





INDUSTRY CODE OF PRACTICE FOR THE LABELING OF FEED ADDITIVES AND PREMIXTURES

FEFANA, FEFAC & EMFEMA 13th November 2007 Version 01

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About FEFANA

FEFANA is the EU Feed Additives and Premixtures Association. It was established on October 13th, 2004 and is the new juridical form of the feed additives producers association that was founded in 1963. With over 82 members (including producers, traders and importers) from 28 countries, the association is the interface between the feed additives and premixtures industry and the European Union authorities, including Member States authorities, in order to promote, safeguard and defend common and general interests of the industry (in several topics like guidelines, register, labelling and definitions, analysis, feed hygiene and food chain safety or non-feed use of additives).

About FEFAC

The European Feed Manufacturers' Federation (FEFAC) was founded in 1959 by five national compound feed associations from France, Belgium, Germany, Italy and the Netherlands.

FEFAC membership today consists of 21 national associations of compound feed and premixtures manufacturers from 20 EU Member States as full members as well as Associations in Switzerland, Turkey and Norway with observer/associate member status. FEFAC is the only independent spokesman of the European Compound Feed Industry at the level of the European Institutions. The mission of FEFAC is to represent, defend and promote the interests of the European compound feed and premixtures industry to the European Institutions in an evenly implemented legal framework and to provide feed companies with professional rules through guides to good practice.

About EMFEMA

EMFEMA is an international non-profit association, founded in 1996 and grouping EU-located producers of inorganic minerals (macro minerals, trace element compounds and specific minerals such as clays of different kinds) for use in animal nutrition.

As associated member EMFEMA counts as well EU producers of on-farm mineral mixes.

Detailed information about EMFEMA's structure, members as well as their respective products can be found on www.emfema.org

EMFEMA's objectives are:

- To provide technical information for the animal feed industry as well as for official and professional organisations, schools, universities and other interested bodies.
- To improve understanding and knowledge for end-users as well as for the public.
- To promote relations with European and international authorities.
- To promote scientific research and development in the field of minerals for animal nutrition.
- To cooperate with other organisations having similar interests.
- To act as a communication and information centre for interested parties.

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Foreword

This Code of Practice provides the feed additives and premixtures' operators information and options for the application of Article 16 of regulation No 1831/2003 on additives in animal nutrition. Feed Additives and Premixtures are produced by responsible feed business operators complying with annex II of the Regulation No 183/2005 on Feed Hygiene and are supplied to feed business operators.

In addition to the compliance with Article 16 of Regulation No 1831/2003, this Code also includes recommendation for the labelling of feed additives regarding other legislation, e.g. Regulation No 1829/2003 on Genetically Modified Food and Feed.

In producing this Code of Practice, FEFAC, FEFANA & EMFEMA support the view from the Authorities that the users of feed additives and premixtures shall be informed regarding the product they purchase and buy. However, FEFAC, FEFANA & EMFEMA consider that there are two main types of information to be delivered to the user of the feed additive or premixture:

- on one hand, the purchaser of the product has the right for informed choice and therefore, he shall have access to all necessary information for making its choice. This relates to conditions for use of the additive or premixture, animal categories and details of the composition. Indeed, the informed choice is linked to the future usage of the product.
- on the other hand, the final user of the product (potentially the same person) needs to have immediate safety information readily visible, when handling and using the products.

While the second type of information shall be linked to the product itself (i.e. to the place where the product is handled, in the working facility), the first type of information is necessary when the purchaser makes its choice (usually in the office of the production site). Therefore, FEFAC, FEFANA & EMFEMA consider that the two types of information can be dealt with by different means and propose the following:

- the safety information necessary for the proper handling and use of the products, which could have an impact on animal, human or environment safety should be placed on a label affixed to the product's container or to be placed at the workplace (in case of bulk deliveries)
- the choice related information can be placed either on the product's label or on a specific document, provided to the purchaser at any time the information in the document is modified. This is called the 'Product Specification Sheet' in the rest of the Code of Practice.

In this way, we achieve the two main goals of the labelling: an informed choice and safe handling of the products. As traceability is also linked to the product (i.e. batch numbers, manufacturing date), FEFAC, FEFANA & EMFEMA consider that this information shall be linked to the product and therefore should be part of the label affixed to the product container's.

Finally, as most of the feed additives and premixtures can be delivered in any of the 27 Member States within the European Union, FEFAC, FEFANA & EMFEMA consider that the information on the labels and Product Specification Sheets should be as a minimum in the local language of the country where the product is used.

To cover all the necessary information, FEFAC, FEFANA & EMFEMA have divided this Code of Practice in four main parts:

- Code of Practice for Labelling Feed Additives
- Code of Practice for Labelling Premixtures
- Templates for Product Specification Sheets for feed additives and premixtures
- Label Templates taking into account the different options recommended in the Code.

This document is foreseen as a support for the Feed Additive and Premixture Operators for the preparation of their labels. It shall also be used as a guide for Member States' Control Authorities, when visiting the feed additives and premixtures operators' facilities.

This document shall be a living document, to be updated with new requirements; new developments or issues faced by the Operators or the Control Authorities. In such cases, the information shall be sent to FEFAC, FEFANA & EMFEMA to be handled by the TF Labelling.

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A. FEFAC, FEFANA & EMFEMA Code of Practice for the Labelling of Feed Additives

Label is used as a tool to inform the user of the additive.

Additional information can be supplied via Product Specification Sheets (PSS) and/or Material Safety Data Sheets (MSDS).

