PROTEINATED AND CHELATED MINERAL COMPLEXES
Livestock

Executive Summary

Chelation refers to a bonding formed between a metal ion (mineral) and a ligand (protein or amino acid chelating agent) carrier. A mineral complex is a mixture consisting of a mineral and an organic compound carrier, such as a protein or polysaccharide; a chelate is a type of complex.

The petition under review requests that mineral chelates and complexes be added to the National List as allowable feed additives in organic livestock production, to serve as dietary nutritional supplements of trace minerals. One of the issues central to the petition is the request that synthetic amino acids be allowed as possible chelating agents. The other two chelating agents listed, proteins and polysaccharides, do not utilize synthetic amino acids.

Currently, there is no NOSB recommendation on synthetic amino acids, although the issue has been examined previously.

Summary of TAP Reviewer's Analyses[1]

Synthetic/ Nonsynthetic	*Allow without restrictions?*	*Allow only with restrictions? (See Reviewers' comments for restrictions)*
Synthetic/Nonsynthetic (3)	No (3)	Yes (2) No (1)

Identification

Names and numbers:

Commonly chelated/complexed minerals:

CAS #	Name	Abbr.	Atomic #	Atomic Weight
7440-70-2	Calcium	Ca	20	40.078
7440-48-4	Cobalt	Co	27	58.933
7440-50-8	Copper	Cu	29	63.546
7439-89-6	Iron	Fe	26	55.845
7439-95-4	Magnesium	Mg	12	24.305
7439-96-5	Manganese	Mn	25	54.938
7440-09-7	Potassium	K	19	39.0983
7440-66-6	Zinc	Zn	30	65.409

[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(M) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.*

Common amino acid chelating agents: [2,3]

CAS #	Name	Abbr.	Formula	Linear Structure
56-87-1	Lysine	Lys	C6-H14-N2-O2	H2N-(CH2)4-CH(NH2)-COOH
72-19-5, 80-68-2	Threonine	Thr	C4-H9-N-O3	CH3-CH(OH)-CH(NH2)-COOH
54-12-6, 73-22-3	Tryptophan	Trp	C11-H12-N2-O2	Ph-NH-CH=C-CH2-CH(NH2)-COOH

Categories of chelates and other complexes:

Metal (Specific Amino Acid) Complexes:
IFN Copper lysine complex
IFN Zinc lysine complex
IFN 6-16-294 Ferric methionine complex
IFN 6-19-212 Manganese methionine complex
IFN 6-16-293 Zinc methionine complex

Metal Amino Acid Complexes:
IFN 6-32-053 Copper amino acid complex
IFN 6-32-054 Zinc amino acid complex
IFN 6-32-055 Magnesium amino acid complex
IFN 6-32-056 Iron amino acid complex
IFN 6-32-058 Calcium amino acid complex
IFN 6-32-059 Potassium amino acid complex
IFN 6-32-060 Manganese amino acid complex

Metal Amino Acid Chelates:
IFN 6-20-981 Calcium amino acid chelate
IFN 6-20-982 Cobalt amino acid chelate
IFN 6-20-983 Copper amino acid chelate
IFN 6-20-984 Iron amino acid chelate
IFN 6-20-985 Magnesium amino acid chelate
IFN 6-20-986 Manganese amino acid chelate
IFN 6-20-987 Zinc amino acid chelate

Metal Proteinates:
IFN 6-09-896 Copper proteinate
IFN 6-09-897 Zinc proteinate
IFN 6-26-149 Magnesium proteinate
IFN 6-26-150 Iron proteinate
IFN 6-26-151 Cobalt proteinate
IFN 6-26-834 Manganese proteinate
IFN 6-16-833 Calcium proteinate

Metal Polysaccharide Complexes:
IFN 8-09-822 Copper polysaccharide complex
IFN 8-09-898 Iron polysaccharide complex
IFN 8-09-899 Zinc polysaccharide complex
IFN 8-19-206 Magnesium polysaccharide complex

Characterization

Composition/Properties:

Definitions of various types of metal chelates/complexes, as provided by the American Association of Feed Control Officials (AAFCO), are as follows:

57.151 **Metal (Specific Amino Acid) Complex** is the product resulting from complexing a soluble metal salt with a specific amino acid. Minimum metal content must be declared. When used as a commercial feed ingredient, it must be declared as a specific metal, specific amino complex: i.e., copper lysine; zinc lysine; ferric methionine; manganese methionine; and zinc methionine. (Proposed 1991, Adopted 1992.)

57.150 **Metal Amino Acid Complex** is the product resulting from complexing a soluble metal salt with an amino acid(s). Minimum metal content must be declared. When used as a commercial feed ingredient, it must be declared as a specific metal amino complex: i.e., potassium amino acid complex; copper amino acid complex; zinc amino

[2] "Amino Acids." Institute of Chemistry, FU Berlin. http://www.chemie.fu-berlin.de/chemistry/bio/amino-acids_en.html
[3] ChemID Plus. http://www.toxnet.nlm.nih.gov/

acid complex; zinc amino acid complex; iron amino acid complex; cobalt amino acid complex; cobalt amino acid complex; calcium amino acid complex; and manganese amino acid complex. (Adopted 1990.)

57.142 **Metal Amino Acid Chelate** is the product resulting from the reaction of a metal ion from a soluble metal salt with amino acids with a mole ratio of one mole of metal to one to three (preferably two) moles of amino acid to form coordinate covalent bonds. The average weight of the hydrolyzed amino acids must be approximately 150 and the resulting molecular weight must not exceed 800. The minimum metal content must be declared. When used as a commercial feed ingredient it must be declared as a specific metal amino acid chelate: i.e., calcium amino acid chelate; iron amino acid chelate; magnesium amino acid chelate; manganese amino acid chelate; or zinc amino acid chelate. (Proposed 1986, Adopted 1988.)

57.23 **Metal Proteinate** is the product resulting from the chelation of a soluble salt with amino acids and/or partially hydrolyzed protein. It must be declared as a ingredient as the specific metal proteinate: i.e., copper proteinate; zinc proteinate; magnesium proteinate; iron proteinate; cobalt proteinate; manganese proteinate; or calcium proteinate. (Proposed 1967, Adopted 1970, Amended 1977, Amended 1987.)

57.29 **Metal Polysaccharide Complex** is the product resulting from complexing of a soluble salt with a polysaccharide solution declared as an ingredient as the specific metal complex: i.e., copper polysaccharide complex; zinc polysaccharide complex; iron polysaccharide complex; cobalt polysaccharide complex; and manganese polysaccharide complex. (Proposed 1971, Adopted 1973.)[4]

How Made:

Chelation, which literally means "bringing together," refers to a bonding formed between a metal ion (mineral) and a ligand (protein or amino acid chelating agent) carrier. A mineral complex is a mixture consisting of a mineral and an organic compound carrier, such as a protein or polysaccharide; a chelate is a type of complex. Chelates are generated by reacting a mineral salt with, for example, an enzymatically prepared mixture of amino acids and small peptides, under controlled conditions. The ligand binds the metal at more than one point such that the metal atom becomes part of a ring. Certain amino acids and protein digestion products such as small peptides are ideal ligands because they have at least two functional groups (amino and hydroxyl) that can form a ring structure with the mineral. The resulting mineral-organic complex is a "chelate."

The primary chelated minerals used in animal feed are the trace elements iron, manganese, cobalt, copper, and zinc. These "Transitional Elements" on the Periodic Table have chemical characteristics intermediate between metal and non-metal elements. Transitional elements prefer to form coordinate covalent bonds, a hybrid form of linkage that gives them their unique ability to form stable complexes--coordination complexes or chelates.[5,6,7] Calcium, magnesium, and potassium are also administered in complexed form.

