Maisons-Alfort, 27 April 2018

The Director General

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on guidelines for assessing claims relating to animal feed

Assessment of dossiers containing evidence of function claims

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with the necessary information concerning these risks as well as the requisite expertise and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are made public.
This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 27April 2018. shall prevail.

On 12 April 2017, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) issued an internal request to conduct the following expert appraisal: Development of guidelines for assessing claims relating to animal feed – *Assessment of dossiers containing evidence of function claims*. The relevance of issuing an internal request on this subject was validated by the DGCCRF after several discussions.

1. BACKGROUND, PURPOSE AND PROCEDURE FOR HANDLING THE REQUEST

1.1. Background

The conditions governing the use of claims are laid down in Article 13 of Regulation (EC) No 767/2009. Although subject to a number of restrictions, these claims are only verified *a posteriori* by the competent authorities of the Member States in which the feed in question is placed on the market. The persons responsible for labelling must be able to provide the scientific evidence to substantiate each claim made, and this must have been collected by them before the products are placed on the market.

For example, regarding claims, Article 13 of Regulation (EC) No 767/2009 on the placing on the market and use of feed stipulates that "*a) the claim is objective, verifiable by the competent authorities and understandable by the user of the feed; and b) the person responsible for the labelling provides, at the request of the competent authority, scientific substantiation of the claim, either by reference to publicly available scientific evidence or through documented company research*."

Two codes have been drawn up by European professional organisations and approved by the Commission:

- Code of good practice for the labelling of compound feed for food-producing animals[1];
- Code of Good Labelling Practice for Pet Food[2].

These codes only cover compound feed, whereas claims may also relate to raw materials. Much of the first code was adopted in France by the AFCA-CIAL trade union, which represents manufacturers of additives and supplements for animal feed, in a draft good practice guide for claims relating to animal feed.

Unlike the Regulation on nutrition and health claims made on foods (Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006), Regulation (EC) No 767/2009 does not include a definition of "claim". Nor does it define the different types of claims[3]. The other major difference concerns the legal regime for these claims. Claims relating to animal feed are subject to *a posteriori* verification by the competent authorities at the time of official controls or following alerts by users. The situation is quite different for claims relating to foods. Firstly, the conditions governing the use of nutrition claims on foods are specified by this 2006 Regulation and these claims are listed in an annex to the Regulation. Secondly, the four types of health claims provided for in this same Regulation are subject to a prior authorisation regime, such that no health claim can be used unless it appears on a list established by a European Commission Regulation. Therefore, when the WG referred to this Regulation and those adopted for its implementation, it first verified that their provisions corresponded to those of Regulation (EC) No 767/2009.

[1] *EU code of good practice for the labelling of compound feed for food-producing animals (COPA-COGECA-FEFAC)*
[2] *Code of Good Labelling Practice for Pet Food (FEDIAF - 20 October 2011 / http://www.fediaf.org/self-regulation/labelling/)*
[3] *After defining the term "claim", Regulation (EC) No 1924/2006 provides definitions for "nutrition claims" and "health claims".*

1.2. Purpose of the request and organisation of the expert appraisal

To ensure the homogeneity and consistency of ANSES's expert appraisal work on claims relating to animal feed and transparency in this work, guidelines (GLs) need to be drawn up for assessing dossiers of claims made for raw materials and/or compound feed for food-producing animals and pets.
These guidelines (GLs) should identify a set of criteria considered relevant by the experts for examining scientific dossiers of claims relating to raw materials and/or compound feed. In particular, they should specify how the evidence provided in support of the claim will be considered.

1.2.1. Scope of the guidelines

In view of the mission of the CES on "Animal feed" (CES ALAN), which is to issue scientific opinions on the dossiers of evidence received at ANSES and relating to animal feed, this internal request is not intended to address the issue of the regulatory positioning of the feed concerned by the claims.

