

Feed additives authorisation guidance

Feed additive authorisation guidance and what you need to submit as part of a feed additive application.

Feed additives ?are products authorised for specific purposes in animal feed, for example:

- in meeting the animals' nutritional requirements
- to improve the quality of feed and the quality of food from animal origin (i.e. meat, fish, milk, eggs)
- to improve the animals' performance and health

Feed additives must be authorised before they are placed on the market in Great Britain (GB) and may only be used for the purpose stated in the authorisation. ?If a feed additive is intended to perform more than one function, a separate authorisation is required for each function.

Register of feed additives

The FSA maintains a register that accurately reflects the authorisation status of feed additives as determined by the appropriate authority (ministers) in England, Scotland and Wales. The? register of feed additives lists the feed additives permitted for use in Great Britain and provides references to their terms of authorisation. Assimilated Regulation (EC) 1831/2003? is the legal basis for the use of individual feed additives.

Feed additive legislation

Assimilated Regulation (EC)?1831/2003 and assimilated Commission Regulation (EC) No? 429/2008? outline the authorisation procedure for these substances, and explain the:

- rules on feed additive authorisations
- conditions of use for additives
- provisions on the labelling of feed additives and their premixtures which must be adhered to

Detailed requirements for submitting an application

The authorisation process includes an evaluation of the analytical method provided by the applicant. For applications submitted within GB, the evaluation must be completed by the reference laboratory (an official laboratory that undertakes analytical testing of food and feed samples).

Tasks assigned to the reference laboratory are set out in <u>assimilated Commission Regulation</u> (EC) No?378/2005.

Application process

To apply for an authorisation of a feed additive in GB:

- Use our?<u>regulated products application portal</u> to complete the application form.?You will be asked to upload all the documents to support your application, taking into account the requirements in assimilated law and following the?European Food Safety Authority (EFSA) ?guidance as appropriate.
- 2. A reference laboratory is responsible for evaluating the method of analysis of the feed additive, and of other relevant methods of analysis related to it. You should also upload documentation on the analytical method used and any relevant information needed for the reference laboratory to undertake an evaluation of the method. If relevant, submit the EU No Fee Acknowledgement Letter or make reference to any evaluation which may have already been undertaken by the EU Reference Laboratory on the feed additive in question. Make it clear in your application if you consider that Article 5(4) of?<u>assimilated Commission Regulation (EC) No 378/2005</u> applies and that the conditions for placing the feed additive on the market fall within the scope of a previously evaluated method.
- 3. If the method requires a full evaluation, the reference laboratory will contact you to agree and set out the process for payment of any fees.?If applicable, they will also provide details on how to send three samples (and standards) to them.

Detailed application guidance

EFSA has previously developed technical guidance on the requirements of application dossiers which is also applicable for dossiers submitted in GB. However, you should follow the parts that relate to the development of dossiers only and not the application process:

- EFSA guidance for feed additive applicants
- EFSA guidance on the assessment of the efficacy of feed additives
- Feed additive applications: Requirements and recommendations

Re-authorisation of Article 10 feed additives

Ongoing applications submitted to EU for existing feed additives under Article 10 of <u>Regulation</u> <u>1831/2003</u> will still need to be submitted to the FSA. We will review these feed additives and provide further information on submission requirements and deadlines in due course.

Urgent authorisations

Urgent feed additive authorisations are provisional authorisations granted for a maximum period of 5 years and used only in exceptional circumstances, such as for the protection of animal welfare.? If you need to apply for an urgent feed additive authorisation, please include this information, and the rationale, in the covering letter that you upload to the application portal.

Getting help

If you have any questions about the authorisation procedure or application requirements, you can contact us at?<u>regulatedproducts@food.gov.uk</u>.

Apply for authorisation

You can now use our online service to?make a regulated product application.