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EU CODE OF PRACTICE ON VOLUNTARY LABELLING PARTICULARS (CLAIMS) FOR FEED ADDITIVES AND PREMIXTURES

DISCLAIMER:

The purpose of the examples provided in this Code of Practice is to illustrate best industry practice for the management of voluntary labelling particulars for feed additives and premixtures.

The use of the Code by operators is at their own responsibility, and it is always advisable to seek legal and other professional advice.

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1. INTRODUCTION

Article 13 of Regulation (EC) No 767/2009[1] on the placing on the market and use of feed defines labelling as follows:

"'Labelling' means 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".

This therefore allows Feed Business Operators (FBOs) to advertise their feed products, including feed additives and premixtures. However, in its Article 13, the Regulation limits the concept of claims to feed materials and compound feed:

"…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… (§2, article 13)".

Although this article refers to feed materials and compound feed, claims[2] in other types of feed are also a common practice. Furthermore, Article 25 of the Regulation promotes the development and use of codes of good labelling practice to support harmonised implementation of the labelling requirements by FBOs, however limiting it to two specific codes, one for feed for food-producing animals and one for pet food.

The term "claim(s)" is neither defined nor mentioned in Regulation (EC) No 1831/2003[3] on feed additives and premixtures. Nevertheless, it is used throughout Commission Regulation (EC) No 429/2008[4], when referring to "the 'claimed' function" declared by the applicant.

In this regulatory context, FEFANA[5] found it appropriate to develop a specific Code of Practice aiming at harmonizing the implementation of labelling by feed additives and premixtures business operators for reasons of transparency, fair competition and for the sake of predictability. In this Code of Practice the term "voluntary labelling particulars" is used instead of the term "claims", although understood having the same meaning.

[1] 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, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.

[2] Claims are marketing expressions of a function and its associated effect(s) used for advertising their products.

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

[4] 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.

[5] www.fefana.org

1.1 General objectives and scope of the Code

This Code of Practice provides industry guidance to operators for the management of voluntary labelling particulars. It aims specifically at promoting a common and transversal understanding on the use, phrasing and substantiation of claims for feed additives and their premixtures.

Regulation (EC) No 767/2009 and Directive 2008/38/EC[6] on feed for particular nutritional purposes, as well as existing industry and national codes/guidelines addressing claims, their substantiation and phrasing, were taken into consideration for the development of this Code.

The present Code shall be considered without prejudice to EU regulations and laws applying to labelling particulars for feed. Therefore, the users of this Code shall evaluate thoroughly all other labelling rules which might be applicable to their product(s).

This Code of Practice on voluntary labelling particulars is applicable to feed additives, premixtures used for food producing and for non-food producing animals. For compound feeds and feed materials it is also appropriate to refer to existing industry codes:

- Code of good labelling practice for pet food developed by the European Pet Food Industry Federation (FEDIAF);
- Code of good practice for the labelling of compound feed for food producing animals developed jointly by the European Feed Manufacturers' Federation (FEFAC) and the organisation representing European farmers and European agricultural cooperative (Copa-Cogeca).

1.2 Legal framework

The content of the present Code is based on the legal framework referred to below and takes into consideration article 25 of Regulation (EC) No 767/2009, which encourages sectors to develop Community Codes in order to improve the appropriateness of labelling and to bring a common understanding with regard to the rules applicable to voluntary labelling.

1.2.1 Information to the users

Article 16 of Regulation (EC) No 178/2002[7] (the General Food Law) requires that the labelling, advertising and presentation of feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Those principles are further described in article 11 of Regulation (EC) No 767/2009. In particular, it requires that labelling and the presentation of feed shall not mislead the user:

[6] COMMISSION DIRECTIVE 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes.

[7] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

a) *as to the intended use or characteristics of the feed, in particular, the nature, method of manufacture or production, properties, composition, quantity, durability, species or categories of animals for which it is intended;*

b) *by attributing to the feed effects or characteristics that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feeds possess such characteristics; or*

c) *as to the compliance of the labelling with the Community Catalogue and the Community Codes of Practice.*

1.2.2 Voluntary labelling particulars

In relation to voluntary labelling and with regards to claims in particular, article 13 of Regulation (EC) No 767/2009 specifies that 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.

Similarly, as applicable to feed materials and compound feed[8], voluntary labelling particulars on feed additives and premixtures (section 1.1) are conceivable ensuring that:

- Those are objective, verifiable by the competent authorities and understandable by the user of the feed;
- The person responsible for the labelling is also responsible for its truthfulness and is able to provide scientific substantiation of the voluntary labelling particular(s) at the request of a national competent authority. As expressed in Regulation (EC) No 767/2009, a claim may be scientifically substantiated by taking into account the totality of the available scientific data, and by 'weighing' the evidence. This will be further elaborated in this Code of Practice.

The voluntary labelling particular should be made in accordance to the principles laid down in Regulation (EC) No 1831/2003 and Regulation (EC) No 767/2009, as amended.

2. USER GUIDE

This Code provides guidance on the management of voluntary labelling particulars for feed additives and premixtures (section 1.1). It lays down the general principles that should be followed (section 1.2.2 and section 4.1) and recommends the level of substantiation required for demonstration of the voluntary labelling particular. Two levels of voluntary labelling particulars are described in the Code: voluntary labelling particulars can be either directly related to the principal function of a feed (i.e. authorised function) or a consequence of that principal function (i.e. associated effect) (see section 4.2).

In addition, different types of voluntary labelling particulars can be made (e.g. comparative, qualitative, physiological) (see section 4.6) which, according to their phrasing and weight, would

[8] Article 13 of Regulation (EC) No 767/2009.

require different level of substantiation (i.e. substantiation classes) (see section 4.5.1). Articulation between those concepts is illustrated in Figure 2.

