

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)

REGULATION (EC) No 1831/2003 OF THE  
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

on additives for use in animal nutrition

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>(2)</sup>,

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>(3)</sup>,

Whereas:

- (1) Livestock production occupies a very important place in the agriculture of the Community. Satisfactory results depend to a large extent on the use of safe and good-quality feedingstuffs.
- (2) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (3) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (4) In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. Since pet food is not part of the human food chain and has no environmental impact on arable land, specific provisions for additives in pet food are appropriate.
- (5) It is a principle of the Community food law enshrined in Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(4)</sup> that food and feed imported for placing on the market within the Community must comply with the relevant requirements of Community legislation or with conditions recognised by the Community to be at least equivalent thereto. It is therefore necessary to subject imports

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from third countries of additives for use in animal nutrition to requirements equivalent to those applying to additives produced in the Community.

- (6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.
- (7) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.
- (8) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>(5)</sup> has shown that it is necessary to review all the rules on additives in order to take into account the need to ensure a greater degree of protection of animal and human health and of the environment. It is also necessary to take into account the fact that technological progress and scientific developments have made available new types of additives, such as those to be used on silage or in water.
- (9) This Regulation should also cover mixtures of additives sold to the end-user, and the marketing and use of those mixtures should comply with the conditions laid down in the authorisation of each single additive.
- (10) Premixtures should not be regarded as preparations covered by the definition of additives.
- (11) The basic principle in this field should be that only those additives approved under the procedure provided for in this Regulation may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation.
- (12) Categories of feed additives should be defined in order to facilitate the assessment procedure with a view to authorisation. Amino acids, their salts and analogues, and urea and its derivatives, which are currently covered by Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition<sup>(6)</sup>, should be included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation.
- (13) Implementing rules concerning applications for authorisation of feed additives should take into account different documentation requirements for food-producing and other animals.
- (14) In order to ensure a harmonised scientific assessment of feed additives, such assessment should be carried out by the European Food Safety Authority, established by Regulation (EC) No 178/2002. Applications should be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRLs).
- (15) The Commission should establish guidelines for the authorisation of feed additives in cooperation with the European Food Safety Authority. In establishing these guidelines, attention should be paid to the possibility of extrapolating the results of the studies carried out on major species to minor species.
- (16) It is also necessary to provide for a simplified authorisation procedure for those additives which have successfully undergone the authorisation procedure for food use provided for in Council Directive 89/107/EEC of 21 December 1988 on the

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approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption<sup>(7)</sup>.

- (17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products. Therefore, the authorisation of an additive should be granted by the Commission.
- (18) In order to ensure the necessary level of protection for animal welfare and consumer safety, applicants should be encouraged to seek authorisation extensions for minor species by being granted one year's additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised.
- (19) Competence for authorising feed additives and establishing conditions for their use and for maintaining and publishing a register of authorised feed additives should be conferred on the Commission in accordance with a procedure by which close collaboration between Member States and the Commission is guaranteed in the framework of the Standing Committee on the Food Chain and Animal Health.
- (20) It is necessary to introduce, where appropriate, an obligation for the holder of the authorisation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment using a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law.
- (21) In order to allow technological progress and scientific development to be taken into account, it is necessary to revise the authorisations of feed additives regularly. Time-limited authorisations should allow this review.
- (22) A register of authorised feed additives should be established, including product-specific information and detection methods. Non-confidential data should be made available to the public.
- (23) It is necessary to establish transitional rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids, their salts and analogues, urea and its derivatives, currently authorised under Directive 82/471/EEC, and silage agents, as well as additives for which the authorisation procedure is in progress. In particular, it is appropriate to provide that such products can remain on the market only insofar as notification with a view to their evaluation has been submitted to the Commission within one year after the entry into force of this Regulation.
- (24) A number of silage additives are currently marketed and used in the Community without an authorisation granted pursuant to Directive 70/524/EEC. While it is indispensable to apply the provisions of this Regulation to such substances in view of their nature and use, it is appropriate to apply the same transitional arrangements. In this way it will be possible to obtain information on all the substances currently used and to establish

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a list of them, which would allow safeguard measures to be taken, where appropriate, for those substances that do not fulfil the authorisation criteria mentioned in Article 5 of this Regulation.

- (25) The Scientific Steering Committee stated in its opinion of 28 May 1999 that: ‘regarding the use of antimicrobials as growth promoting agents, the use of agents from classes which are or may be used in human or veterinary medicine (i.e. where there is a risk of selecting for cross-resistance to drugs used to treat bacterial infections) should be phased out as soon as possible and ultimately abolished’. The second opinion of the Scientific Steering Committee on antimicrobial resistance adopted on 10 and 11 May 2001 confirmed the need to provide a sufficient time to replace those antimicrobials by alternative products: ‘Thus, the phase-out process must be planned and coordinated since precipitous actions could have repercussions for animal health’.
- (26) Therefore, it is necessary to set a date after which the use of the antibiotics still authorised for use as growth promoting agents will be forbidden, while allowing sufficient time for the development of alternative products to replace those antibiotics. Provision should also be made to forbid the authorisation of any further antibiotics for use as feed additives. Within the framework of the phasing out of antibiotics used as growth promoters and in order to ensure a high level of protection of animal health, the European Food Safety Authority will be asked to review the progress achieved in the development of alternative substances and alternative methods of management, feeding, hygiene, etc., before 2005.
- (27) Certain substances with coccidiostatic and histomonostatic effects should be considered as feed additives for the purposes of this Regulation.
- (28) Detailed labelling of the product should be required since it enables the end-user to make a choice with full knowledge of the facts, creates fewer obstacles to trade and facilitates fairness of transactions. In this respect, it is generally appropriate for requirements applying to feed additives to mirror the ones applying to food additives. It is therefore appropriate to provide for simplified labelling requirements for flavouring compounds similar to the ones applied to food flavourings; this should however be without prejudice to the possibility to provide for specific labelling requirements in the authorisation of individual additives.
- (29) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>(8)</sup> provides for an authorisation procedure for the placing on the market of genetically modified food and feed, including feed additives consisting of, containing or produced from genetically modified organisms. Since the objectives of the said Regulation are different from those of this Regulation, feed additives should undergo an authorisation procedure in addition to the authorisation procedure provided for by that Regulation before they are placed on the market.
- (30) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to feed of Community origin or imported from a third country. They allow such measures to be adopted in situations where feed is likely to constitute a serious risk to human health, animal health or the environment and where

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such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.

