United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Lecithin – de-oiled

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
lecithin, deoiled; phosphatidylcholine

Trade Name:
Granulestin; Kelecin; Lecithol; Vitellin

CAS Numbers:
lecithin: 8002-43-5
lecithin, soya: 8030-76-0

Other Codes:
INS number: 322(i)
E number: E322

Summary of Petitioned Use

The National List of Allowed and Prohibited Substances has included lecithin in both unbleached and bleached forms as ingredients in or on processing products since its inception (65 FR 80547). Following petitions in 2008 for each listing, and subsequent National Organic Standards Board (NOSB) recommendations in 2009, bleached lecithin was removed from the National List (USDA AMS, 2012). Unbleached lecithin remained on the list at 7 CFR 205.606 under the modified name: lecithin – de-oiled (USDA AMS, 2012).

Lecithin – de-oiled, is currently on the National List at § 205.606, as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic.”

The most common notation of the substance in industry and academic references is “deoiled lecithin.” This notation will be used throughout this technical report to refer to “lecithin – de-oiled.” Lecithin may be referred to without a deoiled or fluid specification, specifically in instances where the relevant data is not clear about this specification or when discussing the manufacturing processes.

This full scope technical report serves to provide updated information for the NOSB to support the sunset review of “lecithin – de-oiled” listed at § 205.606. This report focuses on uses of deoiled lecithin in organic processing and handling, primarily as a food additive and processing aid.

Characterization of Petitioned Substance

<u>Composition of the Substance:</u>

Lecithin is a complex substance, comprised of the following (Caparosa & Hartel, 2020; Monakhova & Diehl, 2016; Scholfield, 1981):

- Phospholipids: compound lipids that are major components of the cell membrane and assist in the flexible movement of membranes.
- Fatty acids: carboxylic acid-based molecules that are a major component of lipids and are used as fuels and cell structure in living organisms. They may be saturated (having only C-C single bonds) or unsaturated (having one or more C=C double bonds). Double bonds create molecular “kinks” in carbon chains. The quantity of fatty acids varies depending on lecithin type, and the fatty acid content of deoiled lecithin is much lower than that of fluid lecithin.
- Carbohydrates: a category of molecules that includes sugars, starch, and cellulose. These can be categorized further as monosaccharides (one monomeric unit), disaccharides (two monomeric units bonded together), oligosaccharides (several units, but typically less than twelve), and polysaccharides (many units). These compounds are essential energy sources for living organisms and are also utilized as structural components in cells.
- Sterols: unsaturated, steroid alcohols, which are commonly found in lipids.
- A number of minor components, including proteins, vitamin pre-cursors and minerals.

Phospholipids are considered to be the functionally active part of lecithin in processing applications. The specific phospholipids and their quantities vary across lecithin samples, depending on the source of the substance (Caparosa & Hartel, 2020; Scholfield, 1981). Phospholipids, including those found in lecithin, share a common molecular precursor, phosphatidic acid (Caparosa & Hartel, 2020), shown below in *Figure 1*.

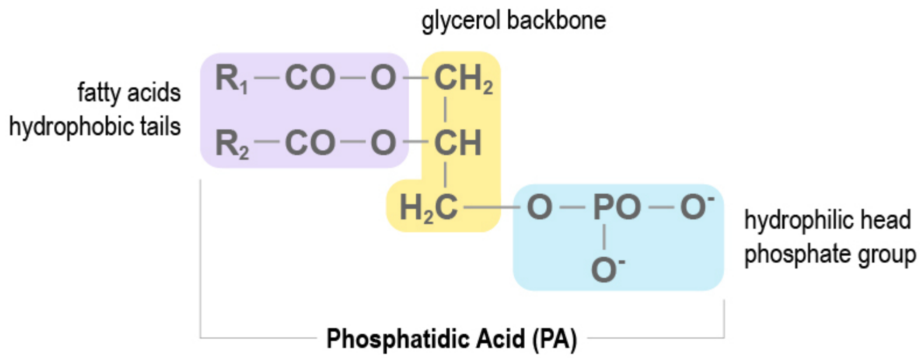

Figure 1: Phosphatidic acid with structural components labeled (adapted from Scholfield, 1981).

All of the phospholipids found in lecithin share a similar molecular structure: hydrophobic fatty acid tails connected to a glycerol backbone, which in turn is attached to a hydrophilic phosphate group (the head) (Scholfield, 1981).

The phospholipid derivatives of phosphatidic acid found in lecithin include:

- phosphatidylcholine (PC)
- phosphatidylethanolamine (PE)
- phosphatidylinositol (PI)
- phosphatidylserine (PS)

The structures of each of these common phospholipids are depicted in *Figure 2* (Caparosa & Hartel, 2020; Scholfield, 1981). Phospholipids all bear a glycerol backbone, however, attached to the phosphate heads are unique functional groups for each compound. The fatty acid tails vary as well, and may be the same fatty acid or different fatty acids within a given phospholipid (Caparosa & Hartel, 2020; Scholfield, 1981).

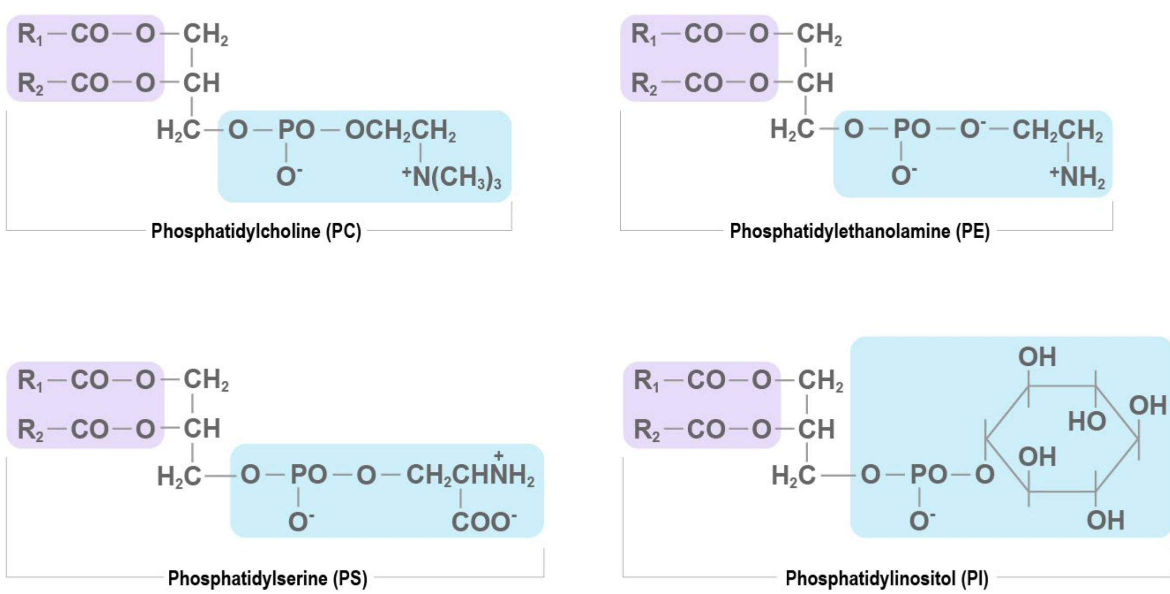

Figure 2: Molecular structures of primary phosphatides found in lecithin.

Of these phospholipids, PC is the most abundant across lecithin sources and is considered the most functionally active (i.e., produces strongest emulsifying effects) phospholipid in lecithin (Caparosa & Hartel, 2020; van Nieuwenhuyzen & Tomás, 2008). Quantities of the other phospholipids vary according to source of the substance, or may be absent altogether (Caparosa & Hartel, 2020; Lončarević et al., 2013; Monakhova & Diehl, 2016). Free fatty acids also vary with lecithin source, however their presence and influence is dramatically reduced in the de-oiling process (Lončarević et al., 2013; van Nieuwenhuyzen & Tomás, 2008).

Oil found in lecithin products can add off-flavors to foods that they are added to (Scholfield, 1981; van Nieuwenhuyzen & Tomás, 2008). Food manufacturers prefer to use deoiled lecithin in certain types of products (such as dry processed products) to avoid this problem. Producers of deoiled lecithin take lecithin-containing crude oil and extract (or expel) it from the source material, which may be soybeans, rapeseed, sunflower seed, eggs, or other lecithin-rich substances. In order to make deoiled lecithin, they then remove oil from the lecithin using acetone or other methods described in *Evaluation Question #1*: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)). (Scholfield, 1981; van Nieuwenhuyzen & Tomás, 2008).

While the de-oiling process removes much of the oil from lecithin, it does not remove all of it. One study compared soy lecithin before and after the de-oiling process (van Nieuwenhuyzen & Tomás, 2008). Researchers found a 56.5% increase in the acetone insoluble content in deoiled lecithin over the standard liquid lecithin. The acetone insoluble fraction includes lecithin's phospholipids, which are the functionally active part of lecithin in food processing applications. This soy-focused study also found a decrease in neutral oil content from 37% in the liquid lecithin product to 3% in the deoiled lecithin product (van Nieuwenhuyzen & Tomás, 2008).

Source or Origin of the Substance:

While lecithin is found in many natural sources, lecithin manufacturers have historically relied on extracting it from soybeans (Sourkes, 2004; van Nieuwenhuyzen & Tomás, 2008). Due to consumer concern about genetic engineering and difficulty with sourcing identity-preserved non-GMO soy lecithin, manufacturers developed alternative lecithin sources (Lončarević et al., 2013).[1] The predominant alternative sources of lecithin include (van Nieuwenhuyzen, 2015):

- egg
- sunflower
- rapeseed

Manufacturers are exploring other sources, including rice and dairy, as alternatives to soybean (Caparosa & Hartel, 2020; Lehri et al., 2019).

