minister that he will comply with the requirements of the Council Directive and of these Regulations, and
(b) checks carried out by an authorised officer confirm the safety of the laboratory in accordance with the provisions of these Regulations and in particular with paragraph 6.3 of the Fourth Schedule.

(12) The Minister may where he is satisfied that there is a serious and immediate health risk, suspend, without affording to the person granted the registration an opportunity of making representations referred to in subparagraph (b) of paragraph (8), a registration granted under this Regulation.

REG 8

Testing of Samples

8. (1) The owner or person in charge of an approved laboratory to which a sample has been submitted in accordance with the provisions of Regulation 5 shall ensure that;

(a) the sample is tested for the presence of salmonella in accordance with a method approved by the Minister;

(b) the result of such a test is reported in writing as soon as practicable to the person who submitted the sample;

(c) where, as a result of the testing outlined in these Regulations, the presence of salmonella enteritidis or salmonella typhimurium is detected in a sample taken from a breeding flock, the Minister shall be informed in accordance with paragraph 4.2 of the Fourth Schedule.

(2) If a person to whom a report is made under paragraph (1) (b) is not the owner of the farm or the hatchery, as the case may be, he shall immediately pass that report to the owner.

(3) In any case where the presence of salmonella enteritidis or salmonella typhimurium is detected in a sample taken from a breeding flock, the owner or person in charge of that flock shall not transport any poultry, poultrymeat or eggs from the hatchery, farm or premises without the consent in writing of an authorised officer.

Part IV Inspection and Supervision

REG 9

Appointment of Authorised Officers

9. (1) The Minister may appoint such and so many persons as he thinks fit to be authorised officers for the purposes of these Regulations.

(2) An authorised officer shall be furnished with a warrant of his appointment by the Minister as an authorised officer and when exercising any power conferred on him by these Regulations such officer shall, if requested by any person affected, produce the warrant to that person.

REG 10

Powers of Inspection

10. (1) An authorised officer or an expert from the Commission, within the meaning of Article 11.1 of the Council Directive, may, for the purpose of carrying out inspections, supervision, sampling or testing required by these Regulations, at all reasonable times enter:

(i) any premises which is registered as an approved supply farm or a licensed hatchery or an establishment approved by the Minister under the European Communities (Live Poultry & Hatching Eggs) Regulations, 1992 (S.I. No. 362 of 1992) and any parts of any other premises or other land which are material to the operation of such premises or,

(ii) all parts of any premises which operates as a supply farm or hatchery for poultry or an establishment where poultry or hatching eggs are reared, produced, bred, fattened, exhibited and any other premises, land or vehicle which are material to the operation of such premises or,

(iii) any other place or vehicle in respect of which the officer has reasonable cause to suspect is used for, or in connection with the rearing, production, breeding, fattening, exhibiting selling or transporting of poultry or hatching eggs.

(2) An authorised officer or an expert from the Commission, within the meaning of Article 11.1 of the Council Directive, shall at all times have free access to all parts of the establishments or premises referred to at paragraph (1) in order to ensure that these Regulations are being complied with and, where there is doubt as to the origin of the poultry, to accounting documents which enable the holding of origin to be traced.

(3) An authorised officer for the purposes of these Regulations and the Council Directive, may, as he considers appropriate;

(a) make such examinations, tests and inspections at all stages of production and on any poultry, and

(b) take such reasonable samples from poultry which he finds in the course of his inspection, and

(c) inspect, take or take copies of, or extracts from, any books, documents, or other records as he finds in the course of his inspection.

(4) A person who is for the time being the owner or operator of a farm, hatchery or premises shall carry out all reasonable directions issued by an authorised officer for the purposes of these Regulations.

PART V

Miscellaneous Provisions

REG 11

Offences

11. (1) An offence under these Regulations may be prosecuted by the Minister.

(2) Any person who contravenes a provision of these Regulations shall be guilty of an offence.

(3) If any person fraudulently—

(a) tampers or otherwise interferes with any poultry, poultrymeat or eggs so as to procure that any sample of it taken under these Regulations does not correctly represent the poultry, poultrymeat or eggs,

(b) tampers or otherwise interferes with any sample taken under these Regulations,

(c) treats or allows treatment of any bird which causes any sample to be invalid,

that person shall be guilty of an offence.