- (31) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(9)</sup>.
- (32) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (33) Directive 70/524/EEC should be repealed. However labelling provisions applicable to compound feedingstuffs incorporating additives should be maintained until a revision of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs<sup>(10)</sup> is completed.
- (34) Guidelines addressed to the Member States for the presentation of an application dossier are contained in Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition<sup>(11)</sup>. Verification of the conformity of dossiers is entrusted to the European Food Safety Authority. It is therefore necessary to repeal Directive 87/153/EEC. However, the Annex should remain in force until implementing rules are adopted.
- (35) A transitional period is needed to avoid disruptions in the use of feed additives. Therefore, until the rules of this Regulation are applicable, the substances already authorised should be permitted to remain on the market and be used under the conditions of the current legislation,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I **U.K.**

### SCOPE AND DEFINITIONS

#### Article 1 **U.K.**

##### Scope

1 The purpose of this Regulation is to establish a <sup>F1</sup>... procedure for authorising the placing on the market and use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the <sup>F2</sup>... market.

2 This Regulation shall not apply to:

- a processing aids;
- b veterinary medicinal products <sup>F3</sup>..., with the exception of coccidiostats and histomonostats used as feed additives.

[<sup>F43</sup>. In this Article 'veterinary medicinal product' means:

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- a any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- b any substance or combination of substances which may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

For the purposes of the definition of ‘veterinary medicinal product’, ‘substance’ means any matter, irrespective of origin, which may be:

- a human, including human blood and human blood products;
- b animal, including micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts and blood products;
- c vegetable, including micro-organisms, plants, parts of plants, vegetable secretions and extracts; or
- d chemical, including elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.]

#### Textual Amendments

- F1** Word in [Art. 1](#) omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **9(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in [Art. 1](#) omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **9(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in [Art. 1\(2\)\(b\)](#) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(2)(a)**
- F4** [Art. 1\(3\)](#) inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(2)(b)**

## Article 2 U.K.

### Definitions

1 For the purpose of this Regulation, the definitions of ‘feed’, ‘feedingstuff’, ‘feed business’, ‘feed business operator’, ‘placing on the market’ and ‘traceability’ laid down in Regulation (EC) No 178/2002 shall apply.

2 The following definitions shall also apply:

- a ‘feed additives’ means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);
- <sup>[F5]</sup>b ‘feed materials’ means products of vegetable or animal origin, whose principal purpose is to meet animals’ nutritional needs, in their natural state, fresh or preserved, and products derived from their industrial processing, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as a carrier of premixtures;
- c ‘compound feed’ means a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete feed or complementary feed;

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- d ‘complementary feed’ means compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed;]
- e ‘premixtures’ means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals;
- f ‘daily ration’ means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;
- [<sup>F6</sup>g ‘complete feed’ means compound feed which, by reason of its composition, is sufficient for a daily ration;]
- h ‘processing aids’ means any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed;
- i ‘antimicrobials’ means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;
- j ‘antibiotic’ means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the growth of other micro-organisms;
- k ‘coccidiostats’ and ‘histomonostats’ means substances intended to kill or inhibit protozoa;
- l ‘maximum residue limit’ means the maximum concentration of residue resulting from the use of an additive in animal nutrition which may be accepted by the [<sup>F7</sup>appropriate authority] as being legally permitted or recognised as acceptable in or on a food;
- m ‘micro-organism’ means: colony-forming micro-organisms.
- n ‘first placing on the market’ means the initial placing on the market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed.
- [<sup>F8</sup>o “third country” means any country or territory other than the British Islands;
- p “prescribe” means prescribe by regulations;
- q “appropriate authority” means—
  - i in relation to England, the Secretary of State;
  - ii in relation to Wales, the Welsh Ministers;
  - iii in relation to Scotland, the Scottish Ministers;
- r “Food Safety Authority” means—
  - i as regards England and Wales, the Food Standards Agency;
  - ii as regards Scotland, Food Standards Scotland;
- s “reference laboratory” means a laboratory designated by the appropriate authority under Article 100 of Regulation 2017/625.]

<sup>F9</sup>3 .....

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#### Textual Amendments

- F5** [Art. 2\(2\)\(b\)-\(d\)](#) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(3)(a)**

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- F6** Art. 2(2)(g) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **8(3)(b)**
- F7** Words in Art. 2(2)(l) substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **10(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 2(2)(o)-(s) inserted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **10(a)(ii)** (as substituted by S.I. 2020/1504, regs. 1(2), **12(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F9** Art. 2(3) omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **10(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER II **U.K.**

### AUTHORISATION, USE, MONITORING AND TRANSITIONAL MEASURES APPLICABLE FOR FEED ADDITIVES

#### Article 3 **U.K.**

##### Placing on the market, processing and use

- 1 No person shall place on the market, process or use a feed additive unless:
- it is covered by an authorisation granted in accordance with this Regulation;
  - the conditions for use set out in this Regulation, including the general conditions set out in Annex IV, unless otherwise provided for in the authorisation, and in the authorisation of the substance are met; and
  - the conditions on labelling set out in this Regulation are met.
- 2 For experiments for scientific purposes, [<sup>F10</sup>the appropriate authority] may authorise the use, as additives, of substances which are not authorised <sup>F11</sup>..., with the exception of antibiotics, provided that the experiments are carried out in accordance with the principles and conditions laid down in [<sup>F12</sup>Regulation (EC) No 767/2009] or the guidelines set out in Article 7(4) of this Regulation and provided that there is adequate official supervision. The animals concerned may be used for food production only if the authorities establish that this will have no adverse effect on animal health, human health or the environment.
- 3 In the case of additives belonging to categories (d) and (e) of Article 6(1) and of those additives falling within the scope of <sup>F13</sup>... legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs), no person other than the holder of the authorisation named in the authorisation Regulation referred to in Article 9, his legal successor or successors, or a person acting under his written authority, shall first place the product on the market.
- 4 Unless otherwise specified, the mixing of additives to be sold directly to the end-user shall be allowed, subject to compliance with the conditions for use laid down in the authorisation for each single additive. Consequently, the mixing of authorised additives shall not be subject to specific authorisations other than the requirements laid down in [<sup>F14</sup>Regulation (EC) No 183/2005].
- [<sup>F15</sup> 5 Where necessary, as a result of technological progress or scientific development, the appropriate authority may prescribe changes to the general conditions set out in Annex 4.]