The quantity and composition of phospholipids and fatty acids vary between soybean-sourced lecithin and alternative sources of lecithin (van Nieuwenhuyzen & Tomás, 2008). However, this variation does not always diminish the effectiveness of the various lecithin sources (Caparosa & Hartel, 2020; van Nieuwenhuyzen & Tomás, 2008). The lecithin extraction processes for soybean alternatives are at various stages of development. This limitation on processing capacity is the primary obstacle limiting the wide-scale application of dairy-based lecithin, and raises the cost of sunflower and rapeseed lecithins (Caparosa & Hartel, 2020; Lončarević et al., 2013; Monakhova & Diehl, 2016; van Nieuwenhuyzen & Tomás, 2008).

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[1] Identity preservation is "the process of differentiating commodities, requiring that strict separation, which typically involves containerized shipping, be maintained at all times." This process is a way of ensuring that a crop or substance from a specific source is what the buyer purchased and receives (USDA OC, 2015).

Properties of the Substance:

Deoiled lecithin is available as a powdered or granular solid with a range of colors, depending on the source material, drying process, and other manufacturing customizations (see *Table 1*, below). The powder and crystal forms are hygroscopic, and will liquefy in humid conditions (American Lecithin Company, 2022).[2]

Important quality metrics for lecithin include the acetone insoluble matter, acid value, peroxide value, and hydrophilic-lipophilic balance (HLB).

Acetone insoluble (AI) matter describes substances that do not dissolve in acetone. In lecithin, AI matter is an approximate indicator for total content of the functional or nutritional constituents, including phospholipids, glycolipids, and carbohydrates (van Nieuwenhuyzen & Tomás, 2008).

Acid value (AV) measures total acidity imbued by ionizable groups of phospholipids and free fatty acids that are added to some liquid lecithins (American Lecithin Company, 2022).

Peroxide value (PV) reports the degree of a product's degradation, which occurs during soybean storage and processing, as unsaturated fatty acids undergo auto-oxidation to produce free radicals (American Lecithin Company, 2022). PV may be increased by residual hydrogen peroxide, following the bleaching process (van Nieuwenhuyzen, 2015). Low PV is desired for food-grade lecithin, as higher PV values are associated with reduced shelf life and negative sensory qualities (List, 2015).

Hydrophilic-lipophilic balance, or HLB, refers to the water or fat affinity of different lecithin products (American Lecithin Company, 2022). Lower values, which fall below 9 on the HLB scale of 1-18, indicate that a product is more hydrophobic, while higher values indicate a product is more hydrophilic (Griffin, 1949). Deoiled lecithin has an HLB of 7, at the middle of the range, indicating that it is water dispersible and ideal for use as a wetting agent (Griffin, 1949).

Table 1: Properties of deoiled lecithin

Property	Value
Physical Appearance	Available in powder and granule form. Ranges in color from white to light brown to dark yellow.
Molecular Formula (Phosphatidylcholine (1+))	$C_{10}H_{21}NO_8P^+$
Molecular Weight (Phosphatidylcholine (1+))	314.25
Phosphatidylcholine (PC) Content	20-25%
Acetone Insoluble Content	>97%
Acid Value (in meq KOH/kg)	<36%
Moisture Content	<2%
Peroxide Value	<5%
Hydrophilic-Lipophilic Balance	7
Specific Gravity (compared to water at 4°C)	1.03g/mL
Solubility	Soluble in ether, chloroform, and fatty acids. Partially soluble in ethanol, alcohol, and water. Not soluble in acetone of fixed oils.

Sources: (American Lecithin Company, 2022; Clarke, 2007; Möllering & Bergmeyer, 1974; PubChem, 2022d)

Specific Uses of the Substance:

Lecithin has dozens of applications in food, animal feed, pharmaceuticals, cosmetics, industrial products, and soil bioremediation (Monakhova & Diehl, 2016; van Nieuwenhuyzen, 2015). In many of these applications, lecithin is added as an emulsifier and processing aid to improve product textures.

[2] Hygroscopic refers to a substance's tendency to draw moisture in from the air (PubChem, 2022c).

In food specifically, common uses include addition to the following (Monakhova & Diehl, 2016; van Nieuwenhuyzen, 2015):

- margarine
- baked goods
- pan-release sprays
- chocolate
- instant powders
- infant food
- reduced-fat cheeses
- iposome encapsulation

Food processors specifically favor deoiled lecithin in baked goods, instant food and drink powders, infant formula emulsions, and post-harvest treatments (van Nieuwenhuyzen, 2015). In general, deoiled lecithin functions best in oil-in-water emulsions, while standard liquid lecithin is preferred in water-in-oil emulsions (American Lecithin Company, 2022).

Baked goods

Commercial baked goods frequently contain deoiled lecithin as an ingredient, including products such as bread, pretzels, donuts, cookies, and crackers, among others (List, 2015, p. 201; Tebben et al., 2022; van Nieuwenhuyzen & Tomás, 2008).

Bakers use deoiled lecithin to help create larger bread loaves. In one study of wheat-based bread, researchers found that adding deoiled lecithin increased water absorption, stickiness, and extensibility (i.e., stretchiness) (Tebben et al., 2022). The greater extensibility associated with lecithin allowed for higher expansion during the dough-proofing and baking processes, leading to an overall increase in loaf volume by an average of 7% compared to the control (Tebben et al., 2022). Volume increases associated with lecithin application do not appear confined to wheat-based bread. For example, Demirkesen et al. (2010) found that using a formulated lecithin product increased loaf volume in rice flour bread (Demirkesen et al., 2010).

Bakers also use deoiled lecithin to smooth surface textures, add gloss, and improve "processing machinability," or the ability of dough to move through processing equipment (van Nieuwenhuyzen, 2015; van Nieuwenhuyzen & Tomás, 2008). For example, in soft pretzel production, bakers can use 1% deoiled lecithin (by weight of flour) for these purposes. Deoiled lecithin is used at a rate of 0.2-0.5% weight of flour to improve processing machinability in the production of reduced-fat cookies and crackers (List, 2015; van Nieuwenhuyzen, 2015). Several other grain products, such as pizza, pie crusts, tortillas, flatbreads, and noodles, use a 0.2-0.5% weight of flour lecithin rate to improve overall processing machinability (List, 2015).

In donut production, deoiled lecithin is used at a 1-3% weight of shortening rate to improve fat absorption of the dough during frying (van Nieuwenhuyzen, 2015).

Cheese and chocolate

Deoiled lecithin is used in cheeses and chocolate (American Lecithin Company, 2022). For example, researchers found the addition of lecithin (sometimes formulated with tapioca starch) increased the yield of reduced/low-fat cheese (Drake et al., 1999; Sipahioglu et al., 1999). Manufacturers use lecithin to reduce the viscosity of chocolate, which thins the product and makes it more spreadable and malleable (Caparosa & Hartel, 2020).

Instant food and drink powder

Lecithin is utilized in instant food and drink powders, including (List, 2015; Zhu et al., 2021):

- athletic beverages
- meal replacement shakes
- soups
- sauces
- gravies
- high-protein nutrition beverages
- dairy/nondairy beverages
- infant formula

Deoiled lecithin is used in hydrophilic instantizing, because it helps powders disperse in liquids and does not add off-flavors or aromas (List, 2015).[3]

When Hammes et al. (2015) treated powdered buffalo milk with deoiled lecithin, they found that the wetting time for the product was reduced compared to untreated, dried, powdered milk. Drapala et al. (2015) reported similar results following their evaluation of cow's milk-based infant formula. The authors found that deoiled lecithin improved wettability when used at a rate of 1-5% weight of milk (Drapala et al., 2015). Furthermore, lecithin improved heat stability and oxidative stability in dairy protein-based formulas. Due to the increased stability, deoiled lecithin can resolve some formula processing challenges (Drapala et al., 2015).

Egg white protein powder (EWPP) is used as an emulsifier and gelling agent in processed foods; however, it does not rehydrate well, which limits its use in some applications (Zhang et al., 2022). Adding deoiled lecithin to EWPP improves rehydration (Zhang et al., 2022).

Deoiled lecithin is used to produce fruit powders that are added to numerous products such as beverages, ice cream, and baby food (Pua et al., 2007). When added to dried fruit, Pua et al. found that lecithin improved the processing machinability, product uniformity, and product texture of drum-dried jackfruit powder.

Post-harvest treatments

In addition to use as a food additive, researchers have begun exploring the use of deoiled lecithin in post-harvest treatments to improve storage quality and extend shelf life (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017). Studies show that when researchers added an edible coating of lecithin to a variety of produce after harvest, the storage quality improved (Cavusoglu et al., 2021; Jatoi et al., 2017).

Researchers in one study found that applying lecithin to goji berries improved every sensory trait evaluated over 16 days of storage, compared to the control (Jatoi et al., 2017). In bananas, lecithin was tested with another phospholipid, lysophosphatidylethanolamine (LPE) (Ahmed & Palta, 2016).[4] This study demonstrated that lecithin positively impacted banana storage quality and shelf life, both independently and synergistically with LPE (Ahmed & Palta, 2016). In another study, researchers examined the impact of lecithin application on mushroom storage quality. They found that lecithin improved the overall quality through reduced weight loss, improved color, and reduced browning, along with lower respiration rates and ethylene production (Cavusoglu et al., 2021).

