

Labeling Products Containing Direct Fed Microorganisms (DFMs), Yeasts, and Enzymes

DIRECT FED MICROBIALS (DFMs)

Pursuant to Kentucky Commercial Feed and Pet Food Regulations (12KAR 2:041)(4) and as outlined in the AAFCO Official Publication Regulation 9(b)(4), commercial feed has three direct fed microbial requirements.

1. The ingredient(s) should meet the appropriate AAFCO fermentation definition and be identified as such in the ingredient statement.
2. The label should contain the statement “Contains a source of live (viable), naturally occurring microorganisms.”
3. The label guarantee should be consistent with Regulation 4(g). The units for the guarantee shall be stated in colony forming units CFU/g or CFU/lb, depending on the directions for use. A parenthetical statement should follow the guarantee, listing each species in order of predominance.

Guaranteed analysis formats for DFMs

Format 1

Total microbial count, minimum1,000,000 CFU/lb

(Lactobacillus acidophilus, Bifidobacterium thermophilum, Bifidobacterium longum, Enterococcus faecium)

Note that the order of microorganisms listed in the parentheses should be listed in order of predominance.

Format 2

Total microbial count, minimum	2X10E6 CFU/lb
Lactobacillus acidophilus, minimum	8X10E5 CFU/lb
Bifidobacterium thermophilum, minimum	6X10E5 CFU/lb
Bifidobacterium longum, minimum	4X10E5 CFU/lb
Enterococcus faecium, minimum	2X10E5 CFU/lb

Note that format 2 is more informative to the consumer as it tells him exactly what species and amounts of these species are present in the product.

It should also be noted the values listed in the guaranteed analysis for DFMs should reflect the activity of those substances present in the product *at the time of purchase*, and should not reflect the amount of enzyme activity *at the time of manufacture*.

Additional guaranteed analysis requirements for DFD guarantees on pet or specialty pet products

Any guarantee that is not noted as essential by the AAFCO Dog or Cat Food Nutrient Profiles should appear last in the order of guarantees and be noted with an asterisk (*) that leads to the following disclaimer: *Not recognized as an essential nutrient by the AAFCO Dog (or Cat) Nutrient Profiles.

Example:

Guaranteed Analysis

Crude protein, minimum	26%
Crude fat, minimum	8%
Crude fiber, maximum	4%
Moisture, maximum	12%
Total Microbial Count, minimum*	2X10E6 CFU/lb
(Lactobacillus acidophilus, Bifidobacterium thermophilum, Bifidobacterium longum, Enterococcus faecium)	

*Not recognized as an essential nutrient by the AAFCO Dog (or Cat) Nutrient Profiles.

Are DFM's required to be guaranteed?

Pursuant to Kentucky Commercial Feed and Pet Food Regulations (12KAR 2:018)(12)(4) and according to AAFCO Regulation 3(XI)(d), guarantees are not required when the commercial feed is intended for a purpose other than to furnish these substances or they are of minor significance relating to the primary purpose of the product and no specific labels claims are made. A microbial guarantee is necessary in all other situations when the commercial feed contains direct fed microorganisms. If you make any claims regarding the addition or inclusion of direct fed microbes in your product, they must be appropriately guaranteed.

The ingredient statement for the above DFM examples might appear as:

Ingredients: xxx, xxx, dried Lactobacillus acidophilus fermentation product, dried Bifidobacterium thermophilum fermentation product, dried Bifidobacterium longum fermentation product, dried Enterococcus faecium fermentation product, xxx, xxx

For pet and specialty pet products, each ingredient must appear in order of inclusion of that ingredient in the overall formula by weight.

VIABLE YEASTS**Guaranteed analysis format for viable yeasts**

These guarantees must be made using Colony Forming Units (CFU). Note that the same additional requirements for pet and specialty pet products described earlier for DFM's (*not recognized as essential...etc. and ingredient order in the ingredient statement) also apply to yeast ingredients and guarantees.

Saccharomyces cerevisiae, minimum	1,000,000 CFU/lb
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It should also be noted that similar to DFM's, the values listed in the guaranteed analysis for viable yeasts should reflect the activity of those substances present in the product *at the time of purchase*.

Are viable yeasts required to be guaranteed?

If viable yeast is included in a product formulation but no claims regarding the addition of that ingredient or claims regarding the function of the yeast in the product or animal are made, no guarantee is required. If there are claims regarding the inclusion of yeasts as a probiotic, or claims regarding the function of live yeast in the animal/feed on the labeling, then an appropriate guarantee is required to substantiate the claim.

How do I list viable yeasts in the ingredient statement?

