OCEAN NUTRITION CANADA
wellness through innovation

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Robert Pooler, Agricultural Marketing Specialist
National Organic Standards Board (NOSB)
USDA-AMS-TMP-NOP
1400 Independence Avenue, SW
Washington, DC 20250-0020

January 12, 2007

Resubmission of petition for the Addition of Fish Gelatin to 205.606

Dear Mr. Pooler,

Please find attached the updated petition submission from Ocean Nutrition Canada, Limited (ONC). ONC is re-submitting this updated petition to the National Organic Standards Board (NOSB) to request the addition of fish gelatin to section 205.606 of the National Organic Program's National List as an agricultural product that is currently not available in an organic form.

This petition submission amends and replaces the previous submission by ONC in August 2006. This petition has been updated according to the December 2006 revised National Organic Program guidelines on the submission for inclusion on or removal from the National List of Substances Allowed and Prohibited in Organic Production and Handling (National List.)

ONC has proceeded with the submission of this petition although this petition may be redundant, due to the fact that on May 7, 2002 the National Organic Standards Board unanimously approved a recommendation to include gelatin on the National List in Section 205.606.

Please do not hesitate to contact us if you require any additional information in relation to this fish gelatin petition.

Sincerely,

Julianne Mayo
Regulatory Affairs Associate

PETITION FOR THE ADDITION OF FISH GELATIN TO 7 CFR 205.606

ITEM A

Category for which substance is being petitioned:

Ocean Nutrition Canada Limited (ONC) is petitioning for the inclusion of fish gelatin in the category of nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" under Section 7 CFR 205.606.

The NOP defines an agricultural product as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock..." The OFPA defines livestock as "any cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other nonplant life." This product is derived from fish, and is therefore an agricultural product.

ITEM B

1. The substance's common name.

Fish gelatin.

2. The producer or manufacturer's name, address and telephone number.

Ocean Nutrition Canada Limited (ONC)
101 Research Drive
Dartmouth, NS
B2& 4T6 Canada
Phone: 902-480-3200
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3. A list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).

Gelatin, including that derived from fish, is regarded as Generally Recognized as Safe (GRAS) as a multi-purpose ingredient in a wide variety of foods, subject only to GMP, by virtue of safe use prior to 1958.

While there are many potential uses for fish gelatin in the organic industry, Ocean Nutrition Canada uses fish gelatin as an ingredient in the conversion of liquid fish oil to a dry powder. Fish oil is micro-encapsulated at the microscopic level, so that miniscule droplets of oil (e.g. ~40-80 um) are coated with a shell. Gelatin makes up the main component of the outer shell that encapsulates the oil. Encapsulating the fish oil in a gelatin shell prevents the oxidation of the oil, masks the odor and taste of the oil and converts liquid oil to a dry powder. Encapsulating at a microscopic scale creates a

powder fine enough that it can be added to a variety of food ingredients. An example of this application is Stonyfield Farm's *YoBaby Plus* yogurt product. Stonyfield's *YoBaby Plus* yogurt is an organic product that contains ONC's microencapsulated fish oil ingredient.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for handling (including processing), the substance's mode of action must be described.

For use in handling as a nonorganic agricultural ingredient.

As identified above, fish gelatin is GRAS for many uses (e.g. emulsifying, gelling, stabilizing, thickening, ingredient). For ONC's purposes, the fish gelatin functions as a coating for microencapsulation of the primary ingredient, fish oil. As such, it protects the fish oil from oxidation, creates a readily handled powder form of the oil, and prevents the product from imparting undesirable tastes or odors to products to which it is added as an ingredient.

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #6.

