Identification of Petitioned Substance

<table>
<thead>
<tr>
<th>Chemical Names:</th>
<th>Trade Names:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium hydroxide</td>
<td>Commonly sold as a generic commodity and not a brand name product.</td>
</tr>
</tbody>
</table>

Other Name:
Caustic potash, potash lye, potassa, potassium hydrate, and lye (although this usually refers to sodium hydroxide or a combo of both); potasa cáustica (Spanish); potasse caustique (French); kali umhydroxid (German)

CAS Numbers:
1310-58-3

Other Codes:
INS 525; RTECS: TT2100000; EINECS: 215-181-3; UN 1813 (dry), UN1814 (aqueous solution)

Summary of Petitioned Use
Potassium hydroxide (KOH) is currently allowed under the National Organic Program (NOP) regulations for use in in organic handling and processing as a synthetic nonagricultural (nonorganic) substance listed at 7 CFR 205.605(b) for use as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” with the following annotation: “prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.” It is used as a direct food additive, formulation aid, pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent.

Characterization of Petitioned Substance

Composition of the Substance:
Molecular formula: KOH
Elemental composition: K 69.68%, O 28.51%, H 1.80%

Source or Origin of the Substance:
Food grade potassium hydroxide sold in the U.S. is obtained commercially from the electrolysis of potassium chloride (KCl) solution in the presence of a porous diaphragm [21 CFR 184.1631(a)]. The manufacturing process is explained more fully under Evaluation Question #1.

Properties of the Substance:
Potassium hydroxide is a white to slightly yellowish solid that is highly deliquescent (prone to liquification). Commercial sources are marketed in several forms, including pellets, flakes, sticks, lumps and powders. When dissolved in water or alcohol, potassium hydroxide generates heat. When exposed to air, potassium hydroxide rapidly absorbs moisture and carbon dioxide and deliquesces. Potassium hydroxide is highly corrosive; it should be stored in a tight container when not in use, and should not be handled without protective gear.

The physical and chemical properties of potassium hydroxide are summarized in Table 1.
Table 1: Physical and Chemical Properties of Potassium Hydroxide

<table>
<thead>
<tr>
<th>Property</th>
<th>Characteristic / Value</th>
<th>Source(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>KOH</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>56.11</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Percent Composition:</td>
<td>K 69.68%, O 28.51%, H 1.80%</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Physical State at 25°C / 1 Atm.</td>
<td>Liquid</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Color</td>
<td>White to slightly yellow</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
<td>(Royal Society of Chemistry 2015)</td>
</tr>
<tr>
<td>Density / Specific Gravity</td>
<td>0.940-0.950</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Melting Point</td>
<td>250°C</td>
<td>(Schultz et al. 2006)</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>380°C</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in 0.9 part water, about 0.6 part boiling water, 3 parts alcohol, and 2.5 parts glycerol</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>1 mm Hg @ 714°C</td>
<td>(Royal Society of Chemistry 2015)</td>
</tr>
<tr>
<td>pH</td>
<td>13.5</td>
<td>(Merck 2015)</td>
</tr>
<tr>
<td>Corrosion Characteristics</td>
<td>Corrosive to metal and tissue</td>
<td>(Royal Society of Chemistry 2015)</td>
</tr>
</tbody>
</table>

Specific Uses of the Substance:

Uses of potassium hydroxide that are Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration (FDA) include use as a formulation aid, pH control agent, processing aid, stabilizer and thickener [21 CFR 184.1631(b)].

Potassium hydroxide’s main food processing uses include use as a pH adjuster, cleaning agent, stabilizer, thickener, fruit and vegetable peeling agent, and poultry scald agent. It is used in dairy products, baked goods, cocoa, fruits, vegetables, soft drinks and poultry. The main foods processed with potassium hydroxide are chicken, cocoa, coloring agents, ice cream and black olives (Ash and Ash 1995).

Soft soap is manufactured with potassium hydroxide. Caustic potash is used by livestock producers to dehorn calves, dissolve scales and hair in skin scraping, and for wart removal. Industrial applications include electroplating, printing, wood mordant, and to manufacture cleaning agents, including some non-phosphate detergents (Merck 2015).

