NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **#5 Enzymes: mold/fungal, yeast**

✓ **NOSB Database Form**

✓ **References**

____ **MSDS (or equivalent)**

____ **FASP (FDA)**

✓ **TAP Reviews from:** **Joe Montecalvo, Rich Theuer, William Zimmer, Steve Taylor**

NOSB/NATIONAL LIST
COMMENT FORM
PROCESSING

Material Name: #5 Enzymes: mold/fungal, yeast

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

COMMENTS/QUESTIONS:

---

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: Aug. 5, 1996

Name of Material: Enzymes: mold/fungal, yeast

Reviewer Name: Steve L. Taylor RECEIVED AUG 0 5 1996

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

Most are Non-synthetic

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

Genetically engineered enzymes should be considered synthetic and should not be allowed on National List

This material should be added to the National List as:

___ Synthetic Allowed ___ Prohibited Natural

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

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

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

Genetically engineered only

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

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

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? ___ Yes; X No

Signature Steve Taylor **Date** 8/5/96

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;

None

(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.

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: Aug. 5, 1996

Name of Material: Enzymes: mold/fungal, yeast

Reviewer Name: R C Theuer RECEIVED AUG 0 5 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate) THIS "SUBSTANCE" IS MANY; SOME ARE

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

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 WITHOUT FURTHER DEFINITION AND SPECIFICATION

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

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

INADEQUATE TO JUDGE ANY SPECIFIC ENZYME

Any additional comments? (attachments welcomed)

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

Signature R C Theuer **Date** 8/5/96

USDA/TAP REVIEWER COMMENT FORM

Original mailing date: 7 Jan 1995.

Name of Materials: Enzymes, bacterial
Reviewer Name: Richard C. Theuer

NOTE: "Bacterial enzymes" is not a single substance. Many bacterial enzymes are allowed for use in food with the physical or technical functional effect described as "enzymes" in Section 21CFR170.3(o)(9). A bacterial enzyme can be judged "natural" or "synthetic" only if its source and method of manufacture are identified. Existing NOSB motions have defined any product of a genetically engineered organism to be synthetic. It is critical for a TAP reviewer to know the precise nature of the bacteria that produces an enzyme.

Several enzymes used as food processing aids could not be located in the list of Generally Recognized As Safe food additives. These include pectinase, pullanase and glucanase.

Bacterial enzymes currently allowed in food are:

21CFR184.1027 - mixed carbohydratase/protease; B. licheniformis
21CFR184.1372 - insoluble glucose isomerase; various bacteria.
21CFR184.1388 - lactase; Kluyveromyces lactis
21CFR184.1685 - chymosin; nonpathogenic Escherichia coli
21CFR184.1924 - urease (wine); Lactobacillus fermentum
21CFR173.110 - amyloglucosidase; Rhizopus niveus
21CFR173.120 - carbohydratase/cellulase; Aspergillus niger
21CFR173.130 - carbohydratase; Rhizopus oryzae
21CFR173.135 - catalase; Micrococcus lysodeikticus
21CFR173.140 - esterase/lipase; Mucor miehei
21CFR173.145 - alpha-galactosidase; Mortierella vinaceae
21CFR173.150 - milk-clotting enzymes; various bacteria.
21CFR173.160 - aqueous citric acid fermentation; Candida guilliermondii
21CFR173.165 - citric acid fermentation from normal alkanes (paraffins); Candida lipolytica

Note that the last item in this list is the bacterium that ferments paraffins to citric acid. In previous discussions the NOSB considered this process synthetic and non-allowable. In contrast, the bacterium listed just before this one ferments carbohydrate to citric acid. The NOSB deemed this citric acid process acceptable for an ingredient in organic foods. This reviewer previously judged citric acid produced by aqueous fermentation to be natural.

Note that enzymes of plant and animal origin also are used in food (e.g., papain and rennet, respective examples).

It is the position of this TAP reviewer that no universal recommendation can be made for the class "bacterial enzymes." Specific bacterial preparations differ technically from each other; each must be evaluated on its individual characteristics.

March 29, 1995

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: Aug. 5, 1996

Name of Material: Enzymes: mold/fungal, yeast

Reviewer Name: JOE MONTECALVO

RECEIVED AUG 0 5 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate) (C can be 3 forms)

IE obtained from NATURAL ORGANISMS - NON SYNTHETIC

If synthetic, how is the material made? (please answer here if our database form is blank) IE bio-Engineered - Should Not be on the NATIONAL LIST!

GENERALLY - ORGANISMS GROW IN CULTURE → SECRETE EXTRACELLULAR ENZYMES IN BROTH CULTURE WHICH IS THEN DEHYDRATED BY FREEZE-DRYING - THIS WOULD BE NATURAL ORGANIC FORM OF THE ENZYME PREPERATION DEPENDS ON THE MANUFACTURING OPERATION AS WELL

This material should be added to the National List as:

__✓__ Synthetic Allowed (IE PURIFIED WITH TRACE CHEMICALS) ____ Prohibited Natural

or, __✓__ Non-synthetic (Allowed as an ingredient in organic food) only IE by NATURAL PROCESS

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

or, __✓__ **this material should not be on the National List** IE BIOENGINEERED

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

YES: MUST BE EXTRACTED AND DRIED WITH NO FURTHER CHEMICAL MODIFICATIONS OR TREATMENTS

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

— VERY GENERAL —

Any additional comments? (attachments welcomed)

THIS IS A VERY DIFFICULT ONE TO EVALUATE BECAUSE THE ENZYMES CAN BE EXTRACTED AND PURIFIED IN DIFFERENT WAYS. MANUFACTURING PROCESS IS CRITICAL FOR ITS CATEGORY PLACEMENT

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

Signature DR. Joe Montecalvo **Date** 7/20/96

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;

none

(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 not many other choices, critical issue is how manufactured and prepared.

