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Guidance
on the substantiation of
Claims made on Animal Nutrition

Veterinary Medicinal Products Unit
The Netherlands

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1. Introduction

Introduction
At the moment that the labelling and the presentation of feed materials and compound feed draws particular attention to the presence or the absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these, this is called a claim.

As of 1 September 2010, it has been possible to display these claims on an animal feed ("feed") label and/or via any other medium. This became possible because the Feed marketing Regulation came into force. The European Commission has left the further details of claim assessment to the individual Member States. The competent authority in the Netherlands for monitoring and enforcement as regards claims on animal feed is the Dutch Food and Consumer Product Safety Authority [*Nederlandse Voedsel en Waren Autoriteit*] (referred to below as the 'NVWA'). In performing these duties, however, the NVWA finds itself faced by a number of substantive problems. The purpose of the present document is therefore to give greater structure and transparency to the method of claim assessment already used in the Netherlands, thus enabling the NVWA to act more effectively in its monitoring and enforcement regarding claims made on animal feed labels.

Current problems
The main substantive problems currently facing the NVWA are:
- There is no European assessment framework and there is a lack of coherence in the approach adopted by the various Member States. The European Commission has published guidelines for dossier requirements for additives, for example, but there are no guidelines for how claims on animal feed must be substantiated;
- There is consequently also no national assessment framework. It is not clear how substantiation of claims must be dealt with. Some of the issues involved are:
  - Must a claim be substantiated for each specific target animal species or is it sufficient for the claim to have been demonstrated only for humans or for a 'major species'?
  - Must substantiation concern the final product, or can it also consist of providing literature regarding the individual components?
  - How many studies or how much literature need/needs to be provided for a claim to be considered as substantiated?

Basic principles
The following basic principles have been applied in working out the national assessment framework for claims on animal feed:
- The consumer must be protected against misleading and prohibited claims;
- Animal health must be guaranteed by preventing misleading and prohibited claims;
- The feed business operator must not be prevented from honestly promoting products;
- Additional testing on animals must be prevented where possible;
- A European level playing field must be encouraged; this means that all feed business operators must operate according to the same rules for substantiating claims;
- Where appropriate, claims can be linked to the claims that have already been accepted by the European Food Safety Authority (referred to below as the 'EFSA') in the context of the assessment of claims on foodstuffs;
- Maximum use should be made of the knowledge already available in the Netherlands as regards assessing claims;
- The Dutch assessment framework must align as far as possible with the codes of practice drawn up by the animal feed sector so as to guarantee maximum uniformity with the other Member States;

- There must be as broad support as possible for the Dutch assessment framework, which is why a number of stakeholders within the animal feed sector were consulted when drawing up the assessment framework.

Structure of this document
One part of this guidance document is the specification of all relevant legislation and regulations. This includes the legislation and regulations that are relevant in the context of deciding whether a product can be classified as animal feed at all or should, for example, be seen as a veterinary medicinal product. The classification of products is then briefly considered, with an overview being given of all the aids that are available on the market in this area. A description is then given of how the claim regulations for foodstuffs are organised and what the differences are to the regulations for animal feed. Claims on animal feed are dealt with in the second part of this document, with details also being given of the problems currently facing the NVWA.

The general principles regarding claims on animal feed will first be set out. The various types of claims will then be considered, as well as prohibited claims. It should be noted that this document does not apply to claims which are made in non-commercial communications, or non-commercial information in the press and in scientific publications.
Finally, the scientific substantiation of the various types of claims will be dealt with in greater detail. It should be noted that one is dealing here with guiding principles and not with a statutory obligation to provide a dossier that is entirely in accordance with these guiding principles.

Dorien Vreeswijk

2. Animal feed legislation

Introduction
The legislation regarding animal feed is known as being extremely extensive and complex; it goes beyond the scope of the present document to describe the entire body of such legislation. We will only touch on the animal feed legislation that is considered relevant to assessing claims on animal feed, namely the Feed marketing Regulation. The following section will deal with the relevant animal feed legislation in the context of determining the type of animal feed.

Feed marketing Regulation
The Feed marketing Regulation (Regulation (EC) No. 767/2009) came into force on 1 September 2010. Pursuant to Article 13 of this regulation, it is possible to display a claim on an animal feed label or via any other medium.

Article 13 reads as follows:

Article 13

Claims
1. The labelling and the presentation of feed materials and compound feed may draw particular attention to the presence or the absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these, provided that the following conditions are met:
   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 [in the Netherlands, the NVWA], scientific substantiation of the claim, either by reference to publicly available scientific evidence or through documented company research. The scientific substantiation shall be available at the time the feed is placed on the market. Purchasers shall have the right to bring to the attention of the competent authority their doubts in respect of the truthfulness of the claim. Where the conclusion is reached that the claim is not sufficiently substantiated, the labelling in respect of such claim shall be considered misleading for the purposes of Article 11. Where the competent authority has doubts regarding the scientific substantiation of the claim concerned, it may submit the issue to the Commission. The Commission may adopt a decision, where appropriate after obtaining an opinion from the Authority, in accordance with the advisory procedure laid down in Article 28(2).

2. Without prejudice to paragraph 1, claims concerning optimisation of the nutrition and support or protection of the physiological conditions are permitted, unless they contain a claim of the type referred to in paragraph 3(a).

3. The labelling or the presentation of feed materials and compound feed shall not claim that:
   a) it will prevent, treat or cure a disease, except for coccidiostats and histomonostats as authorised under Regulation (EC) No. 1831/2003; this point shall not, however, apply to claims concerning nutritional imbalances provided that there is no pathological symptom associated therewith;
   b) it has a particular nutritional purpose, as provided for in the list of intended uses as referred to in Article 9, unless it satisfies the requirements laid down therein.

Pursuant to Article 3.2 (s) of the Feed marketing Regulation the definition of 'labelling' is the following:
'labelling' the attribution of any words, particulars, trademarks, brand name, pictorial matter or symbol to a feed by placing this information on any medium referring to or accompanying such feed, such as packaging, container, notice, label, document, ring, collar or the Internet, including for advertising purposes.

Article 11 of the Feed marketing Regulation also provides that the labelling and presentation of feed must not mislead the user as to the intended use or characteristics of the feed. It is also prohibited to attribute effects or characteristics to the feed that it does not possess, or to suggest that it possesses special characteristics when in fact all similar feeds possess such characteristics.

The European Commission has not specified in detail the requirements for a claim on feed to be considered acceptable; doing so, as well as monitoring, is left to the individual Member States. Under Article 26 of the Feed marketing Regulation, it is possible, however, to establish Community codes of practice for labelling that have been drawn up by the animal feed industry. Currently, the code of practice for pet food has been established, namely the FEDIAF code of good labelling practice for pet food. The code of practice for compound feed for food-producing animals has been established as well in 2016. This is the EU code of good labelling practice for food producing animals.
These codes are important because they can create uniformity of action between the Member States. As far as possible, this national code will be in line with them.
Furthermore FEFANA has published the EU code on voluntary labelling particulars (claims) for feed additives and premixtures. This code has not been endorsed by the EU Commission however.

Enforcement of Feed marketing Regulation
In the Netherlands, the task of monitoring and enforcement regarding claims made on animal feed has been allocated to the NVWA. The NVWA is entitled to require substantiation of a claim made regarding animal feed and to assess the substantiation of the claim. The requested dossier is of course treated with strict confidentiality.
If a claim is considered to be incorrect or insufficiently substantiated, it must be removed or formulated differently. If a claim is found to be unsubstantiated or misleading, the NVWA can impose a measure based on the animal feed intervention policy [interventiebeleid diervoeder] (IB02-SPEC35).

The Animals Act (Regulations regarding Enforcement and Other Matters) [Regeling handhaving en overige zaken Wet dieren *belonging to* Wet dieren] specifies the size of the administrative fines that can be imposed.

3. Types of animal feeds

Introduction
In order to determine whether a claim on an animal feed is justified or not, it must first be decided, of course, whether the product can be classified as an animal feed at all. If it can be, the correct category needs to be determined. There are namely various options, each with its specific characteristics and requirements regarding authorisation. In determining how a claim should be assessed, the main question is whether it should be considered as a feed material, an additive, or as a dietetic feed. These and a number of supplementary definitions (e.g. compound feed and premixture) are given in Appendix I.

Feed materials
A feed material is a product of vegetable or animal origin whose principal purpose is to meet the nutritional needs of animals and which is used for oral feeding (article 3.2 sub g of Regulation (EG) No. 767/2009). The rules regarding the marketing and use of feed materials and compound feeds are included in the Feed marketing Regulation.

Feed materials must be listed in the annex to Regulation 68/2013/EC referred to as the 'Catalogue of Feed Materials' or the 'Catalogue'. Article 24(6) of the Feed marketing Regulation also provides that representatives of the European feed business sector must publish a register of notifications of feed materials that are placed on the market for the first time. The sectors have complied with that obligation by producing the Feed Materials Register. Legal entities that place a feed material on the market for the first time must give notice of their product on this website. The party giving notice of a product is responsible for the content of the registration. No legal status can be derived from the inclusion of a particular product in the Feed Materials Register. Registrations that are added to the Catalogue at some point are then removed from the Feed Materials Register.

Registrations can be removed from the Feed Materials Register if they are considered incorrect after assessment of the notification. Registers that have been removed from the Feed Materials Register and that have not been transferred to the Catalogue may no longer be used in animal feed.

Feed additives
Feed additives – also referred to as additives in animal feedingstuffs – are substances, microorganisms, or preparations that are neither feed materials nor pre-mixtures and that are deliberately added to animal feed or water with the purpose, for example, of improving the quality of the feed or improving animal health (artikel 2.2 sub a of Regulation (EG) No. 1831/2003). Additives in animal feedingstuffs must be permitted in accordance with Regulation (EC) No. 1831/2003. The dossier requirements are included in Regulation (EC) No. 429/2008. There are also various EFSA guidance documents that apply. Feed additives may not be fed to animals directly.

Because the status of a number of products was unclear, the European Commission included a list of products in Regulation (EC) No. 892/2010/EC which are not additives in animal feedingstuffs pursuant to Regulation (EC) No. 1831/2003. The list includes glucosamine and chondroitin sulphate, for example.

If a feed additive is approved, it is then included in the Community Register of feed additives. Person-specific authorisation applies to zootechnical additives, coccidiostats and histomonostats, and if a genetically modified organism (GMO) has been used. This means that only the holder of the authorisation as listed in the Community Register of Feed Additives may actually place the product on the market.

The Feed marketing Regulation provides that feed materials and complementary feeds must not contain levels of feed additives that are higher than 100 times the relevant fixed maximum content in complete feed or five times in the case of coccidiostats and histomonostats. If that level is exceeded, then the feed concerned must be authorised as a dietetic feed. This means that all high-concentrate boli, drenches, and mineral licks must be authorised as dietetic feeds.

Dietetic feeds

Feeds intended for particular nutritional purposes – otherwise referred to as 'dietetic feeds' – are feeds which can satisfy a particular nutritional purpose by virtue of their particular composition or method of manufacture, which clearly distinguishes them from ordinary feeds. A '**particular nutritional purpose**' means the following:

> 'the purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition'.

The rules regarding the marketing and use of dietetic feeds are included in the Feed marketing Regulation. Before being brought onto the market, dietetic feeds must first have been authorised. Regulation (EC) No. 767/2009 establishes the rules for the marketing of "dietetic" feed (feed for particular nutritional purposes). The list with the authorised intended uses for dietetic feed for pets and farmed animals can be found in Regulation (EU) No. 2020/353. Authorisation of a dietetic feed is not person-specific.

An example of a particular nutritional purpose is to reduce the risk of bladder and / or kidney stones in ruminants. The annex to Regulation (EU) No. 2020/353 indicates the conditions attached to the use of this and other special nutritional purposes.

4. Legislation on veterinary and biocidal products

Introduction
The previous section dealt briefly with the relevant animal feed legislation and the various relevant categories of animal feeds that exist. A product may also be subject to legislation that overlaps with the animal feed legislation, namely the legislation on veterinary medicinal products and on biocidal products. The present section will take a very brief look at the relevant legislation. The full definitions are included in Appendix I.

Legislation on veterinary medicinal products
The legislation on veterinary medicinal products is regulated by means of Regulation (EU) No. 2019/6. This gives the following definition of a veterinary medicinal product:

'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions:
a) it is presented as having properties for treating or preventing disease in animals;
b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;
c) its purpose is to be used in animals with a view to making a medical diagnosis;
d) its purpose is to be used for euthanasia of animals.

For the definition of a medicated feedingstuff see Appendix I. The legislation on medicated feedingstuffs is Regulation (EU) No. 2019/4.
In cases of doubt (when a product, in view of its characteristics, falls under both the definition of a veterinary medicinal product and the definition in other Community legislation), the provisions of this directive apply, even if the product also falls within the scope of other Community legislation.

The use and marketing of veterinary medicinal products are subject to strict regulation. In the Netherlands, products may only be marketed as veterinary medicinal products if they comply with the legislation on veterinary medicinal products. These products are generally included in the Database Dutch veterinary medicinal products [*Diergeneesmiddeleninformatiebank*] operated by the Veterinary Medicinal Products Unit [*Bureau Diergeneesmiddelen*]. A small group of medicinal products are not, however, subject to authorisation.

