

**EUROPEAN COMMUNITIES (DISPOSAL, PROCESSING AND PLACING ON THE
MARKET
OF ANIMAL BY-PRODUCTS) REGULATIONS 1994**

I, JOE WALSH, 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. 90/667/EEC(1) of 27 November, 1990 as amended by Council Directive No. 92/118/EEC(2) of 17 December, 1992 and Commission Decision No. 92/562/EEC(3) of 17 November, 1992, hereby make the following Regulations:

- (1) O.J. No. L363 of 27.12.1990, p. 51.
- (2) O.J. No. L62 of 15.3.1993, p. 49.
- (3) O.J. No. L359 of 9.12.1992, p. 23.

REG 1

1. (1) These Regulations may be cited as the European Communities (Disposal, Processing and Placing on the Market of Animal By-Products) Regulations, 1994.
- (2) These Regulations shall come into operation on the first day of September, 1994.

REG 2

2. (1) In these Regulations—
 - "animal by-product" means any carcase or part of any animal or fish or any product of animal origin not intended for direct human consumption with the exception of animal excreta and catering waste;
 - "approved disinfectant" means a disinfectant listed under the Diseases of Animals (Disinfectants) Order, 1975 (Amendment) Order, 1978;
 - "approved seal" means a seal which for the time being stands approved of by the Minister or the Minister for the Marine for the purposes of these Regulations;
 - "authorised officer" has the meaning assigned to it by Regulation 15;
 - "commercial document" means a document authorised by a veterinary examiner or a marine veterinary examiner and bearing the official number of the establishment;
 - "the Council Directive" means Council Directive No. 90/667/EEC of 27 November, 1990 as amended by Council Directive No. 92/118/EEC of 17 December, 1992 and Commission Decision No. 92/562/EEC of 17 November, 1992;
 - "marine veterinary examiner" means, for the purposes of these Regulations, a veterinary inspector who is an officer of the Minister for the Marine;
 - "Member State" means a Member State of the European Communities;
 - "the Minister" means the Minister for Agriculture, Food and Forestry;
 - "premises" includes any land and any buildings, structures or private dwellings;
 - "third country" means a country which is not a member of the

European Communities;

"veterinary examiner" means a veterinary inspector who is an officer of the Minister.

(2) 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.

(3) 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.

REG 3

3. (1) High and low-risk animal by-products, as listed in the First Schedule Parts I and II respectively, shall not be used, sold, offered for sale, processed, disposed of, incorporated into animal feedingstuffs or petfood, supplied, stored or otherwise dealt with for any purpose except in compliance with these Regulations.

(2) The provisions of these Regulations shall not apply to hides, skins, hooves, feathers, wool, horns, blood and similar products from animals slaughtered in the normal way which are not used in the manufacture of feedingstuffs but shall apply to such products when originating from animals which, during veterinary inspection at the time of slaughter, show signs of any disease communicable through that product to man or animals.

(3) Subject to the provisions of Regulations 5, 9 and 11 animal by-products designated as high-risk material or low-risk material shall, as soon as possible, only be disposed of by one of the following methods:

(a) by processing in an establishment approved or registered in accordance with Regulation 6;

(b) where necessary, and subject to a licence granted in accordance with Regulation 4, by incineration or burial—where in the opinion of a veterinary examiner or a marine veterinary examiner, as the case may be:

(i) transport of an animal or an animal by-product to the nearest high-risk material processing plant constitutes a danger of propagation of health risks, or

(ii) an animal or an animal by-product is infected with or suspected of being infected with a serious disease or contains residues which could constitute a risk to human or animal health and which could survive inadequate heat treatment, or

(iii) a wide-spread infectious disease leads to a lack of capacity

at the high-risk material processing plant, or where in the opinion of an authorised officer—

(iv) the animal by-product concerned originates from places with difficult access, or

(v) the quantity and the distance to be covered does not justify collecting the by-product.

(4) Burial or incineration of an animal by-product is permissible, subject to a licence granted by the Minister or the Minister for the Marine, as the case may be, in accordance with Regulation 4, in the event of an emergency situation where, in the opinion of the Minister or the Minister for the Marine, as the case may be, there is a grave danger posed to public or animal health by this animal by-product.

(5) Notwithstanding the provisions of paragraph (3), an authorised officer may require the owner or person in charge of an animal by-product to dispose of such by-product, within a specified time, and the authorised officer may specify the method of disposal.

REG 4

4. (1) The Minister may grant a licence authorising the disposal of animal by-products by burial or burning in cases where he is satisfied that one or more of the criteria specified in Regulation 3 (3) (b) and 3 (4) are met.

(2) Notwithstanding the provisions of paragraph (1), the Minister for the Marine may grant a licence authorising the disposal of certain forms of animal by-products, namely carcasses or parts of fish not intended for direct human consumption, by burial or burning in cases where he is satisfied that one or more of the criteria specified in Regulation 3 (3) (b) and 3 (4) are met.

(3) Notwithstanding the provisions of paragraph (1), a veterinary examiner in a District Veterinary Office may grant a licence authorising the disposal of an animal by-product by burial, in cases where a single animal kept for agricultural production, has died on the farm, and where he is satisfied that the criteria specified in Regulation 3 (3) (b) are met.

(4) In the case of burial, licensed under paragraph (1), (2) or (3), the burial must be deep enough to prevent carnivorous animals from digging up the cadavers or by-products and the ground shall be suitable so as to prevent contamination of waters or any environmental nuisance. Before burial, the cadavers or by-products shall be disinfected as necessary with a suitable approved disinfectant.

(5) The Minister or the Minister for the Marine, as the case may be, shall when considering an application for a licence, under paragraph (1) or (2), for the incineration or burial of animal by-products consult with the local health board and local authority within whose functional area the proposed burial or incineration shall take place and take due notice of any advice of the said health board and local authority regarding the suitability of the

proposed site for such purpose and regarding the attachment of conditions to such a licence to ensure that public health and the environment are not prejudiced by such burial or incineration.

