EU Code of good labelling practice for compound feed for food producing animals

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european farmers european agri-cooperatives

FEFAC

Version May 2016

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1. Introduction

1.1. Context

New European Union rules on the placing on the market and use of feed (Regulation (EC) No 767/2009, hereafter referred to as 'the Regulation') are applicable from 1 September 2010. Articles 25 and 26 of the Regulation introduce a provision to encourage representatives of European feed business sectors to develop a Code of good labelling practice for compound feed for food-producing animals.

The European Feed Manufacturers' Federation (FEFAC) and the organisation representing European farmers and European agricultural cooperatives (Copa-Cogeca) have jointly developed a Code of good labelling practice for compound feed for food producing animals (hereafter referred to as 'the Code').

The authors believe that putting together many of the legal provisions for the labelling of feed materials and compound feed for animals in the Regulation represents major progress when compared to former legislation.

These new rules give feed business operators greater responsibility and aim to modernise and harmonise labelling conditions and procedures.

The authors believe that labelling practices and procedures should meet the following objectives:

- Provide useful information and most importantly facilitate proper use of the product.
- Have the capacity to match the specific requirements of the purchasers and users of the product, including farmers
- Remain flexible enough to enable innovation and allow manufacturers to differentiate their products in a competitive environment.

This jointly developed Code aims to achieve these goals while conforming to the general objectives and specific provisions of the Regulation.

To achieve this, the Code has drawn on the skills and expertise of representatives directly involved in the European animal feed sectors along with the users and purchasers of compound feed. The Code aims to represent the interests of these different categories of operators.

The Code was developed using the procedure included in Article 26 of the Regulation, including consultation of relevant EU feed chain stakeholder organisations, before being submitted for examination by the European Commission, according to the advisory procedure detailed in Article 28, paragraph 2 of the Regulation document. The Code was then made openly available for public comment for a period of one month.

The original version was submitted to the European Commission only in English. Translation into other EU languages is under the exclusive responsibilities of Copa-Cogeca and FEFAC Member Organisations.

The Code applies to all operators in the compound feed sector who are established in the European Union. The references of the Code are published in the Official Journal of the European Union (No C..., page ...).

Any future changes to the current Code will be made by the aforementioned organisations using the same procedure outlined in Article 26 of the Regulation. The Code will be reviewed as required to take into account technical adaptation of the legislation, or at least every two years.

1.2. General objectives

The Code aims to facilitate the labelling of compound feed for food producing animals (in bulk or packed) which is placed on the European market and ensure that information essential for the farmer is appropriately displayed on the label.

- The Code includes some practical advice aiming to make it easier for those responsible for labelling compound feeds.
- The Code clarifies legal requirements of the Regulation relating to the labelling of compound feed: including the content and type of information that the compound feed manufacturer / supplier must provide to the purchaser. This has particular relevance on the type of product composition information that manufacturers / suppliers may need to supply upon request from the purchaser.

  The Code also provides guidance on traceability-related labelling particulars to ensure easy identification of the product, its supplier and/or its manufacturer.
- The Code aims to provide farmers with the information necessary for them to make an informed choice on which products are best suited to their needs.

  The authors therefore aimed to ensure that particular attention is paid to “voluntary labelling” as one of the priority areas for improving the quality of labelling. They believe that this new element (which was introduced by the EU legislator and was included in Articles 22 and 25 of the Regulation) constitutes major progress. It is very important that operators make full use of the options that have been opened up by this new legislation on voluntary labelling.

  The Code aims to provide suggestions as to the type of particulars that could be disclosed on a voluntary basis to encourage operators to provide any further information if they wish to do so. The authors believe that this includes information on the nutritional value of the compound feed which is not required by law. Such details may include energy values, the total trace-element content, protein value, crude ash content for mineral feed, phosphorus content for complementary feeds, the presence of certain additives and/or other additional voluntary labelling information deemed relevant to understand the nutritional quality of the specific compound feed.
- The Code aims to guarantee an appropriate level of information for farmers whilst also protecting and preserving the competitiveness of their suppliers (whether they are private trade partners or cooperatives producing compound feed) by using the relevant aspects of intellectual property law. These concerns are linked in particular to the disclosure of

inclusion rates of feed materials on a voluntary basis or upon request of the purchaser.

The Code also provides further guidance on how to interpret and apply the new legislative framework on claims as referred to in Article 13 of Regulation (EC) No 767/2009 in order to ensure that such claims are meaningful and to allow the purchaser to use the compound feed in an optimised way. Further information regarding the type of claims, their substantiation as well as their phrasing is also provided in the Code.

- Finally, the authors believe that the form and type of labelling used is a very important factor in ensuring that the information is clearly understood by the farmer.

Labelling should reflect and move with the developments in market communication by being able to take into account techniques such as the use of electronic media and the internet.

1.3. The scope of the Code

- As far as the use and the placing on the market of compound feed are concerned, the Code focuses on the provisions included in the Regulation.

- In addition to this, further legislation must be complied with by the manufacturer and the user must also be aware of these. Non-exhaustive examples of such legislation includes, Regulation (EC) No 178/2002 on General Food Law, Regulation (EC) No 1831/2003 on additives for use in animal nutrition, Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes, Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain TSEs, Regulation (EC) No 1069/2009 and Regulation (EC) No 142/2011 on animal by-products and Regulations (EC) No 1829/2003 on GM food & feed and (EC) No 1830/2003 on traceability and labelling of GM food & feed.

- It should be noted that this Code does not apply to feed materials, compound feed for household pets, compound feed for fur animals, feed additives or premixtures of feed additives, which are subject to specific labelling provisions. It applies to medicated feed, without prejudice to specific labelling requirements defined in Directive 90/167/EEC, and to feed destined to organic farming, without prejudice to specific labelling requirements defined in Regulations (EC) No 834/2007 and (EC) No 889/2008.

2. Glossary

2.1. Definitions laid down in Regulation (EC) No767/2009

- The definitions of 'feed-business operator', 'food-producing animal', 'feed materials', 'compound feed', 'complete feed', 'complementary feed', 'mineral feed', 'milk replacer', 'carrier', 'particular nutritional purpose', 'feed intended for particular nutritional purposes', 'minimum storage life', 'batch' or 'lot', 'labelling', 'label', and 'presentation' are laid down in Article 3(2) of Regulation (EC) No 767/2009.

feed-business operator	any natural or legal person responsible for ensuring that the requirements of this Regulation are met within the feed business under their control.
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.
feed materials	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.
compound feed	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.
complete feed	compound feed which, by reason of its composition, is sufficient for a daily ration.
complementary feed	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.
mineral feed	complementary feed containing at least 40 % crude ash.
milk replacer	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.
carrier	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.

particular nutritional purpose	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.
feed intended for particular nutritional purposes	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.
minimum storage life	the period during which, under proper storage conditions, the person responsible for the labelling guarantees that the feed retains its declared properties; only one minimum storage life may be indicated in respect of the feed as a whole, and it is determined on the basis of the minimum storage life of each of its components.
batch or lot	an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together.
labelling	the attribution of any words, particulars, trade marks, 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.
label	any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of feed.
presentation	the shape, appearance or packaging and the packaging materials used for the feed, further to the way in which it is arranged and the setting in which it is displayed.

2.2. Other definitions

- The definitions of 'feed', 'feed business' and 'placing on the market' are laid down in Article 3 of Regulation (EC) No 178/2002.
- The definitions of 'feed additive', 'premixture', 'processing aids' and 'daily ration' are laid down in Article 2 of Regulation (EC) No 1831/2003.
- The definitions of 'establishment' and 'competent authority' are laid down in Article 3 of Regulation (EC) No 183/2005.
- The definitions of 'animal species' or 'animal categories' are laid down in Annex IV to Commission Regulation (EC) No 429/2008.

