Identification of Petitioned Substance

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Numbers</th>
<th>Trade Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignosulfonate</td>
<td></td>
<td>SHADOW – LignoTech USA, Inc. (OMRI, 2013)</td>
</tr>
<tr>
<td>Lignosulfuric acid</td>
<td></td>
<td>Orzan – ITT Rayonnier (Sugar and Spotts, 1986)</td>
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<tr>
<td>Lignosulfonic acid</td>
<td></td>
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<tr>
<td>LST 7</td>
<td></td>
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</tr>
<tr>
<td>Ligninsulfonic acid</td>
<td>8061-51-6 (lignin sulfonic acid, sodium salt)</td>
<td></td>
</tr>
<tr>
<td>Poly(lignosulfonic acid)</td>
<td>9009-75-0 (sodium lignosulfonate)</td>
<td></td>
</tr>
<tr>
<td>Protectol W</td>
<td>8061-54-9 (magnesium lignosulfonate)</td>
<td></td>
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<tr>
<td>Sulfite lignin</td>
<td>8061-53-8 (ammonium lignosulfonate)</td>
<td></td>
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<tr>
<td>(NLM, 2013a)</td>
<td>8061-52-7 (calcium lignosulfonate)</td>
<td></td>
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<td></td>
<td>Other Codes:</td>
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<td></td>
<td>705707 (USEPA PC Code [U.S. EPA 2010b])</td>
<td></td>
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<td></td>
<td>160226 (EPA Reference ID)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>705705, 705708–705714 (U.S. EPA PC Code [U.S. EPA, 2010b], various lignosulfonate salts)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1522 (CODEX Alimentarius Commission INS Number, calcium lignosulfonate)</td>
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</table>

Summary of Petitioned Use

The petitioner is requesting the addition of lignin sulfonate, a synthetic substance, to the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) for use as a synthetic substance allowed for use in organic aquatic animal production. Lignin sulfonate currently is allowed for use as a synthetic substance in organic crop production as a plant or soil amendment (chelating agent) and as a dust suppressant (7 CFR 205.601[i][4]), or as a floating agent in postharvest handling (7 CFR 205.601[l][1]).

Characterization of Petitioned Substance

Composition of the Substance:
Lignin is a constituent of woody plants that functions as a strengthening element. Lignin sulfonate is a derivative of lignin, where the lignin has been sulfonated in a wood pulping process (Zhor and Bremner, 1999). Lignin sulfonate has the chemical formula C_{20}H_{26}O_{10}S_{2} (NLM, 2013b) and its structure is presented in Figure 1. However, lignin sulfonate may be composed of a variety of sulfonated aromatic alcohols which make up lignin polymers, including p-coumaryl alcohol, sinapyl alcohol, and coniferyl alcohol (FAO, 2008). The lignin molecule is complex and not well understood in spite of its prevalence (Pure Lignin, 2010). The sulfonate complex may be in association with calcium, magnesium, ammonium, or sodium (U.S. EPA, 2010b).

The National List identifies lignin sulfonate as a synthetic substance allowed for use in organic crop production (7 CFR 205.601). Because the lignin sulfonate molecule is negatively charged, it typically complexes with various cations to form lignin sulfonate salts. Four specific lignin sulfonate salts are included in the Generic Materials.
List published by the Organic Materials Review Institute (OMRI): sodium lignosulfonate, magnesium lignosulfonate, ammonium lignosulfonate, and calcium lignosulfonate (OMRI, 2013). Although these salts are not specifically named on the National List, this Technical Report provides relevant information about them when available.

![Chemical Structure of Lignin Sulfonic Acid](image)

**Figure 1. Chemical Structure of Lignin Sulfonic Acid, CAS 8062-15-5 (NLM, 2013b)**

**Source or Origin of the Substance:**
Lignin exists naturally in all woody plants and is integrated into the plant cell wall, functioning as a structural and strengthening component. Lignin sulfonates are produced from lignin in the process of sulfite chemical pulping. This process involves cooking softwood chips under pressure in sulfur dioxide-containing cooking liquors. Sulfonated lignin is collected as a liquid byproduct in the spent liquor when the pulping process is complete, and the pulp is used for paper production. The lignin sulfonates that result are further purified through fermentation to remove excess sugars, and the resulting liquid is heated to remove alcohol resulting from fermentation (Zhor and Bremner, 1999; Westvaco Corp., 1987; U.S. EPA, 1990; Gundersen and Sjoblom, 1999).

**Properties of the Substance:**
A molecular weight of 490.5 g/mol has been reported for lignin sulfonate (NLM, 2013b). Other reports on the lignin sulfonates as a group state that they may have molecular weights ranging from 1,000 to 20,000 daltons or higher (up to 100,000 daltons in some cases) depending on their composition (Zhor and Bremner, 1999; Hawley, 1981). Weight-average molecular weights of calcium lignosulfonate are reported to range from 40,000 to 65,000 (unitless). Calcium lignosulfonate is soluble in water and insoluble in organic solvents (FAO, 2008).

Other physical and chemical properties of lignin sulfonate are presented in Table 1. The properties presented in Table 1 describe lignin sulfonate generally, unless a specific salt is otherwise indicated.

**Specific Uses of the Substance:**
The specific petitioned use of lignin sulfonate is as an animal feed additive, specifically a non-nutritive feed binder for use in aquaculture. In general, feed binders are added to fish feed pellets or particles to keep the feed whole during transport and handling and to maintain stability of the feed in water prior to consumption by the fish (Gatlin, 2010; Lende, 2013). Lignin sulfonate used as a binder for feed pellets allows for additional steam to be used during the manufacture of wet feed pellets because of its binding capacity and reduces the amount of fine particle debris leaving the pellets (Gatlin, 2010; Lende, 2013). Lignin sulfonate is typically added at 1–2% of the total pellet mass and at levels up to 4% of the dry weight of the pellets (Lende, 2013).
Table 1. Chemical Properties of Lignin Sulfonate

<table>
<thead>
<tr>
<th>Chemical or Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Light tan to dark brown†† (CAMEO, Undated-a; CAMEO, Undated-b)</td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid (powder) (Hawley, 1981)</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless (CAMEO, Undated-a)</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Decomposes at &gt;200°C (&gt;392°F) (Hawley, 1981)</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Exists in a solid state</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water† (FAO, 2008)</td>
</tr>
<tr>
<td>Stability</td>
<td>Soil half-life up to one year depending on chemical species and soil flora† (Selin et al., 1975)</td>
</tr>
<tr>
<td>Reactivity</td>
<td>Lignin sulfonates are corrosive to aluminum and aluminum alloys in the absence of calcium carbonate (CPWA, 2005)</td>
</tr>
<tr>
<td>Oxidizing or Reduction Action</td>
<td>React as acids to neutralize bases. Usually do not react as reducing or oxidizing agents (CAMEO, Undated-a)‡</td>
</tr>
<tr>
<td>Flammability/Flame Extension</td>
<td>Flash point data not available although probably combustible (CAMEO, Undated-a)‡</td>
</tr>
<tr>
<td>Explodability</td>
<td>Dust explosions may occur if fine particles are mixed with air in the presence of an ignition source. Ignition temperature is approximately 250–300°C (482–572°F)† (Georgia-Pacific West, Inc., 2000)</td>
</tr>
</tbody>
</table>

