Potassium Hydroxide
Processing

Executive Summary

Potassium hydroxide was petitioned to the NOSB for a change in the annotation as listed in 7CFR 205.605(b)(27). This currently states that the substance is "prohibited for use in lye peeling of fruits and vegetables." The petitioner requests that this annotation be changed to permit use in the peeling of peaches for use in a process known as individually quick frozen (IQF) product.

The NOSB originally recommended this material be prohibited for this use in 1995. However it is permitted for all other FDA permitted uses, which include as a direct food additive, formulation aid, pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent. Original concerns regarding lye peeling included the environmental effects of the waste products, and that mechanical or non-chemical alternatives were available for most fruits and vegetables. The stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances.

The reviewers agree that the substance as used commercially is synthetic, although one points out that it may also be naturally produced and has had historical food use. Two out of three reviewers agree with the petitioner that that this annotation unfairly restricts certain types of operations, and find the environmental affects can be mitigated with the use of good wastewater management practices. The third reviewer finds that the principle of minimizing the use of synthetics should be considered more fundamental than the need for a particular form of a product, and is concerned about lack of international acceptance of this material. This reviewer also believes that prohibitions on products and processes will drive innovation and invention for the development of alternative techniques.

Identification

Chemical Name: potassium hydroxide

Other Names: caustic potash, potash lye, potassa, potassium hydrate, and lye (although this usually refers to sodium hydroxide or a combo of both)

CAS Number: 1310-58-3

Other Codes: INS 525

This TAP review is based on information available as of the date of this review.

Summary of TAP Reviewer Analysis [1]

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic (3-0)	*Allow (2)*	Used according to FDA regulations (21CFR 173.315) when used for peeling fruits and vegetables. Rinsing is required to remove residues of the lye peeling agent. A certified wastewater disposal (recycling) plan must be in place.
	Prohibit (1)	n/a

1 *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact or other factors that the NOSB and the USDA may want to consider in making decisions.*

Characterization

Composition: KOH

Properties: It is a white, highly deliquescent caustic solid, which is marketed in several forms, including pellets, flakes, sticks, lumps, and powders.

How Made:
Food grade potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm [21 CFR 184.1631(a)]. The reaction can be characterized as follows:

$$KCl + H_2O \rightarrow HCl + KOH$$

Generally, KOH is considered a by-product of hydrochloric acid and chlorine manufacturing (Curlin, Bommarju, and Hansson, 1991).

Specific Uses:
Its main uses in food processing include use as a direct food additive, formulation aid, pH adjuster, cleaning agent, stabilizer, thickener, and poultry scald agent. It is used in dairy products, baked goods, cocoa, fruits, vegetables, soft drinks, and poultry. Among the main foods that use KOH are: chicken, cocoa, coloring agents, ice cream, and black olives (Ash and Ash, 1995). The petitioned use is to lye peel peaches to be Individually Quick Frozen (IQF) (Finn, 2001).

Non-food uses include: soap manufacture; electroplating; printing; as a mordant for wood; as a highly reactive source of potassium in a wide variety of industrial chemical syntheses and chemical analyses; in veterinary medicine as a caustic used in disbudding calves horns and in aqueous solution to dissolve scales and hair in skin scrapings; manufacture of cleansers; in wart removal and as a 2.5% solution in glycerol as a cuticle solvent. This type of compound is also used in washing powders, some denture cleaners, some non-phosphate "ecology" detergents, and drain-pipe cleaners (Patnaik, 1992, NTP).

Action: Potassium hydroxide is a strong base and is alkaline in solution. It is highly corrosive. Caustic peeling is based on the differential solubilization of the cell and tissue constituents. Pectic substances in the middle lamella are particularly soluble (Lindsay, 1996).

Combinations: It is in aqueous solution. KOH is used with caramel, annatto, turmeric (Ash and Ash, 1995), and soap. Processors will often combine a number of alkali buffering agents (Lindsay, 1996).

Status

OFPA, NOP Final Rule
The relevant OFPA reference to permit use is 7 USC 6517(c)(1)(A)(ii), which states "substance is necessary to the production and handling of the agricultural product because of unavailability of wholly natural substitute products." Currently listed at 7 CFR 205.605(b)(27) as an allowed non-agricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as 'organic' or 'made with organic (specified ingredients or food group(s)).' The annotation prohibits use in lye peeling of fruits and vegetables. The NOSB recommended the additional annotation that it also be prohibited for use where non-synthetic sodium carbonate is an acceptable substitute (NOSB, 1995). This annotation was not included in the Final Rule.

Regulatory
FDA lists as GRAS for humans (21 CFR 184.1631), which are allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables.

EPA/NIEHS/Other Appropriate Sources
EPA – Potassium hydroxide is considered a category C hazardous substance under the Comprehensive Environmental Response, Conservation, and Liability Act (CERCLA) (40 CFR 302.4). The reportable quantity is 1,000 pounds (40 CFR 117). Food processors that use such compounds may be subject to Toxic Release Inventory reporting requirements explained in US EPA, 1998a.

