ANNEX II

GENERAL REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3

2. SECTION II: IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS

2.1. Identity of the additive

2.1.1. Name of the additive

If appropriate, a proposal for the trade name shall be made for additives linked to a holder of authorisation.

2.1.2. Proposal for classification

A proposal for the classification of an additive for one or more categories and functional groups according to its main functions under Article 6 and Annex I of Regulation (EC) No 1831/2003 shall be made.

Any data from other known uses of the identical active substances or agents (e.g. use in food, human or veterinary medicine, agriculture and industry) must be provided. Any other authorisation as feed or food additive, veterinary drugs or other kind of authorisations of the active substance has to be specified.

2.1.3. Qualitative and quantitative composition (active substance/agent, other components, impurities, batch to batch variation)

The active substance(s)/agent(s) and all other components of the additive shall be listed, giving the proportion by weight in the final product. The qualitative and quantitative batch to batch variation of the active substance(s)/agent(s) shall be determined.

For micro-organisms: the number of viable cells or spores expressed as CFU per gram shall be determined.

For enzymes: each declared (main) activity shall be described and the number of units of each activity in the final product given. Relevant side activities shall be also mentioned. The units of activity shall be defined and preferably as μmoles of product released per minute from the substrate, also indicating the pH and the temperature.

If the active component of the additive is a mixture of active substances or agents, each of which is clearly definable (qualitatively and quantitatively), the active substance(s)/agent(s) components must be described separately and the proportions in the mixture given.

Other mixtures in which the constituents cannot be described by a single chemical formula and/or where not all can be identified shall be characterised by constituent(s) contributing to its activity and/or typical major constituent(s).

Without prejudice to any request of supplementary information made by the Authority according to Article 8(2) of Regulation (EC) No 1831/2003, the applicant may omit the description of other components with no safety concerns other than active substances or agents for additives not within the categories of zootechnical additives, coccidiostats and histomonostats, and not in the scope of Regulation (EC) No 1829/2003. In any case, all studies reported in the dossier must be based on the actual additive requested for the authorisation and may provide information on the other possible different preparations that could be made. An in-house identifier may be

allowed, embedded in third-party documents, and a statement is required to list the identifiers and to confirm that the identifier(s) refers to the formulation(s) for which the request is made.

2.1.4. Purity

The applicant shall identify and quantify chemical and microbial impurities, substances with toxic or other undesirable properties that are not intentionally added and do not contribute to the activity of additive. In addition, for fermentation products, the applicant shall confirm the absence of production organisms in the additive. The protocol used for the routine screening of production batches for contaminants and impurities shall be described.

All the data provided have to support the proposal for a specification of the additive.

Specific requirements depending on the production process, complying with existing Community legislation, are listed below.

2.1.4.1. Additives whose authorisation is linked to a holder of authorisation

For additives whose authorisation is linked to a holder of authorisation, the relevant information related to the specific process used by the manufacturer, based on existing standards used for other related purposes, shall be provided. Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications or specifications from European Community food additive authorisations can be used.

2.1.4.2. Additives whose authorisation is not linked to a holder of authorisation

For feed additives whose authorisation is not linked to a holder of authorisation, existing standards used for other related purposes, or that have specifications for food additives as authorised in the European Community or from JECFA can be used. When such standards are not available, or where relevant to the manufacturing process, at least the following particulars shall be described and their concentrations determined:

— for micro-organisms: microbiological contamination, mycotoxins, heavy metals;
— for fermentation products (not containing micro-organisms as active agents): they shall follow the same requirements as for micro-organism products (see above). The extent to which spent growth medium is incorporated into the final product shall also be indicated.
— for plant derived substances: microbiological and botanical contamination (e.g. castor oil plant, weed seeds, rye ergot in particular), mycotoxins, pesticide contamination, maximum values for solvents and, where appropriate, substances of toxicological concern known to occur in the original plant;
— for animal derived substances: microbiological contamination, heavy metals and maximum values for solvents, where appropriate;
— for mineral substances: heavy metals, dioxins and PCBs;
— for products produced by chemical synthesis and processes: all chemicals used in the synthetic processes and any intermediate products remaining in the final product shall be identified and their concentrations given.

The selection of mycotoxins for analysis shall be made according to the different matrices, where appropriate.

2.1.5. Physical state of each form of the product

For solid preparations data on particle size distribution, particle shape, density, bulk density, dusting potential and the use of processes which affect physical properties shall be provided.

For liquid preparations, data for viscosity and surface tension shall be given. Where additive is intended to be used in water, the solubility or extent of dispersion shall be demonstrated.

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)