The CES considers that decisions on the regulatory status of products for animal feed (raw material, additive, premix, feed for a particular nutritional purpose, complete/complementary compound feed) and the question of "borderline" products situated between animal feed and veterinary medicinal products fall within the sphere of competence of on the one hand, the person responsible for labelling the food before it is placed on the market and on the other, the competent authority. This issue should therefore have been settled prior to any formal requests relating to "claims".

According to Paragraph 1 of Article 13 of Regulation (EC) No 767/2009[4], three categories of claims can be distinguished: composition claims, nutrition claims and function claims.

ANSES decided to exclude composition and nutrition claims from the scope of the formal request. These two claims refer to the composition of the feed, and with regard to animal feed ANSES's role is neither to verify its composition nor to validate its nutritional quality compared to that of a standard feed.

In addition, Article 11, Paragraph 1, Point b of Regulation (EC) No 767/2009 states that the labelling and presentation of feed shall not mislead the user, in particular by attributing to the feed effects or characteristics that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feeds possess such characteristics. ANSES will regard function claims based on nutritional intakes that do not differ from national or international nutritional recommendations (INRA, NRC, etc.) as a wrongful distinction.
The person responsible for labelling will therefore have to prove the distinctive nature of their feed in relation to these recommendations.

Concerning feed safety, this field of expertise is not included in the formal request, but the WG reiterates the obligations of operators, which must only place food that is healthy and safe on the market, requirements that are specified by Regulation (EC) No 178/2002: "*Feed shall not*

[4] *"The labelling and the presentation of feed materials and compound feed may draw particular attention to the presence or absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these."* The remainder of the paragraph specifies the conditions that must be met by these claims.

be placed on the market or fed to any food-producing animal if it is unsafe" and by Article 4 of Regulation (EC) No 767/2009: feed must not have an adverse effect on the environment or animal welfare. However, on a case-by-case basis, if the content of the constituent(s) to which the claim relates poses a risk to the safety of the recipient animal, user or consumer of foods derived from the animals that ingested the feed concerned, this point will be addressed in ANSES opinions responding to formal requests relating to claims.

1.2.2. Procedure: means implemented and organisation

ANSES entrusted examination of this request to the Working Group on "Animal feed claims" reporting to the CES on "Animal feed".

The group's expert appraisal work was regularly submitted to the CES. The report produced by the Working Group takes account of the observations and additional information provided by the CES members. The CES on "Animal feed" adopted the work of the expert group and its conclusions and recommendations at its meeting of 13 March 2018 and informed the ANSES General Directorate accordingly.
This work was therefore conducted by a group of experts with complementary skills.
The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

Bibliographic sources

Regulation (EC) No 767/2009 leaves the task of ensuring compliance with the provisions of Article 13 on claims to the Member States. It makes no provision for the adoption of guidelines for dossiers containing evidence of these claims. Moreover, although this Article provides for the possibility that the merits of a claim relating to feed may be referred to EFSA at the Commission's request, no such case seems to have occurred to date. There is therefore no EFSA doctrine on this subject.

These reflections on GLs are based on ANSES's previous assessments of dossiers of claims relating to animal feed.

A hearing with AFCA-CIAL took place on 13 December 2016 at a meeting of the CES ALAN, to clarify certain points and enable it to answer the experts' questions about its draft good practice guide on animal nutrition claims. The final version of this guide was published by AFCA-CIAL in May 2017. It provides a number of additions and refinements to the COPA-COPEGA-FEFAC code, but certain elements have not been included. Representatives of AFCA-CIAL, the SNIA, Coop de France and FACCO were also interviewed at the WG meeting of 30 January 2018.

In addition, the experts searched the literature for the different GLs available (on animal feed or human food) for assessing these types of claims in Europe. The Member States of the European Union were consulted, via the focal points, to ascertain the existing situation regarding the authorities' assessments of claims relating to animal feed. A set of guidelines in the Netherlands was identified[5].
These elements provided input for the WG's discussions.