[3] Hydrophilicity is the degree to which a substance may be described as water-loving, or the strength of the tendency of a molecule to interact with water (List, 2015). In lecithin, this is measured through the hydrophilic lipophilic balance (HLB) index. A higher HLB value is associated with more hydrophilic forms of lecithin, which are generally used in oil-in-water emulsions (List, 2015).

[4] Lysophosphatidylethanolamine (LPE) is a naturally occurring lysophospholipid, and is a minor component of lecithin. LPE is typically extracted from soy lecithin to obtain a pure form (Ahmed & Palta, 2016).

Approved Legal Uses of the Substance:

FDA
The U.S. Food and Drug Administrations (FDA) lists lecithin at 21 CFR 184.1400 - *Direct Food Substances Affirmed as Generally Recognized as Safe* (GRAS). It is listed as an approved food additive for use in food with no limitation other than current good manufacturing practice.

EPA
The U.S. Environmental Protection Agency (EPA) lists lecithin at 40 CFR 180.950 - *Tolerance exemptions for minimal risk active and inert ingredients*, subsection (e) *Specific chemical substances*. Pursuant to this listing, residues resulting from the use of lecithin (deoiled or fluid) as either an inert or an active ingredient in a pesticide chemical formulation (including antimicrobial pesticide chemicals) are exempted from the requirement of a tolerance, if such use is in accordance with good agricultural or manufacturing practices.

USDA NOP
The U.S. Department of Agriculture, National Organic Program lists "Lecithin – de-oiled" at 7 CFR 205.606 *Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."*

Action of the Substance:

Deoiled lecithin is an emulsifier and wetting agent that is utilized in a number of processing and handling applications, including as:

- a crumb softener and to increase volume in wheat-based and gluten-free breads (Demirkesen et al., 2010; Tebben et al., 2022);
- a dough texturizer and emulsifier in pretzel and donut production (van Nieuwenhuyzen, 2015);
- a processing aid to improve machinability in low-fat flour-based products such as cookies and crackers (List, 2015);
- an emulsifier in instant food and drink powders (Drapala et al., 2015; Hammes et al., 2015; Pua et al., 2007; Zhang et al., 2022);
- a post-harvest treatment to improve storage quality and extend shelf life of various fruits, vegetables, and mushrooms (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017).

General action of substance
Food emulsifiers, such as deoiled lecithin, influence the separation of aqueous solutions and liquid fats or oils (Lončarević et al., 2013). When added to a mixture containing two immiscible (i.e., not mixable) substances, such as oil and water, lecithin increases the adhesion between the two substances (Lončarević et al., 2013; van Nieuwenhuyzen & Szuhaj, 1998). The addition of lecithin allows for the oil and water to form an emulsion, in which the two substances form minute droplets and give the appearance of being thoroughly mixed together (van Nieuwenhuyzen & Szuhaj, 1998). An oil and water mixture may form an emulsion briefly using physical agitation and without the addition of lecithin; however, without a stabilizing agent like lecithin, emulsions are unstable and will separate out into two separate phases (van Nieuwenhuyzen & Szuhaj, 1998).

Without lecithin or another emulsifying agent, a product containing oil and water would separate entirely, stabilizing in a way that minimizes adhesion (van Nieuwenhuyzen & Szuhaj, 1998). For example, this happens when oil is added to vinegar, which is water based, and is left to sit without agitation. If an emulsifier, such as lecithin, is added to vinegar along with oil, the adhesion between the two liquids increases, allowing them to be mixed into a well-dispersed product, such as a salad dressing. The phospholipids in lecithin align along the oil-water boundary, with the hydrophobic, fatty acid tails facing the oil surface and the hydrophilic, phosphoric acid head facing the water surface (Lončarević et al., 2013). This alignment reduces the interfacial tension between the oil and water fractions (i.e., increases adhesion and miscibility of the two substances), allowing for the formation of smaller liquid droplets that may be mixed together (Lončarević et al., 2013; van Nieuwenhuyzen & Szuhaj, 1998; van Nieuwenhuyzen & Tomás, 2008).

Each phospholipid acts differently when used in processed foods or other applications. This is because the alignment of phospholipids along the oil-water boundary varies according to phospholipid type (see *Figure 3*) (Scholfield, 1981; van Nieuwenhuyzen, 2015). In order to achieve desired products, the various phospholipids may be used together or alone (if isolated from lecithin's other components) (van Nieuwenhuyzen & Szuhaj, 1998; van Nieuwenhuyzen & Tomás, 2008).

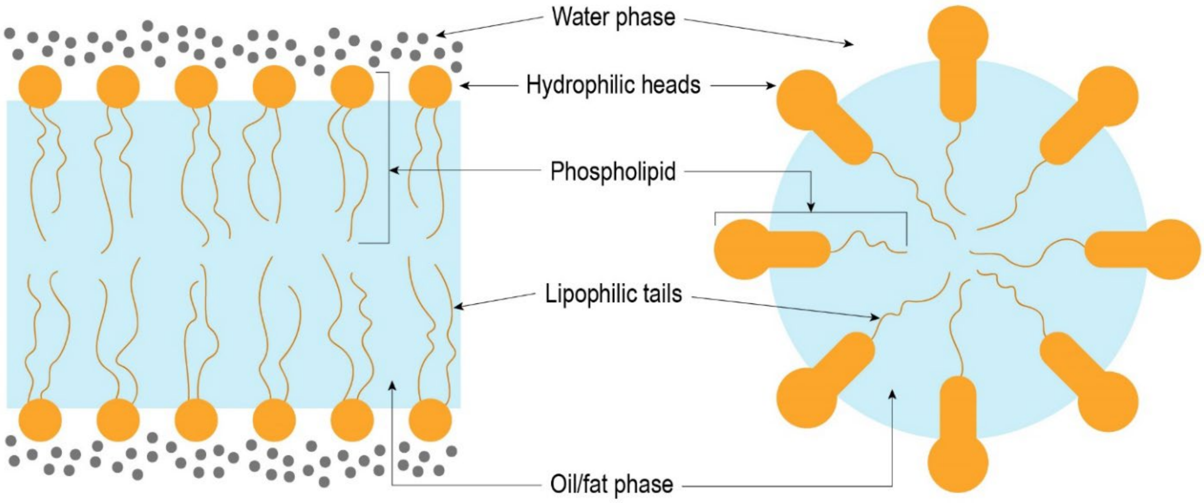

Figure 3: Alignment of lecithin's phospholipid molecules along the oil-water interface. The structure on the left shows the alignment that phosphatidylcholine takes along the oil-water boundary, in a structure called a lamellar layer. The structure on the right shows the alignment of lysophosphatidylcholine around an oil-water interface, where it assumes a structure referred to as a hexagonal phase. Figures modified from van Nieuwenhuyzen, 2015 and van Nieuwenhuyzen & Tomás, 2008.

Specific action of substance

Multiple studies indicate that adding lecithin to bread reduces staling and extends freshness (Helmerich & Koehler, 2005; Tebben et al., 2022; Thangaraju et al., 2020). The underlying mechanism for this has not been fully explored, but Tebben et al. suggest that lecithin interacts with the two components of starch: amylose and amylopectin. Researchers theorize that lecithin complexes with amylose, a component of starch, which prevents the hardening of amylopectin, the other component of starch (Aguirre et al., 2011; Morgan et al., 1997; Tebben et al., 2022).[5] Emulsifiers like lecithin bind to amylose, preventing it from recrystallizing normally (Tebben et al., 2022). This reaction is what researchers hypothesize reduces staleness.

Two studies found that adding lecithin to bread may reduce the surface tension of the gluten network and allow for the formation of a higher quantity and larger size of gas bubbles (Helmerich & Koehler, 2005; Tebben et al., 2022). This alignment increases bread loaf volume. The researchers theorized that the stabilization of more air pockets within the loaf led to increased volume. Both studies state that the stabilization is due to lecithin's phospholipids aligning along the gas bubble and gluten network interface (Helmerich & Koehler, 2005; Tebben et al., 2022).

In addition to aligning between gas bubbles and the gluten network in the dough, lecithin can align between gluten proteins (Thangaraju et al., 2020; van Nieuwenhuyzen, 2015). This lubricates the gluten proteins, improving the elasticity of the dough and reducing dough stickiness. Lecithin is used for this purpose in pretzels and reduced-fat snack foods, leading to improved dough quality (i.e., smooth dough) and machinability (Thangaraju et al., 2020; van Nieuwenhuyzen, 2015).

[5] Starch retrogradation occurs during the cooling and storage period that follows the heating of starch, such as through cooking (Aguirre et al., 2011; Morgan et al., 1997). As the starch molecules cool, they begin to realign themselves into a rigid, crystalline structure that is more similar to their native form (Morgan et al., 1997). This retrogradation correlates to bread hardening, which is associated with staleness (Aguirre et al., 2011; Morgan et al., 1997).

Lecithin improves cheese yields in reduced-fat cheese production through increased moisture retention, as lecithin's phospholipids align between cheese fats and water (Sipahioglu et al., 1999). This alignment allows for the formation of an emulsion, as described in *General action of substance*. The use of lecithin in chocolate appears to reduce the amount of energy required to make solid chocolate flowable, along with reducing the overall viscosity (Caparosa & Hartel, 2020). Researchers suggest this is a result of the emulsifying action of lecithin's phosphatides (Caparosa & Hartel, 2020).