(BLUE, ITALIC BOLD lines: options linked to FEFAC, FEFANA & EMFEMA proposal)

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LABEL INFORMATION

1. COMMERCIAL BRAND NAME

Mandatory: commercial name of the feed additive as mentioned in the regulation authorising a holder specific authorised additive

Optional: commercial name of the feed additive for non-holder specifically authorised additives

2. FUNCTIONAL GROUP

The functional group of the additive shall be placed before the name of the additive and can be used as a heading.

When the additive is listed in more than one functional group, the feed business operator can mention one or more of these functional groups.

Optionally, FEFAC, FEFANA & EMFEMA propose to indicate the functional group(s) only on the PSS. In that case, a reference to the PSS shall be placed on the label.

In any case, the name of the functional group (s) shall conform to the Annex I of Regulation No 1831/2003.

In case of functional groups having a long name (e.g. vitamins, provitamins and other chemically well defined substances having a similar effect), FEFAC, FEFANA & EMFEMA propose abbreviations.

When the additive falls under the scope of Regulation No 1829/2003 and 1830/2003, the relevant labelling information should be placed on the label.

Optionally, FEFAC, FEFANA & EMFEMA propose to replace information on the label regarding Regulation No 1829/2003 and 1830/2003 by the PSS. In that case, a reference to the PSS shall be placed on the label.

3. NAME OF THE ADDITIVE

The name used on the label shall conform to the name used in the authorisation of the additive, as indicated in the Register established according to Regulation No 1831/2003. It shall be accompanied by the identification number (e.g. E number).

The name of the additive shall be accompanied by the concentration of the active substance in the product.

Optionally, FEFAC, FEFANA & EMFEMA provide the possibility to indicate the description of the preparation on the label or on the PSS. In the case a PSS is chosen, a reference to the PSS shall be placed on the label.

4. NAME AND ADDRESS OF THE OPERATOR

Name or business name and the address or registered place of business of the person responsible for placing the feed additive on the market and for labelling information. It shall be the operator, who lastly modifies the name or the packaging of the product or who imports it (the manufacturer or the trader). This operator shall be located in the European Union.¹

In case of trading of the product, the name of the manufacturer may be also placed on the label.

5. APPROVAL OR REGISTRATION NUMBER

Approval or registration number as defined by Regulation No 183/2005 of the person responsible for placing the feed additive on the market and for labelling information.

6. DIRECTIONS FOR USE

Conditions for use provided in the annex of the regulation authorising the product:

- animal species and categories for which the feed additive has been authorised.
- minimal and maximal concentration of the additive in feedingstuffs, as indicated in the authorisation
- specific conditions for use shall be placed on the label.

Optionally, FEFAC, FEFANA & EMFEMA propose to indicate the directions for use on the PSS, with the exception of warning related to the risk of use for specific animal categories (e.g. horses or copper for sheep), which shall be kept on the label. In that case, a reference to the PSS shall be placed on the label.

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¹ In the case of control and potential non-compliance, this will be the operator, who will be contacted by the authorities.

7. IDENTIFICATION NUMBER, BATCH REFERENCE AND DATE OF MANUFACTURE, WEIGHT

Indicate on the label the net weight or, for liquid feed additives, the net volume or the net weight Indicate on the label the batch number and the manufacturing date : the manufacturing date shall contain the day, month and year according to ISO standard No 8601:2000 (yyyy-mm-dd).

For zootechnical additives, coccidiostats and histomonostats, and nutritional additives, indicate on the label the product shelf life from the date of manufacture or the 'best use before' date of the feed additive *according to ISO standard No 8601:2000 (yyyy-mm-dd)*. The shelf life shall be established on the basis of studies under proposed storage conditions.

In case the shelf life of the feed additive is above 6 months, the date of manufacture or 'best use before' can be indicated as follows: yyyy.mm.

The date of 'best use before' can be replaced by the indication of the shelf life expressed in months from the date of manufacture

8. ANY SAFETY RECOMMENDATIONS REGARDING THE USE

When the feed additive is a chemical substance, which shall be classified according to Directive 67/548 or based on the European Food Safety Authority evaluation, some information necessary to protect the workers at the working place, when handling the feed additive, shall be indicated on the label.

In the case of live microorganism, the classification of the microorganism according to Directive 2000/54 shall be given on the label or on a Safety Information Sheet.

When the preparation composition leads to its classification as a dangerous preparation (according to Directive 1999/45), the information necessary to protect the workers at the working place, when handling the feed additive, shall be indicated on the labels (hazard symbols, risk and safety sentences)

The Safety Datasheet shall contain all the necessary information (feed additive classification, risk sentences, safety sentences...) for an appropriate and safe use of the feed additive for the workers handling it.

9. BAR CODING

FEFAC, FEFANA & EMFEMA recommend the use of bar codes on the label of feed additives. These bar codes shall aim to:

- reduce the potential of handling mistakes
- improve traceability of the products.