(4) Any person who obstructs or otherwise interferes with an authorised officer in the exercise of a power conferred on him by these Regulations shall be guilty of an offence.

(5) Where an offence under these Regulations is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to have been facilitated by any neglect on the part of, any director, manager, secretary or other official of such body, each such person shall also be guilty of an offence.

REG 12

Penalties

12. A person guilty of an offence under these Regulations shall be liable, on summary conviction, to a fine not exceeding £1,500 or, at the discretion of the court, to imprisonment for a term not exceeding twelve months or to both such fine and such imprisonment.

REG 13

Prohibition on vaccination

13. No person shall vaccinate any poultry with any vaccine which is likely to affect the result of any test carried out under these Regulations on any sample taken from the poultry, except under the authority of a licence issued by an authorised officer and in accordance with any conditions subject to which the licence is issued.

REG 14

Compensation

14. Compensation may not be payable, in accordance with Article 9 of the Council Directive, in cases where the owner or person in charge of an approved egg supply farm or a licensed poultry hatchery has failed to comply with the provisions of these

Regulations or has failed to take reasonable bio-security measures to prevent the occurrence of salmonella enteritidis or salmonella typhimurium in breeding flocks.

REG 15

Rider

15. These Regulations are in addition to and not in substitution for the Poultry Hatcheries Act, 1947 (No. 49 of 1947), the Fowl Pest Order, 1950 (S.I. No. 15 of 1950) and the European Communities (Trade in Animals and Animal Products) Regulations, 1994 (S.I. No. 289 of 1994).

FIRST SCHEDULE

LIST OF ZONOOSES

- I. (a) Tuberculosis due to *Mycobacterium bovis*;
- (b) Brucellosis and the agents thereof;
- (c) Salmonellosis and the agents thereof;
- (d) Trichinosis.
- II. (a) Campylobacteriosis;
- (b) Echinococcosis;
- (c) Listeriosis;
- (d) Rabies;
- (e) Toxoplasmosis;
- (f) Yersiniosis;
- (g) Other zoonoses and the agents thereof.
- III. Any other zoonosis not found in the Community and the agents of that zoonosis.

SECOND SCHEDULE

SECTION I

MONITORING AND CONTROL — PRESENCE OF SALMONELLA IN BREEDING FLOCKS

I. Breeding Flocks

A breeding flock comprises at least 250 birds (*Gallus gallus*), kept or reared on a single holding for the production of hatching eggs.

II. Monitoring of Salmonella in Breeding Flocks

The owner or person in charge of a hatchery or of a breeding flock shall, at the owner's expense, have samples taken for analysis for the detection of salmonella in a laboratory approved by the Minister in accordance with these Regulations, with the minimum levels of sampling indicated in Table 1 being respected.

A. Rearing Flocks

1. The owner or person in charge of the flock shall ensure that samples shall be taken from birds reared for breeding purposes at least when the chicks are one day old, when the birds are four weeks old and two weeks prior to pullets entering the laying phase.
2. The samples to be taken shall comprise:
 - (a) in the case of day-old chicks, samples, at a minimum of 1 c.m.², shall be taken from the internal linings of the boxes in which the chicks were delivered to the holding from the hatchery, with a minimum of one box-liner sample for every 500 chicks delivered; such samples are to be taken on the day in which the

chicks were delivered to the holding; and

(b) the carcasses of all chicks, up to a maximum of 60, found to be dead on arrival are to be sampled; such samples to be taken on the day in which the chicks were delivered to the holding; and

(c) in the case of pullets at four weeks of age or two weeks prior to the laying phase, pooled faecal samples made up of separate samples of fresh faeces each weighing not less than 1 g taken at random from a number of sites in the building in which the birds are kept shall be collected. Alternatively where the birds have free access to more than one building on a particular holding, pooled faecal samples shall be collected from each group of buildings on the holding on which the birds are kept;

(d) the number of sites from which separate faeces samples are to be taken in order to make a pooled sample shall be as follows:

TABLE 1

Number of birds kept in a Building	Number of faeces samples to be taken in the building or group of buildings on the holding
1 - 24	(number equal to the total number of birds up to a maximum of 20)
25 - 29	20
30 - 39	25
40 - 49	30
50 - 59	35
60 - 69	40
70 - 79	45
80 - 89	50
90 - 99	55
100 - 199	60
200 - 499	60
500 or more	60

B. Adult Breeding Flocks

1. The owner or person in charge of each parent breeding flock shall ensure that the flock is sampled and tested at least once every two weeks in the laying period. The owner or person in charge of each grandparent breeding flock shall ensure that the flock is sampled and tested at least every week during the laying period.