Approved Legal Uses of the Substance:

Potassium hydroxide is FDA GRAS when used in food with no limitation other than current good manufacturing practice [21 CFR 184.1631(c)]. Approved legal uses are as a formulation aid [21 CFR 170.3(o)(14)]; a pH control agent [21 CFR §170.3(o)(23)]; a processing aid [21 CFR 170.3(o)(24)]; and a stabilizer and thickener [21 CFR 170.3(o)(28)]. Approved legal uses are summarized in Table 2.
Table 2: Approved Food Uses of Potassium Hydroxide (EAFUS 2001; 21 CFR 184.1631; 9 CFR 424.21)

<table>
<thead>
<tr>
<th>Use</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrylate ester copolymer coating</td>
<td>21 CFR 175.210(b)</td>
</tr>
<tr>
<td>Chocolate and cocoa (optional ingredient)</td>
<td>21 CFR 163</td>
</tr>
<tr>
<td>Cacao nibs</td>
<td>21 CFR 163.110(b)(1)</td>
</tr>
<tr>
<td>Breakfast cocoa</td>
<td>21 CFR 163.112(b)(1)</td>
</tr>
<tr>
<td>Chocolate liquor</td>
<td>21 CFR 163.111(b)(1)</td>
</tr>
<tr>
<td>Caramel color</td>
<td>21 CFR 73.85(a)(2)(ii)</td>
</tr>
<tr>
<td>Defoaming agents used in the manufacture of paper and paperboard</td>
<td>21 CFR 176.210</td>
</tr>
<tr>
<td>Formulation aid</td>
<td>21 CFR 170.3(o)(14)</td>
</tr>
<tr>
<td>Paper and paperboard components in contact with dry food</td>
<td>21 CFR 176.180</td>
</tr>
<tr>
<td>pH control agent</td>
<td>21 CFR 170.3(o)(23)</td>
</tr>
<tr>
<td>Polyethylene resins, carboxyl modified</td>
<td>21 CFR 177.1600</td>
</tr>
<tr>
<td>Poultry scald</td>
<td>9 CFR 424.21</td>
</tr>
<tr>
<td>Processing aid</td>
<td>21 CFR 170.3(o)(24)</td>
</tr>
<tr>
<td>Stabilizer and thickener</td>
<td>21 CFR 170.3(o)(28)</td>
</tr>
<tr>
<td>Textiles and textile fibers</td>
<td>21 CFR 177.2800</td>
</tr>
<tr>
<td>Washing or peeling of fruits and vegetables</td>
<td>21 CFR 173.315(a)(1)</td>
</tr>
</tbody>
</table>

Action of the Substance:

Potassium hydroxide is a strong base that forms salts when combined with acids, is caustic to metals and non-metals, and saponifies fatty acids. Potassium hydroxide is highly reactive.

Lye or caustic peeling with potassium or sodium hydroxide is based on the principle that the cell and tissue constituents of the peels have different solubility levels in a base solution. The pectin-forming middle layer of the peel is particularly soluble in a base (Lindsay 1996). Elevated temperatures of 60-82°C (140-180°F) and mild abrasion can accelerate the lye peeling process. Tomatoes that are lye peeled can either be immersed in a lye bath or subjected to a lye spray (Luh and Kean 1988). Peeling tomatoes with potassium hydroxide requires half the amount of caustic compared with sodium hydroxide peeling (Das and Barringer 2006).

Peaches peeled for canning or pickling use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. Because hot water cannot be used for freezing peaches, they require a higher solution — about 10% — and a treatment time of about 4 minutes to be peeled. Lye is removed by thorough washing, and again citric acid is used to neutralize the pH of the fruit (Woodroof 1986).

Potassium hydroxide is also used to make soap from the reaction with potassium salts of fatty acids. The process of making soap is known as ‘saponification.’ Triglycerides derived from vegetable oils and animal fats react with a strong base, such as potassium hydroxide. This reaction breaks the ester bond, which releases the fatty acid salt and glycerol. The process is portrayed by the reaction in Figure 1.
Combinations of the Substance:

Potassium hydroxide is used as an aqueous solution or it can be crystallized as caustic potash. In both cases, water is an ingredient. Carbonates, chlorine and heavy metals are possible contaminants. Commercially available food grade potassium hydroxide is subject to Food Chemicals Codex specifications that limit the contaminants and, if in liquid form, require that the percentage solution in water is specified (Food Chemicals Codex Committee 2011).