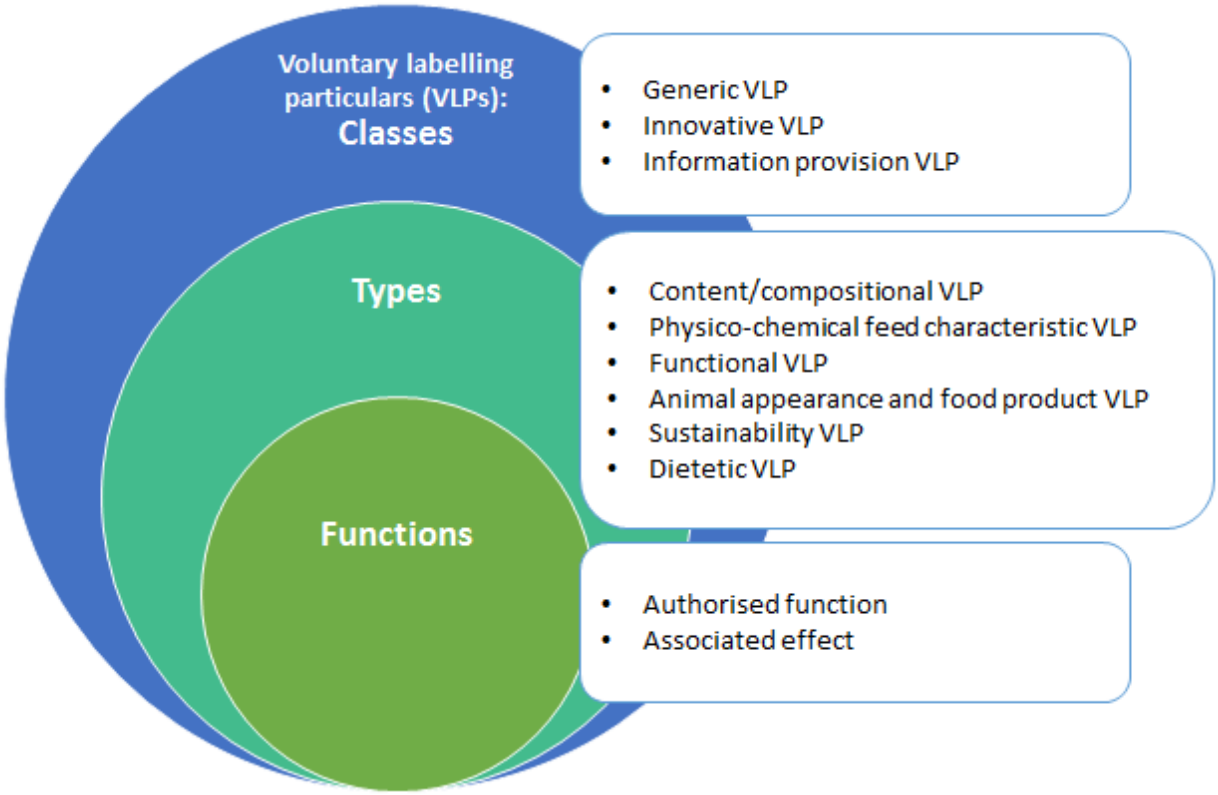

Figure 2 – Voluntary labelling particulars (VLPs): classes, types and functions

The following appendixes are also an integral part of the Code:

- Appendix I – Assessment check list;
- Appendix II – Examples of non-permitted voluntary labelling particulars;
- Appendix III – List of guidance documents;
- Appendix IV – Glossary.

3. ASSESSMENT CHECK LIST

A checklist to help feed business operators is proposed (Appendix I). It aims to assist in ascertaining that all relevant points are taken into account when developing a voluntary labelling particular for feed additives and premixtures.

Feed business operators should take into consideration that:

- Voluntary labelling particulars need to be assessed on a case by case basis;
- Voluntary labelling particulars allowed under a given legal framework might not be acceptable/allowed in another situation[9];
- Voluntary labelling particulars accepted by some competent authorities might be refused by others, even within the same country or region (e.g. within EU);

[9] E.g. a veterinary claim is not accepted under Regulation (EC) 1831/2003, but may be acceptable if complies with requirements of the veterinary medicinal products (Directive 2001/82/EC).

- Any voluntary labelling particular shall be supported by data, appropriate information and/or authorisation. A substantiation dossier (per voluntary labelling particular or per product) shall be available at the time the feed is placed on the market and shall be provided at the request of the competent authorities. On request, operators must be prepared to provide justifications and to be challenged on the content of the substantiation dossier. If a voluntary labelling particular is related to the authorised function only, no substantiation dossier is necessary and the reference to the authorisation and/or the EFSA opinion is sufficient.

4. VOLUNTARY LABELLING PARTICULARS

4.1 General principles

Voluntary labelling particulars are permitted if the following principles are observed:

- Voluntary labelling particulars shall comply with the general principles set for claims for feed materials and compound feeds (i.e. article 11 §1a and §1b and article 13 of Regulation (EC) No 767/2009);
- Voluntary labelling particulars shall not mislead the users on the intended uses;
- Voluntary labelling particulars must provide a clear link to the feed it refers to, as well as to characteristics of the product;
- Voluntary labelling particulars shall be understandable, meaningful, measurable, objective and demonstrable;
- Voluntary labelling particulars shall be substantiated according to the substantiation classes defined in this Code;
- Voluntary labelling particulars shall be re-evaluated with reasonable frequency, considering new scientific evidences;
- Voluntary labelling particulars shall be verifiable by competent authorities.