2. Breeding flocks where eggs are hatched at a hatchery with a total incubator capacity of less than 1,000 eggs shall be sampled, by the owner or person in charge, on the holding and the samples to be taken shall consist of a pooled faeces sample made up of separate faeces samples, each weighing not less than 1 g, collected in accordance with paragraph A.2. b

3. Breeding flocks where eggs are hatched at a hatchery with a total incubator capacity of 1,000 eggs or more shall be sampled, by the owner or person in charge, through the hatchery and the samples to be taken shall consist of:

(a) pooled samples of meconium taken from 250 chicks hatched from eggs supplied to the hatchery from each breeding flock; or

(b) samples of carcasses of 50 chicks which are dead in the shells of eggs or which have been hatched from eggs supplied to the hatchery from each breeding flock.

4. Such samples shall also be taken from breeding flocks comprising less than 250 birds whose eggs are hatched in hatcheries with a total incubator capacity of 1,000 eggs or more.

5. Every eight weeks, the sampling provided for in paragraph B for adult parent breeding stock flocks, and every four weeks in the case of adult grandparent breeding stock flocks shall be replaced by official sampling under the supervision of an authorised officer which shall be conducted in accordance with subparagraph 3.

C. Examination of Samples for Salmonella

The total number of samples taken in each building may be pooled for analysis.

The analyses and tests for salmonella shall be carried out in

accordance with methods which afford the guarantees laid down in Decision 89/610/EEC (5) or other tests and methods may be used provided that they are approved in accordance with the procedure laid down in Article 16 of the Council Directive.

(5) O.J. No. L351 of 2.12.1989, P.34.

III. Notification of Results

Where, as a result of the monitoring carried out in accordance with paragraph II, the presence of salmonella enteritidis or salmonella typhimurium is detected in a sample taken from a breeding flock, the owner or person in charge of the flock or the person responsible for the laboratory carrying out the examination or the person carrying out the examination shall, within a period not exceeding 24 hours, notify the results to the Minister.

IV. Investigation of Flocks declared positive after monitoring

Where the presence of salmonella enteritidis or salmonella typhimurium is notified in accordance with paragraph III, the flock shall be sampled by an authorised officer to confirm the initial results. A sample of birds shall be taken from within each house on the holding, the size of the sample being selected in accordance with Table 2. For the purpose of examination, the birds sampled from each house are grouped in batches of five, and samples of liver, ovary and intestine taken from each batch are examined for salmonella in the Central Veterinary Control Laboratory of the Department of Agriculture, Food and Forestry.

TABLE 2

Number of birds kept in a House Size of sample (Number of Birds) to be taken in the houses or group of houses on the holding

1 - 24	(number equal to the total number of birds up to a maximum of 20)
25 - 29	20
30 - 39	25
40 - 49	30
50 - 59	35
60 - 69	40
70 - 79	45
80 - 89	50
90 - 99	55
100 or more	60

V. Measures to be taken in respect of Flocks where infection is confirmed

The measures to be taken shall comply with the following standards.

1. Where as the result of an investigation carried out in accordance with paragraph IV, the presence of salmonella enteritidis or salmonella typhimurium is confirmed in the birds in a house, the following measures shall be taken:

- (a) the owner or person in charge of the flock shall ensure that no birds leave the house concerned until the Minister has authorised the slaughter and destruction of the carcasses of such birds under the supervision of an official veterinarian or alternatively such birds are slaughtered in a slaughterhouse designated by the Minister in accordance with sub-subparagraph (c) of this subparagraph;
- (b) non-incubated eggs produced by the birds in the house in question shall be destroyed on the spot or, after appropriate marking, be taken under the supervision of an authorised officer to an egg-processing establishment approved by the Minister under the European Communities (Egg Products) Regulations, 1991 (S.I. No. 293 of 1991) to ensure the destruction of any zoonotic agent that may be present;
- (c) all the birds in the house shall be slaughtered in accordance with point 31 (c) of Chapter VI of Annex I to Council Directive 71/118/EEC, the official veterinarian of the slaughterhouse being informed of the decision to slaughter, in accordance with point 25

(a) of Chapter VI of Annex I of that Directive or be slaughtered and destroyed so as to reduce as much as possible the risk of spreading salmonella.

