NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **#17 Nutrient Vitamins**

✓ **NOSB Database Form**

✓ **References**

____ **MSDS (or equivalent)**

____ **FASP (FDA)**

✓ **TAP Reviews from:** **Joe Montecalvo, Rich Theuer**

NOSB/NATIONAL LIST
COMMENT FORM
PROCESSING

Material Name: #17 Nutrient Vitamins

Please use this page to write down comments, questions, and your anticipated vote(s).

COMMENTS/QUESTIONS:

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1. In my opinion, this material is:
_____ Synthetic _____ Non-synthetic.

2. Should this material be allowed in an "organic food" (95% or higher organic ingredients)? _____ Yes _____ No
(IF NO, PROCEED TO QUESTION 3.)

3. Should this substance be allowed in a "food made with organic ingredients" (50% or higher organic ingredients)? _____ Yes _____ No

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Sept 5, 1995

Name of Material: Nutrient Vitamins

Reviewer Name: Dr. Joe Montecalvo.

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Synthetic

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

✓ Synthetic Allowed ____ Prohibited Natural

or, ____ Non-synthetic (Allowed as an ingredient in organic food)

____ Non-synthetic (Allowed as a processing aid for organic food)

or, ____ this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List? none

Please comment on the accuracy of the information in the file: good

Any additional comments? (attachments welcomed) none.

Do you have a commercial interest in this material? ____ Yes; ✓ No

Signature [signature] **Date** 8/22/95

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
None

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; None

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance; None

(4) the effect of the substance on human health;
megadoses of fat soluble vitamins may be harmful.

(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;
None

(6) the alternatives to using the substance in terms of practices or other available materials; and None

(7) its compatibility with a system of sustainable agriculture.
O.K.

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Sept 5, 1995

Name of Material: Nutrient Vitamins

Reviewer Name: R Theuer

Is this substance Synthetic or non-synthetic? Explain (if appropriate) SYNTHETIC

If synthetic, how is the material made? (please answer here if our database form is blank)

SEE ATTACHMENTS CREATED FOR NOSB-PHL COMMITTEE

This material should be added to the National List as:

✓ Synthetic Allowed ____ Prohibited Natural

or, ____ Non-synthetic (Allowed as an ingredient in organic food)

____ Non-synthetic (Allowed as a processing aid for organic food)

or, ____ this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

WHEN REQUIRED ~~FOR~~ BY LAW/REGULATION OR RECOMMENDED BY INDEPENDENT PROFESSIONAL BODY

Please comment on the accuracy of the information in the file:

NEEDS MY ADDENDA

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? ____ Yes; ✓ No

Signature R Theuer **Date** 8/28/95

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

(4) the effect of the substance on human health;

(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;

(6) the alternatives to using the substance in terms of practices or other available materials; and

(7) its compatibility with a system of sustainable agriculture.

VITAMINS

Vitamin activity	Substance (ingredient)	Production method attached
Vitamin A	Vitamin A palmitate	YES
	Vitamin A acetate	YES
	β-Carotene	YES
Vitamin D	vitamin D3 (cholecalciferol)	YES
Vitamin E	Mixed tocopherols	YES
	DL-alpha-tocopheryl acetate	YES
Vitamin K	phylloquinone (phytonadione)	YES
Thiamine (Vitamin B1)	thiamine mononitrate	YES
	thiamine hydrochloride	YES
Riboflavin (Vitamin B2)	riboflavin	YES
Vitamin B6	pyridoxine hydrochloride	YES
Vitamin B12	cyanocobalamin	YES
Niacin	nicotinic acid	YES
niacinamide	nicotinamide	YES
Folic acid (Folacin)	folic acid	YES
Pantothenic acid	calcium pantothenate	YES
Biotin	biotin	YES
Vitamin C (Ascorbic acid)	ascorbic acid	NL
	sodium ascorbate	
	calcium ascorbate	
	ascorbyl palmitate	NO
Choline	lecithin	NL
	choline bitartrate	NO
	choline chloride	NO
Inositol	myo-inositol	YES
	lecithin	NL

NL = substance already reviewed by NOSB.

