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Memorandum

Date **June 24, 1994**

From **CO-STEP, Division of Animal Feeds, HFV-220
Veterinary Medical Officer, HFV-214**

Subject **ORGANIC FOOD REVIEW**

To **Mr. Michael Hankin, Natural Organic Program, USDA
Thru: Deputy Director, Division of Animal Feeds, HFV-220** *W.D. Price*

As per your request, this memo provides the Center for Veterinary Medicine's review and comment on Proposed Inputs For Organic Livestock Production; includes Feed Additives, Health- Care, Sanitation and Pest Control. The regulation applicable to these products are found in Title 21, Code of Federal Regulations. For your information and convenience, we have listed the applicable Part of Title 21 after the compounds.

CATEGORY III:

1. Cobalt is allowed for use in animal feed under 582.80, by regulation*, as the following source compounds:

- Cobalt acetate
- Cobalt carbonate
- Cobalt chloride
- Cobalt oxide
- Cobalt sulfate

The following forms are allowed by FDA discretion as stated by AAFCO** :

- Cobalt choline citrate complex (57.123)
- Cobalt glucoheptonate (57.148)
- Cobalt gluconate (57.147)

* Code of Federal Regulations, Title 21, Part 500

** Official Publication, 1994, Association of American Feed Control Officials, Inc.

2. Choline is allowed for use in animal feed by regulation, as the following source compounds:

- Choline bitartrate (582.5250)
- Choline chloride (582.5252)

Choline xanthate (573.300; choline xanthate may be used as an added source of choline to supplement the diets of poultry, ruminants and swine)

The following form is allowed by FDA discretion as stated by AAFCO:

- Choline pantothenate (90.25)

3. Folic Acid is allowed by FDA discretion as stated by AAFCO:

- Crystalline Folic Acid (90.25)

4. Pantothenic Acid is allowed for use in animal feed by regulation, as the following source compound:

- Sodium pantothenate (582.5772)

Pantothenic acid is allowable by FDA discretion as stated by AAFCO:

- d- Calcium pantothenate (90.26)

5. Iodine is considered GRAS for nutritional purposes when used at levels

under 21 CFR 582.240 in the following forms:

- Calcium iodate
- Calcium iodobenenate
- Cuprous iodide
- 3,5-Diodosaliclic acid
- Ethylenediamine Dihydroiodide (EDDI)***
- Potassium iodate
- Potassium iodide
- Sodium iodate
- Sodium iodide
- Thymol iodide

Calcium periodate is permitted for use in salt for livestock as source of iodine under 21 CFR 573.240.

***EDDI is restricted in cattle to feed levels that provide no more than 10 mg per head per day by FDA Compliance Policy Guide 7125.18. Higher levels are considered to be new animal drugs.

Ionized salt (NaCl) containing not less than 0.007% iodine uniformly distributed is permitted by FDA by regulatory discretion and defined by AAFCO.

6. Biotin is allowed for use in animal feed under 582.5159 (GRAS) as the following substance by regulation:

- Biotin - Commercial Feed Grade

7. Molybdenum is allowed for use in animal feed by FDA discretion as stated by AAFCO:

- Sodium molybdate (57.145)

CATEGORY II

1. Calcium is allowed for use in animal feed, by regulation, under:

- Calcium bitartrate (582.5250)
- Calcium carbonate (582.5191; must have minimum of 3.8% calcium)
- Calcium citrate (582.5195)
- Calcium glycerophosphate (582.5201)

- Calcium oxide (582.5210)
- Calcium phosphate (582.5217)
- Calcium pyrophosphate (582.5223)
- Calcium sulfate (582.5230)

The following sources of calcium are available by FDA discretion within the limitations described by AAFCO :