The Gelatin Manufacturers Institute of America (GMIA) defines gelatin as "a 'product obtained from partial hydrolysis of collagen derived from natural sources such as skin, connective tissue, and bones of animals.' It is an easily digestible protein that contains all the essential amino acids except tryptophan. Gelatin is NOT a chemical or chemically modified substance" http://www.gelatin-gmia.com/html/qanda.html

Fish gelatin can be derived from the skin of edible species of a variety of commercially harvested fish. For example, the fish gelatin typically used by ONC is derived from the skins of tilapia, which are a by-product of the aquaculture industry. The skins can be sourced from South and Central America, Asia and North America and can be processed at locations worldwide. ONC's current supply of fish gelatin is processed in Europe, where the collagen is extracted from the skins.

Fish gelatin is produced by extraction and hydrolysis of fibrous, insoluble collagen from skins or bones. The skins are separated, frozen during storage and transport and thoroughly washed before gelatin is extracted by treatment with hot water. The traditional process for extraction and processing of fish gelatin is based on cooking and boiling the raw ingredient (*i.e.* skins) in water (please see attached manufacturing flow chart). No treatments or additives are used that would result in chemical modifications of the substance.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.

National Organic Standards Board Technical Advisory Panel Review, Gelatin, March 1, 2002. Compiled by Organic Materials Review Institute for the USDA National Organic Program. http://www.omri.org/Gelatin-TAP.pdf

Gelatin was recommended for addition to the National List at 7 CFR 205.606 by the NOSB at its meeting in May, 2002. Neither it nor any other materials have been added by NOP to 7 CFR 205.606 since its initial publication. NOSB Minutes of this recommendation found at http://www.ams.usda.gov/nosb/MayMinutes/MayMinutes.html

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.

Joint FAO/WHO Expert Committee on Food Additives (JECFA) Food Additive Specification for Edible Gelatin at
http://www.fao.org/ag/agn/jecfa-additives/details.html?id=168

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contain the petitioned substance.

CAS Number: 9000-70-8

9. The substance's physical properties and chemical mode of action, including:

The attached MSDS for fish gelatin describe its physical properties.

(a) chemical interactions with other substances, especially substances used in organic production;

No distinct chemical reactions are known to occur.

(b) toxicity and environmental persistence;

See MSDS Examples Attached. Fish gelatin is biodegradable. There is no evidence of any toxicity or environmental persistence.

(c) environmental impacts from its use or manufacture;

Fish gelatin is derived from the skins of edible species of commercially harvested fish. A range of species and harvesting methods may be employed, including wild caught or aquaculture. For example, ONC uses fish gelatin that is a byproduct of Tilapia aquaculture, and is derived from farm-raised fish skins, harvested for the food industry. The fish are raised and harvested in a way that minimizes environmental hazards resulting from either the aquaculture or the processing operation. Tilapia are bred using natural selection, and fed with balanced feeds that are low in protein in order to avoid the risk of damaging pond bottoms and water quality with unconsumed feeds. The feed is

mainly of vegetable origin; however, the fishmeal portion used in the feed formula is from Peru and Ecuador, where fish harvesting is tightly regulated and monitored. Additionally, the Tilapia are polycultured with shrimp in the same ponds so that the shrimp, which are bottom feeders, clean the pond floors.

ONC and the farms are supporting a program of progressive reduction of the sea-based fishmeal, being replaced with processed waste from the farms' own Tilapia and shrimp ponds. Further, they do not use antibiotics prophylactically. In the few cases where permitted therapeutic antibiotic products are used, control systems are in place to ensure that adequate time is left before harvesting the fish to allow the products to be eliminated from the bodies of the fish by natural means. The fish are tested for antibiotic residue; the test results indicate that residue is not detectable at a detection limit of 0.3 ppb. Pesticide residues are also tested; results confirm that organochlorine pesticides are not detected in the fish.

(d) effects on human health;

Fish products such as gelatin can be tested for contaminants, to ensure no negative effects on human health from consumption. ONC has tested the fish gelatin product they use for residues of heavy metals, including Cadmium, Copper, Lead, Mercury, Nickel, Strontium, and Zinc. A sample analysis report is attached, showing levels of metals to be well below thresholds established by the Joint FAO/WHO Expert Committee on Food Additives.