Multiple studies report better wettability of instant powders following lecithin treatment (List, 2015; Zhang et al., 2022; Zhu et al., 2021). Researchers attribute this improvement to the alignment of lecithin along the surface of the milk powder particles, which increases the affinity of the dry powder for water (Drapala et al., 2015; Hammes et al., 2015). Following rewetting, lecithin continues to stabilize the homogenized oil and water fractions in instant food, making it more uniform (Hammes et al., 2015; Zhang et al., 2022).

Ahmed & Palta (2016) suggest that one of lecithin's phospholipids, lysophosphatidylethanolamine, may inhibit phospholipase D. This enzyme is activated during fruit ripening and leads to the degradation of cellular membranes in fruit (Ahmed & Palta, 2016). When exploring this inhibitory effect, Ahmed & Palta (2016) found that lecithin and lecithin-derived phospholipids may be applied to bananas as a post-harvest dip to extend shelf life. Similarly, Cavusoglu et al. (2021) found that applying lecithin as an edible coating on button mushrooms suppressed ethylene production and significantly extended shelf life.

Combinations of the Substance:

Deoiled lecithin includes many major and minor phospholipids, complexed sugars, glycolipids, and a small quantity of residual triglycerides that remain after the deoiling process (American Lecithin Company, 2022).

There are only a few instances in which deoiled lecithin is mixed with non-lecithin substances to create an improved final product (List, 2015).

Silicon dioxide is one such substance. Manufacturers sometimes add silicon dioxide to lecithin products as an anti-caking agent (List, 2015). In addition to its anti-caking functionality, silicon dioxide may be added to lecithin to magnify enzymatic hydrolysis of the phospholipids by phospholipase A (Goerke et al., 1971). Product manufacturers may also add propylene glycol and ethoxylated mono-diglycerides to fluid forms of lecithin (Collins et al., 2018; List, 2015).

Another dry organic lecithin product is comprised of a 50-50 mixture of organic fluid lecithin in an organic rice maltodextrin carrier (List, 2015). However, dry lecithin products have limited availability, as described in *Evaluation Question* #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1))..

Status

Historic Use:

In 1846, Théodore-Nicholas Gobley first isolated the substance known as "lecithin" from egg yolks (Sourkes, 2004). Although derived from the Greek word "lekithos," meaning egg yolk, lecithin is a naturally-occurring substance found in many plant and animal cells (Sourkes, 2004; van Nieuwenhuyzen & Tomás, 2008).

Lecithin began to appear in food processing applications following technological developments in the mid-1920s (List, 2015). It was recovered from oilseed industry waste (List, 2015). It became a well-recognized food additive by 1940 (List, 2015). Lecithin uses expanded into non-food industries by 1950, including the petroleum, textile, cosmetic, and pharmaceutical industries (List, 2015). Food producers continue to use deoiled lecithin as an emulsifier and processing aid, with specific uses in baked goods, instant food and drink powders, and dried infant formula (van Nieuwenhuyzen, 2015).

The National List originally included bleached and unbleached lecithin as food additives in organic processing and handling applications. As discussed in the *Summary of Petitioned Use*, only lecithin – de-oiled remains on the National List at 7 CFR 205.606 (USDA AMS, 2012).

Organic Foods Production Act, USDA Final Rule:

In 1995, lecithin was reviewed for addition to the National List as a food additive for use in processing and handling applications (NOP, 1995). Both bleached and unbleached forms were reviewed. Bleached lecithin was added to the National list at 7 CFR 205.605(b), and unbleached lecithin was added to the National list § 205.606 on December 21, 2000 (USDA AMS, 2000).

Following two petitions in 2008 (one for each listing) and subsequent NOSB recommendations in 2009, bleached lecithin was removed from the National List, while unbleached lecithin remained on the list at § 205.606 under the modified name: lecithin – de-oiled (USDA AMS, 2012).

International

Canada, Canadian General Standards Board – CAN/CGSB-32.311-2020, Organic Production Systems Permitted Substances Lists

Lecithin is listed in the Canadian General Standards Board Organic Production Systems Permitted Substances Lists (CAN/CGSB-32.311 - 2020) in the following locations:

- In Table 6.3, as a food additive. It bears the following origin and use restrictions: *Shall be organic if commercially available. The bleached form is permitted if processed using food-grade hydrogen peroxide.*
- In Tables 6.3 and 6.4, as an ingredient in bakers' yeast.
- In Table 6.5, as a processing aid. It bears the following origin and use restrictions: *Shall be organic if commercially available. The bleached form is permitted if processed using food-grade hydrogen peroxide.*

CODEX Alimentarius Commission – Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Lecithin is listed in the CODEX Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) in the following locations:

- In Table 3.1: *Food additives including carriers*, bearing the restriction that the substance must be "obtained without the use of bleaches and organic solvents."
- In Table 3: *For livestock and bee products*, bearing the specific condition "obtained without the use of bleaches or organic solvents. Milk products/milk based infant food/fat products/mayonnaise."
- In Table 2: *Substances for plant pest and disease control*, as a plant and animal substance allowed for use provided that "need recognized by the certification body or authority."

European Economic Community (EEC) Council Regulation – EC No. 834/2007 and 889/2008, 2018/848, and 2021/1165

The most current EU organic standards, 2018/848, which became enforceable in January 2022, permit lecithin under 2021/1165 Annex V Part A: *Authorised food additives and processing aids*. Lecithin appears in Section A1: *Food Additives, Including Carriers*, for addition to products of plant origin and milk products. Lecithin for these uses must only be derived from substances produced organically.

Japan Agricultural Standard (JAS) for Organic Production

Lecithin is listed in JAS under the Appended Table 1: *Additives*, where it is stated to be "limited to only that which has been produced without the use of bleach processing; also, when used in processed products of livestock origin, limited to the use in dairy products, milk-derived foods for children, edible oils or fats, or dressings."

IFOAM – Organics International
Lecithin is listed in the IFOAM Norms under the Standard for Organic Production and Processing in Appendix 3: Crop Protectants and Growth Regulators as a substance of Plant and Animal Origin. Lecithin is also listed in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids for use as both an additive and a processing/post-harvest handling aid, with the limitation that the substance must be "obtained without bleaches."

Evaluation Questions for Substances to be used in Organic Handling

__Evaluation Question #1:__ **Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).**

Lecithin is a combination of naturally occurring phospholipids, fatty acids, carbohydrates, sterols, and other minor components. It can be isolated from several plant and animal sources (Caparosa & Hartel, 2020; Scholfield, 1981). Commercial production historically relied on soybeans as the primary source of lecithin, primarily as a by-product of soy oil production (van Nieuwenhuyzen, 2015). Some public concern regarding the integrity of non-GMO soybeans drives increasing demand for alternative lecithin sources, which now include rapeseed (or canola), sunflower, and to a lesser degree, eggs (Lončarević et al., 2013; van Nieuwenhuyzen, 2015). The extraction process varies according to the source material (Ceci et al., 2008; List, 2015; Palacios & Wang, 2005).

Seed-derived lecithin manufacturing
As an isolated mixture from seed oil, lecithin yields increase synchronously with oil yields (Demarco & Gibon, 2020). In commercial production, lecithin is extracted at the same time as oil from seeds, such as soy, sunflower, and rapeseed. The manufacturing process for deoiled lecithin from seed sources is shown in *Figure 4*.

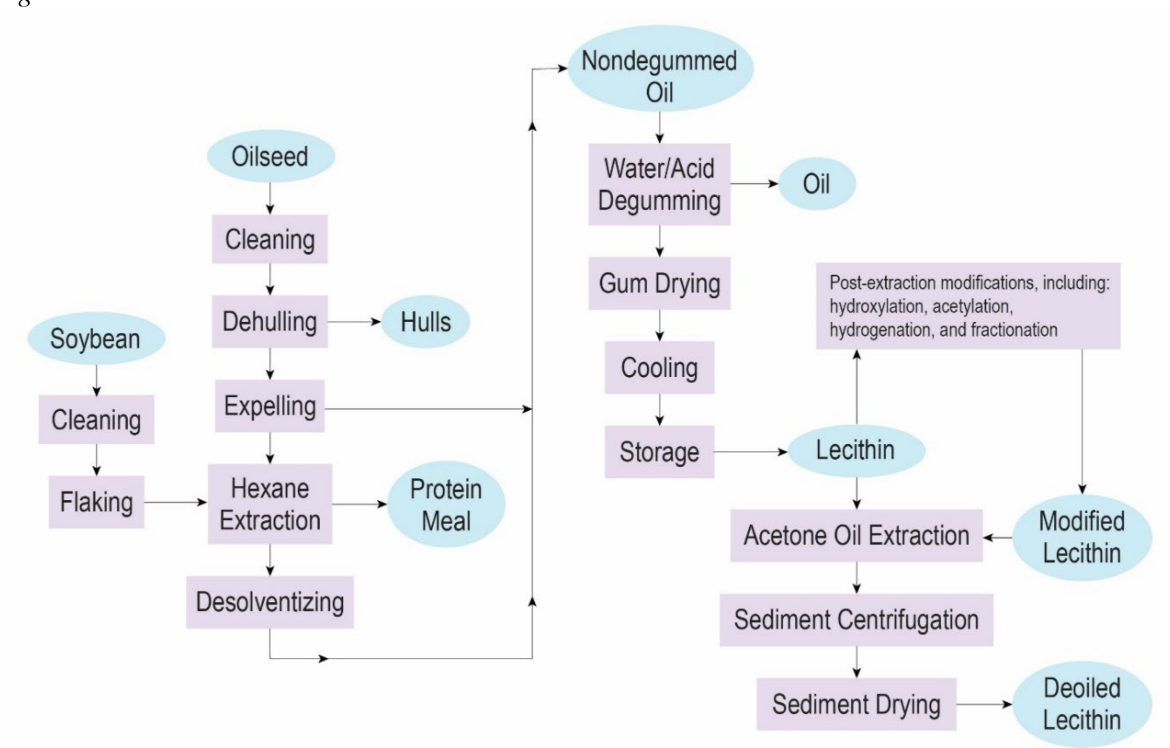

Figure 4: Deoiled lecithin manufacturing process chart for seed sources.