Legislation on biocidal products
The legislation on biocidal products is regulated by means of Regulation (EU) No. 528/2012/EC.
Regulation (EU) No. 528/2012 gives the following definition of a biocidal product:
- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;
- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Treated articles with a primary biocidal function are considered to be biocidal products.

The use and marketing of biocidal products are subject to strict regulation. In the Netherlands, products may only be marketed as biocidal products if they are included in the Dutch Pesticides Database [*Bestrijdingsmiddelentoelatingendatabank*] operated by the Board for the Authorisation of Plant Protection Products and Biocides [*College voor de toelating van Gewasbeschermingsmiddelen en Biociden*].

5. Product classification

Introduction
This section will attempt to give some guidelines for the classification of products, also referred to as status determination. Because definitions overlap, there will always remain scope for interpretation, and it is extremely difficult to create a general framework. Status determination will always need to take place on a product-by-product basis. Below a few guidelines are provided to make decision-making easier. Because the purpose of this document is to draw up a framework for assessing claims on animal feeds and not to develop a model for product classification, it will confine itself to describing the relevant EU legislation and the aids that are available within the market. The definitions are extremely important where the eventual decision is concerned. These are given in Appendix I.

European rules
In 2011, the European Commission issued a Recommendation establishing guidelines for the distinction between feed materials, feed additives, biocidal products, and veterinary medicinal products (Recommendation 2011/25/EU). Besides listing the various definitions, the main conclusions of that recommendation are:

Consequences for the distinction between feed materials and feed additives
- 'Feed additives are substances … other than feed materials': A product cannot be a feed material and a feed additive at the same time.
- 'Animals' nutritional needs': It is not possible to indicate an exhaustive list of relevant elements but the following characteristics of feed materials can be considered to be the most important:
  a) to meet the animals' needs, for example for energy, nutrients, minerals, or dietary fibres, and
  b) to maintain the function of the animals' intestinal tract.
- 'the principal purpose is to meet animals' nutritional needs' and 'primarily used to meet animals' needs': Apart from the usual primary function of delivering nutrients to the animal, feed materials can have other purposes, for example if they are used as carriers or if they are not digestible in the animals' intestinal tract. This is in line with the aims of 'oral feeding' ('meeting the animal's nutritional needs and/or maintaining the productivity of normally healthy animals') which corresponds to the primary intended use according to the 'feed' definition.

Criteria to be simultaneously considered in a case-by-case evaluation
- *Production and processing method:*
  Chemical definition and level of standardisation or purification:
- Products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the simple processing thereof, as well as organic or inorganic substances, can be considered feed materials (e.g. fatty acids or calcium carbonate).
- Chemically well-defined substances that are purified and give a certain level of standardisation guaranteed by the manufacturer might qualify as feed additives (e.g. aromatic oil specifically extracted from plant material). Nonetheless, certain feed materials are chemically well-defined substances and standardised (e.g. sucrose). On the other hand, natural products of whole plants and parts of these or products thereof resulting from a limited physical processing such as crushing, grinding or drying would be feed materials.
- *Safety and mode of use:*
  If for reasons of animal or human health it is necessary to set a maximum content of the product in the daily ration, the products qualify for classification as additive. However, also for certain feed materials maximum inclusion rates apply. Feed additive status might offer improved scope for effective management of the product in terms of stability,

homogeneity and with respect to over-dosage. Feed additives are usually used at low incorporation rates. However, many feed materials, such as mineral salts, are also used at low incorporation rates in the feed ration.

- *Functionality:*
  Feed additives are defined by their functions as laid down in Article 5(3) of Regulation (EC) No. 1831/2003. However, these functions are not exclusive to feed additives. Thus, a feed material can also exert an additive function (e.g. as a thickener) but this should not be the only intended use.

Consequences for the distinction between feed and biocidal products

- By virtue of Article 1(2) of Directive 98/8/EC, products that are defined or that fall under the scope of the feed legislation, including processing aids, are not biocidal products but are to be considered as feed (precedence of the feed legislation over the legislation on biocidal products).
- Products in products types 3 and 4, as set out in Annex V to Directive 98/8/EC, are not considered to be feed.
- However, certain products could qualify for product types 5 or 20 and also be considered as feed, usually feed additives. Due to the above-mentioned precedence of feed legislation over biocidal product legislation, such products are to be considered feed. Products to preserve feed or water for animals are not biocidal products. If such products are listed in product type 5 or 20, they are not intended to be administered to animals.

NB: With the entry into force of Regulation No. 528/2012/EC, this distinction is no longer up to date. Product type 20 has been deleted in this new regulation.

Consequences for the distinction between feed and veterinary medicinal products (VMPs)

- If, after consideration of all the characteristics of an unclassified product, the conclusion is that it might be a VMP, it should be considered a VMP (precedence of the VMPs legislation over feed legislation, except for authorised feed additives).
- Medicated feedingstuffs are not VMPs but, according to Recital 3 of Regulation (EC) No. 767/2009, a form of feed containing medicated pre-mixes and being subject to a prescription by a veterinarian.
- The distinction between feed and veterinary medicinal products is set on the basis of definition of ‘particular nutritional purpose’. The particular nutritional purposes such as ‘support of liver function in the case of chronic liver insufficiency’, ‘reduction of urate stones formation’ or ‘reduction of the risk of milk fever’ can be achieved by feed.

Additionally, the European Commission, by means of Regulation (EU) No. 892/2010 has given a list of products that are not considered to be feed additives. This is based on a comparison between the characteristics of the products included in the Register of Feed Additives on the one hand and of the products mentioned in the Catalogue of Feed Materials on the other. Several criteria may be derived from this for the classification of products as feed material, feed additive or other products.
Useful criteria for this differentiation are amongst others the production and processing method, the level of standardisation, the homogenisation, the purity, the chemical definition and the mode of use of the products. For the sake of consistency, products with similar properties should be classified by analogy. For products for which there were doubts whether they were feed additives, an examination has been carried out taking into account these criteria, and the European Commission has ultimately taken a decision.

Other aids to product classification
A number of aids are available on the market that can assist in determining the status of a product. To achieve the most reliable result, the best thing is to go through both of them and to check whether the outcomes match. Both these classification tools are an interpretation of the European Commission's recommendation as referred to above.

Available aids to product classification

- **GMP+ decision tree for feed material, animal feed, and products in animal feed.** Within the GMP+ the GMP+ Decision tree for feed material, animal feed, and products in animal feed is used.. Going through the decision tree can provide a indication of the status of a product.
- **FEFANA Classification Tool**
  There is also the FEFANA classification tool. On the basis of a number of questions, this tool provides a recommendation as to whether a substance must be considered as a feed material or a feed additive.

Consultation procedures
Authorisation of feed additives is through SCoPAFF – Section Animal Nutrition (the Standing Committee on Plants, Animals, Food and Feed, formerly known as the Standing Committee on the Food Chain and Animal Health (SCoFCAH).

The mandate of the SCoPAFF – which is chaired by the European Commission – covers the entire food chain. All the EU Member States as well as Norway and Iceland are represented. The SCoPAFF has several sections, including the Animal Nutrition section, which meets frequently in Brussels and takes decisions on the authorisation of feed additives, dietetic feeds and on the inclusion of feed materials in the Catalogue of Feed Materials. If a product complies with all the requirements for authorisation and the SCoPAFF- Section Animal Nutrition takes a positive decision, then the product can be admitted to the European market.

If it is not clear whether a product should be classified as a feed additive, then it can be determined on the basis of Article 2(3) of Regulation 1831/2003/EC whether a substance, micro-organism or preparation is a feed additive within the scope of that regulation.

Where the competent authority has doubts regarding the scientific substantiation of the claim concerned, then – on the basis of Article 13 of the Feed marketing Regulation – it may submit the issue to the Commission. The Commission may adopt a decision, where appropriate after obtaining an opinion from the Authority, in accordance with the advisory procedure. There is also the option of submitting the status of a product for consideration by the Borderline Working Group, which falls under the mandate of the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv). The Borderline Working Group can recommend whether or not a product should be considered to be a veterinarian medicinal product.

In a national context, a product can be submitted for advice on its status to the Status Determination Working Party [*Werkgroep Statusbepaling*]. This is a partnership between the NVWA, the Health Care Inspectorate (IGZ), and the Ministry of Health, Welfare and Sport (VWS).

6. Claims on foodstuffs for human consumption

Introduction
Before discussing the claims on animal feeds, we will deal briefly with how this matter is arranged in the case of foodstuffs for human consumption. The use of claims on foodstuffs for human consumption has already been regulated. This has been done by means of the Claims Regulation (Regulation 1924/2006/EC), which came into force in 2006.

Briefly, the Claims Regulation provides that claims (both nutrition claims and health claims) may only be used if they are scientifically substantiated and are on the list of authorised claims. The European Food and Safety Authority (referred to below as the 'EFSA') carries out the necessary assessments.

The Claims Regulation distinguishes between four kinds of claims: nutrition claims, including comparative nutrition claims (Articles 8 and 9), claims regarding reduction of disease risk (Article 14(1)(a)), claims regarding the development and health of children (Article 14(1)(b)), and health claims other than those referring to the reduction of disease risk and to children's development and health (Article 13.1). These are also referred to as 'generic' health claims.

Definitions
The Claims Regulation applies the following definitions:

'**Claim**' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.

'**Nutrition claim**' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:
(a) the energy (calorific value) it
  i) provides;
  ii) provides at a reduced or increased rate; or
  iii) does not provide; and/or
b) the nutrients or other substances it
  i) contains;
  ii) contains in reduced or increased proportions; or
  iii) does not contain.

'**Health claim**' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

'**Reduction of disease risk claim**' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

A further elaboration of these definitions is provided in the document Guidance on the Implementation of Regulation No. 1924/2006 on Nutrition and Health Claims made on Food.

Current situation regarding the Claims Regulation
Healthclaims are included in the Register of health claimsEU Register of health claims made on foods. All other health claims made on foods are prohibited unless the ultimate decision on permitting or rejecting the claim has been suspended. This applies to the claims on the 'on hold list'. These are also health claims that have not been submitted to the EFSA. These claims may no longer be used in foodstuffs

The permitted claims are generic, meaning that every food producer can use these claims if they comply with the conditions that have been set for their use and any restrictions on their use that have been set.

National elaboration of Claims Regulation
In the Netherlands, health and nutrition claims for health products (products whose appearance is similar to that of medicinal products) are regulated by the KOAG/KAG Inspection Board [*Keuringsraad KOAG/KAG*]. This body has been responsible for monitoring health products and the associated claims since 2006. The KOAG/KAG Inspection Board is an approval authority based on self-regulation. Its basic principle, to be found in Sections 19 and 20 (Dutch) Commodities Act [*Warenwet*], is that medical claims are not permitted.

The KOAG / KAG Inspection Board currently uses three indicative lists, namely:

- The historic indicative list (hereinafter called KAG-list) drawn up by the Inspection Board has the primary aim of distinguishing between medical claims (in the 'no' column) and health claims (in the 'yes' column). A health claim in the 'yes' column may only be used if that what is claimed is in fact true. The manufacturer is required to make this 'not implausible' for each product, given that this is also dependent on the content.

- On 14 December 2012, this 'not implausible' test ceased to apply to health claims on products to which the Claims Regulation applies (food supplements). The test continues to apply for other products (mostly health products for external use). The Indicative list of external health products applies to these products and is intended for non-oral health products.

- The test based on the Indicative List of the KOAG/KAG Inspection Board continues to apply to nutrients for which no decision has yet been taken by the EFSA or for nutrients that have been put 'on hold' for a long period (for example all herbal preparations). This will continue to be the case until the EFSA has made a final decision on the nutrients concerned and on the claims for which a request has been submitted. The indicative list of "on hold" claims applies to these products. This is a temporary list. As soon as EFSA has made a decision on these products, this list will no longer be necessary. At that time, these products will be included in the EU register of health claims.

The KOAG/KAG Inspection Board has created a database of the permitted claims on products to which the Claims Regulation applies and has uploaded this claimsdatabase to its website. The website also provides access to the 'Guidance Document on the Use of Health Claims on Foodstuffs' [*Richtsnoerdocument betreffende het gebruik van gezondheidsclaims voor levensmiddelen*].

Relevant differences

We have seen how claims on foodstuffs are regulated. There is in fact a positive list. Only claims that are on the list of EU approved claims can be used, if they comply with the conditions that have been set for the use of the claim concerned and the nutrient concerned. This is in contrast to the legislation applying to animal feed, in which the use of claims is not regulated by means of a positive list but where use must be determined on a product-by-product basis and where each individual Member State must take a decision on the correctness of the claims made. The following sections will deal with the claims on animal feed.

7. General principles of claims made on animal nutrition

Introduction
The general principles regarding claims made on animal nutrition are elaborated below. The NVWA chose a pragmatic approach and wherever possible, existing instruments or guidelines are used. In the Netherlands the originally KAG List is used, as well as the claims that have already been approved or rejected for food, and finally the Codes of good labelling. Because the feed industry is internationally oriented, it is important that individual Member States harmonise their approach regarding the national implementation and enforcement of the claims to feed. Through the Codes of good labelling practice such uniformity is pursued. However, uniformity is not guaranteed because the individual Member States still have some freedom on how to implement and control claims on feed.