Various formulated products used for specific functions may contain potassium hydroxide. It can be used in combination with lauric acid, a fatty acid, in poultry scald water (Hinton and Ingram 2006). Potassium hydroxide is used to make various coloring agents, such as caramel, annatto and turmeric (Ash and Ash 1995; Burdock 1997). Processors will often combine a number of alkali buffering agents to control the speed of reaction (Lindsay 1996). Wetting agents are sometimes combined with lye used for peeling to increase the efficiency and recovery of solids (Woodroof 1986). Various fats and oils are used as sources of fatty acids, which in turn are reacted with potassium hydroxide to manufacture soap (Schumann and Siekmann 2012).

Status

Historic Use:

Historically, potassium hydroxide in the form of lye derived from wood ash has been used to make traditional foods such as brined fish, cured olives, pretzels, hominy grits and Chinese noodles. The first soaps are believed to be made from potassium hydroxide lye using wood ash (Schumann and Siekmann 2012).

Potassium hydroxide was reviewed for inclusion on the National List in 1995. The National Organic Standards Board (NOSB) originally recommended that potassium hydroxide be prohibited for use in lye peeling of fruits and vegetables. That recommendation included an annotation that stated that potassium hydroxide was “prohibited for the lye peeling of fruits and vegetables and where non-synthetic sodium carbonate is an acceptable substitute” (National Organic Standards Board 1995). The first NOP Final Rule carried the annotation “Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables” (USDA Agricultural Marketing Service 2000). Original concerns regarding lye peeling included the environmental effects of the effluent and other waste products, and the perception that mechanical or non-chemical alternatives were available for most fruits and vegetables.

Stone fruits—including peaches, nectarines and apricots—did not appear to have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances. On March 1, 2001, a petitioner requested that the annotation for potassium hydroxide be changed to permit its use in the...
peeling of peaches to produce individually quick frozen (IQF) products (Finn 2001). The NOSB voted in favor of the petitioner’s request in October 2001, recommending that the annotation be changed to add the phrase “except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.” The amendment was finalized by the NOP on November 3, 2003, becoming effective on the following day (USDA Agricultural Marketing Service 2003).

A subsequent petition was received in 2011 to extend this use to include thermally canned peaches (Van Gundy and Montecalvo 2011). On December 2, 2011, the NOSB voted to change the annotation again to remove the phrase “during the Individually Quick Frozen (IQF) production process” (National Organic Standards Board 2011). The NOP codified the annotation change through a final rule published on May 28, 2013, which became effective the following day (USDA Agricultural Marketing Service 2013). This is the current status as of the date of this report.

The NOP recognized in 2005 that personal care products (e.g., soap) made from organically produced agricultural products are covered under the NOP regulations (National Organic Program 2005). That policy was subsequently retained as Policy Memo 11-2 as part of the NOP Handbook (National Organic Program 2011). In 2008, the NOP offered further guidance in the form of a fact sheet on personal care products which states, “If a cosmetic, body care product, or personal care product contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, and labeling standards, it may be eligible to be certified under the NOP regulations” (National Organic Program 2008). The policy memo and fact sheet do not explicitly address saponification or the use of potassium hydroxide. These documents do not specify how potassium hydroxide should be included in the calculation of the percentage of organically produced ingredients of the final product.

**Organic Foods Production Act, USDA Final Rule:**

Potassium hydroxide is allowed in organic processing and handling as a synthetic nonagricultural (nonorganic) substance listed at 7 CFR 205.605(b) for use as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” with the following annotation: “prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.”

**International**

Potassium hydroxide is allowed by most international organic standards for at least some uses.

- **Canada - Canadian General Standards Board Permitted Substances List** – Allowed for pH adjustment only. Prohibited for use in lye peeling of fruits and vegetables (CAN/CGSB 2011 Table 6.6).


- **Japan Agricultural Standard (JAS) for Organic Production** – “Limited to be used for processing sugar as pH adjustment agent” (Japan MAFF 2000).