- Bone ash (57.1)
- Bone charcoal (57.2)
- Bone charcoal, spent (57.17)
- Bone meal, cooked (57.141)
- Bone meal, steamed (57.18)
- Bone phosphate (57.14)
- Calcite (57.3)
- Calcium carbonate precipitated (57.7; not to contain less than 33% calcium)
- Calcium chloride (57.51)
- Calcium formate (source of supplemental calcium in swine diets and not to supply more than 0.6% calcium to the diet)
- Calcium gluconate (57.52)
- Calcium glycerophosphate ((582.5201)
- Calcium hydroxide (57.53)
- Calcium pyrophosphate (582.5223)
- Chalk, precipitated (57.8; not less than 33% Ca)
- Chalk, rock (57.6; not less than 33% Ca)
- Clam shells, ground (57.131; not less than 35% Ca)
- Dicalcium phosphate (57.71)
- Gypsiferrous shale (57.30)
- Limestone, dolomitic (57.11)
- Limestone, ground (57.9)
- Monocalcium phosphate (57.98)
- Oyster shell flour (57.4; must contain not less than 33% Ca)
- Phosphate, defluorinated (57.12)
- Rock phosphate, soft (57.15)
- Rock phosphate, ground (57.20)
- Rock phosphate, ground, low fluorine (57.21)
- Shell flour (57.5; not less than 33 % Ca)
- Tricalcium phosphate (57.113)

2. Copper is allowed for use in animal feed by regulation, in the form of copper gluconate (at a level not exceeding 0.005%) under 582.5260. In the following source compounds under 582.80:

- Copper carbonate
- Copper chloride
- Copper gluconate
- Copper hydroxide
- Copper orthophosphate

- Copper oxide
- Copper pyrophosphate
- Copper sulfate
- Cuprous iodide

The following sources of copper are available by FDA discretion, within the limitations provided by AAFCO:

- Copper lysine complex (57.151)
- Copper, amino acid chelate (57.142)
- Copper choline citrate complex (57.122)
- Copper polysaccharide complex (57.29)
- Copper proteinate (57.23)
- Copper acetate (57.53)

3: Iron is allowed for use in animal feed by regulation, in the following source compounds under 582.80:

- Iron ammonium citrate
- Iron carbonate
- Iron chloride
- Iron gluconate
- Iron oxide
- Iron phosphate
- Iron pyrophosphate
- Iron sulfate
- Reduced iron

Iron is also allowed for use in animal feed under the following FDA regulations:

- Ferric phosphate (582.5301)
- Ferric pyrophosphate (582.5304)
- Ferrous lactate (582.5311)
- Ferrous sulfate (582.5315)

The following mineral products (sources of iron) are available by FDA discretion within the limitations provided by AAFCO:

- Ferric ammonium citrate (57.76)
- Ferric chloride (57.78)
- Ferric choline citrate complex (57.121)
- Ferric formate (57.127)
- Ferric sulfate (57.129)
- Ferrous carbonate (57.77)
- Ferrous chloride (57.128)
- Ferrous fumarate (57.75)
- Ferrous glycine complex (57.139)
- Iron amino acid chelate (57.142)
- Iron polysaccharide complex (57.29)
- Iron proteinate (57.23)

4. Magnesium is allowed for use in animal feed by regulation as:

- Magnesium oxide (582.5431)
- Magnesium sulfate (582.5443)
- Magnesium carbonate (582.1425)
- Magnesium hydroxide (582.1428)
- Magnesium oxide (582.1431)

The following mineral products (sources of magnesium) are available by FDA discretion within the limitations provided by AAFCO:

- Limestone, magnesium (57.11)
- Magnesium chloride (57.126)
- Magnesium mica (57.24)

5. Manganese is allowed for use in animal feed by regulation, in the following source compounds, under 582.80:

- Manganese acetate
- Manganese orthophosphate
- Manganese phosphate (dibasic)

Manganese is also allowed by regulation as the following nutrient and/or dietary supplements:

- Manganese chloride (582.5446)
- Manganese citrate (582.5449)
- Manganese gluconate (582.5452)
- Manganese glycerophosphate (582.5455)
- Manganese hypophosphate (582.5458)
- Manganese sulfate (582.5461)

6. Thiamin is allowed for use in animal feed by regulation as:

- Thiamine hydrochloride (582.5875)
- Thiamine mononitrate (582.5878)

7. Sulfur is allowed for use in animal feed by regulation, in the following, under 582.80:

- Cobalt sulfate
- Copper sulfate
- Iron sulfate
- Sodium sulfate
- Zinc sulfate

and also as:

