Guidance Document
Feed Ingredients Effectiveness Assessment – General Recommendations
July 2026
At Step 7: Steering Committee Endorsement

FEED INGREDIENTS EFFECTIVENESS ASSESSMENT GENERAL RECOMMENDATIONS

Endorsed by the Steering Committee
July 2026

It is recommended for the companies willing to submit applications/dossiers for pre-market authorization, to contact the jurisdictions of the countries concerned to confirm their acceptance of the current guidance document.

The International Cooperation for Convergence of Technical Requirements for the Assessment of Feed Ingredients (ICCF) was launched in 2017 and aims to develop and establish common guidance documents to provide technical recommendations for the assessment of feed ingredients, including new uses of existing feed ingredients.

This guidance document has been developed by the appropriate ICCF Experts Working Group and was subject to consultation by the Parties, in accordance with the ICCF Process.

The founding members of the ICCF include the Canadian Food Inspection Agency (CFIA), the European Commission (DG SANTE), the U.S. Food and Drug Administration (FDA), as well as the American Feed Industry Association (AFIA), the Animal Nutrition Association of Canada (ANAC), the EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA) and the International Feed Industry Federation (IFIF).

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1. INTRODUCTION

1.1. Objective of the guidance

This guidance document provides the general recommendations for the testing of the effectiveness of feed ingredients under their proposed conditions of use. It covers recommendations for study design and statistical analysis, provision of bridging studies, data, and information and the potential for extrapolation of the results and conclusions of the studies. This guidance document shall be used in combination with the available function specific guidance documents, describing the specific requirements for studies for the effectiveness of the feed ingredient on technical effects (ICCF Guidance document 'Feed ingredients effectiveness assessment – Technical effect'), on the provision of nutrients (ICCF Guidance document 'Feed ingredients effectiveness assessment – Nutritional effect'), on the effects on animals (ICCF Guidance document 'Feed ingredients effectiveness assessment – Effect on animals') and/or on animal products (ICCF Guidance document 'Feed ingredients effectiveness assessment – Effect on edible products quality/composition'). While this guidance document describes the general recommendations on the technical information to be submitted, applicants are advised to consult the relevant authority of jurisdiction, where the feed ingredient is intended to be marketed, and, if applicable, their guidance document(s) during the development phase of new feed ingredients or a new use of an approved or authorised feed ingredient.

1.2. Definitions

The definitions applicable in the context of this guidance document are provided in the ICCF Glossary of Terms.

1.3. Scope of the Guidance

This guidance document is applicable for all types of feed ingredients subject to an assessment of effectiveness in the context of their pre-market approval, authorisation, or regulatory acceptance. It covers the evaluation of the intended effect of a feed ingredient.

2. GENERAL PRINCIPLES

The information provided for the evaluation of the effectiveness of a feed ingredient should cover the proposed conditions of use of the feed ingredient as specified (see ICCF Guidance document on 'Manufacturing Process and Specification' and ICCF Guidance document on 'Identification and Characterisation of Feed Ingredients').

The evaluation of the effectiveness of the feed ingredient is based on the assessment of various types of information such as effectiveness studies and/or bridging information. The environmental and technical conditions, the feed composition, and if appropriate the livestock production systems relevant to the jurisdiction(s) where the feed ingredient is intended to be marketed should be considered.

The assessment of the effectiveness of a feed ingredient is based on the comparison of the results of the tested feed ingredient and a control. Hence, the information provided should be clearly reported for all relevant experimental groups tested to facilitate the assessment.

3. INFORMATION RELEVANT TO THE EFFECTIVENESS ASSESSMENT

The effectiveness potential of the active substance(s) contained in the feed ingredient under the proposed conditions of use is assessed based on the integration of data, and information resulting from effectiveness studies, together with other relevant bridging information.

The effectiveness studies should be properly designed, including the use of appropriate control(s). Relevant parameters should be measured, using internationally recognized scientific measurement methods (See ICCF Guidance Document on 'Analytical Methods for Feed Ingredients').

The information provided to justify effectiveness usually contains effectiveness studies and bridging information relevant to the feed ingredient and/or the active substance(s) it contains. The relevance of the bridging information should be properly justified.

The information provided could be generated using *in silico*, *in vitro*, *ex vivo*, and *in vivo* studies or a combination of those, depending on the intended effect of the feed ingredient.

Depending on the type of feed ingredient under consideration, various effects are expected, such as technical effects on feeds, nutritional effects and effects on animal and on the quality of the product of animal origin. Therefore, this guidance document should be considered in combination with the corresponding relevant guidance documents in the efforts to support the effectiveness

assessment of the feed ingredient. Specific intended effects need to be substantiated separately in accordance with the various guidance documents.

3.1. Effectiveness studies

As a general principle, effectiveness studies shall be conducted with the feed ingredient under assessment, in the form it is intended to be used in practice (i.e. feed ingredient or ingredient market formulation(s)) and under the proposed conditions of use. Usually, studies should compare the results obtained with the feed ingredient under assessment (test group) with that of a well justified and appropriate control group(s). Studies should be designed to allow statistical analysis.

The effectiveness studies shall be developed based on an appropriate protocol, established before the start of the study. The protocol should include details on how data and information are to be collected and the statistical procedures to be used to evaluate the intended effect.

When *in vivo* effectiveness studies are necessary for the evaluation of the intended effect, it is necessary that animals participating in the studies are managed with care. In some jurisdictions, an approval by an animal care body is necessary.

After completion of the study and statistical analysis, the results should be properly presented and discussed in a study report.

All relevant reports of effectiveness studies, which are either proprietary or published, including a discussion of their findings and any conclusions, should be provided in the submission package to regulatory agencies.

