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STATUTORY INSTRUMENTS

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**1999 No. 1872**

**The Feeding Stuffs (Establishments  
and Intermediaries) Regulations 1999**

**PART VI**

**APPROVAL OR REGISTRATION OF  
ESTABLISHMENTS LOCATED IN THIRD COUNTRIES**

**Declarations leading to the approval or registration of establishments located in third countries**

**33.**—(1) An eligible person may submit to the Minister a declaration relating to a third country establishment on which there is being exercised, or on which it is intended to exercise, one or more of the following activities—

- (a) the manufacture of an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, with a view to putting it into circulation;
  - (b) the manufacture of a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, with a view to putting it into circulation;
  - (c) the manufacture of a premixture, containing additives of any kind referred to in the fourth or fifth indent of Chapter I.2(a) of the Annex, but not containing a zootechnical additive, with a view to putting it into circulation;
  - (d) the manufacture of a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69, with a view to putting it into circulation;
  - (e) the manufacture of an additive of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, with a view to putting it into circulation;
  - (f) the manufacture of a premixture, containing additives of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but not containing an additive of any kind referred to in Chapter I.2(a) of the Annex, with a view to putting it into circulation;
  - (g) the manufacture of a compound feeding stuff containing a premixture containing additives of any kind referred to in Chapter II(b) of the Annex, but not containing a zootechnical additive, with a view to putting it into circulation; or
  - (h) the manufacture of a compound feeding stuff, containing an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but not containing an additive of any kind referred to in Chapter I.2(a) of the Annex, with a view to putting it into circulation.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the person submitting the declaration,

- (d) contain the name (or business name) and address of that person,
- (e) identify the establishment to which the declaration relates,
- (f) identify the establishment activity which is being exercised or, as the case may be, it is intended to exercise, on that establishment,
- (g) if made by 30th September 1999, state—
  - (i) whether the establishment activity was being exercised on the establishment on 31st December 1998, and
  - (ii) if so, whether an eligible person would have been in a position to submit a declaration equivalent to one under paragraph (1) in relation to the establishment activity, at a date after 30th December 1998 but before 1st May 1999, had paragraph (1) been in force at that date;
- (h) contain a statement that the establishment complies, and an undertaking that when the establishment activity is exercised on it it will comply, with the applicable conditions, and
- (i) contain an undertaking of the kind described in the second indent of Article 6.2 of Directive 98/51.

#### **Approval or registration of establishments located in third countries**

**34.**—(1) Where a declaration complying with regulation 33(2) is submitted under paragraph (1) of that regulation, the Minister shall—

- (a) where the declaration is submitted under sub-paragraph (a), (b), (c) or (d) of that paragraph—
  - (i) approve the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the establishment activity to which the sub-paragraph concerned relates, may be imported into the United Kingdom, and
  - (ii) in accordance with Article 5.1 of Directive 95/69, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, enter the establishment on a register, which the Minister shall maintain, under an individual approval number which identifies the establishment, as an establishment approved in relation to the establishment activity concerned, and
- (b) where the declaration is submitted under sub-paragraph (e), (f), (g) or (h) of that paragraph—
  - (i) register the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the establishment activity to which the sub-paragraph concerned relates, may be imported into the United Kingdom, and
  - (ii) in accordance with Article 10.1 of Directive 95/69, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, enter the establishment on a list, which the Minister shall maintain, under an individual registration number which identifies the establishment, as an establishment approved in relation to the establishment activity concerned.

(2) The Minister shall, for the purposes of paragraph (1) treat, a declaration submitted in anticipation of regulation 33(1) as submitted thereunder and complying with regulation 33(2) if the declaration either—

- (a) complies with all the requirements set out in regulation 33(2), or
- (b) if made after 30th December 1998 but before 1st May 1999, complies with all those requirements other than the requirement set out in regulation 33(2)(g)(ii).

### **Amendment of approvals or registrations**

**35.**—(1) An eligible person may submit to the Minister a declaration relating to an approved or, as the case may be, registered, third country establishment on which it is intended to exercise an establishment activity (“the new establishment activity”)—

- (a) in addition to an establishment activity for the exercise of which the establishment is already approved or, as the case may be, registered, or
- (b) instead of that activity.

(2) A declaration submitted under paragraph (1) shall—

- (a) be in writing,
- (b) be in the English language,
- (c) be signed by or on behalf of the person submitting the declaration,
- (d) contain the name (or business name) and address of that person,
- (e) identify the establishment to which the declaration relates,
- (f) identify the new establishment activity which is being exercised or, as the case may be, it is intended to exercise, on that establishment,
- (g) if made by 30th September 1999, state—
  - (i) whether the new establishment activity was being exercised on the establishment on 31st December 1998, and
  - (ii) if so, whether an eligible person would have been in a position to submit a declaration equivalent to one under paragraph (1) in relation to the new establishment activity, at a date after 30th December 1998 but before 1st May 1999, had paragraph (1) been in force at that date;
- (h) state under which sub-paragraph of paragraph (1) the declaration is submitted,
- (i) contain a statement that the establishment complies, and an undertaking that when the new establishment activity is exercised on it it will comply, with the applicable conditions; and
- (j) contain an undertaking of the kind prescribed in the second indent of Article 6.2 of Directive 98/51.