The tilapia flesh is monitored by the supplier for residues of veterinary drugs, pesticides and heavy metals, although the skins are not analyzed separately. Please see section (c) above, for information concerning pesticide and antibiotic residue results as tested by the fish skin supplier.

(e) effects on soil organisms, crops, or livestock.

Not applicable. Fish gelatin is an ingredient and is not applied to the soil, crops or livestock.

10. Safety information about Fish Gelatin.

Please see attached examples of Safety Data Sheets for two different fish gelatin supplies.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

National Organic Standards Board Technical Advisory Panel Review, Gelatin, March 1, 2002. Compiled by Organic Materials Review Institute for the USDA National Organic

Program. http://www.omri.org/Gelatin-TAP.pdf

The Gelatin Manufacturers Institute of America (GMIA) review at http://www.gelatin-gmia.com/html/qanda.html

12. Petition Justification Statement

Fish gelatin is used in organic products as an ingredient in the micro-encapsulation of fish oil. For example ONC uses fish gelatin as a constituent of its fish oil powder; gelatin is the primary component of the outer shell material that encapsulates the fish oil. The gelatin shell formed around the oil droplet is necessary to protect the oil from oxidation. Encapsulation using gelatin can be employed with other liquid ingredients as well, such as flavors. Encapsulating the liquid ingredient in a gelatin shell allows the presentation of the liquid in a powder form, which facilitates handling and formulation in organic products. As such, the powder form of the liquid can be added to a wider range of foods.

Fish gelatin is integral to the handling of any organic product that uses powdered fish oil as an agricultural ingredient. This ingredient enables organic products to maintain a competitive position with similar conventional products, many of which are fortified with fish oil.

Statement of need for the non-organic form of the ingredient for use in organic handling:

There are currently no NOP standards for organic fish or their derivatives, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. ONC intends to pursue the suitability of potential supplies of organic fish gelatin at such time that the NOP implements standards for organic fish.

It is possible to produce gelatin from pork and beef, both of which may be organically produced. Kosher gelatin is required for a large portion of the worldwide market, since many food companies run 100% kosher manufacturing lines. Pork gelatin is therefore unacceptable as an alternative.

Beef gelatin is eligible for kosher status; however the only known source of kosher beef gelatin cannot provide adequate supplies. An additional issue concerning the use of beef gelatin for ONC is the introduction of bovine material into its manufacturing facilities. ONC's manufacturing facilities are currently 'bovine-free', and altering this status would affect current USDA permits required for import/export with respect to BSE. Some customers also maintain bovine-free facilities and will only use ingredients from bovine-free suppliers.

Information concerning how or why the ingredient/substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling:

There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. ONC intends to pursue the suitability of potential supplies of organic fish gelatin at such time that the NOP implements standards for organic aquaculture.

Information concerning how or why the ingredient/substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling:

There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. There is no other source of gelatin that could be organically produced and that is both kosher and from a non-bovine source. Therefore, there are no organic sources available. ONC intends to pursue the suitability of potential supplies of organic fish gelatin at such time that the NOP implements standards for organic aquaculture.

Information concerning how or why the ingredient/substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling:

There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. ONC intends to pursue the suitability of potential supplies of organic fish gelatin at such time that the NOP implements standards for organic aquaculture.

Information on ingredient/substance non-availability of organic sources:

There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. ONC intends to pursue the suitability of potential supplies of organic fish gelatin at such time that the NOP implements standards for organic aquaculture.

Attachments:

Fish Gelatin Flow Chart, example.

Fish Gelatin MSDS, examples.

Trace Metals Analysis, ONC document.

Label for ONC Fish Oil Powder product, ONC document.

The following chart may be used by the NOSB as Evaluation Criteria for Substances to be Added to the National List Section 205.606.