- Calcium sulfate (582.5230)
- Ferrous sulfate (582.5315)
- Magnesium sulfate (582.1425)
- Manganese sulfate (582.5461)
- Potassium sulfate (582.1643)
- Sulfur dioxide (582.3862; not to be used in meats or in food recognized as a source of Vitamin B1)

The following form is allowed by FDA discretion as stated by AAFCO:

- Ferric sulfate (57.129)
8. Phosphorus is allowed for use in animal feed, by regulation, as the following:
- Diammonium phosphate (573.320) - used in ruminant feeds as a source of phosphorus and nitrogen in an amount that supplies not more than 2% of equivalent crude protein in total daily ration.
 - Ammonium phosphate (582.1141)
 - Calcium glycerophosphate (582.5201)
 - Calcium phosphate (582.1217)
 - Calcium pyrophosphate (582.5223)
 - Manganese glycerophosphate (582.5455)
 - Potassium glycerophosphate (582.5628)
 - Sodium acid pyrophosphate (582.1087)
 - Sodium aluminum phosphate (582.1781)
 - Sodium phosphate (582.5778)
 - Sodium tripolyphosphate (582.1810)

Phosphorus is also allowed by FDA discretion, within the limitations described by AAFCO:

- Bone meal, cooked (57.141)
- Bone meal, steamed (57.18)
- Bone Phosphate (57.14)
- Dicalcium phosphate (57.71)
- Disodium phosphate (57.33)
- Monoammonium phosphate (57.33; not less than 23% P)
- Monocalcium phosphate (57.98)
- Monosodium phosphate (57.99)
- Phosphate, defluorinated (57.12)
- Phosphoric Acid (57.19)
- Rock phosphate, ground (57.20)
- Rock phosphate, ground, low fluorine (57.21)
- Rock phosphate, soft (57.15; min. 9% P and 15% Ca)
- Sodium hexametaphosphate (57.132)
- Tribasic sodium phosphate (57.125)
- Tricalcium phosphate (57.113)

9. Potassium is allowed for use in animal feed, by regulation, as:

- Potassium bicarbonate (582.1613)
- Potassium bisulfite (582.3616)
- Potassium carbonate (582.1619)
- Potassium citrate (582.1625)
- Potassium glycerophosphate (582.5628)
- Potassium hydroxide (582.1631)
- Potassium metasulfite (582.3637)
- Potassium sorbate (582.3640)
- Potassium sulfate (582.1643)

The following mineral product (source of potassium) is available by FDA discretion, within the limitations provided by AAFCO:

- Potassium chloride (57.102)

10. Riboflavin is allowed for use in animal feed, by regulation, under 582.5695 as riboflavin and under 582.5697 as riboflavin-5-phosphate.

Riboflavin is also available by discretion as riboflavin supplement and as stated with the limitations of AAFCO, must contain not less than 1,000 milligrams of riboflavin.

11. Selenium is allowed for use in animal feed, by regulation, under 573.920 as either sodium selenate or sodium selenite.

MAXIMUM PERMISSIBLE SELENIUM LEVELS FOR RUMINANTS:

CLASS	FEED	AMOUNT
dairy	complete	0.1 ppm
beef	complete supplement	0.1 ppm
	salt-mineral mixture	1 MG/HD/D 20.0 ppm (fed at a rate not to exceed 1 MG/HD/D)
sheep	complete supplement	0.1 ppm .23 MG/HD/D
	salt-mineral mixture	0.30 ppm (fed at a rate not to exceed 1 MG/HD/D)

MAXIMUM PERMISSIBLE SELENIUM LEVELS FOR NON RUMINANTS:

CLASS	FEED	AMOUNT
chicken	complete	0.1 ppm
turkey	complete	0.2 ppm
duck	complete	0.1 ppm
swine	complete	0.3 ppm
	prestarter	0.3 ppm
	starter	0.3 ppm
all other	complete	0.1 ppm

12. Sodium is allowed for use in animal feed by regulation as sodium chloride and:

- Sodium acetate (582.1721)
- Sodium acid pyrophosphate (582.1087)
- Sodium aluminum phosphate (582.1781)
- Sodium caseinate (582.1748)
- Sodium citrate (582.1751)
- Sodium hydroxide (582.1763)
- Sodium pectinate (582.1775)
- Sodium phosphate (582.5778)
- Sodium potassium tartrate (582.1804)