Bar Codes shall contain as minimum information:

- the product code
- the lot number

ANNEX: FORMAT OF ADDITIVE CONCENTRATION (FEED ADDITIVES)

ANNEX: FORMAT OF ADDITIVE GROUP	OTHER ADDITIONS			
	CONTENT OF ACTIVE SUBSTANCE ²³ TECHNOLOGICAL ADDITIVES			
PRESERVATIVES		<u> </u>		
PRESERVATIVES	mg/g or %; units of activity/g; cfu/g			
ANTIOXIDANTS	mg/g or %; units of activity/g; cfu/g			
EMULSIFIERS	mg/g or %; units of activity/g; cfu/g			
STABILIZERS	mg/g or %; units of activity/g; cfu/g			
THICKENERS	mg/g or %; units of activity/g; cfu/g			
GELLING AGENTS	mg/g or %; units of activity/g; cfu/g			
BINDERS	mg/g or %; units of activity/g; cfu/g			
SUBSTANCES FOR CONTROL OF RADIONUCLEIDE CONTAMINATION	mg/g or %; units of activity/g; cfu/g			
ANTI-CAKING AGENTS	mg/g or %; units of activity/g; cfu/g			
ACIDITY REGULATORS	mg/g or %; units of activity/g; cfu/g			
DENATURANTS	mg/g or %; units of activity/g; cfu/g			
	SENSORY ADDITIVES			
COLOURANTS				
- All	mg/g or %			
FLAVOURING COMPOUNDS				
- feed flavouring compounds NOT subject to a quantitative, limitation when used in feed	Optional mg/g or %			
- feed flavouring compounds subject to a quantitative limitation when used in feed mg/g or %				
	NUTRITIONAL ADDITIVES			
VITAMINS, PROVITAMINS AND				
CHEMICALLY WELL DEFINED SUBSTANCES HAVING SIMILAR	Proposal for shorter			
EFFECT		name: 'Vitamins'		
All	mg/g; IU/g or %			
COMPOUND OF TRACE ELEMENTS	9.3 , 3	Proposal for shorter		
- All	mg/g or %	name: 'Trace elements'		
AMINO ACIDS, THEIR SALTS AND				
Analogues		Proposal for shorter name: 'Amino Acids'		
- All	mg/g or %	name. Amino Acids		
UREA AND ITS DERIVATIVES	mg/g or %	Proposal for shorter name: 'Urea'		
	ZOOTECHNICAL ADDITIVES			
DIGESTIBILITY ENHANCERS	mg/g or %; units of activity/g; cfu/g			
GUT FLORA STABILISERS	mg/g or %; units of activity/g; cfu/g			
SUBSTANCES WHICH FAVOURABLY AFFECT THE ENVIRONMENT	mg/g or %; units of activity/g; cfu/g	Proposal for shorter name: 'Environment Improver'		
OTHER ZOOTECHNICALS	mg/g or %; units of activity/g; cfu/g			
_	units of activity/g			
ENZYMES	diffes of activity/g			
MICRO-ORGANISMS	. •			
MICRO-ORGANISMS	cfu/g CCIDIOSTATS & HISTOMONOSTATS			

 $^{^2}$ In case of liquid additive, the concentration can be expressed as mg, unit of activity or cfu / ml. 3 The concentration can also be given as mg/kg....





B. FEFAC, FEFANA & EMFEMA Code of Practice for the Labelling of Premixtures

Label is used as a tool to inform the user of the premixture.

Additional information can be supplied via Product Specification Sheets (PSS) and/or Material Safety Data Sheets (MSDS).

(BLUE, ITALIC BOLD lines: options linked to FEFAC, FEFANA & EMFEMA proposal)

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LABEL INFORMATION

1. NAME

Obligatory: the term PREMIXTURE (in capitals). Allowed: commercial name of the premixture

Target animals or animal groups as part of directions for use or in name of premixture

2. CARRIERS

Feed materials are used as carriers for the production of premixtures (e.g. calcium carbonate, wheat middlings..). A heading 'Carrier(s)' shall be used.

In case no carriers are used, the heading shall not be mentioned.

The major carrier in terms of percentage (Feed material) must be mentioned as carrier with applicable name of the feed material (Directive 96/25/EC).

Mentioning of more than 1 carrier is allowed but not mandatory.

In case of more than 1 carrier, mention each of them in descending order of quantities.

In the case the carriers are from Genetically Modified Origin, leading to the labelling requirements of Regulation No 1829/2003 and 1830/2003, the information shall be given on the label.

Optionally, FEFAC, FEFANA & EMFEMA propose to replace all information regarding carriers on the label by the same information on the PSS. In that case, a reference to the PSS shall be placed on the label.

3. DECLARATION OF FEED ADDITIVES (see attached table)

The name and quantities of all feed additives (with the exception of flavouring additives for which no maximum permitted levels in feedingstuffs are set) shall be mentioned on the label according to Article 16 of Regulation No 1831/2003.

Optionally, FEFAC, FEFANA & EMFEMA propose to limit the list on the label to the additives having a legislative maximum permitted level, based on safety. If such an option is taken, the list of all additives shall be indicated on the PSS. In that case, a reference to the PSS shall be placed on the label.

The names used on the label shall conform to the names mentioned in the authorisation of the additives, as indicated in the Register established according to Regulation No 1831/2003. It shall be accompanied by the identification number (e.g. E number).

Optionally, FEFAC, FEFANA & EMFEMA propose to indicate the element (e.g. vitamin A or Copper) for nutritional and silage additives on the label, when the PSS option is taken. In this case, the complete name of the additive with its E number shall be written on the PSS. In that case, a reference to the PSS shall be placed on the label.

The names of the additives will be preceded by the name of the applicable functional groups. On the label, the name of the functional group can be used as a heading.

In case of functional groups having a long name (e.g. vitamins, provitamins and other chemically well defined substances having a similar effect), FEFAC, FEFANA & EMFEMA propose abbreviations.

Optionally and in addition brand names of feed additives are allowed as long as they are not misleading.

In case you use a premixture composed of additives of the same functional group (except flavouring compounds), the brand name of this premixture can be used on the label as long as the individual additives with applicable identification numbers (e.g. E number) of the component of this premixture are mentioned.

In case you use a flavouring compounds mixture, the brand name of this mixture can be used on the label.

When the additive falls under the scope of Regulation No 1829/2003 and 1830/2003, the relevant labelling information should be placed on the label.