(6) The Minister or the Minister for the Marine, as the case may be, may, if he thinks it appropriate to do so for the purpose of ensuring compliance with these Regulations and having regard to the provisions of this Regulation and the Council Directive and to the advice of the Chief Executive of the health board, attach conditions (including those recommended by the appropriate health board and local authority to protect public health and the environment within their functional area) to a licence at the time of the grant of a licence under paragraph (1) or (2) or subsequently and may amend or revoke a condition attached to a licence. A copy of the licence shall be furnished by the Minister or the Minister for the Marine, as the case may be, to the appropriate health board and local authority.

(7) The Minister or the Minister for the Marine, as the case may be, may refuse to grant a licence to a person or may revoke a licence held by a person if—

(i) the person has been convicted of an offence under these Regulations or is for some other reason not, in the opinion of the Minister or the Minister for the Marine, as the case may be, a fit and proper person to hold a licence, or

(ii) the conditions for the disposal of the animal by-product by burial or incineration of such by-product under Regulation 3 (3) (b) and 3 (4) are not, or are no longer, satisfied, or

(iii) the disposal by burial or incineration of the animal by-product concerned, in the opinion of the Minister, or the Minister for the Marine, as the case may be, prejudices or would prejudice animal health, or

(iv) in the opinion of the Minister, or the Minister for the Marine, the site where the animal by-product is to be buried or incinerated is not a suitable location for such form of by-product disposal, or

(v) the burial or incineration of the animal by-product concerned, in the opinion of the Chief Executive Officer of the appropriate health board, prejudices or would prejudice public health.

(8) The person to whom a licence is granted shall take all reasonable care to ensure that any animal by-product, buried or incinerated under the provisions of this Regulation, is disposed of in such a manner as to prevent environmental nuisance or pollution.

REG 5

5. (1) The provisions of Regulations 3 and 4 shall not apply where the Minister or the Minister for the Marine in relation to fish by-product authorises, by licence—

(a) the use of any animal by-product for scientific purposes;

(b) (i) the use of high-risk animal by-products referred to in the First Schedule, Part I (a), (b) and (e) provided such

by-products are not derived from animals which were slaughtered or died as a result of the presence or the suspected presence of a notifiable disease, and of low-risk animal by-products referred to in the First Schedule, Part II for the feeding of zoo, circus or fur animals, packs of hounds and maggot farming for fish bait;

(ii) the local distribution through intermediaries, within the meaning of Article 7 (iii) of the Council Directive, of small quantities of the by-products referred to in subparagraph (b) (i) for the feeding of animals whose flesh is not intended for human consumption provided these by-products do not entail a risk to public and animal health.

(c) The Minister shall only authorise the feeding of the by-products referred to in subparagraphs (b) (i) and (ii) obtained from a premises licensed or approved by the Minister if, prior to supply, the by-products have been stained with a green staining ink, or other officially approved marking material suitable for staining meat which is unfit for human consumption.

(2) (a) Subject to the subsequent provisions of this paragraph, on application to the Minister or the Minister for the Marine, as the case may be, in that behalf by or on behalf of any person and on payment of such fee as he may specify, the Minister or the Minister for the Marine, as the case may be, may, if he is satisfied that the person is qualified and competent to perform on animal by-products the tests and trials for scientific purposes, grant a licence to the person authorising the performance by the person, of the said tests and trials specified in the licence.

(b) The Minister or the Minister for the Marine, as the case may be, may, if he thinks it appropriate to do so and for the purposes of ensuring compliance with these Regulations and having regard to the provisions of this Regulation, attach conditions to a licence at the time of the grant of the licence or subsequently and may amend or revoke a condition attached to a licence.

(c) The Minister or the Minister for the Marine, as the case may be, may revoke a licence held by a person where he is satisfied that the conditions of the licence have not been met by the licensee.

(3) (a) For the purposes of subparagraphs (1) (b) (i) and (ii), on application to the Minister or the Minister for the Marine, as the case may be, in that behalf by or on behalf of any person and on payment to the Minister or the Minister for the Marine, as the case may be, of such fee as he may specify, the Minister or the Minister for the Marine, as the case may be, may grant a licence to the person authorising the use and distribution of the animal by-products, specified in those subparagraphs, of such quantity as may be specified in the licence of the animal by-products so specified.

(b) The Minister or the Minister for the Marine, as the case may be, may attach such conditions to a licence as he considers appropriate, including—

(i) a requirement to keep records of the source of all animal

by-products obtained by him and the subsequent use or disposal of such by-products;

(ii) the provision of suitable and adequate facilities to store and handle the animal by-products;

at the time of the grant of a licence or subsequently and may amend or revoke a condition attached to a licence.

(4) (a) An application for a licence under this Regulation shall be made on such form as the Minister or the Minister for the Marine, as the case may be, may specify.

(b) A person applying for a licence under these Regulations shall furnish the Minister or the Minister for the Marine, as the case may be, with such information as he may reasonably require for the purposes of his functions under these Regulations.

(c) The Minister or the Minister for the Marine, as the case may be, may refuse to grant a licence under these Regulations if, in relation to the application therefor, information required by him has not been furnished to him or information that is, in the opinion of the Minister or the Minister for the Marine, as the case may be, false or misleading in a material particular has been furnished to him.

(d) (i) Where the Minister or the Minister for the Marine, as the case may be, proposes to refuse to grant or to revoke a licence under these Regulations or to amend or revoke a condition attached to, such a licence, he shall notify in writing the person who made the application for or, as the case may be, holds the licence, of his proposal and the reasons for it.

(ii) A notification under this Regulation shall be served on the person to be affected thereby, either by delivering it to him personally, or by leaving it for him at his last known place of abode or business, or by sending it through the post in a prepaid envelope addressed to that person there.

(iii) A person who has been notified of a proposal under subparagraph (i) may, within 14 days of receipt of the notification, make representations in writing to the Minister or the Minister for the Marine, as the case may be, and the Minister or the Minister for the Marine, as the case may be, shall—

(I) before deciding the matter take into consideration any representation duly made to him under this paragraph in relation to the proposal, and

(II) notify the person in writing of his decision and the reasons therefor.