Is the Substance Essential for Organic Production? Substance: Fish Gelatin

Question	Yes	No	N/A	Documentation Source
1. Is the substance an agricultural product?	X			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from a nonorganic agricultural substance?		X		
3. Is the substance created by naturally occurring biological processes?	X			
4. Is there an organic source of the substance? [1]		X		
5. Is the substance essential for handling of organically produced agricultural products? [2]	X			
6. Are there any commercially available alternative organic substances? [3]		X		
7. Is there another practice that would make the substance unnecessary?		X		

[1] Documentation should specify details of efforts made to obtain an organic source and the outcome of that effort.

[2] Documentation should specify the essential qualities required for the product to be suitable, e.g., liquid vs. powder, viscosity, color, flavor profile, etc.

[3] Documentation should specify organic alternatives that have been evaluated and reasons for unacceptability.

EXAMPLE

GELATIN PRODUCTION PROCESS

FISH ACIDE GELATINE

		Temperature (°C)	pH	Time
1 -	**PREHYDROLYSIS STEP**			
	defrost	About 10 - 15		
	washing	About 10 - 15		to clean
	washing	About 10 - 15	from > 6,0 to < 2,0	
2 -	**EXTRACTION**			
	1° extract	55 to 65	4 to 5	2 to 6 hours
	2° extract	60 to 70	4 to 5	2 to 6 hours
	3° extract	70 to 80	4 to 5	2 to 6 hours
	4° extract	85 to 95	4 to 5	2 to 11 hours
	5° extract	85 to 95	4 to 5	2 to 11 hours
3 -	**TREATMENTS ON GELATIN SOLUTION**			
	Filtration	45 to 60	5 to 6	60 minutes
	Demineralisation	45 to 60	5 to 6	60 minutes
	Concentration	85 to 55	5 to 6	about 2 hour
	1° Sterilization	> 139	5 to 6	> 4 seconds
4 -	**DRYING AND TREATMENTS ON DRIED GELATIN**			
	2° Sterilization	> 139	5 to 6	> 4 seconds
	Drying	20 to 55	5 to 6	3 hours
	Grinding	about 25	5 to 6	
	Bagging	about 20	5 to 6	
	Storage	about 20	5 to 6	
5 -	**BLENDING AND FINAL TREATMENTS**			
	Blending	about 20	5 to 6	
	Bagging and labelling	about 20	5 to 6	
	Palettisation and labelling	about 20	5 to 6	
	Storage	about 20	5 to 6	
	Expedition		5 to 6	

Example 1

Safety data sheet

1 Identification of substance/preparation / Manufacturer / supplier
- Identification of substance or its preparation: protein
- Trade name: **Gelatine**
- Manufacturer/supplier: Proprietary

2 Composition / Data on components
- Chemical name: **Gelatine**
- CAS n° Designation: 9000 - 70 – 8

3 Hazard identification
- Main risk: the product is not dangerous

4 First aid measures
- After skin contact: the product is not skin irritating
- After eye contact: rinse opened eyes under running water

5 Fire fighting measures
- The product is not flammable

6 Accidental release measures
- Person related safety precautions: not required
- Measure for environmental protection: do not dispose of on surface or ground water.
- Cleaning and recycling methods: wash with water.

7 Handling and storage

Handling:
- Precautions for safe handling: none
- Incompatible substances: none

Storage:
- Requirements to be met by storerooms and containers: no special requirements.
- Further information about storage conditions: keep in a dry storeroom at room temperature

8 Exposure controls and personal protection

Personal protective equipment
- Breathing equipment: not required
- Protection of hands: not required
- Protection of eyes: not required

Example 1

Safety data sheet

9 Physical and chemical properties
- Form: granular / powder
- Colour: pale yellow
- Odour: none
- pH 45°C, solution 6, 2/3%: 5 – 6.5
- Moisture: <15%
- Flash point: not applicable
- Risk of explosion: the product is not explosive
- Solubility in/miscibility with water: soluble at > 40°C

10 Stability and reactivity
- Thermal decomposition / conditions to be avoided: no decomposition if it used according to specification.
- Dangerous reaction: no dangerous reaction known
- Dangerous products of decomposition: no dangerous products of decomposition.