3.1.1. Protocol

The following overarching elements should be considered when developing the effectiveness study protocol:

- The study hypothesis(es) and objective(s), adequately described and covering the intended effect,
- The type of study (i.e., *in silico*, *ex vivo*, *in vitro* or *in vivo* effectiveness study),
- The description of the test item[1], representative of the product intended to be used in practice,

[1] The test item may be either the feed ingredient or any ingredient market formulation

- The study location and personnel
- The study design including at least the following elements[2]:
    - The composition of the feed and the feed form (e.g. pelleted, mash), and the nutritional values (calculated and/or analyzed), when appropriate,
    - The use of appropriate control group(s),
    - The inclusion amount of the test item in the test feed, including the method used for-analytical confirmation,
    - The method for inclusion of the test item in the feed (e.g. sprayed for liquid or incorporation via premixture),
    - The conditions (e.g. housing parameters, laboratory conditions, as appropriate) of the study,
    - The duration and exact start date of the study,
    - Description of animal used in the study: species, age, production stage, health status, when relevant.
- The parameters tested, indicating the testing frequency and the method(s),
- The experimental unit for statistical purpose,
- The number of independent replicates calculated based on the statistical approach envisioned, and considering the magnitude of the intended effect, the precision and the level of confidence of the measurements, and the statistical power of the study.

The protocol should include detailed description of the collection of data and observations. It should specify the procedures for the randomization of the study groups. Blinding (i.e. masking the identity of the treatments in the group) may be necessary to reduce bias. The protocol should clearly describe how personnel responsible for data collection and observations will be kept unaware of treatment assignments. The applicant should justify when bling ding is not applied.

For published effectiveness studies, the data collection should be properly described and the information peer reviewed.

[2] Further information will be provided in the relevant guidance documents.

At a minimum, the following information regarding the statistical evaluation methods should be included:

- The statistical analysis model,
- The experimental unit, including single items or independent groups of items, should be indicated so that the sample sizes and statistical analyses can be properly evaluated,
- The criteria for blocking the experimental units in each group,
- The management of missing or outlier data,

All data should be processed, and any exclusion of collected data must be justified. Data points should not be excluded only based on numerical outlier analysis. If data points are removed based on physiological or management incidences, relevant details and justification should be provided as to why such datapoints were removed.

3.1.2. Reporting

The report should be drafted based on the protocol (see Section 3.1.1) and provide detailed and organized results of the effectiveness study. Any amendments or deviations from the protocol should be provided and justified. All data collected should be provided in the report, including a glossary explaining the variables collected and their metadata. Missing data should be explained and justified.

The statistical model(s) used should be described, including its (their) specification, software, model, parameters, covariates (if appropriate), response variable and the model equations and formulas. The statistical analysis, including treatment of outliers, if appropriate, log/output as well as explanation of potential removal of experimental units should also be provided in the appendix of the report.

The detailed results should be discussed, considering the available information in addition to potentially referring to observations which are not subject to statistical evaluation, to enable objective conclusions on the effectiveness of the active substance contained in the feed ingredient.

Published effectiveness studies should be from peer reviewed publications.

3.2. Bridging information

In addition to the reports of effectiveness studies, the applicant can provide other data and information (bridging information) to help further support a comprehensive effectiveness assessment. Bridging information may be used to discuss and corroborate the conclusions of the effectiveness studies, close the data gaps, and provide explanations and clarifications to support the effectiveness of the feed ingredient under the proposed conditions of use. Bridging information may also provide evidence to allow the extrapolation to the proposed conditions of use.

As examples, the bridging information may include data on the following elements:

- the mode of action of the feed ingredient,
- the use of the feed ingredient in other conditions of use, as the ones proposed (e.g. other use rates, other feed or target species), for extrapolation,
- the use of (an)other feed ingredient(s) containing the same active substance(s).

A comprehensive narrative should be included to discuss the relevance of the data and information in the context of the feed ingredient under consideration. The data and information should accompany an explanation of all the relevant information and results and include substantiation, such as:

- the demonstration of the equivalence of the feed ingredient or active substance(s) used in the bridging study to the feed ingredient under review. For example, the form (physical, chemical, or biological) and manufacturing method applied to the feed ingredient or active substance(s) used in the study should be equivalent to that of the feed ingredient under review. If the feed ingredient or active substance(s) in the study and the feed ingredient under review are not identical, the bridging rationale should be sufficient to allow making conclusions applicable to the feed ingredient under review,
- the inclusion/amount of the feed ingredient or active substance(s) in the bridging study, when compared to the proposed conditions of use of the feed ingredient under review must be equivalent, to be useful for supporting the effectiveness of the feed ingredient under review.
- the demonstration of the equivalence of the animals used in the bridging study to those considered under the proposed conditions of use of the feed ingredient under review. This must include a discussion of the animals' species, type and production phase in the study, and the relevance to the target animal species, defined in the proposed conditions of use.

A scientific rationale supporting inter- or intraspecies extrapolation is required. Consideration will be given to:

- the physiological similarity between species (e.g., digestive physiology and metabolism), and
- the production purpose (e.g., growth vs reproduction [i.e. milk and egg production])

The applicant should justify the use of bridging information, based on the relevance of the information for assessing the effectiveness of the feed ingredient. Furthermore, if additional studies are proposed, these studies should follow the same rules as the effectiveness studies, such as properly designed studies, statistical analysis, implementation of relevant methodologies and reports. Data and information from peer reviewed publications and textbooks may be used for bridging purposes. The justification shall connect pertinent elements of the bridging information and of the effectiveness studies, e.g. in the form of a discussion.

4. BIBLIOGRAPHY

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