Optionally, FEFAC, FEFANA & EMFEMA propose to indicate all information regarding additives on the PSS. In that case, a reference to the PSS shall be placed on the label and only the information on additives with a maximum permitted limit based on safety will be mentioned on the label.

4. NAME AND ADDRESS OF THE OPERATOR

Name or business name and the address or registered place of business of the person responsible for placing the premixture on the market and for labelling information. This operator shall be located in the European Union.

5. APPROVAL OR REGISTRATION NUMBER

Approval or registration number as defined by Regulation No 183/2005 of the person responsible for placing the premixture of the market and for labelling information.

6. DIRECTIONS FOR USE

- animal species and categories for which the premixture is intended,
- inclusion rate or a range of inclusion rates in feedingstuff (in %, kg per tonne or g per tonne)
- specific requirements mentioned in the authorization of the additives

Optionally, FEFAC, FEFANA & EMFEMA propose adding specific safety requirements to the label with general requirements mentioned in the authorisation of the additive on the PSS.

7. IDENTIFICATION NUMBER, BATCH REFERENCE AND DATE OF MANUFACTURE, WEIGHT

Indicate on the label the net weight or, for liquid premixtures, the net volume or the net weight Indicate on the label the batch number and the manufacturing date: the manufacturing date shall contain the day, month and year according to ISO standard No 8601:2000 (yyyy-mm-dd).

Indicate on the label the product shelf life from the date of manufacture or the 'best use before' date of the premixture according to ISO standard No 8601:2000 (yyyy-mm-dd). The shelf life shall be established on the basis of information regarding the stability of the additives in premixtures.

In case the shelf life of the premixture is above 6 months, the date of manufacture or 'best use before' can be indicated as follows: yyyy.mm.

The date of 'best use before' can be replaced by the indication of the shelf life expressed in months from the date of manufacture

8. Any Safety Recommendations Regarding the use

When the premixture composition leads to its classification as a dangerous preparation (according to Directive 1999/45), the information necessary to protect the workers at the working place, when handling the premixtures, shall be indicated on the labels (hazard symbols, risk and safety sentences)

The Safety Datasheet shall contain all the necessary information (premixture classification, risk sentences, safety sentences...) for an appropriate and safe use of the premixture for the workers handling it.

9. BAR CODING

FEFAC, FEFANA & EMFEMA recommend the use of bar codes on the premixtures labels. These bar codes shall aim to:

- reduce the potential of handling mistakes
- improve traceability of the products.

Bar Codes shall contain as minimum information:

- the product code
- the lot number.

ANNEX: ADDITIVES TO BE LABELLED (PREMIXTURES)

General comments for the use of the table:

In the column FEFANA / FEFAC / EMFEMA under Name of the Additive:

Yes means that the operator shall indicate the name of the additive, if a maximum permitted level in feed is mentioned in the authorisation of the additive

Optional means that the operator may either place on the label the name of the additive, even if there is no maximum permitted limits in the authorisation of the additive or indicate it on the Product Specification Sheet

In the column FEFANA / FEFAC / EMFEMA under Content of Active Substance:

Optional means that when the operator has chosen not to indicate the name of the additive on the label, he shall as well not indicate the concentration of that additive on the label.

pel, he shall as well not indicate the concentration of that additive on the label.							
ADDITIVE GROUP	NAME OF TH	HE ADDITIVE	CONTENT OF ACTIVE SUBSTANCE		OTHER ADDITIONS		
	Art. 16	FEFANA / FEFAC / EMFEMA	Art.1 FEFANA / FEFAC / EMFEMA				
	TECHNO	LOGICAL ADI	DITIVES				
PRESERVATIVES	Yes	Yes / Optional	YES (% or g/kg or mg/kg) (units o activity/ g); (cfu/kg)	; Yes/ f <i>Optional</i> k	In case you use a premixture of these compounds, the name of the active substance can be replaced by the identification numbers (e.g. E numbers), when the brand name of the premixture is placed on the label. The mentioning of the concentrations of the additives depend on the option taken by the operator (label or PSS)		
ANTIOXIDANTS	Yes	Yes / Optional	YES (% or g/kg) or mg/kg) (units o activity/ g); (cfu/kg)	; Yes/ f <i>Optional</i> k	In case you use a premixture of these compounds, the name of the active substance can be replaced by the identification numbers (e.g. E numbers), when the brand name of the premixture is placed on the label. The mentioning of the concentrations of the additives depend on the option taken by the operator (label or PSS)		
EMULSIFIERS	Yes	Yes / Optional	YES (% or g/kg or mg/kg) (units o activity/ g); (cfu/kg)	; Yes/ f <i>Optional</i> k	In case you use a premixture of these compounds, the name of the active substance can be replaced by the identification numbers (e.g. E numbers), when the brand name of the premixture is placed on the label. The mentioning of the concentrations of the additives depend on the		

ADDITIVE GROUP	NAME OF TH	HE ADDITIVE	CONTENT OF ACTIVE SUBSTANCE		OTHER ADDITIONS
	Art. 16	FEFANA/ FEFAC/ EMFEMA	Art.1	FEFANA / FEFAC / EMFEMA	
					option taken by the operator (label or PSS)
STABILIZERS	Yes	Yes / Optional	YES (% or g/kg) or mg/kg) (units o activity/g); (cfu/kg)	; Yes/ f <i>Optional</i> k	
THICKENERS	Yes	Yes / Optional	YES (% or g/kg or mg/kg) (units o activity/g); (cfu/kg)	; Yes/ f <i>Optional</i> k	
GELLING AGENTS	Yes	Yes / Optional	YES (% or g/kg or mg/kg); (units o activity/g); (cfu/kg)	; Yes/ f <i>Optional</i> k	
BINDERS	Yes	Yes / Optional	YES (% or g/kg or mg/kg); (units o activity/g); (cfu/kg)	; Yes/ f <i>Optional</i> k	
SUBSTANCES FOR CONTROL OF RADIONUCLEIDE CONTAMINATION	Yes	Yes / Optional	YES (% or g/kg or mg/kg); (units o activity/g); (cfu/kg)	; Yes/ f Optional k	
Anti-Caking agents	Yes	Yes / Optional	YES (% or g/kg) or mg/kg) (units o activity/g); (cfu/kg)	; Yes/ f <i>Optional</i> k	