Sodium is also allowed by FDA discretion as stated within the limitations provided by AAFCO, as the following:

- Sodium acid pyrophosphate (57.137)
- Sodium bicarbonate (57.106)
- Sodium carbonate (57.133)
- Sodium hexametaphosphate (57.132)
- Sodium sesquicarbonate (57.138)
- Sodium sulfate (57.109)
- Sodium tripolyphosphate (57.110)
- Tribasic sodium phosphate (57.125)

13. Zinc is allowed for use in animal feed by regulation, under 582.80:

- Zinc acetate
 - Zinc carbonate
- and as:
- Zinc chloride (582. 5985)
 - Zinc gluconate (582. 5988)
 - Zinc oxide (582. 5991)
 - Zinc stearate (582. 5994)
 - Zinc sulfate (582. 5997)

Zinc is allowable by FDA discretion within the limitations provided by AAFCO as the following:

- Zinc, amino acid complex (57.29)
- Zinc amino acid chelate (57.142)
- Zinc chlorine diammine complex (57.143)
- Zinc lysine complex (57.151)
- Zinc methionine complex (57.151)
- Zinc polysaccharide complex (57.29)
- Zinc proteinate (57.23)

14. Vitamin A is allowed for use in animal feeds, by regulation, as the following compounds:

- Vitamin A (582. 5930)
- Vitamin A acetate (582. 5933)
- Vitamin A palmitate (582. 5936)

15. Vitamin B12 is allowed for use in animal feeds, by regulation under 582.5945 as vitamin B12.

Vitamin B12 is allowable by FDA discretion within the limitations provided by AAFCO (90.11) and must contain a minimum vitamin B12 activity of 1.5 milligrams per pound.

16. Vitamin D (Calciferol) is allowed for use in animal feeds, by regulation, as the following compounds:

- Vitamin D2 (582. 5950)
- Vitamin D is allowable by FDA discretion within the limitations provided by AAFCO as vitamin D2 supplement (90.4 and 90.8) must contain a minimum of 100,000 USP or IU vitamin D per pound
- Vitamin D3 (582. 5953)
- Vitamin D is allowable by FDA discretion within the limitations provided by AAFCO vitamin D3 supplement (90.7 and 90.15) and must contain a minimum of 100,000 International Chick Units of vitamin D3 per pound

17. Vitamin E is allowed for use in animal feeds by regulation, under 582.5890, as tocopherol. Vitamin E is allowable by FDA discretion as stated within the limitations provided by AAFCO as vitamin E supplement and must contain a minimum vitamin E activity equal to 10,000 IU of vitamin E per pound

18. Vitamin K - The National Research Council ("Vitamin Tolerance of Animals") states that ruminants do not appear to need a source of vitamin K in the diet, because it is synthesized by rumen microorganisms and subsequently utilized.

Vitamin K active substances (VKAS) are regulated by FDA as follows:

1. Menadione - prior sanctioned for use in poultry feed at 2 to 4 grams per ton; food additive for all other uses
2. Menadione Sodium Bisulfite (MSB) - food additive for all uses
3. Menadione Sodium Bisulfite Complex (MSBC) - prior- sanctioned for use in poultry feed at 2 to 4 grams per ton; food additive for all other uses
4. Menadione Dimethylpyrimidinol Bisulfite (MPB) - a food additive regulation, Title 21, CFR, Part 573.620, provides for use in chicken, turkey, and swine feed

CATEGORY I

1. Natural Charcoal - As described in Underutilized Resources as Animal Feedstuffs. under "Forest Residues": The feeding of wood-derived feedstuffs in North America has been largely experimental, with the exception of isolated situations in which wood residues have been fed on a commercial scale. Most untreated woods are indigestible but, generally, whole tree or tree residues are not considered dangerous to the health of livestock. It is essential that diets containing wood residues be properly balanced for all of the essential nutrients. Wood residues must be considered primarily as energy sources; they contain small amounts, or are nearly devoid, of many essential nutrients. Thus, animals health if the diets are improperly balanced