- **IFOAM – Organics International (IFOAM)** – Not found.
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)).

The FDA specifies that food grade potassium hydroxide is made by the electrolysis of potassium chloride (KCl) and water in the presence of a porous diaphragm [21 CFR 184.1631(a)]. Potassium chloride, also known as muriate of potash, is a naturally occurring mineral, with the main global source being Canada. Most U.S. production occurs in New Mexico and Utah (Jacinski 2015). Potassium chloride is put into aqueous solution and is electrolyzed by various processes. Diaphragm cells will produce a liquor that contains 10–15% by weight of KOH and about 10% KCl (Freilich and Petersen 2014). Most of the KCl crystallizes by evaporation and subsequent cooling during concentration. The concentrated KOH is about a 50% solution with about 0.6% KCl.

The reaction can be characterized as follows:

\[
\text{KCl} + \text{H}_2\text{O} + e^- \rightarrow \text{HCl} + \text{KOH}
\]

Potassium hydroxide is regarded by the chemical industry as a by-product of the process for producing hydrochloric acid (Bommaraju et al. 2000).

Mercury cells are used to produce most of the KOH in the United States for energy conservation and greater purity. This is different from the diaphragm process and is not considered to be food grade. A brine saturated with KCl is fed into the cell at a moderate temperature. Purification is important because the process will lead to a strong evolution of hydrogen in the cathodes (Schultz et al. 2006). After purification, in order to remove assorted metal impurities, the brine is fed into the cells, which operate on direct current (DC) systems. These cells have positive (anode) terminals composed of titanium, and negative (cathode) terminals composed of metallic mercury. The charged potassium in brine has a catalytic reaction with the layers of mercury and the amalgam flows into the denuder. Water is added and reacts with the elemental potassium in the amalgam to form potassium hydroxide and hydrogen. The mercury is stripped and recycled into the cells. The potassium is recovered as a 50% KOH solution. The remaining hydrogen is compressed to liquid hydrogen or is used to produce hydrochloric acid (Freilich and Petersen 2014).

The more traditional approach to manufacturing potassium hydroxide involves the use of wood or other plant ashes soaked in rain or soft water (Addison 2015). Ashes are collected in a wooden or plastic barrel with holes in the bottom. Boiling water without mineral impurities is added to the barrel, and then the contents are saturated with cold water. This saturated solution is then left to steep overnight during which time the cations in solution create lye that consists mostly of potassium hydroxide with some sodium hydroxide. After steeping, the barrel is drained and the lye is collected (Norman 2007). This is the lye traditionally used to make soap, but it does not meet the FDA’s standard of identity for food grade.

A relatively new process, known as the membrane process, results in KOH with lower chloride impurities in the cell liquor and concentrations of KOH of about 40-50% after evaporation (Schultz et al. 2006). The process is similar to the diaphragm process, but relies on the use of a fluorinated cation exchange membrane to reduce the chloride content (Oda et al. 1977).
**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.

Potassium hydroxide is classified as a synthetic, nonagricultural substance at 7 CFR 205.605(b). Food grade potassium hydroxide is manufactured by electrolysis, which is a chemical process.

Potassium chloride and water are not agricultural substances. Potassium chloride is listed at 7 CFR 205.605(b) as a nonsynthetic, nonagricultural substance. It is also considered a salt.

While potassium hydroxide could be produced from the leaching of wood ashes as described in Evaluation Question 1, such a source would not meet FDA’s food grade specifications [21 CFR 184.1631].

**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)).

No nonsynthetic or natural sources are known to exist. Lye can be made from wood or other plant-derived ashes (Addison 2015). However, such a source also involves chemical reactions, and results in lower concentrations of KOH with greater impurities than the processes involving KCl.

**Evaluation Question #4:** 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.

Potassium hydroxide is FDA GRAS [21 CFR 184.1631]. Table 2 lists the FDA approved food uses for potassium hydroxide.

**Evaluation Question #5:** 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)).

The primary function of potassium hydroxide is as a pH adjuster, raising the pH of solutions that are too acidic. Potassium hydroxide in poultry chill water increases the shelf life of broilers and other meat birds by killing various spoilage organisms, particularly when used in combination with lauric acid (Hinton and Ingram 2006). To a limited extent, potassium hydroxide will also act as a preservative in the curing of certain foods, such as olives.