Perhaps one of the key issues in this petition is whether or not synthetic amino acids, possible chelating agents in complexed minerals, should be allowed. One of the oldest and most widely used applications of biotechnology in the animal feed industry is that of synthetic amino acids. Methionine and its hydroxyl analogue may be synthesized by means of a chemical process, but the other commercially available amino acids, especially lysine, threonine, and tryptophan, are produced by fermentation technology. This process involves the fermentation of a carbohydrate

[4] "Feed Ingredient Definitions." Association of American Feed Control Officials. 2000. pp. 256-258. http://www.zinpro.com/research/pdf/tb/TB-G-9202.pdf

[5] Hutjens, Michael F. "Importance of Trace Minerals in Dairy Heifer, Dry Cow, and Lactating Cow Rations." http://dairynet.outreach.uiuc.edu/fulltext.cfm?section=2&documentID=345

[6] Hale, Chad and K.C. Olson. "Mineral Supplements for Beef Cattle." University of Missouri-Columbia. 15 February 2001. http://muextension.missouri.edu/xplor/agguides/ansci/g02081.htm

[7] "Minerals." Tri-Quest. http://www.triquestboergoats.com/minerals.htm

source, such as sugar, by an organism which has been genetically modified to produce an excess of the desired amino acid. [8]

Specific Uses:

Chelates and other complexes are useful in animal nutrition to protect trace minerals during digestion. The goal of forming chelates is to increase the bioavailability of minerals to the animals to support metabolic functions. For the modern farmer, genetic selection for maximum production of milk, meat, hair, and offspring in animals has made this cause more important. Chelated and other complexed minerals are administered especially during times of high nutritional demand, such as pregnancy, weaning, or other reproductive stress, rapid growth, environmental stress (such as moisture, heat, or humidity), or health stress. [9,10,11]

Chelates have been studied with regard to their effect on improved immunity (less disease or sickness), reproductive performance (shorter days open, higher conception rates, or less embryonic loss), and herd health.[12] Much of the research on feeding chelated minerals has shown varied results. It is generally recommended that if used, chelates should be utilized in addition to good farm management techniques, not as a replacement.[13]

Action:

Solubility is critical for trace mineral absorption. To maximize uptake, chelates and other complexes should be stable in the rumen and digestive tract of animals. Chelates are stable, electrically neutral complexes which protect trace minerals from chemical reactions during digestion that would render the mineral unavailable to the animal. When inorganic mineral compounds, typically in oxide or sulfide form, are released and ionized in the stomach's low pH, the electrically charged forms of the minerals are able to react with other products of digestion. Complexes with naturally occurring organic ligands must form if absorption is to occur. However, the formation of insoluble, unavailable substances may also result, especially in the small intestine, when pancreatic bicarbonate restores a higher, more neutral pH. Added minerals pre-complexed with organic ligands thus are used to increase bioavailability and uptake. The chelated mineral reaches the plasma intact and separates at the site of action. [14,15,16]

Combinations:

Chelated and other complexed mineral supplements are often administered together in feed. Trace mineral premixtures are formulated to balance mineral profiles and meet specific mineral needs.[17] Using chelated minerals helps avoid absorption problems which may occur when minerals compete for natural carriers. For example, copper

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[8] "Trends in the use of lysine and other amino acids in animal feeds." Lysine Product Information. AECI Bioproducts. http://www.aecibio.co.za/nutrit/lysine_1.html

[9] Hutjens, Michael F. "Importance of Trace Minerals in Dairy Heifer, Dry Cow, and Lactating Cow Rations." http://dairynet.outreach.uiuc.edu/fulltext.cfm?section=2&documentID=345

[10] Hale, Chad and K.C. Olson. "Mineral Supplements for Beef Cattle." University of Missouri-Columbia. 15 February 2001. http://muextension.missouri.edu/xplor/agguides/ansci/g02081.htm

[11] "Minerals." Tri-Quest. http://www.triquestboergoats.com/minerals.htm

[12] Hutjens, Michael F. "Importance of Trace Minerals in Dairy Heifer, Dry Cow, and Lactating Cow Rations." http://dairynet.outreach.uiuc.edu/fulltext.cfm?section=2&documentID=345

[13] Coleman, Bob. "Feeds and Feeding: Chelated Minerals." 15 January 2001. http://www.agric.gov.ab.ca/livestock/horses/feeds/bcoleman4.html

[14] Hutjens, Michael F. "Importance of Trace Minerals in Dairy Heifer, Dry Cow, and Lactating Cow Rations." http://dairynet.outreach.uiuc.edu/fulltext.cfm?section=2&documentID=345

[15] Hale, Chad and K.C. Olson. "Mineral Supplements for Beef Cattle." University of Missouri-Columbia. 15 February 2001. http://muextension.missouri.edu/xplor/agguides/ansci/g02081.htm

[16] "Minerals." Tri-Quest. http://www.triquestboergoats.com/minerals.htm

[17] Hutjens, Michael F. "Importance of Trace Minerals in Dairy Heifer, Dry Cow, and Lactating Cow Rations." http://dairynet.outreach.uiuc.edu/fulltext.cfm?section=2&documentID=345

and zinc interfere with absorption of the other, and excess calcium will influence phosphorus and selenium absorption.[18]

Status

Historic Use by Organic Farmers:

In the North American (nonorganic) feed industry, inorganic, versus organic sources, of minerals are much more commonly encountered. Inorganic sources are mined or chemically synthesized from natural mineral sources and are not bonded to carrier molecules. They are fed to livestock as the naturally occurring inorganic mineral complexes.[19]

One of the limiting factors on the use of chelated minerals has been the high cost. Chelated minerals cost 10 to 15 times more per milligram of mineral compared to inorganic sources. The cost of commercial chelated mineral programs range from 4 cents to 18 cents per cow per day (depending on the combination and level of chelated minerals selected).[20]

In organic systems, organically produced amino acids are permitted.

The use of synthetic amino acids as chelating agents or alone in organic production is forbidden. Synthetic amino acids are not explicitly permitted as approved synthetics on the National List. Furthermore, synthetic amino acids are produced from genetically modified organisms, a violation of the NOP Final Rule in 2000. The NOSB, in 2000, wrote that it would reconsider the issue of synthetically produced amino acids at a later date.

Growth promoters and synthetic trace minerals which stimulate growth or production of livestock are explicitly forbidden in the Federal Organic Foods Production Act of 1990.

Pertinent legal rulings follow.

USDA, FDA Final Rule:

Following rulings are summarized as follows:

1. Federal Organic Foods Production Act of 1990: Growth promoters and synthetic trace minerals which stimulate growth or production of organic livestock are explicitly forbidden.
2. Title 21 - 21CFR582.80: Cobalt, copper, iodine, iron, manganese, and zinc are approved as GRAS as trace minerals added to animal feed. Approved sources of these minerals are listed.
3. Title 21 – 21CFR172.320: The amino acids commonly used as chelates are listed as approved as nutritional additives in human food.
4. Title 21 – 21CFR582.5475: The amino acids commonly used as chelates are listed as approved as GRAS as nutrients and/or dietary supplements in humans.
5. National Organic Program Final Rule 2000/Draft 2002 / NOSB recommendations:
   Organically produced amino acids are permitted to provide for the essential nutritional needs of livestock. Handlers must not provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance. Growth and production promoters are not allowed.
   Livestock must not be treated with any synthetic not included on the National List.
   Synthetic and nonorganic sources of amino acids are forbidden.

[18] Bell, Brian. “Mineral Nutrition in Sheep.” September 1997. http://www.gov.on.ca/OMAFRA/english/livestock/sheep/facts/minernut.htm
[19] Hale, Chad and K.C. Olson. “Mineral Supplements for Beef Cattle.” University of Missouri-Columbia. 15 February 2001. http://muextension.missouri.edu/xplor/agguides/ansci/g02081.htm
[20] “Minerals.” Tri-Quest. http://www.triquestboergoats.com/minerals.htm

Excluded organic practices include any form of genetic modification.
* Controversy over synthetic amino acids explained.

FEDERAL ORGANIC FOODS PRODUCTION ACT OF 1990

6509 ANIMAL PRODUCTION PRACTICES AND MATERIALS.

(a) **In General**. Any livestock that is to be slaughtered and sold or labeled as organically produced shall be raised in accordance with this chapter.

(c) **Practices**. For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm

(1) shall feed such livestock organically produced feed that meets the requirements of this chapter;
(2) shall not use the following feed
(A) plastic pellets for roughage;
(B) manure refeeding; or
(C) feed formulas containing urea; and
(3) shall not use growth promoters and hormones on such livestock, whether implanted, ingested, or injected, including antibiotics and synthetic trace elements used to stimulate growth or production of such livestock. [21]

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Revised as of April 1, 2002

21CFR582.80

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 582--SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A--General Provisions

Sec. 582.80 Trace minerals added to animal feeds.

These substances added to animal feeds as nutritional dietary supplements are generally recognized as safe when added at levels consistent with good feeding practice.[1]

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[1] All substances listed may be in anhydrous or hydrated form.

Element	Source compounds
Cobalt.................................	Cobalt acetate.