Seed quality is of high importance to the end-product quality. Manufacturers remove soil, split seeds, immature seeds, and hulls before the extraction process (List, 2015; van Nieuwenhuyzen, 2015). To improve oil yields, mechanical pressure is used to flake clean soybeans, increasing the surface area of the seed material exposed to solvents in subsequent steps (Ceci et al., 2008; Demarco & Gibon, 2020; van Nieuwenhuyzen, 2015). In some cases, manufacturers inject steam into the flakes, expanding them and further rupturing the seed's cell walls (Demarco & Gibon, 2020). At this stage, the soy flakes are ready for solvent extraction.

When using seeds other than soy, they are heated and pressed into a seed cake (Demarco & Gibon, 2020; van Nieuwenhuyzen, 2015). The seed cake, typically from seeds with high oil content (e.g., sunflower, rapeseed), may be mechanically pressed to remove the majority of the seed oil before the removal of residual oil from the seed cake through subsequent solvent extraction, reducing the oil content in the seed cake from over 40% to 15-20% by weight (van Nieuwenhuyzen, 2015).

After mechanical processing, manufacturers extract additional oil from flaked soy and pressed seed cakes using hexane. Residual oil quantities in soy flakes or press cakes after hexane extraction are generally around 0.5% by weight (Demarco & Gibon, 2020; van Nieuwenhuyzen, 2015). Extraction efficiency is determined by the following (Demarco & Gibon, 2020; van Nieuwenhuyzen, 2015):

- contact time between the seed material and the solvent.
- the ambient temperature of the extraction process, where higher temperatures (~61-65°C) create favorable conditions for solvent diffusion within the flakes or seed cake.
- flake or cake quality.

The residual seed meal is separated from the oils, and is processed (e.g., removal of hexane) into animal feed (Demarco & Gibon, 2020).

At this stage, lecithin exists within the seed-extracted oil/solvent mixture, also known as the miscella. The miscella undergoes a distillation process to remove the solvent (Demarco & Gibon, 2020). In the distillation process, the miscella is moved into oil-stripping tanks wherein heated steam is used to separate the oil and solvent (Demarco & Gibon, 2020). As steam passes through the miscella, it mixes with the solvent and removes it, leaving the oil and lecithin behind.

Modern oil strippers can produce extracted oil with less than 20 ppm of hexane solvent (Demarco & Gibon, 2020). A closed-loop mineral oil process removes vaporous solvents from the effluent air streams before their release into the atmosphere. The mineral oil process reduces the solvent content of the effluent air to less than 1% by weight (Demarco & Gibon, 2020).

Following the desolventizing process, the crude seed oil is degummed, where the water-soluble components are separated from the oil (Demarco & Gibon, 2020). The gums removed from the crude oil contain lecithin. Lecithin's phospholipids vary in water solubility, with phosphatidylcholine, phosphatidylinositol, and lysophosphatidylethanolamine being easily hydrated, and phosphatidylethanolamine and phosphatidic acid being essentially nonhydratable (Demarco & Gibon, 2020; van Nieuwenhuyzen, 2015). If processors intend to recover the nonhydratable phospholipids from the oil, an enzymatic hydrolysis stage can be used to make the nonhydratable phospholipids hydratable (van Nieuwenhuyzen, 2015). Although lecithin manufacturers may utilize enzymatic processes to improve lecithin yields, water degumming is favored over enzymatic degumming in the United States (Demarco & Gibon, 2020; List, 2015).

The most common removal method for hydratable phospholipids is water degumming, in which 2% (by volume) of water is added to the crude oil at 70-80°C (List, 2015). The mixture is stirred in the tank for 15-30 minutes to allow gums to hydrate and precipitate from the crude oil (List, 2015). A centrifugal separation process removes the light, degummed oil phase from the heavy "wet gum" phase, which is a blend of water, water-soluble components of lecithin, and residual oils (Demarco & Gibon, 2020).

The wet gums are dried using continuous drying film evaporators, which quickly reduce the water content to less than 1% without altering or darkening the lecithin color (List, 2015; van Nieuwenhuyzen, 2015). Manufacturers may use batch dryers, particularly when making bleached lecithin (List, 2015). However, the longer drying time in batch dryers degrades color quality (List, 2015). Dried lecithin may then be fluidized with fatty acids or oils, or proceed to a deoiling step (List, 2015).

Manufacturers remove residual oil from dry lecithin gums when producing deoiled lecithin. It is possible to remove the residual oil via membrane filtration or supercritical carbon dioxide extraction (van Nieuwenhuyzen, 2015; Yip et al., 2008). However, industrial manufacturing of deoiled lecithin currently involves acetone extraction (van Nieuwenhuyzen, 2015). In this process, acetone is added to the dry lecithin gums at a 1-to-1.5 gum-to-solvent ratio, and agitated (van Nieuwenhuyzen, 2015). The nonpolar fats dissolve in the acetone, while the more polar phospholipids and other minor components remain precipitated (van Nieuwenhuyzen, 2015). The sediments containing lecithin are then centrifuged and dried with a vacuum oven at room temperature to remove residual acetone (Ceci et al., 2008; van Nieuwenhuyzen, 2015).

Egg-derived lecithin manufacturing

Egg yolk-derived lecithin is extracted using ethanol on dried yolks followed by an acetone de-oiling process, akin to the acetone de-oiling of seed-derived lecithin (Palacios & Wang, 2005; van Nieuwenhuyzen, 2015). This method produces a phosphatidylcholine-enriched fraction, as well as a lower purity fraction that contains minor phospholipids, lipids, and cholesterol (Gładkowski et al., 2012; Palacios & Wang, 2005). To improve the purity of the non-phosphatidylcholine fraction, manufacturers may incorporate alternative extraction approaches, such as omitting the de-oiling step until after fractionation or implementing multiple wash steps of the non-phosphatidylcholine fraction with cold acetone (Gładkowski et al., 2012).

Alternative lecithin manufacturing

De-oiling lecithin through membrane technology or supercritical CO_2 extraction are possible alternatives to acetone-extraction. If brought to a commercial scale would allow for the more widespread production of organic deoiled lecithin (Demarco & Gibon, 2020; List, 2015; van Nieuwenhuyzen, 2015).

Post-extraction modifications

To produce lecithin with specific qualities, manufacturers can modify lecithin in several ways (see Table 2). Some of these modifications, such as bleaching or hydrogenation, are noted on labels for lecithin products. Other modifications may not be indicated on labels but should be identifiable within manufacturing process information.

Table 2: Post-extraction modifications of deoiled lecithin

Modification	Functionality Goal	Process Description	Sources
Chemical hydroxylation (bleaching)	Increased water solubility; improved oil-in-water emulsifying properties; removal of natural pigments or pigments caused by manufacturing process (i.e., drying)	Hydrogen peroxide and organic acids, commonly lactic acid, are applied to crude lecithin oil to hydroxylate the double bonds in the fatty acid tails of the phospholipid molecules.[6] Lecithin wet gums may be bleached to achieve desired pigmentation, most commonly using hydrogen peroxide as the bleaching agent. Lecithin may be double-bleached to achieve lighter color, by applying benzoyl peroxide to the wet or dried gums.	(List, 2015; van Nieuwenhuyzen , 2015)
Chemical acetylation	Improved oil-in-water emulsifying properties; resistance to browning when heated	Acetic anhydride is applied to dried lecithin where it reacts with the amino group in PE to form acetyl-PE. This process may take place at room temperature, or at 50-60ºC, raising the efficiency of acetylation.	(List, 2015; van Nieuwenhuyzen , 2015)
Enzymatic hydroxylation	Improved oil-in-water emulsifying properties	Phospholipase A_2 or lipase may be used to hydrolyze a fatty acid tail of a phospholipid molecule.[7] This alters the water and/or fat solubility ratios of the phospholipid, leading to the desired changes in the emulsifying properties of the lecithin.	(van Nieuwenhuyzen , 2015)
Enzymatic acetylation	Maximization of lecithin hydrophilicity; improved oil-in-water emulsifying properties	Phospholipidase A_1, lectase, purafine, and lysomax A_1 enzymes, are applied to lecithin, where they react with the phospholipids' fatty acid tails to form lysophosphatides.	(List, 2015)
Hydrogenation	Increased melting points; protection against oxidation (spoilage)	Chemical catalysts, such as palladium, are used to hydrogenate (add hydrogen molecules) to the fatty acid tails of the phospholipid molecules.	(van Nieuwenhuyzen , 2015)
Alcohol Fractionation	Enriched PC content of lecithin blend	Crude lecithin oils are mixed with alcohols, wherein PC dissolves more quickly than other phospholipids Following this extraction process, the alcohols are then evaporated and a PC-enriched lecithin remains.	(van Nieuwenhuyzen , 2015)
Chromatographic Fractionation	Isolation of pure PC	Deoiled lecithin is run through a chromatographic column, containing either aluminum oxide or silica gel adsorbents to remove impurities from the lecithin. This process produces PC-enriched fractions with a purity of up to 70-95%.	(van Nieuwenhuyzen , 2015)

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Deoiled lecithin is a nonsynthetic, agricultural substance, as listed on the National List at 7 CFR 205.606. As noted in *Evaluation Question #1*: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21))., there are a number of steps in the manufacture of deoiled lecithin, involving both chemical and naturally occurring biological processes.