Envirofacts Master Chemical Integrator (EMCI) - did not maintain information on KOH as of April 25, 2001.

NIEHS - National Toxicology Program (NTP) is attached. The toxicology literature on potassium hydroxide is quite extensive and is summarized below under the OFPA criteria.

Status among U.S. Certifiers

Most have prohibited KOH for use in lye peeling of fruits and vegetables, as per NOSB recommendation. Since 1998 and 1999, it has been allowed by Oregon Tilth and QAI for peeling of peaches used for freezing.

International

CODEX – Allowed for pH adjustment for sugar processing (Annex 2, Table 4, Codex, 1999).
EU 2092/91 – Does *not* appear in Annex VI.
IFOAM – Does *not* appear in Appendix 4 (IFOAM, 2000).
Canada – Does *not* appear in Appendix C, Permitted Substances List for processing.
Japan – Allowed for pH adjustment for sugar processing (Processing Table 1).

OFPA 2119(m) Criteria

(1) *The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.*
This is being considered as a processing material.

(2) *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*
See processing criteria 3, below.

(3) *The probability of environmental contamination during manufacture, use, misuse or disposal of such substance.*
This is considered below under item 2.

(4) *The effect of the substance on human health.*
The substance is highly corrosive and can cause severe burns of eyes, skin, and mucous membranes (Cheremishinoff, 2000). Generally, studies and surveys regarding the toxicity of potassium hydroxide are included with studies of sodium hydroxide, and they are collectively known as 'caustics' or 'lye.' Lye poisoning results in numerous deaths annually, generally as accidents involving cleaners. Lyes are particularly penetrating and corrosive with tissue. This is due to the solubilizing reactions with protein, saponification of fats, and dehydration of tissue (Gosselin, Smith, and Hodges, 1984). Further health effects are considered in the context of the effect on nutrition in processing criteria 3, below, as well as the consideration of GRAS and residues in processing criteria 5, below.

(5) *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*
This is primarily of concern in terms of processing waste management, see item 2 below.

(6) *The alternatives to using the substance in terms of practices or other available materials.*
See discussion of alternatives in processing criteria 7, below.

(7) *Its compatibility with a system of sustainable agriculture.*
This is considered more specifically below in the context of organic handling in processing criteria 6, below.

Criteria from the February 10, 1999 NOSB Meeting

(The TAP review contract indicates these criteria are to be used.)

A PROCESSING AID OR ADJUVANT may be used if;

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
A traditional naturally-occurring source of potassium hydroxide was produced by the leaching of wood ashes. The 21 CFR states that it is commercially derived from potassium chloride, and requires that the ingredient meet the specifications of the Food Chemicals Codex [21 CFR 184.1631(a)]. Potassium chloride is natural, but electrolysis renders the product synthetic.

Solutions of some natural acids such as citric and tartaric have been used to peel peaches. This works by disintegrating the peel and requires large volumes of water. It also prevents browning. However, this is not apparently used due to the corrosive effect of the solutions on metal equipment (Woodruff, 1986).

Naturally occurring sodium carbonate, or sodium bicarbonate, may be used as a substitute for lye in some food uses, such as pretzel baking. In pretzel manufacture, dough is passed through an alkaline bath of 0.5% sodium hydroxide or 2% sodium carbonate (Lorenz, 1991). This is done to enhance browning reactions and aid gelatinization of the starch that allows for the characteristic smooth, shiny surface of the pretzel.

The FDA also permits potassium hydroxide to be used as an alkali ingredient in cacao nibs [21 CFR 163.110(b)(1)], chocolate liquor [21 CFR 163.111(b)(1)], and breakfast cocoa [21 CFR 163.112(b)(1)]. However, these uses are all optional and the reference in 21 CFR lists sodium carbonate and bicarbonate as FDA approved alternatives to potassium hydroxide for each of these products.

Lye treatment of olives also uses sodium hydroxide in three to five applications of 0.5-1.5% solution to facilitate oxidation and polymerization of natural phenolic compounds in California-style black olives to form a black pigment. It is also used in the production of California-style ripe green olives and Spanish-style pickled green olive to remove bitterness. In all cases the olives are washed to remove the lye (Pederson, 1988). Alternatives for this use are not identified, although rates can be reduced after longer brining periods.

See number 7 for discussion of alternative processes.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling.*

A lye peeling processing method is of concern to the agroecosystem due to handling of waste from the plant. Large volumes of water are used, which enter the waste stream along with the soluble potassium and alkali ions. Lye peeling with sodium hydroxide is more of a disposal problem due to undesirable sodium content that may be soil applied, whereas residual potassium is a plant nutrient, although it would be considered synthetic and not permitted for an organic farming system.

Peach processing plants using lye peeling are generally restricted by state and local waste water treatment requirements, which has resulted in a limited number of plants and sites in operation (O'Bara, 2001). Data supplied by the petitioner indicates that alkalinity of waste is not a factor, due to the natural acidity of the fruit, which must be additionally buffered during on-site treatment (Finn, 2001). Conventional tomato lye peeling processes may use 9800/liters water /ton of tomatoes peeled. Advances in technology to combine lye peeling with mechanical scrubbers reduced the water consumption (Luh, 1988).