[21] Federal Organic Foods Production Act of 1990. http://www.ams.usda.gov/nop/orgact.htm

	Cobalt carbonate.
	Cobalt chloride.
	Cobalt oxide.
	Cobalt sulfate.
Copper................................	Copper carbonate.
	Copper chloride.
	Copper gluconate.
	Copper hydroxide.
	Copper orthophosphate.
	Copper oxide.
	Copper pyrophosphate.
	Copper sulfate.
Iodine................................	Calcium iodate.
	Calcium iodobehenate.
	Cuprous iodide.
	3,5-Diiodosalicylic acid.
	Ethylenediamine dihydroiodide.
	Potassium iodate.
	Potassium iodide.
	Sodium iodate.
	Sodium iodide.
	Thymol iodide.
Iron..................................	Iron ammonium citrate.
	Iron carbonate.
	Iron chloride.
	Iron gluconate.
	Iron oxide.
	Iron phosphate.
	Iron pyrophosphate.
	Iron sulfate.
	Reduced iron.
Manganese.............................	Manganese acetate.
	Manganese carbonate.
	Manganese citrate (soluble).
	Manganese chloride.
	Manganese gluconate.
	Manganese orthophosphate.
	Manganese phosphate (dibasic).
	Manganese sulfate.
	Manganous oxide.
Zinc..................................	Zinc acetate.
	Zinc carbonate.
	Zinc chloride.
	Zinc oxide.
	Zinc sulfate.[22]

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21CFR172.320

[22] 21CFR582.80. United States. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=582.80

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Subpart D--Special Dietary and Nutritional Additives

Sec. 172.**320** Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:
(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated or anhydrous form or as the hydrochloride, sodium or potassium salts:

L-Alanine
L-Arginine
L-Asparagine
L-Aspartic acid
L-Cysteine
L-Cystine
L-Glutamic acid
L-Glutamine
Aminoacetic acid (glycine)
L-Histidine
L-Isoleucine
L-Leucine
L-Lysine
DL-Methionine (not for infant foods)
L-Methionine
L-Phenylalanine
L-Proline
L-Serine
L-Threonine
L-Tryptophan
L-Tyrosine
L-Valine
(b) The food additive meets the following specifications:
(1) As found in ``Food Chemicals Codex,'' National Academy of Sciences/National Research Council (NAS/NRC), 3d Ed. (1981), which is incorporated by reference (copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) for the following:

L-Alanine
L-Arginine
L-Arginine Monohydrochloride
L-Cysteine Monohydrochloride
L-Cystine
Aminoacetic acid (glycine)
L-Leucine
DL-Methionine
L-Methionine

L-Tryptophan
L-Phenylalanine
L-Proline
L-Serine
L-Threonine
Glutamic Acid Hydrochloride
L-Isoleucine
L-Lysine Monohydrochloride
Monopotassium L-glutamate
L-Tyrosine
L-Valine

(2) As found in ``Specifications and Criteria for Biochemical Compounds,'' NAS/NRC Publication, 3rd Ed. (1972), which is incorporated by reference (copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) for the following:

L-Asparagine
L-Aspartic acid
L-Glutamine
L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source, provided that:
(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the ``reference'' adult male recommended by the National Academy of Sciences in ``Recommended Dietary Allowances,'' NAS Publication No. 1694, 7th Ed. (1968), which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.
(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.
(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily-intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.
(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

Percent by weight of total protein (expressed as free amino acid)	
L-Alanine..	6.1
L-Arginine..	6.6
L-Aspartic acid (including L-asparagine)......................	7.0
L-Cystine (including L-cysteine)..................................	2.3
L-Glutamic acid (including L-glutamine)....................	12.4
Aminoacetic acid (glycine)...	3.5
L-Histidine..	2.4
L-Isoleucine..	6.6
L-Leucine..	8.8

L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212-43.216, ``Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.
(2) The amounts of each amino acid contained in any mixture.
(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

[42 FR 14491, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 11836, Mar. 19, 1982; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 59 FR 14550, Mar. 29, 1994; 61 FR 14480, Apr. 2, 1996][23]

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Revised as of April 1, 2001

21CFR582.5475

TITLE 21--FOOD AND DRUGS

[23] 21CFR172.320. United States. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=172.320

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 582--SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart F--Nutrients and/or Dietary Supplements [1]

Sec. 582.**5118** Alanine.
(a) Product. Alanine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5145** Arginine.
(a) Product. Arginine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5017** Aspartic acid.
(a) Product. Aspartic acid (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5271** Cysteine.
(a) Product. Cysteine (L-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5361** Histidine.
(a) Product. Histidine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5381** Isoleucine.
(a) Product. Isoleucine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5406** Leucine.
(a) Product. Leucine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5411** Lysine.
(a) Product. Lysine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5475** Methionine.
(a) Product. Methionine.
(b) [Reserved]
(c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in animal feeds in accordance with good manufacturing or feeding practice.

Sec. 582.**5590** Phenylalanine.
(a) Product. Phenylalanine (L- and DL-forms).

(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5650** Proline.
(a) Product. Proline (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5701** Serine.
(a) Product. Serine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5881** Threonine.
(a) Product. Threonine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5915** Tryptophane.
(a) Product. Tryptophane (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5920** Tyrosine.
(a) Product. Tyrosine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

Sec. 582.**5925** Valine.
(a) Product. Valine (L- and DL-forms).
(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.[24]

NOP:

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
7 CFR Part 205
[Docket Number: TMD-00-02-FR]
RIN: 0581-AA40

NATIONAL ORGANIC PROGRAM

AGENCY: Agricultural Marketing Service, USDA.
ACTION: Final Rule with request for comments.

SUMMARY: This final rule establishes the National Organic Program (NOP or program) under the direction of the Agricultural Marketing Service (AMS), an arm of the United States Department of Agriculture (USDA). This national program will facilitate domestic and international marketing of fresh and processed food that is organically produced and assure consumers that such products meet consistent, uniform standards. This program establishes

[24] 21CFR582**.**5475. United States.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=172.320

national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. This final rule establishes a national-level accreditation program to be administered by AMS for State officials and private persons who want to be accredited as certifying agents. Under the program, certifying agents will certify production and handling operations in compliance with the requirements of this regulation and initiate compliance actions to enforce program requirements. The final rule includes requirements for labeling products as organic and containing organic ingredients. This final rule also provides for importation of organic agricultural products from foreign programs determined to have equivalent organic program requirements. This program is authorized under the Organic Foods Production Act of 1990, as amended.

National Organic Program Overview

Subpart A – Definitions

Description of Regulations

This subpart defines various terms used in this part. These definitions are intended to enhance conformance with the regulatory requirements through a clear understanding of the meaning of key terms.

We have amended terms and definitions carried over from the proposed rule where necessary to make their wording consistent with the language used in this final rule. We have revised the definitions of the following words for greater clarity: person, practice standard, inert ingredient, processing, tolerance. We have removed the definitions for the following terms because the terms are not used in this final rule or have been determined to be unnecessary: accredited laboratory, estimated national mean, system of organic production and handling. We received comments on some of these definitions that have been deleted. We have not addressed those comments here because the relevant definitions have been deleted.

Definitions - Changes Based on Comments

(3) Some commenters stated that allowing nonagricultural or synthetic substances as feed supplements contradicted the definition for "feed supplement" in the proposed rule. These commenters stated that the definition stipulated that a feed supplement must, itself, be a feed material and that the proposed definition for "feed" did not include nonagricultural or synthetic substances. <u>These commenters stated that the definition of "feed supplement" needed to be amended to accommodate nonagricultural or synthetic substances, or such substances should not be allowed. We agree with these commenters and amended the definition for "feed supplement" to read "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." One commenter recommended modifying the definition of "feed additive" to "a substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals."</u> We agree that this modification provides a more precise description of "feed additive" and have included the change. The changes to the definitions for "feed supplement" and "feed additive" are further discussed under item (4) of Livestock Production - Changes Based on Comments.

Subpart C - Organic Crop, Wild Crop, Livestock, and Handling Requirements

Description of Regulations

General Requirements
This subpart sets forth the requirements with which production and handling operations must comply in order to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." The producer or handler of an organic production or handling operation must comply with all applicable provisions of subpart C. Any production practice implemented in accordance with this subpart must maintain or improve the natural resources, including soil and water quality, of the operation. Production and handling operations which sell, label, or represent agricultural products as organic in any manner and which are exempt or excluded from certification must comply with the requirements of this subpart, except for the development of an organic system plan.

Livestock Production

Any livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from the last third of gestation or hatching with three exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of such products, except for the conversion of an entire, distinct herd to organic production. For the first 9 months of the year of conversion, the producer may provide the herd with a minimum of 80-percent feed that is either organic or produced from land included in the organic system plan and managed in compliance with organic crop requirements. During the final 3 months of the year of conversion, the producer must provide the herd feed in compliance with section 205.237. Once the herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of gestation.

