

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Glycerin
October 21, 2014**

Summary of Proposed Action:

Petitioner has requested removal of glycerin from §205.605(b) (synthetic materials for handling), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required. The petitioner believes that the process of microbial fermentation – used to produce organic glycerin – is a superior method for the production of organic glycerin, because it uses only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). Further, they state, “An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used “only when the product is not commercially available in organic form.” Certified organic glycerin is currently available, but there is no “commercial availability” requirement to incentivize processors to use it or certifiers to require it. Consequently, glycerin should be removed from the National List in order to encourage organic agricultural production.”
(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924>)

There has been a significant amount of confusion regarding the classification of glycerin as synthetic/non-synthetic because of the various methods by which it can be manufactured. In April 2013, the National Organic Program (NOP) issued draft guidance on classification of materials that should provide some clarification on the status of glycerin produced by these various methods. However, as of this date, this guidance document has not been issued in its final form. Further, the Handling subcommittee recognizes the irony that glycerin produced from organic source materials using hydrolysis could be classified as both organic and synthetic.

Additionally, public written and oral comments presented for the Spring 2014 and the Fall 2014 NOSB meetings indicated that the removal of glycerin from §205.605(b) could have significant negative impact on natural flavorings used in organic products, due to the fact that glycerin is often used as a carrier. The comments generally expressed concern regarding the commercial availability of sufficient quantities of organically produced glycerin to meet the demand. With the current listing for flavors at §205.605(a), the annotation is as follows: “non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.” During the Handling subcommittee discussion, the question came up as to whether current practice is to allow glycerin – from hydrolysis of fats and oils – currently classified as synthetic, to be used as a carrier in natural flavorings.

Because of the confusion around classification of glycerin (depending upon the manufacturing methods and source material), and the concerns regarding commercial availability of organically produced glycerin, the Handling subcommittee, after significant discussion, is proposing the listing of glycerin at §205.606 and removal of glycerin from §205.605(b).

Based upon the draft classification of materials document, glycerin that would qualify for listing at §205.606 would include glycerin produced by microbial fermentation of carbohydrate substances as well as glycerin produced from hydrolysis of fats and oils using mechanical/physical methods, as long as the original source material was agricultural. It is the Handling subcommittee’s intent with this recommendation to provide an incentive to increase the amount of organic glycerin used, while also recognizing the possibility of issues around commercial availability.

Background

Glycerin is a viscous fluid that has a sweet taste. It is used in a wide variety of products including food, cosmetics, medical and industrial applications. As listed at §205.605(b), glycerin is formulated from hydrolysis of fats and oils. Per the Technical Review (line 122), there are a variety of methods for manufacture of glycerin from hydrolysis of fats and oils:

Table 2 Processes for producing glycerin by hydrolysis of fats and oils	
Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantages claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245°C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.
Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495°F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.

Additionally, per the petitioner, "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils."

Hydrolysis of fats and oils does change the chemical properties of the source material, therefore, it is considered a synthetic.

The forms identified below as agriculture would be allowed at §205.606. Synthetic forms would not be allowed unless produced organically.

Per the petition: Four general methods of commercial glycerin production are or have been used:

1. Chemical synthesis by hydrogenolysis of carbohydrates (21 CFR 178.3500; 21CFR 172.866)) or by synthesis from propylene (mentioned in the 1995 Technical Advisory Panel report on glycerin). Neither chemical synthetic process has ever been deemed worthy of serious consideration for use in organic. Per the draft classification of materials guidance document, this form would be considered synthetic.
2. Biodiesel production comprises reaction of natural fats and oils – triglycerides – with methyl alcohol or ethyl alcohol to produce the methyl or ethyl esters of fatty acids. These synthetic fatty acid esters are the diesel fuel. Glycerin is a synthetic waste byproduct of this chemical process. The commercialization of the biodiesel process in the past few years has created an enormous supply of biodiesel glycerin that has largely displaced chemical synthesis from propylene. In fact, the low cost of biodiesel glycerin has resulted in commercialization of processes to use it as a raw material to produce epichlorohydrin, acrolein, propylene glycol, and other organic chemicals. There are safety concerns with biodiesel glycerin, discussed in Section B-11. *Per the draft classification of materials guidance document, this form would be considered non-agricultural synthetic.*
3. Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel (TAP) Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List. Glycerin produced by saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation “produced by hydrolysis of fats and oils.” It is currently included on the National List as a synthetic nonagricultural substance at §205.605(b) [and also for livestock use at §205.603(a)(12)]. Certified organic glycerin is being produced by saponification of organic fats and oils. *Per the draft classification of materials guidance document, glycerin produced using saponification of natural fats and oils using steam would be considered agricultural. However, the material would be considered synthetic if an alkali catalyst was used.*
4. Microbial fermentation of carbohydrate substances (analogous to citric acid currently included in the National List at §205.605(a)) to produce non-synthetic glycerin. This production method is briefly mentioned generically in the 1995 TAP Report and referred to in the Merck Index monograph on glycerol (glycerin), which cites a U.S. Patent No. 3,012,945 issued to Noda in 1961 for yeast fermentation to produce glycerin. Currently, microbial fermentation of organic cornstarch by the yeast *Candida krusei*¹ is used commercially to produce certified organic glycerin as well as non-synthetic non-organic glycerin. *Per the draft classification of materials guidance document, this form would be considered agricultural.*

According to the Technical Report, glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List. Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch (TR lines 130 – 131). There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674)

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	X No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	X No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	X No	<input type="checkbox"/> N/A

Substance Fails Criteria Category 2, 3, 4

Subcommittee Action & Vote

Classification Motion: Motion to classify glycerin as agricultural when derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270(a).