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin A Palmitate (retinol palmitate)
Reviewer: Richard C. Theuer

SYNTHETIC Commercial retinol is produced by the major American manufacturer (Hoffmann-LaRoche) by synthesis. Natural retinol palmitate is the predominant form in fish liver oils.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin A Acetate (retinol acetate)
Reviewer: Richard C. Theuer

SYNTHETIC Commercial retinol is produced by the major American manufacturer (Hoffmann-LaRoche) by synthesis. The acetate form is more stable to air oxidation than free retinol.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin A: Carotene
Reviewer: Richard C. Theuer

SYNTHETIC Practically all beta-carotene on the market is of synthetic origin. Carotene can be isolated from carrots, but it is expensive and not commercially feasible.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin D3: Cholecalciferol
Reviewer: Richard C. Theuer

SYNTHETIC Cholecalciferol is made from cholesterol isolated from natural sources. The cholesterol is converted chemically into 7-dehydrocholesterol, which is then irradiated with ultraviolet light to form cholecalciferol. This same reaction occurs in the skin upon exposure to sun light.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin K_1 (Phytonadione/Phylloquinone)
Reviewer: Richard C. Theuer

SYNTHETIC Commercial Vitamin K_1 is synthesized from 2-methyl-1,4-naphthoquinone and phytyl derivatives.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin B1: Thiamine salts (mononitrate, hydrochloride)
Reviewer: Richard C. Theuer

SYNTHETIC All commercial production is by synthetic chemical processes.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin B2: Riboflavin
Reviewer: Richard C. Theuer

SYNTHETIC All commercial production for human food and therapeutic use is by synthétic chemical processes. Concentrates for poultry and livestock feeds are produced by fermentation using microorganisms.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin B6: Pyridoxine Hydrochloride
Reviewer: Richard C. Theuer

SYNTHETIC All commercial production is by synthetic chemical processes. Natural forms are present in very small amounts in foods. Some fermentation processes have been developed, but these are economically disadvantaged.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin B12: Cyanocobalamin
Reviewer: Richard C. Theuer

SYNTHETIC Vitamin B12 for food and therapeutic human use is produced by microbial fermentation, followed by extraction with cyanide and synthetic solvents. Concentrates used for animal feed are the fermentation broth evaporated. Vitamin B12 is present in animal foods in extremely small amounts.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Niacin: Nicotinic acid and Nicotinic acid amide
Reviewer: Richard C. Theuer

SYNTHETIC All commercial production is synthetic. Natural forms are present in very small amounts in foods. In addition, some natural forms are unavailable.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Folacin (Folic Acid)
Reviewer: Richard C. Theuer

SYNTHETIC Commercial folic acid is produced by chemical synthesis from acetone, guanidine and glutamic acid.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Pantothenic Acid
Reviewer: Richard C. Theuer

SYNTHETIC Commercial sources are produced by chemical synthesis. Pantothenic acid is very oily. The calcium salt is crystalline and reasonably stable in air and light.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Biotin
Reviewer: Richard C. Theuer

SYNTHETIC Commercial biotin is produced synthetically from fumaric acid by the "Hoffmann-LaRoche" industrial synthesis or "Sternbach" process.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: myo-Inositol
Reviewer: Richard C. Theuer

SYNTHETIC Commercial inositol is produced from plant phytin by degradative processes. Phytin (phytic acid) is the hexa-phosphate of inositol. The inositol in this natural form is biologically unavailable. Only free inositol is used in infant foods as a source of inositol. Some vegetable "lecithins" contain phosphatidyl inositol which is biologically available, but the material is unstable because of the fat component of this material.

COMMENTS RE SECTION 2119(m) CRITERIA:

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date:

Material: Vitamin E: DL-alpha tocopheryl acetate
Mixed Tocopherols
Reviewer: Richard C. Theuer

NATURAL & SYNTHETIC Alpha-tocopheryl acetate is the principal commercial form of Vitamin E for food fortification, dietary supplementation and medicinals, and for domestic animals.

Concentrates of mixed tocopherols can be obtained from vegetable oils by treatment with chemicals. Inactive natural forms are converted to active forms **synthetically**, but are considered "natural" in the trade. Totally synthetic pure tocopherols also are commercially available.