(iv) A notification under subparagraph (i) shall include a statement that the person concerned may make a representation to the Minister or the Minister for the Marine, as the case may be, within 14 days of the receipt by him of the notification.

(v) Notwithstanding any other provision of this Regulation, the Minister or the Minister for the Marine, as the case may be, may revoke a licence or require immediate suspension of some or all of the activities provided for under the licence if the Minister or the Minister for the Marine, as the case may be, is of the

opinion that the continued operation of the activities provided for by the licence poses a grave and immediate danger to public or animal health or the environment arising from the manner in which the animal by-products are used, distributed or stored or from the manner in which the premises or facility where such activities take place is managed or maintained.

REG 6

6. (1) The Minister may for the purposes of Regulation 3 approve a high-risk or a low-risk processing plant for the collection and processing of animal by-products in respect of which he is satisfied that the plant—

(a) meets the requirements set out in Chapter I of the Third Schedule,

(b) handles, processes, treats and stores animal by-products in accordance with Chapter II of the Third Schedule,

(c) ensures that the products after processing satisfy the requirements of Chapter III of the Third Schedule,

(d) has or has the use of a laboratory, approved annually by the Minister, to analyse samples needed to comply with the conditions of Regulation 7 and to ensure that the requirements set down in Chapter III of the Third Schedule are met, and

(e) complies with the provisions of Council Directive No. 92/118/EEC(4) of 17 December, 1992.

(4) O.J. No. L62 of 15.3.1993, p. 49.

(2) The Minister may for the purposes of Regulation 3 register a premises using low-risk material for the preparation of pet food in respect of which he is satisfied that the premises—

(a) has adequate facilities for safely storing and treating animal by-products,

(b) has adequate facilities for destroying unused raw animal by-product remaining after production, or it must be sent to a processing plant or to an incinerator,

(c) has adequate facilities available to destroy waste material arising during the production process which is unsuitable on the grounds of animal or public health for inclusion in other animal food or send it to a high-risk processing plant or to an incinerator,

(d) has or has the use of a laboratory, approved annually by the Minister, to ensure that the requirements set down in Chapter III of the Third Schedule and Chapter 4 to Annex I of Council Directive 92/118/EEC are met, and

(e) complies with the other relevant provisions of Directive No. 92/118/EEC of 17 December, 1992.

(3) The Minister for Health may for the purposes of Regulation 3 register a premises using low-risk material for the preparation of pharmaceutical or technical products in respect of which he is satisfied that the premises—

(a) has adequate facilities for safely storing and treating

animal by-products,

(b) has adequate facilities for destroying unused raw animal by-product remaining after production, or it must be sent to a processing plant or to an incinerator,

(c) has adequate facilities available to destroy waste material arising during the production process which is unsuitable on the grounds of animal or public health for any other purpose or have it sent to a high-risk processing plant or to an incinerator, and

(d) complies with the provisions of Directive No. 92/118/EEC of 17 December, 1992.

(4) The Minister for the Marine may for the purposes of Regulation 3 register a premises using low-risk material for the exclusive preparation of fishmeal in respect of which he is satisfied that the premises—

(a) has adequate facilities for safely storing and treating animal by-products,

(b) has adequate facilities for destroying unused raw animal by-product remaining after production, or it must be sent to a processing plant or to an incinerator,

(c) has adequate facilities available to destroy waste material arising during the production process which is unsuitable on the grounds of animal or public health for any other purpose or have it sent to a high-risk processing plant or to an incinerator, and

(d) ensures that the fishmeal satisfies the requirements laid down in Chapter III of the Third Schedule.

(5) Where low-risk material is stored prior to being processed in a premises producing petfood or fishmeal or technical or pharmaceutical products, the Minister, the Minister for the Marine or the Minister for Health, as the case may be, may lay down such conditions, including the specific location of storage facilities and the keeping of records, as he may deem necessary for the safe storage and handling of such material.

(6) When an establishment is approved or registered, as the case may be, in accordance with paragraph (1), (2), (3) or (4), an official number shall be allocated to it, by the Minister, the Minister for Health or the Minister for the Marine, as the case may be, which identifies the establishment as processing high-risk or low-risk material, or producing petfood or fishmeal or technical or pharmaceutical products from animal by-products. All registered or approved establishments will receive a single official number. The owner or person in charge of the establishment shall be notified in writing of the registration or approval, as the case may be, and of the number.

(7) The Minister, the Minister for Health or the Minister for the Marine, as the case may be, may attach conditions to an approval or registration under this Regulation at the time of the grant of the approval or registration or subsequently and may amend or revoke a condition attached to the approval or registration, as the case may be, and shall notify the owner or person in charge of the establishment concerned in writing of the conditions, amendment or

revocation concerned.

(8) A person who is for the time being the owner or person in charge of an establishment approved or registered, as the case may be, under these Regulations shall carry out all reasonable directions issued by an authorised officer for the purposes of these Regulations.

(9) A list of establishments approved or registered, as the case may be, under this Regulation shall be maintained by the Minister, the Minister for Health or the Minister for the Marine, as the case may be.

(10) For the purposes of this Regulation the mixture of low-risk material processed together with high-risk material shall be deemed to be high-risk material.

7. (1) (a) A person who is for the time being the owner or person in charge of a high or low-risk processing plant approved by the Minister in accordance with Regulation 6 shall take all necessary measures to ensure that these Regulations are complied with, and shall in particular, to the satisfaction of the Minister—

(i) identify and control the critical points, within the meaning of Article 9.1 of the Council Directive, in the processing plant, and

(ii) take representative samples from each processed batch to check compliance with the microbiological standards set in Chapter III of the Third Schedule, and

(iii) record the results of the various checks and tests and keep them for a period of at least two years for presentation to an authorised officer, and

(iv) introduce a batch system, within the meaning of Article 9.1 of the Council Directive, that makes it possible to link each batch dispatched and the time when it was produced.

