

Regulation (EC) No 183/2005 of the European Parliament  
and of the Council of 12 January 2005 laying down  
requirements for feed hygiene (Text with EEA relevance)

CHAPTER II

**OBLIGATIONS**

*Article 4*

**General obligations**

1 Feed business operators shall ensure that all stages of production, processing and distribution under their control are carried out in accordance with Community legislation, national law compatible therewith, and good practice. They shall ensure in particular that they satisfy the relevant hygiene requirements laid down in this Regulation.

2 When feeding food-producing animals, farmers shall take measures and adopt procedures to keep the risk of biological, chemical and physical contamination of feed, animals and animal products as low as reasonably achievable.

*Article 5*

**Specific obligations**

1 For operations at the level of primary production of feed and the following associated operations:

- a transport, storage and handling of primary products at the place of production;
- b transport operations to deliver primary products from the place of production to an establishment;
- c mixing of feed for the exclusive requirements of their own holdings without using additives or premixtures of additives with the exception of silage additives,

feed business operators shall comply with the provisions in Annex I, where relevant for the operations carried out.

2 For operations other than those referred to in paragraph 1, including mixing of feed for the exclusive requirements of their own holdings when using additives or premixtures of additives with the exception of silage additives, feed business operators shall comply with the provisions in Annex II, where relevant for the operations carried out.

3 Feed business operators shall:

- a comply with specific microbiological criteria;
- b take measures or adopt procedures necessary to meet specific targets.

The criteria and targets referred to in points (a) and (b) shall be adopted in accordance with the procedure referred to in Article 31(2).

4 Feed business operators may use the guides provided for in Chapter III to help them comply with their obligations under this Regulation.

5 Farmers shall comply with the provisions set out in Annex III when feeding food-producing animals.

6 Feed business operators and farmers shall only source and use feed from establishments which are registered and/or approved in accordance with this Regulation.

### *Article 6*

#### **Hazard analysis and critical control points (HACCP) system**

1 Feed business operators carrying out operations other than those referred to in Article 5(1) shall put in place, implement and maintain, a permanent written procedure or procedures based on the HACCP principles.

2 The principles referred to in paragraph 1 are the following:

- a identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
- b identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
- c establish critical limits at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;
- d establish and implement effective monitoring procedures at critical control points;
- e establish corrective action when monitoring indicates that a critical control point is not under control;
- f establish procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;
- g establish documents and records commensurate with the nature and size of the feed businesses to demonstrate the effective application of the measures set out in points (a) to (f).

3 When any modification is made in a product, process or any stage of production, processing, storage and distribution, feed business operators shall review their procedure and make the necessary changes.

4 As part of the system of procedures referred to in paragraph 1, feed business operators may use guides to good practice in conjunction with guides on the application of HACCP, developed in accordance with Article 20.

5 Measures to facilitate the implementation of this Article, including for small businesses, may be adopted in accordance with the procedure referred to in Article 31(2).

### *Article 7*

#### **Documents concerning the HACCP system**

1 Feed business operators shall:

- a provide the competent authority with evidence of their compliance with Article 6 in the form requested by the competent authority;
- b ensure that any documents describing the procedures developed in accordance with Article 6 are up-to-date at all times;

2 The competent authority shall take into account the nature and size of the feed business when fixing requirements as to the form referred to in paragraph 1(a).

3 Detailed arrangements for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 31(2). Such arrangements may facilitate certain feed business operators' implementation of HACCP principles developed in accordance with Chapter III, with a view to complying with the requirements of Article 6(1).

#### *Article 8*

### **Financial guarantees**

1 To prepare for an effective system of financial guarantees for feed business operators, the Commission shall submit to the European Parliament and to the Council by 8 February 2006 a report on financial guarantees in the feed sector. In addition to examining the existing national legal provisions, systems and practices relating to liability in the feed sector and related sectors, the report shall be accompanied, where appropriate, by legislative proposals for such a feasible and practicable guarantee system at Community level. Those guarantees should provide cover for the total costs for which operators could be held liable as a direct consequence of the withdrawal from the market, treatment and/or destruction of any feed, animals and food produced therefrom.

2 Feed business operators shall be liable for any infringements of the relevant legislation on feed safety and operators within the meaning of Article 5(2) shall submit proof that they are covered by the financial guarantees required by the Community legislative measures referred to in paragraph 1.

#### *Article 9*

### **Official controls, notification and registration**

1 Feed business operators shall cooperate with the competent authorities, in accordance with the relevant Community legislation and national law compatible therewith.

2 Feed business operators shall:

- a notify the appropriate competent authority of any establishments under their control, active in any of the stages of production, processing, storage, transport or distribution of feed, in the form required by the competent authority with a view to registration;
- b provide the competent authority with up-to-date information on any establishments under their control as referred to in point (a), including notifying the competent authority of any significant change in activities and any closure of an existing establishment.