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Listing Motion: Motion to list glycerin at §205.606, produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Basis for annotation: X To meet criteria above Other regulatory criteria Citation

Notes:

Listing Motion: Motion to remove glycerin - produced by hydrolysis of fats and oils – from §205.605(b)

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB December 2, 2014

NOSB Evaluation Criteria for Substances Added to the National List - Handling

Category 1. Adverse impacts on humans or the environment?

Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		Wide variety of uses for food and industrial applications. Long-term history of safe use, TAP indicates no incidence of industrial poisoning. Glycerin should not come into contact with a strong oxidizing agent.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		For current listing: Manufactured from hydrolysis of fats and/or oils using steam splitting. Theoretically possible to have spill of oils, but this is unlikely. Fermentation methods: Unlikely
3. Are there any adverse impacts on biodiversity? (§205.200)			X	However, the petitioner claims that the residue from biodiesel production is used in the manufacture of glycerin, and one could argue that growing corn for biodiesel does have an impact on biodiversity.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Per Environmental Working Group (EWG), there seems to be no persistence in the environment. TAP and other documentation have no comment.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		Glycerin is considered GRAS and has a long history of safe use in a wide variety of food, cosmetic and medical applications. It is metabolized as a carbohydrate in the body.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			See above comment.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		Manufactured from hydrolysis of fats and oils using steam splitting and then concentrated using distillation. Fermentation methods include isolation of cornstarch from organic corn.

NOSB Evaluation Criteria for Substances Added to the National List - Handling

Category 2. Is the Substance Essential for Organic Production? Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X	X		As currently listed it is not considered agricultural. However, the petitioner makes the argument that it should have been listed at §205.606; if it is manufactured using steam, then it should be considered agricultural. The fermentation method could be considered agricultural since it is manufactured using isolated cornstarch from organic corn.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			<p>Per the petition: "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List."</p> <p>Hydrolysis of fats and oils does change the chemical properties of the source material.</p> <p>Fermentation methods: The process for producing organic glycerin by microbial fermentation from carbohydrate substrates begins with organic corn from which cornstarch is isolated. The cornstarch is treated with enzymes to hydrolyze the starch and liberate glucose. The glucose is then fermented with an appropriate microorganism to produce glycerin. The glycerin is purified by passing through ion-exchange columns to remove inorganic elements required for growth of the microorganism and through activated charcoal to remove color and impurities.</p>
3. Is the substance formulated or manufactured by a process that	X			Hydrolysis is the opposite of condensation. A large molecule is split

<p>chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]</p>			<p>into smaller sections by breaking a bond, adding -H to one section and -OH to the other. The products are simpler substances. Since it involves the addition of water, this explains why it is called hydrolysis, meaning splitting by water. A-B + H₂O --> A-H + B-OH (http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)</p> <p>For fermentation method, see above.</p>
<p>4. Is the substance created by naturally occurring biological processes? [§6502(21)]</p>		X	<p>The process of hydrolysis is a naturally occurring process, but this material is manufacturing using high heat and pressure. Incidentally, all (food) digestion reactions are examples of hydrolysis, and the involvement of water is often not appreciated. Generally these reactions are controlled by enzymes such as carbohydrases, proteases, lipases, nucleases, more specific examples of which are fairly well known. (http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)</p> <p>For fermentation, see above.</p>
<p>5. Is there a natural source of the substance? [§ 205.600(b)(1)]</p>		X	
<p>6. Is there an organic substitute? [§205.600(b)(1)]</p>	X		<p>Petitioner claims to have a fully organic version of manufacturing using a fermentation process. See glycerin petition (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924)</p> <p>Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.</p>
<p>7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]</p>	X		<p>Glycerin is used in a wide variety of products including food, cosmetics, industrial and medical. It is a strong humectant. In organic food products it is used to improve texture, increase volume</p>

				and is a major carrier for flavorings and colorings.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]				Alcohols could be used as carriers for flavorings. There are myriad of other materials that could have a similar functional use in other formulations (such as softening and mouth feel in ice cream, keeping baked items soft, etc.) but glycerin is unique in that it can serve in all these functions.
9. Are there any alternative substances? [§6518(m)(6)]	X			Glycerin manufactured from petroleum products, glycerin from saponification of fats and oils and fermentation methods.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X	X		Given the wide use of glycerin, it is likely that there are substitutes for particular uses, but it is unlikely that any one material would work in all the applications where glycerin is used.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

Category 3. Is the substance compatible with organic handling practices? Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			TAP says consistent when used with specific food products
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		Current version on the National List is considered a synthetic; therefore, it would not be compatible with organic handling. According to the petitioner, there is now sufficient capacity for organically produced glycerin to supply the organic market.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]				
4. Are the ancillary substances reviewed compatible with organic handling? [?]			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		One of the uses of glycerin is as a preservative but it has many more uses
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			Glycerin is used as a flavor and/or color carrier, and it is used to improve textures.

NOSB Evaluation Criteria for Substances Added to the National List - Handling

Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, §6518, §6519, §205.2, § 205.105(d), §205.600(c)] **Substance: Glycerin**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			X	Petition is for removal of synthetic glycerin. Petitioner claims there is sufficient quantity of organic glycerin available. Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	See above. Petitioner claims there is sufficient organic glycerin available and the synthetic version is no longer necessary.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?	X			See petition at: http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?	X			When synthetic glycerin was recommended for inclusion on the National List, there was an insufficient supply of organic glycerin. According to the petitioner, that is no longer the case. Per the TR: There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products.
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);	X			
b. Number of suppliers and amount	X			There are currently 21 USDA certified

produced;				organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674)
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;	X			
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or	X			
e. Other issues which may present a challenge to a consistent supply?	X			