Should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from the last third of gestation may not be sold, labeled, or represented as organic slaughter stock. The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

Except for nonsynthetic substances and synthetic substances included on the National List that may be used as feed supplements and additives, the total feed ration for livestock managed in an organic operation must be composed of agricultural products, including pasture and forage, that are organically produced. Any portion of the feed ration that is handled must comply with organic handling requirements. The producer must not use animal drugs, including hormones, to promote growth in an animal or provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance for the species at its specific stage of life. The producer must not feed animals under organic management plastic pellets for roughage or formulas containing urea or manure. The feeding of mammalian and poultry slaughter by-products to mammals or poultry is prohibited. The producer must not supply animal feed, feed additives, or feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide a feed ration including vitamins, minerals, protein, and/or amino acids, fatty acids, energy sources, and, for ruminants, fiber. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

The producer of an organic livestock operation must administer vaccines and other veterinary biologics as needed to protect the well-being of animals in his or her care. When preventive practices and veterinary biologics are inadequate to prevent sickness, the producer may administer medications included on the National List of synthetic substances allowed for use in livestock operations. The producer may not administer synthetic parasiticides to breeder stock during the last third of gestation or during lactation if the progeny is to be sold, labeled, or represented as organically produced. After administering synthetic parasiticides to dairy stock, the producer must observe a 90-day withdrawal period before selling the milk or milk products produced from the treated animal as organically produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

The producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones for growth promotion is prohibited in organic livestock production, as is the use of synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

A livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. These standards will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. The organic system plan must reflect a proactive approach to health management, drawing upon allowable practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer must provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production; conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes nutrient recycling.

Livestock Production - Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(4) Provisions for Feed Supplements and Feed Additives. The proposed rule provided that nonagricultural products and synthetic substances included on the National List could be used as feed additives and supplements. Many commenters stated that allowing nonagricultural products and synthetic substances as feed supplements contradicted the definition for "feed supplement" found in the proposed rule. That definition stipulated that a feed supplement must, itself, be a feed material, and the definition for "feed" in the proposed rule precluded using nonagricultural products and synthetic substances. These commenters requested that either the definition of "feed supplement" be changed to make it consistent with the allowance for nonagricultural products and synthetic substances or else that the term be dropped from the final rule. The Food and Drug Administration (FDA) recommended modifying the definitions for "feed additive" and "feed supplement" and further specifying the components required in a feed ration under the livestock health care practice standard.

We amended the definition in the final rule to state that a feed supplement is "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." We retained the second component of the proposed definition, which described how a feed supplement could be offered to livestock. We amended the definition of "feed additive" to "a substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals." The definitions for "feed supplement" and "feed additive" in the proposed rule were originally recommended by the NOSB. While our intent in the proposed rule was to codify as fully as possible the recommendations of the NOSB, we agree with commenters that the proposed definitions were was incompatible with the overall provisions for livestock feed. The definitions in the final rule are consistent with the NOSB's objective to create clear distinctions between feed, feed supplements, and feed additives while clarifying the role for each within an organic livestock ration. We also incorporated FDA's recommendation to include protein and/or amino acids, fatty acids, energy sources, and fiber for ruminants as required elements of a feed ration in the livestock health care practice standard. These additions make the livestock health care practice standard more consistent with the National Research Council's Committee on Animal Nutrition's Nutrient Requirement series, which we cited in the proposed rule as the basis for feed requirements.

Many commenters addressed provisions in the proposed rule to allow or prohibit specific materials and categories of materials used in livestock feed. Among these, some commenters questioned whether enzymes were defined as a feed additive and, therefore, allowed. One certifying agent requested guidance on the status of supplementing livestock feed with amino acids. At its October 1999 meeting, the NOSB discussed the Technical Advisory Panel (TAP) reviews on the use of enzymes and amino acids in livestock feed. The NOSB determined that natural sources of enzymes exist and that their use should be allowed in organic production. Their discussion of natural sources of enzymes concluded that enzymes derived from edible, nontoxic plants and nonpathogenic bacteria or fungi that had not been genetically engineered should be allowed as a nonorganic feed additive. The NOSB did not take a position on amino acids during this meeting but indicated that it would revisit the subject in the near future. Based on these recommendations, the final rule allows the use of natural enzymes but not amino acids as nonorganic feed additives.

The NOSB's recommendation that natural sources of enzymes existed and were compatible with organic livestock production supports allowing them without adding them to the National List. Some commenters discussed the animal welfare and environmental benefits associated with providing amino acids in livestock feed and supported allowing them. However, without a recommendation from the NOSB that amino acids are natural or should be added to the National List as a synthetic, the final rule does not allow their use.

Commenters questioned whether nonsynthetic but nonagricultural substances, such as ground oyster shells and diatomaceous earth, would be allowed in agricultural feed. In 1994, the NOSB recommended that natural feed additives can be from any source, provided that the additive is not classified as a prohibited natural on the National List. We agree with this recommendation and have amended the final rule to allow such materials as feed additives and supplements. The only additional constraint on these materials is that every feed, feed additive, and feed supplement be used in compliance with the Federal Food, Drug, and Cosmetic Act, as stated in section 205.237(b)(6).

The NOSB recommended that ruminants maintained under temporary confinement must have access to dry, unchopped hay. Although this position was an NOSB recommendation and not part of the proposed rule, several commenters responded to it. Most of these commenters stated that the language was too restrictive and could preclude the use of many suitable forage products. One dairy producer stated that the requirement would not be practical for operations that mix hay with other feed components. We agree that the NOSB's proposed language is too prescriptive.

National List - Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(4) Adding Amino Acids to the National List. Some commenters recommended that amino acids should be added to the National List as allowed synthetic substances for livestock production. We have not added amino acids to the National List because the NOSB has not recommended that they should be allowed. This subject is discussed further in item 4, Livestock - Changes Based on Comments, subpart C.

(8) Neurotoxic Substances on the National List. Many commenters requested that the NOP remove particular substances from section 205.605 of the National List. They stated these substances were sources of neurotoxic compounds that negatively effect human health. The substances cited were yeast (autolysate and brewers),

carrageenan, and enzymes. Moreover, these commenters argued against including on the National List some amino acids or their derivatives which the commenters claim have neurotoxic side effects. These commenters requested that amino acids should be prohibited from the National List due to the possibility that neurotoxic substances could be utilized for either organic agricultural production or handling.

We do not agree with the requests of the commenters and we have not made the requested changes. There are no amino acids currently on the National List; therefore, synthetic sources of amino acids are prohibited. Unless recommended for use by the NOSB, synthetic amino acids will not be included on the National List. The NOP has established a petition process for substances to be evaluated for inclusion on or removal from the National List of Allowed and Prohibited Substances in organic production and handling. Anyone seeking to have a particular substance removed from the National List may file a substance petition to amend the National List.

§ 205.2 Terms defined.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. [25]

NOSB:
The NOSB will be reviewing proteinated and chelated minerals for use in livestock in September 2002.[26]

Previous reviews of the use of synthetic amino acids in organic livestock, as seen above in the NOP ruling, have been inconclusive.

Status Among U.S. Certifiers

State Organic Certifiers:
Minnesota: Follows USDA suggested guidelines.
Oregon: Follows USDA suggested guidelines.
Pennsylvania: Follows OMRI suggested guidelines.

International

The European Standards do not include amino acids among permitted feedstuffs (European Union, 1999). Canadian standards allow essential amino acids, but explicitly prohibit ones from genetically engineered sources and state that the material may have some additional requirements. Operators are instructed to consult with their certification body for approval (Canadian General Standards Board, 1999).

IFOAM: In 2000, IFOAM ruled that "pure amino acids" shall not be allowed in feed. Synthetic amino acid chelates, if considered "synthetic growth promoters," or chelates derived from genetically engineered organisms are also forbidden by IFOAM for these reasons. IFOAM also ruled that trace elements should be administered from natural sources if possible, but left it up to the "standard-setting organization" to rule exactly when exceptions may

[25] *Final Rule, 2002*. NOP. http://www.ams.usda.gov/nop/nop2000/nop2/finalrulepages/entirerule2.htm 2002.
[26] *Materials to Review*. NOSB. http://www.ams.usda.gov/nop/materialsmay2002.pdf 2002.

be made.[27] The wording in the 2002 Final Draft is slightly different, but the meaning is basically the same. Pertinent excerpts follow.

INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS
Basic Standards for Organic Production and Processing
Final Draft 2002

To be voted on at the general assembly
Victoria, August 26-28, 2002

Standards shall require that:

10.8.5. The following products shall not be included in or added to the feed or in any other way be given to the organisms:
- Synthetic growth promoters and stimulants
- Synthetic appetisers
- Synthetic antioxidants and preservatives
- Urea
- Feedstuffs subjected to solvent (e.g. hexane) extraction
- Amino acid isolates
- Material from the same species/genus/family as the one being fed
- Synthetic colouring agents
- Genetically engineered organisms or products thereof

10.8.6. Vitamins, trace elements and supplements used shall be of natural origin when available. The use of substances from synthesised or unnatural sources shall only occur under conditions established by the standard-setting organization.[28]

CODEX/WHO/FAO: There is no Codex ruling on livestock materials. However the following is noted concerning plant products in Annex 2: Permitted Substances for the Production of Organic Foods:

TABLE 3: INGREDIENTS OF NON AGRICULTURAL ORIGIN
3.5 Minerals (including trace elements), vitamins, essential fatty and amino acids, and other nitrogen compounds. Only approved in so far as their used is legally required in the food products in which they are incorporated.[29]

EEC/UK: Chelates derived from genetically modified sources, and synthetic amino acids, are forbidden. It is noted that certain trace elements "may need to be used under well-defined conditions" to satisfy the nutritional requirements of livestock.[30]

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[27] "IFOAM Basic Standards for Organic Production and Processing, Final 2000." International Federation of Organic Agriculture Movements. http://www.ifoam.org/standard/basics.html
[28] "IFOAM Basic Standards for Organic Production and Processing: Final Draft 2002." International Federation of Organic Agriculture Movements. http://www.ifoam.org/standard/ibs_final02.html
[29] "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Food: Proposed Draft Amendments." Codex Alimentarius Commission. http://www.hc-sc.gc.ca/food-aliment/friia-raaii/ip-pi/codex/pdf/e_cl01_48e.pdf December 2001.
[30] "Council Regulation (EEC) No 2092/91 of 24 June 1991." European Union. February 2002. http://www.defra.gov.uk/farm/organic/reg2092consol.pdf

Annex VI
A.5. Minerals (including trace elements) and vitamins
Minerals (trace elements included), vitamins, amino acids and other nitrogen compounds, only authorized as far their use is legally required in the foodstuffs in which they are incorporated.[31]

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From the UK Organic Farmers & Growers Organic Assurance Scheme:

Section 8: Livestock Production Standards
8.4 Feed
Trace Elements

8.4.37 (4.16) In order to satisfy nutritional requirements of livestock, only the trace elements listed below can be used for animal feeding. *Minerals in a chelated form are permitted but the production of these must not involve the use of genetically modified organisms or their derivatives (eg. GM soya protein).*

8.4.41 *Synthetic amino acids are not permitted as feed supplements*. [32]

Canadian General Standards: Vitamins, trace elements, and pure amino acids may be used at the discretion of the certification body. Ones from genetically modified sources are explicitly forbidden. [33]

Synthetic and unnatural amino acids and trace minerals are regulated in the British Columbian Standards.

9.2 Feed Supplements
9.2.2. Regulated
1) Synthetic vitamins, amino acids, and mineral supplements.
2) Trace minerals and vitamins not derived from natural sources.
 a) May only be used when natural sources are not commercially available and when used to supplement an otherwise balanced ration that includes access to pasture and sunlight. [34]

This is from the Certified Organic Associations of British Columbia (COABC) Livestock materials list:

COABC Status	Name of Material	Class	Annotation
Allowed	Amino acids from fermented sources	Livestock Feed	To supplement livestock and poultry rations
Regulated	Amino acids from synthetic sources	Livestock Feed	To supplement livestock and poultry rations where sufficient sources are not available from natural sources
Regulated	Minerals	Livestock Feed	Non-synthetic mined minerals that are registered for use in livestock feed. Synthetic nutrients minerals may be used in non-synthetic sources are unavailable. Minerals may not be used to stimulate growth or production. Minerals from any source are allowed for medical use.

[31] "Annexes I-VIII to Council Regulation (EEC) No 2092/91 of 24 June 1991." European Union. February 2002. http://www.defra.gov.uk/farm/organic/reg2092annex.pdf
Standards for Organic Food Production. UK Register of Organic Foods Standards. February/November 2001. http://www.defra.gov.uk/farm/organic/ukrofs/standard.pdf
[32] "Section 8: Livestock Production Standards." *UK Organic Farmers & Growers Organic Assurance Scheme*. 3 January 2001.
http://www.organicfarmers.uk.com/files/genpdfs/manual%20pdfs/CM%20%208%20Livestock%20Production.pdf
[33] "National Standard for Organic Agriculture." Canadian General Standards Board Sales Centre Public Works and Government Services Canada, Hull, Quebec, K1A 1G6
[34] "Certified Organic Management Standards." Certified Organic Associations of British Columbia.
http://www.certifiedorganic.bc.ca/Standards/Bk2_COABC_Organic_Management_Standards_Version4-03-02.pdf

Japan Agricultural Standards for Organic Agricultural Products and Their Processed Foods: Both trace minerals and amino acids are not mentioned. [35]

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. *The potential of the substance for detrimental interactions with other materials used in organic farming systems.*

Please see *2*. below.

2. *The toxicity and mode of action of the substance and of its break down products or any contaminants, and their persistence and areas of concentration in the environment.*

Amino acids, when administered in extreme excess to either livestock or humans, may be toxic. Lysine, methionine, and threonine, the common chelating agents, are all approved as nutritional additives to human food, and GRAS for dietary and/or nutrient supplementation in humans.

Cobalt, copper, iodine, iron, manganese, and zinc are approved as GRAS as trace minerals added to animal feed. Note: the sources listed are not amino acid, protein, or polysaccharide chelates.

Nitrogen excreted in urine and feces, the breakdown products of amino acid and protein chelating agents, may contaminate water sources. Excess minerals excreted may also be pollutants to the soil. Airborne pollution is also a concern.

The biochemical effects of livestock excretion of nitrogen in soil is well summarized in the excerpt below from an article for the Research Consortium Sustainable Organic Production. Following are summaries for the same organization on the harmful effects of over-administration of nitrogen, zinc, and copper to livestock, as well as strategies for combating them.

The Environment
Impact of Livestock Production on Soil

…Chemical and biological impacts of manure and urine

Although many of the impacts of animal wastes on the environment concern losses to water or the atmosphere, soil is an intermediary and as such these impacts deserve space here. The amount of urine delivered to soil by a grazing cow is of the order of 2 litre applied to an area of about 0.4 m^2 (e.g. Addiscott *et al*, 1991). This represents an instantaneous application of 400-1200 kg N ha^{-1}. Such an amount burns vegetation and is often toxic to plant roots which cannot immediately recover to take up the N (full recovery can take up to 12 months and the problem is obviously worst in areas where animals congregate). Urea in soil is quickly hydrolysed and given that grass can take up perhaps 400 kg N ha^{-1} annually without loss, pollution of groundwater or the atmosphere is almost inevitable whenever urine is applied to soil. Both Calcium and Magnesium are also lost in substantial amounts from urine patches on pasture soils (Early et al., 1998).

Losses of N from urine and manure will normally be as ammonia, dinitrogen and nitrous oxide (during denitrification) or as nitrate leaching. Two key processes deserve mention. The first is that during dentrification (of nitrate to N_2 or N_2O) the major product is almost always N_2. If conditions for this process are in anyway sub-optimal, especially if there is a deficiency of organic carbon relative to nitrate such as might occur under a urine patch, N_2O production increases (e.g. Swerts, 1996). Since N_2O is a potent greenhouse gas its emission from soil is

[35] Japanese Agricultural Standards. http://www.fas.usda.gov/gainfiles/200004/25647377.pdf

clearly undesirable. Secondly nitrate is produced from urine and manure during nitrification which is itself a multi-stage process. Where organic matter levels are high such as in or around manure not all the N is converted to the end product, nitrate (NO_{3-}), and some remains as nitrite (NO_{2-}). Nitrite is equally susceptible to leaching as nitrate but is far more toxic. Debate in recent years has focussed wrongly on nitrate, which is in fact a precursor to the production of NO (nitric oxide) that is one of the first lines of the body's defence against pathogenic organisms. Most instances of damage to health that have been attributed to nitrate are in fact the result of nitrite such as methaemoglobinaemia from well water contaminated with nitrate but also nitrite. Incidence of stomach cancers have been found to be negatively correlated with nitrate in the diet but a theoretical link assumed that nitrate could be reduced in situ to nitrite in the stomach. Fortunately nitrite in the wider environment is generally short-lived, but arises during sub-optimal nitrification of ammonia to nitrate, for example where ammonium is washed directly into surface waters either from the soil or because the animal urinates close-by. Nitrite is nonetheless occasionally found in natural waters at levels that exceed EU limits.