Scope
This document applies to the labelling and the presentation of feed materials and compound feed. It should be noted that this document does not apply to claims which are made in non-commercial communications, or non-commercial information in the press and in scientific publications.

General principles
In line with the Claims Regulation (EC) No. 1924/2006, the following general principles apply:

- A wide range of nutrients and other substances, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts can be present in a feed, for which a nutritional or physiological effect can be claimed. Therefore, general principles should be defined for all claims on feed, to ensure a high level of protection for the animal, to supply the consumer with information necessary to make informed choices, and to create a level playing field for the feed industry.

In addition, the following general principles in the Feed marketing Regulation are expressed:

- The claim is objective, verifiable by the competent authorities and understandable for the user of the feed;
- In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body (please note, this does not necessarily mean ‘absorbed’ as e.g. for fibres this is not the case) . In addition, and where appropriate, the substance for which a nutritional effect is claimed must be delivered in sufficient quantity by an amount of feed of which it is reasonable to assume that it can be consumed by an animal without detrimental effects e.g. weight gain;
- The scientific substantiation is important and feed business operators using claims should justify them. To substantiate a claim, all scientific information should be taken into account;
- Scientific evidence can consist of existing scientific publications, published or unpublished new research or a mixture of the two;
- The scientific substantiation shall be available at the time the feed is placed on the market. The person responsible for the labelling of feed shall make available to the competent authorities any information concerning the composition or claimed properties of the feed placed on the market by that person, which allows the accuracy of the information given by the labelling to be verified, including the exact percentages by weight of feed materials used in compound feed;

- The labelling or the presentation of feed materials and compound feed shall not give the impression that it will prevent, treat or cure a disease, except for coccidiostats and histomonostats as authorised under Regulation (EC) No. 1831/2003. However, this point shall not apply to claims concerning nutritional imbalances provided that there is no pathological symptom associated therewith. Claims concerning optimisation of the nutrition and support or protection of the physiological state are allowed;
- The labelling and presentation of feed materials and compound feed must not give the impression that it has a particular nutritional purpose, unless it meets the requirements set out therein.

The following more specific principles are expressed in the Feed marketing Regulation:
- In case the presence of a component is emphasised on the labelling in words, pictures or graphics than this means:
  - For a **feed material** that the name and percentage by weight shall be indicated on the label (Article 17, 2(a));
  - For a feed additive that the name as laid down in the relevant legal act authorising the feed additive in question and the added amount of the feed additive shall be indicated on the label (Annex VI (food producing animals), paragraph 2 and Annex VII (non-food producing animals), paragraph 3).

In addition, from EFSA's reasons for rejecting certain claims made on food, the following general principles are conducted:
- The component that is bearing the claim should be clearly defined. For example, food claims with regard to 'probiotics' were rejected because the specific composition was not stated;
- The claims must be clearly formulated. EFSA considered claims with the words ‘more energy’ and ‘vitality’ too vaguely defined;
- Claims consisting of complete feed categories are often too broad. For example, the claims on 'fruit and vegetables' and 'dairy' were rejected by EFSA because they were too broadly defined.

Contrary to the EU Feed marketing Regulation the following general principles are used in the Netherlands:
- Pursuant to Article 11b of the Feed marketing Regulation it is forbidden to suggest that the feed has special characteristics when in fact all similar feeds possess such characteristics. The Netherlands will deviate slightly because this would mean for example for a feed rich in vitamins, that it could not claim the inclusion of vitamins as all similar feeds possess such characteristics as well. All feeds rich in vitamins are in our opinion allowed to bear vitamin claims. The feed business operator would otherwise be hindered in the recommendation of his product.

The above principles are used as a basis in the following chapters. The next chapter will describe the different types of claims made on animal nutrition.

8. Types of claims made on animal nutrition

Introduction
In the Feed marketing Regulation a claim is described as follows:
'The labelling and the presentation of feed materials and compound feed may draw particular attention to the presence or the absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these.'
In addition to this, the definition of a claim from the Claims Regulation can be used. 'A claim means any message or representation, which is not mandatory under Community or National Legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food (in this context feed) feed has particular characteristics.'

Various types of claims
Which types of claims can be distinguished is described in detail in the European Commission endorsed 'FEDIAF code of good labelling practice for pet food' of October 2011. This FEDIAF code is a self-regulatory code of conduct and is intended for claims used on pet food. An additional category is required to describe the claims that can be used for food producing animals. This additional category is described in the 'EU code of good labelling practice for food producing animals'.
In this Chapter a brief overview of the different categories as mentioned in both the 'Code of good labelling practice for use in food producing animals' and the 'FEDIAF code of good labelling practice for pet food' has been given. The classification differs slightly between both Labelling codes. For further information see both Labelling codes.

Nutrition Claims

A **nutrition claim** is a claim that states, suggests or implies that a specific feed, nutrient, ingredient or additive in the feed has particular beneficial nutritional properties due to:
a) the energy (calorific value) it
    i) provides;
    ii) provides at a reduced or increased rate; or
    iii) does not provide; and/or
b) the nutrients or other substances it
    i) contains;
    ii) contains in reduced or increased proportions; or
    iii) does not contain;

- In the 'FEDIAF Code of good labelling practice for pet food' these claims are called **content claims**, and they refer to the presence, or a high or low inclusion level of a particular substance such as a feed material, additive, nutrient, flavour, characteristic, or other. These 'content claims' are further subdivided into:

    Component claims
    A **component claim** refers to the presence of a particular feed material or particular characteristic.

    For example: Contains liver.

Nutrient and Additive claims
A **nutrient and additive claim** makes reference to the presence or a specific level of a nutrient or additive, including fatty acids, minerals, vitamins, trace elements, amino acids etc. with no further connection to health effects.

For example: Contains vitamin E.

- In the 'Code of good labelling practice for use in food producing animals' this category is called **Nutritional and compositional claims** and the following has been added:
  - Nutritional and compositional claims can be based on a specific production process which improves the quality of the animal feed, e.g. pelleted.

Product descriptors
In the 'FEDIAF Code of good labelling practice for pet food' so-called **product descriptors** are mentioned as well. This category will not be discussed any further but it refers to terms like 'natural', 'fresh', 'light' etc. In addition, comparative claims fall under this category, e.g. 'less', 'better' and so on. For support and further elaboration of this category check the 'FEDIAF Code of good labelling practice for pet food'.

Functional claims

A **functional claim** describes the effect of - a feed or a nutrient, component or additive in the feed, or of the appearance of the animal feed, or of a specific process undergone by the animal feed - on growth, development or normal functions of the body.
This provides a specific physiological benefit and may concern 'optimisation of the nutrition and support or protection of the physiological conditions' (R. 767/2009, Art. 13.2). These effects go beyond meeting basic nutritional needs of the animals.

- In the 'FEDIAF Code of good labelling practice for pet food' this type of claims is further subdivided into:

Nutrient function claims
A **nutrient function claim** simply links the presence in a feed of a nutrient or a combination of nutrients to the physiological role in growth, development and normal functions of the body. No further details are given about the level or the degree/mechanism of the effect.

For example: Contains calcium supporting the healthy condition of bones and teeth.

Enhanced function claims
An **enhanced function claim** describes the specific beneficial effect of nutrients or other substances, alone or in combination, on physiological functions or biological activities in the body. Enhanced function means an effect that *either* exceeds their usual role in maintaining normal metabolic functions including growth and development; *or* is related to a substance that is not essential for the animal but provides a benefit beyond nutrition. No reference should be made to particular diseases or pathological states.

For example: Vitamin B2 helps to protect cells from oxidative damage.

Health maintenance Claims
A **health maintenance claim** describes the specific beneficial effect of nutrients or other substances, alone or in combination, on the maintenance of physiological functions or health.

For example: Contains omega-3 fatty acids to maintain healthy joints.

- In the 'Code of good labelling practice for use in food producing animals' it is mentioned in addition that they can:
  - Support physiological functions of the animal or enable the return to a normal physiological status;
  - Enhance animal performance;
  - Enhance the efficiency of the compound feed.

Reduction of disease risk claims*
A **reduction of disease risk claim** means any claim that states, suggests or implies that the consumption of a feed or a nutrient, component or additive in the feed, significantly reduces a risk factor in the development of a disease.

For example: It has been shown that plant sterols lower the blood cholesterol. High cholesterol is a risk factor for developing coronary heart disease.

* In the 'FEDIAF Code of good labelling practice for pet food' this category is combined with the 'Health maintenance claims'. However, in analogy with the Claims regulation the Netherlands has classified this as a separate category.

Dietetic feeds
Contrary to the functional claims as described above, dietetic feeds will need an authorisation before they can be placed on the market. In chapter three the regulatory framework of dietetic feeds is described.

It is possible for dietetic feeds to add one or more additional functional claim(s) to the dietetic claim. In the chapter 'Substantiation of claims by type of substance' this is further discussed.

For example: Dietetic feed for cats to reduce struvite stones.
Example additional claim: With fish oil for a shiny coat.

Livestock management (or zootechnical) claims
These claims are related to the role of a feed with specific effects on managing environmental, sanitary risks or improving the quality of food. They may be connected to a specific feed material, feed additive or constituent, or to the appearance of the animal feed or a specific process undergone by the animal feed.

See the 'EU code of good labelling practice for food producing animals' for further guidance.

Borderline cases between 'reduction of disease risk claims' and 'dietetic feed'
The distinction between a dietetic feed claim and a reduction of disease risk claim needs some further clarification.

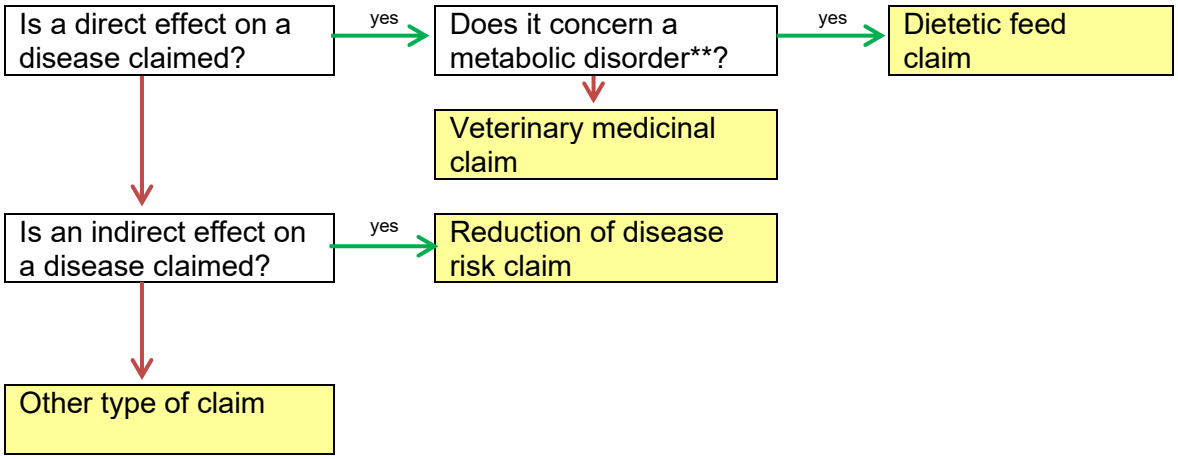
Dietetic feed claims assume a **particular nutritional purpose** which means:
'The purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition.'

So dietetic feed is intended for animals that already have a disturbance or already are at risk of disruption of the healthy state, and it is therefore possible to claim a direct effect on a disease. Please note, this is only allowed as long as the disease is related to an impairment of the animals' metabolism, or an impairment of its process of assimilation or absorption. In all other cases claiming a direct effect on a disease can be seen as a medicinal claim and is restricted to products which fall under the scope of the Veterinary medical products Legislation.

Contrary, claiming a direct effect on a disease is never allowed for a 'reduction of disease risk claim'. In this case only an effect on the risk factor can be claimed. A 'reduction of disease risk claim' can be used when a risk factor for the development of a disease is reduced or prevented, and not the disease itself. A reduction of a risk factor of a disease can be made with or without mentioning the disease name.

Example: lowers [naming risk factor]

The above mentioned is shown schematically below*:



* Please note, this scheme is only an indicator for the type of claim.
** With metabolic disorder is meant a disorder which relates to a temporarily or irreversibly impaired process of assimilation, absorption or metabolism of the animal, or to a possibility thereof.

So claiming a direct effect on a disease is restricted to products which fall under the scope of the Veterinary medical products Legislation (or to specific dietetic feed under the conditions as mentioned above). Besides claiming a direct effect on a disease there are certain words that may be considered medicinal as they are normally associated with authorised veterinary medicinal products.

The next chapter will further elaborate on prohibited claims.

9. Prohibited claims

Introduction
The Feed marketing Regulation states that the labelling or the presentation of feed materials and compound feed shall not claim that it will prevent, treat or cure a disease (except for coccidiostats and histomonostats as authorised under Regulation (EC) No. 1831/2030. This point shall not, however, apply to claims concerning nutritional imbalances provided that there is no pathological symptom associated therewith.

Furthermore, the following claims are not permitted:
- Claims that suggest that feed has a specific function or composition while actually the claimed effect is the same for all similar compounds*;
- Claims that contradict generally accepted knowledge on nutritional and health principles;
- Claims that give the impression that not consuming a particular food can harm the health of the animal;
- Claims that lead to doubt about the safety and /or the nutritional adequacy of other feed;
- Claims that seem to indicate that it has a particular nutritional purpose (as provided for in the list of intended uses as referred to in Article 9 of the Feed marketing Regulation), in case the requirements on composition and labelling are not met.