*Sodium lignosulfonate  
†Ammonium lignosulfonate  
‡Calcium lignosulfonate

Lignin sulfonate is used in organic crop production as a plant or soil amendment (dust suppressant, chelating agent) and as a floating agent for postharvest handling of products (e.g., pears). Lignin sulfonate acts as a dust suppressant due to its large size and affinity for binding with other polar and nonpolar compounds. The smaller dust compounds adsorb to the lignin sulfonate and form a larger, heavier complex that is not as friable, which suppresses the dust (CWPA, 2005).

Chelating agents are large, organic molecules that are used to envelop highly-reactive trace metal ions. Lignin sulfonates can be used for the complexation of metal ions for the purpose of environmental remediation of heavy metals. Garcia-Valls et al. (2001) cited the biodegradability and relatively inexpensive nature of the lignin sulfonates as factors supporting their use in remediation. Lignin sulfonates have also been used in bioremediation at dairy operation facilities and meat and seafood canneries. Lignin sulfonates were applied to waste streams at the facilities to help remove dairy and seafood waste. The lignin sulfonates formed complexes with the waste materials, which then precipitated out of wash solutions. This process allowed for diversion of some food waste from waterways. The resulting food waste/lignin sulfonate complex was then used in animal feed (USDA, 1969). Lignin sulfonate is also used as a chelating agent to bind soil amendments (e.g., nutrients such as sulfate, phosphorus, calcium, and nitrogen; and biologically relevant metals including copper, iron, manganese, zinc, and others (7 CFR 205.601(j)(6)) for slow release (USDA, 1969).

When used as a floating agent, lignin sulfonate is added to dump water for fruit processing to increase the density of the water. Dump water is used to fill containers that receive fruit; the fruit is “dumped” into totes containing the water to limit damage during processing. This is necessary for fruits such as pears that may be heavier than water. Increasing the density of the dump water with lignin sulfonate allows the pears to float and, therefore, the pears are less likely to be damaged during processing (Agar and Mitcham, 2000).

Calcium lignosulfonate may be used as an inert ingredient or adjuvant (mixing agent/sticking aid) in pesticide products under 21 CFR §172.715, except for those exempt under Section 25(b) of the Federal...
Insecticide, Fungicide, and Rodenticide Act (FIFRA)\(^1\) (OMRI, 2013). Calcium lignosulfonate is also used as an encapsulating agent or carrier for fat-soluble carotenoids, vitamins, and other functional ingredients in foods such as fruit-based beverages, hard candies, vitamin drinks, and dairy products (Toledo and Kuznesof, 2008). As discussed in the Composition of the Substance section, other lignin sulfonate salts exist (U.S. EPA, 2010b) and are included on the OMRI Generic Materials List (OMRI, 2013), but little specific information is available about them.

**Approved Legal Uses of the Substance:**
Lignin sulfonate is currently included on the National List as a synthetic substance allowed for use in organic production (7 CFR 205.601). Lignin sulfonate may be used in organic crop production as a plant or soil amendment (dust suppressant, chelating agent, or floatation agent) or as a floatation agent in postharvest handling (see 7 CFR 205.601[j][4] and 7 CFR 205.601[l][1]). The OMRI generic materials list includes the following lignin sulfonate salts: sodium lignosulfonate, magnesium lignosulfonate, ammonium lignosulfonate, and calcium lignosulfonate (OMRI, 2013). These lignosulfonate salts are not specifically identified on the National List.

Under 21 CFR 573.600(a) and (b), the FDA Food Additives Permitted in Feed and Drinking Water of Animals, lignin sulfonate (including the ammonium, calcium, magnesium, or sodium salts of lignin sulfonate) may be used in a liquid form (moisture not to exceed 50% by weight) or a dry form (moisture not to exceed 6% by weight) in animal feeds. As specified at 21 CFR 573.600(b), lignin sulfonate may be used in an amount calculated on a dry weight basis:

1. As a pelleting aid in the liquid or dry form in an amount not to exceed 4 percent of the finished pellets.
2. As a binding aid in the liquid form in the flaking of feed grains in an amount not to exceed 4 percent of the flaked grain.
3. As a surfactant in molasses used in feeds, as a liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses.
4. As a source of metabolizable energy, in the liquid or dry form, in an amount not to exceed 4 percent of the finished feed.

Calcium lignosulfonate (CAS No. 8061-52-7) and sodium lignosulfonate (CAS No. 8061-51-6) may be used as inert ingredients in pesticide products. These inert ingredients are on EPA’s former inert ingredients list (List 4B) which, in combination with List 4A, is used as a reference for allowed inert ingredients in organic pesticide products. In 2006, EPA changed its classification system for inert ingredients, but lists 4A and 4B are still referenced by the USDA organic regulations. The NOP still allows inert ingredients on these lists to be used as inert ingredients in pesticide products unless the ingredients were removed following EPA reassessment. Calcium lignosulfonate and sodium lignosulfonate have not been removed from the EPA List 4B and are therefore allowed for use as inert ingredients in pesticide products (USDA, 2009; U.S. EPA, 2010).

According to OMRI, ammonium lignosulfonate is an allowed form of lignin sulfonate, with restrictions, for use as a nutrient chelate in organic fertilizer products. According to OMRI, formulated fertilizer products that contain ammonium lignosulfonate may not make nitrogen claims on the label and/or the contribution of ammonium lignosulfonate to the total nitrogen content of the formulated product must be less than 1% based on 7 CFR 205.601(j)(4), 7 CFR 205.601(l)(1), and OMRI, 2013.

Lignin sulfonate is exempt from the requirement of a tolerance when used as an inert ingredient in pre- and post-harvest agricultural production and as an inert ingredient applied to animals (40 CFR 180.910, 40 CFR 180.930). Tolerances are acceptable levels of pesticide residues on food products that are set by the U.S. EPA and enforced by the USDA and FDA. According to 40 CFR 180.900, “An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw foods...

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\(^1\) FIFRA is the federal law that regulates pesticide products in the United States and is administered by the U.S. EPA.
agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.”

