ANNEX III

SPECIFIC REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3 WITH RESPECT TO CERTAIN CATEGORIES OF ADDITIVES OR CERTAIN PART ICULAR SITUATIONS, AS PROVIDED FOR IN ARTICLE 7(5) OF REGULATION (EC) No 1831/2003

3. NUTRITIONAL ADDITIVES

3.1. Section I: summary of the dossier

The whole of Section I of Annex II applies.

3.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives not subject to a specific holder of the authorisation the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply;

— for other additives subject to a specific holder of the authorisation, the whole of Section II applies.

3.3. Section III: studies concerning the safety of the additives

3.3.1. Studies concerning the safety of use of the additive for the target species

3.3.1.1. Tolerance of the target species

1. No studies are required for urea, and amino acids, their salts and analogues authorised by Directive 82/471/EEC and compounds of trace elements and vitamins, pro-vitamins and chemically well-defined substances having similar effect which do not have a potential to accumulate already authorised as feed additives under Directive 70/524/EEC.

2. For those additives that fall within the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’ and having a potential to accumulate, tolerance will only be required to be demonstrated for compounds for which potency is expected or has been demonstrated to be different from that of the well established vitamin(s). In certain cases elements of the tolerance test (design or criteria) could be combined with one of the efficacy trials.

3. Tolerance will be demonstrated for urea derivatives amino acid analogues and compounds of trace elements not previously authorised. The fermentation products will be requested by tolerance demonstration, unless the active substance is separated from the crude fermentation product and highly purified, or the production organism has a history of apparent safe use and well known about its biology to exclude a potential for the production of toxic metabolites.

4. Where the application is for all animal species/categories, one tolerance study on the most sensitive species (or even an appropriate laboratory animal) under the most recent knowledge is sufficient.

3.3.1.2. Microbial studies

The whole of subsection 3.1.2 of Annex II applies.

3.3.2. Studies concerning the safety of use of the additive for consumers

3.3.2.1. Metabolic and residue studies

Metabolic studies normally are not required. For urea derivatives, ruminal metabolism shall be studied in the efficacy trials.

Residue or deposition studies are only required for those additives that fall within the functional group ‘vitamins, pro-vitamins and chemically well-defined substances, having similar effect’ that have a potential for accumulation in the body and for the functional group of compounds of trace elements where bioavailability has been enhanced. In that case, the procedure described in subsection 3.2.1 of Annex II does not apply. The requirement is limited to the comparison of the levels in the tissues or products between the group supplemented with the highest dose of the substance claimed and a positive control (reference compound).

3.3.2.2. Toxicological studies

These are required for fermentation products and additives not already authorised. For fermentation products, genotoxicity and subchronic toxicity studies must be provided unless:

1. the active substance is separated from the crude fermentation product and is highly purified; or

2. the production organism has a history of apparent safe use and there is sufficient knowledge of its biology to exclude a potential for the production of toxic metabolites.

Where the production organism belongs to a group in which some strains are known to produce toxins, their presence shall be specifically excluded.

3.3.2.3. Assessment of consumer safety

The whole of subsection 3.2.3 of Annex II applies.

3.3.3. Studies concerning the safety of use of the additive for users/workers

The whole of subsection 3.3 of Annex II applies

3.3.4. Studies concerning the safety of use of the additive for the environment

The whole of subsection 3.4 of Annex II applies for new active substances belong to the compound of trace elements.

3.4. Section IV: studies concerning the efficacy of the additive

Efficacy studies are not required for urea, amino acids, amino acid salts and analogues already authorised as feed additives, compounds of trace elements already authorised as feed additives and vitamins, pro-vitamins and chemically well-defined substances having similar effect already authorised as feed additives.

A short term study is required to support efficacy for urea derivatives, amino acid salts and analogues not already authorised as feed additives, compounds of trace elements not already authorised as feed additives and for vitamins, pro-vitamins and chemically well-defined substances having similar effect not already authorised as feed additives.

For other substances for which a nutritional effect is requested at least one long term efficacy study under provisions of Section 4 of Annex II is requested.

Where required, studies shall demonstrate that the additive can provide the animals' nutritional requirements. Tests shall include a test group with a diet that contains the nutrient at concentrations below the animals' requirements. However, trials using a severely deficient

control group shall be avoided. Generally, it will be sufficient to demonstrate efficacy in a single animal species or category including laboratory animals.

3.5. Section V: post-market monitoring plan

This section shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 429/2008. 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 the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/654 reg. 81
- Annex 2 s. 4 words substituted by S.I. 2019/654 reg. 83(e)(i) (This amendment not applied to legislation.gov.uk. Reg. 83(e)(i) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 12(15)(d)(i))
- Annex 2 s. 2 words substituted by S.I. 2019/654, reg. 83(c)(iii) (as substituted) by S.I. 2020/1504 reg. 12(15)(b)(i)
- Annex 2 s. 2 words substituted by S.I. 2019/654, reg. 83(c)(iv) (as substituted) by S.I. 2020/1504 reg. 12(15)(b)(ii)
- Annex 2 s. 2 words substituted by S.I. 2019/654, reg. 83(c)(v) (as substituted) by S.I. 2020/1504 reg. 12(15)(b)(iii)
- Annex 2 s. 3 words substituted by S.I. 2019/654, reg. 83(d)(iii) (as substituted) by S.I. 2020/1504 reg. 12(15)(c)(i)
- Annex 2 s. 3 words substituted by S.I. 2019/654, reg. 83(d)(iv)(aa) (as substituted) by S.I. 2020/1504 reg. 12(15)(c)(ii)
- Annex 2 s. 3 words substituted by S.I. 2019/654, reg. 83(d)(iv)(bb) (as substituted) by S.I. 2020/1504 reg. 12(15)(c)(ii)
- Annex 2 s. 4 words substituted by S.I. 2019/654, reg. 83(e)(i) (as substituted) by S.I. 2020/1504 reg. 12(15)(d)(i)
- Annex 2 s. 4 words substituted in earlier amending provision S.I. 2019/654, reg. 83(e)(ii) by S.I. 2020/1504 reg. 12(15)(d)(ii)