(b) A person who is for the time being the owner or person in charge of a processing plant approved by the Minister in accordance with Regulation 6 having taken the necessary measures described in paragraph (1) and where the result of a test on a sample of a product produced in accordance with that paragraph shows that the sample is not in compliance with the provisions of Chapter III of the Third Schedule shall—

(i) notify an authorised officer immediately, and

(ii) establish the causes of failure of the sample to comply with the standards set in Chapter III of the Third Schedule, and

(iii) ensure that no material suspected or known to be contaminated is moved from the plant before being reprocessed and resampled under the supervision of an authorised officer to ensure compliance with the standards set in Chapter III of the Third Schedule. If it is not possible to reprocess the contaminated material for any reason, it must be used for purposes other than animal feedingstuffs and its use notified to an authorised officer.

(c) Authorised officers may from time to time carry out inspections and random checks at approved high and low-risk processing plants as to—

(i) their compliance with the provisions of these Regulations and in

particular with regard to the Second Schedule and Chapters I, II and III of the Third Schedule, and

(ii) the microbiological standards of the products after treatment.

The microbiological controls shall include, in particular, examination for salmonella and enterobacteriaceae in accordance with Chapter III of the Third Schedule.

(2) Where an inspection carried out by an authorised officer for the purposes of these Regulations reveals non-compliance by an establishment with the controls and standards set out in these Regulations, the officer shall instruct the owner or person in charge of the establishment to take the necessary action to ensure that these standards are observed and, if appropriate, require the suspension of production until the required action is taken by the owner or person in charge of the establishment. In particular, in relation to non-compliance with the microbiological standards and the types of microbiological controls outlined in these Regulations, an authorised officer shall require a person who is for the time being the owner or person in charge of the establishment to take the following measures—

(i) process or reprocess the contaminated lot under the supervision of an authorised officer, and

(ii) increase the intensity of sampling and testing of production, and

(iii) investigate raw material records appropriate to the finished feed sample, and

(iv) instigate appropriate decontamination and cleaning procedures in the establishment.

(3) A person who is for the time being the owner or person in charge of an establishment shall carry out any instruction given to him by an authorised officer under this Regulation.

REG 8

8. (1) The Minister, the Minister for Health or the Minister for the Marine, as the case may be, may, if he is not satisfied that the relevant provisions of these Regulations are being complied with in relation to an establishment, refuse to approve or register, as the case may be, the establishment and shall notify the owner or person in charge of the establishment in writing of the refusal and the reasons for such refusal.

(2) Subject to the provisions of paragraph (3), the Minister, the Minister for Health or the Minister for the Marine, as the case may be, if he is not satisfied that all of the relevant provisions of these Regulations are being complied with as regards an approval or registration which was given under Regulation 6, may revoke or suspend the approval or registration.

(3) The Minister, the Minister for Health or the Minister for the Marine, as the case may be, shall not—

(a) revoke or suspend an approval or registration given under Regulation 6, or

(b) refuse to approve or register an establishment on foot of an application, without—

(i) notifying the holder of, or applicant for, the approval or registration, as the case may be, of his intention to revoke, suspend or refuse the approval or the registration, as the case may be; and

(ii) specifying his reason for the intended suspension, revocation or refusal, as the case may be; and

(iii) affording the holder of, or applicant for, the approval or registration, as the case may be, an opportunity of making representations within 14 days or having representations made on his behalf, to the Minister, the Minister for Health or the Minister for the Marine, as the case may be, in relation to the proposed revocation, suspension or refusal, as the case may be.

(4) Where an approval under Regulation 6 is suspended or revoked the Minister shall prohibit the placing on the market, supply, sale or use of products originating from that plant subsequent to the date of revocation or suspension, as the case may be.

(5) Where an approval or registration under Regulation 6 is suspended or revoked the Minister, the Minister for Health or the Minister for the Marine, as the case may be, may issue a notice requiring that establishment to cease production from a date specified in that notice.

(6) Notwithstanding the other provisions of this Regulation, the Minister, the Minister for Health or the Minister for the Marine, as the case may be, may where he is satisfied that there is a serious and immediate risk to animal and human health, suspend without notice an approval or registration granted under Regulation 6.

REG 9

9. (1) A person shall not engage in intra-Community trade in any animal by-product unless the animal by-product concerned complies with:

(a) the requirements of the Second Schedule; and

(b) the provisions of these Regulations including, in particular, the conditions relating to production, control, dispatch, storage and transport of such materials.

(2) High-risk and low-risk materials intended for processing in a plant in another Member State or processed products obtained from high-risk or low-risk materials must be accompanied if they come from a processing plant approved in accordance with Regulation 6, by a commercial document specifying—

(i) if appropriate, the nature of the treatment, and

(ii) whether the goods contain ruminant protein.

(3) Processed products obtained from low-risk materials and intended for animal feedingstuffs coming from any other form of plant must be accompanied by a certificate issued and signed by a veterinary

examiner or marine veterinary examiner indicating—

(i) the methods of treatment used on the consignment, and

(ii) the results of the salmonella tests, and

(iii) whether the goods contain ruminant protein.

(4) High-risk and low-risk materials coming from any other form of plant must be accompanied by a certificate issued and signed by a veterinary examiner or marine veterinary examiner indicating whether the goods contain ruminant proteins.

(5) In addition to the requirements of this Regulation, dealers, within the meaning of Article 12 of Council Directive No. 90/425/EEC(5) of 26 June, 1990, who engage in intra-community trade in animal by-products and processed products obtained from high-risk or low-risk material must:

(5) O.J. No. L224 of 18.8.1990, p. 29.

(a) register with the Minister or the Minister for the Marine, as the case may be, by giving their name and the address of their premises, and

(b) keep a record of all receipts and deliveries of animal by-products and of their subsequent destination, for inspection, when requested, by an authorised officer, and

(c) retain such records, including commercial documents or certificates, for a period of at least 2 years.

REG 10

10. (1) Animal by-products must be transported in accordance with the provisions of the Second Schedule.

(2) The owner or person in charge of a vehicle in which animal by-products are being transported shall comply with the conditions relating to the transport of animal by-products specified in the Second Schedule and with any other conditions, including sealing, which a veterinary examiner or a marine veterinary examiner may decide are necessary for the purposes of this Regulation.

(3) Plants where high-risk and low-risk material is processed and other establishments using low-risk materials must keep records of receipt of animal by-product material. Such records must be retained, by a person who is for the time being the owner or operator of an establishment approved or registered, as the case may be, under these Regulations for a period of at least 2 years and these records must accord with the requirements of the Second Schedule.

(4) A person by whom records are kept in pursuance of these Regulations shall produce the records to, and allow them to be inspected by an authorised officer on a request being made in that behalf by such officer.

REG 11

11. (1) A person shall not import high-risk material described in the First Schedule, Part I (a) to (f) from a third country.

(2) A person shall not import high-risk material as described in the First Schedule, Part I (g) to (j) or low-risk animal by-product from a third country unless the Minister or the Minister for the Marine, as the case may be, is satisfied that such material has undergone adequate treatment and complies with the standards of Chapter III of the Third Schedule and the relevant provisions of Directive No. 92/118/EEC of 17 December, 1992.

(3) Any animal by-product imported into the State from a third country in accordance with the provisions of this Regulation shall be eligible for trade in accordance with the provisions of Regulation 9.

REG 12

12. In relation to the sale, offer for sale or importation into or exportation from the State of any goods, a person who is the owner of such goods or a person acting on his behalf or with his authority shall not hold out such goods as being an animal by-product complying with Regulations 5 and 6 if such goods do not so comply.

REG 13

13. (1) An application for a certificate or for the authorisation of a commercial document required for the purposes of compliance with these Regulations shall be made to an authorised officer and shall be in such form and contain such particulars as the Minister or the Minister for the Marine, as the case may be, may require and, unless the Minister or the Minister for the Marine, as the case may be, otherwise agrees, such an application shall be received by the authorised officer to whom it is made not later than the day, being a day which is not a Saturday, Sunday or a bank or public holiday, preceding the day on which the certificate or the authorisation of the commercial document is required by the applicant.

(2) A person shall not supply false or misleading particulars to an authorised officer for the purpose of obtaining a certificate or the authorisation of a commercial document.

REG 14

14. (1) Where in relation to any animal by-product an authorised officer forms an opinion that there is a risk to public or animal health—

(a) he may seize any animal by-product, or

(b) he may serve or cause to be served on any person who is

the owner of the animal by-product or an importer, or exporter of such animal by-product or the person who appears to such officer to be in control for the time being of such animal by-product a notice requiring either the owner, importer, exporter, or person in control for the time being of the animal by-product, that such by-product—

(i) be destroyed in such manner and at such place as the authorised officer shall direct, or
(ii) be used or disposed of in such manner as the authorised officer shall direct, and
(iii) any costs pertaining to action required under subparagraphs (i) and (ii) will be borne by the person on whom the notice is served.

(2) A requirement contained in a notice may specify a time limit within which it is to be complied with.

(3) A requirement specified in a notice served under paragraph (1) (in this paragraph referred to as "the earlier notice") may be modified or withdrawn in a further such notice and in that event the earlier notice shall have effect subject to such modification or withdrawal.

(4) A notice may require the owner, importer, exporter, or person in control for the time being of the animal by-product to choose between two or more of the requirements specified in the notice.

(5) A notice referred to in paragraph (1) may be served on the owner, importer, exporter, or person in control for the time being of the animal by-product by delivery of it by hand, or by sending it by prepaid registered post to or by leaving it at his last known place of abode or business.

(6) (a) An owner, importer, exporter or person in control for the time being of the animal by-product may appeal within 7 days of the seizure of such animal by-product or service of the notice under paragraph (1) to the Judge of the District Court having jurisdiction in the District Court District where such by-product is situated or to the Judge of the District Court having jurisdiction in the District Court District where the person bringing the appeal ordinarily resides or carries on business on the grounds that the seizure or the notice or any of the terms thereof are not justified having regard to the provisions of these Regulations.

(b) An appeal made pursuant to subparagraph (a) may be heard at any sitting of the District Court within the appropriate District Court District.

(c) (i) Notice of an appeal made pursuant to subparagraph (a) shall be served on the Minister, the Minister for Health or the Minister for the Marine, as the case may be, and the said notice shall be served at least 48 hours prior to the hearing of the appeal by serving it on the Minister, the Minister for Health or the Minister for the Marine, as the case may be, or by leaving it at the place and in the manner specified in the notice issued under this Regulation;

(ii) the notice of appeal shall contain a statement of the grounds

upon which it is alleged that the seizure or the notice or any of the terms thereof are not justified.

(d) A copy of the notice of appeal shall be lodged with the District Court Clerk in the manner specified in the notice issued pursuant to paragraph (1), at least 48 hours prior to the hearing of the appeal.

(e) The Minister, the Minister for Health or the Minister for the Marine, as the case may be, shall, as well as the appellant, be entitled to be heard and to adduce evidence at the hearing of an appeal brought under paragraph (6) of this Regulation in opposition to an appeal made pursuant to this Regulation.

(7) On the hearing of an appeal under this Regulation a Judge of the District Court may, at his discretion, confirm, modify, or annul the action taken under paragraph (1).

(8) (a) No person including a person upon whom a notice has been served under paragraph (1), shall deal with the animal by-product concerned other than in accordance with the terms of the notice.

(b) In the event of an appeal against the terms of a notice referred to in subparagraph (a), pursuant to paragraph (6), no person, including the person appealing, shall deal with the animal by-product concerned pending the determination of the appeal other than in accordance with such directions as shall be given in writing to the appellant by an authorised officer.

