Information to be provided by the applicant

In order to obtain permission for testing with a non-authorised additive for animal feed, a dossier must be submitted together with the application form. This dossier also contains reports from which can be concluded that the requested test can be carried out safely and responsibly.

This dossier must clearly show that the tests are in particular being carried out to determine the effectiveness and/or the safety. The tests can be carried out at specialised research institutions or at practical facilities.

When applying for permission, you must submit all important data that is available. This information is necessary to allow assessment of the safety of humans, animals and the environment. Based on that data, a decision can be made about whether particular precautions have to be taken. These may be imposed for the processing of the product or the feed that is being investigated. They may also be about whether the animal product may be used for human consumption, possibly after a waiting period.

Note: the Working Conditions Act and the Experiments on Animals Act also apply to permission to carry out tests with additives for animal feed.

Your request and the data you provide will of course not be made public to third parties.

A request must contain the following items:

General description of the test
This must be described briefly and clearly in order to get a good picture of the test.

This applies among other things for:

- the legal basis: is the request compliant with Regulation 1831/2003 (inter alia for the product, objective, dossier building, etc.)?
- administrative details
- content and design (is it a scientific test, for example with a negative control group; are the test design and dosages clear, etc?)

If there are any permits that could be used to support the request, is it sensible to submit them (e.g. DEC, GMO, etc.)?

Justification for leaving out data
If you, in your role as applicant, believe that it is not necessary to provide certain data, you must substantiate that.

Product description
A sufficiently detailed and specific description of the product:

- the complete and unambiguous name of the product
- the form of the product (powder, granulate, solution, suspension, etc.)
- identity (specific) and a clear description of the active component
- composition of the entire additive

- any impurities present in the additive (heavy metals, organic and microbial contaminants; the latter particularly in substances that are produced by microorganisms)
- any toxins. Mycotoxins are important in the case of products that are produced by fungi; bacterial toxins are important for bacteria

Confidential data
If the supplier of the additive considers certain data to be confidential, it is possible to send data directly to the Veterinary Medicinal Products Unit (bypassing you in your role as the applicant). The supplier must then give permission for that information to be assessed.

Regulations for specific groups

Microorganisms
Microorganisms may be present as such (for example in probiotics). They may also have had a role as production organisms (for example for enzymes, amino acids, etc.).

Microorganisms must be suitably safe from the various perspectives (including with regard to toxins).

Non-modified microorganisms
Microorganisms that are on the QPS list (Qualified Presumption of Safety) from the EFSA will be assumed to be safe in the request (note: sometimes a strain may have to meet additional conditions before it is seen as QPS-compliant). If they are not on the list or if they are on the list but on the condition that additional information is supplied, then the additional safety requirements must be demonstrated.

Genetically modified microorganisms
Where microorganisms have to be regarded as GMOs under EC Regulation no. 1829/2003, then that regulation also says that they must be assessed and a permit must be submitted for them insofar as applicable. This is only rarely the case.
An additive produced by a GMO can be purified to remove organisms and GMO-related DNA.

This means that it is possible that the additive is no longer covered by Regulation 1829/2003 but instead falls under Regulation 1831/2003 or Regulation 429/2008. This must be demonstrated.
Any negative effects from the original organism and/or the production process of the GMO may still be present. These must be properly described and demonstrated not to be harmful (the EFSA Guidance – EFSA Scientific opinion 2011; 9(6): 2193 – can be used to help show this).

The following data must be provided:

- details of the identity (detailed description of the origin of the organism) and the nature of the modification
- the presence of cells and the genetic material (recombinant DNA)
- statement of whether the original organism is on the QPS list
- the presence and harmful effects of any toxins that are produced by the organism
- any other harmful effects

Herbaceous plants
Extracts, tinctures and other processed forms are generally deemed to be additives. If complete parts of plants are used, these are generally deemed to be feed.
It must be demonstrated that the product made from the plants or parts of plants in question is not classified as a forbidden product under any legislation.
Its safety must be demonstrated.

Any other groups
Suitable information (emphasising the safety) must be provided for other groups of products with specific properties/risks.

Safety of the user
The safety of the user must be assured sufficiently while the test is being carried out. This must be stated for all relevant situations, such as during production of the feed, administering it to the animals in drinking water applications, etc.
If there are risks for anyone applying the product other than during production, these must be described separately. (Submitting an SDS is a good way of doing this, but other types of description may be sufficient too.)

Residues
The possibility of residues being formed in animal products from the tests that are used for consumption must be clearly described.

In addition to the active components, impurities can also result in residues.
These must therefore also be covered in the arguments presented.

The result must be that clearly argued withdrawal periods are proposed.
As a result of carry-over during production of the test feed (and/or earlier stages), residues can also be present in feed that is produced afterwards. This will often be feed for non-target animals. If this risk is present, it must be quantified. Quantitatively substantiated measures must then be proposed that reduce carry-over to an acceptable level (e.g. rinsing, production sequence, etc.).

Special and/or high-risk situations
Insofar as permitted, situations involving additional risks must be described and controlled so that the risks are acceptable.

Feed production, feed processing and feeding animals

Recognised animal feed company:
You must give a clear description of how the animal feed as used in the test (including any pre-mix) is produced. The proportion of the pre-mix in the feed must be stated. This also applies to relevant aspects of transport, storage and administration to the animals (including any use of water).
The animal feed company must have the required Feed Hygiene Regulation (Regulation EC no. 183/2005 by the European Parliament and the Council) registration/recognition. Additional requirements apply in special cases.

Because this Regulation has a broad scope, there may be some cases where requirements are also imposed on other types of production locations and other locations (e.g. production of a premix or processing the additive via a food mixer unit at a livestock farm, etc.).

When additional conditions/information are required above the basic requirements as formulated in the Feed Hygiene Regulation, these must be provided (e.g. homogenous mixing and carry-over in the case of inter alia coccidiostats, etc.).

Any residues of test feed and/or additive may not be used other than in the test. The method of responsible disposal of these residues must be stated.

Other types of processing
Permission may be given for preliminary stages of the final product/studies.
This means that non-standard situations may apply (e.g. tablets, provision on top of the feed, provision in the rumen/gut, etc.)

There are also additives for administration in the drinking water.

In these cases, information must be provided about the above-mentioned items insofar as they are applicable, appropriate for the modified format.

Insofar as applicable, there must be description of the way in which all the above-mentioned points are implemented and controlled

Concluding remark

Because the situations in which permission to carry out tests is requested can vary widely and are often not standard, the overview given above is an indication which can never be complete. The option of asking additional questions is always available.

The signatory is responsible for the entirety of the test requested.