

30 June 2006

Mr. Robert Pooler  
National Organic Standards Board  
USDA/AMS/TM/NOP, Room 2510-So.,  
Ag Stop 0268, P.O.Box 96456  
Washington, D.C. 20090-6456  
Phone: 202/720-3252  
Fax: 202/ 205-7808  
Email: nlpetition@usda.gov.

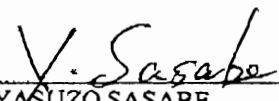
Dear Mr. Robert and National Organic Standards Board:

This letter is the petition to asking my substance for inclusion on the National List. Higashimaru shoyu Co.,Ltd. hopes that National Organic Program will evaluate this petition.

This petition is consist of 4 documents showed as below,

1. PETITION ---update to NOP 7 CFR PART 205.606
2. Exhibit 1
3. Exhibit 2
4. Exhibit 3

Sincerely,

  
YASUZO SASABE

Higashimaru Shoyu Co.,Ltd.  
Hyogo,Japan.  
Fax: +81-(0)-791-63-4637

PETITION-----UPDATE TO NOP 7 CFR PART 205.606

This petition is drawn up according to web page,

<http://www.ams.usda.gov/nop/Petition/PetitionHome.html>.

1. The substance is being petitioned for inclusion on the National List.  
Nonorganic substances allowed in or on processed products labeled as "organic".

2. The substance's common name.

Koji mold

3. The manufacturer's name, address and telephone number.

Higashimaru Shoyu Co., Ltd

100-3 Tominaga, Tatsuno-cho Tatsuno-shi, Hyogo, JAPAN

Phone: +81-(0)-791-63-4567

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4. The intended use of the substance such as use as nonorganic ingredient.

In soy sauce manufacturing, the *Koji mold* plays a very important role to control its quality, and is also as important as yeast in fermentation as a starter. Since soy sauce manufacturer originally has been selecting and breeding the *Koji mold* for long time to gives special features to the product, each manufacturer has the unique *Koji mold*. So, under this background, it is impossible to purchase the *Koji mold* to serve manufacturer's purpose in the market. For example, the *Koji mold* of our company is the most suitable for manufacturing light colored soy sauce. Whatever commercially available *Koji mold* never can satisfy our company quality.

The *Koji mold* is made of non-organic flattened barley, however, since the *Koji mold* is prepared after removing culture media, non-organic flattened barley, and is used as microorganism starter, like yeast in beer, the amount of the *Koji mold* in final product, soy sauce, is only 0.001% and counts for nothing as "certified organic" (requires that at least 95% of its ingredients calculated without salt or water are certified organic). It goes without saying that manufacturing soy sauce is never executed without the *Koji mold*.

Furthermore, the *Koji mold* is used in many manufactures, e.g. soy sauce, *miso*, *sake*, *shochu*, enzymes, etc. The *Koji mold* in soy sauce fermentation plays equivalent role to the malt in beer fermentation, namely, these are used for saccharification of materials. The economic scale of *Koji mold* utilization in industry is five trillions yen,

this corresponds to 1% of GNP in Japan. So, it is impossible to think the *Koji* mold apart from Japanese industry.

For these reasons mentioned above, we would like to have you to list up the *Koji mold* on the National List for the material of organic soy sauce.

5. A list of the handling(processing) activities for which the substance will be used.

<i>miso</i> (soybean paste)	use as a starter, like yeast in wine or beer
<i>sake</i> (Japanese rice wine)	use as a starter, like yeast in wine or beer
<i>shochu</i> (Japanese spirit)	use as a starter, like yeast in wine or beer
<i>awamori</i> (Japanese spirit)	use as a starter, like yeast in wine or beer
enzymes	use as a starter, like yeast in wine or beer

6. The source of the substance and a detailed description of its processing procedures from the basic component to the final product.