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### Textual Amendments

- F10** Words in Art. 3(2) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **11(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in Art. 3(2) omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **11(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Words in Art. 3(2) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(4)(a)**
- F13** Word in Art. 3(3) omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **11(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Art. 3(4) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(4)(b)**
- F15** Art. 3(5) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **11(c)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 4 **U.K.**

### Authorisation

1 Any person seeking an authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

2 An authorisation shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation, or in accordance with [<sup>F16</sup>Article 53] of Regulation (EC) No 178/2002.

<sup>F17</sup>3 .....

### Textual Amendments

- F16** Words in Art. 4(2) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(5)**
- F17** Art. 4(3) omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **12**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 5 **U.K.**

### Conditions for authorisation

1 No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated in accordance with the implementing measures referred to in Article 7 that, when used in accordance with conditions to be set out in the Regulation authorising the use of the additive, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3.

2 The feed additive shall not:

- a have an adverse effect on animal health, human health or the environment,
- b be presented in a manner which may mislead the user,
- c harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.

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- 3 The feed additive shall:
- a favourably affect the characteristics of feed,
  - b favourably affect the characteristics of animal products,
  - c favourably affect the colour of ornamental fish and birds,
  - d satisfy the nutritional needs of animals,
  - e favourably affect the environmental consequences of animal production,
  - f favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs, or
  - g have a coccidiostatic or histomonostatic effect.
- 4 Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.

*Article 6* **U.K.**

**Categories of feed additives**

- 1 A feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, in accordance with the procedure set out at Articles 7, 8 and 9:
- a technological additives: any substance added to feed for a technological purpose;
  - b sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;
  - c nutritional additives;
  - d zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;
  - e coccidiostats and histomonostats.
- 2 Within the categories referred to in paragraph 1, feed additives shall further be allocated within one or more of the functional groups mentioned in Annex I, according to their principal function or functions, in accordance with the procedure specified in Articles 7, 8 and 9.
- [<sup>F18</sup> 3 Where necessary, as a result of technological progress or scientific development, the appropriate authority may prescribe additional feed additive categories and functional groups.]

**Textual Amendments**

**F18** Art. 6(3) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, 13; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F19</sup> *Article 7* **U.K.**

**Application for authorisation**

- 1 An application for an authorisation as provided for in Article 4 must be sent to the appropriate authority. The appropriate authority must without delay forward the application to the Food Safety Authority.
- 2 The Food Safety Authority must—

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- a acknowledge receipt of the application, including the particulars and documents referred to in paragraph 3, in writing, to the applicant within 15 days of its receipt, stating the date of receipt;
  - b make any information supplied by the applicant available to the appropriate authority;
  - c make the summary of the dossier mentioned in paragraph 3(h) available to the public, subject to the confidentiality requirements laid down in Article 18(2).
- 3 At the time of application, the applicant must send the following particulars and documents directly to the Food Safety Authority—
- a the applicant's name and address;
  - b the identification of the feed additive, a proposal for its classification by category and functional group under Article 6, and its specifications, including, where applicable, purity criteria;
  - c a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;
  - d a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(2) and (3);
  - e proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary [<sup>F20</sup>feed] and animal species and categories for which the feed additive is intended;
  - f a written statement that three samples of the feed additive [<sup>F21</sup>will be made available, upon request,] to the reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex 2;
  - g for additives which, according to the proposal under point (b), do not belong to either category (a) or category (b) referred to in Article 6(1), and for additives falling within the scope of retained EU law relating to the marketing of products consisting of, containing or produced from GMOs, a proposal for post-market monitoring;
  - h a summary containing the information provided under points (a) to (g);
  - i for additives falling within the scope of retained EU law relating to the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted in accordance with the applicable legislation.
- 4 The appropriate authority, having first consulted the Food Safety Authority, may prescribe rules for the application and implementation of this Article, including rules concerning the preparation and the presentation of the application. <sup>F22</sup>...
- 5 After the Food Safety Authority has been consulted, specific guidelines for the authorisation of additives may be established, where necessary for each category of additive referred to in Article 6(1). These guidelines must take account of the possibility of extrapolating the results of the studies carried out on major species to minor species.
- 6 Rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food may be prescribed by the appropriate authority.
7. Other implementing rules may be prescribed by the appropriate authority, which rules must, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets.

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*Changes to legislation:* There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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8. The Food Safety Authority must publish detailed guidance to assist the applicant in the preparation and the presentation of its application.]

#### Textual Amendments

- F19** Art. 7 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **14**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** Word in Art. 7(3)(e) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(6)(a)(i)**
- F21** Words in Art. 7(3)(f) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(6)(a)(ii)**
- F22** Words in Art. 7(4) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(6)(b)**

Article 8 **U.K.**

### Opinion of the <sup>F23</sup>Food Safety Authority]

1 The <sup>F23</sup>Food Safety Authority] shall give an opinion within six months of receipt of a valid application. This time limit shall be extended whenever the <sup>F23</sup>Food Safety Authority] seeks supplementary information from the applicant under paragraph 2.

2 The <sup>F23</sup>Food Safety Authority] may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the <sup>F23</sup>Food Safety Authority] after consultation with the applicant.

3 In order to prepare its opinion, the <sup>F23</sup>Food Safety Authority]:

- a shall verify that the particulars and documents submitted by the applicant are in accordance with Article 7 and undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5;
- b shall verify the report of the <sup>F24</sup>reference laboratory].

4 In the event of an opinion in favour of authorising the feed additive, the opinion shall also include the following elements:

- a the name and address of the applicant;
- b the designation of the feed additive including its categorisation and allocation within functional groups provided for in Article 6, its specification, including, where applicable, purity criteria and method of analysis;
- c depending on the outcome of the assessment, specific conditions or restrictions in relation to handling, post-market monitoring requirements and use, including animal species and categories of animal species for which the additive is to be used;
- d specific additional requirements for the labelling of the feed additive necessary as a result of conditions and restrictions imposed under (c);
- e a proposal for the establishment of Maximum Residues Limits (MRLs) in the relevant foodstuffs of animal origin, unless the opinion of the <sup>F23</sup>Food Safety Authority] concludes that the establishment of MRLs is not necessary for the protection of consumers or MRLs have already been established in <sup>F25</sup>Regulation (EC) No [470/2009](#)].

<sup>F26</sup>5 The Food Safety Authority must without delay forward its opinion to the appropriate authority including a report describing its assessment of the feed additive and stating the reasons for its conclusion.]