2. Once a house occupied by a flock infected with salmonella enteritidis or salmonella typhimurium has been emptied of birds, effective cleansing and disinfection shall be carried out, including safe disposal of manure and litter, in accordance with the procedure laid down by an official veterinarian. Restocking shall be with chicks satisfying the requirements of paragraph II (A) (1) and only after the official veterinarian is satisfied that all precautions have been taken to prevent recycling of infection.

3. When eggs for hatching from flocks in which the presence of salmonella enteritidis or salmonella typhimurium has been confirmed are still present in the hatchery, they shall be destroyed or treated as high-risk material in accordance with the provisions of the European Communities (Disposal, Processing and Placing on the Market of Animal By-products) Regulations, 1994 (S.I. No. 257 of 1994).

SECTION II

INSPECTION FOR SALMONELLA AT THE FINAL PRODUCTION STAGE OF COMPOUND FEEDINGSTUFFS FOR POULTRY

When official samples are being taken on a holding or in cases of justified suspicion, on the part of an authorised officer, sampling may be carried out on the instructions of such officer, on the compound feeding stuffs used to feed poultry.

When a sample is positive for salmonella, the Minister may carry out an investigation in order to:

- (a) identify the source of contamination, in particular by means of official sampling taken at different stages of production;
- (b) examine the rules and controls concerning the disposal and processing of animal waste in accordance with the European Communities (Disposal, Processing and Placing on the Market of Animal By-products) Regulations, 1994 (S.I. No. 257 of 1994);
- (c) establish procedures for good manufacturing practices and ensure compliance with recognised procedures.

The owner or person in charge of the holding shall comply with any instructions issued to him by an authorised officer in connection with this Section.

THIRD SCHEDULE

PART I

RECORDS OF SAMPLES TAKEN IN RESPECT OF A BREEDING FLOCK OR A HATCHERY

The person in charge of a poultry hatchery or a supply farm or an other form of holding on which a breeding flock of domestic fowl is kept shall keep a record of samples taken in respect of the flock. This record shall contain the following information—

- (i) the date on which the sample was taken;
- (ii) a description of the type of sample taken; and
- (iii) in the case of samples taken in respect of the breeding flock, the identity of the building or group of buildings from which the samples were taken. In the case of samples taken from a hatchery, the address of the holding which supplied the hatching eggs from which the samples were obtained shall be provided.

PART II

RECORDS OF THE MOVEMENT OF POULTRY, CHICKS AND EGGS ONTO AND OFF ANY HOLDING ON WHICH A BREEDING FLOCK IS KEPT

The owner or person in charge of any holding, hatchery or supply farm on which a breeding flock of domestic fowl is kept shall keep a record of the movement of any domestic fowl, their chicks and eggs onto and off such holding. This record shall contain the following information—

- (i) the date of the movement;
- (ii) the number of domestic fowl, their chicks or eggs moved;
- (iii) the identity of the building or group of buildings in which any domestic fowl, their chicks or eggs moved onto the holding were placed or from which any domestic fowl, their chicks or eggs were moved off the holding;
- (iv) in the case of any domestic fowl, their chicks or eggs moved onto the building, the address from which they were brought there;
- (v) in the case of any domestic fowl, their chicks or eggs moved off the holding, the address to which they were moved.

PART III

RECORDS OF THE MOVEMENT OF EGGS ONTO AND OFF, AND OF THE MOVEMENT OF CHICKS OFF, ANY PREMISES WHICH ARE USED AS HATCHERY

The owner or person in charge of any premises used as a poultry hatchery shall keep a record of the movement of eggs or chicks of domestic fowl to or from such premises. Such record shall contain the following information —

- (i) the date of the movement;
- (ii) in the case of the movement of any eggs onto the premises, the address of the premises from which they were moved and the number of eggs moved;
- (iii) in the case of the movement of any eggs or chicks off the premises the address to which they were moved and the number of eggs or chicks moved.

FOURTH SCHEDULE

CONDITIONS OF APPROVAL FOR PRIVATE LABORATORIES

1. USE OF PRIVATE LABORATORIES

1.1 All testing in private laboratories shall be carried out at the flock owners' expense. Only methods of sampling and testing approved by the Minister may be used. The Department of Agriculture, Food and Forestry through the Central Veterinary Research Laboratory (CVRL) shall be responsible for monitoring laboratories.