[5] *Guidance on the Substantiation of Claims made on Animal Nutrition (CBG/MEB), Veterinary Medicinal Products Unit. The Netherlands. August 2016, Version 1.2 (67 pages)*

EFSA's publications on claims relating to human food were analysed by the experts, in particular on what can be transposed to animal feed.

1.2.3. Prevention of risks of conflicts of interest

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.
The experts' declarations of interests are made public via the ANSES website (www.anses.fr).

2. ANALYSIS AND CONCLUSIONS OF THE CES

2.1. Content of a dossier of evidence

For health claims made on foods for human consumption, Commission Regulation (EC) No 353/2008 of 18 April 2008[6] establishes implementing rules for applications for authorisation of health claims, including those for the preparation and presentation of such applications. There is no such regulation in the case of claims relating to animal feed since, as mentioned above, such claims are not subject to prior authorisation.
This section describes what ANSES expects from a dossier containing evidence of function claims in order to ensure that its assessment is carried out under the best possible conditions. In the text below, use of the term "must" does not confer any mandatory nature. These are only recommendations that may facilitate the task of the person responsible for labelling in preparing the dossier of evidence before the food to which the claim in question relates can be placed on the market.

The claim must be objective, verifiable and justified. The documentation provided must form a complete dossier, with copies of the publications cited, details of the study and any other documents cited.

In general terms, the dossier must include:

- The wording and a note presenting the claim;
- The composition of the feed and the "basis" of the claim (see 2.1.2);
- A chapter on the evidence enabling assessment of the link between the basis of the claim and the claim in the target species.

2.1.1. The wording and a note presenting the claim

2.1.1.1. The wording of the claim

The dossier of evidence must include the exact wording of the claim. In the case of multiple claims, i.e. announcing multiple properties, separate dossiers of evidence must be provided for each property, unless a direct link between the properties can be demonstrated. The wording of the claim must be such that the supporting studies can present one or more response variables that

[6] *Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.*

are measurable and relevant to the claim. Three types of wording can be distinguished (see examples in Table 1):

- targeted wording, which contains the response variable(s);

- broad wording, which does not clearly contain a response variable but implies or suggests many parameters or organisational scales;

- wording that is too vague and does not refer to measurable responses; these claims cannot be scientifically proven and therefore cannot be validated.

Table 1: Examples of claim wording

Targeted wording
Increases phosphorus uptake through Y phosphate, in which the phosphorus is more than 98% soluble in 2% citric acid
Reduces releases of phosphorus into the environment through a highly digestible source of X phosphate
Increases egg-shell strength
Increases average egg weight
Pigment-rich food for an intense egg-yolk colour
Increases weight gain in pigs infected with Y virus
Reduces milk secretion for successful dry-off
Reduces ammonia absorption in the rumen
Reduces the postprandial drop in ruminal pH
Increases uterine tone
Increases biliary secretion
Reduces tartar formation
Increases hairball elimination and reduces the discomfort caused: vomiting and/or constipation
Decreases urinary pH and the risk of infection
Facilitates hairball elimination and reduces the discomfort caused: vomiting and/or constipation
Broad wording
X phosphate is selected for better use by the animal
Reduces releases into the environment
Enhances the value of the protein in the feed intake
Optimises egg-laying in layer hens
Improves egg quality
Improves hoof quality
Avoids skin disorders
Improves liver function at the start of lactation
Increases elimination of all types of waste products from the body
Stimulates liver function
Increases natural defences in cats and dogs
Helps to maintain a healthy urinary system
Strengthens the immune system in piglets
Vague wording
Harmonious growth of poultry
X phosphate is a wise choice
Contributes to ensuring maximum digestive safety
Helps optimise ammonia management in ruminant feed intake
Contributes to proper development of ruminal flora

Enables better use of the soluble nitrogen in grass Activates rumen flora and facilitates digestion
Helps stimulate metabolism and promote energy use
High levels of DHA, a component naturally found in breast milk that is essential for the development of brain structure
Eases breathing
Intelligent control of parasitism

The red indicates the words or expressions leading to the classification of the wording

2.1.1.2. A note presenting the claim

The dossier of evidence must contain a note specifying the following information:

- a description of the context in which the claim is made (farming context, benefit for the animal or breeder, health conditions, etc.);

- the target population;

- the conditions of use: how to use the feed, how long it should be used to achieve the claimed effect, rate of intake;

- the extent of the effect (e.g. simple improvement or return to normal of a physiological disorder marker), the durability of the effect;

- the criterion/criteria (response variables) that will be used to characterise the claim; these must be measurable.