ADDITIVE GROUP	NAME OF THE ADDITIVE		,	CONTENT OF ACTIVE SUBSTANCE		OTHER ADDITIONS	
	Art. 16	FEFANA/ FEFAC/ EMFEMA	Art.1 FEFANA / FEFAC / EMFEMA		EFAC/		
ACIDITY REGULATORS	Yes	Yes / Optional	or g/kg or mg/kg/ (units of activity g); (cfu/kg	YES (% or g/kg or mg/kg); (units of activity/k		In case you use a premixture of these compounds, the name of the active substance can be replaced by the identification numbers (e.g. E numbers), when the brand name of the premixture is placed on the label. The mentioning of the concentrations of the additives depend on the option taken by the operator (label or PSS)	
DENATURANTS	Yes	Yes / Optional	YES (% or g/kg or mg/kg) (units cativity g); (cfu/kg)	g); of v/k	Yes/ Optional		
	SEN	SORY ADDITIV	VES				
COLOURANTS							
- All	Yes	Yes / Optional	YES (g/kg o mg/kg	or	Yes/ Optional		
FLAVOURING COMPOUNDS							
- feed flavouring compounds NOT subject to a quantitative, limitation when used in feed	Mention inixture of havouring		NO		O	Brand name is allowed. In case a mixture of flavouring is included in a complete premixture, the operator shall indicate the incorporation rate of this mixture in the complete premixture.	
- feed flavouring compounds subject to a quantitative limitation when used in feed	YE	ES	YE	YES (mg/kg)		Brand name is allowed	
NUTRITIONAL ADDITIVES							
VITAMINS, PROVITAMINS AND CHEMICALLY WELL DEFINED SUBSTANCES HAVING SIMILAR EFFECT			YES (IU/kg, g / kg or mg/kg)			Proposal for shorter name: Vitamins'	
All	Yes	Yes / Optional				Traine. Vicanins	

ADDITIVE GROUP	NAME OF THE ADDITIVE		1	CONTENT OF ACTIVE SUBSTANCE		OTHER ADDITIONS
	Art. 16	FEFANA / FEFAC / EMFEMA	Art.1 FEFANA / FEFAC / EMFEMA		EFAC/	
COMPOUND OF TRACE ELEMENTS						Dunner of female auton
- All	Yes	Yes / Optional	kg or	YES (g / Yes/ kg or mg/kg)		Proposal for shorter name: 'Trace elements'
AMINO ACIDS, THEIR SALTS AND ANALOGUES						Proposal for shorter
- All	Yes	Yes / Optional	YES (g/kg o mg/kg)	Yes/ Optional	name: 'Amino Acids'
UREA AND ITS DERIVATIVES	Yes	Yes / Optional	YES (% or g/kç or mg/kg	g	Yes/ Optional	
	ZOOTE	CHNICAL ADD	ITIVES			
DIGESTIBILITY ENHANCERS	Yes	Yes / Optional	mg/kg) (units o	(g/kg or mg/kg); (units of activity/k g);		
GUT FLORA STABILISERS	Yes	Yes / Optional	YES (g/kg of mg/kg) (units of activity) g); (cfu/kg); of _' /k	Yes/ Optional	
SUBSTANCES WHICH FAVOURABLY AFFECT THE ENVIRONMENT	Yes	Yes / Optional	YES (g/kg o mg/kg) (units o activity g); (cfu/kg	or); of v/k	Yes/ Optional	Proposal for shorter name: 'Environment Improver'
OTHER ZOOTECHNICALS	Yes	Yes / Optional	YES (g/kg or mg/kg); (units of activity/k g); (cfu/kg)		Yes/ Optional	
Enzymes	Yes	Yes / Optional	YES (units of activity/k g)		Yes/ Optional	
MICRO-ORGANISMS	Yes	Yes / Optional	YES (cfu/kg		Yes/ Optional	

ADDITIVE GROUP	NAME OF TH	HE ADDITIVE	CONTENT OF ACTIVE SUBSTANCE		OTHER ADDITIONS
	Art. 16	FEFANA / FEFAC / EMFEMA	Art.1	FEFANA / FEFAC / EMFEMA	
COCCIDIOSTATS & HISTO				TATS	
COCCIDIOSTATS AND HISTOMONOSTATS	YE	ES	YES (g/kg or mg/kg)		Mention specific measures as defined upon authorization of the additive







C. Product Specification Sheets

In order to ensure that all information is available to the customer for decision making and for proper handling of the feed additive or of the premixture, FEFAC, FEFANA & EMFEMA have designed templates of Product Specification Sheet, which may be used, when the FEFAC, FEFANA & EMFEMA options are taken according to the Code of Practice.

The final format of the product Specification Sheet shall be left to each company. However, the information not mentioned on the label shall be present in the PSS

The information on the label takes precedent (in case of inconsistency)

.