11 Toxicological information: the product is not toxic

12 Ecological information:
- General notes: do not dispose of the product in the environment

13 Disposal consideration
- Recommendation: disposal must be according to official regulation

14 Transport information
- The product is not classified as dangerous for the transport.
- Land transport ADR/RID and RTMDR/RTMDF (regulation concerning the transport of dangerous product - train transport) (Gross-border/domestic):
  Class ADR/RID-RTMDR/F (regulations concerning the transport of dangerous products - road and train): not classified
- Maritime transport IMDG (regulations concerning the transport of dangerous products):
  Class IMDG: not classified
- Air transport ICAO-TI and IATA-DGR:
  Class ICAO/IATA: not classified

15 Regulatory information
- Code letter and hazard designation of the product: in accordance with EC Directives: not necessary.

16 Other information
These data are based on our present knowledge. However, they do not constitute a guarantee for any product features and do not establish a legally valid contractual relationship.

Example 2

SAFETY DATA SHEET

1 - PRODUCT AND COMPANY IDENTIFICATION :

. PRODUCT NAME : **GELATINE** **– FISH - KOSHER**
GELATINE **– FISH**

. SUPPLIER : Proprietary

2 - COMPOSITION / INFORMATION ON INGREDIENTS :

FISH GELATINE
Dehydrated substance of animal protein type.
Hazard contributing ingredients : none.

3 - HAZARDS IDENTIFICATION :

. MAIN HAZARDS : none.

. SPECIFIC HAZARDS : none.

4 - FIRST-AID MEASURES :

Non-toxic grain , neither through eye nor skin contact, nor by inhalation or ingestion. Slightly sticky, it can be removed by rinsing with warm water.

5 - FIRE-FIGHTING MEASURES :

. SUITABLE EXTINGUISHING MEANS :
All means such as water, powders, or foams, without any other hazards, methods or specific protection, as in the case of a classic fire extinguishment.

6 - ACCIDENTAL RELEASE MEASURES :

. PERSONAL PRECAUTIONS :
No specific precautions.

. ENVIRONMENTAL PRECAUTIONS :
No specific precautions.

. METHODS FOR CLEANING-UP :
Rinsing with water or incineration.

7 - HANDLING AND STORAGE :

. HANDLING :
Technical measures : to be handled in its original packaging.
Precautions : pour slowly to avoid formation of dust (non - toxic).
Safe handling advice : incompatible materials : none.

. STORAGE :
Technical measures : keep in its original packaging to protect from moisture.
Suitable storage conditions : keep in a closed and dry place, and at room temperature.
Storage conditions to be avoided : outdoors (product deterioration).
Incompatible products : none.
Recommended packaging materials: bags with a polyethylene inner lining.
Unsuitable packaging materials : all packaging that does not protect the product from moisture and external contamination.

8 - EXPOSURE CONTROLS / PERSONAL PROTECTION :

Personal protective equipment : no specific equipment.
Specific hygiene measures : any measure needed for handling of edible products.

9 - PHYSICAL AND CHEMICAL PROPERTIES :

. PHYSICAL APPEARANCE : grain
. COLOUR : - dry : pale beige,
: - in solution : uncoloured to pale yellow.
. ODOUR : no unpleasant odour.
. pH at 1% concentration : 4,0 to 7,0.
. SETTING POINT at 10% concentration : 20 to 25°C.
. MELTING POINT at 10% concentration : 25 to 30°C.
. DECOMPOSITION TEMPERATURE : carbonization at 150°C.
. FLASHPOINT : 255°C.
. AUTOIGNITION TEMPERATURE : > 600°C.
. EXPLOSION PROPERTIES : none.
. DENSITY : 0.7 kg/litre approx.
. SOLUBILITY : soluble in mild aqueous liquid medium, forms a jelly when cooled down.