2.1.2. The composition of the feed and the "basis" of the claim

The dossier of evidence must specify the composition of the feed to which the claim relates and its variability between batches, as well as its stability during storage. It must highlight the specific characteristic of the feed on which the claimed properties are based. This specific characteristic will be referred to in this report as the "basis of the claim". This basis may be:

- one or more raw materials: a precise description, for example for plants: family, genus, species, variety, part used, manufacturing process (drying, grinding, extrusion, etc.), rate of incorporation in the feed to which the claim relates and quantity of feed in the daily intake to achieve the claimed effect;
- one or more nutrients[7], source of nutrients or other products or substances: name, a precise description if it is in a specific chemical/physical form in the feed, bioavailability (if the claim indicates or suggests greater bioavailability than the usual values), rate of incorporation in the feed to which the claim relates and quantity in the daily intake to achieve the claimed effect, etc. In the case of a nutritional constituent, the person responsible for labelling must demonstrate how the feed to which the claim relates differs (in terms of an increase or decrease) from a feed meeting national or international recommendations (INRA, NRC, etc.). For complementary feeds, this comparison will be based on the daily intake reconstituted according to the instructions for use.
- other (manufacturing process, physical characteristics, etc.): a precise description.

[7] *The term nutrient is defined as a chemical species that can be absorbed and helps meet nutritional needs*

Examples are presented in Table 2 and Table 3.

If the presentation of the feed or of the basis of the claim (in solid, liquid, granular or powder form, etc.) could influence its effects, it must be specified.
If the claim is comparative, both the replaced and replacement products must be described precisely.

In particular, these data should help demonstrate that the documentary evidence presented corresponds to the feed to which the claim relates.

Table 2: Examples of nutrients that are the bases of claims

	Distinctive	Non-distinctive
Nutrient	"High" methionine content in dairy cow feed Omega 3 fatty acids (DHA) of natural origin Calcium: moderately restricted amount	Calcium at the recommended level in a complete feed for layer hens

Table 3: Examples of bases of claims other than nutrients

	Sufficiently precise	Insufficiently precise
Raw material or combination of raw materials	*Ulva fasciata* dehydrated seaweed Soya lecithin	High-quality meal
Source of nutrients	Casein	Milk proteins
Other substance or group of substances	Chestnut tannins	Dietary fibres Antioxidants
Production process	Flaked cereals Extruded seed	Heat-treated seed
Physical characteristic	Finely ground (with the particle size distribution) Dehydrated long-stem alfalfa (more than x% of particles greater than y mm) Fibrous matrix resistant to crumbling	Finely ground Long fibres

2.1.3. A chapter on the evidence enabling assessment of the link between the basis of the claim and the claim in the target species

The information provided in the dossier must demonstrate a link between the basis(es) of the claim and the claim, and it must be proven that the claimed effect is achieved:

- with the quantity of the basis of the claim found in the feed for the intake recommended by the instructions for use, when the basis of the claim is one or more components of the feed;
- with the quantity of feed recommended by the instructions for use, when the basis of the claim is not a component (in the case of manufacturing processes or physical characteristics).

This chapter should be presented in the form of an argumentative monograph relating to the basis of the claim. This monograph should be based on evidence from literature data and/or study results.
The bibliography must reflect current knowledge, whether or not this knowledge validates the claimed effect. Recital 16 of Regulation 767/2009 states that the claim must be substantiated by taking into account the totality of the available scientific data. As the assessment is carried out *a posteriori*, it must be based on the knowledge at the time of the expert appraisal. Therefore, this summary, which must be written when the feed is placed on the market, must be updated (new literature references, new tests, etc.) whenever new data become available, as long as the feed is marketed with the same claim.