3. Typology of labelling particular

3.1. Product information provided through labelling

3.1.1. Traceability related information

• <u>Commercial name of the product:</u> ☞ The person responsible for the labelling may mention on the label the commercial name of the compound feed. This may also be accompanied by a unique identification number to ensure traceability and correct use of products.	
☞ The commercial name of the product should not mislead the user as regards the intended uses and characteristics of the product and should always respect the general principles as well as the provisions on claims.	R. 767/2009, Art 11(1) R. 767/2009, Art 13
• <u>Type of compound feed</u> ☞ Indicate the description of the type of compound feed: 'complete feed' or 'complementary feed', as appropriate - For 'complete feed', the designation 'complete milk replacer feed' may be used, if appropriate, - For 'complementary feed', the following designations may be used if appropriate: 'mineral feed' or 'complementary milk replacer feed'.	R. 767/2009, Art 15(a)
☞ Indicate the animal categories or by default, species for which the compound feed is destined to. It is recommended to combine the description of the type of compound feed and the species of destination (e.g. complete feed for turkey).	R. 767/2009, Art. 17, 1 (a)
☛ <u>For dietetic feed</u>, the qualifying expression 'dietetic' should be mentioned next to the designation of the feed (e.g. dietetic complete feed).	
• <u>Identification of the feed business operator responsible for the labelling</u> ☞ The person responsible for the labelling shall be the feed business operator who first places compound feed on the market or, where applicable, the feed business operator under whose name or business name the feed is marketed. This means that a retailer placing a compound feed on the market under its name is responsible for all the labelling particulars. In any case, the person responsible for labelling shall be established in the European Union.	R. 767/2009, Art. 12

☞ Shall be specified on the label: - The name or business name of the person responsible for labelling;	R. 767/2009, Art. 15 (b)
- If the person responsible for labelling holds approval as a feed establishment in accordance with article 10 of Regulation (EC) No 183/2005 on feed hygiene, this approval number;	R. 767/2009, Art. 15 (c)
- If the person responsible for labelling does not hold approval as a feed establishment but holds an approval granted in accordance with Article 24 of Regulation (EC) No 1069/2009 on animal by-products[1], this approval number. For the sake of traceability, a company that has an approval number for the production of certain feeds (e.g. production of feed containing coccidiostats) should also specify this approval number on the label of other types of feed they are producing but which do not require an approval (e.g. production of a grain mixture for ornamental birds without additives).	
☞ In cases where the producer is not the person responsible for the labelling, the following shall be provided in addition to the above labelling particulars: - The name and address of the producer or business name , or - An identifying number which shall be: o The approval number of the producer for approved feed manufacturers in accordance with article 10 of Regulation (EC) No 183/2005; o By default, an identifying number in accordance with Articles 9, 23 or 24 of Regulation (EC) No 183/2005; o By default, an identifying number allocated at the request of the producers or the importing feed business operator, which shall be in accordance with the format laid down in Chapter II of Annex V to Regulation (EC) No 183/2005.	R. 767/2009, Art. 17 (c)
• <u>Batch or lot reference number</u>	
☞ A batch (also called a lot) is an identifiable quantity of feed determined to have common characteristics (such as composition, species of destination, packer or labelling). In the case of compound feed, the batch number shall refer uniquely to a unit of production from a single plant using uniform production parameters (such as same formulation, presentation) or a	R. 767/2009, Art. 15 (d)

[1] It must be stressed that Regulation (EC) No 767/2009 refers to Regulation (EC) No 1774/2002 on Animal-By-Products, which has been replaced in the meantime by Regulation (EC) No 1069/2009 and Regulation (EC) No 142/2011. For the purpose of the indication of approval numbers related to the Animal-By-Products legislation, the correspondence between the relevant articles of Regulation (EC) No 1774/2002 and Regulation (EC) No 1069/2009 is based in particular on the Correlation Table in Annex of Regulation (EC) No 1069/2009).

number of such units, when produced in continuous order and stored together. ☞ The purpose of the indication of the batch number on the label is to facilitate the traceability of the product placed on the market. The determination of the size and characteristics of the batch shall be established as part of the traceability system designed by the manufacturer as required under Annex II of the EU Feed Hygiene Regulation (EC) No 183/2005. The format of the batch number is left to the manufacturer. It is recommended that the elements making up the batch number are meaningful to allow ease of identification. • <u>Net quantity</u> ☞ The net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquids.	R. 767/2009, Art. 15 (e)

3.1.2. Instructions for use	
a) <u>General instruction for proper and appropriate use:</u> ☞ The labelling of all types of compound feed shall also include the general instructions for proper and appropriate use, indicating the purpose for which the compound feed is intended and when required by the legislation, animal categories or species to which the compound feed must not legally be fed. ☞ Attention should be paid to the existence of specific instructions for use linked to the presence of certain feed additives / feed materials: - For compound feed containing certain additives for which legal instructions are mentioned in the authorisation decision (e.g. for coccidiostats or copper), please refer to the legal act authorising the feed additive, accessible via the Community register of feed additives. - For compound feed containing coccidiostats and histomonostats, draw attention to the obligation to ensure a withdrawal period before slaughtering or placing on the market of the food of animal origin as specified in the legal act authorising the feed additive. - For compound feed containing feed materials of animal origin where its use is subject to restrictive conditions (e.g. non-ruminant PAPs, fishmeal, blood meal or blood products), the nature of the feed materials included and the species for which the use of the feed is prohibited shall be specified on the label (for example: 'contains processed animal protein derived from non-ruminants — shall not be fed to farmed	R. 767/2009, Art. 17(b) R. 999/2001, Annex IV, chapter IV

animals except aquaculture animals and fur animals').	
☞ For complementary feed containing additives in excess of the maximum levels fixed for complete feed, specify the maximum quantity of the complementary feed: - in grams or kilograms or units of volume of complementary feed per animal per day, or - percentage of the daily ration based on 12% moisture content, or - per kilo of complete feed or percentage in complete feed, in order to ensure that the respective maximum contents of feed additives in the daily ration are complied with.	
☛ For dietetic feed, the nutritional objective and information related to essential nutritional characteristics as laid down in column 1 and 2 of Commission Directive 2008/38/EC.	
☛ For dietetic feed, indicate that 'The opinion of a nutrition expert or veterinarian should be sought before using the feed or before extending its period of use.' and describe any additional particular that would be required in column 6 of Directive 2008/38/EC.	
☛ For dietetic feed, the recommended period of use indicated in column 5 of part B indicates a range within which the nutritional purpose should normally be achieved. Manufacturers can refer to more precise periods of use, within the fixed limits.	
b) Minimum storage life (Use before date / Best before date):	
☞ The 'minimum storage life' means the period during which, under proper storage conditions, the person responsible for the labelling guarantees that the feed retains its declared properties; the minimum storage life shall be indicated in respect of the feed as a whole, based on the minimum storage life of each of its components.	R. 767/2009, Art. 17(d)
☞ The setting of the best before date is the responsibility of the person responsible for labelling and shall take into account deterioration of certain elements of the compound feed such as vitamins. The determination of compound feed storage life should take into account (amongst other factors) the storage life of its different components (feed additives, feed materials as relevant) as specified by the supplier(s) of the component(s).	
☞ The minimum storage life will be expressed as "use before date" or "best before date" depending on the perishability of the compound feed. - The use before date is mainly used for microbiologically perishable products (e.g. for liquid compound feed). The	

numeric indication of dates shall follow the order of day, month and year and the format shall be indicated on the label by means of the following abbreviation: 'DD/MM/YY'. - The best before date is used for types of compound feed other than microbiologically perishable ones. It is determined taking into account the best before dates of the constituents (feed additives, feed materials) and the specificities of the compound feed (e.g. presentation). The numeric indication of dates shall follow the order of month and year and the format shall be indicated on the label by means of the following abbreviation: 'MM/YY'. ☞ The manufacturing date (day, month and year) may be mentioned on the label. In such case, the use before date or the best before date as appropriate can be indicated as follows: '(period in days or months as appropriate) after manufacturing date.	