When viable yeast is included in a formulation, the appropriate ingredient definition should be taken from section 96 'Yeast' of the AAFCO Official Publication. The two classifications of viable yeast noted in this section include *Saccharomyces cerevisiae* and *Kluyveromyces marxianus*. Note that while the yeast *Candida utilis* (formerly *Torulopsis utilis*) is included in this section, the ingredient definition is for non-viable source *Candida* only.

Examples of acceptable viable yeast feed ingredient definitions include:

- 96.2 Active dry yeast
- 96.8 Yeast culture
- 96.8 Yeast culture (_____)

Note that the specific two part scientific name of the yeast (*Saccharomyces cerevisiae* or *Kluyveromyces marxianus*) replaces the blank in the above definition.

Examples of inappropriate ways to list viable yeast in the ingredient statement include:

- Dried (or Liquid) *Saccharomyces cerevisiae* fermentation product
- Dried *Saccharomyces cerevisiae* fermentation extract
- Dried *Saccharomyces cerevisiae* fermentation solubles
- *Saccharomyces cerevisiae*
- Yeast (*Saccharomyces cerevisiae*)
- Yeast

ENZYMES

Appropriate enzymes for animal feeds including pet foods can be found in Section 30 of the AAFCO OP in Table 30.1 titled 'Enzymes/Source Organisms Acceptable for Use in Animal Feeds.' In all cases, it is understood that the enzymes should be produced from nonpathogenic and nontoxigenic strains. The table lists acceptable enzymes according to source organism, typical substrate, function and current supported use.

Guaranteed analysis format for enzymes

Enzyme guarantees should follow PF 4(h) which refers to Model Bill Regulation 4 (h). Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, with the unit being consistent with label feeding/use directions. If the assay description is too long for the guaranteed analysis section, the assay description may be placed elsewhere on labeling as long as a sufficient explanatory footnote is provided. The source organism for each type of enzymatic activity shall be specified. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.

Examples of appropriate enzyme guarantee:

- Protease (*Bacillus subtilis*), minimum ... 5.5 mg amino acids liberated/min/milligram
 - Phytase (*Aspergillus niger*), minimum ... 300 FTU¹/lb
- ¹ One FTU is the amount of phytase which liberates one micromole of phosphorus per minute from sodium phytate at 37° C and pH 5.5 (under conditions of the assay).
- Protease (*Aspergillus niger*, *Bacillus subtilis*) minimum ... 5.5 mg amino acids liberated/min/milligram

Since enzymes are not recognized as essential nutrients by the AAFCO Dog or Cat Food Nutrient Profiles, these guarantees should follow the rules for guaranteeing non-essential guarantees as described elsewhere in this labeling guide. This includes appearing after all essential nutrients in order of the guaranteed analysis, inclusion of the non-essential by asterisk (*) leading to the disclaimer immediately following the guaranteed analysis section.

Similar to DFMs and viable yeasts, the values listed in the guaranteed analysis for enzymes should reflect the activity of those substances present in the product *at the time of purchase*.

Are enzyme guarantees required?

Where claims regarding the presence and/or function of enzymes are made on animal or pet food labeling, appropriate guarantees are required to be provided in the Guaranteed Analysis section of the label. Also please note that a statement of enzyme functionality (what the enzyme does) needs to be included in the product description statement for a product making claims about its enzyme content.

How do I list enzymes in the ingredient statement?

While Table 30.1 lists accepted enzymes, please note that the enzyme name (ex. protease) is not the complete ingredient definition that should be used in the ingredient statement. Where enzymes are added to animal and pet foods, the ingredient name used should be listed according to source organism. Appropriate ingredient definitions for enzymes include those found in section 36 'Fermentation Products.'

Examples of appropriate enzyme ingredient definitions include:

- 36.6 Dried _____ Fermentation Extract
- 36.7 Dried _____ Fermentation Solubles
- 36.12 Liquid _____ Fermentation Product
- T36.11 Dried _____ Fermentation Product
- Dried pineapple

Note that the specific two part scientific name of the source microorganism replaces the blank in the above definitions. For example, a phytase product produced from *Aspergillus niger* might be listed by source organism in the ingredient statement as 'Dried *Aspergillus niger* fermentation extract.' It is not appropriate to include the enzyme name in the ingredient statement.

Enzymes derived from plants or animals should be listed in the ingredient statement according to the common and usual name of the ingredient that is the source of that enzyme activity (ex. Dried pineapple, fig extract, dried pancreas).

Examples of unacceptable ways to list enzymes in the ingredient statement.

- Protease
- Protease (*Aspergillus niger*)
- Dried *Aspergillus niger* fermentation extract (protease)
- Bromelain (pineapple)

Please contact the Registration Specialist at the University of Kentucky Division of Regulatory Services Feed Program if you have additional questions: (859) 257-4496.