* As already indicated in chapter 7, the Netherlands has a pragmatic approach on this rule.

National implementation
The KAG list of Inspection Board KOAG/KAG is the Dutch national guidance on the terminology that may be used in the formulation of a feed claim. This list is not developed for use in animal feed, however, it gives sufficient general guidance for use in animal feed as well. For example, mentioning the names of pathogens is not allowed according to the KAG list. This applies to animal feed as well.

In general, claims should not use the following terms ‘prevention, treatment or cure of a disease’. However, the words ‘for prevention’ may be used when the claim is not related to a disease, e.g. ‘prevents hairballs’.

In the FEDIAF and FEFAC labelling codes several examples are given of wordings that might suggest that the product is a veterinary medicinal product and, therefore, in general, shall not be used:

Examples mentioned in the FEDIAF labelling code:
- Dose/Dosage*
- Heals / Cures
- Treatment
- Prevents
- Prevention
- Repairs

* The use of the term dosage as such is insufficient cause to mark a product as a veterinary medicinal product in the Netherlands. For example, also for the addition of feed additives to feed mixtures the term ‘dosage’ is quite commonly used.

In the FEFAC labelling code it is additional mentioned that the following words cannot be used when they refer to a certain physiological function:

- Stimulates**
- Increases**
- Improves**
- Reinforces**

** However, if one of the above mentioned claims is specifically mentioned in the KAG-list or in the EU register on nutrition and health claims it is acceptable to use such a claim in the Netherlands as long as it may be relevant in animals. For example: ‘stimulates appetite’ is accepted in the KAG list, while ‘stimulates hormone production’ is not acceptable.

Also the use of the words ‘veterinary’ or ‘veterinarian’ gives the impression that the feed is a veterinary medicinal product and should therefore be avoided. This does not apply to feeds intended for a particular nutritional purpose (dietary feeds or PARNUTs) as for for PARNUTs it is advised to indicate that ‘The opinion of a veterinarian should be sought before using the feed or before extending its period of use.’

It is also not allowed to mention the name or logo of the NVWA or other authorities on the packaging, in order to create the impression that the product has been positively assessed by the authorities.

Below, a selection of the wordings that are usually not suggesting that it is a veterinary medicinal product and, therefore, in general can be used:

- Use
- Minimum and Maximum levels
- Soothes
- Supports
- Provides
- Maintains
- Helps

To what extent certain terms can or cannot be used strongly depends on the exact wording and context, and the examples listed above are only intended to provide a general impression of permitted and non-permitted wordings. Thus, the claim 'to support the digestive system' is a (permitted) health claim: digestion is a normal function of the body. The claim in no way suggests that the digestion is impaired at the moment. However, the claim 'to enhance an impaired digestion' is not allowed as health claim. An impaired digestion is not part of a normal physiological functioning of the body; it is an enhancement of the physiological function and therefore tends to be a veterinary medicinal claim.

10. Substantiation of claims

Introduction
In accordance with the Feed marketing Regulation the degree of claim substantiation may differ. In this respect we classify claims in two major groups, the generic claims and the innovative claims. The type of claim hereby determines the degree of substantiation. Depending on the type of claim, substantiation can be provided by 'generally accepted knowledge' (for generic claims) or by scientific evidence (for innovative claims). Furthermore we will give general guidance on the extrapolation between target species and on the difference between product based evidence versus component based evidence. Annex V is a general checklist of the data that should be presented in a claim substantiation dossier, and in Annex VI the detailed requirements for claim substantiation dossiers are given.

Substantiation of generic claims
A generic claim is a claim which is generally accepted and whose scientific basis can be found by means of publicly available scientific data, such as scientific publications in peer-reviewed scientific journals.
The component on which the claim is based should be present (or absent) in the feed in such an amount that it can contribute to the claimed effect. In order to demonstrate this, an appropriate method of analysis should be available.

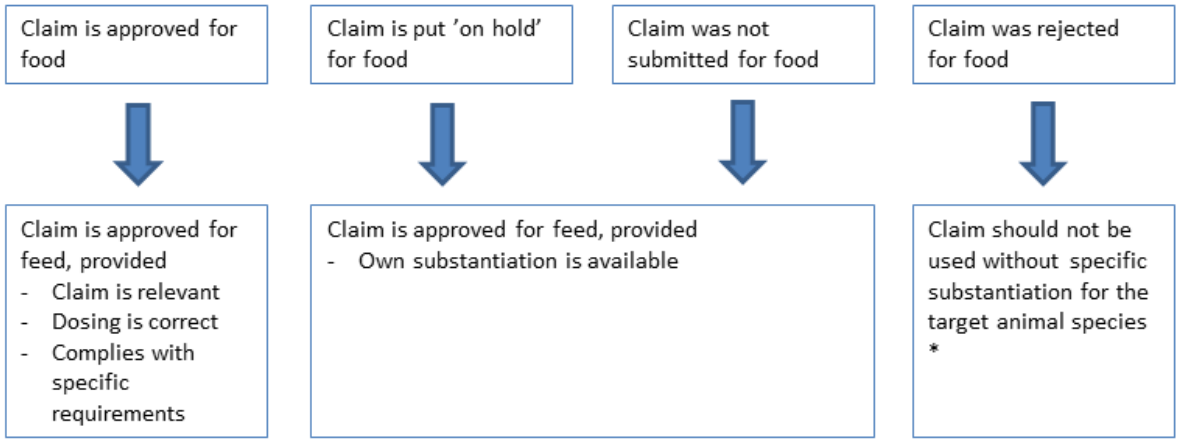
Authorised health claims on food
All authorised health claims assigned to a particular component in food are seen as a generic claim. This is because sound scientific studies underlie these claims and these claims are considered generally accepted.
If one or more claims on a particular component in a foodstuff are authorised, these claims can be used on feed as well in the Netherlands. Provided that the particular component is sufficiently present in the feed and that all other general conditions as described in the Claims Regulation are taken into account. In addition, the specific requirements per authorised health claim as described in the conditions of authorisation of that health claim should be met as well.

In the majority of authorised food claims criteria for the (minimum) quantity of the food ingredient are given. For example, a minimum amount of 15% of the daily reference intake for vitamins and trace elements should be present in the food product (per 100 mg or ml product).
The human daily reference intakes for vitamins and minerals are given in table XIII of Directive (EU) No. 1169/2011 on the provision of food information to the consumer.
The inclusion levels of the components and the validity of the claim shall be based on nutritional requirements of the target animal for which the feed is intended.
As a basis for this, generally accepted tables on nutritional requirements can be used e.g. CVB tables. For horses also the NRC requirements can be used.
Also, FEDIAF published FEDIAF Nutritional Guidelines for dogs, cats and rabbits.
The correlation table shown in Annex III can be used to convert the amount of product per kg of body weight in humans to animal species.
Please note, in case the product contains feed additives, the minimum and maximum inclusion levels as set out in the Annex of the Regulation(s) of authorisation shall be respected.

In addition, there can be other conditions to the food claim, regarding the restriction of the use of the food and any additional comments or warnings that should be labelled. For example, it is possible that the food matrix in which the nutrient is incorporated is important

for the effect of the component. Where scientific evidence (confirmed by EFSA) has shown that the claimed health effect only occurs after incorporation of a nutrient in a certain food matrix, it would be misleading to make these claims when the nutrient is incorporated in a different food matrix, e.g. as absorption may only occur from this particular food matrix. Where such specific provisions apply to a food claim then the feed business operator must argument that this condition is met.

Below is shown schematically how the Dutch competent authority sees the relationship between the Claims Regulation (food) and claims made on animal feed:



* If a claim is rejected for food it cannot be used for animal feed, unless:

- A food claim has not been granted because the requested product was not clearly specified or because insufficient data were supplied; in this case the feed business operator is permitted to use the claim on feed, provided that own substantiation is available;
- Its own evidence data show that the claim - unlike the claim on food – has been sufficiently substantiated for feed when used for specific target species.

Product based evidence versus component based evidence

The authorised health claims on foods are based on individual components. In case a claim can be made for a particular component, the general idea is that this claim can also be made for the finished product in which this component is included, provided that there is a clear connection between the claim and the component.
If a finished food product contains various components for which claims can be made, all claims can be made simultaneously. No substantiation of the claim is needed for the finished food product itself.
To maintain consistency with Food Legislation, in the Netherlands these rules apply for feed as well.

However, in the following cases, the substantiation of the claim should be made based on the finished product itself:

- For innovative claims where the claim is closely related to the exact composition of a feed;
- If the compound feed undergoes a processing step to which the claim is linked, for example fermentation of the feed;
- Where a claim involves more than the 'sum of its parts', in other words the claim goes beyond what can be claimed based on the individual components (as a result of a possible synergistic effect between the individual components);
- If the claim is not substantiated based on the individual components, for example, because the inclusion levels of the individual components are too low to achieve the claimed effect;
- If the claim is based on the presence of a certain feed additive (as authorised under 1831/2003/EC) and the claim is not covered by the function group of the additive authorisation.

Concluding, if a claim is linked to an individual component of the feed, then the substantiation of the claim can be made on the component itself and not necessarily on the finished product. However, when the claim relates to a specific composition or specific processing of the finished product than the claim should be substantiated on the finished product itself. Claims based on the presence of a feed additive shall be in line with the function of the feed additive as described in its authorisation. If this is not the case than the claim should be substantiated on the finished product itself. See also Annex IV.

Connection between claim and component
As stated above, there must be a clear connection between the claim and the component on which the claim is based. For example choline, in which case it is allowed to claim:

> *'Choline contributes to the maintenance of a normal liver function'*

It is also allowed to claim:

> *'This product contains choline and choline contributes to the maintenance of a normal liver function'*

But it is not allowed to claim (on the finished product):

> *'This product contributes to the maintenance of a normal liver function'*

Because in the latter it is not clear to the consumer on which component the claim is based.

Furthermore whenever the name of one or more components is described in a claim other than referring to its absence, the names and total amounts of these components shall be indicated on the label.

Connection between claim and product
It is also not allowed to suggest on an animal feed ("feed") label and/or via any other medium that a product has a particular medicinal effect by telling a general story or by placing statistical information on the animal feed label.

For instance, on a label or website the following sentence is displayed:

'Approximately10% of all dogs suffer from arthritis'

It is not mentioned on the label that the product itself cures arthritis, however it does give the impression that is does have a beneficial effect in dogs with arthritis.

Above mentioned example is not allowed as all general information which is in some way linked to the product, can be seen as a recommendation of that particular product.
See the definition of 'labelling' (Article 3.2 (s) Regulation (EC) No. 767/2009).

Substantiation per target species versus extrapolation between species
For generic claims, for which it is widely accepted that they apply to almost all target species (e.g. 'calcium supports the healthy condition of bones') and which have been authorised for food under the Claims Regulation, no additional proof is needed for a particular animal species. However, a literature search still should be done to indicate any potential indications from literature that could support the claim. Besides, the inclusion level of the relevant component in the feed product should be based on the nutritional needs of the target animal species. For this we refer to the nutritional tables in the Annexes.

Claims regarding behaviour
Psychological and behavioural functions, can be influenced by many factors other than dietary ones. This is an extremely complex mechanism and it is not easy to convey in a short feed claim that is complete, truthful and meaningful. Besides, behaviour is not easily comparable between species. Therefore, claims regarding psychological and behavioural aspects are preferably supported by target species specific, scientifically justified information. Scientific literature can be used for this purpose as well.

Extrapolation between target species
If there is any research to be performed it is sometimes possible to extrapolate from a different species. In general this means that the degree in which two species are physiologically comparable with respect to the claimed effect, this defines the degree in which substantiation can be extrapolated.

If a claimed effect is already substantiated for a physiologically similar species and for the same function (that is claimed) and when the mode of action of the product is known or has been shown, it will be sufficient to demonstrate the physiological resemblance of both species. In case species are too different from physiological perspective, substantiation per species should be provided, following the general rules for efficacy studies, as mentioned in Regulation (EC) No. 429/2008 and elaborated in the EFSA Guidance on the assessment of the efficacy of feed additives.

If efficacy studies have to be performed, in some cases it may be appropriate to combine animal species of the same productive stage (e.g., goats and sheep used for milk production). As a general rule, significance should be demonstrated in each study ($P \leq 0.1$) or, if feasible, by meta-analysis ($P \leq 0.05$).

If efficacy must be demonstrated, the duration of the efficacy study should correspond to the comparable production stages of the physiologically comparable major species. In other cases, it is recommended that the minimum duration of the efficacy study is in accordance with the provisions of sub section 4.4 of Annex II and Annex IV of Regulation (EC) No. 429/2008.

Substantiation of innovative claims

For innovative claims scientific research should be the basis for the substantiation of the plausibility of a claim. The Dutch principle in this is that it shall be demonstrated that a claim is ‘not implausible’.

In Annex IV, further rules on permitted and non-permitted claims are given for a number of components. In Annex VI a detailed guidance on the content of a claim dossier is given for both generic and innovative claims.

Annex I Definitions

Below are the relevant definitions from the European Animal feed Legislation, the Veterinary medicinal products Legislation and Biocide Legislation. These definitions are an important tool in the determination of the status of products.