The literature search conditions must be specified: databases used and search equations, criteria for inclusion/exclusion of studies, and the date on which the literature search was carried out.
The bibliography should not only focus on positive effects but also consider possible negative effects, for example on certain categories of animals (contraindicated in certain animals) or in the event of misuse (for example, if consumption exceeds that recommended in the instructions for use, or if the duration of use is longer than that recommended).

Ideally, this monograph should include a summary table specifying for each document (bibliography, internal trial, etc.):
- the exact characteristic of the basis of the claim tested;
- the presentation form;
- the method of distribution;
- the exact amount of basis of the claim in the daily intake of the recipient animal;
- the duration of distribution;
- the characteristics of the animals to be tested (species, production, physiological stage, etc.);
- the exact characteristics of the "control" feed;
- the criterion or criteria measured to characterise the claim;
- the results that are relevant to the claim.

2.2. The different types of evidence

Evidence to support the claim may come from a variety of sources. There is no *a priori* exclusion on its origin provided that it is argued and analysed to justify the claim. However, studies may have different weights depending on their scientific quality and the evidence they contain. In any event, the evidence will be considered on a case-by-case basis, after analysis by the ANSES experts. The evidence may concern the field of animal feed but also that of human food, provided that the extrapolation between humans and the species targeted by the claim is well argued.

2.2.1. Source of the evidence

2.2.1.1. Research trial reports

Research trial reports constitute evidence of claims. They will be taken into account in the analysis according to the following ranking:

1: Meta-analysis of trials carried out by the operator, accompanied by the trial reports or publications used to conduct this meta-analysis;
2: Unpublished trial report but carried out by an independent body or laboratory: research laboratory, technical institute, chamber of agriculture, etc.;
3: In-house trial report.
Additional credit will be given to results from facilities with certified good practices (ISO, GEP, etc.).

2.2.1.2. Scientific literature

Publications by reference organisations as well as articles published in peer-reviewed journals are benchmarks in the scientific field and will therefore also be taken into account in the analysis of the claim according to the following ranking:
1: Meta-analysis;
2: Scientific summary (including opinions and publications by reference organisations such as EFSA, FDA, ANSES, etc.);
3: Article from a peer-reviewed journal;
4: Doctoral thesis;
5: Poster and communication abstract;
6: Other theses, dissertations, etc.

2.2.2. Type of studies

Trials can be conducted in a variety of ways. There is no *a priori*, but the trials or studies will be taken into account according to the following ranking:

1: *In vivo* experimental studies under controlled conditions (experimental station);

2: *In vivo* experimental studies under field conditions (farms);

3: Epidemiological and observational studies;

4: *Ex vivo, in sacco, in vitro, in silico* studies.

2.3. Quality and quantity of evidence supporting the claim

Each item of data will be assessed by an analysis of the quality of the overall approach followed, to ensure that the claim can be established on objective facts, under conditions of sufficient power and repeatability. There is therefore no quantified score, as the diversity of types of evidence means that a universal scale cannot be established.

2.3.1. Relevance of the evidence supporting the claim

2.3.1.1. Relevance of the trial conditions

To be able to consider and analyse the evidence submitted, the following information is the minimum that must be provided, and will be used to determine whether the trial was carried out under conditions similar to the conditions of use of the feed for which the claim is made.

2.3.1.1.1. Feed to be tested: precise composition and physical form

The operator must describe all the constituents of the feed to be tested and, where applicable, the processes it has undergone, in order to verify the correspondence with the feed for which the claim is made.
If the product to be tested does not have the same name as the basis of the claim, the equivalence of the name and concentration should be stated.
If the trial concerns a constituent of the feed for which the claim is made, it should be stated whether this constituent is sufficient to explain the claimed effect and whether there is a known interaction effect resulting from its combination with other constituents.
If the product tested in the trial is different from the one for which the claim is made, the extrapolation should be justified.