**Evaluation Question #6:** 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)).

Nothing in a review of the scientific or technical literature indicated that potassium hydroxide is used for any of these purposes.

**Evaluation Question #7:** 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)).

Potassium is an essential mineral nutrient (Institute of Medicine 2004). Treatment of certain grains and legumes with KOH can remove tannins that would interfere with nutrient uptake, for example with sorghum (Chavan et al. 1979). KOH increases the solubility of protein in soybeans and is commonly used
as a solvent to determine protein quality and total soluble protein in assays (Parsons et al. 1991; Batal et al. 2000).

Potassium hydroxide can be used as a substitute for the traditional calcium hydroxide (lime water) used to remove the pericarp of corn, a process known as ‘nixtamilization’ (Cortina and Madrazo 1964). Wood ashes were used to make masa from corn in Meso-America (Wacher 2003). Nixtamilization increases the nutritional quality of corn, sorghum and other grains by removing the pericarp or bran, and increasing the digestible or available protein (Mertz 1970; Katz et al. 1974). Nixtamilization is believed to have prevented widespread malnutrition in the pre-Columbian Americas, with the potassium in wood ash leaching playing a regional secondary role to the more widespread practice of treating corn with lime water. Some tribes would use wood ashes in combination with lime water (Katz et al. 1974).

Removal of fruit peels results in nutrient loss, and the less flesh that is removed, the better the nutrient retention. Nutrient loss can also occur from leaching of water soluble constituents or degradation of heat sensitive compounds. Ascorbic acid and thiamin were reduced by 12% as a result of lye peeling, although carotenoids were not reduced. Fruit that is canned without peeling retains more nutrients than peeled canned fruit (Salunkhe et al. 1991). Mechanical peeling, coring and slicing have the least effect on nutrients, but these are not options for soft fruits.

By comparison with peeled canned fruit, frozen fruit does not have significant nutrient loss after peeling (Salunkhe et al. 1991), indicating that the higher levels of lye used in peeling frozen fruit do not reduce nutritional content. Oxygen sensitive nutrients such as vitamin C can decline during storage if the fruit is not properly protected. Fruit maturity is a key factor in the overall quality and levels of nutrients found in fruit. Fruit that is picked earlier for satisfactory texture in freezing may not have as high a content of various nutrients, but other forms of processing such as canning and pureeing will result in a loss of nutrients as well (Eskin 1991).

**Evaluation Question #8:** 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)).

Food grade specifications for the content of potassium hydroxide, including heavy metals and contaminants, are listed in Table 3.

**Table 3: Food grade specification for potassium hydroxide (Food Chemicals Codex Committee 2011)**

<table>
<thead>
<tr>
<th>Identification</th>
<th>Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry caustic potash: 1 g dissolves in mL of water; Potassium hydroxide solution: 1.5 g of potassium hydroxide in 40 mL of recently boiled and cooled water</td>
<td>Not less than 85% and not more than 100.5% of total alkali, calculated as KOH</td>
</tr>
<tr>
<td>Carbonate (as K₂CO₃)</td>
<td>Not more than 3.5%</td>
</tr>
<tr>
<td>Lead (as Pb)</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Mercury (as Hg)</td>
<td>Not more than 0.1 mg/kg</td>
</tr>
<tr>
<td>Insoluble Substances</td>
<td>Sample solution is complete, clear and colorless</td>
</tr>
</tbody>
</table>

**Evaluation Question #9:** 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)).

The amount of fresh water used in the lye peeling process and the release of effluent that increases biological oxygen demand are two key environmental concerns about the lye peeling process (Stone 1974). The release of potassium hydroxide in untreated or improperly treated wastewater will raise the pH and potassium levels of the body of water receiving it.
Lye peeling of tomatoes by industry conventional methods, which would be prohibited under the current NOP regulations, used 9,800 liters of water per metric ton of fruit (Luh and Kean 1988). Once used, the water must be treated and discharged. The EPA has determined that potassium hydroxide is a category 1 water pollutant, and has established a reportable quantity of 1,000 pounds (454 kg) [40 CFR 302.4]. Dry caustic peeling of clingstone peaches can reduce water use by 90% and biological demand of effluent by 60% (Stone 1974).