2. Enzymes (Natural/Synthetic status) - As stated within the limitations provided by AAFCO under "Status of Enzyme Bearing Materials " (page 130): Enzyme bearing materials (such as fermentation products containing enzymatic activity) can be permitted in animal feeds where a food additive regulation has been issued to so provide. Carbohydrase and protease enzyme preparations derived from Bacillus subtilis, var.; carbohydrase and protease enzyme preparations derived from Aspergillus oryzae; and carbohydrase, cellulase, glucose oxidase, catalase, pectinase and lipase enzyme preparations derived from Aspergillus niger, var. are considered to be generally recognized as safe (GRAS) for use in food and are not food additives. Clearance for the use of any substance not considered GRAS will require a food additive petition.

NOTE : In order for the FDA to provide further opinions on enzymes, information on the following questions should be answered -

1. What specific enzymes are being considered?
2. What are the source organisms?

HEALTH CARE

1. Synthetic colostrum whey antibodies - These products are either biologics or new animal drugs depending on their intended uses, and must either be licensed by USDA or approved by FDA.

2. Electrolytes - Oral electrolytes are considered to be new animal drugs. However, CVM is currently exercising regulatory discretion with regard to these products provided the only claim is as a source or supplemental source of nutrients contained in the product.

Parenteral electrolytes (i.e. via fluid replacement) are considered to be new animal drugs of low regulatory priority provided they bear the veterinarian's prescription legend.

3. Glucose - If labeled as an aid in the treatment of primary, uncomplicated ketosis in cattle, glucose is generally considered to be a new animal drug of low regulatory priority and can be marketed over-the-counter. If intended for use in treating hypoglycemia in other species, or as a supplemental source of energy or nutrients, or in treatment of shock, glucose products are considered new animal drugs and must bear the veterinarian's prescription legend.

4. Mineral oil - If intended for use as a laxative, mineral oil is considered a new animal drug of low regulatory priority.

5. Probiotics - Direct-fed microbial products are regulated in accordance with CPG 7126.41. Depending on label and promotional claims, whether microorganisms are listed by AAFCO, whether the product is purported to contain live microorganisms, and other factors, these products may be regulated as new animal drugs, food additives, or foods.

6. Calcium/magnesium medications - These products are generally considered to be new animal drugs of low regulatory priority provided they bear the veterinary prescription legend.

7. Alcohol - Alcohol intended for therapeutic use in or on animals is considered a new animal drug. If used as a topical antiseptic it would be of low regulatory priority. Regulatory status of alcohol for other uses in animals would be determined on a case-by-case basis.

8. Copper sulfate - If intended for therapeutic purposes in animals, copper sulfate would be considered a new animal drug. The regulatory priority of this product would depend on its intended use.

9. Magnesium sulfate - If intended for therapeutic purposes in animals, magnesium sulfate would be considered a new animal drug. The regulatory priority of this product would depend on its intended use.

10. Oxytocin - Oxytocin is a new animal drug requiring an approved NADA for legal marketing and use. There are a number of approved NADAs for oxytocin for use in food-producing animals.

11. Local anesthetics (i.e., lidocaine) - Local anesthetics are considered to be new animal drugs. Regulatory status of these drugs are determined on a case-by-case basis.

12. Aspirin - Aspirin is considered to be a new animal drug requiring an approved NADE when intended for use in animals.

Animal vaccines and bacterins are biologics and, as such, are not under FDA jurisdiction.

We recommend that the chemicals listed in the pest control section be reviewed by EPA. In the past, CVM has expressed concern over the use in food animals of certain chemicals for which pesticide registration has been canceled by EPA for use on food animals. These include citronella, eucalyptus oil, and rotenone. A new animal drug for use in food animals which contains any of these substances requires an approved NADA prior to legal marketing in the U.S. In addition, CVM has taken the position that *Melaleuca alternifolia* (Australian tea tree oil, or Oil of Cajeput) cannot be marketed in the U.S. for use in food animals without an approved NADA. We recommend that the chemicals listed in the sanitation section be reviewed by EPA as well.

if you have additional questions concerning the information provided, please contact Dr. Susan Homire (301) 594-1758. All other should be directed to Dr. William Price (301) 594-1724.

Alison Martini
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cc:
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DAF 94428