4.2 Functions and associated effects

4.2.1. Functions and voluntary labelling particulars for feed additives and premixtures

According to article 6 §2 of Regulation (EC) No 1831/2003 feed additives shall be allocated to one or more functional groups, according to their principal function or functions. Two levels of voluntary labelling particulars are proposed for feed additives:

- Voluntary labelling particular(s) on the authorised function(s) and
- Voluntary labelling particular(s) on the associated effect(s).

a) Authorised function(s)

The **authorised function(s) of a feed additive** is the function(s) for which the additive is **authorised**. Since one additive may have several authorised functions, the claimed function(s) can only be related to categories and/or functional groups for which the additive is authorised; and as per the authorised conditions of use (e.g. use levels and target species).

Such voluntary labelling particular(s) are the marketing expression of the authorised function(s) of feed additives. They are only possible in relation with the functional group(s) for which the additives are authorised. It is not permitted to claim a function listed in Annex I of Regulation (EC) No 1831/2003 if the additive is not authorised for that function (see section 4.3).

Example of permitted authorised voluntary labelling particular: *"Feed X protects feed against deterioration caused by microorganisms" → Label of Feed X refers that product contains propionic acid (E280), which is authorised as 'preservative'. Indeed, Annex I of Regulation (EC) No 1831/2003 defines 'preservatives' as "substances or, when applicable, micro-organisms, which protect feed against deterioration caused by micro-organisms or their metabolites".*

Example of non-permitted authorised voluntary labelling particular: *"Feed X reduces contamination of mycotoxin during storage" → Label of Feed X refers that product contains propionic acid (E280), which is only authorised as 'preservative' while the voluntary labelling particular fits the definition of another existing functional group. In fact, as per Annex I of Regulation (EC) No 1831/2003, this function is exerted by "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.*

b) Associated effect(s)

Associated effects(s) are the marketing expression of the direct consequence(s) of the authorised function(s). The associated effect cannot be an existing additive function listed in Annex I of Regulation (EC) No 1831/2003.

Although the level of substantiation of a voluntary labelling particular does not differ between authorised function(s) and associated effect(s), understanding this concept is important to consider the information required to substantiate the voluntary labelling particular (e.g. specific product trials vs. literature data).

Example of permitted associated effect: ***"****Feed X prevents growth of mould and therefore formation of mycotoxin during storage" → Label of Feed X refers that product contains propionic acid (E280), which is authorised as preservative and then states the direct consequence of prevention of mould growth. Note that "…formation of mycotoxin during storage" is the associated claim. Wording is very much important, e.g. use of word "formation" and not "reduction of contamination".*

Example of non-permitted associated effect: ***"****Feed X prevents growth of mould and therefore reduces contamination of mycotoxin during storage", since this is a function of an existing functional group, for which an authorisation would be required. As per Annex I of Regulation (EC) No 1831/2003 this function is exerted by "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".*

4.3 Non-permitted statements

An exhaustive list of "types of claimed effects[10]" acceptable under the scope of this Code is presented in section 4.6. Therefore, voluntary labelling particulars that cannot be categorized under those types are *out of scope* or non-permitted.

In agreement with article 13 § 3 (a and b) of Regulation (EC) No 767/2009, it is not permitted to claim that feed additives and/or their premxitures:

(a) 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) has a particular nutritional purpose, as listed in Directive 2008/38/EC, as amended, unless it satisfies the requirements laid down there.

Other statements concerning optimisation of the nutrition and support or protection of the physiological conditions are permitted (see also section 4.4).

4.3.1 Examples of non-permitted statements

1. Veterinary claims: claims on prevention, treatment, cure of diseases;
2. For feed additives, feed additive function(s) related to a category and/or a functional group of additives for which it is not authorised and/or cannot be defined as authorised function or associated effect (see section 4.2);
3. Misleading statement(s): statement(s) infringing the principles for labelling and presentation of feed as described in article 11(b) of Regulation (EC) No 767/2009 (i.e. by attributing to the feed effects or characteristics that it does not possess or by suggesting that it possesses special characteristics when in fact all similar feeds possess such characteristics; see also section 1.2.1);
4. 'Dietetic feed like' claims on a product that by composition does not support such a particular nutritional purpose listed in Directive No 2008/38/EC (see sections 4.6.6);
5. Other 'non-permitted statements':
   - 'Non-sense statements' are those with no link between the feed as such and the benefit (e.g. description of 'non-feed' like devices, equipment, personnel, buildings, etc.);
   - 'Indispensable use statement(s)' are those stating the indispensable necessity of a feed additives and premixtures;
   - 'Indirect statement(s)' are those made via images or descriptions that would give misleading perception about a feed additive or premixture and suggest that it has a particular effect (e.g. on a document pertaining to the product the following is mentioned:

[10] The 'types of claimed effects' take into account characteristics such as functionality, mode of action, maintenance of health and well-being and technical and physical aspects suitable to feed additives and their premixtures.

'*Approximately 10% of all dogs suffer from arthritis*'. It is not mentioned that the product itself cures arthritis; however, it gives the impression that is does have a beneficial effect in dogs with arthritis. Such indirect statements are not allowed since any general information somewhat linked to the product can be seen as a recommendation of that particular product[11]);

- The name of a product could also generate some misunderstanding and can lead to a misleading interpretation (e.g. a product name containing the words "BIO" or "organic" although, by composition, it can be used in organic production according to the EU legal framework[12], but cannot be certified as organic).

Examples of the above listed non-permitted statements are detailed in Appendix II including justifications for non-acceptance.

