Labels for Enzymes Used in Feed

Mika Alewynse
Division of Animal Feeds
Center for Veterinary Medicine

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Enzyme Labels

- Where are the enzyme regulations
- What should be on the label
- Trouble spots

Enzymes and the CFR

- Approved ingredients listed in:
  - 21 Code of Federal Regulations
    - 582.1585 Papain
    - 582.1685 Rennet
    - 573.130 Aminoglycoside 3'-phosphotransferase II for use in bioengineered oilseed rape, tomato, cotton
- Nothing unique for enzymes

Enzymes and the OP

- Accepted ingredients listed in Table 30.1
- Unique aspects – Enzyme Marketing Coordination document
- Model regulations
  - Acceptability - regulation 9(b)(5)
  - Purpose – regulation 3(a)(3)(VI)
  - Guarantees - regulation 4(h)
- Pet & specialty pet food regulations
  - Guarantees – regulation PF4(h)

Enzyme Labels

- Enzyme labels are not unique
- Everything that is needed for a “regular” feed label is also needed for enzymes
- So, what should be there?

Federal Requirements

- Name (sort of)
- Ingredient list
- Use directions
- Caution/ warning statements
- Net Contents
- Manufacturer or distributor identifier
- Firm name and location

AAFCO Regulations

- More detailed than federal requirements
- Name
- Purpose statement
- Guarantees
- Use directions

Complete Label

- Name
- Purpose statement
- Guarantees
- Ingredient list
- Detailed use directions
- Caution/ warning statements
- Manufacturer/ distributor identifier
- Firm name and location
- Net content

Problem Areas for Labels

- Ingredient list
- Use directions
- Guarantees
- “Use by” dates (not mandated)

Ingredient List

- No
  - Phytase
  - Phytase from Aspergillus niger
  - Aspergillus niger fermentation extract (phytase)
- Yes
  - Aspergillus niger fermentation extract
- If product contains a fermentation ingredient
  - Use definition from Section 36, Fermentation Products

Ingredient List (cont)

- Can I use an organism listed in 36.14, the Direct-fed Microorganisms, for an enzyme product?
- An enzyme and the organism that produces it are linked, as indicated in Table 30.1
  - Cannot mix and match

Potential Definitions

- Which fermentation ingredient?
- Look at the definitions
  - 36.6 Dried ____ Fermentation Extract

    is the dried product resulting from extracting and precipitating by means of non-aqueous solvents or other suitable means, the water soluble materials from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganism in accordance with good manufacturing practices.

  - 36.7 Dried ____ Fermentation Solubles

    is the dried material resulting from drying the water soluble materials after separation of suspended solids from a fermentation conducted for maximum production of enzymes using a non-pathogenic strain of the microorganism in accordance with good manufacturing practices.

Potential Definitions (cont)

- 36.11 Dried ____ Fermentation Product

  is the product derived by culturing ____ on appropriate nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and dried in accordance with approved methods and good manufacturing practices. Protein, amino acids, fat, fiber, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable...

- 36.12 Liquid ____ Fermentation Product

  is the liquid product derived by culturing or fermenting ____ on appropriate liquid nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and stabilized by approved methods in accordance with good manufacturing practices. Percent solids, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable...

Potential Definitions (cont)

- What about enzymes obtained from plants or animals?
  - What is the common and usual name of the “ingredient?”
    - Dried pineapple
    - Fig extract
    - Dried pancreas
    - Phytase canola

Use Directions

- Remember the end user
  - Include avoirdupois units
  - If different species or animal classes require different amounts, state that
    - Phytase - use rates often differ among layers, broilers, turkeys, and swine

Those Pesky Guarantees

- Regulation 4(h)
  - Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for each type of enzymatic activity shall be specified, such as: Protease (Bacillus subtilis) 5.5 mg amino acids liberated/min./milligram. 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.

Guarantees (cont)

- Enzyme Marketing Coordination document
  - Either avoirdupois or metric, correspond to the use directions
  - Include source organism
  - Include units
  - List sources by contribution of enzymatic activity

Guarantees (cont)

- What is in the guarantee?

  Protease (Bacillus subtilis) 5.5 mg amino acids liberated/ minute/ milligram

  – Protease – type of enzyme activity

  – B. subtilis – source organism

  – mg amino acids liberated/ minute/ mg – unit of enzymatic activity

Guarantees (cont)

- Guarantees can be long
  - Protease (Bacillus subtilis) 5.5 mg amino acids liberated/ minute/ milligram
- Firms can split and can explain units elsewhere on label
  - Protease (Bacillus subtilis) 5.5 units*/ mg

  * 1 unit of protease activity liberates 1 mg amino acid from casein/ minute

Guarantees (cont)

- Most problematic are the units
- What is there?

  mg amino acids liberated/ minute/ mg

  – mg amino acids liberated – what the enzyme does

  – minute – time unit

  – mg – unit of enzyme product

Guarantees (cont)

- Units are enzyme specific – what enzyme does
- Units are also assay specific for a particular type of activity

Guarantees-Enzyme Specific

mg amino acids liberated/ minute

- Look at Function in Table 30.1
  - Phytase – hydrolyzes phytate
  - Protease – hydrolyzes proteins
  - Lipase – hydrolyzes triglycerides (fat)
  - Cellulase – breaks down cellulose

Enzyme Specific Uses

- Why are there so many different enzymes used in feed?
  - Added to affect processing of ingredient
    - amylase
  - Added to alter digestibility of feed ingredient
    - phytase
  - Added to alter characteristics of digesta
    - xylanase

Enzyme Specific Uses (cont)

- There is no such thing as a generic animal feed
  - Multitude of species
    - Companion animals, traditional livestock, non-traditional species (fish, llamas, ostriches)
  - All stages of an animal's lifespan
    - Neonate, growing, mature, breeding, elderly (primarily companion animals)

Enzyme Specific Uses (cont)

- Plants and byproducts are large proportion of many feeds
- Often contain undesirable components
  - Phytate, reduces phosphorus availability
  - Stachyose and raffinose, less available sources of energy

Guarantees-Assay Specific

- Units are also assay specific for a particular type of activity
- Few standard assays
- Assay can measure 1 of 2 things
  - Change in substrate
    - Decrease in protein concentration
    - mg casein hydrolyzed/ minute
  - Change in end product
    - Increase in amino acid levels
    - mg amino acids liberated/ minute

Guarantees-Assay Specific (cont)

- What to choose?
  - Pick easiest to measure, generally, breakdown product
    - Protease – increase in amino acid concentrations
    - Phytase – increase in amount of free phosphorus
    - Amylase – increase in sugar levels

Guarantees (cont)

- Are there any Standards?
  - AOAC
  - Food Chemical Codex

“Use by” Dates

- Not required
- Why include them?
  - Enzymes are proteins and activity depends on protein structure
  - Protein structure degrades with time even with preservatives
- Inclusion could prevent questions concerning guarantees with an out-of-date product

Questions?