2. REGISTER OF APPROVED LABORATORIES

2.1 A register of Laboratories approved under these Regulations shall be held and updated as necessary at the CVRL and will contain the names, addresses and telephone numbers of laboratories approved by the Department of Agriculture, Food and Forestry to examine samples submitted under the provisions of these Regulations. A list of approved laboratories shall be made available to any person who wishes to have samples tested.

3. PROCEDURE FOR REGISTRATION AS AN APPROVED LABORATORY

3.1 Requests for application forms should be made to the Central Veterinary Research Laboratory, Abbotstown, Castleknock, Dublin 15. Applications to register as an approved laboratory may be made at

any time.

3.2 Following application, the laboratory shall be inspected by Veterinary Research Officers from the CVRL. The inspection shall focus on qualifications and training of personnel, suitability of the premises, equipment, operating procedures, bacteriological techniques, quality assurance and record keeping. If the results of this inspection are satisfactory, the laboratory shall be approved to examine samples submitted under the regulations and the name, address and telephone number of the laboratory shall be entered in a Register of Approved Laboratories at the CVRL, following written acceptance of any conditions of approval.

3.3 If the laboratory is already approved by the Irish Laboratory Accreditation Board for Salmonella testing this shall be taken into account during the assessment process.

3.4 Each laboratory shall be required to participate in a Quality Assurance Scheme operated by the CVRL.

4. UNDERTAKINGS TO BE GIVEN BY EACH LABORATORY

All laboratories shall give the following undertakings.

4.1 Examination of Samples.

The laboratory will examine all samples submitted under these Regulations using approved methods.

4.2 Reporting Salmonella isolations.

If, as a result of a laboratory examination, *Salmonella enteritidis* or *Salmonella typhimurium* is isolated from a sample, the owner or person in charge of the laboratory shall forthwith make an immediate verbal report followed by a written report, within 24 hours, of the isolation to the Poultry Division, Agriculture House, Kildare Street, Dublin 2.

4.3 Keeping records.

4.3.1 The laboratory shall maintain a record of all examinations carried out under these Regulations for a period of one year.

The record shall contain the following information:

- (i) The nature of the sample examined.
- (ii) The name and address of the premises at which the sample was taken.
- (iii) The date on which the sample was taken.
- (iv) The date on which the sample was received by the laboratory.
- (v) The date on which the sample was examined by the laboratory.
- (vi) The result of the examination and date of the report.
- (vii) The known or suspected identity of any salmonella organism isolated and the date on which any subculture of the salmonella was sent to the CVRL.

4.3.2. Upon request, the laboratory will make available to an authorised officer all records relating to the examination of samples under these Regulations.

4.3.3. At the end of each calendar month the owner or person in charge of the laboratory shall forward to the CVRL a report of the examinations carried out during that month.

The report shall contain the following information:

- (i) The number and types of samples submitted to the laboratory in that month.
- (ii) The number of each type of sample examined that month.
- (iii) The number of each type of sample examined in that month which on examination appeared to be sterile.
- (iv) The number of each type of sample examined in that month from

which a salmonella was isolated, the identity or suspected identity of such isolates and the owner of flock of origin of that sample.

(v) The number of premises from which samples were submitted for examination that month.

5. QUALITY ASSURANCE (QA)

5.1 All laboratories shall participate in the CVRL Quality Assurance Scheme for the examination of samples for salmonella.

The scheme shall take the following form:

(i) QA samples shall be issued on a number of occasions during the year. At least five samples will be issued on each occasion. These may contain a variety of species of salmonella aimed at assessing the laboratory's ability to isolate and serotype the organisms to Group level. Laboratories shall be informed two weeks prior to sample despatch.

(ii) Laboratories shall be allowed fourteen days from the date of despatch to examine the samples and to submit a written report of the results to the CVRL.

(iii) After analysis of the returns, laboratories shall be notified whether their performance is satisfactory or unsatisfactory. Intended results shall not be issued following each distribution of QA samples.

6. REMOVAL OF A LABORATORY FROM THE REGISTER OF APPROVED LABORATORIES

6.1 Where there is evidence that a laboratory has failed to abide by any of the conditions set out in paragraph 4 the name, address and telephone number of that laboratory shall be removed by the Minister from the register forthwith and from that date it shall cease to be an approved laboratory for the purposes of the Regulations.