**Action of the Substance:**
Lignin sulfonate and other feed binders are added to feed mixtures to improve the durability and water stability of the feed by binding or sticking the composite feed together (New, 1987). Lignin sulfonate is known to have chelating or sticking properties based on its use as a dust control agent, chelating agent, and mixing agent/sticking aid in pesticide products (OMRI, 2013). To make pelleted fish feed, a finely ground feed mixture containing proteins of various types, carbohydrates, fats, vitamins, and trace minerals is prepared (FAO, 1980). Lignin sulfonate is added to the mixture before the mixture is added to the conditioning chamber and steam is applied (Uniscope, 2007). When the pellet mixture is passed through the conditioning chamber, water is added at a rate of 4–6% by weight, usually as steam, which causes the lignin sulfonate to become soluble and form an adhesive coating (FAO, 1980; Gatlin, 2010; Uniscope, 2007). The steam may also gelatinize existing starches in the feed, which contributes to feed stability (Gatlin, 2010). The feed is compressed by the pellet mill and forced through holes in a ring-type die, and the pressure forces the lignin sulfonate further into the pellet (FAO, 1980; Uniscope, 2007).

**Combinations of the Substance:**
Lignin sulfonate is formulated into feed pellets where it is combined with proteins of various types, carbohydrates, fats, vitamins, and trace minerals. Two of the synthetic substances allowed for use in organic livestock production as identified in 7 CFR 205.603(d) are typically used in fish feed: trace minerals, used for enrichment or fortification when FDA approved; and vitamins, used for enrichment or fortification when FDA approved. Lignin sulfonate sold as a feed binder is not combined with other materials, but is intended for combination with the pellet mixtures (FAO, 1980; Gatlin, 2010).

**Status**

**Historic Use:**
Lignin sulfonate has been used in organic agricultural production as a dust suppressant, chelating agent for micro- and macronutrient fertilizer applications, flotation agent in pear production, and as an emulsifier and stabilizer for pesticide applications. A previous technical report for lignin sulfonate was created as part of the 1995 petition process to add lignin sulfonate to the National List (USDA, 1995). A second technical report was prepared in 2011 for the Sunset Review of lignin sulfonate as an allowed synthetic substance used as a flotation agent, chelating agent, or dust suppressant (USDA, 2011).

Lignin sulfonate has been investigated for its potential as a chelating agent in the environmental remediation of heavy metals and in the remediation of food processing wastes (Garcia-Valls et al., 2001; USDA, 1969). Lignin sulfonate also has been used as an encapsulating agent for vitamins and other ingredients in food products (Toledo and Kuznesof, 2008).

Lignosulfonates have a variety of industrial applications. One of the main applications of lignosulfonates is in the concrete industry, where they may be used as dispersing agents and to delay the setting of concrete. In other industries, they may be used as additives in oil well drilling, dispersants for dyestuffs, cleaning agents, and as a partial substitute for phenol in the manufacture of adhesives. Sodium lignosulfonate is potentially useful in inhibiting corrosion and scale formation in recirculating cooling water systems (Ouyang et al., 2006).

**Organic Foods Production Act, USDA Final Rule:**
Lignin sulfonate is included within the scope of the Organic Foods Production Act of 1990 by implied inclusion in the group, “...an active synthetic ingredient in the following categories: copper and sulfur compounds...”

Lignin sulfonate is explicitly identified on the National List in 7 CFR Part 205, as follows:

- 205.601(j)(4) – Lignin sulfonate—chelating agent, dust suppressant.
205.601(l) – As floating agents in postharvest handling; (I) Lignin sulfonate

International:

Until 2008, lignin sulfonate was not allowed to be used in the production of certified organic products exported to Japan from the United States. In 2008, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan lifted the ban of lignin sulfonate on organic crops imported to Japan. However, the products containing lignin sulfonate must be accompanied by an export certificate and must be imported by a JAS-certified importer (USDA, 2009).

The International Federation of Organic Agriculture Movements (IFOAM) includes calcium lignosulfonate on its “Indicative List of Substances for Organic Production and Processing.” No other lignin sulfonates are included (IFOAM, 2008). As of 2009, calcium lignosulfonate is allowed by the CODEX Alimentarius Commission as a food additive, and the compound has been assigned INS Number 1522 (Codex Alimentarius Commission, 2010).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inert of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

(A). Lignin sulfonate is listed by inference as part of the group, “copper and sulfur compounds” in the OFPA, Section 2118 (c)(1)(B)(i).

(B). Lignin sulfonate is a synthetic inert ingredient that is not classified by EPA as an inert of toxicological concern. Lignin sulfonate (and the lignosulfonate salts) are exempt from the requirement of a tolerance under 40 CFR parts 180.910 and 180.930.

Evaluation Question #2: 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)).

Lignin sulfonates are produced from the process of sulfite chemical pulping. Sulfite pulping involves cooking softwood chips under pressure in sulfur dioxide-containing cooking liquors. When the cooking process is complete, sulfonated lignin is collected as a liquid byproduct in the spent liquor, while the pulp is used for paper production. The lignin sulfonates that result from the spent liquor of the sulfite pulping process must be further purified to remove excess sugars. This is done by fermentation of the liquor followed by heating to remove the alcohol generated by fermentation. The resulting lignin sulfonate polymers can have high molecular weights ranging from less than 1,000 to more than 100,000 daltons (Zhor and Bremner, 1999; Westvaco Corp., 1987).

Lignin sulfonates may also be obtained from the Kraft pulping process; these are referred to as Kraft lignins. Kraft pulping is similar to sulfite pulping, but involves treating the wood at high temperature and pressure in a water solution containing sodium sulfide and sodium hydroxide. This process dissolves lignin into a soluble salt which dissolves in the pulping liquor. The lignin is removed by precipitation from the liquor using carbon dioxide (CO₂). The Kraft lignins must then be sulfonated after extraction by a
reaction of the material with bisulfate or a sulfite compound (Gundersen and Sjoblom, 1999; U.S. EPA, 1990).

A third pulping process, acid sulfite pulping, is similar to Kraft pulping, but different chemicals are used. Sulfurous acid, used in place of sodium hydroxide, is combined with sodium, magnesium, calcium, or ammonium bisulfite. After the cooking is complete, the pulp is separated from the spent liquor, which may then be treated to obtain various chemical materials (U.S. EPA, 1990).

**Evaluation Question #3:** 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)).

Lignin exists naturally in all woody plants as a structural and strengthening component. Because lignin is integrated into the plant cell wall, there are no natural processes that liberate lignin other than natural decomposition of wood by microorganisms. Lignin sulfonates are produced from the application of pressure and heat to wood in the presence of sulfur dioxide or by the addition of alkali and various acids and sulfates, as described for Evaluation Question #2. This process adds the sulfonate moiety (part of a molecule) to the lignin, thus modifying it chemically, and the sulfonate moiety remains in the finished product. Purification of lignin sulfonate obtained from sulfite pulping is accomplished through fermentation to remove excess sugars. Although fermentation is a natural process, the heating of wood pulp under high pressure with the addition of acids is not a naturally-occurring process (U.S. EPA, 1990; Gundersen and Sjoblom, 1999).