4.4 Phrasing/wording

The context into which a statement is made (see 'indirect statement(s)' in section 4.3.1 above) and its phrasing are of utmost importance to assess its correct use. Any phrasing/context that indicates or implies an effect not applicable to feed may lead to its non-acceptance i.e. is a non-permitted statement.

As a result, some words, phrases, and definitions are considered unacceptable, namely:

- Names/descriptions of diseases/afflictions/ailments/detrimental physiological conditions and their respective treatment;
- Treatment indications, when related to a disease, identifiable and accompanied by terms like: cure(s), dose, treat, treatment, prevents, heals, medicate;
- Context describing any of the above with the goal to promote a product (e.g. indirect veterinary claim via pictures or articles, see also section 4.3.1 and 5);
- Product names that imply any of the above.

In contrast, the following expressions are not considered as related to veterinary products and can be used: 'help', 'stimulate', 'improve', 'support', 'provide', 'maintain' and/or 'optimise' etc. as long as they refer to normal functions of the body, in the sense of assisting in maintaining the good health, well-being or performance of the animals and/or the characteristics of the feed. Those expressions can be used in connection with terms such as "health" or "immunity" as long as the effects are on animals in good health.

The extent to which certain terms can or cannot be used strongly depends on the exact wording and on the context. For example, the statement *'Product X helps to maintain the animal's good digestive health*' is acceptable since digestion is a normal function of the body; and the wording does not suggest that the digestive system of the animals is affected.

[11] Guidance on the substantiation of Claims made on Animal Nutrition - Veterinary Medicinal Products Unit - The Netherlands - August 2016 (version 1.2)

[12] REGULATION (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.

However, stating '*Product X enhances health in case of digestive disorders*' is not allowed, as an impaired digestion is not part of a normal physiological functioning of the body. The use of such health-related statement is restricted to veterinary medicinal products (and medicated feed containing them) and/or feed for Particular Nutritional Purpose (dietetic feed) authorised accordingly, if existent.

Depending on the context, statements such as '*calcium supports the healthy condition of bones*', '*supports gut/intestinal health*', '*supports immune system*' could be acceptable (see Chapter 3 and Appendix I).

Due to the precedence of the feed legislation over the legislation on biocidal products (Regulation (EC) No 528/2012[13]), the use of words and/or phrases such as "destroying", "deterring", "rendering harmless", "preventing the action of", or otherwise exerting a controlling effect on any harmful organism are allowed when the effect is on the feed itself.

4.5 Substantiation

Substantiation[14] should be **available at the time the feed additive and/or the premixture is/are placed on the market** and shall be presented to the competent authority upon request. It can consist of several parts:

- Introduction (e.g. context, background, information on the feed business operator);
- Identity of the product;
- Substantiation of the voluntary labelling particulars (i.e. efficacy and/or functionality and/or composition);
- References.

Requirements of Regulation (EC) No 429/2008, regarding the preparation and the presentation of applications and the assessment and the authorisation of feed additives (sections 2/identity and section 4/efficacy) can be used as a guide to prepare a substantiation dossier. Substantiation of a voluntary labelling particular can also be based on the mode of action of the feed additive and/or premixture.

The phrasing and weight of a voluntary labelling particular (see section 4.4) determines the substantiation required.

4.5.1. Information to present for substantiation

a) Composition evidence

Description of the formulation and content of certain substances can be used for statements based on the presence/absence of this substance. In this case, the substance referred to must

[13] 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.

[14] If the voluntary labelling particular is only related to the authorised function of the feed additive, a dedicated substantiation dossier is not necessary and it is sufficient to refer to the authorisation of the feed additive and/or the relevant EFSA opinion.

either be present and available to the animal in quantities sufficient to ensure the claimed effect or absent if the absence is the stated characteristic.

b) Literature search

To select the appropriate scientific data from existing information the following methodology shall be used:

- Product(s) reported in the reference shall be of comparable composition or quality as the feed on which the statement is made;
- Demonstration and/or explanation of the mode of action shall be used if available/applicable;
- Documents selected to support the statement shall be objective and representative of all the studies and the conclusions should be available.

In case of meta-analysis, the selection of the studies shall be clearly explained in order to demonstrate that all data (significant and non-significant) have been taken into account.

c) Study reports

Feeding (in vivo) trials

Studies shall report the following information:

- Aim of the trial according to the claimed effect;
- Animals used (age, physiological status, number, breed);
- Protocol: experimental design, duration of experimental period, number of treatments, quantity of product used, feed composition;
- Sampling methodology: organ(s) sampled, analytical method(s);
- Description of the statistical test and analysis (incl. all raw data).

In silico and in vitro trials

As in the case of feeding trials, reports should be sufficiently detailed and contain all the necessary information to support the statement (protocol, end-points, statistical analysis, etc.).

4.5.2. Aspects to consider for substantiation

Three classes of substantiation are defined based on the type of information used to create a statement. The substantiation class determines the level of information required.

a) Generic class

Substantiation based on '*generic information*', i.e. well documented information accessible to everyone.

This is, for example, the case of information available in the authorising regulation of a feed additive, textbooks, publically available monographs, scientific opinions and publications of international and national authorities, in peer reviewed scientific journals and proceedings of conferences.

Such approach is possible when the available knowledge can be extrapolated to the feed additive/premixture on which the statement is made. Operators should, for example, demonstrate that their feed additive/premixture has similar characteristics, based on its content or mode of action, as the feed additive(s)/premixture(s) on which information is available, or that the information referring to a given target species is applicable to other species.

b) Innovative class

The term *innovative* refers to a unique statement based on newly developed information and therefore cannot be based on existing substantiation. Innovative statements shall be supported by additional information specific to the feed additive/premixture on which the statement is made e.g. from in-house research report(s) or scientific opinions for a new authorisation in case of feed additives.