(c) Where the terms of a notice referred to in subparagraph (a) are confirmed with or without modification by the Judge of the District Court hearing the appeal made under the said paragraph (6) no person, including the person who made the appeal, shall deal with the animal by-product concerned other than in accordance with such notice as confirmed.

(9) (a) where:—

(i) an owner, importer, exporter or a person for the time being in control of the animal by-product fails to comply with the terms of a notice served upon him under paragraph (1) within the time specified therein, or

(ii) an authorised officer has reasonable grounds for believing that the terms of a notice served under paragraph (1) will not be complied with, or

(iii) a notice served under paragraph (1) has been confirmed with or without modification under paragraph (7) and the notice has not been complied with, or

(iv) an authorised officer has reasonable grounds for believing that the terms of a notice served under paragraph (1) which has been confirmed with or without modification under paragraph (7) will not be complied with, or

(v) pending the determination of an appeal made pursuant to subparagraph (a) of paragraph (6), an authorised officer has reasonable grounds for believing that directions given pursuant to paragraph (8) have not been or shall not be complied with, an authorised officer may at any time seize the animal by-product

at such premises or place as he thinks fit in the circumstances of the case.

(b) In relation to any seized animal by-product, an authorised officer may destroy it, or cause it to be destroyed in such manner and at such place as the authorised officer shall direct, or such animal by-product may be used or disposed of in such manner as the authorised officer shall direct.

(c) Any profits arising out of the disposal of the animal by-product referred to in subparagraph (b) shall be paid to the owner of such animal by-product less any expenses incurred in connection with the said disposal.

(10) The costs of disposal or destruction of an animal by-product under this Regulation shall, subject to the provisions of subparagraph (9) (c), be recoverable by the Minister, the Minister for Health or the Minister for the Marine, as the case may be, as a simple contract debt in any court of competent jurisdiction from the person who was the owner of such animal by-product at the time the disposal or destruction was carried out.

(11) In this Regulation:—

"animal by-product" includes any goods represented to an authorised officer as being an animal by-product;

"importer" and "exporter" include any person who, whether as owner, consignor, consignee, agent or broker is in possession of or in any way entitled to the custody or control of the animal by-product which is being or has been imported into or exported from the State.

REG 15

15. (1) In these Regulations, "authorised officer" means—

(a) a veterinary examiner or other officer of the Minister appointed by the Minister to be an authorised officer for the purposes of these Regulations,

(b) in relation to all premises other than those approved or registered by the Minister or the Minister for the Marine, as the case may be, and means of transport, and for the purposes of Regulation 4, paragraphs (3), (5), (6), (7), (8) and (9) of Regulation 6, paragraphs (2) and (3) of Regulation 7, Regulation 8, Regulation 10 in so far as it relates to the Second Schedule and Regulations 14 and 18 and paragraph (b) of Part I of the First Schedule, an officer authorised by the Minister for Health or an authorised officer within the meaning of the Food Hygiene Regulations, 1950 to 1989,

(c) in relation to all premises other than those approved or registered by the Minister or the Minister for Health, as the case may be, and means of transport, and for the purposes of Regulations 4 and 5, paragraphs (4), (5), (6), (7), (8) and (9) of Regulation 6, paragraphs (2) and (3) of Regulation 7, Regulation 8, paragraphs (3), (4) and (5) of Regulation 9, Regulation 10 in so far as it relates to the Second Schedule and Regulations 11, 13, 14, 16 and

18 and paragraph (b) of Part I of the First Schedule, a marine veterinary examiner or other officer authorised by the Minister for the Marine.

(2) An authorised officer shall be furnished with a warrant of his appointment by the Minister or the Minister for Health or the Chief Executive Officer of a health board on instruction from the Minister for Health or the Minister for the Marine, as the case may be, 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.

(3) Subject to the provisions of paragraph (1), an authorised officer or a veterinary expert from the Commission may at all reasonable times enter—

(a) an establishment approved or registered under Regulation 6 or for which an application for approval or registration has been received or a premises issued a licence under Regulation 5 or for which an application for a licence has been received; and

(b) any other land, premises, structure or other place in which he has reasonable grounds for believing that—

(i) there are animals (whether alive or dead or slaughtered or not) from which animal by-products are intended to be or are derived, or

(ii) there are kept animal by-products either on importation from or for export to a Member State or third country, or

(iii) there are kept animal by-products which he reasonably believes to have been produced in contravention of these Regulations or the Council Directive, and

(c) any railway wagon, vehicle, aircraft, ship or other vessel, or any other means of transport, in which he has reasonable grounds for believing that any animal by-product is either destined for export to or imported from a Member State or third country, or being kept for transport, import or export, or there is kept animal by-products which he reasonably believes to have been produced in contravention of these Regulations or the Council Directive, and either there or at any other place:—

(A) make such examinations and tests, and

(B) take such reasonable samples of any animal by-products, 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 which he finds in the course of his inspection,

as he may consider appropriate for the purposes of these Regulations and the Council Directive.

REG 16

16. (1) A person shall not make or cause to be made, order, import, purchase, sell, offer or expose for sale an approved seal or anything purporting to be an approved seal, save with the consent in writing of the Minister or the Minister for the Marine, as the case may be.

(2) A person shall not print or cause to be printed, order, import, purchase, sell, offer or expose for sale a certificate for the purposes of these Regulations ("a certificate") or any document purporting to be or in any way resembling a certificate save with the consent in writing of the Minister or the Minister for the Marine, as the case may be.

(3) A person shall not have in his possession or under his control a certificate or any document purporting to be or in any way resembling a certificate unless he is—

(i) an authorised officer or an officer of the Minister or the Minister for the Marine, or

(ii) a person who is in possession or control of the certificate or document with the consent in writing of the Minister or the Minister for the Marine, or

(iii) a person who is in possession or control of the certificate or document, in accordance with the provisions of these Regulations.