Lignin produced from the Kraft pulping process, as described in the response to Evaluation Question #2, is removed from the pulping liquor using CO₂ and is then sulfonated after extraction. Sulfonation is carried out by reacting lignin with bisulfate or another sulfite compound, which remains as part of the resulting lignin sulfonate product (Gundersen and Sjoblom, 1999; U.S. EPA, 1990). Acid sulfite pulping is similar to Kraft pulping, but sulfurous acid is used in combination with sodium, magnesium, calcium, or ammonium bisulfite, and the product is further treated to yield the remaining lignin sulfonate (U.S. EPA, 1990). These are not naturally-occurring processes, and the materials used in the processes are not naturally occurring. For all processes, the remaining chemical moiety attached to lignin is sulfonate, which does not naturally occur in the lignin of woody plants and is the only material created in processing that remains in the final product.

**Evaluation Question #4:** Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Lignin sulfonates are used to modify feed for aquatic animals that are raised under controlled conditions. These controlled conditions can be generally described as open or closed aquaculture systems. In an open system, fish are raised in netted pens that are in direct hydraulic exchange with surrounding water bodies. Closed aquaculture systems are closed off or away from surface water bodies, at least directly, and utilize water recycling practices (Cottee and Petersan, 2009). Closed systems may be more sensitive to environmental impacts due to their much smaller size, but open systems can have broader to larger scale environmental systems. It is much easier to control the environmental impacts of closed systems compared with open systems, and long-term impacts to open systems may be more difficult to detect.

Lignosulfonates discharged into water bodies from open systems may cause foaming and discoloration. Due to their high biological oxygen demand (BOD) during breakdown in water, lignosulfonates will remove dissolved oxygen from waterways in amounts that may be harmful to aquatic organisms in both open and closed systems (CPWA, 2005). This may be of concern if high amounts of lignin sulfonate are used in feed, or if large amounts of feed go to waste in ponds or tanks used to raise fish. However, the maximum amount of lignin sulfonate typically used in feed is 4% by weight, and 10% of the feed is typically not eaten by the fish (Craig and Helfrich, 2002). For larger aquaculture systems, in which considerable amounts of feed must be distributed in tanks or ponds where fish are raised, this could lead to larger deposits of lignin sulfonate from uneaten feed. Fish waste and waste feed, which also has a high BOD upon decomposition, will be present at much higher levels in aquaculture systems than lignin sulfonate, especially in closed systems. Management of nutrient balances would likely be included in the
regular maintenance of wastewater systems in aquaculture production as required by EPA (U.S. EPA, 2012a; U.S. EPA, 2006). Little additional information is available in the published literature on the degradation pathways for lignosulfonates in water, and no information was found on environmental accumulation or bioaccumulation of lignosulfonates.

The half-life of lignosulfonates in soil, as evidenced by the loss of sulfates or sulfonic acid groups, is up to one year. Soil microorganisms, enzymatic reactions, and ultraviolet (UV) radiation contribute to the breakdown of lignosulfonates. The structure of lignosulfonates may be altered by wood-rotting fungi, with polymerization being the main pathway, based on a decrease in phenolic hydroxyl groups (Selin et al., 1975). Laccase, an enzyme produced by fungi, increased degradation of lignosulfonates to low-molecular weight fractions under laboratory conditions (Cho et al., 2004). In addition to microbial decomposition, enzymatic oxidative reactions contribute to the early breakdown process of lignosulfonates. Light (UV radiation) also hastens the degradation of lignosulfonates by creating radicals capable of degrading the lignosulfonate molecular structure. This breakdown process yields lower molecular weight lignosulfonate fragments and CO₂. The CO₂ may account for 15–20% of the original organic carbon. As lignosulfonates degrade, they become more susceptible to further degradation by microbial populations. Due to the complex and heterogeneous structures of lignosulfonates, the breakdown products are complex and variable (Lauten et al., 2010). Lignin sulfonate is not used as a fuel source when it is broken down by microorganisms, but rather incorporated into biomass through biosynthesis which broadens the scope of potential reaction pathways (Lauten et al., 2010). Given that lignin is a naturally-occurring component of wood, once the sulfonic acid groups have been cleaved, the lignin that remains would likely be broken down in a manner very similar to that of rotting wood.

**Evaluation Question #5:** Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

Lignin sulfonates are soluble in water, and it is likely that long-term addition of feeds containing lignin sulfonate would increase their concentration in a given body of water, particularly in closed systems that are not regulated properly. Lignin sulfonate and its breakdown products have the potential to adversely affect environmental systems in several ways. Lignin sulfonate and its breakdown products may cause acute or chronic toxicity to fish that ingest the feed although toxicity has only been observed at doses much higher than would exist in feed (Weber and Ramesh, 2005, as cited in Munro and Baines, 2009). Decreased dissolved oxygen (as well as decreased pH) may result from lignin sulfonate decomposition in aquatic systems. Lower pH levels can increase the availability of some metals in aquatic systems, leading to higher exposures in fish.

One study on lignosulfonates has shown toxicity to fish. A 48-hour LC₅₀ of 7,300 parts per million (ppm) was observed by Roald (1977) in rainbow trout (*Onchorhynchus mykiss*). As lignosulfonates break down in water, they consume dissolved oxygen in the water due to their high BOD, which may adversely affect aquatic organisms through a decrease in available oxygen for respiration (CPWA, 2005; Jones and Mitchley, 2001). Lignin sulfonates readily dissolve in water (forming acids) and may decrease the pH of waters they contaminate. The severity of this effect will depend on the amount discharged and the characteristics of the receiving water body (CPWA, 2005).

Due to the acidifying potential of lignin sulfonate, large spills of lignin sulfonate in water may decrease pH. If those same bodies of water are contaminated with mercury or other metals, the mercury may be more likely to enter the aquatic food chain (Reddy et al., 1995; USGS, 2009). One study in guppies (*Poecilia reticulata*) showed that while lignosulfonate in aerobic sediments helped to bind mercury and make it less bioavailable, lignosulfonate in anaerobic sediments stimulated the methylation of mercury, a more toxic metabolite of mercury (Gillespie, 1972). Methylation of mercury is also increased by decreasing pH, and pH is lowered when large amounts of lignin sulfonates are in water bodies (CPWA, 2005; Jones and Mitchley, 2001). For these reasons, mercury in waterways used to raise fish may be more likely to be taken up by fish, potentially leading to adverse health effects and human consumption (USGS, 2009). Findings of methyl mercury concentrations in farmed fish are contradictory; some studies have observed no effects.
Sodium lignosulfonate is relatively low in toxicity based on results of tests in laboratory animals, including rats, rabbits, and guinea pigs (Luscombe and Nicholls, 1973; Marcus and Watts, 1974). However, high doses of sodium lignosulfonate have been found to cause adverse health effects in laboratory animals. Rats that were given drinking water containing purified sodium lignosulfonate at a 10 g/100 ml concentration for 16 weeks had skin lesions at the bases of their tails, decreased weight gain, increased leukocyte counts, and increased kidney, spleen, and liver weights (Luscombe and Nicholls, 1973). In a study with guinea pigs and rabbits administered sodium lignosulfonate at a 1% concentration for a two- to six-week period, a high percentage of the animals developed ulcerative colon disease (Marcus and Watts, 1974). A median lethal oral dose of greater than 40 g/kg has been reported for rats (Luscombe and Nicholls, 1973). This dose corresponds to the U.S. EPA Toxicity Category IV for oral exposure (greater than 5000 mg/kg), which is the lowest toxicity category (U.S. EPA, 2007).