6.2 Where a laboratory has failed to achieve a satisfactory performance in the quality assurance scheme, the name, address and telephone number shall be removed from the Register forthwith and from that date it shall cease to be an approved laboratory.

6.3 A laboratory whose name has been removed from the Register of Approved Laboratories because of an unsatisfactory performance in the CVRL quality assurance scheme may not apply to have its name restored to the Register until it has produced a satisfactory performance in four consecutive QA distributions undertaken at its own expense.

7. Fees

The Minister may prescribe fees in respect of approval of laboratories under these Regulations and these fees shall be subject to annual revision.

8. APPROVAL CRITERIA FOR PRIVATE LABORATORIES

8.1 As part of the approval process authorised officers, assisted when necessary by other staff, from the CVRL shall visit and inspect laboratories applying to be registered and perform an assessment on their suitability.

8.2 Objectives

The measurement of suitability shall be made against the following objectives:

8.2.1 The laboratory shall be of sufficient standard to be able to examine efficiently material submitted for the presence of salmonella and to report accurately the results. The standards considered necessary to achieve these objectives are those encompassed by Good

Laboratory Practice.

8.2.2 The inspection process is designed to examine all aspects of the laboratory's operation including qualifications and training of personnel, suitability of premises, equipment, operating procedures, determinative bacteriology, culture media and reagents, QA/QC programmes and record keeping.

8.3 Personnel

The laboratory shall have an adequate number of appropriately qualified and experienced personnel to carry out the work.

(i) Any work on the isolation and identification of salmonella organism shall be carried out or directly supervised by a person holding a recognised academic qualification in a microbiological subject and who has a minimum of two years laboratory experience in microbiology.

(ii) Possession of an academic qualification in itself does not guarantee ability to perform a test effectively and laboratory staff shall demonstrate to the inspecting officer's satisfaction an understanding of the basic principles of salmonella bacteriology.

(iii) Details of numbers of staff, their qualifications and experience shall be provided.

(iv) An on-going commitment to in-house training or support for external training programmes whilst not essential shall be more likely to endorse a laboratory's claim to operate Good Laboratory Practice.

(v) A senior member of staff shall be clearly identified with the overall responsibility for salmonella work and record keeping.

8.4 Premises

The laboratory premises shall be of a suitable size, design, construction and location, for the purpose of testing samples for salmonella without the risk of cross-contamination or sample mis-identification.

(i) The testing laboratory shall be located away from livestock of any kind and if livestock are kept on the premises there shall be restricted laboratory access to specialist staff only and with suitable gowning and personal cleaning facilities provided.

(ii) The laboratory shall be of a size and design which allows reasonable separation of sample reception, processing, microbiological plate reading, identification, and culture media and reagent preparation. Such preparation should if possible take place in different rooms or specifically designated and well spaced work areas.

(iii) The laboratory ventilation system shall be such as to minimise the risk of cross-contamination of samples through excessive air movement and the spread of aerosols and dust. If possible dry materials (e.g. feeds or feed ingredients) should be handled in a ventilated cupboard or a safety cabinet.

(iv) The laboratory accommodation, benches and equipment shall be maintained in a clean state and surfaces shall be impermeable and of a type which can be cleaned and disinfected as necessary.

(v) The arrangements for the treatment and disposal of biological and laboratory waste shall be such that there is no risk of contamination of equipment and laboratory environment or members of the public. Preferably this should be by means of autoclaving before incineration and disposal through normal domestic refuse collection.

8.5 Equipment

There should be adequate equipment available for the effective conduct of salmonella work and that all equipment shall be suitable for its intended use, properly calibrated and maintained to ensure accurate performance.

- (i) There shall be a sufficient number of incubators to allow salmonella testing at the various temperatures defined by the Minister.
- (ii) Indicators showing the operating temperature of incubators shall be clearly visible and there shall be evidence of weekly calibration by use of an independent certified thermometer placed inside the incubator.
- (iii) Water baths, if used, shall be monitored as for incubators.
- (iv) Ph meters shall be checked before use against calibration solutions.
- (v) Autoclaves shall be fitted with visible means of temperature or pressure measurement and subject to frequent checks with indicator strips, spore suspensions, thermocouples or other appropriate means.
- (vi) Deionizers shall be operated in accordance with manufactures' instructions and cartridges changed as required.
- (vii) Samples, cultures and contaminated materials shall not be stored in the same refrigerator or freezer as culture media, reagents and antisera.
- (viii) Balances shall be calibrated regularly using known weights.
- (ix) All equipment shall be maintained in a clean state.
- (x) There shall be operating instructions for each piece of equipment.
- (xi) Records of maintenance and repair schedules shall be kept and made available to authorised officers.