A premixture could also be considered as innovative, based on the synergetic effects between its components, while making sure the statement does not relate to a functional group in which the additive(s) in the premixture is(are) not authorised.

c) Quantitative/qualitative class

Those are voluntary labelling particulars that describe a characteristic of a feed that can only be proven by proper documentation and/or control. Information to support the voluntary labelling particular is either quantitative (e.g. '*particle size above 100 µm*', '*pellets of Feed X measure 5 to 7 mm*') or qualitative (e.g. '*can be used in organic farming*'). They are substantiated with official documents such as statements from control agencies or authorities, legal texts, or with analytical certificates or in-house statements.

Such voluntary labelling particulars can lead to 'generic' and/or 'innovative' statements: e.g. '*Pellets of compound Feed X measure 5 to 7 mm ensuring a good uptake by the animal*'.

Other elements to consider:

1. Voluntary labelling particulars on the authorised function of a feed additive are restricted to its terms of authorisation(s) (see section 4.2).
2. The substantiation depends on the nature of the feed additive(s) and/or their premixture(s) and on the 'weight' of the voluntary labelling particular made on these products (e.g. 'may' voluntary labelling particular *versus* 'does' voluntary labelling particular).
3. Studies used for substantiation shall provide information on the recommended use level needed to elicit the claimed effect of the feed additive and/or the premixture. Efficacy is considered demonstrated when a statistically significant difference is shown between a treatment group and a control group (same level of statistical level as in the feed additive guidelines, i.e. $p < 0.05$ for monogastrics and $p < 0.1$ for ruminants and pets). Additionally, the following should be considered[15]:

[15] COPA-COGECA / FEFAC Code of Good labelling practices for compound feed for food producing animals

- If the voluntary labelling particular is linked to a certain composition, the substantiation shall be provided for the specific or comparable product based on animal trials.
- Voluntary labelling particulars referring to a potential effect (i.e. 'may' voluntary labelling particular) can be based on one trial. In this case, the voluntary labelling particular is written as 'may improve'.
- Voluntary labelling particulars referring to an expected effect (i.e. 'do' voluntary labelling particular) should be based on at least three trials with meaningful results. In this case, the voluntary labelling particular is written as 'does/do improve'.

Table 1 summarises the substantiation level required for different types of feed additive(s) and/or their premixture, considering the voluntary labelling particular classes (see above) and categories (section 4.2).

Table 1. Type of substantiation required for feed additive(s) and/or their premixtures.

Number of studies/supportive information	Products
0	Voluntary labelling particulars on authorised function of a feed additive
	Voluntary labelling particulars on authorised function of the feed additive(s) included in a premixture
1	Voluntary labelling particulars on associated effect(s) of a feed additive
	Voluntary labelling particulars on associated effect(s) of the feed additive(s) included in a premixture
	Premixture or complementary feed with "may" voluntary labelling particulars
3	Premixture with innovative "do" voluntary labelling particulars

4.6 Types of voluntary labelling particulars

In this section, the different types of voluntary labelling particulars that can be made on feed additives and their premixtures are presented along with their definition and substantiation needed for supporting the voluntary labelling particular(s). Several voluntary labelling particulars (from the same or different types) can apply simultaneously to the same feed additive and/or premixture. Examples are further provided.

The 'types of voluntary labelling particulars' take into account characteristics such as functionality, mode of action, maintenance of health and well-being as well as technical and physical aspects suitable to feed additives and premixtures as such or when included in a compound feed.

4.6.1 Content/compositional voluntary labelling particulars

Content or compositional voluntary labelling particulars refer to the presence/absence of certain ingredients, which result in certain characteristics of a product in comparison with other feed products.

4.6.1.1 Comparative voluntary labelling particular	
Definition	It refers to the difference in the quantity of a nutrient, the compositional analysis and/or the physico-chemical characteristics of a feed as compared to other feeds.
Substantiation	The comparative voluntary labelling particulars can be based on analysis, technical data or production process descriptions.
Examples	➢ Feed X contains a higher content of omega-3 than Feed Y. ➢ Feed X provides a better stability to steam pelleting during processing than Feed Y. ➢ New Feed X: new formulation for less dust.

4.6.1.2 Quantitative voluntary labelling particular	
Definition	It refers to the quantitative content of a specific substance or ingredient made on a voluntary basis. The voluntary labelling particular refers to the total content of this substance/ingredient in the feed. The quantity should be guaranteed and labelled.
Substantiation	Quantity can be guaranteed by analysis or formula. Stability data can be provided to support the voluntary labelling particular.
Examples	➢ Feed X contains xx mg of Vitamin B12 per kg. ➢ Feed Y is stable at pelleting up to 90°C.

4.6.1.3 Qualitative voluntary labelling particular	
Definition	It refers to qualitative aspects of the feed as well as to the absence or presence of a specific substance.
Substantiation	The voluntary labelling particular can be supported by product data sheet, certificate(s) of analysis, official documentation (e.g. issued by authorities or certification bodies). To be noted: ➢ Obvious absence or presence cannot be claimed. ➢ A voluntary labelling particular such as "GMO free" cannot be made, unless the feed is in line with Regulations (EC) No. 1829/2003[16] and 1830/2003[17], as amended. ➢ "Not added…", "without added…", "formulated without…", "made without…" imply that the substance has not been deliberately added to the product either directly via formulation or indirectly via feed materials or feed additives. ➢ "Absence" or "free" mean that there are not even traces of the substance claimed

[16] REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed.

