



Submission of reference samples and standards

Article 3 of assimilated [Regulation 378/2005](#) on detailed rules for the implementation of assimilated [Regulation 1831/2003](#) concerning applications for authorisations of feed additives states that any person submitting an application for an authorisation for a feed additive or for a new use of a feed additive shall supply three reference samples in a form in which the feed additive is intended to be placed on the market by the applicants.

In addition, the applicant shall also provide reference standards of the pure active agents in the case of feed additives:

- belonging to the category zootechnical additives referred to in Article 6(1)(d) of assimilated Regulation 1831/2003, except feed additives consisting of or containing micro-organisms;
- belonging to the category coccidiostats and histomonostats referred to in Article 6(1)(e) of assimilated Regulation 1831/2003;
- falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs);
- for which Maximum Residue Limits have been established in Annex I or III of assimilated Regulation 2377/90 or following assimilated Regulation 1831/2003.

An expiry date shall be provided for all reference samples and reference standards. Prior to the expiry date being reached it is expected that replacement samples and standards, where applicable, will be sent to LGC. These replacement samples shall be clearly marked, as detailed below, including with the original FSA reference (RP) number.

Quantity

Three reference samples of the feed additive, each weighing between 10 g and 100 g shall be supplied. The weight provided should take into consideration (a) the concentration of the active ingredient in the product and (b) the maximum proposed dose.



The quantity of the reference standard supplied should be sufficient to allow for 100 analyses and should not be less than 1 g.

For coccidiostats, 100 mg of reference standard is sufficient.

If there are any questions or doubts about the reference samples and standards that should be supplied, please contact LGC using the e-mail address:

feed.additives@lgcgroup.com.

Packaging

The containers the reference samples and standards are packaged in should not affect the physical or chemical properties of the feed additive. The containers shall be sealed with a tamper-evident closure.

The following containers are suitable:

- High density polyethylene (HDPE) bottles. For photosensitive substances, amber / brown HDPE bottles should be used.
- Glass containers should be avoided unless the feed additive is incompatible with plastic. For photosensitive substances, amber / brown glass bottles should be used. Glass bottles with external plastic coating should be used for any hazardous substances.
- Closures: polypropylene (pp), Teflon or Polytetrafluoroethylene (PTFE)-coated screw closures with tamper-evident seals should be used.

Labelling

Each reference sample and standard container shall be labelled clearly with the following:

- Name of feed additive
- FSA Authorisation application reference number (RP number)
- Expiry date / shelf life
- Storage temperature



Transportation

The applicant is responsible for ensuring the reference samples and standards are received at LGC in an acceptable condition and that appropriate transport conditions, for example with respect to temperature, are used. All containers shall be packed appropriately so no damage / leakage occurs during transport and should comply with all relevant transport regulations.

The samples and standards are to be sent to the following address:

Feed Additives National Reference Laboratory
LGC Ltd
Queens Road
Teddington
TW11 0LY
United Kingdom

When the samples / standards have been dispatched, LGC should be notified (feed.additives@lgcgroup.com) of the transportation method, for example the name of the courier used, expected delivery date and tracking number, if available.

If samples / standards require cold storage, delivery to LGC should not be made outside 08:00 – 16:30 Monday to Friday.

Documentation

The following documents need to be completed for each set of samples / standards sent to LGC:

- Sample or standard submission form - One to be completed for each different reference sample or standard sent
- Sample submission cover letter - To be signed, dated and printed on company headed paper
- Material safety data sheet (MSDS) for all relevant materials.
- Where the application concerns a feed additive consisting of or containing micro-organisms, an authorisation for LGC to access the microbial strain



deposited at the internationally recognised culture collection mentioned in point 2.2.1.2. of Annex II of assimilated Regulation 429/2008, is also required.

Hardcopies of all of these documents, apart from the MSDS, are to be included with samples / standards.

Copies of all of the documents are to be e-mailed to feed.additives@lgcgroup.com prior to the samples / standards being dispatched.

The FSA reference number is to be included in the title of all e-mail correspondence.