Compaction of and damage to soil also limits the growth and use pasture can make of available nutrients. Douglas and Crawford (1998) found between 1.7 and 2.1 t ha^{-1} reduction in dry matter production in a compacted sward and reduction in recovery of N from 71% to 55% of that applied in the uncompacted and compacted swards respectively. Cattle sometime spread pathogenic organisms by picking them up from a point source but urinating or defecating elsewhere. Weeds, plant diseases, e-coli O157 are all thought to be spread in this way.

The amounts of nutrients in manure are equally a source of waste, a missed opportunity and potentially of pollution. Manure is partly microbial in composition derived from fermentation during digestion and partly composed of recalcitrant components of the feed. As such it is rather less decomposable than fresh plant material and does not supply N to soil as rapidly or damagingly as urine. It does, however, block light and grass growth underneath manure will be temporarily retarded. Some regrowth occurs with penetration where the pasture is well enough established, some with reseeding directly into the manure.

Application of manures is not necessarily harmful. As implied in much of what has been said above, manure and urine contain nutrients that grass or crops can use. Because manure is relatively long-lived in soil it releases its nutrients slowly and can continue to benefit crop production for many years. Whitmore and Schroder (1996) estimate that applications of slurry to maize during the 1970s and 80's has increased the N-supplying power of Dutch soils by about 70 kg N ha^{-1}. Because the extra fertility is long-lived this extra N-supply is expected to take 10 years to decline to half its current level. This is beneficial, however, only so long as a pasture or crop recovers the N. The N can also mineralise during winter or at some other time when the crop is not growing at its full potential. Under these circumstances losses to the environment are inevitable. The fertility is only maintained as long as the pasture remains in place. Ploughing a grassland soil results in a burst of nutrient availability that slowly declines. Whitmore et al. (1992) showed that the intensive ploughing of grassland during the 1940's and 50's in the UK is a probable cause of the increases in nitrate found in aquifers in the 1970's onwards. Watts et al. (1996) have shown that increased levels of organic C in soil confers desirable resilience to soils in relation to tillage. Mineral pasture soils almost certainly resist hoof damage in proportion to their organic matter content.

The impact of manure and urine on soil from livestock is not simply one of perturbing nutrient cycles. Additives such as copper, zinc, antihelminthics and antibiotics or other veterinary treatments are given to animals. The presence of Cu and Zn can make manure unsuitable for use as a fertilizer on other farms and metals such as these pose a long-term risk in pasture soils because they can accumulate and are only slowly removed by leaching or offtake in vegetation. Heavy metals have been shown to reduce the microbial life and diversity in soil (Griffiths, 2000) and the activity of N-fixers in particular (Giller, 1999).

Nutrient balances

One rough and ready way of assessing the impact of livestock farming has been to consider the balance between inputs and measured outputs of the nutrients used in livestock farming. The difference is usually large and positive implying enormous loss of nutrients to the wider environment or retention in soil. Given that in the majority of the loss pathways nutrients pass through the soil, impacts on soil is an appropriate place to consider this imbalance. As a very rough rule of thumb worries about surpluses of N are immediate in that more N is lost than retained by soil; worries about P concern the gradual build-up over many years that leads to subsequent but sustained losses. On one

Dutch dairy farm in the 1980's about 400 kg N, 23 kg P and 56 kg K ha^{-1} annually of 467, 35, and 73 kg ha^{-1} applied respectively was unaccounted for. More generally 75% of the 1.1 x 109 kg N applied annually throughout the whole of the Netherlands is thought to be wasted (Whitmore and Van Noordwijk, 1995). Surpluses of N on UK dairy farms were recently reported to range from 63-667 g N ha^{-1} with a mean of 257 kg N ha^{-1} (Jarvis 2000) and exports in produce were estimated to be only 20% of the N applied (Jarvis 1993). Haygarth (1998) estimated gains of P by soil in a typical UK dairy farm to be 26 kg P ha^{-1} annually with a stocking density of 2.26 animals ha^{-1} on average. On an upland sheep farm the gain was 0.24 kg P ha^{-1} only. Strategies to reduce the impact of animal manure and slurry on the environment usually focus on limiting spreading according to the amount of P (e.g. Van der Molen *et al.*, 1998). This is because the relative amounts of NPK required by pasture and arable crops differ from the rate these elements are found in manure; manure is too enriched in P relative to N.

Grazing systems can have an effect on soil and more particularly water courses if manure or silage is not stored properly and leaks out. The resultant point source contamination can affect soil for many years, destroy aquatic life and make water unfit for consumption.[36]

The Environment
Pollutants in Animal Manure: Factors of Emission and Strategies for Reduction

…Nitrogen

Nitrogen is an essential component of protein in feed as well as in food. N emissions from animal husbandry are therefore inevitably coupled with the production of protein-rich foods (meat, milk and egg). In practice, however, the efficiency of N transformation is quite low. On average only about one third of the feed N is transferred into the protein of animal products while the rest is eliminated via excrements (mainly urine). Most of these N quantities remain in the manure and are transferred to the agricultural area. But up to about one fourth may be emitted into the atmosphere directly after excretion and during the storage of manure. Therefore, it seems reasonable to observe the primary N emission of the animal rather than only N in manure.

One major reason for high N-losses is an excessive protein content of the feed. Since the capacity of an animal to grow or to produce milk and eggs is limited, any surplus of dietary protein cannot be utilised by the metabolism and the respective N of the protein has to be eliminated from the body. However, in the course of the production cycle (pregnancy/lactation, start/end of fattening) the animals' protein requirement changes to a considerable extent. In order to guarantee a sufficient protein supply, the farmers chiefly adjust the protein content of the feed to the level of the maximum requirement of the animal. Consequently, the animals receive excessive amounts of protein for most of the time.

Another reason for N-losses especially in monogastric species (e.g. pig, poultry) is the low quality of the feed protein due to deficient contents of essential amino acids (mainly Lys, Thr, Met). In order to secure a sufficient supply of the most limiting essential amino acid, higher quantities of the total protein have to be fed. This generates an additional surplus of non-limiting amino acids whose nitrogen has to be eliminated from the body.

In ruminants, the aspect of protein quality refers mainly to the extent to which utilisable protein reaches the final site of digestion (duodenum, small intestine) after it has been transformed by microbes along the passage through the forestomachs. In this context, considerable N-losses may occur due to a high ruminal degradability of feed protein as well as due to an excessive ratio between N and energy in the feed.

An additional source of N-emission via excrements is the N, which originates from the inevitable and "non-productive" maintenance metabolism.

Thus, there are 3 general strategies available to minimise N-emissions from livestock production:

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[36] "The Environment: Impact of Livestock on Soil." Research Consortium Sustainable Animal Production. 30 July 2001. http://agriculture.de/acms1/conf6/ws4lives.htm

1) Applying the official recommendations for protein supply and avoiding dietary protein surplus by adjusting the protein content in the feed to the changing requirement of the animal.

2) Improving the quality of feed protein. This may be achieved in pigs and poultry by adding limiting amino acids in a chemically pure form. In cattle it refers mainly to the use of feed proteins with low ruminal degradability.

3) Increasing the animals' performance in order to "dilute" the indispensable N emission from maintenance turnover among a higher amount of products.

The dominant contribution to reduce the N emissions will arise mainly from the strategy a) and b). Strategy a) may be realised to a large extent by rather simple feeding techniques such as phase feeding (e.g. 3 feed mixes for pigs along the fattening procedure). Also strategy b) may be applied directly to practice, since the relevant amino acids and feed proteins are commercially available. By using such feeding strategies, N emissions from animals may be reduced by 30 to 40 % compared to the present situation (WINDISCH 2000).

…Zinc and copper

Zn and Cu are essential trace elements with various biological functions. However, they may exert also pharmacological effects especially in piglets, such as prevention of diarrhoea and promotion of production performance. These effects require dietary doses of about 50 to 100 times above the requirement, which reflects the (mis)use of the toxic potential of heavy metals rather than the biological function of essential trace elements (WINDISCH et al. 1999, 2000). Pharmacologically effective doses of Zn are prohibited by feed directives and may be applied only under veterinary control, while equivalent doses of Cu may be used legally in practical piglet diets. In total, the pig feeding practice shows an increasing interest in such excessive doses of Zn and Cu. It obviously reflects the search for substitutes to antibiotic feed additives.