Definitions under the Legislation on Animal Nutrition

Definition of feed according to 178/2002/EC (General Food Law)
'Feed' means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

(Feed can be subdivided into feed materials, compound feed, additives, premixtures and medicated feed. Water is not covered by this definition.)

Definition of feed materials according to 767/2009/EC (Feed marketing Regulation)
'Feed materials' are products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures.

Furthermore, recital 11 of Regulation (EC) No. 767/2009 as follows: '(...).
Feed materials are primarily used to meet animals' needs, for example for energy, nutrients, minerals or dietary fibres. They are usually not chemically well-defined except for basic nutritional constituents. Effects which can be justified by scientific assessment and which are exclusive to feed additives or veterinary drugs should be excluded from the objective uses of feed materials.
(...) '.

Oral feeding of animals means the introduction of feed into an animal's gastrointestinal tract through the mouth with the aim of meeting the animal's nutritional needs and/or maintaining the productivity of normally healthy animals.

Definition of compound feed according to 767/2009/EC (Feed marketing Regulation)
'Compound feed' is a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed:

1. **complete feed** means compound feed which, by reason of its composition, is sufficient for a daily ration
2. **complementary feed** means compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feed.

Definition of mineral feed according to 767/2009/EC (Feed marketing Regulation)
'Mineral feed' means complementary feed containing at least 40 % crude ash.

Definition of milk replacer according to 767/2009/EC (Feed marketing Regulation)
'Milk replacer' means compound feed administered in dry form or after dilution in a given quantity of liquid for feeding young animals as a complement to, or substitute for, post-colostral milk or for feeding young animals such as calves, lambs or kids intended for slaughter.

Definition of carrier according to 767/2009/EC (Feed marketing Regulation)
'Carrier' means a substance used to dissolve, dilute, disperse or otherwise physically modify a feed additive in order to facilitate its handling, application or use without altering its technological function and without exerting any technological effect itself'.

Definition of feed intended for particular nutritional purposes according to 767/2009/EC(Feed marketing Regulation)
'Feed intended for particular nutritional purposes' is feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC.

A particular nutritional purpose means the purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition.
If a particular nutritional purpose is accepted, it is included in the list of intended uses of animal feedingstuffs for particular nutritional purposes (Regulation (EU) nr. 2020/354).

Definition of processing aids according to Regulation 1831/2003/EC
'Processing aids' are any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed.

Definition of premixture according to Regulation 1831/2003/EC
'Premixtures' are mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals;

Definition of feed additive according to Regulation 1831/2003/EC
'Feed additives' are substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);

The feed additive shall (Article 5, paragraph 3.)
a) favourably affect the characteristics of feed;
b) favourably affect the characteristics of animal products;
c) favourably affect the colour of ornamental fish and birds;
d) satisfy the nutritional needs of animals;
e) favourably affect the environmental consequences of animal production;
f) favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs or,
g) have a coccidiostatic or hostomonostatic effect.

3. Antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives.

Categories of feed additives*

In the category '**technological additives'**, the following functional groups are included:

a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;
b) antioxidants: substances prolonging the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by oxidation;
c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs;
d) stabilisers: substances which make it possible to maintain the physico- chemical state of feedingstuffs;
e) thickeners: substances which increase the viscosity of feedingstuffs;
f) gelling agents: substances which give a feedingstuff texture through the formation of a gel;
g) binders: substances which increase the tendency of particles of feedingstuffs to adhere;
h) substances for control of radionucleide contamination: substances that suppress absorption of radionucleides or promote their excretion;
i) anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere;
j) acidity regulators: substances which adjust the pH of feedingstuffs;
k) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage;
l) denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials;
m) substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action;
n) hygiene condition enhancers: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination;
o) other technological additives: substances or, when applicable, microorganisms added to feed for a technological purpose and which favourably affect the characteristics of the feed.

2. In the category '**sensory additives'**, the following functional groups are included:

a) colourants:
   i) substances that add or restore colour in feedingstuffs;
   ii) substances which, when fed to animals, add colours to food of animal origin;
   iii) substances which favourably affect the colour of ornamental fish or birds;
b) flavouring compounds: substances the inclusion of which in feedingstuffs increases feed smell or palatability.

3. In the category '**nutritional additives'**, the following functional groups are included:

a) vitamins, pro-vitamins and chemically well-defined substances having similar effect;
b) compounds of trace elements;
c) amino acids, their salts and analogues;
d) urea and its derivatives.

4. In the category '**zootechnical additives'**, the following functional groups are included:

a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
b) gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
c) substances which favourably affect the environment;
d) other zootechnical additives;
e) physiological condition stabilisers: substances or, when applicable microorganisms, which, when fed to animals in good health, favourably affect their physiological condition, including their resilience to stress factors.

5. **Coccidiostats and histomonostats**.

A regulation granting authorisation for additives belonging to categories zootechnical additives, coccidiostats and histomonostats and also for additives consisting of, containing or produced from GMOs, shall include the name of the holder of the authorisation.

Definitions under the Legislation on Veterinary Medicinal Products

Definition of a veterinary medicinal product according to Directive (EU) 2019/6:
‘veterinary medicinal product’ means any substance or combination of substances which fulfils at least one of the following conditions:
(a) it is presented as having properties for treating or preventing disease in animals;
(b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;
(c) its purpose is to be used in animals with a view to making a medical diagnosis;
(d) its purpose is to be used for euthanasia of animals.

Article 3 Conflict of laws
1. Where a veterinary medicinal product referred to in Article 2(1) of this Regulation also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council (20) or Regulation (EC) No 1831/2003, and there is a conflict between this Regulation and Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, this Regulation shall prevail.

Definition of a medicated feed according to Regulation (EU) 2019/4
‘medicated feed’ means a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products or intermediate products with feed materials or compound feed.

Definition of a intermediate product according to Regulation (EU) 2019/4
‘intermediate product’ means a feed, which is not ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products with feed materials or compound feed, exclusively intended to be used for the manufacture of medicated feed.

Furthermore, Regulation (EU) 2019/4 states:
Regulation (EU) 2019/6 applies to veterinary medicinal products, including what is referred to as 'premixtures' in Directive 90/167/EEC, until those products are incorporated into medicated feed or intermediate products, after which this Regulation applies to the exclusion of Regulation (EU) 2019/6.

Definition of a homeopathic veterinary medicinal product according to Directive Regulation (EU) 2019/6:
‘homeopathic veterinary medicinal product’ means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States.

Definitions under the Legislation on Biocidal products

Definition of a biocidal product according to Regulation 528/2012/EC:
- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
A treated article that has a primary biocidal function shall be considered a biocidal product.

Definition of a active substance according to Regulation 528/2012/EC:
'Active substance' means a substance or a micro-organism that has an action on or against harmful organisms

Definition of a harmful organism according to Regulation 528/2012/EC:
'Harmful organism' means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

Annex V contains a description of 22 biocidal product types. The most important are listed below:

MAIN GROUP 1: Disinfectants

Product-type 3: Veterinary hygiene
Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product-type 4: Food and feed area
Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

Products used to impregnate materials which may enter into contact with food.

Product-type 5: Drinking water
Products used for the disinfection of drinking water for both humans and animals.

Under Article 2 of Regulation 528/2012/EG it is stated that the Biocide Regulation shall not apply to biocidal products that fall within the scope of the Animal Feed Legislation or that fall within the scope of the Legislation on Veterinary Medicinal Products.

Annex II List of relevant Legislation

Below, all the relevant Legislation and other documents that appear to be relevant in the context of the claim assessment are listed.

Please note: Legislation may change. Always check Eur-lex for any updates.

For this overview mainly Community Legislation has been used. In the Netherlands this Legislation is incorporated in the Wet dieren.

Relevant Feed Legislation
Feed:

REGULATION (EC) NO 767/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 July 2009 on the placing on the market and use of feed:

Hyperlink: Regulation (EC) No. 767/2009

COMMISSION REGULATION (EU) NO 68/2013 of 16 January 2013 on the Catalogue of feed materials:

Hyperlink: Regulation 68/2013/EC

COMMISSION RECOMMENDATION of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (2011/25/EU):

Hyperlink: Recommendation 2011/25/EU

Feed Additives:

REGULATION (EC) No. 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on additives for use in animal nutrition:

Hyperlink: Regulation (EC) No. 1831/2003/EC

COMMISSION REGULATION (EC) No. 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives:

Hyperlink: Regulation (EC) No. 429/2008

COMMISSION REGULATION (EU) No. 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council:

Hyperlink: Regulation 892/2010/EC

Community Register of feed additives:
Hyperlink: Register of Feed Additives

Feed for particular nutritional purposes:

The rules for the marketing of 'dietetic' feed (feed for particular nutritional purposes) are laid down in Regulation (EC) No. 767/2009 (see above.) Furthermore the following Legislation applies.

Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC:
Hyperlink: Regulation (EU) 2020/354

Relevant Industrial Guidelines

Feed Materials Register:
Hyperlink: Feed Materials Register

Regulation (EC) No. 767/2009 on the placing on the market and use of feed states in article 24(6): 'the person who, for the first time, places on the market a feed material that is not listed in the Catalogue shall immediately notify its use to the representatives of the European feed business sectors referred to in Article 26(1). The representatives of the European feed business sectors shall publish a Register of such notifications on the Internet and update the Register on a regular basis'. A notification to this Register is not an application for listing of the feed material in the EU Catalogue of feed materials (article 24 of Regulation (EC) No. 767/2009). The information listed in the Register is the sole responsibility of the notifying feed business operator.

EU code of good labelling practice for compound feed for food producing animals September 2018:
Hyperlink: EU code of good labelling practice for food producing animals

This Code of Practice developed jointly by COPA-COGECA and FEFAC provides producers of compound feed with clear and practical recommendations on how to label compound feed in accordance with the provisions laid down in Regulation (EC) No. 767/2009 on the placing on the market and use of feed and enables farmers to better understand labelling particulars and better assess the nutrition value of a compound feed. It includes in particular a section on claims (permitted claims, justification of claims) as well as examples of labels. This Code was developed in accordance with article 25 of Regulation (EC) No. 767/2009 and submitted

to the EU Commission for validation in accordance with article 26 of the same Regulation. This code was endorsed by the EU Commission.

F.E.D.I.A.F. CODE OF GOOD LABELLING PRACTICE FOR PET FOOD October 2011 (revised October 2018):

Hyperlink: FEDIAF code of good labelling practice for pet food

This Code was endorsed by the EU Commission.

The Dutch association is the NVG

FEFANA EU code of practice on voluntary labelling particulars (claims) for feed additives and premixtures:

Hyperlink:

EU code on voluntary labelling particulars (claims) for feed additives and premixtures

CODE OF PRACTICE FOR THE APPLICATION OF THE LABELLING RULES LAID DOWN IN REGULATION (EC) No. 1831/2003 FOR FEED ADDITIVES AND PREMIXTURES FEFANA, FEFAC and EMFEMA-September 2011 Version 8:

Hyperlink: Code of practice labelling 1831-2003

This Code of practice developed jointly by EMFEMA, FEFAC and FEFANA aims at providing feed additives and premixtures manufacturers with recommendations on how to provide labelling information to the customers. It is based on the labelling rules laid down in Regulation (EC) No. 1831/2003 on additives in animal nutrition and also takes on board the innovative concept of label and labelling as established in Regulation (EC) No. 767/2009 on the placing on the market and use of feed. In the absence of legal basis, this code could not be submitted for validation to the EU Commission.

Fefana classification tool:

Hyperlink: FEFANA classification tool

This tool aims to help the feed business operators and the competent control authorities of EU Member States have a consistent approach for the classification of substances, with regard to the differentiation between feed additives (as defined in the Regulation (EC) No. 1831/2003 and its amendments) and feed materials (as defined in Regulation (EC) No. 767/2009 and its amendments).

Feed material decision tree , feed and feed products in GMP +:

Hyperlink: Decision tree feed materials GMP+

Relevant Veterinary medical products Legislation

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products:

Hyperlink: Regulation (EU) No. 2019/6

Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed:

Hyperlink: Regulation (EU) No. 2019/4

Database Dutch Veterinary medical products unit:

Hyperlink: Database Dutch veterinary medicinal products

Relevant Biocide Legislation

REGULATIONS REGULATION (EU) No. 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products:

Hyperlink: Regulation (EU) No. 528/2012/EC

Pesticides Database of the Board for the admission of Pesticides and Biocides:

Hyperlink: Pesticides Database: Dutch Pesticides Database

Relevant regulations for food claims

REGULATION (EC) No. 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods:

Hyperlink: Regulation 1924/2006/EC

In addition:

Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council (2013/63/EU)

Hyperlink: Commission Implementing Decision of 24 January 2013

COMMISSION REGULATION (EU) No. 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods :

Hyperlink: Regulation 432/2012/EC

GUIDANCE ON THE IMPLEMENTATION OF REGULATION N ° 1924/2006 ON NUTRITION AND HEALTH CLAIMS MADE ON FOODS (December 2007):

Hyperlink: Guidance on the implementation of regulation N° 1924/2006 on nutrition and health claims made on food

Inspection Board KOAG / KAG:

Hyperlink: KOAG KAG

With links to:

Dutch historic indicative list (the KAG-list)

-
- Guidance document (in Dutch);
- Dutch database on nutrition and health claims made on foods as based on the Claims Regulation

EU Register of health claims made on foods:

Hyperlink:
EU Register of Health claims made on foods

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers:

Hyperlink: Regulation No. 1169/2011

Relevant nutritional tables

NRC (National Research Council) Nutrient requirements of horses:

This is a book which is not available as a hyperlink.