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

6 The [<sup>F23</sup>Food Safety Authority] shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 18(2).

#### Textual Amendments

- F23** Words in Art. 8 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **15(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 8(3)(b) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **15(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Words in Art. 8(4)(e) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(7)**
- F26** Art. 8(5) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **15(c)**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F27</sup> Article 9 **U.K.**

**Authorisation**<sup>F28</sup>...

1 Within three months of receipt of the opinion of the Food Safety Authority, the appropriate authority must determine whether to authorise the feed additive and the conditions upon which the feed additive is authorised. In making its determination, the appropriate authority must take into account the requirements of Article 5(2) and (3), retained EU law and other legitimate factors relevant to the matter under consideration and in particular benefits for animal health and welfare and for the consumer of animal products. [<sup>F29</sup>The authorisation must be prescribed by the appropriate authority and must include the elements mentioned in Article 8(4)(b), (c), (d) and (e) and an identification number.] Where the authorisation is not in accordance with the opinion of the Food Safety Authority, the appropriate authority must provide an explanation of the reasons for the differences. Where, in the opinion of the appropriate authority, the application raises exceptionally complex issues, the three-month deadline may be extended.

2 Rules for the implementation of this Article and in particular concerning an identification number for authorised additives may be prescribed by the appropriate authority.

3 The appropriate authority must without delay inform the applicant of the [<sup>F30</sup>authorisation] made in accordance with paragraph 1.

<sup>F31</sup>4 .....

5 An authorisation for additives belonging to categories (d) and (e) referred to in Article 6(1) and also for additives consisting of, containing or produced from GMOs, must include the name of the holder of the authorisation, and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

6 Where the levels of residues of an additive in food from animals fed with that additive might have a detrimental effect on human health, the authorisation must include MRLs for the active substance or for its metabolites in the relevant foodstuffs of animal origin. In this case the active substance must be considered for the purposes of Council Directive 96/23/EC as falling under Annex 1 to that Directive. Where an MRL for the substance concerned has already been

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established in retained EU law, that MRL must also apply to residues of the active substance or its metabolites originating from the use of the substance as a feed additive.

7 The authorisation is valid for 10 years and is renewable in accordance with Article 14. The authorised feed additive must be entered in the Register of Feed Additives referred to in Article 17 (the Register). Each entry in the Register must state the date of authorisation and must include the particulars referred to in paragraphs 4, 5 and 6.]

#### Textual Amendments

- F27** Art. 9 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **17**; 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Art. 9 heading omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **16**; 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in Art. 9(1) substituted (18.4.2022) by The Food and Feed Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/377), regs. 1(2), **6(2)**
- F30** Word in Art. 9(3) substituted (18.4.2022) by The Food and Feed Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/377), regs. 1(2), **6(3)**
- F31** Art. 9(4) omitted (18.4.2022) by virtue of The Food and Feed Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/377), regs. 1(2), **6(4)**

### Article 10 **U.K.**

#### Status of existing products

1 By way of derogation from Article 3, a feed additive which has been placed on the market pursuant to Directive 70/524/EEC and urea and derivatives, an amino acid, salt of an amino acid or analogous substance, which was listed in points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC, may be placed on the market and used in accordance with the conditions specified in Directives 70/524/EEC or 82/471/EEC and their implementing measures, including in particular specific labelling provisions concerning compound feed and feed materials, provided that the following conditions are met:

- a within one year of the entry into force of this Regulation, persons first placing the feed additive on the market or any other interested parties shall notify this fact to the Commission. At the same time, the particulars mentioned in Article 7(3)(a), (b) and (c) shall be directly sent to the Authority;
- b within one year of the notification mentioned under (a), the Authority shall, after verification that all the information required has been submitted, notify the Commission that it has received the information required under this Article. The products concerned shall be entered in the Register. Each entry in the Register shall mention the date on which the product concerned was first entered in the Register and, where applicable, the expiry date of the existing authorisation.

2 An application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC. A detailed calendar listing in order of priority the different classes of additives to be re-evaluated may be adopted in accordance with the procedure referred to in Article 22(2). The Authority shall be consulted in drawing up the list.

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3 Products entered in the Register shall be subject to the provisions of this Regulation, in particular Articles 8, 9, 12, 13, 14 and 16, which without prejudice to specific conditions concerning the labelling, placing on the market and use of each substance pursuant to paragraph 1, shall apply to such products as if they had been authorised pursuant to Article 9.

4 In the case of authorisations not issued to a specific holder, any person who imports or manufactures the products referred to in this Article or any other interested party may submit the information as referred to in paragraph 1 or the application as referred to in paragraph 2 to the Commission.

[<sup>F325</sup> Where the notification and accompanying particulars referred to in paragraph 1(a) are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 2 within the period specified, the appropriate authority may prescribe that—

- a the additives concerned must be withdrawn from the market;
- b that, for a limited period of time, existing stocks of the product may remain, or continue to be placed, on the market.]

6 Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the [<sup>F33</sup>appropriate authority] takes a decision. The [<sup>F33</sup>appropriate authority] shall inform the applicant of this extension of the authorisation.

7 By way of derogation from Article 3, substances, micro-organisms and preparations used in the Community as silage additives at the date referred to in Article 26(2), may be placed on the market and used provided that points (a) and (b) of paragraph 1 and paragraph 2 are complied with. Paragraphs 3 and 4 shall apply accordingly. For these substances, the deadline for application as referred to in paragraph 2 shall be seven years after the entry into force of this Regulation.

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#### Textual Amendments

- F32** Art. 10(5) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **18(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F33** Words in Art. 10(6) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **18(b)**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F34</sup> Article 11 **U.K.**

#### Phasing out

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#### Textual Amendments

- F34** Art. 11 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **19**; 2020 c. 1, Sch. 5 para. 1(1)

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[<sup>F35</sup>Article 12 U.K.]

**Supervision**

1 After an additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a feedingstuff into which it has been incorporated, or any other interested party must comply with any conditions or restrictions which have been imposed on the placing on the market, use and handling of the additive or feedingstuffs containing it.

2 Where monitoring requirements, as referred to in Article 8(4)(c), have been imposed, the holder of the authorisation must ensure that monitoring is carried out and must submit reports to the appropriate authority in accordance with the authorisation. The holder of the authorisation must immediately communicate to the Food Safety Authority any new information that might influence the evaluation of the safety in use of the feed additive, in particular health sensitivities of specific categories of consumers. The holder of the authorisation must immediately inform the Food Safety Authority of any prohibition or restriction imposed by the competent authority of any third country in which the feed additive is placed on the market.]