2.3.1.1.2. Quantity of the feed or of the basis of the claim

The daily amount of feed or basis of the claim in the trial must be the same as that for which the claim is made. If the quantity in the trial is different, the relevance of the extrapolation must be justified.

2.3.1.1.3. Duration of use

The duration of use of the feed during the trial must be specified. If the instructions for the feed for which the claim is made mention a duration of use and if this duration is different from that of the trial, the difference must be justified.

2.3.1.1.4. Animal species, gender, age and physiological stage

Any extrapolation of the trial results to another species or physiological stage should be justified.

2.3.1.1.5. Health conditions

The health conditions on the farm during the trial (good or degraded) must be similar to those of the target population, otherwise the extrapolation must be justified.

2.3.1.2. Relevance of the measured criteria

The measured criterion can be one that:

- directly reflects the claim;

- indirectly reflects the claim. A criterion that indirectly reflects the claim may be considered relevant if the link between this criterion and the claim can be demonstrated, either by the bibliography or by trials.

The absence of evidence obtained with relevant criteria will lead to the conclusion that the claim is not scientifically proven. In the presence of relevant criteria, scientific validation will only be

established if the evidence is of sufficient quality (see also the guidelines). Table 4 provides examples of relevant criteria for several claims.

Table 4: Examples of relevant criteria to support a claim

Claim	Direct criteria	Indirect criteria
Improves bone strength	Resistance of bones to breaking Downgrading rate in slaughterhouses because of fractures	Calcium and phosphorus digestibility Plasma concentrations of calcium and phosphorus Ash content
Reduces phosphorus releases	Amount of phosphorus in manure (per animal) Faeces and urine composition	Phosphorus digestibility
Strengthens the immune defence properties of colostrum in lactating females	Blood immune markers in young and test for disease resistance	Favourable immune factors in colostrum
Maintains joint integrity	Concentration (or activity) of cartilage-degrading enzymes Collagen synthesis by chondrocytes	Quality of locomotion (score measured by a practitioner)

2.3.1.3. Ranking of documentary evidence

Evidence that does not correspond to the conditions of use of the feed for which the claim is made, and that lacks measured criteria with a justified link to the claim, will not be considered.

2.3.1.3.1. Evidence obtained under conditions reproducing the conditions of use of the feed for which the claim is made

This includes *in vivo* test(s), carried out in the recipient animal species and category, at the same physiological stage, under the same health conditions (normal or degraded), with a basis of the claim that is strictly identical in nature and quantity per animal (including where the basis of the claim is a mixture of substances), with the same duration of use, and in which the measured criteria are relevant and directly related to the claim. This evidence will be considered on a priority basis.

2.3.1.3.2. Evidence established under conditions different from those intended for the feed for which the claim is made, or with criteria that are indirectly related to the claim

This includes, among other things, data obtained in other species including humans, *in vitro* tests, etc.
These tests may be considered as evidence if the operator provides acceptable arguments for extrapolation to the conditions of use of the feed, or justifies the link between the indirect criterion and the claim.

Ex vivo, *in sacco*, *in vitro* and *in silico* studies can only be used for preliminary screening or for studying the mechanisms of action, but in general they are not sufficient evidence. They can only be used to support *in vivo* studies.
Nevertheless, approaches other than *in vivo* are, in some cases, regarded as reference methods (e.g. ruminal degradability of proteins measured *in sacco*). These studies may then be sufficient in the dossier of evidence.

2.3.2. Methodological quality of evidence (intrinsic quality)

The methodological quality aspects described below represent an optimum and not a requirement.
They constitute an indicative, non-exhaustive list of the information to be provided as qualitative and quantitative support for the claim made by the operator.