While the manufacture of organic fluid lecithin relies on physical extraction methods, deoiled lecithin is commercially produced using two chemical solvents: hexane and acetone (Demarco & Gibon, 2020; Gładkowski et al., 2012; List, 2015). Other manufacturing steps require physical methods, such as drying at temperatures that do not illicit chemical changes, centrifugation, and physical filtration (Demarco & Gibon, 2020; List, 2015; van Nieuwenhuyzen, 2015).

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[6] Hydroxylation reactions are oxidation reactions wherein carbon-hydrogen (C-H) bonds are oxidized into carbon-hydroxyl (C-OH) bonds (Merriam-Webster, 2022).
[7] Hydrolysis refers to a type of chemical reaction in which a water molecule breaks a chemical bond or bonds, including substitution, elimination, and solvation reactions (Gold, 2019).

The distillation process removes hexane solvent using modern oil strippers, which are capable of producing crude seed oil with less than 20 ppm residual hexane (Demarco & Gibon, 2020). Following distillation, acetone-deoiled lecithin moves into belt dryers or fluid-bed dryers to remove any residual acetone solvent from the deoiled lecithin, preventing the development of off-flavors that would otherwise form (van Nieuwenhuyzen & Tomás, 2008). Though the hexane and acetone extractions both involve the use of chemicals, the removal of these solvents through subsequent evaporation meets the requirements of a nonsynthetic extract described by the NOP Guidance 5033 Classification of Materials (NOP, 2016b).

When evaluating the synthetic/nonsynthetic status of deoiled lecithin with NOP Guidance 5033 Classification of Materials, the substance passes through Box 1 with a status of "Extracted." Box 2b requires an evaluation of the following criteria:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

Provided that the deoiled lecithin product has not undergone any additional modifications that result in chemical change, it passes through Box 2b and Box 2 to a final status of nonsynthetic. If the deoiled lecithin has undergone any of the modifications described in *Table 2*, with the exceptions of alcohol or chromatographic fractionation, it will still pass through Box 2b, but move from Box 2 to Box 3 in order to determine if the chemical change is a result of naturally occurring biological processes. Considering the modifications that result in a chemical, only the enzymatic hydroxylation and enzymatic acetylation result in a final product that is considered nonsynthetic.

Deoiled lecithin may be classified as nonsynthetic according to NOP Guidance 5033 *Classification of Materials* if it is produced with the following methods:

- no additional modifications beyond the standard solvent extractions
- alcohol or chromatographic fractionation
- enzymatic hydroxylation
- enzymatic acetylation

Deoiled lecithin should be classified as synthetic if it is produced with the following methods:

- chemical hydroxylation
- chemical acetylation
- hydrogenation

The agricultural/nonagricultural status of deoiled lecithin must also be evaluated with NOP Guidance 5033-2: Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling (NOP, 2016a).

When evaluating deoiled lecithin for agricultural status, the substance should pass through Boxes 1 and 2 with a response of "No," and Box 3 with a response of "Yes." In Box 4, the use of post-extraction modifications on deoiled lecithin becomes relevant.

Deoiled lecithin may pass through Box 4 with a response of "No" and be classified as agricultural if it is produced with the following methods:

- no additional modifications beyond the standard solvent extractions
- alcohol or chromatographic fractionation

Deoiled lecithin may pass through Box 4 with a response of "Yes" and Box 5 with a response of "Yes" to be classified as agricultural if it is produced with the following methods:

- enzymatic hydroxylation
- enzymatic acetylation

Deoiled lecithin may pass through Box 4 with a response of "Yes" and Box 5 with a response of "No" to be classified as nonagricultural if it is produced with the following methods:

- chemical hydroxylation
- chemical acetylation
- hydrogenation

Deoiled lecithin is only allowed in forms that are classified as nonorganic agricultural ingredients.

Modifications that alter lecithin's structure through chemical processes produce a final product that is nonagricultural and synthetic. These modifications include chemical hydroxylation, chemical acetylation, and hydrogenation. These forms would not be allowed for use in any products labeled "organic" or "made with organic (specified ingredients or food group(s))."

Additionally, some synthetic processing aids may remain in the lecithin following chemical processing. For example, after the chemical hydroxylation of wet gums, hydrogen peroxide bleaching agent may remain in the lecithin after centrifugation and drying. The residual hydrogen peroxide is tracked as the peroxide value (POV) of lecithin (List, 2015; van Nieuwenhuyzen, 2015).

<u>Evaluation Question #3:</u> If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)).

Allowed forms of the material are not synthetic.

The National List includes deoiled lecithin at 7 CFR 205.606, as an allowed substance, provided it is nonsynthetic and agricultural. As discussed above, forms that have undergone chemical modifications are synthetic (nonagricultural) when reviewed to Guidance NOP: 5033-2, and therefore not allowed.

Currently, there are 121 operations that produce or otherwise sell/distribute certified organic lecithin products, according to the Organic Integrity Database (USDA AMS, 2022a). Among these, three operations specifically list organic deoiled lecithin (see *Table 3*, below). In addition to deoiled lecithin, 28 operations separately list organic lecithin powder. Organic lecithin powder is not synonymous with organic deoiled lecithin, and may be referring to either deoiled or dry lecithin products (List, 2015).

Table 3: Organic lecithin products (by country) listed in the Organic Integrity Database (USDA AMS, 2022a).

Operation location	Organic lecithin	Organic deoiled lecithin	Organic lecithin powder
United States	56	2	10
China	29	0	11
India	24	1	4
Other	12	0	3
Total	**121**	**3**	**28**

<u>Evaluation Question #4:</u> Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.

Deoiled lecithin, in both bleached and unbleached form, is considered a GRAS substance per 21 CFR 184.1400 (U.S. FDA, 2022e).

The GRAS listing describes commercial lecithin as a "naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids." The listing mentions soy, safflower, and corn oil and sources of lecithin, but does not mention canola, sunflower, or any animal-derived lecithin sources. Bleached lecithin is specifically noted, with hydrogen peroxide and benzoyl peroxide noted as bleaching agents. There are no limitations on the use of lecithin as an ingredient, provided that it follows good manufacturing practice (U.S. FDA, 2022e).

<u>Evaluation Question #5:</u> **Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR 205.600(b)(4)).**

Food manufacturers use lecithin for multiple purposes, but its primary use is as an emulsifier (JECFA, 2021). Manufacturers also use lecithin as an antioxidant. For example, lecithin is used in post-harvest handling as an edible fruit and vegetable coating (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017).[8]

The antioxidant uses of lecithin are associated with reduced appearance of rancidity or spoilage in food (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017). As noted in *Specific Uses of the Substance*:, lecithin may slow ripening and reduce spoilage in fruit and vegetable crops when used as a post-harvest dip (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017). The ethylene-inhibiting action of lecithin in these applications is not fully understood. However, Ahmed & Palta (2016) and Jatoi (2017) suggest this activity may be attributed to antioxidant function by lecithin.

While the effect of these post-harvest coatings may be "preservative" in character, Franco et al. (2019) describe the food industry distinction between the two as follows: "preservatives are used to avoid rotting while antioxidants are used to prevent the chemical (oxidization) reactions leading to unpleasant taste and/or smell." Per this definition, deoiled lecithin has an antioxidant function but not a preservative function.

<u>Evaluation Question #6</u>: **Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR 205.600(b)(4)).**

Deoiled lecithin is not used to improve flavor, color, or nutritive values. Lecithin is used to improve the texture of food. Food producers also use lecithin to maintain existing flavor and colors.

Deoiled lecithin is frequently used as an emulsifier to improve textures. These textures are not necessarily lost in processing but are novel textures altogether. The mechanism by which lecithin improves texture varies, depending on the example:

- <u>Instant foods (e.g., fruit or milk powders):</u> lecithin improves the texture of both the dried product and the re-wetted dry product compared to products lacking lecithin altogether (Hammes et al., 2015; Pua et al., 2007). Lecithin improves the texture of instant food by aligning along the powdered product's surface, allowing for more rapid and improved rewetting.
- <u>Reduced-fat cheeses and chocolates:</u> lecithin reduces cheese firmness as the protein structures are weakened through greater hydration (Sipahioglu et al., 1999). A similar textural change occurs in chocolate, where lecithin reduces the viscosity of cocoa butter to create a more spreadable final product (Cavusoglu et al., 2021). Lecithin softens the texture of cheese and chocolate by aligning between cheese or chocolate fats and water, creating an emulsion and a softer texture.
- <u>Bread and gluten-free bread:</u> lecithin softens dough, resulting in decreased firmness in gluten-free bread and high loaf springiness in wheat-based bread. Lecithin enacts these textural changes by aligning between gas bubbles and the dough network, allowing for softer and springier bread.

[8] Antioxidants are chemical compounds that may be added to foods or other substances to limit autoxidation, or the process in which substances combine with ambient oxygen (Franco et al., 2019).

Additional details on the specific mechanisms of these textural changes are included in *Action of the Substance*:.