3 The competent authority shall maintain a register or registers of establishments.

#### *Article 10*

### **Approval of feed business establishments**

Feed business operators shall ensure that establishments under their control and covered by this Regulation are approved by the competent authority, where:

- (1) such establishments carry out one of the following activities:

- (a) manufacturing and/or placing on the market of feed additives covered by Regulation (EC) No 1831/2003 or products covered by Directive 82/471/EEC and referred to in Chapter 1 of Annex IV to this Regulation;
  - (b) manufacturing and/or placing on the market of premixtures prepared using feed additives referred to in Chapter 2 of Annex IV to this Regulation;
  - (c) manufacturing for placing on the market, or producing for the exclusive requirements of their holdings, compound feedingstuffs using feed additives or premixtures containing feed additives and referred to in Chapter 3 of Annex IV to this Regulation;
- (2) approval is required under the national law of the Member State where the establishment is located;
- or
- (3) approval is required by a Regulation adopted in accordance with the procedure referred to in Article 31(2).

#### *Article 11*

#### **Requirements**

Feed business operators shall not operate without:

- (a) registration as provided for in Article 9;
- or
- (b) approval, when required in accordance with Article 10.

#### *Article 12*

#### **Information on national rules on approval**

Any Member State requiring the approval under Article 10(2) of certain establishments located on its territory shall inform the Commission and the other Member States of the relevant national rules.

#### *Article 13*

#### **Approval of establishments**

1 The competent authority shall approve establishments only where an on-site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements of this Regulation.

2 The competent authority may grant conditional approval if it appears, from the on-site visit, that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears, from a new on-site visit carried out within three months of granting conditional approval, that the establishment meets the other requirements referred to in paragraph 1. If clear progress has been made, but the establishment still does not meet

all of these requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

#### *Article 14*

### **Suspension of registration or approval**

The competent authority shall temporarily suspend the registration or the approval of an establishment for one, more or all of its activities, where it is shown that the establishment no longer fulfils the conditions applicable to those activities.

Such suspension shall last until the establishment again meets those conditions. Where such conditions are not met within one year, Article 15 shall apply.

#### *Article 15*

### **Revocation of registration or approval**

The competent authority shall revoke the registration or the approval of an establishment, for one or more of its activities, where:

- (a) the establishment ceases one or more of its activities;
- (b) it is shown that the establishment has not fulfilled the conditions applicable to its activities, for a period of one year;
- (c) it identifies serious deficiencies or has had to stop production at an establishment repeatedly and the feed business operator is still not able to provide adequate guarantees regarding future production.

#### *Article 16*

### **Amendments to registration or approval of an establishment**

Upon request, the competent authority shall amend the registration or approval of an establishment, where it has demonstrated its capacity to develop activities which are additional to those for which it was first registered or approved, or which replace them.

#### *Article 17*

### **Exemption from on-site visits**

1 Member States are exempted from the obligation to carry out on-site visits, as provided for in Article 13, of feed businesses which act solely as traders, without holding the products on their premises.

2 Such feed businesses shall submit to the competent authority a declaration, in a form decided upon by the competent authority, to the effect that the feeds placed on the market by them comply with the conditions of this Regulation.

## Article 18

### Transitional measures

1 Establishments and intermediaries approved and/or registered in accordance with Directive 95/69/EC may continue their activities, on condition that they submit, by 1 January 2006, a notification to this effect to the relevant competent authority in whose area their facilities are located.

2 Establishments and intermediaries requiring neither registration nor approval in accordance with Directive 95/69/EC, but requiring registration in accordance with this Regulation may continue their activities, on condition that they submit, by 1 January 2006, an application for registration to the relevant competent authority in whose area their facilities are located.

3 By 1 January 2008 the applicant must declare, in a form decided upon by the competent authority, that the conditions laid down in this Regulation are being met.

4 The competent authorities shall take account of the systems already existing for the collection of data and request the notifier or the applicant to provide only additional information which guarantees compliance with the conditions of this Regulation. In particular, the competent authorities may consider as an application under paragraph 2 a notification pursuant to Article 6 of Regulation (EC) No 852/2004.

## Article 19

### List of registered and approved establishments

1 For each activity, the competent authority shall record in a national list or lists the establishments it has registered in accordance with Article 9.

2 Establishments approved by the competent authority in accordance with Article 13 shall be recorded in a national list, under an individual identifying number.

3 Member States shall keep updated the records of establishments in the lists referred to in paragraphs 1 and 2 in accordance with the decisions referred to in Articles 14, 15 and 16 to suspend, revoke or amend registration or approval.

4 The list referred to in paragraph 2 must be drawn up in accordance with the model set out in Annex V, Chapter I.

5 The identifying number referred to in paragraph 2 shall be in the form set out in Annex V, Chapter II.

6 The Commission shall compile and make available to the public the part of the Member States' lists which includes the establishments referred to in paragraph 2 for the first time in November 2007, and thereafter each year, by 30 November at the latest. The compiled list shall take into account the amendments made during the year.

7 The Member States shall make available to the public the lists of establishments referred to in paragraph 1.