Various Tables CVB:

These are available on the website of the CVB.

Hyperlink: CVB

FEDIAF Nutritional Guidelines Cats and Dogs and for Feeding Pet Rabbits:

Hyperlink: FEDIAF Nutritional Guidelines

Nutrition for horses, Flemish Government Agriculture and Fisheries Policy (Written in Dutch):

Hyperlink: Nutrition horses Flemish government

Relevant documents regarding herbal products

Kruideninformatiebulletin (in Dutch):

Hyperlink: Informatiebulletin kruidengebruik bij dieren

EFSA guidance additives:

EFSA guidance botanicals: Botanicals | EFSA (europa.eu)

Study on the assessment of plants / herbs, plant / herb extracts and their naturally or synthetically produced components as 'additives' for use in animal production:
Hyperlink: EFSA doc 70828

Statement on the preparation of guidance for the assessment of plant / herbal products and their constituents used as feed additives:
Hyperlink: EFSA doc 1694

Compendium of botanicals reported to contain naturally occuring substances of possible concern for human health when used in food and food supplements:
Hyperlink: EFSA doc 2663

Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements:
Hyperlink: EFSA doc 1249

Other relevant documents

EFSA guidance documents regarding the authorisation of additives:
Hyperlink: EFSA guidance documents
Including: Guidance tolerance and efficacy studies

Borderline Working Group Regulatory Framework, Jurisprudence (case law) and National Guidance:
Hyperlink: Overview regulatory framework for borderline products

Guidance surrounding Member States:

Germany: Guideline for the Labelling of Feed Materials and Compound Feed - BVL.BUND.DE. June 2010:
Hyperlink: Feed labelling guidance Germany

Belgium: Labelling of feedingstuffs and compound feed (written in Dutch)
Hyperlink: Feed labelling guidance Belgium
With included a 'indicatieve lijst gezondheidsbeweringen'.

Annex III Conversion human to animal use levels

Introduction

To check if the usage level of a feed additive is similar to that used in food, the EFSA 'Guidance for the preparation of dossiers for additives already authorised for use in food' may be used.

This EFSA guidance is actually meant to check whether a tolerance study is needed, but it can also function as a rough comparison between the authorised level used in food and the level that could be used in a feed for a particular target animal. It should be noted however that nutritional requirements may differ between humans and the animal species described below as well as between animal species.

Studies Concerning the safety of use of the additive for the target animals.

If the usage level of the feed additive is less than or similar to that used in food [expressed as quantity per metabolic body weight (usually mg/kg$^{0.75}$)], a tolerance study is normally not required.

Actual exposure can be calculated by multiplying the tabulated exposure (Table 1) with the intended feed concentration in mg/kg complete feed. These values should then be compared to the human exposure value, considering a metabolic body weight of 21.6 kg$^{0.75}$.

Table 1: Default values for body weight and feed intake and resulting target animal exposure per 1 mg feed ingredient/kg complete feed.

Animal category	**Body weight (kg)**	**Metabolic body weight (mbw) (kg$^{0.75}$)**	**Mean feed intake (g/day)**	**Target animal exposure (µg/mbw (kg^{075})/day)**
Chickens for fattening	2	1.7	120	71
Turkeys for fattening	12	6.4	400	63
Laying hens	2	1.7	120	71
Piglets	20	9.5	1000	105
Pigs for fattening	100	31.6	3000	95
Sows	200	53.2	6000	113
Veal calves (milk replacer)	100	31.6	2000	63
Cattle for fattening	400	89.4	8000	89
Dairy cows	650	128.7	20000	155
Salmonids	2	1.7	40	24
Dogs	15	7.6	250	33
Cats	3	2.3	60	26

Annex IV Claim substantiation per type of component

Introduction
A claim can relate to a feed additive that has been incorporated into the final product and/or to certain feed materials that are present in the product. In the case of feed additives, reference is made more specifically to functions.

An attempt will be made below to clarify the permitted and prohibited claims for each type of component, and how they can best be assessed. We will first discuss all the functional groups for feed additives and then look in greater detail at a number of specific types of feeds and dietetic feeds.

Feed additives
All the authorised feed additives are listed in the Community Register of feed additives. Some feed additives are described in great detail in the Register, while others are not. This has to do with the functional group for which the particular additive is authorised and with whether the product has already been re-authorised under the Additives Regulation.

Feed additives are permitted under certain functional groups. It is not permitted to claim a function for a feed additive which has not been approved. A feed additive must be authorised for each function that is claimed.

In the Dutch view there is a difference between a function and a claim however. This is best explained by some examples.

Example 1 - preservatives:
Preservatives are substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites.

For a feed additive authorised in the functional group preservatives can therefore be claimed ‘protects feed against deteriotarion caused by micro-organisms or their metabolites’

For an organic acid, for example, a reduction in pH in the animal may only be claimed if it is also authorised for that function. If three different functions are claimed for a feed additive, then the additive must therefore be authorised under three different functional groups.

Example 2 - silage additives:
It is not allowed to claim that a silage additive, which is authorised with the purpose of ensiling the feed, can have an effect on the animal itself, as it is not authorised for that function, the only function it is authorised for is having a specific effect on the feed, more particular ensiling the feed.

Example 3 - nutritional additives:
Nutritional additives (vitamins and trace elements) on the other hand do have a clear nutritional function in the body and additional claims related to the nutritional function they are authorised for are allowed in the Dutch view. The claim gives a further specification of the particular function a nutritional additive has in the body.

In the Dutch view, claims which are authorised by EFSA for Foodstuffs can be extrapolated to animals (when relevant for the target animal). For instance EFSA has authorised claims which relate to the immune system, like ‘Iron contributes to a normal function of the immune system’ (EFSA Journal 2009; 7(9):1215). In line with this, in the Netherlands these type of claims can be acceptable when used on nutritional additives incorporated in animal feed as well, as long as these claims are properly substantiated and relevant for the target animal.

Therefore in the Netherlands these type of claims are not limited only to zootechnical additives.

For the inclusion in the Register of Feed Additives a number of general rules apply:

- If no target animal categories are specified, then this means that the additive may be used in feed intended for all target animals (provided the additive concerned has the intended effect in those animals; silage additives are permitted, for example, in all target animals but they must have a silaging function for the animal feed concerned).
- If no minimum and maximum content are indicated, it means that no further requirements have been set for these. This does not detract from the fact that the quantities added must be in relation to the function that the additive has in the feed concerned, or has for the target animal concerned.
- If a manufacturer is indicated, only that manufacturer is permitted to produce the feed additive concerned; this is also referred to as person-specific authorisation.
- Feed additives may not be fed to animals directly.

NB
The Feed marketing Regulation provides that feed materials and complementary feeds must not contain levels of feed additives that are higher than 100 times the relevant fixed maximum content in complete feeds or five times in the case of coccidiostats and histomonostats. If that level is exceeded, then the feed concerned must be authorised as a dietetic feed.
Feeds to which this applies must display the claim as it is listed in the list of intended uses (see Regulation (EU) No. 2020/354).

1. Technological additives
These include preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, substances for control of radionuclide contamination, anti-caking agents, acidity regulators, silage additives, denaturants, mycotoxin binders, hygiene condition enhancers and other technological additives, which are substances or, when applicable, microorganisms added to feed for a technological purpose and which favourably affect the characteristics of the feed. More detailed specifications are sometimes given regarding the categories of target animals or maximum contents.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation. They may also relate, for example, to the absence of some of the categories listed above, for example stating ‘free of preservatives’. Such claims are substantiated by means of the formula; no additional substantiation is required. If the claim relates, for example, to reduced use, then a comparison must be made with a reference product; see the FEDIAF code of good labelling practice for pet food for further guidance.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Technological feed additives that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Technological feed additives incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.

- Technological feed additives incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Technological feed additives may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

NB There is sometimes a lack of clarity regarding the products permitted under Category 1k, **silage additives**. Silage additives may only be added to feed if they have a silaging function in the feed concerned. The microorganisms and enzymes listed under 1k may not be added to an animal feed for other purposes. At the moment for some of these products transitional measures exist. In the Register of Feed Additives they are now shaded grey.

2. Sensory additives

2.a Colorants

A large number of colorants have been authorised. These include, for example, astaxanthin and canthaxanthin. More detailed specifications are sometimes given regarding the categories of target animals or maximum contents.

Permitted:

- Claims that are permitted be in relation to the function for which they have been permitted under the Additives Regulation, i.e. giving a colour.

- Claims may also relate, for example, to the absence of colorants. Such claims are substantiated by means of the formula; no additional substantiation is required. If the claim relates, for example, to reduced use, then a comparison must be made with a reference product; see the FEDIAF code of good labelling practice for pet food for further guidance. If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Colorants that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Colorants incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Colorants incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives. Colorants may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

2.b Flavouring compounds

These are substances that are added to feed or water to increase the smell or palatability, i.e. ‘fragrances and flavourings’. This category is divided into two major groups, chemically defined products and botanical products. The latter category comprises mainly herbal

extracts, oils, and tinctures. More detailed specifications are sometimes given regarding the categories of target animals or maximum contents.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been authorised under the Additives Regulation. Claims may also relate, for example, to the absence of fragrances and flavourings. Such claims are substantiated by means of the formula; no additional substantiation is required. If the claim relates, for example, to reduced use, then a comparison must be made with a reference product; see further the FEDIAF code of good labelling practice for pet food for further guidance.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Flavouring compounds that are not listed in the Register of Feed Additives may not be used in animal feed.
- Flavouring compounds incorporated into a complete compound feed may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Flavouring compounds incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives. Flavouring compounds may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

Claims are often displayed on herbs; these will therefore be dealt with in greater detail under feed materials. Herbal extracts, oils, and tinctures are subject to the Additives Regulation, whereas fresh or dried herbs are considered to be feed materials.

3. Nutritional additives

3.a Vitamins, provitamins, and substances with a similar effect

Vitamins are subject to the Additives Regulation. The Register of Feed Additives gives the maximum contents and target animal categories for which they are permitted. The FEDIAF code of good labelling practice for pet food gives the conversion factors for the various vitamin sources to their vitamin activity.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation.
- All permitted claims are included for each vitamin in the EU Register of health claims made on foods. The claims as permitted there for each vitamin may be used, if relevant, for the vitamin concerned in the target animal categories and subject to the conditions set out in the Register of Feed Additives.
- A Nutrient & Additives claim may also be displayed.

Not permitted:

- Vitamins that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Vitamins incorporated into complete compound feeds may not be used if the level is higher than the relevant maximum content indicated in the Register of Feed Additives.
- Vitamins incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than the relevant maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives. Vitamins may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

3.b Trace elements

Trace elements are subject to the Additives Regulation. The Register of Feed Additives gives the maximum contents and target animal categories for which they are permitted.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation.
- All permitted claims are included for each trace element in the EU Register of health claims made on foods. The claims as permitted there for each trace element may be used, if relevant, for the trace element concerned in the target animal categories and subject to the conditions set out in the Register of Feed Additives.
- A Nutrient & Additives claim may also be displayed.

Not permitted:

- Trace elements that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Trace elements incorporated into complete compound feeds may not be used if the level is higher than the relevant maximum content indicated in the Register of Feed Additives.
- Trace elements incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than the relevant maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Trace elements may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

3.c Amino acids, their salts and analogues

In the past, all bioproteins were subject to Directive 82/471/EEC. However, the lack of feeds with a high protein content led to most products being transferred to feed materials. Only the amino acids, together with their salts and analogues, and urea and its derivatives have been transferred from Directive 82/471/EEC to the Additives Regulation.
For the specific provisions and any updates, please consult the Register of Feed Additives.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation. If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Amino acids that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Amino acids incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Amino acids incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Amino acids may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

3.d Urea and its derivatives

In the past, all bio proteins were subject to Directive 82/471/EEC. However, the lack of feeds with a high protein content led to most products being transferred to feed materials. Only the amino acids, together with their salts and analogues, and urea and its derivatives have been transferred from Directive 82/471/EEC to the Additives Regulation. For the specific provisions and any updates, please consult the Register of Feed Additives.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation, namely being a source of proteins.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Feed additives that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Feed additives incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Feed additives incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Feed additives may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

4. Zootechnical additives
Zootechnical additives are in general intended to support the productivity of healthy animals. Zootechnical additives are subject to person-specific authorisation. For additives with person-specific authorisation it is preferable for producers to incorporate the claims that they wish to display in their authorisation dossier.
Any changes in the function must be submitted subject to the Additives Regulation.

The following categories are distinguished:

4.a Digestibility enhancers
These are substances that, when administered to animals, increase the digestibility of their feed because they act on certain feed materials. This concerns mainly enzymes and microorganisms, which are subject to person-specific authorisation and for which the minimum contents and the target animals are specified.

Permitted:

- Claims that are permitted to be displayed on these must be in relation to the function for which they have been permitted under the Additives Regulation. If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Digestibility enhancers that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Digestibility enhancers incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Digestibility enhancers incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Digestibility enhancers may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

4.b Gut flora stabilisers:
These are micro-organisms or other chemically defined substances that when administered to animals have a favourable effect on the gut flora. This concerns specifically microorganisms, which are subject to person-specific authorisation and for which the minimum contents and the target animals are specified.

