
DRAFT STATUTORY INSTRUMENTS

2019 No.

The Animal Feed (Amendment) (EU Exit) Regulations 2019

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation 1831/2003

14. For Article 7, substitute—

“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—

- (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

feedingstuffs and animal species and categories for which the feed additive is intended;

- (f) a written statement that three samples of the feed additive have been sent by the applicant directly 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. Until such rules are prescribed, the application must be submitted in accordance with retained EU law.

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.

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