2.3.2.1. Quality of the description

The quality of the description of the evidence will be judged on the basis of the following points:

- Criteria for inclusion and exclusion of herds/animals;
- Conditions on the farm or experimental station (level of production, health status and history (accidents) of health status, buildings, breeding area, time of year: these indications are particularly important when studies concern comparisons between farms);
- Year of the trial (for analysing the correspondence between the breeding conditions (e.g. genetic level) during the trial and when the feed is placed on the market);
- Diet (see 2.1.2;
- Measurement and laboratory analysis methods, compliance with good practice rules.

2.3.2.2. Experimental design

- Presence of controls not receiving the basis of the claim or, in the case of nutrients, receiving the recommended amount (NRC, INRA, etc.);
- Randomisation;
- Definition of the experimental unit (individual, litter, cage, batch, herd, etc.) and number. Where the experimental unit is a herd, the experimental design should enable the appropriate statistical analysis;
- Power of the test procedure, statistical analysis method;
- Definition of the time unit (one-off or repeated measurements).

2.3.2.3. Test results and conclusions

- Statistical and biological significance;
- Consistency between variables.

2.3.3. Quantity of evidence supporting the claim

The CES's opinion is issued considering all the documents provided. ANSES will make an assessment on a **case-by-case basis**, as the quantity of evidence needed to support the claim depends on its quality. However, the CES will not demand a dossier of evidence exceeding in

quantity and quality what is expected in an application for authorisation of an additive in accordance with the guidelines in force.

2.4. Types of conclusions in opinions following formal requests relating to claims

When the dossier of evidence demonstrates the claimed effect with relevant criteria covering the entire claim and positive trials of good scientific quality, the claim is validated if the effects are consistent between trials. When the available scientific data (whether or not these are present in the operator's dossier of evidence) show that the effect is not systematically observed (non-convergent effects), the conclusion may be qualified ("may") or the claim may not be validated.

In the case of broad claims, if the measured criteria are unable to validate all the situations or functions implied or suggested by the wording, ANSES will conclude that there is a contribution to the effect or will limit validation of the claim to the points demonstrated by the dossier of evidence.
Tables 5 to 8 provide examples of conclusions on claims according to the information presented in the dossiers of evidence.

Table 5: Example of a broad claim for a feed for fattening pigs:

"reduces releases into the environment"

Criterion/criteria	Justification if criterion is indirect and/or argument if conditions of use differ	Quantity and quality of evidence	Convergence of effects	Conclusions of the assessment
Direct: measurement of releases of major pollutants on a fattening pig holding, with valid arguments on the choice of pollutants	Not applicable	Good	Yes	Validated
		Good	No	May reduce releases or not validated*
		Poor		Not validated
Direct: measurement of nitrogen releases only, on a fattening pig holding	Not applicable	Good	Yes	Not validated Reduces nitrogen releases
		Good	No	May reduce nitrogen releases or not validated*
		Poor		Not validated
Indirect: measurement of phosphorus digestibility in pigs	Valid argument	Good	Yes	Not validated Reduces phosphorus releases

Indirect: measurement of phosphorus digestibility in pigs	No argument on the link with a reduction in phosphorus releases	Good	Yes	Not validated
Indirect: measurement of phosphorus digestibility in another species (e.g. laboratory animal)	Valid argument	Good	Yes	Not validated Reduces phosphorus releases
Indirect: measurement only of *in vitro* digestibility of phosphorus on pig intestine	Valid argument	Good	Yes	Not validated

* according to the balance between the tests where an effect was observed and the tests with no observed effect.