$\label{lem:company} \textbf{Company name (responsible for the information on PSS and on the label-approval or registration)} \\$

number)

Date: XXXXX

Issue: XXX

Product Code: Internal numbering

Product Code: Internal numbering Page: XXXX

Brand name

Name of the feed additive (as defined in regulation 1831/2003)

1 - Product Description:

General description of the nature of the product as sold

2 - Regulatory status:

- Name of the additive as listed in Regulation No 1831/2003 (if available)
- Identification number (e.g. E number)
- Additive groups Regulation (EC) No. 1831/2003
 - Category: XXXX
 - Functional group: XXXXXX

3 - Guaranteed analysis:

- Active substance / activity level: XXXX in IU, mg, CFU....
- Specifications criteria as defined in the register, where appropriate

4 - Physical Characteristics:

- Appearance: XXXXX
- Bulk Density: XXXXX

And all relevant information for the use of the product

5 Compliance with other regulations (optional)

Indicate the compliance with relevant (i.e. for which the product must comply) regulations, which should be clearly mentioned,

- e.g. product complies with Directive 2002/32 limits on dioxin.
- e.g. product is produced from a Genetically Modified Organism and falls under the scope of Regulation No 1829/2003.

Company name (responsible for the information on PSS and on the label – approval or registration

number)

XXX

Product Specifications Internal numbering

Product Code: Internal numbering Date: XXXXX Page: XXXX

Issue:

If under GM scope, this statement should be compulsory for ease and accuracy of use in premixtures and feeds

6 - Animal category(ies) and species:

As defined in the Register, name of the categories and limitations or recommended dosages.

Company recommended dosages may also be included here.

7 - Directions for use:

As defined in the register for the specific feed additive (i.e. current 'other provisions') and as defined in Article 10 of Regulation 1831/2003.

Company may also indicate here specific recommendations.

8 -Safety recommendations:

See safety data sheet (Reference to Safety Datasheet as defined in Directive 67/548.and/or 1999/45)

9 - Storage and Shelf Life:

- Storage conditions: defined by the Company
- Shelf life: defined by the Company (if necessary)

10 - Packaging:

Size and type (bag, carton, big bag...)

(Optional)

Distributor reference:

Stamp of the distributor containing name, address and approval/registration number as appropriate

Company name (responsible for the information on PSS and on the label – approval or registration

number)

Issue:

Date: XXXXX

XXX

Product Specifications Internal numbering
Product Code: Internal numbering

Product Code: Internal numbering Page: XXXX

Brand Name of the premixture

1 - Product Description:

PREMIXTURE of specified feed additives

2 - Composition:

- For PREMIXTURE of flavouring compounds:
 - 'Mixture of flavouring compounds'
 - Name of the additive; incorporation rate of the flavouring compound when there is a maximum permitted level.
- For other PREMIXTURE, each additive in the PREMIXTURE:
 - Name of the additive
 - Active substance / activity level: in case of a maximum permitted level, the exact quantity in the premixture; in case of recommended dosage, a range of activity or active substance; in case there is no limitation, no active substance / activity level (according to FEFAC / FEFANA position)
 - Functional group
 - Mention: 'Mixture of flavouring compounds' without any further information regarding its composition.
- Carrier(s): XXXXX

3 - Physical Characteristics: (Optional)

Appearance: XXXXX

• Bulk Density: XXXXX

And all relevant information for the use of the product

4 Compliance with other regulations (Optional)

Indicate the compliance with relevant (i.e. for which the product must comply) regulations, which should be clearly mentioned,

Company name (responsible for the information on PSS and on the label – approval or registration

number)

Issue: XXX

Product Specifications Internal numbering Date: XXXXX

Product Code: Internal numbering Page: XXXX

e.g. the premixture complies with Directive 2002/32 limits on dioxin.

e.g. the premixture contains the additive xxx produced from a Genetically Modified Organism falling under the scope of Regulation No 1829/2003.

Indicate the non relevant regulations, by mentioning they do not apply to this product.

If under GM scope, this statement should be compulsory for ease and accuracy of use in feeds.

5 - Animal category(ies) and species:

Mention the animal category(ies) and species for which the premixture is intended

6 - Directions for use:

Mention the incorporation rate

7 -Safety recommendations:

See safety data sheet (Reference to Safety Datasheet as defined in Directive 67/548.and/or 1999/45)

8 - Storage and Shelf Life:

- Storage conditions: defined by the Company
- Shelf life: defined by the Company (if necessary)

9 - Packaging:

Size and type (bag, carton, big bag...) (Optional)

Distributor reference:

Stamp of the distributor containing name, address and approval/registration number as appropriate







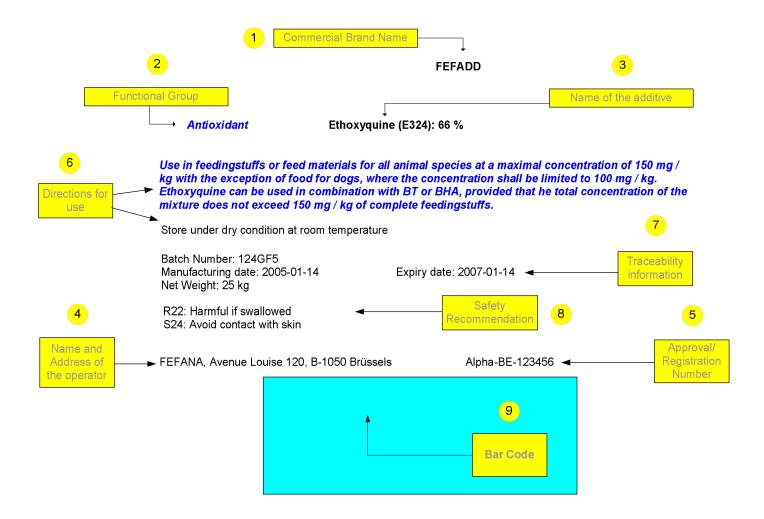
D. Labels Examples

The objective of this section is to show some examples, based on real products, of labels and Product Specification Sheets as they will look like based on recommendations of the Code of Practice here above. It is aimed to visualise the differences between the different options and support the members in the application of the above mentioned rules.