3.1.3. Compound feed specifications	
a) <u>Declaration of feed materials:</u> (i) <u>General principles</u> ☞ Given that compound feeds are produced on the basis of the percentages of incorporation of each feed material on a weight basis and not on the basis of the moisture content of the compound feed, it is appropriate for technical and control reasons to list the feed materials incorporated into a compound feed in descending order by weight as included. The list of feed materials shall bear the heading 'Composition' and shall indicate the name of each feed material.	R. 767/2009 Art. 17(1)(e)
☞ When a feed material with a high moisture content is incorporated in the compound feed (such as for a liquid compound feed), it is suggested - at the purchaser's request - that information is provided on the quantitative composition of the compound feed on a dry matter basis.	
☞ The possibility for feed manufacturers to indicate percentages of all feed materials incorporated into a compound feed on a voluntary basis is intended to give an incentive to feed manufacturers to provide purchasers with additional product information. It is therefore recommended to favour the use of a range of +/- 15% of the actual value so as to grant sufficient know-how protection while ensuring a comprehensive and meaningful flow of product information to the purchasers.	
☞ If the presence of a feed material is emphasised on the labelling in words, pictures or graphics, in particular in the commercial name of	R. 767/2009, Art

the compound feed, the name and percentage by weight of this emphasised feed material shall be indicated.	17(2)(a)
☛ For dietetic feed, describe the feed materials where the declaration is mandatory in accordance with column 4 of Directive 2008/38/EC together with percentage of inclusion. The declarations required in column 4 of Part B with the reference 'if added' are compulsory where the feed material has been incorporated or increased specifically to enable the achievement of the particular nutritional purpose.	
(ii) Names of the feed materials:	
☞ The person responsible for the labelling shall ensure that the names used to declare feed materials under the "Composition" headline are not misleading for the purchaser and comply with the general labelling principles.	
☞ It is recommended to use the name of feed materials listed in the EU Catalogue of feed materials (Regulation (EC) No 68/2013) as referred to in Article 24 of Regulation (EC) No 767/2009. Using a name of a feed material listed in the Catalogue requires compliance with all relevant provisions for the specific feed material as laid down in the Catalogue (in particular description).	R. 767/2009 Art. 11(1) R. 767/2009 Art. 24(5)
☞ It is required that the name of feed materials provided by the supplier on the feed material label, if listed in the Catalogue of feed materials, must meet the Catalogue requirements and therefore may be used by the compound feed manufacturer when declaring feed materials on the compound feed label.	
☞ When declaring the composition of a compound feed, the person responsible for the labelling may supplement the name of a feed material listed in part C of the Catalogue of feed materials with additional information, e.g. trade name. In such a case, the additional information should be provided between brackets directly after the denomination used in the Catalogue. (Example: soybean meal (Hypro)).	
☞ The person responsible for labelling may use a name not listed in the Catalogue of feed materials because he wants to use a more descriptive name (e.g. a brand name) or where the specific feed material does not align well with existing descriptions given in the Catalogue. In such cases, it is required that the name of the feed material is not misleading. It is recommended to include in the denomination of the feed materials a reference to the process undertaken as appropriate. Feed materials declared on the compound feed or the feed materials label under a name not listed in the Catalogue of Feed Materials shall have been notified to the register of feed materials (www.feedmaterialsregister.eu).	
☞ When a compound feed contains one or several genetically modified (GM) feed materials (e.g. GM soya) or feed materials of GM origin	

(e.g. soybean meal from GM soya), the GM origin of the feed material shall be mentioned along the following principles: - For feed materials which contain or consist of GMOs, the words "genetically modified [name of the organism]" shall appear either in parentheses immediately following the specific name of the feed material or as a footnote in immediate proximity to the declared composition. In all cases, reference to the GM nature of the feed material shall be printed in a font of at least the same size as the list of feed materials. - For feed materials derived from GMOs, the words "produced from genetically modified [name of organism]" shall appear either in parentheses immediately following the specific name of the feed material or as a footnote in immediate proximity of the declared composition printed in a font of at least the same size as the list of feed material. - If appropriate, labelling particulars must comply with additional requirements referred to in the individual authorisation decision of the GM events related to the characteristics of the feed (composition, nutritional properties, intended use), implications for the health of certain animal species, characteristics or properties where a feed material may pose ethical or religious concerns. The individual authorisations for GMOs may be found at the following link: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.	R. 1829/2003 Art. 25
b) Declaration of feed additives:	
☞ Feed additives must be declared under the heading "Additives" as appropriate with the most suitable unit of quantity referred to in the additive authorisation. Next to the heading "Additives", it is recommended to include 'per kg' or 'per litre' in brackets as appropriate.	R. 767/2009 Art. 15(f)
☞ Name, added amount and identification number of the following additives and name of the functional group or the category of the following additives shall be declared: - Additives where a maximum content is set for any kind of target species; - Zootechnical additives and coccidiostats and histomonostats; - Additives belonging to the functional group of 'urea and its derivatives' of the category 'nutritional additives' as laid down in Annex I to Regulation (EC) No 1831/2003; - Other feed additives requiring mandatory declaration according to their authorisation act (e.g. Hydroxy Analogue of Methionine (MHA) and its various forms authorised as a feed additive).	R. 767/2009 Annex VI Chapter I (1) R. 469/2013
☞ Some or all other additives may be declared voluntarily. In this case, the name should be provided as well under the heading "Additives" and other information such as added amount or ID number may also	R. 767/2009 Annex VI Chapter

be provided. However, in case of voluntary declaration of the presence of a sensory or a nutritional feed additive, its added amount shall be included. For flavouring compounds, the list of additives may be replaced by the words "mixture of flavouring compounds" together with the added amount of the mixtures of flavouring compounds if none of the flavouring compounds present in the mixture are subject to limitation in the complete feed, i.e. to mandatory declaration.	I (4) and (5)
☞ Operators should carefully consult the specific labelling requirements laid down in individual authorisation acts of each feed additive, accessible via the Community register of feed additives.	
☞ There is no specific order imposed by the legislation regarding the listing of feed additives. The name of the feed additives shall be the one mentioned in the relevant legal act authorising the feed additives. These names may be found in the legal act authorising the feed additive, accessible via the Community register of feed additives.	
☞ The name of functional groups or categories shall be as described in Annex I to Regulation (EC) No 1831/2003.	
☞ Feed additives belonging to the same categories or functional groups should be described together so that the name of the category/functional group is mentioned only once.	
☞ The name and added amount of a feed additive shall be disclosed if its presence is emphasised on the labelling in words, pictures or graphics.	R. 767/2009 Annex VI Chapter I (2)
☞ The amount to be declared shall be the amount added at the point of addition. This is important in particular for certain feed additives where the amount can be affected by the processing or decreases naturally over time, such as for vitamins or antioxidants.	
☞ If a feed additive is authorised for more than one functional group, the functional group or category appropriate to its principal function in the case of the specific compound feed shall be indicated.	
☞ If a feed additive is a GMO or is produced from a GMO in accordance with Regulation (EC) No 1829/2003, or contains a carrier of GM origin the labelling particulars mentioned above for feed materials shall apply.	R. 767/2009 Annex VI Chapter I (6) R. 1829/2003 Art. 25
c) Analytical constituents	
☞ The information on the nutritional value of the compound feed varies depending on animal species and shall be disclosed in accordance with Annex VI chapter 2 of the Regulation. It is recommended to describe them together under a heading "Analytical constituents". In addition, the moisture content shall be disclosed under the same heading where it exceeds: - 5% in the case of mineral feed containing no organic substances, - 7% in the case of milk replacer feeds and other compound feed	R. 767/2009 Annex VI Chapter II

with a milk-product content exceeding 40%, - 10% in the case of mineral feed containing organic substances, - 14% in the case of other compound feed.	
☞ The level of ash insoluble in hydrochloric acid shall not exceed 2.2% of the dry matter. Provided that it is indicated on the label, the 2.2% level may, however, be exceeded for: - compound feed containing authorised mineral binding agents, - mineral feed, - compound feed containing more than 50% of rice or sugar beet by-products, - compound feed intended for farmed fish with a fish meal content of over 15%.	R. 767/2009 Annex I (5)
☛ For dietetic feed, the analytical constituents where declaration is mandatory in accordance with column 4 of Directive 2008/38/EC shall be described together with the total amounts. The declarations required in column 4 of Part B with the reference 'if added' are compulsory where the additive has been incorporated or increased specifically to enable the achievement of the particular nutritional purpose. In addition, the amount of additional analytical constituents listed in column 4 of the Annex of Directive 2008/38/EC shall also be described.	Directive 2008/38/EC
☞ If the energy value and/or protein value are indicated, such indication shall be in accordance with the EC method if available, or with the respective official national method in the Member State where the compound feed is placed on the market, if available.	R. 767/2009 Annex VI Chapter II (3)
☞ When amino acids, vitamins and/or trace elements are indicated under the heading of analytical constituents, the amount to be declared shall be the total quantity of the amino acid, vitamin or element (e.g. copper) provided by feed materials and feed additives present at the end of the minimum storage life and that can be analysed by the official method of analysis when available. The amount of methionine declared as analytical constituent shall include the amount of methionine provided by feed materials and by any forms of DL and/or L methionine authorised as feed additive, as relevant. It shall not include the amount of Hydroxy Analogue of Methionine (MHA) in any of its forms authorised as feed additives as the official analytical method for methionine (see page 24 in Commission Regulation (EC) No 152/2009) is different from the methods for the determination of the various forms of Hydroxy Analogue of Methionine.	R. 767/2009 Annex VI Chapter II (2)
☞ When the feed contains any form of MHA authorised as feed additives, the person responsible for labelling may provide under the Analytical Constituents Heading and on the top of the mandatory declaration of methionine additional information to reflect the overall methionine equivalent value of the feed taking into account the	R. 469/2013

contribution of MHA in its different forms. Specific guidance on the voluntary declaration of the methionine equivalent value of the feed in case of addition of MHA is given in Annex V. ☞ Voluntary disclosure of calculated nutritional constituents other than energy or protein values (e.g. calculated content of digestible/available phosphorus) shall be made according to, and with reference to recognised official national and/or international tables/methodologies. In other cases, the opinion of an independent expert scientist in animal nutrition on the relevance of the calculated nutritional constituent is required. The used method must be verifiable by the competent authorities. ☞ Other analytical constituents disclosed on a voluntary basis shall be meaningful for the purchaser and be recognised as a valuable indicator of the nutritional value of the compound feed. This should be substantiated either by national legislation, public literature or an independent expert scientist in animal nutrition. The declared amount of the analytical constituents shall be verifiable by an EC method, if available or with the respective official national method in the Member State where the compound feed is placed on the market. In other cases, the opinion of an independent expert scientist in analytical methods is required. ☞ Tolerances for analytical constituents are established in Annex IV of the Regulation. The tolerance established for a feed additive is also applicable for the total amount of the substance present in the feed as native (endogenous) and added amount. For calculated nutritional values or equivalent values, the tolerance to be applied shall be determined on the basis of the tolerances applying to the different analytical constituents and feed additives on which the nutritional or equivalent value is calculated. For analytical constituents not mentioned in the Annex IV the competent authority may consider individual tolerances with regard to the correctness of the declaration.	
d) Claims ☞ 'Claim' may be defined as 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.[2] ☞ The claim is the essential medium for passing on information in relation to a compound feed to the purchaser to ensure an optimal and informed choice and use of the product. Advertising or promoting the company with no direct reference to a product is not regarded as a	R. 767/2009 Art. 13

[2] Inspired from the definition of claims laid down in Regulation (EC) No 1924/2006 on nutritional and health claims made on food

claim and is not covered by the present Code. ☞ Claims on a compound feed may be made in relation to specific characteristics of the compound feed itself or, to the presence of one or more feed materials / feed additives or to a function thereof. ☞ Using claims requires compliance with a number of obligations. The key principles are as follows: - The use of claims is subordinate to the fulfilment of certain conditions listed in Annex I. - Claims shall not attribute to the feed effects or characteristics that it does not possess or by suggesting that it possesses specific characteristics when in fact all similar feeds possess such characteristics. - Claims should be scientifically substantiated. - The person responsible for the labelling is responsible for the accuracy of the claims. ☞ Annex I provides detailed provisions regarding the nature of the claims and the requirements for substantiation.	

3.2. Information available on purchaser's request

3.2.1. Quantitative declaration of feed materials

☞ The person responsible for the labelling shall make available to the purchaser, on request, information on the quantitative composition data within a range of +/- 15% of the value according to the feed formulation. ☞ The obligation to provide the purchaser with further compositional information applies without prejudice to the provisions laid down in Directive 2004/48/EC on the enforcement of intellectual property rights. It must be noted that, as a legal act not directly applicable in national legislation, the various provisions of this Directive may not be interpreted and enforced in the same way at national level. ☞ Guidance laying down further detailed information on how to implement in practice at national level the provision of Article 17(2) b is provided in Annex IV of this Code of Practice.	R. 767/2009 Art. 17(2)b)

3.2.2. Declaration of feed additives other than those subject to mandatory labelling requirements

☞ For the additives not referred to in Annex VI chapter I (1) of the Regulation, the person responsible for the labelling shall make	R. 767/2009 Annex VI Chapter

available to the purchaser, on request, the name, the identification number and functional group of feed additives for which there are no mandatory labelling requirements. The disclosure of the quantity is not required. ☞ For flavouring compounds, the list of additives may be replaced by the words “mixture of flavouring compounds” together with the added amount of the mixtures of flavouring compounds. It must be reminded that flavourings with maximum daily restrictions in the complete diet shall be declared on the label.	1 (3)

4. Listing and specificities of commonly used labelling information media

4.1. General principles	
☞ All mandatory labelling particulars shall be given in their entirety in a prominent place on the packaging, the container, on a label attached thereto or on the accompanying document (when the compound feed is delivered in bulk), in a conspicuous, clearly legible and indelible manner, in the official language or at least one of the official languages of the Member State or region in which it is placed on the market. Recommendations to ensure legibility of the label are provided in Annex III. ☞ If a decision is taken to provide voluntary information, voluntary labelling particulars may be provided partly or totally on the label or other media. If provided on the label, attention should be paid to not overload the label and it is verifiable with an EC method or with the respective official national method in the Member State where the compound feed is placed on the market. Voluntary labelling information not provided on the label should preferably be collated on a single medium. Such additional information may be provided at the time of order or delivery at the latest, and made available by different means, e.g. by paper or electronically. ☞ A summary table with labelling particulars that have to be on the label or may be on the label, is given in Annex II.	R. 767/2009 Art 14

4.2. Design of the label	
☞ For compound feed, the label shall be attached to the packaging of the compound feed when sold in bags. When delivered in bulk, the compound feed shall be accompanied by a document containing all mandatory labelling particulars required by the Regulation and other relevant EU legislation. ☞ In order to guarantee the legibility and easy accessibility of the labelling information for the purchaser of the compound feed, it is recommended to use headings and sub-headings which are either mandatory or added on a voluntary basis where appropriate.	R. 767/2009 Art 14 (1) and 11 (2)

4.3. Additional documents or media (paper, internet, telephone…)	
☞ Additional and complementary documents or media may be used to provide additional information/advice to the user of the compound feed and/or to provide information required by the purchaser as provided for in Article 17 2(b) and Annex VI chapter 1, par. 3 of Regulation (EC) No 767/2009. ☞ When additional information regarding a batch (lot) as delivered is provided on a separate media than the label, the batch number of the lot shall be specified on the two media (i.e. label and second format) for purpose of of traceability of labelling information.	

4.4. Distance selling	
☞ There are different forms of distance communication (i.e. Internet or phone) where the simultaneous presence of the supplier and the consumer is not required for the conclusion of a contract between those parties. ☞ When the compound feed is offered for sale through this distance selling, the mandatory labelling particulars specified in Chapter III.1 of the present Code shall appear on the material supporting the distance selling or shall be provided through other appropriate means prior to the conclusion of the distance contract. ☞ The following particulars are exempted before the conclusion of the distance contract but shall be provided by the point of delivery of the feed: - the name or business name and the address of the feed business operator responsible for the labelling - the batch or lot reference number - the net quantity expressed in units of mass in the case solid products, and in units of mass or volume in the case of liquid products - the minimum storage life for additives other than technological additives - the indication of the minimum storage life. ☞ For packed feed, it is recommended to provide indication of the quantity of one unit (e.g. kg/bag).	R. 767/2009 Art 11 (3)

ANNEXES

ANNEX I

Management Of Claims

<u>Warning</u>: the examples of claims mentioned in this annex are given for illustration purpose only and do not preclude of the lawfulness of their use which depends on circumstances and ability to justify.

1. Guidance on the implementation of Article 13 and Article 11(1)(b) of Regulation (EC) No 767/2009 on claims

This annex of the Code provides guidance to the person responsible for the labelling on the development of and the presentation of claims.

In this introduction of this annex it is meaningful to provide a delineation of claims in order to provide guidance and assistance to the operators, purchasers and the authorities. The following sections of this annex will provide further detailed guidance of the relevant aspect of development and presentation of claims

1.1. Basic conditions for use of a claim

Claims are permitted providing that the following conditions are met:

- The claim is objective;
- The claim is verifiable by the competent authorities;
- The claim is understandable by the user of the compound feed;
- The claim is substantiated (further details in part 2 of the present annex);
- The claim is not misleading;
- The claim is not prohibited.

1.2. Basic description of a claim

Claims on compound feed may be made in relation to specific characteristics of the compound feed itself including the following properties of the compound feed:

- Appearance / processing of the compound feed;
- Composition of the compound feed (feed additives, feed materials or combinations thereof, including where relevant any specific processes undergone by the feed additives or feed materials);
- Nutritional and/or analytical characteristics of the compound feed;
- The function of the compound feed.

As such, a claim can include reference to the nutritional nature and/or functional effect of the compound feed as well as its effect on animal performance, quality of animal products and

livestock management aspects provided that the claim is substantiated according to the criteria as specified in part 2 of the present annex and does not conflict with the following limitation:

The labelling of the compound feed cannot include a claim that contains reference that the compound feed will prevent, treat or cure diseases, 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 are no pathological symptoms associated therewith.

Claims in relation to functions listed in Regulation (EC) No 1831/2003 on feed additives may be made for compound feed when this function is exerted in the compound feed, whether this function is linked to the presence of an authorised feed additive for this function or to a feed material or a substance in a feed material or to the compound feed itself.

Claims concerning optimisation of the nutrition and support or protection of the physiological conditions are permitted, with the exception of those listed in Article 13(3) of the Regulation.

Where a claim can be made for a particular component, 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. Whenever the name of one or more feed additives and/or feed materials and/or analytical constituent is described in a claim other than referring to its absence, the names and total amounts of substances/products shall be indicated on the label under the appropriate heading.

Feed additives shall be used for the purpose they are authorised for. Claims related to the presence of a feed additive shall relate to (one of) the function(s) corresponding to the functional groups indicated in the regulation authorising the additive providing that it is present at the level required in accordance with the authorisation.

Claims concerning nutritional imbalances are permitted provided there is no pathological symptom associated therewith, except for claims related to feed for specific nutritional purposes, as long as the specific feed satisfies all relevant legal requirements (Directive 2008/38/EC).

1.3. Phrasing of a claim

Feed may exert certain functions that are of clear benefit for animal health. However, depending on the way the claim is formulated, a product could be considered by public authorities either as a feed or as a (non-authorised) veterinary medicinal product. The wording of a claim is therefore extremely important and shall not, as required by the legislation refer to prevention, treatment or curation of a disease.

This means in particular that:

- Words such as “supports”, “maintains”, “contributes”, optimises, “provides” “fosters”, etc. would generally be acceptable. Words such as “stimulates”, “increases”, “improves” or “reinforces” may also be acceptable unless they refer to a certain physiological function;
- Words such as dose, dosage, cures, treat, treatment, remedy, prevent, relieves, heals, etc. shall not be used;
- Names of diseases are prohibited (except for feed for specific nutritional purposes, in accordance with authorisations of nutritional purposes (Directive 2008/38/EC)).

1.4. Basic approach on substantiation of a claim

Annex I part 2 will in further detail provide guidance on the substantiation of a claim. Basically, the substantiation may consist of one or more of the following:

- Formulation evidence
- Scientific literature (peer reviewed articles)
- Scientific opinions and publications from worldwide authorities (e.g. EFSA, FDA, national feed/food authorities)
- Research & Development trials
  - o External
  - o In-house

Long standing and well recognised use may also constitute one, but not the only element of proof (e.g. yellow coloration of egg yolk when incorporating maize in the diet).

The claim can include reference to conclusions from the above, provided that the claim meets the criteria as described above in the description of a claim. This means that the claim can include among others the following wordings provided that such claims can be verified and substantiated through the above-mentioned means of substantiations of the claim:

- "stimulates appetite",
- "increases daily weight gain",
- "improves feed conversion ratio"
- "fosters increased pigmentation of egg yolk colours"
- "supports normal peristalsis through contribution to motility in the digestive tract"

1.5. Typology of claims

Below is a typology of claims based on their nature. In practice, claims may be a combination of several of the claims listed below, one (primary claim) being directly connected to the other (secondary claim).

One example is rumen protected methionine which will increase milk yield and the protein content of milk, as methionine plays an important role in the mobilization of fat deposits and further methionine supports the liver more effectively to eliminate waste metabolites.

Another example is particle size profile of compound feed as coarse particle size:

- will support growth of lactobacillus in the digestive tract of pigs;
- will support the normal function of the gizzard in poultry and lower the pH of the content in the gizzard and the digestive tract.

1.5.1. Nutritional and compositional claims

The purpose of this type of claim is to justify the coverage of quantitative and qualitative requirements in essential nutrients (energy, proteins, vitamins, minerals, etc.) or a constituent exerting a function in the compound feed, whether this function is claimed or not. Nutritional and compositional claims can be based on any of the following origins or combination thereof:

☞ on the presence/absence of a substance (feed material, feed additive, analytical constituent)

Examples:

- "Contains / brings / source of / provides / concentrated in / rich in [substance]" (e.g. vitamins)
- "Naturally rich in [substance]" (e.g. beta-carotene)
- "Contains added amino acid(s) allowing a reduction of total protein concentration in this feed."
- "Enriched with [substance]" (e.g. bicarbonate)
- "High in [substance]" (e.g. energy)
- "Low in [substance]" (e.g. fibre)

☞ a feed additive/feed material present in the compound feed under a special form, process or origin (often associated with a functional or livestock management claim).

Examples:

- "Contains digestible / available / chelated / coated / rumen-protected / micronized [substance]" (e.g. vitamins, feed material)
- "Contains [specified feature] [name of substance]" (e.g. origin controlled, proteins of vegetable origin exclusively, natural pigments from tagetes).

It must be reminded that the qualifiers above may be used only when not all similar feeds possess such characteristics.

☞ a specific production process which improves the quality of the compound feed (often associated with a functional or livestock management claim).

Examples:

- Heat-treated
- Expanded
- Coarse-ground
- Pelleted

1.5.2. Functional claims

These claims are related to a specific effect on certain physiological functions of the animal (growth, development, etc.). They may be connected to a specific feed material, feed additive or constituent, whether its presence is claimed or not, or to the appearance of the compound feed, e.g. its physical form (meal, crumbles, particle size etc) or a specific process undergone by the compound feed (heat treatment, pelletisation).

☞ Support physiological functions of the animal or enable return to normal physiological status. These are claims other than those related to specific authorised nutritional purposes (Directive 2008/38/EC).

Examples

- Contributes to good liver function
- Preserves udder integrity
- Supports starting growth
- Facilitates digestive transit
- Fosters feed /drinking water intake / digestion / appetence

- Maintains bowel flora balance
- Optimises rumen fermentation
- Helps a good transition in case of change in feed
- Supports rumen activity

☞ Enhancing animal performance

Examples

- Stimulates, fosters, improves growth
- Increases milk production, milk secretion (e.g. sows) / egg-laying rate

☞ Enhancing the efficiency of the compound feed

Examples

- Contributes to reducing the feed conversion ratio
- Improves nitrogen retention
- Contains phytase, which increases the digestibility of phytic phosphorus, hence improving phosphorus absorption.

1.5.3. Livestock management claims

These claims are related to the role of compound feed with specific effects on managing environmental, sanitary risks or improving the quality of food (e.g. pigmentation, selenium content). They may be connected to a specific feed material, feed additive or constituent, whether its presence is claimed or not, or to the appearance of the compound feed, e.g. its physical form (meal, crumbles, particle size etc) or a specific process undergone by the compound feed (heat treatment, pelletisation).

☞ Reduction of an environmental risk

Examples

- Contributes to improving the litter
- Reduces ammonia / methane emissions
- Contains 'phytase', which increases the digestibility of phytic phosphorus thus having a favourable impact on the environment

☞ Reduction of hazard

Examples

- Contains [substance] which contributes to control the impact of mycotoxins

☞ Enhancing the quality (nutritional, organoleptic, microbiological, etc.) and/or value of animal products (meat, egg, milk, etc.)

Examples

- Contains [substance], which enhances/accentuates the colour of the egg / flesh
- Limits meat oxidation
- Improves egg shell solidity
- Increases egg weight
- Only for coccidiostats and histomonostats: Aids in the prevention of coccidiosis / histomonosis caused by …

1.5.4. Prohibited claims

☞ The following claims are prohibited:

- Claims concerning optimization of the nutrition and support or protection of the physiological conditions which explicitly use the following words “preventing, treating or curing a disease”.
- Claims with words such as “stimulates”, “increases”, “improves” or “reinforces” when they refer to a certain physiological function.
- Claims suggesting that, whatever the process, a compound feed provides specific/enhanced characteristics whereas such features are common to all similar compound feeds.

☞ The labelling or the presentation of the compound feed shall not claim that:

- It will prevent, treat or cure 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.
- It has particular nutritional purposes as referred to in the list of authorised intended uses referred to in Directive 2008/38/EC unless its specific provisions are complied with.

2. Substantiation of claims

Article 13, par. 1.b) of Regulation (EC) No 767/2009 provide that "the person responsible for the labelling provides, at the request of the competent authority, scientific substantiation of the claim, either by reference to publicly available scientific evidence or through documented company research. The scientific substantiation shall be available at the time the feed is placed on the market."

The purpose of this section is to help operators establishing a "substantiation dossier" containing the elements required to support the claim. It remains however the prerogative of control authorities to evaluate the content of the substantiation dossier, in particular whether the evidence provided is sufficient to establish the link between the cause and the claimed effect. The substantiation dossier shall be objective: literature when used as evidence shall be representative of the existing publications on the issue, including those not supporting the claim. The substantiation dossier shall be transmitted to authorities on their request.

2.1. Substantiation of a claim

- ☞ The following types of substantiations, depending on the type of claims, can be considered:
  - Formulation evidence
  - Scientific literature (peer reviewed articles)
  - Scientific opinions and publications from worldwide food authorities (EFSA, FDA and national feed/food authorities).
  - Research & Development trials
    - o External
    - o In-house
  - Documentation proving the longstanding and well recognised use.
- ☞ For claims made on a compound feed and not specifically related to a feed material/feed additive or combination thereof, the specific characteristics of the compound feed should be close to the ones used in the substantiation dossier.

2.2. Evidence suggested per type of claims

2.2.1. <u>General principles</u>

- ☞ The origin of a claim may lay in:
  - the physical form of the compound feed (meal, pellets etc.),
  - a particular process used in the production of the compound feed (heat treatment, pelletizing etc.) and/or
  - a particular constituent and/or feed additive and/or feed material and/or combination thereof
- ☞ The importance of evidence and the corresponding degree of substantiation must be relevant to the claimed effect and its degree of assertion.

- Concerning claims related to the presence of a feed material, feed additive, or analytical constituent, the substance subject to the claim must be present in the feed and available to the animal in quantities that are sufficient to ensure the claimed effect. When the claim is made in relation to a complementary feed, the substance subject to the claim shall be present in the complementary feed and available to animals in quantities that are sufficient to ensure that the claim is substantial in the daily ration or complete feed. 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 which can be consumed by an animal without detrimental effects, e.g. on weight gain.
- A claim in relation to a function of a feed additive present in the compound feed does not need to be substantiated if the feed additive is authorised for this function and the additive is included in quantities sufficient to exert its function in the daily ration / complete feed as provided in the feed additive authorisation. In other circumstances, the substantiation of a claim should be provided in accordance with the following table and the additional specific requirements in section 2.2.2 and 2.2.3.

<table>
<tr><th rowspan="2">Claims</th><th rowspan="2">Principle</th><th colspan="3">Substantiation</th></tr>
<tr><th>Quantification</th><th>Science (physiological)</th><th>Science</th></tr>
<tr><td rowspan="2">Nutritional</td><td>Presence/Absence</td><td>Yes</td><td></td><td></td></tr>
<tr><td>Process</td><td></td><td>Yes</td><td></td></tr>
<tr><td rowspan="3">Functional</td><td rowspan="2">Presence/Absence</td><td rowspan="2">Yes</td><td colspan="2">Yes</td><td rowspan="2"></td></tr>
<tr><td>ADD/NUT</td><td>FM/ADD/NUT</td></tr>
<tr><td>Process</td><td></td><td>(dossier)</td><td>Yes</td></tr>
<tr><td rowspan="3">Livestock management</td><td rowspan="2">Presence/Absence</td><td rowspan="2">Yes</td><td colspan="2">Yes</td><td rowspan="2">Yes</td></tr>
<tr><td>ADD/NUT</td><td>FM/ADD/NUT</td></tr>
<tr><td>Process</td><td></td><td>(dossier)</td><td>Yes</td></tr>
<tr><td></td><td></td><td>Yes</td><td>Yes</td></tr>
</table>

ADD --> Feed additives
FM --> Feed materials
NUT --> Nutrient

Quantification: Evidence on the amount of a substance is needed when the claim, whichever type of, is based on the presence/absence of a substance. Such evidence is based on formulation and analytical method.

Science (Physiological): Scientific evidence is needed to support a claim, whichever type of, based on a physiological process which occurs at animal level.

Science: Scientific evidence is needed to support a claim, whichever type of, claiming an effect on management aspects.

Example:

Assuming that a substance allows a better assimilation of nitrogen with a consequent reduction in nitrogen in the manure, the following claims could be made:

- "contains [substance]" - nutritional claims, the substantiation is based on the formulation;
- "improves assimilation of nitrogen" - functional claim, the substantiation is based on the formulation showing that the substance has been added and on scientific dossier demonstrating that the substance physiologically improves the use of nitrogen by the animal;
- "reduces nitrogen impact–" - livestock management claims – the substantiation is based on the formulation showing the substance has been added; a scientific dossier demonstrating that substance physiologically improves the use of nitrogen by the animal; a scientific dossier showing that this allows reducing nitrogen in manure.

2.2.2. Specific requirements for compositional claims

- For compositional claims linked to the presence or absence of a substance/constituent, the defined characteristics of the compound feed shall be the source of the substantiation.
- Claims related to the presence of a substance can be made on the condition that this substance is generally not present in comparable standard compound feed.
- Claims related to the absence of a substance can be made on the condition that this substance is generally present in comparable standard feed.
- For claims related to the amount of the substance (i.e. "rich in...", "low in...", "contains..." "balanced in..."), the reference against which the claim shall be compared should preferably be recommendations endorsed by feed chain partner organisations, if available (e.g. for trace-elements or vitamins) for the complete feed / daily ration. By default, international/European/national public standards or scientific publications should be used.
- For claims such as "rich in...", the reference should be the upper level of the reference recommendation when available. For claims such as "contains...", the amount contained in the feed should at least meet the minimum level of the reference recommendation when available. In other cases, the required level of statistical significance of analysis for comparative claims shall be proportionate to the degree of assertion of the claim. The following percentages of reduction/increase when compared to the incorporation rate in a regular standard compound feed are recommended as a general guidance:
  - Reduced < 15%
  - Increased > 15%

  Different percentages may be used on the basis of scientific evidence.

  Concerning complementary feed, the above percentages shall not correspond to the content of the substance in the complementary feed itself but the content in the daily ration/complete feed when the complementary feed is used in accordance with instructions.
- The dossier shall include a reference to a method of analysis for the constituent subject to the claim or, in case of absence of published recognised methodology/table for calculated nutritional value, expert advice along the principles laid down in part 3.1.3 c) of the main part of the present code.

- If the claim is linked to a specific process undergone by a specific feed material or feed additive, the specific features of the processed feed material or feed additive (stability, availability, rumen protection) based on suppliers information can be used to substantiate the claim. It must be stressed that a specific authorisation of the process undergone by a feed additive subject of the claim may be required whenever the feed safety profile of the feed additive having undergone the process would be significantly affected.

2.2.3. Specific requirements for functional and livestock management claims

- The basis for the substantiation of functional and livestock management claims shall be the direct measurement of the claimed effect. However, as regards claims related to physiological functions, the following basis for substantiation may be used:
  - direct measurement of the effect (haematology 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).
- For functional claims and livestock management claims, the level of substantiation should follow the following guidance:
  - If the claim is linked to the presence of the 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 supplier:
    - Claims shall be substantiated on the basis of scientific information, e.g. peer reviewed journals; report from research institutes, field trials with control groups. If the effect is based on mode of action, this shall be accurately described on the basis of trials or peer reviewed references;
    - Trials shall provide information on the minimum dosage to be used in order to elicit the claimed effect.
  - 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, optimally with control groups and at a minimum in livestock holding surveys (minimum 2-3 farms and relation to historical results)
  - Claims referring to a potential for effect should be based on at least one trial[3] 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.

[3] Trial here, means source of information (e.g. one peer reviewed publication)

P<0.05 for monogastrics and P<0.1 for ruminants) – in this case, the claim is written as 'improve…'

3. Methodology for compiling an evidence file

3.1. Conditions for carrying out and validating studies

- 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 quantified and distinguished (yes/no, etc.)
- The method of measurement is acknowledged ("as 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 evidence relevant to the study is assured and filed.

3.2. Experimental protocol

- Bibliography: bibliographic research shall be objective and representative of the diversity of scientific opinions on the truthfulness of the claim. Bibliographic references are typically:
  - 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.
  - Publications by renowned scientific authors, etc.
  - Peer reviewed scientific journals
  - International congress proceedings
- Livestock holding survey:
  - Field surveys without control groups, with recording of results and/or frequency on a sufficient number of livestock holdings or animals which achieve statistical significance

- These field surveys might be compared to regional average values on equally long periods, to an expected value or to average values from former periods; they might also be used for statistical analysis.

☞ Field tests with control group:
- Classical comparison between control group and test group with or without replication.
- Collecting of non-biased samples, definition of analysis criteria.
- Appropriate statistical analysis (average value comparison, etc.) with significant results.

☞ Tests in public or private experimental research centres:
- In vitro or in vivo experiments; the research centre has as a minimum to comply with rules laid down for field tests and surveys, given that these are normally part of their specifications and good practice.
- Appropriate statistical analysis (average value comparison, etc.) with significant results.

☞ 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 Professional qualification are appropriate.
- The executive report and raw data are saved and kept available for control authorities.

ANNEX II

Summary Table On Labelling Particulars To Be Disclosed On The Labelling

The summary table below presents the labelling particulars that must, or may be disclosed on the labelling. All mandatory labelling requirements (except information on request of the purchaser) shall be provided on the label. The labelling particulars not mentioned on the label are transmitted to the purchaser on additional media. Information provided to purchasers on request may be conveyed using any other appropriate communication media.

Labelling particulars on the label (or accompanying document for bulk deliveries)	**Mandatory**	**Possible**
Headers	**X**	
Traceability information		
Commercial name		**X**
Type of compound feed	**X**	
Name & address of Feed Business Operator responsible for the labelling	**X**	
Approval number of Feed Business Operator responsible for the labelling when available	**X**	
Name & address of manufacturer or approval or identification number of manufacturer	**X**	
Batch or lot number	**X**	
Net quantity	**X**	
Instructions for use		
General instructions for use	**X**	
Species and category of target animals	**X**	
Restrictions for certain species	**X**	
Warnings	**X**	
Best before date	**X**	

Labelling particulars on the label (or accompanying document for bulk deliveries)	Mandatory	Possible
Compound feed specifications		
Declaration of feed materials in descending order of weight	X	
Percentage declaration of certain feed materials whose presence is emphasised	X	
Percentage declaration of feed materials on a voluntary basis		X
Declaration of certain specific feed additives (name, added amount, ID number and name of functional group or category)	X	
Declaration of certain feed additives where its presence is defined (name, added amount)	X	
Declaration of other feed additives on a voluntary basis (name and/or added amount and/or ID number and/or name of functional group or category)		X
Declaration of other feed additives on purchaser's request (name, ID number and name of functional group or category)		X
Mandatory nutritional constituents	X	
Additional information on constituents		X
Claims		X