Results of a 28-day oral toxicity study in which calcium lignosulfonate was incorporated into the diet of rats at target doses of 0, 500, 1500, or 4000 mg/kg body weight per day showed no observed adverse effects other than chronic inflammation of the rectum at the highest dose level (4000 mg/kg-day). The no-observed-adverse-effect level (NOAEL), the concentration below which no adverse effects were observed, from this study was identified as 1300 and 1350 mg/kg-day for males and females, respectively (Weber and Ramesh, 2005, as cited in Munro and Baines, 2009). By comparison, 4000 mg/kg-day is 4 parts per thousand, or roughly ten times higher than the highest concentration of lignin sulfonate used in fish feed, which is 4 parts per 100, or 4%.

In a 90-day study with Wistar rats dosed with calcium lignosulfonate in the diet at target doses of 0, 500, 1000, and 2000 mg/kg-day, the rats showed no adverse clinical signs or organ weight changes following complete pathological evaluations. Test results for primary immune response in the rats were normal. The only observed adverse effect was a dose-related increase in the incidence of histiocytosis (abnormal increase in the number of immune cells) of the mesenteric lymph nodes in male and female rats, with no observed histiocytosis in other lymph tissues. The Joint FAO/WHO Committee reviewed the finding of histiocytosis and concluded that it does not represent an adverse effect, based on findings with other compounds with similar properties (Munro and Baines, 2009).

No evidence of genotoxicity (the ability of a chemical to damage DNA or other genetic material) was found for calcium lignosulfonate in Salmonella typhimurium and Escherichia coli assays, and in a test for chromosomal aberration in Chinese hamster cells. No developmental effects were found in a study with calcium lignosulfonate and pregnant female Wistar rats. The no-observed-effect level (NOEL) for reproductive effects was identified as 1000 mg/kg-day, the highest dose tested (Thiel et al., 2006b, as cited in Munro and Baines, 2009).

As discussed in a previous technical report on lignin sulfonate (USDA, 2011), the petitioner for lignin sulfonate (Western Chemicals) addressed concerns with dioxin as a contaminant from the process of paper pulping. Dioxin is a highly-toxic contaminant that is considered a likely human carcinogen (U.S. EPA, 2010c). The petitioner noted that dioxins are generally associated with the Kraft pulping process and that dioxins are produced as part of pulp bleaching. The original petitioner for lignin sulfonate for crop production noted that the Georgia-Pacific Corp. generates its lignosulfonates using the bisulfite pulping process (USDA, 2011). The petitioner also explained that the sulfite liquor, which contains the lignosulfonates, is removed from the pulp before the bleaching process; thus, it is not likely that dioxins would be found in the lignosulfonates generated from this process (USDA, 2011). In addition, the petitioner reported that they had analyzed their lignosulfonate products for dioxins and furans and have not detected the contaminants in their lignosulfonate products above the level of detection (USDA, 2011).
Environmental contamination varies by the system before its disposal. (Craig and Helfrich, 2002)

Describe any environmental contamination that could result from the petitioned substance’s manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Environmental concentrations of lignin sulfonate in aquaculture are a function of multiple factors, including feed decomposition, feeding rates, utilization efficiency of feed, water circulation and exchange in a closed or open system, and the fate of lignin sulfonate given local conditions and the management of the system (Craig and Helfrich, 2002; Gatlin, 2010; New, 1987). Additionally, the potential for environmental contamination varies by life cycle scenarios, including manufacture, use, misuse, and disposal (Gatlin, 2010). The potential for contamination will also vary depending on whether a closed or open aquaculture system is used (Coppee and Petersan, 2009).

Manufacture: Spent sulfite liquors from the paper pulping process contain lignin sulfonate. Before the widespread use of lignin sulfonates, these liquors were treated as waste from the sulfate pulping process and discarded or burned for energy recovery. Given that lignin sulfonate is recovered from waste products of the paper pulp industry after manufacture, the likelihood of environmental contamination from its manufacture is reduced. However, there is still the possibility that spills of effluent from paper pulping operations could contribute large amounts of lignin sulfonate to soils, nearby waterways, or environmentally-sensitive areas. The same possibility of spills exists in manufacturing facilities that produce feed pellets for aquatic organisms, where lignin sulfonate may be stored in bulk. As discussed in the responses to Evaluation Questions #4 and #5, large spills of lignin sulfonate could acidify soils or bodies of water, decrease the available oxygen in bodies of water, or make mercury contamination of fish more likely in already contaminated waterways.

Use: Lignin sulfonates used as feed binders will be deposited in water bodies or closed aquaculture systems based on their usage pattern in fish feed. If the lignin sulfonate binder works as petitioned, then the fish feed is unlikely to break down before the fish consume the feed. The maximum concentration of lignin sulfonate in feed is 4% (Lende, 2013) and a maximum of 50% of that amount will likely be available in aquatic systems based on assumptions of the amounts of food eaten and waste produced by fish (Craig and Helfrich, 2002). The primary concerns regarding lignin sulfonates in waterways are their high BOD upon decomposition and potential to acidify the aquatic environment. In closed systems, this change will only have internal effects on the system until the water is disposed. In open systems, lignin sulfonate would be available to circulate through the aquatic ecosystem, broadening the exposure area but decreasing levels through dilution. High BOD leads to removal of dissolved oxygen (DO) from the water (CPWA, 2005). DO is a very important water quality indicator, and low DO levels can trigger stress responses in fish (Francis-Floyd, 2012). In addition a decrease in pH, resulting from lignin sulfonate decomposition, may also cause stress in aquatic organisms and make metals such as mercury more bioavailable (Francis-Floyd, 2012; Gillespie, 1972).

