Guidance for trials using feed additives not authorised

Only feed additives which are authorised may be placed on the market, processed or used. A definition of feed additives is available on the following link.

Application process

The process is set out in legislation (Article 3(2)) in assimilated Regulation (EC) 1831/2003 for trials in GB. Regulation (EC) 1831/2003 sets out the requirements for trials in NI. Both regulations allow for the use of non-authorised feed additives in trials.

Annexes II and III of assimilated Commission Regulation (EC) 429/2008 and for NI Regulation (EC) 429/2008 can be used as a guide as to what information might be submitted.

- For trials taking place in England, please submit your request and documentation to FeedAdditives@food.gov.uk
- For trials taking place in Wales, please submit your request and documentation to regulated.products.wales@food.gov.uk
- For trials taking place in Northern Ireland please submit your request and documentation to nioperationalpolicy@food.gov.uk
- For trials taking place in Scotland please submit your request and documentation to feedadditivetrials@fss.scot

FSA/FSS requests that feed additive trial applications are submitted at the earliest opportunity. If information required for the safety evaluation of the trial is not provided in the original submission, supplementary information will be requested and the application will be paused until supplementary information is received.

The FSA/FSS application process is expected to take 12 weeks, although timescales may vary depending on whether additional information is required.

The application process consists of an FSA/FSS review of the safety of the feed additive itself, and an appraisal of the trial design undertaken by an expert third party organisation in confidence.

All information shared by applicants will only be shared with those involved in the authorisation process as required. FSA/FSS complies to UK Privacy Laws, including the UK GDPR and Data Protection Act 2018.

Information required

England, Northern Ireland and Wales

WORD
View Animal feed trials application form as Word(Open in a new window) (97.45 KB)

Applicants must complete the trial application form and return to the FSA/FSS.

The trial (experimental) protocol- applicants must supply the full trial protocol when submitting an application.

Risk assessment of the animal feed trial

A risk assessment should be undertaken by the applicant and should include consideration of safety for humans, animals and the environment.. Supporting data may be required, for example characterisation information of the additive. Justification should be provided if any of these are not submitted. If further information is required, the applicant will be contacted by the FSA/FSS.

Any changes in trial will require an updated FSA/FSS trial protocol, to be sent to FSA/FSS. Once a trial is authorised, the experimental protocol cannot be amended.

Post trial animals entering the food chain

If applicants wish to place any trial animals into the food chain (control animals only or all animals) or products (e.g. eggs or milk from animals fed the additive) then this should be made clear in the trial protocol and the trial application form. Further information should be provided on the onward destination of the animals including; details of the registered onward farm, the growing on period before slaughter, the location of slaughter, and the withdrawal period from the unauthorised feed additive (pre-slaughter).

If animals are not to enter the food chain, following approval this decision cannot be changed.

Contact Details

- England: FeedAdditives@food.gov.uk
- Wales: regulated.products.wales@food.gov.uk
- Northern Ireland: nioperationalpolicy@food.gov.uk
- Scotland: feedadditivetrials@fss.scot

Relevant websites

- Animal feed additives
- Feed additives authorisation guidance
- GB Register of Feed Additives
- EU Feed Additives Register
- Gov.uk for home office licenses
- FSS webpage on feed trials in Scotland
- Veterinary Medicines Directorate (VMD) (for non-authorised coccidiostats and histomonostats or veterinary medicinal substances).
- For EU applications and rules on pre-notification please refer to: Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance)

Annex A: List of relevant legislation

- Regulation (EC) 1831/2003) Article 3 (2)
- Regulation 767/2009
- Regulation (EC) 429/2008
- Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance)