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)

## CHAPTER II

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

# [<sup>F1</sup>Article 9

## Authorisation<sup>F2</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>F3</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  $[^{F4}$ authorisation] made in accordance with paragraph 1.

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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 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 **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

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**

- F1 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)
- F2 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)
- **F3** 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)
- **F4** 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)**
- **F5** 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)**

### **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

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))