Misuse: Misuse of lignin sulfonate feeds by overfeeding could result in higher loads of the feed and, therefore, larger amounts of lignin sulfonate deposited to bodies of water or tanks and ponds used to raise fish. Dry decomposition of lignin sulfonate can release SO₂, which is an eye and airway irritant although it is unclear if this occurs in aquatic systems (Sullivan and Krieger, 1992; Georgia-Pacific West, Inc., 2000). Excessive amounts of feed containing lignin sulfonate or spills of feed into bodies of water may have the same effects. Dust explosions may occur if finely-divided lignin sulfonate is mixed with air in the presence of an ignition source. Excessive accumulation of dust should be avoided to help prevent explosions (Georgia-Pacific West, Inc., 2000).

Disposal: Water from closed aquaculture systems containing lignin sulfonate may need to be processed in a treatment system before its disposal. Any discharge of solids such as uneaten feed, waste, or animal
remains must be minimized according to EPA aquaculture regulations (U.S. EPA, 2012b). For open systems, wastewater discharge must be limited (U.S. EPA, 2012b). As described in a fruit processing manual where lignin sulfonate is used in the process water, the goal for treatment of these waters before disposal is a reduction in BOD to a level that does not impact aquatic life (McLellan and Padilla-Zakour, 2005). The U.S. EPA has published Aquatic Life Criteria for DO in salt water in coastal areas from Cape Cod, MA to Cape Hatteras, NC (U.S. EPA, 2000). The criteria state that DO cannot be below 5 mg/L for “long periods,” the level at which larval stages of many marine fish and shellfish are harmed (U.S. EPA, 2000). Untreated water could adversely affect aquatic organisms by competing for DO or lowering pH.

Under the Clean Water Act (Section 402), aquaculture projects are required to obtain National Pollutant Discharge Elimination System (NPDES) permits. NPDES permits are used to track and control discharges into navigable waters and are meant to protect the waters’ ability to support aquatic life or permit recreation (U.S. EPA, 2012b). This includes any discharges into a “defined managed water area which uses discharges of pollutants into that designated area for the maintenance or production of harvestable freshwater estuarine or marine plants or animals” (U.S. EPA, 2012a). In addition, any concentrated aquatic animal production facilities, which are considered direct dischargers, require an NPDES permit if they produce more than 9090 kg (about 20,000 lbs.) harvest weight of cold water fish or produce more than 100,000 pounds of warm water fish annually (U.S. EPA, 2012a). The permits must be reviewed to determine whether the discharge may impair the waters’ ability to support aquatic life, and would be denied if they are found to impair aquatic life (U.S. EPA, 2012a).

In the case of spills or accidents involving lignin sulfonate from closed systems, the area should be washed with water to dilute the spill (Georgia-Pacific West, Inc., 2000). To the extent possible, care should be taken to ensure that wastewater with high levels of lignin sulfonate does not flow directly to water bodies from closed systems. For these types of spills, waste disposal methods include customary procedures for industrial waste treatment (Georgia-Pacific West, Inc., 2000). Spills or releases of lignin sulfonate are not subject to the reporting requirements of the Federal Superfund Amendments and Reauthorization Act (SARA) of 1986 (Georgia-Pacific West, Inc., 2000).

Other: Lignin sulfonates have been investigated for their potential role as chelating agents for the complexionation of metal ions, including copper, magnesium, and mercury, for the purpose of environmental remediation. The biodegradability and relatively inexpensive nature of the lignin sulfonates were cited as factors that support their use in remediation (Garcia-Valls et al., 2001).

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

By virtue of their intended use, chemical interactions of lignin sulfonates with other substances such as components of fish feed (proteins, fats, carbohydrates, ash, phosphorous, water, and trace amounts of vitamins and minerals) would be expected (Craig and Helfrich, 2002). Lignin sulfonates are generally nonreactive by nature, as evidenced by their uses in dust suppressants and emulsifiers. When used as emulsifiers, lignin sulfonates keep chemical mixtures dispersed in solution by limiting interaction between the two constituents of the mixture (Gundersen and Sjoblom, 1999). When lignin sulfonates come into contact with small soil particles through their use as dust suppressants or chelating agents, the soil particles are adsorbed to the lignin sulfonate due to the presence of polar and non-polar areas on the surface of the lignin molecule. These interactions do not generally result in chemical change but are mostly limited to a physical binding and adsorption. The exception to this is the observed corrosion of aluminum and its alloys by lignin sulfonates when the material is used as a dust suppressant (CPWA, 2005). Alum (aluminum sulfate) is used in aquaculture applications to clear muddy ponds (Williams, 2000). As shown in road dust applications, mixing the lignin sulfonate with calcium carbonate in slurry neutralizes the acidic lignin sulfonate and decreases the reaction with aluminum (CPWA, 2005). It may be possible to prevent corrosion and acidification of the water with a similar treatment in aquaculture applications although no specific methods were found. Appropriate water testing is urged when using alum in aquaculture to prevent acidification of water (Williams, 2000).
Information on human health effects from chemical interactions with lignin sulfonate was not available. As a chelating agent, lignin sulfonates could serve to reduce environmental health effects and potential toxicity to humans from exposure to the free metal ions (Garcia-Valls et al., 2001). The biodegradability and relatively inexpensive nature of the lignin sulfonates were cited as factors supporting their use in remediation (see Specific Uses and Historic Use sections and the response to Evaluation Question #6).

**Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).**

Aquaculture is performed in either open or closed systems. In open systems, finfish are raised in netted pens that are in direct hydraulic exchange with surrounding water bodies. Open aquaculture systems could also be used for shellfish such as clams, oysters, or shrimp, which may use other methods for exclusion of the farmed fish from the environment. Closed systems are closed off or away from surface water bodies, at least directly, and utilize water recycling practices (Cottee and Petersan, 2009). In both systems, wasted feed and animal wastes are two outputs that may adversely affect the agro-ecosystem although the adverse effects of waste are not all attributable to lignin sulfonate. The majority of waste material from aquaculture waste is not lignin sulfonate based on the fact that the highest concentration in fish feed is 4% by weight. These wastes are rich in nutrients that may affect BOD much more than the lignin sulfate additive.

Open aquaculture systems are more likely than closed systems to affect the environment at large because the water used in those systems is in continuous direct exchange with the surrounding aquatic ecosystem without waste management. However, the impact on farmed fish in open systems may be lessened by dilution with the surrounding water body. There are restrictions in place for open systems, such as the requirement of an NPDES permit for certain operations such as aquaculture projects or concentrated aquatic animal production facilities (U.S. EPA, 2012a). Under the NPDES system, aquaculture projects are defined as open systems that use “discharges of pollutants into that designated area for the maintenance or production of harvestable freshwater estuarine or marine plants or animals” (U.S. EPA, 2012b). Concentrated aquatic animal production facilities meet the following criteria: They produce more than 9,090 kg (about 20,000 lbs.) harvest weight of cold water fish or produce more than 100,000 pounds of warm water fish annually (U.S. EPA, 2012b).