Permitted:

- Claims that are permitted be in relation to the function for which they have been permitted under the Additives Regulation. If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Gut flora stabilisers that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Gut flora stabilisers incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.

- Gut flora stabilisers incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Gut flora stabilisers may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

4.c Substances with a beneficial effect on the environment

This concerns products that are subject to person-specific authorisation and for which the minimum and maximum contents and the target animals are specified.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation.

Not permitted:

- Substances with a beneficial effect on the environment that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Substances with a beneficial effect on the environment incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Substances with a beneficial effect on the environment incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Substances with a beneficial effect on the environment may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

4.d Other zootechnical additives

This mainly concerns products which have a beneficial effect on feed conversion and/or growth, but in fact all products not covered by the other categories of zootechnical additives may be included in this category. This concerns products that are subject to person-specific authorisation and for which the minimum and/or maximum contents and the target animals are specified.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Zootechnical additives that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Zootechnical additives incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.

- Zootechnical additives incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Zootechnical additives may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

4.e Physiological condition stabilisers:
This concerns substances or, when applicable microorganisms, which, when fed to animals in good health, favourably affect their physiological condition, including their resilience to stress factors. This concerns products that are subject to person-specific authorisation and for which the minimum and/or maximum contents and the target animals are specified.

Permitted:

- Claims that are permitted must be in relation to the function for which they have been permitted under the Additives Regulation.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Zootechnical additives that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Zootechnical additives incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Zootechnical additives incorporated into feed materials or complementary feeds may not be used at a level that is more than 100 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Zootechnical additives may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- Claims that are not in relation to the function for which they have been permitted under the Additives Regulation may not be used without further substantiation.
- Veterinary claims are not permitted.

5. Coccidiostats and histomonostats

These are veterinary medicinal products that are exempt from authorisation under the legislation on veterinary medicinal products. This concerns products that are subject to person-specific authorisation and for which the minimum and maximum contents and the target animals are specified.
For this specific category of products a national basic rule has been imposed that something may only be claimed if it is substantiated by the dossier as submitted subject to Regulation No. 1831/2003/EC and as expressed in the relevant EFSA opinion. Any changes in the function must be submitted subject to the Additives Regulation.

Permitted:

- Claims that are permitted to be displayed on these must be in relation to the function for which they have been permitted under the Additives Regulation.

Not permitted:

- Coccidiostats and histomonostats that are not listed in the Register of Feed Additives may not be used in animal feed or water.
- Coccidiostats and histomonostats incorporated into complete compound feeds may not be used if the level is higher than any maximum content indicated in the Register of Feed Additives.
- Coccidiostats and histomonostats incorporated into feed materials or complementary feeds may not be used at a level that is more than 5 times higher than any maximum content that may have been set for complete feeds as indicated in the Register of Feed Additives.
- Coccidiostats and histomonostats may not be used for categories of target animals other than those indicated in the Register of Feed Additives.
- All claims that do not relate to the function for which they have been permitted under the Additives Regulation are prohibited, including after further substantiation at national level. Any changes or additions in/to the function must be submitted subject to the Additives Regulation.
- Veterinary claims other than a coccidiostatic or histomonostatic effect are not permitted.

Feed materials and Compound feeds
All the various categories of feed additives have now been discussed. First the dietetic feeds and then a number of feed materials or groups of feed materials will be discussed below whose status is frequently the subject of discussion.

6. Dietetic feeds
Feeds intended for particular nutritional purposes – referred to below as 'dietetic feeds' – are feeds which can satisfy a particular nutritional purpose by virtue of their particular composition or method of manufacture, which clearly distinguishes them from ordinary feeds. A 'particular nutritional purpose' means the following:

> 'the purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition'.

The rules regarding the marketing and use of dietetic feeds are included in the Feed marketing Regulation. Before being brought onto the market, dietetic feeds must first have been authorised. Dietetic feeds that have been approved are included in the annex to Regulation (EU) No. 2020/354. Authorisation of a dietetic feed is not person-specific.

Permitted:

- It is permissible to claim a particular nutritional purpose if that particular nutritional purpose is included in the annex to Regulation (EU) No. 2020/354 and if it can be shown, by means of supplementary substantiation, that the provisions included in this list of intended uses applies to the feed concerned. The particular nutritional purpose as described in the annex to Regulation (EU) No. 2020/354 shall be mentioned on the label in exactly the same wordings.
- Mentioning a particular disease or symptom (like diarrhea) is only allowed in case it is part of the description of the particular nutritional purpose in the annex to Regulation (EU) No. 2020/354 itself as well.
- Furthermore all relevant labelling rules as indicated in Reg. (EC) No. 767/2008 apply.
- A supplementary functional claim may be displayed on dietetic feeds if it is sufficiently substantiated.

Not permitted:

- It is not permitted to claim a particular nutritional purpose if that particular nutritional purpose is not included in the annex to Regulation (EU) No. 2020/354.
- Dietetic feeds may not be used for categories of target animals other than those indicated in the list of intended uses.
- Dietetic feeds may not be used for a period longer than that indicated in the list of intended uses.
- Veterinary claims are not permitted unless explicitly mentioned in the annex to Directive 2008/38/EC.

There is an enforcement problem as regards dietetic feeds – especially the non-recently included ones - in that there is no mention of specific permissible maximum and minimum contents but only references in general terms to 'high content' and 'low content'.
Feeds with a particular nutritional purpose may only be marketed as such if they comply with the essential nutritional characteristics for the nutritional purpose indicated in that list. This means, therefore, that any feed business operator who places a product on the market as a dietetic feed must be able to demonstrate that it complies with the essential nutritional characteristics, and must therefore be able to provide scientific substantiation to show that the levels concerned in fact serve that purpose. That scientific substantiation can be for each

separate component by means of references to scientific publications or nutritional reference tables.

7. Prebiotics

Prebiotics are classified among feed materials because they are in fact non-digestible components. Most prebiotics are oligosaccharides and dietary fibres. For a long time, there was uncertainty about prebiotics, but in 2005 the Standing Committee decided that fructo-oligosaccharides, mannan-oligosaccharides, inulin, inactivated Aspergillus, and the residues of fermentation and beta-glucans are not subject to the Additives Regulation.
Possible mechanisms of action attributed to them are that they might selectively stimulate the growth and/or activity of one or more species of bacteria in the large intestine.

Permitted:

- Claims that are permitted to be displayed on these must be substantiated by the claimant's in-house research or studies of the literature, and the terminology must be in accordance with the KAG list.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Claims that are not included in the Register of health claims may not be used without further substantiation.
- Veterinary claims are not permitted.

8. Herbs

Entire plants (or parts thereof) that have perhaps undergone a simple physical treatment (for example drying, grinding, crushing, ...) can in general be regarded as feed materials. It is up to the feed business operator that places the feed material on the market to guarantee that it is safe and not harmful to the health of the animal or the consumer.
Herbs are subject to the same conditions as other feed materials as regards inclusion in the Catalogue of Feed Materials.

On the other hand, plant extracts, distillates, concentrates,... (with certain specific active components being extracted from a plant or parts of a plant) are subject to the Additives Regulation. Currently, all permitted 'extracts' are placed in the category of sensory additives, more specifically 'flavouring compounds' for animal feed.

In the summary report of the Standing committee on Plants, Animals, Food and Feed held in brussels on 23 may 2017 - 24 may 2017 a declaration on the differentiation between botanical flavourings as feed additives and plant extracts as feed materials can be found under point A.08 (summary report) .

The EFSA has put the evaluation of all herbs used in food on hold. This probably means that for the coming years no claims will be included in EU Register of health claims made on foods. All claims in respect of herbs must therefore be accompanied by detailed substantiation. The terminology used should be based on the KAG list.

Animal feed must always be safe for the target animal for which it is intended. This is a basic principle and does not need to be demonstrated in order to substantiate the claim. In the case of herbs, however, it is especially important – in order to prevent any undesirable effects – to determine which herbs each target animal can tolerate properly and up to what levels it can do so.

If herbs are represented by means of a potency – for example Ø, D6, C30 – then they are homoeopathic veterinary medicinal products. They must therefore be authorised as veterinary medicinal products, and they therefore fall outside the scope of the present document.

The use of herbs can fall under the scope of different legislation. The Informatiebulletin kruidengebruik bij dieren has been adopted in the Netherlands to give an overview of the different legislation.

Permitted:

- Claims that are permitted to be displayed on these must be substantiated by the claimant's in-house research or studies of the literature, and the terminology must be in accordance with the KAG list.
- If a claim for a component is registered as approved in the Register of health claims, it may also be used for animal feed, if relevant.

Not permitted:

- Claims that are not included in the Register of health claims may not be used without further substantiation. Veterinary claims are not permitted.

Annex V Check list claim substantiation

Guidance for a check list for the scientific dossier to substantiate functional claims

Source. Fediaf

Chapter	Section	Generic	Innovative	Comments
Summary (one page)	a. Description	X	X	
	b. Substantiation	X	X	
	c. Characteristics of the product essential to the claim (such as inclusion levels, process parameters, specific quality monitoring points to be implemented during production)	X	X	
	d. Target species	X	X	
Packaging, layout and other ways of communication	a. Name and description of the product, including: essential characteristics, identification of any components on which claims are based and inclusion level of the active nutrient/non nutrient, product recipe, as well as specific labelling requirements, intended use, warnings and contra-indications	X	X	
	b. Claims	X	X	
	c. Example of pack layout and other communication tools (e.g. pack, leaflet, web, advertisement)	X	X	
	d. Date of introduction	X	X	
The science behind claims	a. Description	X	X	
	b. Published relevant literature	X	X	
	c. Research: - research centre which conducted the research, - research protocol, - study results, - references		X X X X	
	d. Scientific testimonials	X	X	
Bibliography	a. Scientific publications	X	X	
	b. Abstracts or copies of scientific publications	X	X	

Annex VI Dossier requirements

Introduction
In Regulation (EU) 429/2008 the general dossier requirements for the authorisation of feed additives are described. This regulation can be used as an example to compose a claim dossier. However, not all parts are relevant. Parts that are not relevant for claim substantiation are deleted. In addition, the requirements are completed or partly changed based on the 'EU code of good labelling practice for compound feed for food producing animals'.

Disclaimer
The guidance mentioned below does only apply to the substantiation of the claims. Feed business operators are at all times responsible for adherence to all Legislation in force in the Community regarding manufacturing, processing, administration and distribution of feed as well as applicable National Legislation and good practices. A feed must be safe and not have a direct adverse effect on the environment or animal welfare. According to article 4 of the Marketing of feed regulation, a feed should be sound, genuine, unadulterated, fit for its purpose and of merchantable quality.

The guidance mentioned below can only be used as a voluntary guidance for the composition of claim dossier as it has no legal status. European Legislation can at all times overrule this guidance document and the feed business operators are not obliged to follow this guidance document.

Feed business operators should at all times follow the scientific developments in the field related to the claims they use. When new scientific insight changes the common view on a claimed effect, this cannot be ignored. The substantiation of a claim should always be based on the latest information.

Scope
The dossier requirements mentioned below are entirely applicable for functional claims as defined in chapter 8 (both generic and innovative claims). For non-functional claims, only part I up to III apply. For substantiation of non-functional claims the FEDIAF code of good labeling practice should be used.

Submission of the dossier
In Regulation (EC) No. 767/2009 it is stated that the scientific substantiation shall be available at the time the feed is placed on the market. The person responsible for the labelling of feed shall make available to the competent authorities any information concerning the composition or claimed properties of the feed placed on the market by that person, which allows the accuracy of the information given by the labelling to be verified, including the exact percentages by weight of feed materials used in compound feed.
'Shall make available' does actually mean that a copy of the claim dossier will be send to the competent authority.

General requirements for the conduct of a claim dossier

General requirements:

- Whilst all claims must be verifiable and substantiated, the degree of substantiation will depend on the type of claim. In general the feed business operator shall provide all information, however the feed business operator may submit a dossier not satisfying the requirements below, provided that a justification is submitted for each element not complying with those requirements. For example by providing evidence that the claim in question is widely accepted (generic). For a generic claim the feed business operator may refer to a claim authorised under the Claims Regulation.
- The dossier shall include detailed reports of all the studies performed. The dossier shall include references and copies of all published scientific data mentioned and the copies of any other relevant opinions which have already been produced by any recognised scientific body. Where these studies have already been evaluated by a European scientific body following the Legislation in force in the Community, a reference to the result of the evaluation shall be sufficient. Data from studies that have been conducted and published previously or coming from peer review shall clearly refer to the same product.
- The effect must be maintained over the whole period of time that the feed is given to the animal and cannot be a short term response to which the body adjusts, unless a short or medium term benefit is specifically wanted and relevant.
- The claim must be based on a systematic review of all data, and not only data supporting the claim.