**Textual Amendments**

**F35** Art. 12 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **20**; 2020 c. 1, Sch. 5 para. 1(1)

[<sup>F36</sup>Article 13 U.K.]

**Modification, suspension and revocation of authorisation**

1 On its own initiative or following a request from the appropriate authority, the Food Safety Authority must issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. The Food Safety Authority must immediately transmit this opinion to the appropriate authority and, where applicable, to the holder of the authorisation. The opinion must be made public.

2 The appropriate authority must examine the opinion of the Food Safety Authority without delay. The appropriate authority must, in light of the opinion of the Food Safety Authority, determine whether to modify, suspend or revoke the authorisation.

3 If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the appropriate authority, accompanied by the relevant data supporting the request for the change, the Food Safety Authority must transmit its opinion on the proposal to the appropriate authority. The appropriate authority must, in light of the opinion of the Food Safety Authority, determine whether to modify, suspend or revoke the authorisation.

4 The appropriate authority must, without delay—

- a inform the applicant of any determination the appropriate authority makes under this Article;
- b invite the Food Safety Authority to amend the Register where appropriate.

5 Articles 7(1) and (2), 8 and 9 apply accordingly.

<sup>F37</sup>6. .... ]



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### Textual Amendments

- F36** Art. 13 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **21**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Art. 13(6) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(8)**

## <sup>F38</sup> Article 14 **U.K.**

### Renewal of authorisation

1 Authorisations under this Regulation are renewable for 10 year periods. An application for renewal must be sent to the appropriate authority at the latest one year before the expiry date of the authorisation. In the case of authorisations not issued to a specific holder, any person who first places the additive on the market or any other interested party may submit the application to the appropriate authority and must be considered as the applicant. In the case of authorisations issued to a specific holder, the holder of the authorisation or the holder's legal successor may submit the application to the appropriate authority and is deemed to be the applicant.

2 At the time of application, the applicant must send the following particulars and documents directly to the Food Safety Authority—

- a a copy of the authorisation for placing the feed additive on the market;
- b a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation;
- c any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;
- d where appropriate, a proposal for amending or supplementing the conditions of the original authorisation, including, among other things, the conditions concerning future monitoring.

3 Articles 7(1), (2), (4), (5), (6) and (7), 8 and 9 apply accordingly.

4 Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product is automatically extended until the appropriate authority makes a determination. Information on this extension of the authorisation must be made available to the public in the Register.]

### Textual Amendments

- F38** Art. 14 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **22**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F39</sup> Article 15 **U.K.**

### Urgent authorisation

In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the appropriate authority may provisionally authorise the use of an additive for

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a maximum period of five years. The authorisation is to be in a form prescribed by the appropriate authority.]

#### Textual Amendments

**F39** Art. 15 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **23**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER III **U.K.**

### LABELLING AND PACKAGING

#### Article 16 **U.K.**

#### Labelling and packaging of feed additives and premixtures

1 No person shall place on the market a feed additive or a premixture of additives unless its packaging or container is labelled under the responsibility of a producer, packer, importer, seller or distributor established within [<sup>F40</sup>the British Islands] and bears the following information, in a conspicuous, clearly legible and indelible manner, in [<sup>F41</sup>English or in English and Welsh] in relation to each additive contained in the material:

- a the specific name given to the additives upon authorisation, preceded by the name of the functional group as mentioned in the authorisation;
- b the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this Article;
- c the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;
- [<sup>F42</sup>d where appropriate, the approval number of the establishment manufacturing or placing on the market the feed additive or the premixture pursuant to <sup>F43</sup>... Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 12 January 2003 laying down requirements for feed hygiene <sup>(12)</sup><sup>F44</sup> ...;]
- e directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the authorisation, including animal species and categories for which the additive or premixture of additives is intended;
- f the identification number;
- g the batch reference number and date of manufacture.

[<sup>F45</sup>In the case of premixtures, points (b), (d), (e) and (g) shall not apply to the incorporated feed additives.]

2 For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed and drinking water.

[<sup>F423</sup> In addition to the information specified in paragraph 1, the packaging or container of a feed additive belonging to a functional group specified in Annex III or of a premixture containing an additive belonging to a functional group specified in Annex III shall bear the information, presented in a conspicuous, clearly legible and indelible manner, indicated in that Annex.]

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[<sup>F42</sup>4 In the case of premixtures, the word ‘premixture’ shall appear on the label. Carriers shall be declared, in the case of feed materials, in compliance with Article 17(1)(e) of Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed <sup>(13)</sup>, and, where water is used as a carrier, the moisture content of the premixture shall be declared. Only one minimum storage life may be indicated in respect of each premixture as a whole; such minimum storage life shall be determined on the basis of the minimum storage life of each of its components.]

5 Additives and premixtures shall be marketed only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

[<sup>F46</sup>6 The appropriate authority may prescribe amendments to Annex 3 to take technological progress and scientific development into account.]

#### Textual Amendments

- F40** Words in Art. 16(1) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(9)(a)**
- F41** Words in Art. 16(1) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **24(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F42** Substituted by [Regulation \(EC\) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation \(EC\) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC \(Text with EEA relevance\)](#).
- F43** Words in Art. 16(1)(d) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(9)(b)(i)**
- F44** Words in Art. 16(1)(d) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(9)(b)(ii)**
- F45** Inserted by [Regulation \(EC\) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation \(EC\) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC \(Text with EEA relevance\)](#).
- F46** Art. 16(6) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **24(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## CHAPTER IV **U.K.**

### GENERAL AND FINAL PROVISIONS

#### Article 17 **U.K.**

##### <sup>F47</sup>...Register of Feed Additives

[<sup>F48</sup>1 The Food Safety Authority must establish and keep up to date a Register of Feed Additives.]

2 The Register shall be made available to the public.

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

### Textual Amendments

- F47** Word in Art. 17 heading omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **25(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F48** Art. 17(1) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **25(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 18 U.K.

### Confidentiality

1 The applicant may indicate which information submitted under this Regulation he wishes to be treated as confidential on the ground that its disclosure might significantly harm his competitive position. Verifiable reasons must be given in such cases.

2 The [<sup>F49</sup>appropriate authority] shall determine, after consultation with the applicant, which information other than that specified in paragraph 3 should be kept confidential and shall inform the applicant of its decision.