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

only if extracted in natural form.

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: Aug. 5, 1996

Name of Material: Enzymes: mold/fungal, yeast

Reviewer Name: William A. Zimmer D.V.M. RECEIVED JUL 3 0 1996

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

non 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?

Natural fermentation products should not need to be on list, but genetically engineered sources of enzymes meet prohibited status due to wide availability of naturally produced sources

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

limited to processing.

Any additional comments? (attachments welcomed)

Uses – feed additive, digestion of animal, human feeds. Production, performance improvements.

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

Signature William A Zimmer DVM **Date** 7-8-96

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 under normal conditions

(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 under normal conditions

(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;

positive effects on digestion, physiological processes.

(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;

livestock - improved digestive organism performance, improved feed utilization

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

natural forms are common - limit organic use to these natural forms/sources vs. chemical or recombinant DNA sources.

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

Compatible

NOSB Materials Database

Identification

Common Name Enzymes: mold/fungal, yeast

Chemical Name

Other Names

Code #: CAS

Code #: Other

N. L. Category Non-agricultural

MSDS ○ yes ◉ no

Chemistry

Family

Composition Biologically active proteins which are sometimes conjugated with metals, carbohydrates and/or lipids. Whole cells, parts of cells, or cell-free extracts.

Properties Activity measured according to reaction catalyzed by individual enzymes.

How Made Derived from microbial sources by controlled fermentation: Carbohydrase from Aspergillus niger var., Aspergillus oryzae var., Rhizopus oryzae var., Saccharomyces species, or Trichoderma reesei var.; Carbohydrase & Protease mixed from Bacillus licheniformis and Bacillus subtilis; Catalase from Aspergillus niger var., and Micrococcus lysodeikticus; Glucose isomerase from Actinoplanes missouriensis and many others; Glucose Oxidase from Aspergillus niger var.; Lipase from Aspergillus niger var. and Aspergillus oryzae var., Protease from Aspergillus niger var., and Aspergillus oryzae var.; and Rennet (Microbial) from Endothia parasitica and Mucor species. A few may be genetically engineered.

Type of Use Processing

Use/Action

Specific Use(s) Carbohydrase: preparation of starch syrups, alcohol, beer, fruit juices, chocolate syrups, bakery products, liquid coffee, wine, dextrose, dairy products, candy and ice cream; Pectinase: clarification of wines and fruit juices. Catalase: manufacture of cheese; Glucose isomerase: manufacture of high fructose corn syrup; Glucose Oxidase: removal of sugar from liquid eggs, deoxygenation of citrus beverages; Lipase: hydrolysis of lipids (fish oil concentrates); Protease: chillproofing of beer, bakery products, meat tenderizing, production of protein hydrolysates; and Rennet: manufacture of cheese.

Action Enzymes as biocatalysts accelerate the rate of specific chemical reactions. Each enzyme is highly specific as to the reaction it effects.

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc

Directions

Safety Guidelines

Historical status

Internationl status

NOSB Materials Database

OFPA Criteria

2119(m)1: chemical interactions

2119(m)2: toxicity & persistence

2119(m)3: manufacture & disposal consequences

Some enzymes are genetically engineered and such sources will become more common. Rennet (chymosin) is available as genetically engineered, as natural microbial enzyme, and as extract from calf stomach. (ST).

2119(m)4: effect on human health

None, because they are naturally present in foods. Used in tiny amounts; easily digested.

2119(m)5: agroecosystem biology

2119(m)6: alternatives to substance

Usually alternative is natural fermentation but this is not always possible to use. Some enzymes have chemical alternatives, although the chemicals are not as specific and not as easily controlled.

2119(m)7: Is it compatible?

References

AU: Valjakka,-T.T.; Ponte,-J.G.-Jr.; Kulp,-K.
TI: Studies on a raw-starch digesting enzyme. I. Comparison to fungal and bacterial enzymes and an emulsifier in white pan bread.
SO: Cereal-chem. St. Paul, Minn. : American Association of Cereal Chemists, 1924-. Mar/Apr 1994. v. 71 (2) p. 139-144. CN: DNAL 59.8-C33

SO: International Conference on UHT Processing and Aseptic Packaging of Milk and Milk Products, November 27-29, 1979 : proceedings / sponsored by Department of Food Science, North Carolina State University, Raleigh, North Carolina, and Dairy Research, Inc., U.D.I.A. International Conference on UHT Processing and Aseptic Packaging of Milk and Milk Products, November 27-29, 1979 : proceedings / sponsored by Department of Food Science,