Part I: Administrative data

The following administrative data shall be included in the claim dossier:

- Name and contact details of the feed-business operator;
- Name and description of the product;
- A description of the claims present on the product;
- Characteristics of the product essential to the claim;
- Date of introduction of the claim;
- The full quantitative product composition;
- Example of pack layout and other communication tools;
- If applicable, warnings and contra-indications;
- The animal species or categories, age group or production stage of the target animals;
- Details on the intended use, in feed or water;
- Details on the proposed method of administration and inclusion levels in premixtures, compound feed or water for drinking. In addition, the inclusion levels in the complete feed and the proposed duration of administration and proposed withdrawal period must be provided where appropriate;
- A detailed index with reference to volumes and pages shall be added;
- Each dossier shall contain a detailed scientific summary in order to enable the product concerned to be identified and characterised. The summary should contain information on each part of the documentation submitted to support the claim. The summary must address all the different parts with reference to the relevant pages of the dossier. Additionally it is required for a qualified expert to justify the validity of each claim, using the data provided. In case the claim is supported by literature data, it needs to be clearly indicated how the products/preparations in the literature relate to the product in question with respect to content, type of extract, standardisation, active substances etc.

Part II: **Product quality**

Quantitative and qualitative composition
The full quantitative and qualitative composition of the product should be described. Proof of its allowed use in feed, in the proposed form and concentration, should be given. Copies of the inclusion in the Feed Additive Register, Catalogue of feed Material or the Feed Materials Register should be provided (when applicable). If available, an abstract of the Feed Safety Database should be included as well. For a dietetic feed proof of the inclusion in the annex of Regulation (EU) nr. 2020/354 should be provided.

Impurities
Feed shall comply with the technical provisions on impurities and other chemical determinants set out in Annex I to the marketing of feed Regulation. In accordance with good practice, feed materials shall be free from chemical impurities resulting from their manufacturing process and from processing aids, unless a specific maximum content is fixed in the Catalogue. Substances which are not allowed in animal feed, cannot be present in the feed.

Methods of analysis
The general procedures of the analytical methods to be used for the analysis for the official controls of the ingredient on which the claim is based shall be described. If applicable reference can be made to previous approved methods of analysis (e.g. EURL evaluations of methods of analysis of additives).

Part III: Product safety

The safety of the product for the target species at the highest proposed levels of incorporation in the feed or water for drinking shall be made plausible. Legal or toxicological maximum levels cannot be exceeded.

The daily intake of the product should fit in a balanced diet and should meet the nutritional needs of the target species, and cannot have any detrimental side effects such as unwanted weight gain.

Part IV: Substantiation of a claim

Studies shall demonstrate the claimed efficacy for each proposed use. In case the claim is only substantiated by bibliographical data a justification shall be given.

The basis for the substantiation of claims shall be the direct measurement of the claimed effect. The following basis for substantiation may be used:

- Direct measurement of the effect (hematology or biochemical blood parameters, biomarkers in vitro activity of white cells, antioxidant capacity, zootechnical parameter for reproduction, etc.); or
- Indirect measurement (e.g. mortality or morbidity of young animals for improved immunity); or
- Relation between mode of action and claimed effect (mode of action and general literature on link between mode of action and effect.

The level of substantiation should follow the following guidance:

- If the claim is linked to the presence of a feed additive in its functional group and at the minimum recommended dose, there is no need for further substantiation.

- If the claim is linked to the presence of a specific feed material, the substantiation shall be provided by the feed business operator:

  – Claims shall be substantiated on the basis of scientific information, e.g. peer reviewed journal; report from research institute, field trials with control groups;

  – If the effect is based on mode of action, the mode of action shall be precisely described on the basis of trials or peer reviewed references;

  – Trials shall provide information on the minimum content to be used in order to get the claimed effect;

  – If a claim is already authorised for use in food under the Claims Regulation, no additional substantiation of the claim is needed in case the amount of the relevant component in the feed product is based on the nutritional requirements of the target animal species.

If the claim is linked to a specific composition of the compound feed, the substantiation shall be provided for the specific feed composition on the basis of field trials, preferably with control groups, performed in at least 2-3 farms and related to historical results.

Methodology for compiling a claim substantiation dossier

Experimental protocol

Bibliography

For substantiation of a claim based on bibliographical data, the following sources can be used:

- Reference books and reports: research and technical reference centres, technical institutes, Chamber of Agriculture, etc.;
- Scientific opinions and publications from the National Food Safety Agencies, EFSA, etc.;
- Monographs of the World Health Organisation (WHO), American Botanical Council (ABC), European Scientific Cooperative on Phytotherapy (ESCOP), National Institute of Health (NIH) etc.;
- Publications by renowned scientific authors, etc., peer reviewed scientific journals;
- International congress proceedings.

The following sources are considered unsatisfactory:

- (scientific) publications which only describe part of the claim;
- Links to (scientific) publications or websites;
- Summaries of (scientific) publications;
- Pamphlets, leaflets or statements of individual scientists.

Substantiation by research

For a claim substantiated by research the following rules apply:

Experimental design

The experimental design must be justified in relation to to the use of the product, the animal species and category. If animal studies are performed, the trials shall be conducted in such a way that neither the health status of the animals nor the husbandry conditions can adversely affect the interpretation of results. The positive and negative effects, both technological and biological, shall be described for each experiment. Trials shall ideally be compliant with the criteria established by a recognised, externally-audited, quality assurance scheme.

In the absence of such a scheme, evidence shall be provided to show that the work was done by qualified personnel using appropriate facilities and equipment and responsible to a named study director.

The trial protocol shall be carefully drawn up by the study director with regard to general descriptive data, for example methods, apparatus and materials used, details of the species, breed or strain of the animals, their number and the conditions under which they were housed and fed. For all studies involving animals, the experimental conditions shall be described. Final reports, raw data, study plans and well characterised and identified test substances shall be archived for future reference.

The ‘EU code of good labelling practice for compound feed for food producing animals’ states the following with respect to study design and execution:

- The criteria chosen for the study are clearly identified and explained.

  Examples: average daily gain, fat level, protein level, litres of milk, number of cows with a milk cell concentration, viability, number of pests, number of placenta retentions, of lameness cases, of embryos, biochemical serum dosage, dosage of a special biochemical mediator, etc.
- The criteria chosen for the study are measurable; i.e. can be put into figures and distinguished (yes/no, etc.)
- The method of measurement is acknowledged (‘scientifically valid’) or accurately described (milk yield recording, individual weighing, qualitative or quantitative coprology, biochemical dosage, classification of carcasses, etc.).
- A clear and detailed experimental protocol must be available. The method used for collecting the samples on which the study is based (organs, animals, herd, etc.) must be described.
- The elements specifying freedom from bias of testing devices or their possible limits are explicitly specified (e.g.. sampling representativeness, compliance with random sampling if any, objectivity of criteria or blind criterion in case of subjective criteria, etc.).
- Statistical information processing (comparison of average values, frequency analysis, etc.) and interpretation of statistical results (level of significance, etc.) are described. The purpose is to demonstrate a benefit in a sufficient number of cases in order to justify the use of the examined product or technique.
- Documentary management is clearly defined, e.g. type of documents, validation and filing, etc., and the traceability of all documentary elements relevant to the study is assured and filed.

Studies shall be designed to demonstrate the claimed efficacy of the lowest recommended dose of the product by targeting sensitive parameters in comparison to a negative and, optionally, a positive control group. Such studies shall also include the maximum recommended dose, where this is proposed. No single design is recommended, flexibility being provided to allow for scientific discretion in the design and conduct of the studies.

In vitro studies
For all products affecting the characteristics of feed, efficacy shall be demonstrated using a laboratory-based study. The study shall be designed to cover a representative range of materials to which the product will be applied. Results shall be evaluated preferably by parameter-free tests, and shall demonstrate expected changes with a probability of $P \leq 0,05$. *In vitro* studies, particularly those which simulate aspects of the gastrointestinal tract, may be used for other types of products in order to support the efficacy. These studies should be suitable for statistical evaluation

Short term efficacy studies with animals
Bioavailability studies may be used to demonstrate the extent to which a novel product can substitute for an equivalent product already approved or established. This is only possible if the feed business operator has access to the dossier of the reference product and is able to submit it to the authorities on their request.

Digestion/balance studies may be used in support of animal performance studies to provide evidence of mode of action. In some cases, particularly in relation to environmental benefits, the claimed efficacy may be better demonstrated by balance studies and may be used in preference to long term efficacy studies. Such experiments shall use numbers and species/categories of animals appropriate to the conditions of use proposed.

Other short term efficacy studies with animals may be proposed as appropriate, and these may substitute for long term efficacy studies with animals, provided that this is fully justified.

Long term efficacy studies with animals
The experimental design used must include consideration of adequate statistical power. The protocol must be sufficiently sensitive to detect any effects from the product at the minimum recommended dose ($P \leq 0.05$ in general and $P \leq 0.1$ for ruminants, minor species, pets and non-food producing animals) and of sufficient statistical power to guarantee that the experimental protocol meets the study objective

It is recognised that the nature of some products make it difficult to define experimental conditions under which optimal results may be achieved. Consequently, the possibility of using meta-analysis shall be considered when the number of trials available is greater than three. For this reason, similar protocol designs shall be used for all trials so that data can eventually be tested for homogeneity and pooled (if tests so indicate) for statistical evaluation at a level of $P \leq 0.05$

Duration of long term efficacy studies with target animals
Generally, the duration of efficacy trials shall correspond to the application period claimed. Efficacy trials shall be carried out according to farming practices in European Union and be of the minimum duration as stated by Annex IV of regulation 429/2008/EC.

If a product is applied for a specific and shorter period than given by the animal category definition, it shall be administered according to the proposed conditions of use. However, the observation period shall not be shorter than 28 days and shall involve the relevant end-points. In some specific situations an observation period of 14 days can be accepted. In that case a clear substantiation must be given why an observation period of 28 days is not possible.

For other species or animal categories for which a minimum duration period of studies was not established in Annex IV of regulation 429/2008/EC, a period of administration shall be taken in to account, according to the proposed conditions of use.

Efficacy requirements
Claims referring to a potential effect should be based on at least one trial with significant results (same level of statistical level as in the feed additive guidelines, i.e. $P<0.05$ for monogastrics and $P<0.1$ for ruminants) – in this case, the claim is written as ‘may improve….’

Claims referring to an expected effect should be based on at least three trials with significant results (same level of statistical level as in the feed additive guidelines, i.e. $P<0.05$ for monogastrics and $P<0.1$ for ruminants) – in this case, the claim is written as ‘improves….’

However, for some products having an effect on animals, short term efficacy studies may be accepted if efficacy can be unequivocally demonstrated. Depending on the properties of the product, outcome measures may be based either on performance characteristics (e.g. feed efficiency, average daily gain, increasing of animal products), carcass composition, herd performance, reproduction parameters or animal welfare. Evidence of the mode of action can be provided by short term efficacy studies or laboratory studies measuring relevant end-points.

For products without a direct effect on animals at least one *in vitro* efficacy study shall be provided.

Executive report:

Bibliographic analysis and tests should always lead to the production of a report.

- For surveys or tests, the report should include at least 6 chapters:
  Chapter 1: Introduction (object of the study, context, background)
  Chapter 2: Materials and methods
  Chapter 3: Recorded results
  Chapter 4: Analysis and discussion on results
  Chapter 5: Conclusions
  Chapter 6: Bibliography
- The person responsible for the study and the team of researchers are identified and their vocational qualifications are appropriate;
- The executive report and basic data are saved and kept available for control authorities.

Annex VII Version management

Main adaptations in version 1.4 (May 2023) versus version 1.3 (April 2021)

- Update of the framework based on the revised veterinary legislation
- Hyperlinks adjusted where relevant

Main adaptations in version 1.3 (April 2021) versus version 1.2 (August 2016):

- High concentrate products are deleted
- New legislation on dietetic feed has been added.

Chapter 4:

– The new legislation on veterinary medicinal products is added.

Chapter 6:

– The available lists of the Keuringsraad KOAG/KAG have been adjusted.

Chapter 9:

– The use of the words ‘veterinary’ and ‘veterinarian’ is added.
– The prohibition of mentioning pathogens is highlighted.

Chapter 10:

– Paragraph about the connection between claim and component is further elaborated.

Annex I:

– The new categories of additives are added.

Annex II:

– Hyperlinks have been updated where appropriate.

Main adaptations in version 1.2 (August 2016) versus version 1.1 (June 2014)

Chapter 1:

- Scope of the document has been added.

Chapter 2:

- Definition of labelling has been added.

Chapter 5:

- Change of name SCoPAFF.

Chapter 7:

- Scope of the document has been added.
- Some specific provisions of the Feed marketing Regulation have been added.

Chapter 8:

- The Categories of claims have been brought in line with the 'Code of good practice for the labelling of compound feed for food producing animals'.

Chapter 9:

- The prohibited claims have been brought in line with the 'Code of good practice for the labelling of compound feed for food producing animals'.

Chapter 10:

- The conditions for product based evidence have been brought in line with the current insights of the Dutch Competent Authority.
- Paragraph about the connection between claim and product has been added.

Annex I:

- Definitions have been updated where appropriate.

Annex II:

- Hyperlinks have been updated where appropriate.

Annex IV:

- The Dutch view on the difference between a claim and a function has been clarified.
- For the Dietetic feeds it is stipulated that a name of a disease can only be used when explicitly mentioned in the annex to Regulation (EU) nr. 2020/353.
- Link to the Dutch 'Kruideninformatiebulletin' has been added.

Annex VI:

- Section about the submission of dossiers has been added.

Annex VII

- The old Annex VII has been deleted and a list of amendments has been added.