[17] REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

	to be absent (i.e. the substance is not present at detectable levels in the product).
Examples	➢ Feed X does not contain added synthetic colourants. ➢ Feed X contains only organic compounds of trace minerals. ➢ Feed X is an organic certified feed. ➢ Feed X is produced in a facility with approval number xxxx and which is FAMI-QS certified.

4.6.2 Voluntary labelling particulars on physico-chemical characteristics of feed

These voluntary labelling particulars refer to improvement of physico-chemical characteristics of feed resulting from (1) a specific production process or (2) the use of certain feed additives and premixtures.

4.6.2.1 Characteristic of feed via process	
Definition	It refers to the characteristics of a feed (e.g. grist size, flowability, lack of dust) that can be positively affected via specific production process(es).
Substantiation	The claimed parameters (e.g. dust content, flowability etc.) should be measured with appropriate methods, if possible, internationally recognized.
Examples	➢ Feed X is produced with the patented "low dust drying technology" that enables to manufacture a dust free product (dusting potential lower than xx g/m^3). ➢ Feed X is produced with the patented "free granulate technology" that enables to manufacture a free flowing product.

4.6.2.2 Characteristic on feed via use of feed additives and premixtures	
Definition	It refers to the characteristics of a feed specifically related to the presence of a technological or sensory additive.
Substantiation	Demonstration with information on the composition of the product (e.g. via a product data sheet) is sufficient when the effect is due to the authorised function of a feed additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2.
Examples	➢ Use of "*thymus* aroma mix" gives a typical thyme flavour to Feed X. ➢ "Colorant X" restores the colour of canned wet pet food. ➢ "Pellet binder X" improves pellet durability index.

4.6.3 Functional voluntary labelling particulars

Functional voluntary labelling particulars are related to optimisation of the nutrition and support or protection of the physiological conditions. These may refer to maintenance of animal health, animal welfare and vitality and/or to the contribution to an appropriate diet fulfilling the physiological and behavioural needs of the animals.

Three 'functional' voluntary labelling particulars are identified:

4.6.3.1 Animal performance voluntary labelling particular	
Definition	It refers to feed maintaining and/or enhancing the performance of animals.
Substantiation	Demonstration with information on the composition of the feed (e.g. via a product data sheet) is sufficient when the effect is due to the presence of an authorised feed additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2.
Examples	➢ Feed X increases body weight gain. ➢ Feed X improves the feed conversion ratio (FCR). ➢ Feed X improves the milk/meat yield. ➢ Feed X increases the egg-laying rate. ➢ Feed X positively affects survival rate.

4.6.3.2 Feed efficiency voluntary labelling particular	
Definition	It refers to feed enhancing the efficiency of final feed, improving the availability and/or increasing the digestibility of the nutrients.
Substantiation	Demonstration with information on the composition of the feed (e.g. via a product data sheet) is sufficient when the effect is due to the presence of an authorised feed additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2.
Examples	➢ Feed X improves the feed conversion ratio (FCR). ➢ Feed X increases nutrient retention/absorption. ➢ Feed X increases nutrient digestibility/degradability.

4.6.3.3 Physiological condition voluntary labelling particular	
Definition	It refers to products helping to support or to protect physiological conditions[18] of the animal or to enable maintenance of physiological status, and/or linked to basic nutritional requirements.
Substantiation	Demonstration with information on the composition of the product (e.g. via a product data sheet) is sufficient when the effect is due to the presence of an authorised feed additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2.
Examples	➢ Feed X enhances fertility of sows. ➢ Feed X supports the immune system of salmonids. ➢ Feed X supports the liver functionality of dairy cows. ➢ Feed X supports gut health of young broilers.

[18] Reg. (EC) No 767/2009 - Article 13(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)."*

4.6.4 Voluntary labelling particulars on animal appearance and quality of products of animal origin

These types of voluntary labelling particulars are referring to enhanced appearance of animals (mainly non-food producing animals) or improved quality of products of animal origin due to the presence/absence of certain ingredients in the diet.

Two 'appearance' voluntary labelling particulars are identified:

4.6.4.1 Enhancement of characteristics of the animals	
Definition	It refers to feed that can improve the coloration of skin, feathers or other phenotypical characteristics of the animals.
Substantiation	Demonstration with information on the composition of the feed (e.g. via a product data sheet) is sufficient when the effect is due to the presence of an authorised feed additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2.
Examples	➢ Feeding feed product X will result in a visible stronger tone of orange in your ornamental fish and birds. ➢ Feeding product X ensures a shiny and clean look of the fur.

4.6.4.2 Enhancement of characteristics of food products of animal origin	
Definition	It refers to feed that can improve the coloration or nutritional characteristics of food of animal origin.
Substantiation	Demonstration with information on the composition of the feed (e.g. via a product data sheet) is sufficient when the effect is due to the presence of an authorised feed additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2.
Examples	➢ Feeding feed X will result in a visible stronger tone of yellow of the egg yolk or of the prepared broiler skin. ➢ Feeding feed X will result in a visible stronger tone of red of salmonids' flesh. ➢ Feed Y at a concentration of xx mg/kg complete feed increases the Vitamin D content of trout flesh. ➢ Feeding feed X may reduce numbers of Enteropathogens on broiler carcasses.

4.6.5 Sustainability voluntary labelling particulars

This type of voluntary labelling particulars refers to the impact of a product on sustainability. This can therefore be related to social responsibility, economic development or environmental protection.