3 The following information shall not be considered confidential:

- a name and composition of the feed additive and, where appropriate, indication of the production strain;
- b physico-chemical and biological characteristics of the feed additive;
- c the conclusions of the study results on effects of the feed additive on human and animal health and on the environment;
- d the conclusions of the study results on effects of the feed additive on the characteristics of animal products and its nutritional properties;
- e methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

[<sup>F50</sup>4 The Food Safety Authority must, on request, supply the appropriate authority with all information in its possession, including any identified as confidential pursuant to paragraph 2.]

<sup>F51</sup>5 .....

[<sup>F52</sup>6 The appropriate authority and the Food Safety Authority must keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment.]

7 If an applicant withdraws or has withdrawn an application, the [<sup>F53</sup>appropriate authority and the Food Safety Authority must] respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the [<sup>F54</sup>appropriate authority] and the applicant disagree as to its confidentiality.

### Textual Amendments

- F49** Words in Art. 18(2) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F50** Art. 18(4) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(b)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- F51** Art. 18(5) omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **26(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F52** Art. 18(6) substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **26(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F53** Words in Art. 18(7) substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **26(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F54** Words in Art. 18(7) substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **26(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F55</sup> Article 18A **U.K.**

### Regulations and devolved powers

1. Any power to make regulations under this Regulation—
  - a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
  - b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
3. Any power to make regulations under this Regulation includes power—
  - a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
  - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument or Scottish statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—
  - a in the case of England, of either House of Parliament;
  - b in the case of Wales, of Senedd Cymru;
  - c in the case of Scotland, of the Scottish Parliament;
5. In this Regulation, any power—
  - a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
  - b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
  - c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;]

#### Textual Amendments

- F55** Art. 18A inserted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **27** (as amended by S.I. 2020/1504, regs. 1(2), **12(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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## Article 19 U.K.

### Administrative review

Any decision taken under, or failure to exercise, the powers vested in the [<sup>F56</sup>Food Safety Authority] by this Regulation may be reviewed by the [<sup>F57</sup>appropriate authority] on its own initiative or in response to a request from <sup>F58</sup>... any person directly and individually concerned.

For that purpose, a request shall be submitted to the [<sup>F57</sup>appropriate authority] within two months after the day on which the party concerned became aware of the act or omission in question.

The [<sup>F57</sup>appropriate authority] shall take a decision within two months requiring, if appropriate, the [<sup>F56</sup>Food Safety Authority] to withdraw its decision or to remedy its failure to act within a set time limit.

#### Textual Amendments

- F56** Words in Art. 19 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **28(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F57** Words in Art. 19 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **28(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Words in Art. 19 omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **28(c)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 20 U.K.

### Data protection

1 The scientific data and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used.

2 In order to stimulate efforts to obtain authorisations for minor species for additives whose use is authorised for other species, the 10-year data protection period shall be extended by one year for each minor species for which a use extension authorisation is granted.

3 The applicant and the previous applicant shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat toxicological tests on vertebrates. If, however, no such agreement is reached on sharing the information, the [<sup>F59</sup>appropriate authority] may decide to disclose information necessary to avoid repeating toxicological tests on vertebrates, while ensuring a reasonable balance between the interests of the parties concerned.

4 On the expiry of the 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the [<sup>F60</sup>Food Safety Authority] for the benefit of another applicant.

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### Textual Amendments

- F59** Words in Art. 20(3) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **29(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F60** Words in Art. 20(4) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **29(b)**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F61</sup> Article 21 **U.K.**

### Reference laboratory

1. The duties and tasks of the reference laboratory are laid down in Annex 2.
2. Applicants for the authorisation of additives must contribute to supporting the cost of the duties and tasks of the reference laboratory.
3. The appropriate authority may prescribe rules for implementing Annex 2.
4. The appropriate authority may prescribe amendments to Annex 2.]

### Textual Amendments

- F61** Art. 21 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **30**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F62</sup> Article 21a **U.K.**

### Exercise of the delegation

### Textual Amendments

- F62** Art. 21a omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **30A** (as inserted by S.I. 2020/1504, regs. 1(2), **12(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

<sup>F63</sup> Article 22 **U.K.**

### Committee procedure

### Textual Amendments

- F63** Art. 22 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

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## Article 23 U.K.

### Repeals

1 Directive 70/524/EEC shall be repealed with effect from the date of application of this Regulation. However, Article 16 of Directive 70/524/EEC shall remain in force until Directive 79/373/EEC has been revised to include rules concerning the labelling of feedingstuffs incorporating additives.

2 Points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC shall be deleted with effect from the date of application of this Regulation.

3 Directive 87/153/EEC shall be repealed with effect from the date of application of this Regulation. However, the Annex to that Directive shall remain in force until the implementing rules provided for in Article 7(4) of this Regulation are adopted.

4 References to Directive 70/524/EEC shall be construed as references to this Regulation.

## <sup>F64</sup> Article 24 U.K.

### Penalties

.....

#### Textual Amendments

**F64** Art. 24 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 25 U.K.

### Transitional measures

1 Applications submitted under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be treated as applications under Article 7 of this Regulation where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have not yet been forwarded to the Commission. Any Member State selected as rapporteur in respect of any such application shall immediately forward the dossier submitted in support of that application to the Commission. Notwithstanding Article 23(1), such applications shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have already been forwarded to the Commission.

2 The labelling requirements laid down in Chapter III shall not apply to products which have been lawfully manufactured and labelled in the Community or which have been lawfully imported into the Community and put into circulation, before the date of application of this Regulation.



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Article 26 **U.K.**

**Entry into force**

1 This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2 It shall apply from 12 months after the date of publication of this Regulation.

F65  
...

**Textual Amendments**

**F65** Words in *Signature* omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **32**; 2020 c. 1, Sch. 5 para. 1(1)

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## ANNEX I U.K.

## ADDITIVE GROUPS

1. In the category 'technological additives', the following functional groups are included: U.K.
  - (a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;
  - (b) antioxidants: substances prolonging the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by oxidation;
  - (c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs;
  - (d) stabilisers: substances which make it possible to maintain the physico-chemical state of feedingstuffs;
  - (e) thickeners: substances which increase the viscosity of feedingstuffs;
  - (f) gelling agents: substances which give a feedingstuff texture through the formation of a gel;
  - (g) binders: substances which increase the tendency of particles of feedingstuffs to adhere;
  - (h) substances for control of radionucleide contamination: substances that suppress absorption of radionucleides or promote their excretion;
  - (i) anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere;
  - (j) acidity regulators: substances which adjust the pH of feedingstuffs;
  - (k) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage;
  - (l) denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials;
  - (m) <sup>F66</sup>substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action<sup>F67</sup>;]
  - (n) <sup>F68</sup>hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination<sup>F69</sup>;]
  - (o) <sup>F70</sup>other technological additives: substances or, when applicable, microorganisms added to feed for a technological purpose and which favourably affect the characteristics of the feed.]