Regardless of the restrictions, impacts from open systems, including discharges of fish waste and feed waste, reduced DO, and decreased pH, may be more difficult to mitigate (Cottee and Petersan, 2009). Sediments high in nutrients resulting from deposition of open system waste may also decrease DO as they decompose and affect aquatic life in areas outside of the farming operation (Kutti et al., 2007). One report found that oxygen consumption in the sediment below a fish farm could be as much as 15 times higher than in natural areas (Iwama, 1991, as cited in Cottee and Petersan, 2009). The DO and pH impacts may be exacerbated by lignin sulfonate breakdown. The impacts from open systems may adversely affect wild fish and the surrounding ecosystems due to nutrient imbalances and the production of large amounts of waste (Cottee and Petersan, 2009). Due to the likely effects on sediments, bottom-feeding fish and benthic (living at the bottom of a water body) organisms in open systems may be most intensely affected, while effects on pelagic (open water) fish and other organisms that live in the water column may be less severe. It is important to note that while adverse effects on aquatic systems may result from aquaculture practices, the total impact on those systems from lignin sulfonate in pelleted fish feed would be relatively small compared with overall waste and feed waste. In addition, the use of lignin sulfonate as a feed pellet binder slows the decomposition of feed and might prevent some waste from entering aquatic ecosystems.

In closed aquaculture systems, animal waste may have an increased impact on the quality of water in the system due to reductions in DO levels, increases in carbon dioxide, and increases in levels of ammonia, nitrate, nitrite, and suspended solids (Cottee and Petersan, 2009). The use of lignin sulfonate in feed in those systems may lead to additional reductions in DO and decreases in pH. Fish respond to low levels of DO and decreased pH with a stress response, which may lead to infections of the blood and other tissues.

According to U.S. EPA guidelines for aquaculture NPDES permits, solid wastes from aquaculture production, including waste feed and fecal matter, are required to be captured from liquid wastewater and disposed (U.S. EPA, 2006). These solids might be disposed on land (e.g., as fertilizer, compost) or in evaporation ponds or reed drying beds (U.S. EPA, 2006). All of these methods aim to limit waste discharge and encourage recycling of nutrients in a manner that limits environmental impacts (U.S. EPA, 2006).

Although it is not likely, if wastewater is not disposed of properly and discharged to soils, it could have adverse effects. When lignin sulfonate decomposes in soil, sulfates, sulfonic acid groups, and CO₂ are liberated (Selin et al., 1975). The breakdown of a large amount of lignin sulfonate in the soil (resulting in the release of additional CO₂) could acidify the soil because CO₂ forms carbonic acid in the presence of water. These changes due to the addition of large amounts lignin sulfonate (which would be unlikely based on the low percentage of lignin sulfonate in fish feed) could adversely affect plants and soil organisms. These effects have not been quantified in the published literature. These impacts would not be of issue if the wastes are disposed of according to U.S. EPA regulations.

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

As discussed in the responses to Evaluation Questions #4 through #8, lignin sulfonates may contaminate waterways through buildup of waste feed over time in open systems or disposal of large amounts of water from closed aquaculture systems. Lignin sulfonates readily dissolve in water (forming acids) and decrease the pH of waters they contaminate. Contamination from improper disposal of aquaculture waste containing lignin sulfonate or accidental spills would lead to decreased DO in the waterways due to the high BOD of aquaculture wastes and lignin sulfonate. As discussed in the response to Evaluation Question #7, lignin sulfonate is a minor component of aquaculture waste but could still lead to decreased DO in aquaculture systems. Decreased DO and lower pH can adversely impact all aquatic life, as evidenced by increased stress responses in fish (CPWA, 2005; Francis-Floyd, 2012). Increased stress responses can lead to higher prevalence of diseases in both the farmed fish and any aquatic organisms in open systems.

The severity of effects on the aquatic environment due to lignin sulfonate in feed will vary depending on the amount discharged and the characteristics of the receiving water body. Lignin sulfonate used in open systems is more likely to adversely impact the environment, while closed systems may be managed in a way that limits environmental impacts. Certainly, the adverse impacts of aquaculture will exist regardless of whether lignin sulfonate is used as a pellet binder in aquatic feeds. The low concentration (4%) of lignin sulfonate in feed indicates that it will play a minor role in the overall environmental impact of aquaculture waste. Although it is likely low, the precise environmental impact of lignin sulfonate used in aquaculture has not been studied and is as yet unknown for both open and closed systems.

Evaluation Question #10: 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)).

No data were found that indicate there would be direct adverse effects on human health from use of lignin sulfonate in the formulation of fish feed. The U.S. EPA issued an exemption from the requirement of a tolerance for lignin sulfonates when they are used as inert ingredients pre- and post-harvest in agricultural production under 40 CFR 180.910. This exemption is based on the conclusion that there is a "...reasonable certainty that no harm will result..." to the general public, infants, and children from aggregate exposures (includes all dietary, drinking water, and nonoccupational exposures) to lignosulfonates, as defined by the
Federal Food, Drug, and Cosmetic Act (FFDCA) and the Food Quality Protection Act of 1996 (FQPA) (U.S. EPA, 2011b). Although this is not a guideline based on aquaculture use, the “incorporation” of lignin sulfonate into fish that will become food likely retains a low level of concern. There is no published evidence of lignin sulfonate accumulating in fish that are fed pellets containing lignin sulfonate.

**Evaluation Question #11:** Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (I) (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)).

Many substances are used as feed binders for increasing water stability of aquaculture feeds (New, 1987). Substances used to make feed more stable include: casein, gelatin, collagen, chitosan, guar gum, locust bean gum, agar, carrageenan, corn starch, tapioca starch, wheat gluten, sodium alginate, hemicellulose, bentonite, banana waste, and (New, 1987). Chitosan, carageenan, and collagen have been evaluated as feed binders but are not commonly used (Lende, 2013). Some of the substances listed above may be available in organic forms, such as organic corn, tapioca, or potato starch; and some of the compounds listed may be used in organic handling (7 CFR 205.605 and 7 CFR 205.606), such as bentonite, guar and locust bean gum.

The most widely used of these substances as feed binders are starches (corn, tapioca, or potato), bentonite, lignin sulfonate, and hemicellulose (Lende, 2013). Table 2 below shows the water stability of test pellets made with many different types of binders including rice dust, soybean flour, and corn solids in a standard feed formula. In this series of experiments in which a number of binders were tested (FAO, 1980), rice mill dusts (a starch from the milling of rice) had the longest solids retention time (i.e., the duration that feed pellets remain solid before breaking down) of all the binders tested.