4.6.5.1 Sustainability voluntary labelling particular	
Definition	Sustainability voluntary labelling particulars can refer to social, economic or environmental aspects.
Substantiation	Demonstration with information on the composition of the feed (e.g. via a product data sheet) is sufficient when the effect is due to the presence of an authorised feed

	additive. Otherwise evidence can be provided via scientific literature or study reports as described in section 4.5.2. Examples of substantiation: ➢ Concentration of phosphate in feed; ➢ Certification from RSPO (Round Table on Sustainable Palm Oil) or from RTRS (Round Table on Responsible Soy); ➢ ISO 22000 certification; ➢ LCA (Life Cycle Assessment) analysis according to the Product Environmental Footprint rules from the EU; ➢ Information on the energy sourcing from the company; ➢ Information on emission compliance of the factory; ➢ Local environmental certifications; ➢ Demonstration of economic development (local employment figures in regions with elevated unemployment figures); ➢ Information of local sourcing of raw materials.
Examples	<u>Voluntary labelling particulars on sustainable use of resources</u> ➢ Raw materials sourcing: - 'sourced from certified sustainable production area', e.g. RSPO (Round Table on Sustainable Palm Oil), RTRS (Round Table on Responsible Soy); - 'reduce the use of feed materials in compound feed that may have an impact on deforestation'. ➢ Resource depletion: - 'sourced from renewable raw materials'; - 'reduce the use of non-renewable phosphate source'. <u>Voluntary labelling particulars on sustainable production processes</u> ➢ Responsible production of products: - 'produced with renewable energy sources'; ➢ Biodiversity: 'takes into account the effect of human activities on… habitat alteration/ eutrophication/ deforestation'; ➢ Human health and safety: 'has a possible human health promoting outcome when fed to animals'. <u>Voluntary labelling particulars on environmental effects</u> ➢ Reduces the emission of ammonia from manure management; ➢ Feed X contributes to the reduction the quantity of nutrients (to be defined) loss in the manure; ➢ Feed X contributes to reduced emission of greenhouse gases (to be defined); ➢ Feed X contributes to the reduction of the environmental footprint of animal production. <u>Voluntary labelling particulars on social sustainability</u> ➢ Feed X is manufactured to reduce dust exposure for workers and end-users; ➢ Feed X is manufactured to reduce the contact/exposure of workers and end-users with the active substances; ➢ Feed X ingredient(s) are locally sourced; ➢ Feed X is produced with local labour from an economical developing area.

4.6.6 Dietetic feed claims (Particular Nutritional Purpose claims)

Those are claims that can be made on feeds that carry a dietetic feed 'tag' and this tag should be added to the designation of the feed as a qualifying expression as stated in article 18 of Regulation

(EC) No 767/2009. The tag is provided by the attribution of a particular nutritional purpose to that specific feed. The claims that reflect the functionality of the feed itself must be as much as possible in line with the entry in Directive 2008/38/EC.

4.6.6.1 Dietetic feed claims	
Definition	It refers to the role of feed additives to be included into compound feeds as such or via premixture, and whose use is according to Directive (EC) No 2008/38 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes, as amended.
Substantiation	Because dietetic claims are regulated, substantiation should in principle be limited to "formulation and labelling evidence" showing that the feed/product complies with the requirements set in Directive (EC) 2008/38 for that Particular Nutritional Purpose (PNP). However, it is recommended to have data from at least one efficacy trial to demonstrate that the PNP applies to the product on which the voluntary labelling particular is made.
Examples	➢ 'Feed X is a complementary dietetic feed that stabilizes the water and electrolyte balance in case of digestive disorders'. ➢ 'Feed X is a good option in case of diarrhoea'.

APPENDIX I – VOLUNTARY LABELLING PARTICULARS ASSESSMENT CHECK-LIST

This list is a helping tool to address voluntary labelling particulars. It aims at assuring that all relevant aspects of this Code are taken into account.

Reminder:

- Voluntary labelling particulars should be assessed on a case by case basis;
- Some voluntary labelling particulars might not be acceptable/allowed under a certain legal framework but allowed under another[19];
- Some voluntary labelling particulars might be accepted by some competent authorities, but not by others, even within the same country or region;
- Any voluntary labelling particular should be substantiated and the substantiation should be available at the time the feed is placed on the market.

	Questions	Reference	Comments
1	To which product does the voluntary labelling particular refer to? (feed additive or premixture)	Section 1.1	
2	Is the phrasing of the voluntary labelling particular acceptable? Did you check whether it is misleading?	Sections 1.2.1 & 4	
3	If "yes" to Q2, in which legal framework is it accepted?	Section 1.2.2	
4	Has other applicable guidance/guidelines be taken into account	Appendix III	
5	Is it a valid principal voluntary labelling particular?	Section 4.2	
6	If "no" to Q5: is it a valid associated effect voluntary labelling particular?	Section 4.2	
7	Which type of voluntary labelling particular is it? (this shall guide which type of substantiation is needed)	Section 4.6	
8	Has the product composition been considered while addressing the voluntary labelling particular?	Section 4.5.1	
9	How should the voluntary labelling particular be substantiated?	Sections 4.5 & 4.6	
10	It is necessary to compile a substantiation	Section 4.5	

[19] E.g. a veterinary claim is not accepted under regulation (EC) 1831/2003, but may be acceptable if complied with requirements of the veterinary medicines regulation.

	dossier for this type of voluntary labelling particular?		
11	If “yes” to Q10: has the substantiation dossier been compiled?	Section 4.5	