**Textual Amendments**

**F66** Inserted by [Commission Regulation \(EC\) No 386/2009 of 12 May 2009 amending Regulation \(EC\) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives \(Text with EEA relevance\).](#)

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**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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- F67** Substituted by Commission Regulation (EU) 2015/2294 of 9 December 2015 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives (Text with EEA relevance).
- F68** Inserted by Commission Regulation (EU) 2015/2294 of 9 December 2015 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives (Text with EEA relevance).
- F69** Substituted by Commission Regulation (EU) 2019/962 of 12 June 2019 amending Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of two new functional groups of feed additives (Text with EEA relevance).
- F70** Inserted by Commission Regulation (EU) 2019/962 of 12 June 2019 amending Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of two new functional groups of feed additives (Text with EEA relevance).

2. In the category 'sensory additives', the following functional groups are included: **U.K.**
- (a) colourants:
- (i) substances that add or restore colour in feedingstuffs;
- (ii) substances which, when fed to animals, add colours to food of animal origin;
- (iii) substances which favourably affect the colour of ornamental fish or birds;
- (b) flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability.
3. In the category 'nutritional additives', the following functional groups are included: **U.K.**
- (a) vitamins, pro-vitamins and chemically well-defined substances having similar effect;
- (b) compounds of trace elements;
- (c) amino acids, their salts and analogues;
- (d) urea and its derivatives.
4. In the category 'zootechnical additives', the following functional groups are included: **U.K.**
- (a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
- (b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
- (c) substances which favourably affect the environment;
- (d) other zootechnical additives<sup>[F69;]</sup>
- (e) <sup>[F70]</sup>physiological condition stabilisers: substances or, when applicable microorganisms, which, when fed to animals in good health, favourably affect their physiological condition, including their resilience to stress factors.]

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

## ANNEX II **U.K.**

### DUTIES AND TASKS OF THE <sup>F71</sup>... REFERENCE LABORATORY

#### Textual Amendments

**F71** Word in [Annex 2](#) heading omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **33(a)**; 2020 c. 1, Sch. 5 para. 1(1)

1. <sup>F72</sup>...

#### Textual Amendments

**F72** [Annex 2](#) point 1 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **33(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[<sup>F73</sup>1A. The reference laboratory may be assisted by scientific experts or official laboratories with the performance of the duties and tasks set out in this Annex.]

#### Textual Amendments

**F73** [Annex 2](#) point 1A inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(10)(a)**

[<sup>F74</sup>2. <sup>F75</sup>... **U.K.**

The [<sup>F76</sup>reference laboratory] shall be responsible for:

#### Textual Amendments

**F76** Words in [Annex 2](#) point 2 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **33(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

- 2.1. the reception, storage and maintenance of the samples of the feed additive sent by the applicant as provided for in Article 7(3)(f);
- 2.2. evaluating the method of analysis of the feed additive, and of other relevant methods of analysis related to it, on the basis of the data provided in the application for authorisation of the feed additive as regards its suitability for official control in accordance with the requirements of the implementing rules referred to in Article 7(4) [<sup>F77</sup>, (6), and (7)] and the guidance of the [<sup>F78</sup>Food Safety Authority] referred to in Article [<sup>F79</sup>7(8)];
- 2.3. submitting a full evaluation report to the [<sup>F80</sup>Food Safety Authority] on the results of the duties and tasks referred to in this Annex;
- 2.4. where necessary, the testing of the method(s) of analysis.

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

#### Textual Amendments

- F77** Words in Annex 2 point 2.2 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F78** Words in Annex 2 point 2.2 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F79** Word in Annex 2 point 2.2 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(d)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F80** Words in Annex 2 point 2.3 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(e)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Textual Amendments

- F74** Substituted by Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (Text with EEA relevance).
- F75** Words in Annex 2 point 2 omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

3. The [<sup>F81</sup>reference laboratory is] responsible for coordination of the validation of the method(s) of analysis of the additive, in accordance with the procedure provided for in Article 10 of Regulation (EC) No 378/2005 <sup>(14)</sup>. This task may involve the preparation of food or feed test material.

#### Textual Amendments

- F81** Words in Annex 2 point 3 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(f)**; 2020 c. 1, Sch. 5 para. 1(1)

4. The [<sup>F82</sup>reference laboratory must] provide scientific and technical assistance to the [<sup>F83</sup>appropriate authority], especially in cases where [<sup>F84</sup>there are reasonable grounds to] contest the results of analyses related to the duties and tasks referred to in this Annex, without prejudice to any role defined for it under [<sup>F85</sup>Regulation (EU) 2017/625].

#### Textual Amendments

- F82** Words in Annex 2 point 4 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(g)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F83** Words in Annex 2 point 4 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(g)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F84** Words in Annex 2 point 4 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(g)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F85** Words in Annex 2 point 4 substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **8(10)(b)**

5. On request by the [<sup>F86</sup>appropriate authority], the [<sup>F87</sup>reference laboratory] may also be responsible for conducting special analytical or other related studies in a manner

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similar to the duties and tasks referred to in point 2. This may be the case, in particular, for existing products notified under Article 10 and included in the Register and for the period until an application for authorisation under Article 10(2) is submitted in accordance with Article 10(2).

#### Textual Amendments

- F86** Words in Annex 2 point 5 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(h)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F87** Words in Annex 2 point 5 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(h)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

- [<sup>F88</sup> 6. The reference laboratory shall:
- (a) be responsible for the overall coordination of scientific experts or official laboratories; and
- (b) ensure that the relevant data concerning the applications are made available to the scientific experts or official laboratories.]

#### Textual Amendments

- F88** Annex 2 point 6 inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **8(10)(c)**

7. Without prejudice to the responsibilities of the [<sup>F89</sup>reference laboratory] laid down in [<sup>F90</sup>Regulation (EU) 2017/625], the [<sup>F91</sup>reference laboratory] may create and maintain a database of methods of analysis available for control of feed additives and make it available to <sup>F92</sup>... other interested parties.]