(3) Where a declaration complying with paragraph (2) is submitted under paragraph (1), the Minister shall approve or, as the case may be, register, the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the new establishment activity, may be imported into the United Kingdom.

(4) Where, pursuant to paragraph (3), the Minister approves or, as the case may be, registers an establishment, he shall amend the register or, as the case may be, list, maintained by him under regulation 34(1)(a) or, as the case may be, (b), to show all the establishment activities in relation to which the establishment is approved or, as the case may be, registered, under regulation 34(1)(a) or, as the case may be, (b), under paragraph (3).

(5) The Minister shall, for the purposes of paragraphs (3) and (4), treat a declaration submitted in anticipation of paragraph (1) as submitted thereunder and complying with paragraph (2) if the declaration either—

- (a) complies with all the requirements set out in paragraph (2), or
- (b) if made after 30th December 1998 but before 1st May 1999, complies with all those requirements other than the requirement set out in paragraph (2)(g)(ii).

### **Cancellation of approvals or registrations**

**36.**—(1) The Minister shall cancel an approval or, as the case may be, registration, relating to the exercise of an establishment activity on an approved or, as the case may be, registered, third country establishment if, as a result of official checks, or an on-the spot inspection carried out pursuant to Article 5.1 of Directive 98/51, and after following the procedure in regulation 37, he is not satisfied that the person exercising on the establishment the activity concerned (“the manufacturer”), is fulfilling, in relation to that activity, the essential conditions or that the representative of that establishment established within the United Kingdom is fulfilling the essential representative conditions.

(2) Where, pursuant to paragraph (1), the Minister cancels an approval or, as the case may be, a registration, he shall amend the register or, as the case may be, list, maintained by him under regulation 34(1)(a) or, as the case may be, (b), by deleting from it the entry in respect of the establishment activity in relation to which approval or, as the case may be, registration, has been cancelled.

### **Procedure relating to the cancellation of approvals or registrations**

**37.**—(1) Where, in the circumstances described in regulation 36(1), the Minister proposes to cancel an approval or, as the case may be, registration, relating to the exercise of an establishment activity on an approved or, as the case may be, registered, third country establishment, he shall not cancel it unless—

- (a) he serves a written notice complying with the requirements of paragraph (2) on the representative established within the United Kingdom of the establishment (“the recipient”), and
  - (b) after the time for compliance with the notice has expired, he is not satisfied that the manufacturer or, as the case may be, the recipient, has complied with the requirements specified in the notice.
- (2) A notice served by the Minister under paragraph (1) shall—
- (a) state that he proposes to cancel the approval or, as the case may be, registration, relating to the establishment activity concerned, because he is not satisfied that—
    - (i) the manufacturer is complying, in relation to that activity, with the essential conditions, or, as the case may be,
    - (ii) the recipient is complying with the essential representative conditions;
  - (b) specify—
    - (i) the essential conditions or, as the case may be, the essential representative conditions, he is not satisfied that the manufacturer or, as the case may be, the recipient, is complying with; and
    - (ii) the requirements that the manufacturer or, as the case may be, the recipient, must comply with in order to satisfy the Minister as to compliance with those essential conditions or, as the case may be, those essential representative conditions; and
  - (c) state that, unless he is satisfied that the manufacturer or, as the case may be, the recipient, has complied with those requirements, within such reasonable time as is specified in the notice, the approval or, as the case may be, registration, relating to the establishment activity concerned will be cancelled.

## **Obligation of competent bodies to supply certain information to the Minister of Agriculture, Fisheries and Food**

**38.** Where any competent body comes into possession of information which it considers will assist the Minister to exercise his functions under regulations 36 and 37, it shall as soon as practicable provide that information to him in writing.

## **Interpretation of Part VI**

**39.** In this Part—

“the applicable Chapter” means—

- (a) in the case of a declaration made pursuant to regulation 33(1)(a) or 33(1)(b), Chapter I.1(b) of the Annex;
- (b) in the case of a declaration made pursuant to regulation 33(1)(c), Chapter I.2(b) of the Annex;
- (c) in the case of a declaration made pursuant to regulation 33(1)(d), Chapter I.4 of the Annex; and
- (d) in the case of a declaration made pursuant to regulation 33(1)(e), (f), (g) or (h), Chapter II(c) of the Annex;

“the applicable conditions” means conditions at least as stringent as the conditions laid down or referred to in the applicable Chapter;

“approved third country establishment” means a third country establishment approved by the Minister pursuant to regulation 34(1)(a) or, as the case may be, 35(3);

“eligible person” means a person who is entitled to submit a declaration to the Minister in accordance with Article 6.2 or 6.3 of Directive 98/51;

“essential conditions” means the essential conditions contained or referred to in the applicable Chapter;

“essential representative conditions”, in relation to a representative established within the United Kingdom of a third country establishment, has the same meaning as the expression “essential condition applicable to their activities” in Article 6(4)(b) of Directive 98/51 has in relation to him;

“establishment activity” means an activity specified in sub-paragraph (a), (b), (c), (d), (e), (f), (g) or (h) of regulation 33(1); and

“registered third country establishment” means a third country establishment registered by the Minister pursuant to regulation 34(1)(b) or, as the case may be, 35(3).