ANNEX III

Best Practice Recommendation For Legibility Of A Label

	Recommended	Use with care	Best avoided
Layout	~Headings to be clear, short and consistent; ~ Use bold type and/or upper case text to distinguish headings; ~ Where space allows, group information which belongs together; ~ Where appropriate, separate different groups of information with frames or boxes; ~ Text should start and be aligned with the left margin;	~ Extensive use of upper case and underlining; ~ Text in other format than blocks; ~ Text wrapping; ~ Centre alignment; ~ Text aligned with the right margin;	~ Over hyphenation of text; ~ Blocks of texts without headings, titles or any separation; ~ Placing a large amount of text with only one or two words on each line; ~ Placing the information in circles. ~ Too many or overly complex symbols.
Font, Colour and Contrast	~ A letter height of 1mm or more; ~ Adequate character spacing; ~ Inter-linear spacing of 120% of the font size; ~ Easy-to-read (Sans serif) fonts; ~ Choose a typeface designed for use at small font size; ~ Clear contrasting colours.	~ Letter height below 1mm; ~ Inter-linear spacing of less than 120% of the font size Italic; ~ Serif typefaces; ~ Stylised, ornate decorative fonts; ~ Subtle contrasts, shadowing, 3D effects, watermarking or non-uniform background; ~ Where packaging is transparent, good contrast is necessary with food product forming the visible background.	~ Character spacing condensed by more than 1pt; ~ Inter-linear spacing of less than 0,5pt more than the font size; ~ Colours with similar tonal contrasts - light type on a light background or dark type on a dark background;
Packaging / Printing	~ High quality printing	~ Printing on deformation zones; ~ Heat sealed areas; ~ Plastic shrink wrap; ~ Metallic and shiny printing surfaces;	~ Labels printed on curved surfaces. ~ Zones of the packaging which are not directly accessible; ~ Areas where the destruction of the package is required to read the text.

ANNEX IV

Guidance On The Obligation To Make Available Information On Quantitative Composition Data On Purchaser's Request

Under Article 17(2) b of Regulation (EC) No 767/2009, it is foreseen that:

"If the percentages by weight of the feed materials contained in compound feed for food-producing animals are not indicated on the labelling, the person responsible for the labelling shall, without prejudice to Directive 2004/48/EC, make available to the purchaser, on request, information on the quantitative composition data within a range of +/– 15% of the value according to the compound feed formulation".

The purpose of the provisions laid down in Article 17(2) b is to strike the right balance between a sufficient know-how protection of feed manufacturers and a valuable and meaningful disclosure of compositional product information to the farmers. The guidance hereafter is designed to set practical rules for operators for the implementation of this article in order to avoid as far as possible request for arbitration and/or legal recourses before national jurisdictions in the light of Directive 2004/48/EC.

EU representatives of livestock farmers and farmers' cooperatives and compound feed manufacturers consider that sufficient freedom should be left to private parties to further determine, on a contractual basis, the conditions and modalities under which further compositional information should be made accessible to the purchaser of the compound feed.

As a consequence, this Annex does not intend to cover all possible practical situations that operators may encounter in their daily business activities, but rather aims to provide a set of minimum requirements to be complied with in order to ease the implementation of such legal requirements at national level.

- When is this information to be made available?

On purchaser's request, the information on quantitative composition data should only be required in principle after the physical delivery of the compound feed to the purchaser. However, the transmission of such information may possibly occur prior to or during the delivery based on a voluntary agreement between interested parties in the frame of normal commercial practices.

- Who is allowed to request information on the quantitative composition data?

Although the target group of the legislator for this provision of information on request was primarily the final users/farmers, the wording used does not restrict this right to farmers only. In particular, in case of sales of compound feed via a retailer, the retailer shall source the information from the manufacturers to be able to answer his own customer's request. In order to preserve intellectual property rights, it is recommended that any operator other than the final

user initiating or transmitting a request for information on quantitative composition data shall sign a confidentiality agreement.

- Who needs to make the information accessible and to whom?

Unless otherwise specified in the contract agreed upon between interested parties, the request for information on quantitative composition data should be transmitted by the purchaser to the person responsible for the labelling. However, requests may also be addressed to the supplier, even if not responsible for labelling. The request should then be channelled to the owner of the information, most likely the manufacturer of the compound feed. The owner of the information may require a copy of the request from the final user together with his identity. He may provide the requested data directly to the initiator of the request or forward it via the retailer(s).

- What information needs to be made accessible to the purchaser?

In case the percentages by weight of the feed materials are not specified on the label itself, the purchaser, on request to its supplier, shall have access to quantitative composition data within a range of +/- 15% of the value according to the compound feed formulation without prejudice to intellectual property rights. In case of divergence of views between supplier and purchaser, it is up to the authorities of the respective Member State(s) to decide if the objection to the disclosure of percentages based on intellectual property rights is justified.

It must be noted that the lower the incorporation rate of a feed material, the higher the uncertainty regarding the actual percentage by weight of this feed material. The risk of exceeding the range of +/-15 % at lower level is therefore considerably high.

It is generally acknowledged that the know-how of feed manufacturers lays more with micro-ingredients than macro-ingredients. Thus, in order to facilitate the practical implementation of Article 17(2)b, it is recommended that suppliers do not claim intellectual property rights for inclusion rates above 5%. Nevertheless, upon request purchasers may also obtain further information on the composition concerning feed materials below 5%.

- How should the information be made accessible to the purchaser?

The media upon which the information on quantitative composition data should be provided to the purchaser is left to the consideration of the interested parties.

ANNEX V

Guidance For The Declaration Of Methionine Under The Analytical Constituents Heading In Case Of Addition Of MHA

The declaration of the amount of methionine under the “Analytical Constituent” heading as measured by standard analytical methods may not always provide completely meaningful information on the true value of the compound feed, especially when MHA, calcium salt of MHA, isopropyl ester of MHA or any other authorized form of MHA is added to the compound feed since the official analytical method for the analysis of methionine cannot quantify MHA.

In this case, in addition to the amount of methionine declared as analytical constituent (i.e. native methionine + added DL-methionine), the compound feed manufacturer can, on a voluntary basis, declare under the ”Analytical constituents” heading the ”methionine equivalent value” (abbreviated: methionine eq. value) of the compound feed being the sum of native methionine + any of the authorised added forms of DL or L-methionine + methionine equivalent value of any of the authorised added forms of MHA. The methionine equivalent value of MHA in any of its authorised forms shall be calculated using a bio-equivalence factor for MHA as compared to methionine.

The person responsible for labelling shall substantiate the bio-equivalence factor it uses according to the principle laid down in Annex 1 part 2 of the present code. This substantiation dossier can be based on the information provided by the feed additive supplier, including literature and/or trials. When literature is used as evidence, it shall be representative of the existing publications on the issue.

Example of a voluntary declaration of the methionine equivalent value of a compound feed supplemented by 2,000 mg / kg of the feed additive “Hydroxy analogue of methionine” pure at 88% when using a bio-equivalence factor of 85% on an equimolar basis.

Methionine equivalent value of the added amount of the feed additive “Hydroxy analogue of methionine”: 2,000 mg/kg * 0.88 * 0.85 = 1,500 mg/ kg methionine equivalent = 0.15% methionine equivalent

ANALYTICAL CONSTITUENTS

Crude Protein	19%	Methionine	0.35%
Crude Fibre	4.0%	Total **methionine equivalent value**	**0.50%**
Crude Oils and fats	5.0%	Calcium	0.7%
Crude Ash	5.5%	Sodium	0.17%
Lysine	1.4%	Phosphorus	0.5%