#### Textual Amendments

- F89** Words in Annex 2 point 7 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(j)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F90** Words in Annex 2 point 7 substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **8(10)(d)**
- F91** Words in Annex 2 point 7 substituted (31.12.2020) by The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(j)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F92** Words in Annex 2 point 7 omitted (31.12.2020) by virtue of The Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654), regs. 1, **33(j)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

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## [<sup>F93</sup> ANNEX III U.K.]

### Textual Amendments

**F93** Substituted by [Commission Regulation \(EU\) 2015/327 of 2 March 2015 amending Regulation \(EC\) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations \(Text with EEA relevance\).](#)

1. SPECIFIC LABELLING REQUIREMENTS FOR CERTAIN ADDITIVES AND FOR PREMIXTURES. **U.K.**
  - (a) Zootechnical additives, coccidiostats and histomonostats:
    - the expiry date of the guarantee or the storage life from the date of manufacture,
    - the directions for use, and
    - the concentration.
  - (b) Enzymes, in addition to the abovementioned indications:
    - the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given,
    - the International Union of Biochemistry identification number, and
    - instead of concentration: units of activity (units of activity per gram or units of activity per millilitre).
  - (c) Micro-organisms:
    - the expiry date of the guarantee or the storage life from the date of manufacture,
    - the directions for use,
    - the strain identification number, and
    - the number of colony-forming units per gram.
  - (d) Nutritional additives:
    - the active-substance level, and
    - the expiry date of the guarantee of that level or storage life from the date of manufacture.
  - (e) Technological and sensory additives with the exception of flavouring compounds:
    - the active substance level.
  - (f) Flavouring compounds:
    - the incorporation rate in premixtures.
2. ADDITIONAL LABELLING AND INFORMATION REQUIREMENTS FOR CERTAIN ADDITIVES CONSISTING OF PREPARATIONS AND PREMIXTURES CONTAINING SUCH PREPARATIONS. **U.K.**
  - (a) Additives belonging to the categories referred to in Article 6(1)(a), (b) and (c) and consisting of preparations:
    - (i) the indication on the packaging or container of the specific name, the identification number and the level of any technological additive contained

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- in the preparation for which maximum levels are set in the corresponding authorisation;
- (ii) the following information via any written medium or accompanying the preparation:
- the specific name and the identification number of any technological additive contained in the preparation, and
  - the name of any other substance or product contained in the preparation, indicated in descending order by weight.
- (b) Premixtures containing additives belonging to the categories referred to in Article 6(1) (a), (b) and (c) and consisting of preparations:
- (i) if appropriate, the indication on the packaging or container that the premixture contains technological additives included in additive preparations, for which maximum levels are set in the corresponding authorisation;
- (ii) upon request from the purchaser or the user, information on the specific name, the identification number and an indication of the level of technological additives referred to in point (i) of this paragraph included in the additive preparations.]

## ANNEX IV U.K.

### GENERAL CONDITIONS OF USE

1. The quantity of additives that also exists in the natural state in certain feed materials shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorisation Regulation.
2. Mixing of additives shall be permitted only in premixtures and feedingstuffs where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.
3. Supplementary feedingstuffs, diluted as specified, may not contain levels of the additives which exceed those fixed for [<sup>F94</sup>complete feed].

#### Textual Amendments

**F94** Words in [Annex 4](#) point 3 substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), regs. 1(1), **8(11)**

4. In the case of premixtures containing silage additives the words ‘of silage additives’ must clearly be added on the label after ‘PREMIXTURE’.
- [<sup>F95</sup>5. Technological additives or other substances or products contained in additives consisting of preparations shall only modify the physico-chemical characteristics of the active substance of the preparation and shall be used in accordance with their conditions of authorisation where such provisions are provided for. U.K.



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Physico-chemical and biological compatibility between the components of the preparation shall be ensured in relation to the effects desired.]

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**Textual Amendments**

**F95** Inserted by [Commission Regulation \(EU\) 2015/327 of 2 March 2015 amending Regulation \(EC\) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations \(Text with EEA relevance\).](#)

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- (1) [OJ C 203 E, 27.8.2002, p. 10.](#)
- (2) [OJ C 61, 14.3.2003, p. 43.](#)
- (3) Opinion of the European Parliament of 21 November 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 ([OJ C 113 E, 13.5.2003, p. 1](#)), Decision of the European Parliament of 19 June 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
- (4) [OJ L 31, 1.2.2002, p. 1.](#)
- (5) [OJ L 270, 14.12.1970, p. 1.](#) Directive as last amended by Regulation (EC) No 1756/2002 ([OJ L 265, 3.10.2002, p. 1](#)).
- (6) [OJ L 213, 21.7.1982, p. 8.](#) Directive as last amended by Directive 1999/20/EC ([OJ L 80, 25.3.1999, p. 20](#)).
- (7) [OJ L 40, 11.2.1989, p. 27.](#) Directive amended by Directive 94/34/EC of the European Parliament and of the Council ([OJ L 237, 10.9.1994, p. 1](#)).
- (8) See page 1 of this Official Journal.
- (9) [OJ L 184, 17.7.1999, p. 23.](#)
- (10) [OJ L 86, 6.4.1979, p. 30.](#) Directive as last amended by Regulation (EC) No 807/2003 ([OJ L 122, 16.5.2003, p. 36](#)).
- (11) [OJ L 64, 7.3.1987, p. 19.](#) Directive as last amended by Commission Directive 2001/79/EC ([OJ L 267, 6.10.2001, p. 1](#)).
- (12) [<sup>F42</sup>[OJ L 35, 8.2.2005, p. 1.](#)]
- (13) [<sup>F42</sup>[OJ L 229, 1.9.2009, p. 1.](#)]
- (14) [<sup>F74</sup>[OJ L 59, 5.3.2005, p. 8.](#)]

#### Textual Amendments

- F42** Substituted by Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (Text with EEA relevance).
- F74** Substituted by Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (Text with EEA relevance).

### Changes to legislation:

There are outstanding changes not yet made to Regulation (EC) No 1831/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

#### Changes and effects yet to be applied to :

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)
- Art. 7 para. 2 Point (c) replacement by [EUR 2019/1381 Regulation](#) (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 7 para. 1 replacement by [EUR 2019/1381 Regulation](#) (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Art. 16(1) words substituted by [S.I. 2019/654 reg. 24\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 24(a)(i) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 12(4))
- Art. 18 replacement by [EUR 2019/1381 Regulation](#) (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)

#### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 2(2)(o)-(t) inserted by [S.I. 2019/654 reg. 10\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 10(a)(ii) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 12(3))
- Art. 18A(4)(d) words substituted by [S.I. 2019/1013 reg. 32](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))