The excessive amounts of Zn and Cu are almost completely excreted into the manure. By this way, pure piglet manure supplemented with excessive amount of Zn and Cu may contain these heavy metals in the magnitude of about 15 g Zn and 1 g Cu per kg of dry matter. This would severely exceed the respective limits to sewage sludge. However, piglet manure is usually diluted by manure of other animals. Nevertheless, the excessive use of Zn and Cu in piglet feeding is still visible in the 2fold and 5fold higher mean value for Zn and Cu contents of mixed pig manure compared to the respective contents in cattle manure (LBP 1997).

The average transfer of Zn and Cu via pig manure to the agricultural area ranges at about 0,8 kg Zn and 0,4 kg Cu per hectare and year. It exceeds the withdrawal by plant harvest at about factor 4 (Zn) and up to 20 (Cu) (LBP 1997). In the case of Cu, the mean transfer rates range already above the limit given by the German soil protection directive. Since the mobility of Zn and Cu in the soil is extremely low, these heavy metals are progressively accumulated in areas fertilised with pig manure at rates of about 0,7 kg Zn and 0,4 kg Cu per hectare and year on average (LBP 197). The extent of Cu accumulation is comparable to than on agricultural areas fertilised with sewage sludge.

In total, there is no physiological need to tolerate such high accumulations of Zn and Cu in the manure, because the pharmacological and growth promoting effect of excessive doses of Zn and Cu may be retrieved also by ecologically compatible alternatives (e.g. by organic acids). Furthermore, if Zn and Cu are fed to animals only according to the nutritional recommendations, the respective transfer rates to the agricultural area will decrease to the level of the withdrawal by plant harvest. In this case, the ecological risks of the high contents of Zn and Cu in manure from animal production will completely disappear. [37]

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[37] "The Environment: Pollutants from Manure: Factors of Emission and Strategies for Reduction." Consortium Sustainable Animal Production. 30 July 2001. http://agriculture.de/acms1/conf6/ws4poll.htm

3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*

Please see *2*. above.

4. *The effects of the substance on human health.*

Please see *2*. above.

The degree of concentration increase in minerals or amino acids, proteins, or polysaccharide complexing agents in the livestock or livestock products themselves as a result of mineral supplementation would not be of sufficient concentration to negatively impact human health when they are consumed.

5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock.*

Please see *2*. above.

6. *The alternatives to using the substance in terms of practices or other available materials.*

Amino acid or other chelating agents which are organically produced may be used in place of synthetic ones.

7. *Its compatibility with a system of sustainable agriculture.*

The use of chelated and other complexed minerals decreases mineral waste excreted in urine and feces and increases the efficiency of mineral absorption in livestock. This may improve the health and quality of the livestock. The use of amino acids and protein chelates will also lead to increased excretion of nitrogen, which is beneficial to an organic farming system, as manure may be used to fertilize crops.

Again:
In organic livestock production, feeding is primarily based on home-grown feedstuffs, including a high amount of legumes. As a result, crude protein content in the diet often exceeds the requirements of the animals and nitrogen in the manure is on a high level do it this any excreted products of amino acid and protein chelating agents. In contrast to conventional production where farmers are asked to reduce nitrogen in the diet in order to reduce nitrogen in the manure, this is a desirable effect as excreta is a nitrogen source for the innerfarm nutrient cycle. When trying to utilize this nitrogen source, organic farmers are encouraged simultaneously to minimize nitrogen emission from the manure. Due to the limited nitrogen resource, organic farmers have to find the balance within a dual strategy: increasing nitrogen in the manure and minimizing nitrogen emission form the manure. [38]

However, if chelates are in any way deemed growth or production promoters, which may increase intensity of production to unacceptable levels, chelated minerals are not compatible with a system of sustainable agriculture. Also, the introduction of products from genetically modified organisms in the form of synthetic amino acids is not consistent with the current standards of organic production or sustainable agriculture.

TAP Reviewer Analyses

[38] "The Environment: Organic Livestock Production." Research Consortium Sustainable Animal Production. 30 July 2001. http://agriculture.de/acms1/conf6/ws4orga.htm

Reviewer 1 *[Ph.D. Chemistry; Professor, Chemistry. Central U.S].*

Observations/OFPA Criteria

Petition asks that Proteinated and Chelated Mineral Complexes be added to the National List as allowable feed additives. There are two separate components of the petition. One involves the use of synthetic amino acids as chelating agents. The other involves proteinated metal ions.

The issues are so different between the two components that they must be reviewed separately.

I. Proteinated Mineral Complexes

Relevant legal and regulatory criteria

Only proteins derived directly from living things are yet economically available. The petition is only for complexes made from such proteins. The need for mineral supplements is recognized in the Act, and bioavailability depends in many instances on having the metal ions complexed by proteins. Thus the only possible issue is the prohibition of synthetic substances, 7 USC 6502(21).

Recommendation and reasoning

Clearly, naturally occurring protein/mineral complexes that are extracted or concentrated using only allowable processing means are legitimate within both the letter and spirit of the Act. For example, supplying magnesium or iron by concentrating photosynthetic centers or hemoglobin, respectively, are "organic." For ionically-bound or weakly complexed ions, one may exchange any of the cations listed in the petition for any other, given only an aqueous solution of an appropriate metal salt and time. Such ion exchange can also occur *in vivo*. Indeed, if any supplementation of animal feed with minerals is carried out, the presence of moisture in the feed would generate such complexes via natural processes whether permitted or not. Provided that the proteins employed are non-toxic per the other provisions of the Act (so, for example, one should not employ prions or dura matter that might harbor prions as complexing agents for metals), proteinated mineral complexes should be permitted. Some complexes may require harsh formation conditions, but these would be prohibited via restrictions on processing methods, not on their composition.

II. Synthetic Amino Acids for Chelated Mineral Complexes

Relevant legal and regulatory criteria

Critical here are the definition of "synthetic" 07 USC 6502(21) and the guidelines for exemptions 7 USC 6517(c)(1) and 7 USC 6517(c)(2). Chelated mineral complexes such as chlorophyll or hemoglobin are clearly permitted if extracted in an otherwise permitted manner. The only question is whether amino acids, derived from non-biological sources or from aggressive processing of biological materials should be permitted. One must differentiate between enzymatic hydrolysis of plant or animal products or use of strong acid or strong base in terms of the legal definition of "synthetic".

Additional perspective precedent to recommendation

From a purely rationalist viewpoint, the question is irrelevant. One may, by chemical analysis, determine the composition and purity of any purported amino acid, regardless of source. Naturally-occurring amino acids may be chromatographically separated from biological fluids, and may be either more or less pure than amino acids from chemically-rendered biological materials or fully synthesized. Why should anyone care whether a calcium chelate uses natural or synthetic lysine? In fact, the act makes clear that its purpose is to support farming in a philosophically "organic" manner, not just a pro-forma "organic" manner. Composition alone is not the issue, else synthetic vs. natural composition considerations would not have been written into the Act. Consumers expect that organically-grown meat will have avoided the use of synthetic processes, whether the composition of the resulting feed is analytically distinguishable from naturally-derived materials. One suspects that petitioners have discovered that synthetic processes are economically more efficient than natural processes, and so hope to use synthetics to lower production costs while maintaining the "organic" label valued by some consumers.

In the popular scientific literature, the natural/synthetic dichotomy is perhaps most lucidly described in Roald Hoffman and Shira Liebowitz Schmidt's *Old Wine in New Flasks* (W. H. Freeman, 1997). While this reviewer has not read the congressional testimony that led to the act, he is sufficiently familiar with the desires of the organic foods community to believe that adaptation of synthetic anything should be looked at askance, not because of the effect on the environment, the animals, or the consumer's physiology, but rather because of the philosophy of that organic consumer.

Recommendation and reasoning

Use of fully synthetic amino acids (i.e. those obtained other than from plants or recently-living animals) as chelating agents would violate both 7 USC 6517(c)(1)(iii) and 7 USC 6517(c)(2)(A)(ii) in that their use would not be consistent with organic farming. Such use would also violate USDA implementing regulation Subpart G §205.600(b)(1), in that there ARE natural sources and metal-rich plants so that use of synthetic sources is inappropriate. Based on the definition of "synthetic," the only amino acid chelating agents that should be legal are those that have been separated from biological sources chromatographically or those that have been freed from biological feedstocks by fermentation. Those generated with cell-free enzyme systems are in a philosophical Neverland. If the enzymes are genetically-engineered, they would violate the rules against use of human-revised biological processes. If the enzymes come from natural sources and are purified by means otherwise acceptable in organic processing, fermentation of naturally-occurring substances by such enzymes to produce "synthetic" amino acids falls (barely) within the letter of the law. Intriguing also is whether chelates formed from any purified amino acid, regardless of source, should be permitted. The definition of "synthetic" speaks of "…a process that chemically changes a substance extracted…," and surely chelation is a chemical reaction. By the letter of the law, hemoglobin is a legitimate iron supplement, but lowering pH to the point that iron is ejected from the heme moity, then reforming the ferric heme by raising pH results in a prohibited substance.