Exhibit No.1 (Process of *Koji mold*)

7. Supporting documents for continued allowance of the substance  
Organic JAS (Japanese Agricultural standard)

8. The substance's physical properties and chemical mode of action

Exhibit No.2 (Evaluation criteria for substances added to the National List)

9. Safety information about the substance

Exhibit No.3 (MATERIAL SAFETY DATA SHEET)

Exhibit No.1 : Process of Koji mold

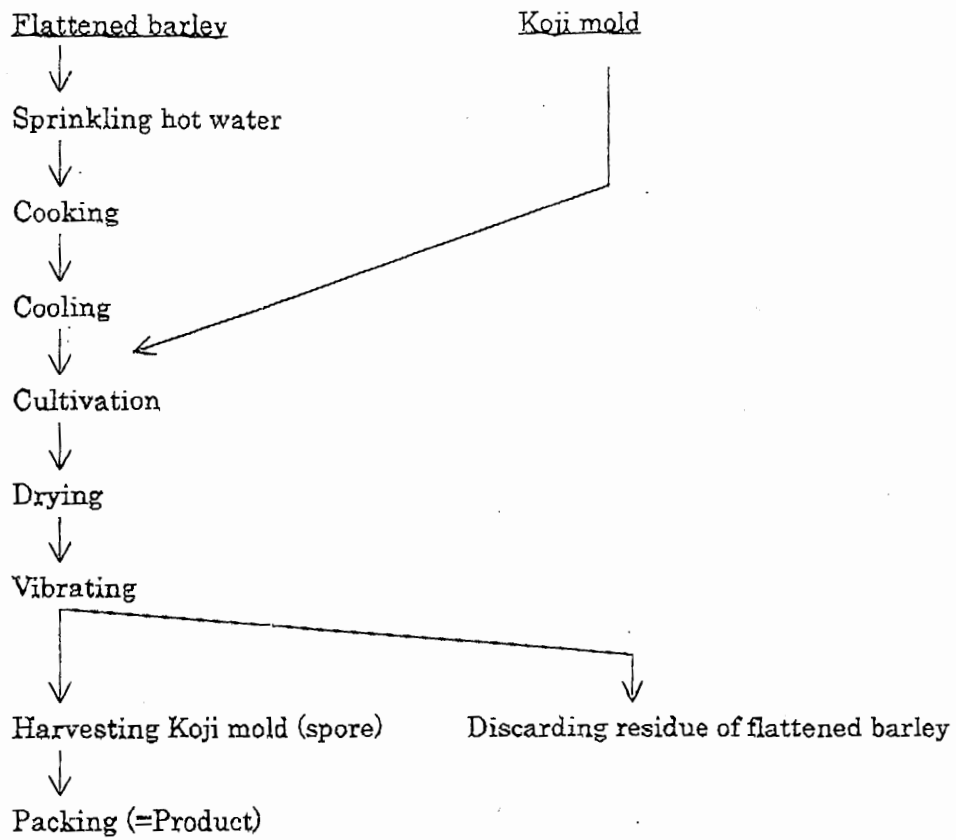


Exhibit No.2 : Evaluation CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance Koji\_mold

Question	Yes	No	N/A	Documentation (TAP, petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		<input type="radio"/>		
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		<input type="radio"/>		
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		<input type="radio"/>		
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		<input type="radio"/>		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		<input type="radio"/>		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		<input type="radio"/>		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		<input type="radio"/>		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		<input type="radio"/>		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		<input type="radio"/>		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		<input type="radio"/>		
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		<input type="radio"/>		
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	<input type="radio"/>			It is mentioned as <i>Aspergillus oryzae</i> which is science name.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances [§205.600 b.5]		<input type="radio"/>		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance Koji mold

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		<input type="radio"/>		
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		<input type="radio"/>		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	<input type="radio"/>			This substance is created by the mold selected from microorganisms universally existing in a natural environment.
4. Is there a natural source of the substance? [§205.600 b.1]	<input type="radio"/>			The mold constructing this substance is microorganism universally existing in a natural environment.
5. Is there an organic substitute? [§205.600 b.1]			<input type="radio"/>	There is no substitute in the strict sense of the word, because we select the best suited mold for soy sauce manufacture at each company, like the best suited yeast used in wine manufacture. We cannot prove that this mold is not commercial available, however, hardly think it's commercial available. We recognize the mold is equal to yeast which had been included on the National List.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	<input type="radio"/>			The substance in soy sauce fermentation plays equivalent role to the malt in beer fermentation, namely, these are used for saccharification of materials. So, this substance is essential.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			<input type="radio"/>	This is the natural substance.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	<input type="radio"/>			
9. Is there any alternative substances? [§6518 m.6]		<input type="radio"/>		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		<input type="radio"/>		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A— not applicable.