In red: effect validated by the CES with regard to the dossier

Table 6: Example of a broad claim for a feed for dairy cows: "improves hoof quality"

Criterion	Justification if criterion is indirect and/or argument if conditions of use differ	Quantity and quality of evidence	Convergence of effects	Conclusions of the assessment
Direct: measurement of hoof hardness and observation of lesions	Not applicable	Good	Yes, regarding the effects of the feed, but factors other than feed are known to affect hoof quality	Contributes to improving hoof quality
Indirect: measurement of a locomotor score (observation of lameness)	No valid argument on the unequivocal link between locomotion score and hoof quality	Good	Yes	Not validated Improves locomotion

In red: effect validated by the CES with regard to the dossier

Table 7: Example of a broad claim for a feed for dairy cows: "improves liver function at the start of lactation"

Criterion	Justification if criterion is indirect and/or argument if conditions of use differ	Quantity and quality of evidence	Convergence of effects	Conclusions of the assessment
Direct: measurement of gluconeogenesis in cows at the start of lactation	Not applicable	Good	Yes	Not validated Increases glucose synthesis by the liver or Helps to improve liver function
Direct: measurement of hepatic gluconeogenesis in rats	Absent	Good	Yes	Not validated
Indirect: blood glucose measurement in cows at the start of lactation	Absent	Good	Yes	Not validated Increases blood glucose levels
Indirect: measurement of mRNAs of some genes involved in gluconeogenesis and increase in blood glucose levels	Valid	Good	Yes	Validated
Indirect: measurement of mRNAs of some genes involved in gluconeogenesis	Valid	Good	Yes	Not validated
Direct: literature on the role of the component that is the basis of the claim on VLDL synthesis	Valid (demonstration of the limiting nature of the basis of the claim)	Good	Not applicable	Not validated Increases the export of liver lipids
Direct: literature on the role of the component that is the basis of the claim on VLDL synthesis	Not valid (no demonstration of the limiting nature of the basis of the claim)	Good	Not applicable	Not validated

In red: effect validated by the CES with regard to the dossier

Table 8: Example of a broad claim for a feed for pregnant sows:

"strengthens the immune defences in piglets"

Criterion	Justification if criterion is indirect and/or argument if conditions of use differ	Quantity and quality of evidence	Convergence of effects	Conclusions of the assessment
Direct: measurement of the frequency of several infectious diseases affecting several organs or tissues	Not applicable	Good	Yes	Validated
Direct: measurement of the frequency of infectious diarrhoea	Valid argument on the dominant pathology	Good	Yes	Validated
Direct: measurement of the frequency of infectious diarrhoea	Absent	Good	Yes	Not validated Reduces the frequency of diarrhoea
Indirect: measurement of the immunoglobulin content of colostrum	Absent	Good	Yes	Not validated Increases the immunoglobulin content of colostrum
Indirect: measurement of piglet weight at weaning	Absent	Good	Yes	Not validated

In red: effect validated by the CES with regard to the dossier

2.5. Conclusion of the working group and the CES

At the request of the DGCCRF, ANSES is tasked with assessing certain dossiers of scientific evidence on claims relating to animal feed. The CES on "Animal feed" has drawn up guidelines that present the information on which it will base its assessment of the dossiers of scientific evidence relating to function claims in animal feed.
They will enable operators placing animal feed on the market with such claims to compile complete dossiers of evidence. On the basis of the information provided in the dossiers, ANSES will make assessments on a case-by-case basis, as the quantity of evidence needed to support the claim depends on its quality.
In terms of form, the information presented in these guidelines does not constitute a restrictive framework. In substance, it is not a limited framework; in particular, the examples presented are intended simply to illustrate the concepts put forward, and are not designed to hinder innovation in any way.
These guidelines may evolve in light of future collective expert appraisals.

The CES is disappointed by the absence of guidelines drawn up at European Union level. It hopes that this absence will be remedied in order that, in all Member States, the rules are the same for everyone, giving each user of animal feed equal confidence in the function claims relating to feed available on the European market and enabling them to make informed choices.

3. ANSES'S CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the conclusions and recommendations of its CES ALAN.

Dr Roger Genet

KEYWORDS

Lignes directrices, aliments pour animaux, allégations, dossier de preuve, évaluation

Guidelines, animal feed, claims, evidence, assessment

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Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

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PREAMBLE: The expert members of the Expert Committees and Working Groups or designated rapporteurs are all appointed in a personal capacity, *intuitu personae*, and do not represent their parent organisation.

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