10 - STABILITY AND REACTIVITY :

. STABILITY :
Recommended conservation : 5 years : However, because of its low residual moisture content, gelatine can be kept for a nearly unlimited period of time, if stored in the original unopened packaging in a dry place protected from humidity.

. HAZARDOUS REACTIONS : none.

. HAZARDOUS DECOMPOSITION PRODUCTS : by pyrolysis : none.

11 - TOXICOLOGICAL INFORMATION :

. ACUTE TOXICITY : none.

. LOCAL EFFECTS : none.

12 - ECOLOGICAL INFORMATION :

Gelatine is 100% biodegradable.

13 - DISPOSAL CONSIDERATIONS :

. WASTE FROM RESIDUES :
Incineration of powder / grain residues ; rinsing the liquid residues in water, then washing down the drain.

. CONTAMINATED PACKAGING :
Incineration.

14 - TRANSPORT INFORMATION :

. INTERNATIONAL REGULATION :
Non-hazardous product, not submitted to classification or codes.

15 - REGULATORY INFORMATION :

This product is conform to current standards in the country of destination.

16 - OTHER INFORMATION :

None.

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Trace Metals Analysis – Fish Gelatin

Parameter	Example Fish Gelatin Results (mg/kg)	FAO/WHO specification (mg/kg)
Arsenic	0.22	Not more than 1
Cadmium	<0.01	Not more than 0.5
Lead	<0.05	Not more than 1.5
Mercury	<0.005	Not more than 0.15

Ocean Nutrition Canada Ltd.

Product Name:	**Omega-3 Powder-KD (Microencapsulated Fish Oil)**
ONC Code:	**MC601812TG-KD**
ONC Lot:	**XXXXXX**
Manufacture Date:	**YR MN DY**
Best Before:	**YR MN DY (12 month shelf life)**
Net Weight:	**10 kg**
CFIA registration #:	**3565**
U.S. Patent:	**6,974,592**

Ingredients: Refined fish oil (anchovy & sardine), fish gelatin (Tilapia), sodium polyphosphate, ascorbic acid, sodium hydroxide, natural flavour, canola oil, tocopherols, sunflower oil, citric acid.

Manufacturer Recommendations

- Ensure package is intact upon receipt.
- Store in a tight, light resistant container.
- Store in a cool, dry place at 4°C (39.2°F).
- Nitrogen purge after each opening.
- Ocean Nutrition Canada Ltd. does not assume any responsibility for product that is not stored according to our instructions with respect to: containers, temperature or nitrogen purge.

- This bulk package is not for consumer retail.
- Product of Canada

FISH

Manufactured by: Ocean Nutrition Canada (Tel: 1-888-980-8889)
Head Office: 101 Research Dr, Dartmouth, Nova Scotia, Canada B2Y 4T6

Bag Number:_____

National Organic Standards Board Meeting, May 6-8, 2002, Austin, Texas

Processing Committee Final Recommendation: Gelatin

Introduction:

Gelatin is petitioned primarily for use as a processing aid used to clarify tea. It is also used as a fining agent in wine, and as a stabilizer, thickener, and texturizer for a range of products. It can be used as either a processing aid or ingredient.

Background:

Gelatin can be made from many different sources of collagen. It may be prepared in a way that is more like cooking or in ways that would render it synthetic. The TAP reviewers recommended that gelating be added to the National List. One recommended that it be prohibited for use in organic processing and handling.

Recommendation:

Gelatin to be listed in 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic" (specified ingredients or food group(s)).

Committee Vote:

Approved – 5
Disapproved – 0
Absent – 0

Conclusion:

This recommendation determines gelatin to be an agricultural product to be listed in 205.606 for use in products labeled as "organic" or "made with organic."