<table>
<thead>
<tr>
<th>Test Pellet</th>
<th>Percentage of Solids Retained</th>
</tr>
</thead>
<tbody>
<tr>
<td>5% gelatinized corn solids (dry)</td>
<td>85.0</td>
</tr>
<tr>
<td>5% bentonite</td>
<td>88.6</td>
</tr>
<tr>
<td>Control formula - unground</td>
<td>90.0</td>
</tr>
<tr>
<td>5% guar meal</td>
<td>90.2</td>
</tr>
<tr>
<td>5% gelatinized corn solids - wet</td>
<td>92.0</td>
</tr>
<tr>
<td>Control formula ground through 2 mm screen</td>
<td>93.0</td>
</tr>
<tr>
<td>5% rice mill dust, 75 microns diameter</td>
<td>93.0</td>
</tr>
<tr>
<td>5% soybean flour</td>
<td>94.0</td>
</tr>
<tr>
<td>5% lignin sulfonate</td>
<td>94.0</td>
</tr>
<tr>
<td>5% rice mill dust sifted through 180 microns</td>
<td>96.2</td>
</tr>
<tr>
<td>10% rice mill dust sifted through 180 microns</td>
<td>98.2</td>
</tr>
<tr>
<td>20% rice mill dust sifted through 180 microns</td>
<td>98.5</td>
</tr>
</tbody>
</table>

*Measured as percentage of solids retained on a screen after 10 minutes in quiet water (FAO, 1980). Starches (from wheat, rice, or corn) are used as binders in aquatic feeds that are steam pelleted or extruded, where gelatinization of the starches by water and heat dissolves the starch granules and distributes the gelatinized starch to bind the pellet (Tucker and Robinson, 1990). For pellet feeds, depending on the temperature and pressure under which the pellets are produced, the starch may cause the pellets to float or sink, a characteristic that is set depending on the variety of aquatic livestock being fed (e.g., floating pellets are preferred for salmonids, sinking pellets are better for catfish) (Stickney, 2009). Due to the heat and pressure of the extrusion process, it is usually not necessary to add binders like lignin sulfonate to floating feeds that contain starch because the starch binds the feed sufficiently (Tucker and Robinson, 1990).
Pelletized feeds may require additional non-nutritive binders such as lignin sulfonate, bentonite, or cellulose to provide additional stability and decrease the amount of feed dust (Tucker and Robinson, 1990). Pregelatinized starches have been characterized as relatively expensive (Smiley, 2012), but starches and sugars are noted as some of the most economical sources of energy for fish diets (Craig and Helfrich, 2002).

Bentonite is a type of clay that is added to fish feed and consists mainly of colloidal aluminum silicate with varying amounts of iron, alkalies, and alkaline earths (21 CFR 184.1155[a]; FDA, 1977). Bentonite is added to compressed, dry fish feeds at no more than 2% as a binding agent and lubricant for feed pellet mills (Lende, 2013). Bentonite is naturally occurring and is used in the food industry to clarify liquids and as an ingredient in coatings and adhesives for food packaging (FDA, 1977). Bentonite is considered generally recognized as safe (GRAS) by the U.S. FDA (21 CFR 184.1155[c]). As shown in Table 2, bentonite had the shortest solids retention time with the exception of corn solids (FAO, 1980).

Another alternative to the use of lignin sulfonate in pelleted feeds is hemicellulose. Hemicellulose is a nondigestible starch that is used as a non-nutritive binder in steam pelleted feeds. Hemicellulose extract is allowed for use in animal feed if it meets the following conditions as specified in 21 CFR 573.520:

a) The additive is produced from the aqueous extract obtained by the treatment of wood with water at elevated temperatures (325 degrees-535 degrees F) and pressure (80 to 900 pounds per square inch) and contains primarily pentose and hexose sugars.

b) The additive may be used in a liquid or dry state with the liquid product containing not less than 55 percent carbohydrate and the dry product containing not less than 84 percent carbohydrate.

c) The additive is used as a source of metabolizable energy in animal feed in accordance with good manufacturing and feeding practices.

Table 3 provides a list of selected companies that manufacture feed binders or nonorganic fish feed using alternate binding materials.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Company</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rice starch (premanufactured feed)</td>
<td>Wet Thumb Aquatics</td>
<td>52700 Base St., New Baltimore, MI 48047 <a href="http://www.wetthumbaquatics.com">www.wetthumbaquatics.com</a></td>
</tr>
<tr>
<td>Bentonite (for adding to feed)</td>
<td>Bentonite Performance Minerals, LLC</td>
<td>3000 N. Sam Houston Pkwy. East Houston, TX 77032 <a href="http://www.bentonite.com">www.bentonite.com</a></td>
</tr>
<tr>
<td>Hemicellulose (premanufactured feed)</td>
<td>M-G Feed Inc.</td>
<td>P.O. Box 697 Weimar, TX 78962; m-ginc.com</td>
</tr>
</tbody>
</table>

**Evaluation Question #12:** Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Types of aquatic feed formulations include pellets, crumbles, and finely ground meals, and most contain no more than 10% moisture (Gatlin, 2010). Most diets are sold as dry products although some semi-moist diets are made for early life stages or carnivorous fish (Gatlin, 2010). Moist diets with moisture contents of 35% to 70% will always require a binder, whereas semi-moist feed with 25% to 35% moisture can be made into pellets by selecting feed ingredients that also act as binders, such as certain starches (Halver and Hardy, 2002). The use of starches to bind the pellets is an alternative to non-nutritive binders such as lignin sulfonate, and the types of starches may vary, but include rice, corn, wheat, tapioca, and potato starch (New, 1987). However, if nutritive binders are not included in the feed recipe, then non-nutritive binders must be used (Halver and Hardy, 2002).

Compression pelleting of feeds is the most common type of feed manufacture for sinking pellets, while cooking extrusion is the most common form for floating pellets, and is also very costly (Gatlin, 2010).
compression pelleting, starch gelatinizes during the preconditioning and pelleting processes, which increases cohesion and durability of the pellets, which may preclude the need for additional binders (Gatlin, 2010). However, sometimes a pellet binder is still included to increase the durability of feed pellets (Gatlin, 2010). With the extrusion process, the feed is still heated during preconditioning, but it is then heated to a higher temperature at higher moisture content than with compression pelleting, causing the pellets to expand when they exit the extrusion barrel, reducing their density (Gatlin, 2010).

Water stability of feeds can be improved by using finely ground raw materials as well as die plates that produce smaller pellets (New, 1987). However, these techniques and others aimed at increasing feed water stability may considerably increase the cost of processing the feed (New, 1987). One report suggests that the need for extremely well-bound feed is up to the farmer. If the diet is consumed within a few minutes of feeding or if more frequent feeding can be accommodated, then the need for extremely well-bound feed may be decreased (New, 1987). New techniques are available for formulating feeds—including microbinding, microencapsulation, or microcoating—that may eliminate the need for some types of binders (Lovell, 1998).

References


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