Soap manufacturing can also threaten environmental health in the immediate vicinity of the soap manufacturing facility (Mustafa and Ahmed 2014). Nutrient loading of potassium may result in algal blooms and eutrophication. Effluents from soap manufacturing include not only excessive lye, which can increase foam, biological oxygen demand (BOD) and total dissolved solids (TDS), but also elevated levels of manganese (Mn), copper (Cu), zinc (Zn), lead (Pb) and cadmium (Cd) (Odoi, Armah, and Luginaah 2011).

Mitigation of the adverse environmental impacts of lye peeling and research on alternatives have become priorities for the food processing industry because of the adverse effects of caustic substances released into the environment (Yaniga 2007; Rock et al. 2012).

**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)).

The corrosive effects from ingestion of potassium hydroxide and other alkali compounds are well known (LSRO 1973). Accidental ingestion may cause irreversible gastro-intestinal damage and death. While less common than sodium hydroxide poisoning, potassium hydroxide can result in comparable injuries and death. Incidents reported of strong alkali or lye poisoning often do not distinguish between sodium or potassium hydroxide. The fatal dose of sodium hydroxide may be less than 10 g for an adult, with 5 g in solution causing serious injury (Willimott and Gosden 1934).

Ingestion of lye inevitably leads to esophagus damage, with over 90% of the cases also involving stomach damage. In a review of 31 cases of human poisonings involving lye, 13% were fatal (Zargar et al. 1992). Prediction and prevention of irreversible organ damage and death after ingestion depend on a number of factors. Death results from shock, perforation of the esophagus, aspiration from the esophagus into the trachea, pneumonitis, inflammation of tissues in the chest, inability to retain water and digest food, or infection (HSDB 2015). Age, body weight, physical condition, and cause of ingestion are all factors in the extent of damage and the probability that ingestion will be fatal. Ingestion of caustic alkalis by children is almost always accidental (Riffat and Cheng 2009), while ingestion by adults is more likely to be a deliberate act of suicide, and therefore is often more serious and more likely to be fatal (Gumaste and Dave 1992; Satar, Topal, and Kozaci 2004; Cheng et al. 2008).

Literature did not indicate that the use of potassium hydroxide in organic food processing would have negative human health effects.

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

Sodium hydroxide is a substitute for many uses of potassium hydroxide. Sodium hydroxide is listed at 7 CFR 205.605(b) with the annotation: prohibited for use in lye peeling of fruits and vegetables. Although sodium hydroxide is less expensive, potassium hydroxide is used in situations where sodium levels need to be restricted (Saltmarsh 2000). Potassium carbonate may also be used for some applications where a strong base is not necessary and natural sodium carbonate is not appropriate.
Mechanical, steam or hand peeling is an alternative to lye peeling. The NOSB considered a petition that explained why mechanical and hand peeling were not practical with peaches prepared for individual quick freezing (IQF) (Finn 2001). The petition to allow potassium hydroxide for use in processing thermally canned peaches claimed that steam peeling resulted in lower quality (Van Gundy and Montecalvo 2011). Electrical current in water with a salt solution using either sodium chloride (NaCl) or potassium chloride (KCl) can reduce the amount of caustic used, but complete elimination of potassium hydroxide is not as efficient (Sastry and Wongsa-Ngasri 2009). Other physical methods that are being explored include infrared, ohmic heating, and physical ultrasonics (Rock et al. 2012; Li et al. 2014). While these are promising alternatives that may address the various problems caused by lye peeling, they are not yet considered commercially viable.

**Evaluation Question #12:** 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)).

For the adjustment of pH, there are some naturally occurring alkali substances, such as sodium carbonate and sodium bicarbonate, which may be alternatives to potassium hydroxide. Both sodium carbonate and sodium bicarbonate are listed at 7 CFR 205.605(a). However, these are less soluble than potassium hydroxide in water and are not always effective in raising the pH.

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

No agricultural product has the same functionality as potassium hydroxide.

**References**