COMMENTS RE SECTION 2119(m) CRITERIA:

NOSB Materials Database

Identification

Common Name **Nutrient vitamins** **Chemical Name**

Other Names Vitamins A, D, E, K, C, B6, B12, folic acid, thiamin (B1), riboflavin (B2), niacin, biotin.

Code #: CAS see attached. **Code #: Other**

N. L. Category Synthetic Allowed **MSDS** No

Chemistry

Family

Composition varies

Properties varies, see under "Action". Generally divided into fat soluble (A, D, E, K) and water soluble. Generally sensitive to heat and air.

How Made

Vitamin A: Synthetic process starting from acetone. Acetone-->citral-->ionone--> Vitamin A acetate. Then the acetate is transesterified with methyl palmitate to form Vitamin A palmitate.
Vitamin B12: Microbial fermentation followed by extraction with cyanide and synthetic solvents. Concentrates are the fermentation broth evaporated. Can be totally synthesized.
Biotin: Fumaric acid is brominated and then treated with solvents and sulfur.
B6: Pyroxidine is made by a condensation reaction and the Diels-Alder reaction of oxazoles. (synthetic)
B1: Made from joining pyrimidine and thiazol moieties through synthesis.
Vitamin C: Culture fermentation from dextrose. Extracted and purified using synthetic acidulants. The Reichstein process is used in which D-glucose is hydrogenated to D-sorbitol, which is oxidized microbiologically to L-sorbose. L-sorbose is reacted with acetone to form an intermediate which is then oxidized and rearranged by treatment with hydrogen chloride to yield L-ascorbic acid.
Vitamin D: Made from cholesterol isolated from natural sources. The cholesterol is converted chemically into 7-dehydrocholesterol, which is then irradiated with ultraviolet light to form cholecalciferol.
Vitamin E: Vacuum steam distillation of edible vegetable oil products, or chemical extraction from vegetable oils.

Use/Action

Type of Use Processing

Use(s) nutrient supplement. Antioxidants (Vitamins C and E). Colorants (Vitamin A). Vitamin C also improves flour dough and inhibits can corrosion.

Action Vitamin A: Necessary for healthy skin and teeth.
Vitamin B complex: includes ribflavin, nicotinic acid (niacin), pantothenic acid, biotin, B12, thiamin. Necesary for skin health, normal growth, and protein synthesis. Also important in various metabolic reactions.
Vitamin C: absence causes scurvy. (ascorbic acid)
Vitamin D: Helps salts of calcium and phosphorus to be absorbed into the system and made use of in the calcification of bone. Absence causes rickets. Too much is harmful.
Vitamin E: Tocopherol. Important for neuromuscular function and maintenance of red blood cells.
Vitamin K: Quinones. Required for the synthesis of blood-clotting factors. Common in human diet.

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc RDI's (formerly RDA's) have been developed for 12 major vitamins for use in nutritional labelling. Milk and infant formulas are among foods required to be fortified with vitamins.

Safety Guidelines

Registration

Historical status

Internationl status

Directions

State Differences

OFPA Criteria

2119(m)1: chemical interactions

Vitamins are essential for health and play a role in the body much larger than the quantity consumed. They are often deficient naturally due to food being grown on depleted soils, over-processing of food, and stress of daily life.

2119(m)2: toxicity & persistence

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

Vitamins help maintain health and prevent certain diseases. Both deficiencies and toxicities of vitamins can occur. Deficiencies can result from either lack of sufficient vitamin in the diet, or from disease which impairs absorption of vitamins.

2119(m)5: agroecosystem biology

2119(m)6: alternatives to substance

whole food feeds, cod liver oil, yeasts, other food-derived supplements.

2119(m)7: Is it compatible?

References

Kirk-Othmer Encyclopedia of Chemical Technology. 3rd Edition, 1982. John Wiley and Sons, NY

Giese, James, Vitamin and Mineral Fortification of Foods. 1995. *Food Technology*, Institute of Food Technology, Chicago, IL. May 1995.

Machlin, L.J. 1984. Handbook of Vitamins., Marcel Dekker, Inc., NY

FDA Title 21 CFR 104.20, Fortification policy for foods.