

# NOSB NATIONAL LIST FILE CHECKLIST

## PROCESSING

**MATERIAL NAME:** #2 Chymosin (microbial rennet)



**NOSB Database Form**



**References**



**MSDS (or equivalent)**



**FASP (FDA)**



**TAP Reviews from:** Brian Baker, Joe  
Montecalvo, Steve Taylor

**NOSB/NATIONAL LIST  
COMMENT FORM  
PROCESSING**

**Material Name: #2 Chymosin (microbial rennet)**

*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: Chymosin (Microbial Rennet)

Reviewer Name: Brian Baker

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

Both

If synthetic, how is the material made? (please answer here if our database form is blank) Isolated from calves ~~non rDNA~~ = non synthetic  
Isolated from rDNA modified E. coli = synthetic  
Isolated.

This material should be added to the National List as:

Synthetic Allowed  Prohibited Natural

or,  Non-synthetic (Allowed as an ingredient in organic food) from calves only  
 Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List  
from E. coli

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

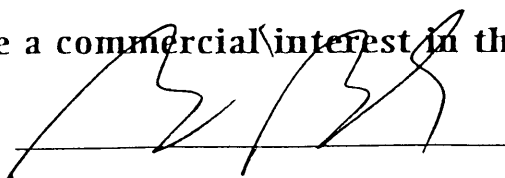
Not from rDNA modified sources

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;  No

Signature



Date

8/6/96

**USDA/TAP Reviewer  
Comment Form**

Name of Material: Chymosin (Microbial Rennet)

Reviewer Name: Brian Baker

=====

**Synthetic**

Chymosin is an enzyme that occurs naturally in calves, known also as rennin. It can also be produced through the genetic manipulation of the *E. coli* bacteria strain K-12. The gene that expresses chymosin is inserted into the *E. coli* K-12 bacteria, which is then grown through fermentation culture. The NOSB has recommended that all organisms that have been genetically modified by these techniques be considered synthetic.

1. This is used as a processing material.
2. Generally regarded as safe by FDA.
3. Fermentation process relatively contained.
4. No adverse effects reported. Relatively new product: not enough experience to know long-term effects.
5. Processing material--not applicable.
6. Non-synthetic chymosin is available from calves. Other non-synthetic microbial enzymes are also available.
7. It is questionable whether any product of rDNA can be considered compatible with sustainable agriculture. The technology is too new to confidently predict long-term effects.

**Recommendation:**

Synthetic: Yes. Allowed: No.

The NOSB should establish criteria for rDNA technology to be compatible with sustainable agriculture before evaluating any individual materials produced by these techniques before recommending their addition to the National List. This will also allow for more time to collect information on the long-term effects of the use of genetically modified organisms and their products. The product is not necessary because rennin is available from calves, and substitute enzymes are available from microorganisms that have not been genetically modified by rDNA techniques.

# 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: Chymosin (Microbial Rennet)

Reviewer Name: \_\_\_\_\_ RECEIVED AUG 05 1996

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

if bioengineered - Synthetic; if from calf - nonsynthetic  
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) - if from calves

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

or,  this material should not be on the National List if bioengineered

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

As nonsynthetic - none.

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

partially complete - not accurate in label

Any additional comments? (attachments welcomed)

none

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

Signature Dr. Joe Montanari

Date 7/26/96

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 None

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

good if extracted from CALVES

# NOSB Materials Database

1

## Identification

Common Name **Chymosin (Microbial Rennet)** Chemical Name  
Other Names **Rennin**  
Code #: CAS Code #: Other  
N. L. Category MSDS  yes  no

## Chemistry

Family  
Composition  
Properties  
How Made  
Type of Use

Extracted from the stomach of slaughtered ~~newly born~~ calves; it may also be made using chymosin produced by genetically altered micro-organisms.

Processing → An enzyme produced by the gastric glands and found in the gastric juices of young calves. It is extracted from the 4th stomach of 1-2 wk old suckling calves.

*(NO) - the animal must digest food source in order to produce gastric juice.*

## Use/Action

Specific Use(s) Used as a coagulant in cheese manufacture — *rennet curd, junket and rennet custards*

Action Consists of highly specific reaction w/ K-casein that promotes syneresis and curd packing and result in more cohesive structures of specific cheeses.

Combinations

## Status

OFPA  
N. L. Restriction  
EPA, FDA, etc  
Directions  
Safety Guidelines  
Historical status  
international status

# NOSB Materials Database

## OFPA Criteria

2

2119(m)1: chemical interactions

2119(m)2: toxicity & persistence

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

2119(m)5: agroecosystem biology

2119(m)6: alternatives to substance

2119(m)7: Is it compatible?

### References

See attached. see → SOURCE BOOK FOR FOOD SCIENTISTS, OCKERMAN, AVI  
SOURCE BOOK AND HANDBOOK SERIES, VOL 1 PP. 229



# TAP REVIEWER COMMENT FORM for USDA/NOISB

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: Chymosin (Microbial Rennet)

Reviewer Name: Steve L. Taylor RECEIVED AUG 05 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)

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

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

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;  No

Signature Steve L. 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.

**USDA/TAP Reviewer  
Comment Form**

Name of Material: Chymosin (Microbial Rennet)

Reviewer Name: Brian Baker

=====

**Synthetic**

Chymosin is an enzyme that occurs naturally in calves, known also as rennin. It can also be produced through the genetic manipulation of the *E. coli* bacteria strain K-12. The gene that expresses chymosin is inserted into the *E. coli* K-12 bacteria, which is then grown through fermentation culture. The NOSB has recommended that all organisms that have been genetically modified by these techniques be considered synthetic.

1. This is used as a processing material.
2. Generally regarded as safe by FDA.
3. Fermentation process relatively contained.
4. No adverse effects reported. Relatively new product: not enough experience to know long-term effects.
5. Processing material--not applicable.
6. Non-synthetic chymosin is available from calves. Other non-synthetic microbial enzymes are also available.
7. It is questionable whether any product of rDNA can be considered compatible with sustainable agriculture. The technology is too new to confidently predict long-term effects.

**Recommendation:**

Synthetic: Yes. Allowed: No.

The NOSB should establish criteria to evaluate rDNA technology before recommending that any individual organism or material produced by these techniques before be added to the National List. This will also allow for more time to collect information on the long-term effects of the use of genetically modified organisms and their products.

# NOSB Materials Database

1

## Identification

**Common Name** Chymosin (Microbial Rennet) **Chemical Name**  
**Other Names** Rennin  
**Code #: CAS** **Code #: Other**  
**N. L. Category** **MSDS**  yes  no

## Chemistry

**Family**  
**Composition**  
**Properties**  
**How Made** Extracted from the stomach of slaughtered newly-born calves; it may also be made using chymosin produced by genetically altered micro-organisms.  
**Type of Use** Processing

## Use/Action

**Specific Use(s)** Used as a coagulant in cheese manufacture  
**Action** Consistis of highly specific reaction w/ K-casein that promotes syneresis and curd packing and result in more cohesive structures of specific cheeses.  
**Combinations**

## Status

**OFPA**  
**N. L. Restriction**  
EPA, FDA, etc  
**Directions**  
**Safety Guidelines**  
**Historical status**  
**International status**