As an edible coating for fresh fruits and vegetables, deoiled lecithin maintains flavor and color of fresh fruits and vegetables that may otherwise be lost through storage and ripening (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017). The precise mechanism for this action remains under exploration, but researchers suggest that lecithin interferes with ethylene-mediated ripening (Ahmed & Palta, 2016; Cavusoglu et al., 2021; Jatoi et al., 2017).

<u>Evaluation Question #7:</u> Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).

As an agricultural product, deoiled lecithin has nutritional value, including macronutrients, vitamin pre-cursors, and minerals. However, the scale of this influence on foods depends on both the manufacturing process for the lecithin and the end use.

The protein content of lecithin varies with source and form, with ranges of (EFSA et al., 2017):

- 115–27,000 mg/kg for crude soya lecithins
- 232–1338 mg/kg for fluid soya lecithin
- 65–480 mg/kg for deoiled soya lecithin
- 49 mg/kg for egg lecithins

However, the actual impact of lecithin-derived protein on the protein content of processed products is insubstantial, given the typical concentrations of lecithin used in foods (Scholfield, 1981). Sipahioglu et al. found that the use of lecithin reduced protein content compared to cheeses made without lecithin in the production of reduced-fat and low-fat cheeses. The researchers report that this reduction is likely a dilution effect that is associated with increased water absorption in lecithin-containing cheeses.

Following lecithin ingestion, the human body metabolizes the phosphatidylcholine fraction of lecithin into choline (EFSA et al., 2017). The quantity of choline that is theoretically released from the phosphatidylcholine fraction of deoiled lecithin ranges from 2.2%-3.6%, depending on the source material. Choline is an important nutrient in the human body, where it supports enzymatic reactions, forms the neurotransmitter acetylcholine, and is a major component of cell membranes (Zeisel et al., 2018). Although the human body naturally generates some choline, it is primarily sourced through food or dietary supplements (Zeisel et al., 2018). Depending on the quantity and dose consumed, lecithin is a good source of dietary choline when used as a food additive (EFSA et al., 2017).

In addition to the direct provision of choline, lecithin improves the digestibility of proteins when added to infant formula (Zhu et al., 2021). Researchers found this effect to be optimized when the lecithin use rate is 5%, as higher concentrations may result in the replacement of protein in the formula by lecithin molecules (Zhu et al., 2021).

<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).

Several heavy metals and contaminants are tracked in lecithin products (EFSA et al., 2017, 2020).

The European Food Safety Authority (EFSA) evaluated contaminants in lecithin products in 2017 using industry-reported data from 2007–2009 (EFSA et al., 2017). They tracked a variety of lecithin product types, including (but not limited to) deoiled lecithin (EFSA et al., 2017). EFSA re-evaluated lecithin in 2020, with a focus on infant food (EFSA et al., 2020). In the 2020 study, part of the range of levels of lead in industry-reported samples exceeded FDA Action Levels, while all other contaminants were below the action level threshold. The range of contaminant levels was derived from a sample pool of more than 100 samples, but the study did not report the proportion of these samples that exceeded FDA Action Levels (EFSA et al., 2020).

The results of these two evaluations are shown in *Table 4*, along with maximum levels permitted by FDA Action Levels, or other related guidance and regulations.

Table 4. Industry-reported ranges and regulatory action levels for common contaminants found in lecithin.

Contaminant	Maximum Quantity per FDA Action Levels, Guidance, or Regulation	Levels Reported in 2007-2009 Industry Data	Levels Reported in 2020 Industry Data	Regulatory Source
Arsenic	0.01-0.4 mg/kg	< 0.1 mg/kg	< 0.1–0.11 mg/kg	(U.S. FDA, 2022a, 2022d)
Lead	0.003-0.05 mg/kg	< 0.1 mg/kg	< 0.05–0.12 mg/kg	(U.S. FDA, 2022a, 2022d)
Mercury	1 mg/kg	< 0.005 mg/kg	0.0017 – < 0.02 mg/kg	(U.S. FDA, 2022a, 2022d)
Cadmium	0.05-0.13 mg/kg	No data	0.01–0.12 mg/kg	(U.S. FDA, 2022a, 2022d)
Residual hexane	< 25 mg/kg	< 1 mg/kg	No data	(U.S. FDA, 2022c)
Residual acetone	< 30 mg/kg	< 2.5 mg/kg	No data	(U.S. FDA, 2022b)
Pesticides, Varies	0.03-3 mg/kg	None detectable	No data	(U.S. FDA, 2022a, 2022d)
Aflatoxins	20 µg/kg	< 0.2 µg/kg	No data	(U.S. FDA, 2022a, 2022d)
Polycyclic aromatic hydrocarbons	No data	0.5 µg/kg-7.8 µg/kg	No data	None
Enterobacteriaceae	No data	negative/1 g	No data	None
Salmonellae	Negative test	negative/25 g	No data	(U.S. FDA, 2022a)

Polycyclic aromatic hydrocarbons, which are not currently subject to FDA regulation, were reported at levels ranging from 0.5 µg/kg-7.8 µg/kg (EFSA et al., 2017, 2020). These industry-reported levels do not exceed levels of concern, according to recommended threshold levels found in the literature (Zelinkova & Wenzl, 2015).

Lecithin source material (i.e., eggs, soy, rapeseed, etc.) has the most significant influence on heavy metal and other contaminant quantities (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2020; van Nieuwenhuyzen, 2015). Van Nieuwnhuyzen (2015) noted that bleaching lecithin with hydrogen peroxide reduces total microbiological counts in lecithin products, but this would result in a synthetic deoiled lecithin product per NOP Guidance 5033 Classification of Materials (NOP, 2016b).

<u>Evaluation Question #9</u>: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Impact of substance manufacturing

As described in *Evaluation Question #1*: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21))., the predominant method for commercial deoiled lecithin manufacture begins with agricultural production of oilseeds, followed by hexane extraction, oil degumming, wet gum drying, dry gum bleaching (optional), acetone extraction of oil, and final drying of deoiled lecithin. The energy consumption and extraction solvents associated with lecithin production pose indirect and direct risks to the environment, respectively.

Solvent extraction is the manufacturing stage in which successive hexane washes pull wet gums from the seed flakes or press cake. Desolventizing is the manufacturing stage in which heated steam removes hexane from the wet gums. Solvent extraction and desolventizing, together, are estimated to be responsible for over 70% of a crushing plant's energy consumption (Demarco & Gibon, 2020). Electricity consumption from the solvent extraction process alone is estimated to be less than 5 kWh/metric ton of initial seed material (Demarco & Gibon, 2020).

The U.S. Energy Information Administration estimates the CO_2 required to produce 1 kWh of electricity to be 0.855 pounds of CO_2, although this number may be as high as 2.44 pounds of CO_2 depending on fuel source (U.S. EIA, 2022). Using industry data from 1994-2010, average annual lecithin production in the U.S. was estimated to be slightly above 98,000 metric tons (List, 2015).[9] Using the lower end of the aforementioned values, a conservative emissions estimate for the annual solvent extraction of lecithin in the Unites States is roughly 72,393 metric tons of CO_2. This is approximately equivalent to the annual emissions of 15,738 passenger vehicles (U.S. EPA, 2016). Due to increasing demand for lecithin, actual current emissions may be higher (Demarco & Gibon, 2020).

Lecithin manufacturers release hexane-containing steam into the air. Following the desolventizing of the wet gums, hexane-containing steam may be stripped of the solvent using a mineral oil system. These systems aim to reduce the residual solvent in the steam to less than 1% by weight and to recycle the hexane back to the crushing facility (Demarco & Gibon, 2020). After the mineral oil stripping, steam is released into the atmosphere, with typical hexane levels of 7-10 grams/m^3. In the absence of mineral oil systems, the released steam may contain hexane at levels of 50-70 grams/m^3. Seed meal, frequently used in animal feed, also contains residual hexane. Hexane levels in the seed meal are less than 250 ppm (Demarco & Gibon, 2020).

Hexane is considered a high-risk substance for chronic toxicity, and a moderate-risk substance for thermal risk, acute toxicity, and ecotoxicity (Cheng et al., 2018). It has been reported as a highly flammable neurotoxin and is of specific concern as an air pollutant (Russin et al., 2011; Toda et al., 2016). In the air, hexane degrades into CO_2 through a reaction with –OH radicals in the ambient atmosphere, with a half-life of 24 hours (PubChem, 2022b).

Hexane is primarily found in the atmosphere, as it does not quickly dissolve in water; however, if hexane does enter aquatic systems it can pose significant risk (PubChem, 2022b). In aquatic systems, hexane is acutely toxic to a number of fish and crustaceans. Additionally, it can reduce the photosynthetic capacity of several green algae species by 50% (PubChem, 2022b).

The production of deoiled lecithin also requires a second solvent extraction process, in which acetone removes residual oil from dried lecithin gums (PubChem, 2022a). Similar to hexane, acetone is a highly flammable solvent. Ecotoxicity studies indicate that high doses (above 5,500mg/L) of acetone in ambient water may lead to the immobilization of crustaceans or the death of fish. Researchers observed no mortality or intoxication associated with the addition of acetone to quail and pheasant diets at high doses, exceeding 40,000 ppm (PubChem, 2022a). The primary source of acetone in waterways is leachate from landfills, and lecithin manufacturing is not expected to be a source of waterway contamination by acetone (Agency for Toxic Substances and Disease Registry, 2022).