<u>Reviewer 1 Conclusions</u>

While this reviewer finds the consequences of the Act to lead to absurd ends, the legal definitions and restrictions mean:

- Naturally-occurring chelates extracted from plants and animals may be used as feed additives.
- Chelates produced directly via fermentation may be used.
- Chelates intentionally formed either from naturally-occurring or synthetic amino acids may not be used, as they violate the prohibition on synthetic substances when natural substances are available.
- Any chelates accidentally formed by mixing naturally-occurring amino acids with other feed supplements (including inorganic metal oxides and salts) are permitted in that the components are allowed and any compounds formed from their interaction prior to consumption by the animal need not be removed.
- Only amino acids extracted as pure compounds or produced by fermentation may be used. Wholly synthetic amino acids may not be used.
- The nutritional ends to which chelates lead should be met instead by feeding metal-rich grains and algae. Numerous plants that can concentrate metals are known, and their growth in soils well-laden with the desired metals are the preferred means to enrich animal feeds with bio-available metals.

<u>Reviewer 1 Recommendations Advised to the NOSB</u>

The substance is <u>Synthetic/Nonsynthetic</u>.

For Livestock, the substance should be Added to the National List with restrictions.

Reviewer 2 *[PhD, Animal Science; Associate Professor, Animal Science--Anaerobic and Gastrointestinal Microbiology. Research interests include ruminal anaerobic physiology and biochemistry. Southeast U.S.]*

Introduction. The TAP report provided selected background information on the current use of proteinated and chelated mineral complexes in livestock production, discussion of potential benefits derived from feeding such materials, and extensive information on the regulatory status of amino acid use in foods and feeds in the United States and around the world. The report was, in the reviewer's opinion, not exhaustive and did not provide adequate information on the production methods used to produce mineral chelates and complexes. This is unfortunate given the fact that there appears to be considerable controversy surrounding the use of amino acids in organic livestock production. Since these chelates are made with amino acids and peptides, information on production methods is critical to fully evaluate the potential impacts of their use in organic agriculture. Beyond this, there is the larger (and more important) question of whether the Federal Organic Foods Production Act and the National Organic Program have adequately considered and defined practices and philosophies involving the feeding of animals.

Intent of OFPA and NOP Rules. The feeding and care of domestic livestock involves the complex interaction of animal metabolism and behavior with feed material, environment, and human intervention. In many regards, the organic production of livestock is a more challenging undertaking than producing crops organically. Although the OFPA and NOP rules provide some guidance for producing organic animal products, there is considerable vagueness about definitions and intent. The resultant uncertainty raises critical questions with regard to animal husbandry practices and the consideration of substances for inclusion in organic production. For instance, the OFPA states that producers "….shall not use growth promoters…..and synthetic trace elements….to stimulate growth or production of such livestock" (section 6509 (c) (3)). The NOP Final Rule further states that organic producers must "not…provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life" (205.237 (b) (2)). Although one obvious intent of these regulations is to prohibit the use of hormones and antimicrobial compounds, it is much less clear how a broad range of other potential feed components (namely, the wide array of supplements and additives) are to be considered. Perhaps most problematic are the phrases "to stimulate growth or production" and "adequate nutrition". The National Research Council Committee on Animal Nutrition has established nutrient requirements for various domestic animals, and these requirements define nutrient inputs needed by animals at different ages and production levels (e. g., milk output, tissue deposition). In this sense, "adequate nutrition" is defined by the desired production level. But nutrients available from a particular combination (diet) of organically produced feedstuffs may not meet the nutrient demands dictated by a particular production level or physiological state, and the only way to meet that demand is by inclusion of a feed supplement(s) or additive(s). Although the supplement/additive may be natural and/or organically produced, it is clearly 'promoting' and 'stimulating' growth and production beyond a level constrained by either the quantity and/or the quality of the basic diet. In this sense, it is not clear whether the intent of the NOP is to permit producers to design feeding strategies to maximize production or whether producers are to be constrained by the feed and environmental circumstances inherent to their specific production system. It should be realized that maximizing production, even if done using organic materials, is not always a sustainable practice in all scenarios. Consideration of these issues is critical to determining whether the use of compounds such as mineral chelates is appropriate in organic animal production.

Mineral Chelates. There is increasing evidence that the bio-availability of certain mineral chelates is superior to inorganic salts. This better utilization appears to be due, in part, to an increased efficiency of absorption of the minerals when chelated to organic molecules such as amino acids and peptides. It is theorized that since certain ionic forms of minerals (which are free and not bound to organic molecules) share common uptake systems, competition for uptake from the gut by these ions leads to inefficient absorption. Chelated minerals are not taken up by these ion systems, thus avoiding competition. The increased absorption means that less minerals has to be fed and there is also less excretion of minerals into the environment. Despite the potential nutritional benefits of chelates, as is many times the case when evaluating the effectiveness of micro-nutrient supplementation, inclusion of chelated minerals into animal diets leads to variable production responses. It appears that such supplementation is most beneficial in intensive operations and at high production levels which are often characteristic in intensive animal operations.

If one assumes that the inclusion of mineral chelates in animal rations constitutes a sustainable practice and is consistent with the intent of the organic program, one question becomes whether these compounds can be produced in an organic manner. A considerable fraction of the amino acids and peptides used in the animal feed industry are produced using 'synthetic' processes which involve genetically recombinant microorganisms. Since the cost of organically producing such chelates would presumably be even higher than the already substantial cost of chelates using synthetic amino acids, it seems clear that they would not be economical for most producers at the present time. However, the TAP Review did not provide adequate background in this area and so it is difficult to fully evaluate the question.

Reviewer 2 Conclusions

Summary. Mineral chelates appear to promote the absorption of trace mineral ions under certain production regimes. Their use could, in theory, promote the retention of minerals in animal flesh and products and subsequently reduce excretion of certain trace minerals. However, (i) given the lack of information about chelate production methods, (ii) the uncertainty regarding the status of synthetic amino acids (and peptides) in organic animal agriculture, and (iii) the very vague definitions surrounding organic animal nutrition and production, the reviewer recommends that proteinated and chelated mineral chelates not be recommended for inclusion on the National List at this time. In the reviewer's opinion, each of the three points noted above must be very carefully considered prior to further consideration of the chelate compounds. Finally, there needs to much more thoughtful consideration given to the specific intent of feeding animals supplements and additives in sustainable production systems.

Reviewer 2 Recommendations Advised to the NOSB

The substance is Synthetic/Nonsynthetic.

For Livestock, the substance should be Excluded from the National List.

Reviewer 3 *[PhD, Biochemistry. Associate Professor, Department of Biochemistry and Molecular Biology. Southern U.S.]*

Comments on Report

How made:

It will be helpful to describe here more clearly about the differences among synthetic amino acids, organically produced amino acids, and amino acids produced from genetically modified organisms.

Observations

Status:

I don't recommend that synthetic amino acids be included in the National List.

Part 582 -- Substances generally recognized as safe:

The D-form of most amino acids is not considered a natural product of mammals. Although the synthetic L-form of each amino acid is chemically identical to those organically produced amino acids, they should not be allowed on the National List. I would like to point this out just in case those synthetic amino acids are recommended to be allowed in the National List by other reviewers. I would be strongly against the inclusion of both D- and L- forms.

Reviewer 3 Conclusions

I recommend that mineral chelates and complexes be added to the National List as allowable feed additives in organic livestock production, to serve as dietary nutritional supplements of trace minerals. I agree that organically produced amino acids are permitted. However, I recommend that synthetic amino acids should not be allowed as possible chelating agents. I also agree that growth promoters and synthetic trace minerals that stimulate growth or production should not be allowed.

Reviewer 3 Recommendations Advised to the NOSB

The substance is Synthetic/Nonsynthetic.

For Livestock, the substance should be Added to the National List with restrictions.

TAP Conclusion

All three reviewers agree that mineral chelates and complexes may be considered either nonsynthetic or synthetic, depending on the chelating agent used. They also agree that synthetic amino acids should not be allowed in organic animal production.

One reviewer believes that proteinated and chelated mineral complexes should not be added to the National List at this time, while the other two reviewers believe they should be allowed on the National List with restrictions. Concerns include the methods of production of both the chelates and chelating agents.