(4) A person shall not procure by fraud or by misrepresentation, forge, or without lawful authority or excuse, alter or tamper with, any document purporting to be a certificate or a properly authorised commercial document or any other document purporting to be issued under these Regulations or for the purposes of the Council Directive or any thing purporting to be an approved seal not utter any such certificate, document or seal knowing it to be procured by fraud or by misrepresentation, forged, altered or tampered with.

(5) A person shall not apply an approved seal or any thing purporting to be an approved seal to any means of transport of animal by-products unless he is an authorised officer.

(6) Nothing in paragraph (1) or (2) shall be construed as prohibiting the importation of a certificate or a seal where such importation is for the purpose only of complying with Regulations 9 and 11.

REG 17

17. (1) (a) There may be charged by the Minister in respect of an approval under Regulation 6 and in relation to the performance of functions under these Regulations such fees as the Minister, with the consent of the Minister for Finance, may determine.

(b) A fee charged under this Regulation shall be payable by the owner or person in charge of the establishment to which the approval concerned relates and the Minister may refuse to grant or may revoke an approval until such fee has been paid.

(2) Fees under this Regulation shall be collected and taken in such manner as the Minister directs and shall be paid into or disposed of for the benefit of the Exchequer in accordance with the directions of the Minister for Finance.

(3) A fee payable under this Regulation may be recovered by the Minister from the person by whom it is payable as a simple contract debt in any court of competent jurisdiction.

(4) A fee charged under this Regulation shall not exceed an amount

equal to the costs, estimated by the Minister, incurred in relation to the approval concerned and the performance of functions under these Regulations to the establishment concerned by authorised officers for the purposes of the approval.

(5) The Public Offices Fees Act, 1879, shall not apply in respect of fees charged under this Regulation.

REG 18

18. An offence under these Regulations may be prosecuted by the Minister, the Minister for Health or a health board, in whose functional area the offence was committed, or the Minister for the Marine.

REG 19

19. (1) Any person who contravenes a provision of these Regulations or a condition of a licence granted under these Regulations shall be guilty of an offence.

(2) If any person fraudulently—

(a) tampers or otherwise interferes with any animal by-product so as to procure that any sample of it taken under these Regulations does not correctly represent the animal by-product, or

(b) tampers or otherwise interferes with any sample taken under these Regulations,
he shall be guilty of an offence.

(3) Any person who obstructs or otherwise interferes with an authorised officer in the exercise of a power conferred on him by these Regulations or fails or refuses to comply with a request made by or to a question asked by such officer pursuant to these Regulations shall be guilty of an offence.

(4) A person guilty of an offence under these Regulations shall be liable, on summary conviction, to a fine not exceeding £1,000 or, at the discretion of the court, to imprisonment for a term not exceeding twelve months or to both such fine and such imprisonment.

(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 be guilty of an offence.

REG 20

20. These Regulations are in addition to and not in substitution for the Diseases of Animals Act, 1966 (No. 6 of 1966) and Orders made under or continued in force by that Act.

FIRST SCHEDULE.

High-Risk Animal By-products.

Part I.

- (a) All bovine animals, pigs, goats, sheep, solipeds, poultry and all other animals kept for agricultural production, which have died on the farm but were not slaughtered for human consumption, including stillborn and unborn animals;
- (b) dead animals not referred to at (a) above but which are considered by an authorised officer to be a danger to public or animal health;
- (c) animals which are killed in the context of disease control measures either on the farm or in any other place designated by the Minister;
- (d) animal by-products including blood originating from animals which show, during veterinary inspection carried out at the time of slaughtering, clinical signs of diseases communicable to man or other animals;
- (e) all those parts of an animal slaughtered in the normal way which are not presented for post mortem inspection, with the exception of hides, skins, hooves, feathers, wool, horns, blood and similar products;
- (f) all meat, poultrymeat, fish, game and foodstuffs of animal origin which are spoiled and thus present a risk to human and animal health;
- (g) animals, fresh meat, poultrymeat, fish, game, and meat and milk products, imported from third countries, which fail to comply with the veterinary requirements for their importation into the Community, unless they are re-exported or their import is accepted under restrictions laid down in Community provisions;
- (h) farm animals which have died in transit, other than those slaughtered for reasons of welfare;
- (i) animal by-products containing residues of substances which may pose a danger to human or animal health; milk, meat or products of animal origin rendered unfit for human consumption by the presence of such residues;
- (j) fish which show clinical signs of diseases communicable to man or to fish.

Low-Risk Animal By-products.

Part II.

- (a) Animal by-products other than those listed in Part I of this Schedule which do not present serious risks of spreading communicable diseases to animals or man;
- (b) products excluded from Part I (e) of this Schedule in so far as they are used in the manufacture of feedingstuffs;
- (c) fish caught in the open sea for the purposes of fishmeal production;
- (d) fresh fish offal from plants manufacturing fish products for human consumption.

SECOND SCHEDULE.

Requirements for the Collection and Transport of Animal By-products.

1. Any animal by-product must be collected and transported to registered establishments or to high or low-risk processing plants in suitable containers or vehicles in such a way as to prevent leakages. The containers or vehicles must be adequately covered.
2. Vehicles, tarpaulin covers and reusable containers must be maintained in a clean condition.
3. Any consignor, of any animal by-product listed in the First Schedule, must keep a record of each consignment and must ensure that identifying documentation accompanies the animal by-product during its journey. Such records and copies of documentation must be retained by the consignor for two years and must show—
 - (a) the date on which the animal by-product was removed;
 - (b) the quantity, description and source of the animal by-product;
 - (c) the destination to which the animal by-product was delivered;
 - (d) the name of the haulier who transported the animal by-product;
 - (e) any other relevant information previously requested by an authorised officer.
4. The owner or person in charge of containers or vehicles must ensure that the original identifying documentation, mentioned in paragraph 3, accompanies the by-product during its journey and is surrendered to the consignee.
5. Plants where any animal by-product described in the First Schedule is to be processed and other establishments using low-risk materials must keep a record of incoming consignments of such material. The records must be kept for a period of two years and must show—
 - (a) the date on which this by-product material arrived;
 - (b) the source, quantity and description of the animal by-product;
 - (c) the use to which the animal by-product was put;
 - (d) the name of the haulier who transported the animal by-product and the original of the transport documentation referred to in paragraph 3;
 - (e) any other relevant information previously requested by an authorised officer.
6. Where certain meat, dairy and fish products not intended for human consumption and derived from animals or fish, the meat or milk of which has been approved for human consumption are transported directly in bulk to a processing plant, the information on the origin, name and nature of the animal by-products and the words 'not for human consumption' must be indicated on a label attached to the container, cartons or other packaging material in

letters at least 2 cm high.