**Category 3. Is the substance compatible with organic production practices?**

Substance Koji mold

Question	Yes	No	N/A	Documentation (TAP, petition, regulatory agency, other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	<input type="radio"/>			
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	<input type="radio"/>			
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			<input type="radio"/>	Not agriculture
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	<input type="radio"/>			
5. Is the primary use as a preservative? [§205.600 b.4]		<input type="radio"/>		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		<input type="radio"/>		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		<input type="radio"/>		
a. copper and sulfur compounds;		<input type="radio"/>		
b. toxins derived from bacteria;		<input type="radio"/>		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		<input type="radio"/>		
d. livestock parasiticides and medicines?		<input type="radio"/>		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		<input type="radio"/>		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A— not applicable.

Exhibit No.3 : MSDS

MATERIAL SAFETY DATA SHEET

Issue Date:21,06,2006

## 1. PRODUCT AND COMPANY IDENTIFICATION

Commercial Product Name: Koji Mold

Description: Soy sauce Koji Mold

Manufacturer: HIGASHIMARU SHOYU Co.,Ltd.

100-3, Tominaga, Tatsuno-cho, Tatsuno-shi, Hyogo 679-4167,  
JAPAN

Emergency Phone Number: Japan (Head Office); +81-(0)-791-63-4567

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components (Chemical Name)	CAS#	OSHA PEL	ACGIH TLV	OTHER LIMITS	PERCENTAGE
FEED GRADE INGREDIENTS	NA				100.0%

## 3. HAZARDS IDENTIFICATION

Emergency overview

Route(S) of Entry: Inhalation; No, Skin; No, Eyes; No, Ingestion; No

Potential Health Effects (Acute and Chronic)

Carcinogenicity: NTP; IARC Monographs; OSHA Regulated;

Carcinogenicity/Other Information

Signs and Symptoms of Exposure: Dust Irritation

Medical Conditions Generally Aggravated by Exposure: None Known

## 4. FIRST AID MEASURES

Emergency and First Aid Procedures: Flush eyes with water.

Note to Physician

## 5. FIRE-FIGHTING MEASURES

Flash PT: N.A. Method Used:

Explosive Limits: LEU: UEL:

Autoignition PT: N.A. Extinguishing Media: Water

Fire Fighting Instructions: Use NIOSH/MSHA approved positive pressure self-contained breathing apparatus and full protective clothing.

Flammable Properties and Hazards: None known

Hazardous combustion Products



potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.

Eye Protection: Chemical goggles

Protective Gloves: Rubber or neoprene gloves

Other Protective Clothing: Clothes to prevent skin contact

Engineering controls (Ventilation etc.): Good general ventilation should be sufficient to control airborne levels.

Work/Hygienic/Maintenance Practices: Wash hands before eating, smoking, or using restroom.

## 9. PHYSICAL AND REACTIVITY

Physical States: Solid

Boiling Point: N.A.

Melting Point: N.A.

Specific Gravity (water=1):

Vapor Pressure (vs. Air or mm Hg):

Vapor Density (vs. Air=1):

Evaporation Rate (vs. Butyl Acetate=1):

Solubility in Water:

Other Solubility Notes: nil

Percent volatile: N.A.

pH:

Appearance and Odor: Dark green with slightly odor

## 10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to avoid Instability:

Incompatibility-Materials to Avoid: Avoid oxidation as it may affect potency of vitamins.

Hazardous Decomposition or Byproducts:

Hazardous Polymerization: Will not occur

Conditions to Avoid-Hazardous Polymerization:

#### 11. TOXICOLOGICAL INFORMATION

#### 12. ECOLOGICAL INFORMATION

#### 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose of according to local, state, and federal regulation.

#### 14. TRANSPORT INFORMATION

Dot Proper Shipping Name:

Dot Hazard Label: None

UN/NA Number:

Additional Transport Information

#### 15. REGULATORY INFORMATION

#### 16. OTHER INFORMATION

The information and data herein are believed to be accurate and have been compiled from sources believed to be reliable. It is offered for your consideration, investigation and verification.