8.6 Operating Procedures

The laboratory shall have written standard operating procedures that are sufficient to ensure the quality and accuracy of results generated.

- (i) Each laboratory shall have immediately available copies of standard operating procedures relevant to the activities carried out in that area.
- (ii) These instructions shall define precisely the methods to be employed for the reception, identification and labelling of samples, media preparation, inoculation, dilution and transfer of samples, plating and incubation of cultures, identification procedures including the use and interpretation of biochemical media and the performance and interpretation of serological tests, the use of QA/QC materials, the disposal of contaminated waste, and the logging, recording and reporting of test results.
- (iii) Copies of the Salmonella Monitoring Programme issued by the Department of Agriculture, Food and Forestry shall be available to laboratory staff.
- (iv) The laboratory shall demonstrate that it is capable of adhering to approved methods.

8.7 Determinative bacteriology

The laboratory shall be capable of isolating and identifying salmonella.

- (i) The methods used for the plating out and sub-culturing of bacterial cultures shall be such as to achieve isolated colonies capable of being visually identified and differentiated.
- (ii) The determination of colonial characteristics shall be strictly

in accordance with the specifications of the media being used.

(iii) Identification of organism by the use of composite media shall be strictly in accordance with the interpretation criteria for the media being used.

(iv) Serological tests shall be performed in accordance with relevant EU legislation, recognised international standards or Commission decisions on serology.

(v) Serotyping of salmonella isolates shall be by a systematic use of somatic and flagellar antigens.

(vi) Appropriate controls shall be used and colonies checked for auto agglutination.

(vii) Both biochemical and serological criteria shall be used to determine an organism's identity.

8.8 Culture media and reagents

The laboratory shall use culture media and reagents capable of detecting the presence of salmonella in material submitted under these Regulations.

(i) The culture media and reagents shall be prepared in accordance with the manufacturer's instructions.

(ii) The quality of the media shall be checked according to clarity, consistency and Ph.

(iii) The culture media, reagents and antisera, shall not be stored for too long a period in conditions detrimental to their effectiveness.

(iv) The culture media, reagents and antisera shall be used within the expiry dates indicated by the manufacturers.

(v) If ready for use media are bought in they shall be stored in accordance with the manufacturers instructions and used within the expiry dates indicated.

8.9 QA/QC Programmes

There shall be a mechanism by which the laboratory is able to ensure that the culture media and methods are working correctly and that they are able to isolate and identify salmonella from control samples.

(i) There shall be evidence that bacterial cultures are used to control different batches of culture media and reagents.

(ii) There shall be evidence that internal quality control of laboratory methods takes place using control cultures.

(iii) The laboratory when testing/analysing QA samples shall produce results within defined parameters.

8.10 Record Keeping

The laboratory shall have a means of recording samples and results in a form which can be assessed by an authorised officer and which provides all the information needed by the Department.

(i) There shall be a sample recording system which details the samples received on a daily basis with no gap in sequencing of samples.

(ii) These records shall show the date of receipt, the origin, owner and type of samples and the laboratory results.

(iii) Salmonella results with the date of reporting to the Department of Agriculture, Food and Forestry shall be shown. Where results are maintained on computer there shall be the facility to produce a hard copy summarising details of specimen, type, owner and result as indicated at subparagraph (ii).

(iv) There shall be provision for presenting monthly returns to the

Department regarding total numbers of samples received according to product type and the total number of positive samples found for each product type.

Given under my Official Seal, this 3rd day of January, 1996.

Ivan Yates
Minister for Agriculture, Food and Forestry.

EXPLANATORY NOTE

The purpose of these Regulations is to implement Council Directive 92/117/EEC on measures to protect against specific zoonoses and to provide information on such zoonoses. It also provides for the taking of samples for bacteriological testing for Salmonella and for the slaughter of breeding domestic fowl confirmed as being infected with Salmonella enteritidis or Salmonella typhimurium.