APPENDIX II - EXAMPLES OF NON-PERMITTED VOLUNTARY LABELLING PARTICULARS

Examples	Justifications for rejection of the voluntary labelling particular	Type of non-permitted voluntary labelling particular (see 4.3.1)
'Feed (additive) X' enables treatment of Newcastle disease	Veterinary claims not allowed according to Article 13 of Regulation (EC) 767/2009.	1. Veterinary claim
Ketosis is a serious problem on a dairy farm. 'Feed (additive) X' works perfectly to provide glycogenic energy sources.	The first sentence of the voluntary labelling particular is making the link with a veterinary issue with the goal to promote a feed product. Veterinary claim not allowed according to Article 13 of Regulation (EC) 767/2009.	1. Veterinary claim
Ketosis is a serious problem on a dairy farm. 'Feed (additive) X' reduces the risk of ketosis.	This is a dietetic claim acceptable only if the characteristics of the feed meet the requirements set in the authorisation for the claimed particular nutritional purpose (see section 4.6.6); otherwise, non-permitted voluntary labelling particular.	1. Veterinary claim and 4. Dietetic claim
Efficiency of 'Feed X' is improved when 'Premixture of Feed preservatives Y and Z' is used.	Improve efficiency of feed is a zootechnical voluntary labelling particular (i.e. a principal function) and would require the authorisation of the Feed preservatives Y and Z as zootechnical additives. In contrast, that voluntary labelling particular would be allowed in case of a feed material or mixture having similar effect.	2. Functionality voluntary labelling particular
'Flavouring compound X' has feed antioxidant properties.	Antioxidant is a functional group under the category of Technological additive (i.e. a principal function). Such voluntary labelling particular would require a specific authorisation of the 'Flavouring X' as antioxidant.	2. Functionality voluntary labelling particular
'Feed X' is edible.	The claimed characteristic is common to all (similar) feeds.	3. Misleading voluntary labelling particular
'Feed X' increases milk	Non-sense voluntary labelling	5. Other non-permitted

production because it is blue.	particular.	voluntary labelling particular
'Feed X' is needed in order to improve milk production yield	Indispensable use voluntary labelling particular (other products available on the market may have the same effect).	5. Other non-permitted voluntary labelling particular
Veterinary reference (article or picture) linked to a non-medicated feed	Indirect voluntary labelling particular.	5. Other non-permitted voluntary labelling particular

APPENDIX III - GUIDANCE DOCUMENTS

Source	Reference Guidance
BE	List of acceptable claims (French and Dutch only)
NL	Guidance on the substantiation of Claims made on Animal Nutrition
DE	Guideline for the Labelling of Feed Materials and Compound Feed
UK	Guidance on the Interpretation and Application of Certain Aspects of European Parliament and Council Regulation 767/2009 of 13 July 2009 on the Placing on the Market and Use of Feed
DK	Guidance on feed and feed companies (Danish only)
CH	Vertus thérapeutiques prêtées à des préparations non autorisées par Swissmedic (French only)
British Equestrian Trade Association (UK)	Code of Practice for the Marketing of Equine Feeding Stuffs
FEDIAF	Code of good labelling practice for pet food
FEFAC / COPA-COGECA	Code of Good labelling practices for compound feed for food producing animals

APPENDIX IV – GLOSSARY

A. Definitions from legislation

Term	Definitions	References
Competent authority	The authority of a Member State or of a third country designated to carry out officials controls.	Regulation (EC) No 183/2005 Article 3, 2(e)
Compound feed	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.	Regulation (EC) No 767/2009 Article 3, 2(h)
Feed or Feedingstuff	Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.	Regulation (EC) No 178/2002 Article 3, 4
Feed additives	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) of Regulation (EC) No 1831/2003. NOTE THAT: for the purposes of this Code, the wording 'feed additive' only refers to feed additives authorised as per Regulation (EC) No 1831/2003 and to substances that would qualify as feed additives according to the same Regulation. It is advisable to use the FEFANA classification tool (http://www.fefana.org/ClassTool/) to confirm whether the substance falls into the feed additives classification.	Reg. (EC) No 1831/2003
Feed business	Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding.	Regulation (EC) No 178/2002 Article 3, 5
Feed business operator	Natural or legal person responsible for ensuring that the requirements of the food law and feed hygiene Regulations are met within the feed business under their control.	Regulation (EC) No 178/2002 Article 3, 6 Regulation (EC) No 183/2005 Article 3, 2(b)
Feed materials	Products of vegetable or animal origin, whose principal objective is to meet 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.	Regulation (EC) No 767/2009 Article 3, 2(g)

Food-producing animal	Any animal that is fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption, but that belong to a species that is normally used for human consumption in the Community.	Regulation (EC) No 767/2009 Article 3, 2(c)
Labelling	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.	Regulation (EC) No 767/2009 Article 3, 2(s)
Non-food producing animal	Any animal that is fed, bred or kept but not used for human consumption such as fur animals, pets and animals kept in laboratories, zoos or circuses.	Regulation (EC) No 767/2009 Article 3, 2(d)
Premixtures	Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended to direct feeding to animals (article 2(2)(e) of Regulation (EC) No 1831/2003).	Reg. (EC) No 1831/2003

B. Other definitions

Term	Definitions	References
Voluntary labelling particular	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: the presence or the absence of a substance in a feed, a specific nutritional characteristic or process, and relates any of these to a specific function	COPA-COGECA / FEFAC Code of Good labelling practices for compound feed for food producing animals
Function/functionality	Specific purpose of a feed product	
Ingredient	A constituent/component/product added to a mixture	
Mixtures	Are 'premixtures'	
Phrasing	Wording of a voluntary labelling particular, or of a beneficial effect (technological, nutritional, health benefit)	
Feed additives and feed materials	It is advisable to use the FEFANA classification tool for the distinction between the two types of products	