Notice, the information below shall not be considered as being valid for the said examples.

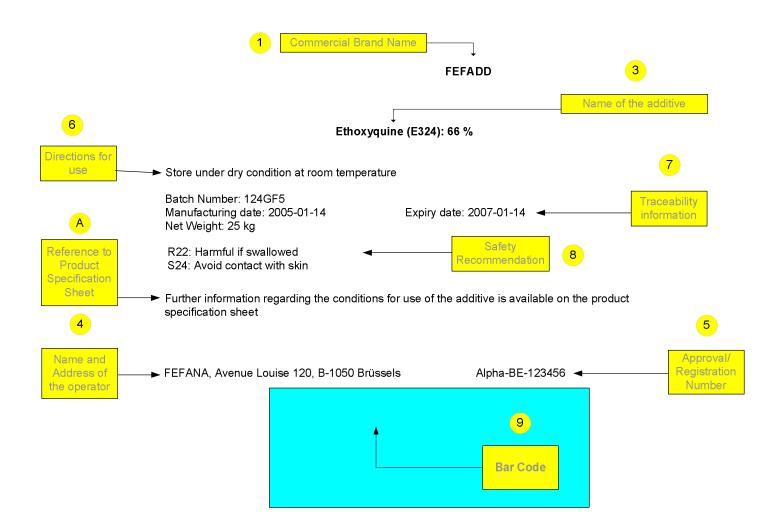
Feed Additive Label Example

This example corresponds to the current Article 16 for the additive Ethoxyquine. This does not refer to any Product Specification Sheet and shall be translated in one of the official languages where the product is to be delivered and used.



Feed Additive Label Example FEFANA / FEFAC / EMFEMA Option

This example corresponds to the same label as above, with the application of the FEFANA / FEFAC / EMFEMA Option. Some information is on the labels, while others are on the product Specification Sheet. In this case, the product shall be accompanied with the product Specification Sheet (see next page)



Product Specification Sheet – FEFANA / FEFAC / EMFEMA Option **FEFADD**

Ethoxyquine

1 - Product Description:

FEFADD is a fine, white free flowing powder

2 - Regulatory status:

Ethoxyquine

E number: E 324

Additive groups

- Category: Technological

- Functional group: Antioxidant

3 - Guaranteed analysis:

Active substance / activity level: min. 66 % of ethoxyquine

4 - Physical Characteristics:

• Appearance: fine white powder

Bulk Density: 1.1 g / ml

FEFADD shall be stored away from humidity, while it has a tendency to cake.

5 Compliance with other regulations

As FEFADD is an active substance produced by chemical synthesis, it does not fall under the scope of Directive 1990/219 on the contained use of Genetically Modified Microorganism, nor under the scope of the regulation NO 1829/2003 on Genetically Modified Food and Feed.

No limits have been set up on any of the undesirable substances listed in the Directive 2002/32.

6 - Animal category(ies) and species:

Ethoxyquine can be used in feedingstuffs for all animal categories at a maximum concentration in complete feed of 150 mg / kg feedingstuffs, with the exception of dogs, where the maximum dose is 100 mg / kg dog complete feedingstuff.

Ethoxyquine can be used in combination with BHA and BHT, provided that the total concentration of the mixture does not exceed 150 mg /kg.

FEFADD shall be incorporated in feedingstuffs at a concentration between 50 and 100 mg / kg, depending on the concentration and composition of fat.

7 - Directions for use:

FEFADD shall be added directly in the feed materials containing high level of unsaturated fats or via a premixture into complete feedingstuffs. When using feed materials rich in fat, it should be taken care of the concentration of antioxidant in these feed materials before adding FEFADD in the complete feed.

8 -Safety recommendations:

FEFADD is labelled as harmful if swallowed. Specific handling measures are available on the Product Safety Datasheet.

9 - Storage and Shelf Life:

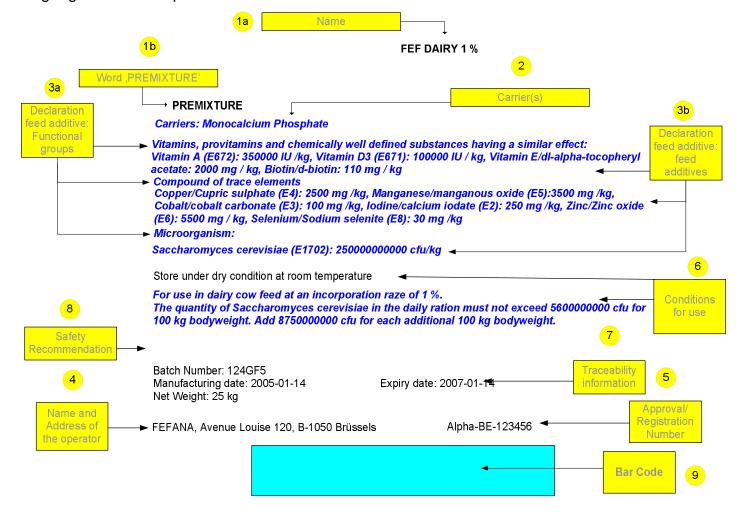
- FEFADD shall be stored under dry condition at a temperature below 25 %.
- When stored under the above mentioned conditions, the product is stable for a period of minimum 2 years from the date of manufacture. When the package is open, use the content in a short period of time.