7. Where any animal by-product is to be collected and transported to registered establishments or to high or low-risk processing plants, that journey should be conducted, wherever possible, from the point of origin to the point of destination without any intermediate stops. In the event that an intermediate stop is required, the vehicle containing the animal by-product must not, in the interest of animal health, be parked on any farm or in the vicinity of any farm.

THIRD SCHEDULE.

Hygiene Requirements for Animal By-products Processing Plants.

Chapter I.

REQUIREMENTS FOR ANIMAL BY-PRODUCTS PROCESSING PLANTS.

1. Premises and facilities must meet at least the following requirements:

- (a) the premises of the processing plant must be adequately separated from the public highway and other premises such as slaughterhouses. Premises for the processing of high-risk material must not be at the same site as slaughterhouses, unless in a completely separate part of a building; unauthorised persons and animals shall have no access to the plant;
- (b) the plant must have a clean and an unclean section, adequately separated. The unclean section must have a covered place to receive the material for rendering and must be constructed in such a way that it is easy to clean and disinfect. Floors must be laid in such a way as to facilitate the draining of liquids. The plant must have adequate lavatories, changing rooms and washbasins for staff;
in the unclean section, where appropriate, there must be adequate facilities for de-skinning or de-hairing of animals and a storage room for hides;
- (c) the plant must have sufficient capacity and hot water and steam production for the processing of material in accordance with Chapter II;
- (d) the unclean section must, if appropriate, contain equipment to reduce the size of material for rendering and equipment for loading the crushed material into the processing unit;
- (e) a closed processing installation is required in which the material must be processed in accordance with Chapter II. Where heat treatment is required, this installation must be equipped with:
 - (i) measuring equipment to check temperature and, if necessary, pressure at critical points;
 - (ii) recording devices to record continuously the results of measurements;
 - (iii) an adequate safety system to prevent insufficient heating;
- (f) to prevent recontamination of the finished processed material by incoming raw material, there must be clear separation between the area of the plant where the incoming raw material is unloaded and

processed and the areas set aside for further processing of the heated material and the storage of the finished processed product.

2. The processing plant must have adequate facilities for cleaning and disinfecting the containers or recipients in which animal by-products are received and the vehicles—other than ships—in which they are transported.

3. Adequate facilities must be provided for disinfecting the wheels, immediately before their departure, of vehicles transporting high-risk material or leaving the unclean section of a processing plant.

4. A waste-water disposal system meeting hygiene requirements is required for the processing plant.

Chapter II.

Hygiene Requirements Relating to Operation in Animal By-products Processing Plants.

1. Animal by-products must be processed as soon as possible after arrival. They must be stored properly until processed.

2. Containers, recipients and vehicles used for the transport of animal by-products must be cleaned, washed and disinfected after each use.

3. Persons working in the unclean section must not enter the clean section without changing their working clothes and footwear or without disinfecting the latter. Equipment and utensils shall not be taken from the unclean section into the clean section.

4. Waste water originating in the unclean section must be treated to ensure that no pathogens remain.

5. Preventive measures against birds, rodents, insects or other vermin must be taken systematically.

6. Animal by-products must be processed under the following conditions:

(a) high-risk material must be heated to a core temperature of at least 133°C for 20 minutes at a pressure of 3 bar. The

particle size of the raw material prior to processing must be reduced to at least 50 mm by means of a prebreaker or grinder;

(b) recording thermographs must be provided at the critical points of the heating process to monitor the heat treatment;

(c) other systems of heat treatment may be used provided that they are approved in accordance with the procedure laid down in Article 19 of the Council Directive.

Such alternative heat treatment systems may be approved only where the final product has been sampled on a daily basis over a period of one month to ensure compliance with the microbiological standards laid down in paragraphs 1 and 2 of Chapter III. Subsequent routine sampling of the products as provided for in Regulation 7(1) must also be carried out.

7. Installations and equipment must be kept in a good state of repair and measuring equipment must be calibrated at regular intervals.

8. The finished products must be handled and stored at the processing plant in such a way as to preclude recontamination.

9. Hides must be salted using sodium chloride.

Chapter III.

Requirements Concerning the Products after Processing.

1. In the case of high-risk materials, samples of the finished products, taken directly after heat treatment, must be free from heat-resistant pathogenic bacteria spores (*Clostridium perfringens* absent in 1g of the product).

2. Samples of the final products from both low-risk and high-risk material taken during or upon withdrawal from storage at the processing plant must comply with the following standards:

Salmonella: absence in 25g: $n = 5$, $c = 0$, $m = 0$, $M = 0$,

Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 3 \times 10^2$ in 1g,

where

n = number of units comprising the sample;

m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed m ;

M = maximum value for the number of bacteria: the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more;

c = number of sample units the bacterial count of which may be between m and M , the sample still being considered acceptable if the bacterial count of the other sample units is m or less.

GIVEN under my Official Seal, this 3rd day of August, 1994.

JOE WALSH,

Minister for Agriculture, Food
and Forestry.

EXPLANATORY NOTE.

The purpose of these Regulations is to implement Council Directive No. 90/667/EEC of 27 November, 1990, as amended by Council Directive No. 92/118/EEC of 17 December, 1992 and Commission Decision No. 92/562/EEC of 17 November, 1992, laying down the veterinary rules for the disposal and processing of animal by-products, for their placing on the market and for the prevention of pathogens in feedingstuffs of animal or fish origin.