# Feed additives authorisation guidance

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

This page is part of the Regulated products application guidance

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. They are generally authorised for ten years.

### Register of feed additives

The <u>register of feed additives</u> sets out a list of feed additives permitted for use in Great Britain and provides reference to the individual feed additive legislation. The register does not replace assimilated <u>Regulation (EC) 1831/2003</u> which is the legal basis for the placing on the market and 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 set out:

- · 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

Before conclusion of an authorisation, an evaluation of the analytical method supplied by the applicant must be undertaken by the reference laboratory. The tasks assigned to the reference laboratory are set out in <u>assimilated Commission Regulation (EC) No 378/2005</u> and include maintaining samples of feed additives for the duration of the authorisation period.

### **Application process**

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

- Use our <u>regulated products application service</u> to complete the application form. This is where you will be asked to upload all the documents to support your application, taking into account the requirements in assimilated law and as appropriate following the EFSA guidance.
- 2. You should also upload documentation on the analytical method and any relevant information needed for the reference laboratory to undertake the 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 clear in your application if you consider that Article 5(4) of <a href="mailto:assimilated Commission Regulation">assimilated Commission Regulation</a> (EC) No 378/2005 applies and that the conditions for placing the feed additive on the market fall within the scope of a previously evaluated method.

3. After receiving your application, we will contact you to agree and set out the process for payment of any fees due to be paid for the analytical assessment as laid down in the legislation. We will also provide details on how to send the three samples (and standards) where applicable to the Reference Laboratory.

### **Detailed application guidance**

The European Food Safety Authority (EFSA) has previously developed technical guidance on the requirements of application dossiers. This guidance generally remains relevant as our approach is based on EU processes. You should follow the parts that relate to the development of dossiers only and not the application process:

- EFSA guidance for feed additive applicants
- (applicable to applications submitted until 26 March 2021

### **Existing authorisations**

If your feed additive was authorised by the European Commission (EC) and the Regulation entered into force before 1 January 2021 and the necessary legislation is in place, that authorisation will remain valid in Great Britain.

#### Re-authorisation of feed additives

Ongoing applications submitted to EU for existing feed additives under Article 10 of <a href="Regulation">Regulation</a>
<a href="1831/2003">1831/2003</a> will still need to be submitted to us but there are no immediate deadlines for doing this. We will review these feed additives and provide further information on submission requirements and deadlines in due course.

# All other feed additive applications

Similarly, applications for renewal previously submitted to the EU before 1 January 2021 for which the assessment process was not completed do not need to be submitted until requested. Applications after 1 January 2021 should be submitted to us using our <u>regulated products</u> application service.

#### These include:

- new authorisations (Article 4 of Regulation 1831/2003)
- modification to authorisation (Article 13)
- renewal of authorisations (Article 14)- to be submitted at least one year prior to the authorisation expiry date.

When completing the application, you will be asked to provide your EFSA question number where applicable.

# **Urgent authorisations**

Urgent authorisation for feed additives may be progressed to ensure the protection of animal welfare. Urgent authorisations may be granted for a maximum period of five years.

# How long will my application take?

The legislation includes deadlines for key steps in the process. In most cases, applications will take at least a year.

The quality of the dossier, and the information provided will significantly affect the time needed for assessment and authorisation. We encourage applicants to follow the guidance and provide as much information as possible to ensure we can process your request as efficiently as possible.

### **Getting help**

If you have any questions about the authorisation procedure or application requirements, you can contact us at <a href="mailto:regulatedproducts@food.gov.uk">regulatedproducts@food.gov.uk</a>

# Apply for authorisation

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

#### Northern Ireland

The EU law that applies to Northern Ireland after the transition period is specified in Annex II to the Northern Ireland Protocol. This means that if you're seeking a new authorisation for a feed additive to be placed on the Northern Ireland market you will have to continue to follow EU rules.