Impact of alternative manufacturing processes

Alternative manufacturing methods, such as expeller pressing of oilseeds and membrane filtration for oil removal, may be less harmful to the environment (Demarco & Gibon, 2020). However, these technologies are not currently utilized at large, commercial scale, as expeller pressing is both high-cost and energy-intensive, and membrane filtration has not been brought to scale (Cheng et al., 2018; Demarco & Gibon, 2020; Kumar et al., 2017).

An alternative to the hexane extraction process, enzyme-assisted aqueous extraction (EAEP), has been proposed as a way to reduce the environmental impacts of the seed oil extraction process (Cheng et al., 2018). Despite the absence of the hexane solvent, the EAEP method does not appear to be environmentally favorable at this time, as it demands over 4x the energy (in kWh) and requires the use of sodium hydroxide to alter pH during the extraction process (Cheng et al., 2018).

[9] The annual U.S. lecithin production of 98,000 metric tons is equivalent to roughly 32,666,667 metric tons of raw seed material, based on 0.3% lecithin content by seed weight (List, 2015).

Impact of use

As a naturally occurring substance found in the biological membranes of plants and animals, lecithin's constituents are considered ubiquitous in the environment (van Nieuwenhuyzen, 2015). In our evaluation of the current literature, no data was found to suggest a negative impact on the environment or biodiversity resulting from lecithin's use in food.

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).

Acute and chronic toxicity

Acute toxicity associated with dietary consumption of lecithin by humans is not widely reported.

The maximum exposure level for humans is 199-812 mg/kg body weight, depending on age. Infants from 12 weeks to 11 months consume the most lecithin per body weight, primarily because manufacturers commonly include lecithin in baby formula. Lecithin consumption gradually decreases along the human age gradient, with individuals over the age of 65 consuming the least lecithin by body weight (EFSA et al., 2017).

The only data we found that described the rate of lecithin intake that produced toxic effects was for rodent studies and was not intended for direct comparison to human consumption. In an acute toxicity study in rodents, the LD_{50} following consumption of lecithin ranged from 4,750-16,000 mg/kg body weight (EFSA et al., 2017). The relationship between chronic lecithin consumption by rodents and various toxic effects was explored within the following categories: genotoxicity, developmental toxicity, and neurotoxicity. Long-term consumption of lecithin doses ranging from 1,000-3,750 mg/kg body weight did not produce detrimental changes in any of the toxicity subgroups (EFSA Panel on Food Additives and Flavourings (FAF) et al., 2020).

Allergen risk

The soy-specific immunoglobulin response, indicative of a soy allergy response, may also be triggered through the inhalation of soy lecithins. When inhaled, either in bakeries or manufacturing settings, soy-based lecithins can induce respiratory symptoms, including lecithin-induced asthma (EFSA et al., 2017). Dietary sources of soy lecithin appear to have comparatively low allergenicity, except when lecithin is consumed at higher doses as a dietary supplement (EFSA et al., 2017).

Unlike in soy-based lecithins, heat denaturation and other manufacturing processes do not consistently reduce the allergenicity of egg-based lecithins (EFSA et al., 2017). Egg-based lecithins are more likely than soy-based lecithins to trigger an allergic response through dietary consumption (EFSA et al., 2017).

Sunflower and rapeseed lecithin have a lower risk of allergenic effects than other lecithin sources (List, 2015).

Health benefits

The primary active phospholipid in lecithin, phosphatidylcholine, is rapidly hydrolyzed in the body into free choline by phospholipases (EFSA et al., 2017). As noted in *Evaluation Question #7*, choline is an important nutrient in the human body.

Choline consumption is associated with several health benefits, including:

- supporting neurological function, as observed in aging mice (Xiao et al., 2020);
- reducing cholesterol absorption from food through interference with lipid mobilization (Blesso, 2015; Xiao et al., 2020);
- reducing serum and hepatic lipid levels compared to control groups that received equivalent cholesterol without phospholipids (Blesso, 2015);
- reducing serum and gastrointestinal inflammation (Blesso, 2015);
- inhibiting the development of colitis (Li et al., 2022).

<u>Evaluation Question #11:</u> **Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).**

When used as an emulsifier, deoiled lecithin improves textures to meet consumer preferences, such as softer gluten-free bread (Demirkesen et al., 2010).

For many products, the omission of lecithin is possible, although it may lower a product's end quality. For example, powdered milk products can be produced without the use of deoiled lecithin, if there is strict control of processing parameters, particularly temperature, during the drying stage (Hammes et al., 2015).

Using ultrafiltration before spray-drying milk can improve the physical structure of the powder. This reduces wetting time when end users rehydrate the powdered milk, and makes the powder disperse in a liquid more easily (Jinapong et al., 2008). Ultrafiltration removes some of the sugar molecules from milk, which can cause crystallization and caking within the powder (Jinapong et al., 2008).

Instead of using deoiled lecithin in post-harvest handling dips, vacuum packaging of produce and storage at 9ºC may be sufficient to extend the shelf-life of fresh produce (Othman et al., 2021). In addition to temperature control, controlled atmosphere facilities extend the shelf life of fresh foods by balancing ambient O_2 and CO_2 concentrations to slow ripening (Ahmed & Palta, 2016).

<u>Evaluation Question #12:</u> **Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518(m)(6)).**

Naturally occurring enzymes derived from edible plants or nonpathogenic bacteria and fungi may be alternatives to deoiled lecithin, particularly in processed grain products. One study found that in comparison with soy lecithin, the enzyme transglutaminase improved the elasticity of wheat noodles and their overall eating quality (Niu et al., 2017). Another study found transglutaminase and glucose oxidase produced wheat bread with improved crumb structure and slower staling rate when compared with lecithin-treated or control samples. Researchers also found that bread containing glucose oxidase had nearly equivalent consumer acceptability to lecithin-treated bread, with transglutaminase bread ranking slightly lower (Cao et al., 2021). Both transglutaminase and glucose oxidase can be isolated from sources that are allowed under the USDA organic regulations: bacteria in the case of transglutaminase, and fungi in the case of glucose oxidase (Kieliszek & Misiewicz, 2014; Wong et al., 2008).

Pectin is on the National List at 7 CFR 205.606 as an allowed nonorganically produced agricultural product (USDA AMS, 2022b). Several researchers have explored the use of pectin derived from okra as an alternative substance to lecithin in gluten-free bread, chocolate, and nut milk (Abe-Inge et al., 2020; Datsomor et al., 2019; Tufaro et al., 2022). When added to gluten-free bread, okra pectin improved dough hydration and stability and produced a softer loaf texture (Tufaro et al., 2022). Datsomer et al. (2019) compared okra pectin and lecithin for use as emulsifiers in chocolate formulations. They found that okra pectin produced a similar chocolate quality to lecithin. When added to tigernut milk to reduce separation, okra pectin increased viscosity with no significant differences in sensory properties, aside from a slight reduction in consumer acceptance of the appearance of okra pectin-treated milk (Abe-Inge et al., 2020).

The National List includes several gums at §§ 205.605(a) and 205.606, including tragacanth gum, gum Arabic, guar gum, and carob bean gum, that can be used as replacements for lecithin in some circumstances. These gums are derived from the seeds or sap of several trees and shrub species. In food processing applications, these gums are frequently used as beverage stabilizers (i.e., emulsifiers), fat replacers in dairy products, thickening agents in sauces, and as edible coatings to extend the shelf life of fresh produce and dairy products (Mudgil et al., 2014; Nejatian et al., 2020; Patel & Goyal, 2015). In 2018, a technical report on Gums was published. This report contains detailed information on the manufacturing, use, and environmental impact of each of these gums (NOP, 2018).

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).

Organic deoiled lecithin availability

As noted in *Table 3* (see *Evaluation Question #3*: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1))., above), there are 121 operations with certified organic lecithin on their products lists at the time of this report (USDA AMS, 2022a). *Evaluation Question #3*: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)). discusses the nature of these products in more detail. Organic deoiled lecithin and organic lecithin powder are currently available.

Organic lecithin powder is not synonymous with organic deoiled lecithin and may refer to either deoiled or other dry lecithin products (List, 2015). While dry and deoiled lecithin products may be visually similar, their performance in food processing applications is not the same. Following the removal of oils via acetone extraction, deoiled lecithin has a higher content of acetone insoluble molecules (i.e., phospholipids), and is therefore a more effective emulsifier in instant powders (List, 2015). Furthermore, deoiled lecithin has significantly lower levels of triglycerides than dry lecithin, which reduces the incidence of lecithin transferring unwanted flavors and aromas into food products (List, 2015).

Organic deoiled lecithin alternatives

Eggs are a major source of lecithin. Organic eggs can replace nonorganic eggs in the production of deoiled lecithin (Zhang et al., 2022). Egg white proteins are available in powdered form and are used in emulsification, gelation, and foaming applications (Zhang et al., 2022). Egg yolks have also been used to improve the texture of dried fruit flakes (Pua et al., 2007). Although capable of producing some desired effects in processing, the yolk oil found in eggs alongside natural phospholipids may interfere with product quality when deoiled ingredients are favored (van Nieuwenhuyzen, 2015; Zhang et al., 2022).

In organic chocolate, where lecithin use improves viscosity, equal product quality may be achieved by adding more organic cocoa butter to the product (Caparosa & Hartel, 2020). Higher quantities of cocoa butter decrease chocolate viscosity, as the higher fat content allows particulates to flow more easily. As noted by Caparosa and Hartel (2020), a 5% cocoa butter addition produces a similar textural results in chocolate to the addition of 0.5% lecithin.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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