10 - Packaging:

Bag with plastic inline of 25 kg

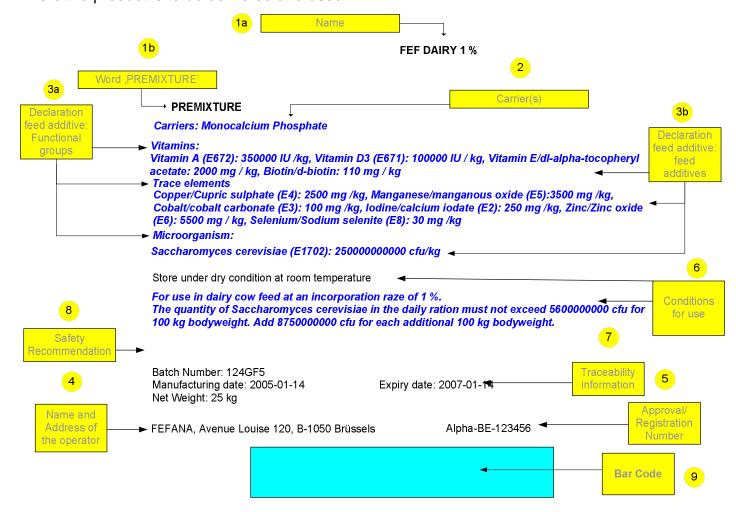
Premixture Example Template

This example corresponds to the current Article 16 for a specific type of premixture. This does not refer to any Product Specification Sheet and shall be translated in one of the official languages where the product is to be delivered and used.



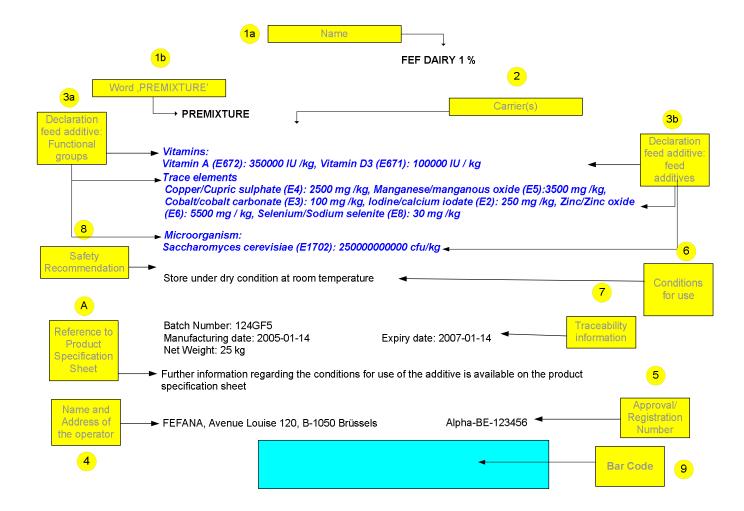
Premixture Label Example – FEFANA / FEFAC / EMFEMA Short names

This example corresponds to the current Article 16 for a specific type of premixture, but using the FEFANA / FEFAC / EMFEMA option to functional group short names. This does not refer to any Product Specification Sheet and shall be translated in one of the official languages where the product is to be delivered and used.



Premixture Label Example FEFANA / FEFAC / EMFEMA Option

This example corresponds to the same label as above, with the application of the FEFANA / FEFAC Option. Some information is on the labels, while others are on the product Specification Sheet. In this case, the product shall be accompanied with the product Specification Sheet (see next page)



FEF Dairy 1 %

1 - Product Description:

PREMIXTURE for incorporation in compound feedingstuffs for dairy cow at a concentration of 1 %

2 - Composition:

- Vitamins
 - Vitamin A (E672): 350.000 IU / kg
 - Vitamin D3 (E671): 100.000 IU / kg
 - Vitamin E/dl-alpha-tocopheryl acetate
 - Biotin/d-biotin
- Trace elements
 - lodine/calcium iodate (E2): 250 mg / kg
 - Cobalt/cobalt carbonate (E3): 100 mg / kg
 - Copper/Cupric sulphate (E4): 2.500 mg /kg
 - Manganese/Manganous oxide (E5): 3.500 mg / kg
 - Zinc/Zinc oxide (E6): 5.500 mg / kg
 - Selenium/Sodium selenite (E8): 30 mg / kg
- Microorganism
 - Saccharomyces cerevisiae NCYC Sc 47 (E 1702): 250 x 10⁹ cfu / kg
- Carrier(s): Monocalcium phosphate

3 - Physical Characteristics:

• Appearance: Grey free flowing powder

Bulk Density: 0.9 kg / l

4 Compliance with other regulations

5 - Animal category(ies) and species:

This premixture is intended for use in compound feedingstuffs for dairy cows.

6 - Directions for use:

The premixture shall be incorporated in feed at a concentration of 1 %.

The premixture contains Saccharomyces Cerevisiae NCYC Sc47. The quantity of Saccharomyces Cerevisiae in the daily ration must not exceed 5.6 x 109 cfu for 100 kg of bodyweight. Add 8.75 x 109

cfu for each additional 100 kg bodyweight.

7 -Safety recommendations:

Further information regarding the handling of the product can be found in the Premixture Safety Data

Sheet.

8 - Storage and Shelf Life:

The premixture shall be stored in dry place below 25 °C.

Under these conditions, the product can be stored for a period of 6 months

9 - Packaging:

Bags with plastic inliner: 25 kg