Dry caustic peeling was advocated in the 1970s to substantially reduce the amount of plant wastewater discharged (National Canners Association, 1970). This process uses infrared energy at 1650 degrees to condition the surface of fruit that is treated with stronger sodium hydroxide solutions. The peel is removed mechanically by soft rubber scrubbing rolls rather than by water, so that about 90% of the peel is removed as a thick heavy "peanut butter-like" substance, which must be disposed of (Woodroof, 1986). Caustic peeling continues to be considered more effective at peel removal with substantial reduction in wastewater when compared with conventional peeling (Lindsay, 1996).

Disposal of KOH can be potentially dangerous. Mercury cells are used to produce most of the KOH in the United States (Freilich and Petersen, 1996). The stripped mercury is generally recycled and discharge of mercury is forbidden.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*

Potassium is an essential mineral nutrient. Lye peeling with sodium hydroxide has been shown to reduce the amount of the Pru p 1 protein in peaches (Brenna, et al., 2000). This is regarded as the major allergen in peaches and therefore may be considered of nutritional benefit. Allergans in rosaceae fruit are associated with the skin (Fernandez-Rivas, 1999). The petitioner has submitted experimental data showing no increase in potassium content of the fruit due to the use of potassium hydroxide. In data from 1998, samples tested after hand peeling had comparable levels of potassium to those that had been through the treatment line (average 665 ppm and 661 ppm respectively). After blanching, the potassium content drops substantially, to 422 ppm.

Peeling methods can effect product nutrient loss, with the less flesh removed the better the nutrient retention. Nutrient loss can also occur from leaching out of water soluble constituents or degrading of heat sensitive compounds. Ascorbic acid and thiamin were reduced by 12% by lye peeling, although carotenoids were not reduced. Fruit that is canned without peeling, for instance, retains more nutrients (Saluhnke, 1990). Mechanical peeling, coring, and slicing has the least effect on nutrients, but is not an option for soft fruits.

Freezing of fruit is not shown to contribute to nutrient loss, whereas canned fruit does lose nutrients (Saluhnke, 1990). 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 level 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).

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

KOH does not serve as a preservative nor does it recreate or improve flavor or color. It does aid in preserving texture in the final product, though this is not strictly a recreation of texture.

5. *Is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*

Potassium Hydroxide is Generally Recognized As Safe under 21 CFR 184.1631. Federally approved food uses are summarized in Table 1.

Table 1
Approved Food Uses of Potassium Hydroxide

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

†Unless otherwise noted.
Sources: EAFUS, 2001; 21 CFR 184.1631 (2000); 9 CFR 424.21

FDA specifies that when used for washing or peeling, potassium hydroxide must be used only in the amount needed, followed by rinsing with potable water to remove, to the extent possible, residues of the chemicals. No limits are placed on food use other than current good manufacturing practices, and the ingredient must meet the specifications of the Food Chmeicals Codex. Potassium hydroxide may also be used as a poultry scald agent in an amount sufficient for the purpose. The processing aid must be removed by subsequent cleaning operations (9 CFR 424.21). Maximum amounts allowed are contained in Table 2.

The Food Chemicals Codex (1996) specifications for KOH are as follows:
Identification A 1 in 25 solution tests positive for potassium.
Assay Not less than 85% and not more than 100.5% of total alkali, calculated as KOH.
Carbonate (as K_2CO_3) Not more than 3.5%.
Heavy Metals (as Pb) Not more than 0.002%.
Insoluble Substances Passes test.
Lead Not more than 10 mg/kg.
Mercury Not more than 0.1 mg/kg.

Table 2
Potassium Hydroxide Limitations Under Current Good Manufacturing Practices (As Served)

Product Category	Limit	CFR†
cacao nibs	(b) Optional ingredients. The following safe and suitable ingredients may be used: (1) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, added as such, or in aqueous solution. For each 100 parts by weight of cacao nibs, used as such, or before shelling from the cacao beans, the total quantity of alkali ingredients used is not greater in neutralizing value (calculated from the respective combined weights of the alkali ingredients used) than the neutralizing value of 3 parts by weight of anhydrous potassium carbonate.	163.110(b)(1)
caramel color	consistent with good manufacturing practice.	73.85(a)(2)(ii)
chocolate liquor	Optional ingredients. The following safe and suitable ingredients may be used: Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, used as such, or in aqueous solution . . .	163.111(b)(1)
breakfast cocoa	(b) Optional ingredients. The following safe and suitable ingredients may be used: (1) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, used as such, or in aqueous solution;	163.112(b)(1)
poultry scald	Amount sufficient for the purpose. The processing aid must be removed by subsequent cleaning operations	9 CFR 424.21
other uses	Not to exceed current good manufacturing practice.	21 CFR 184.1631(c)

Sources: EAFUS, 2001; CFR, 2000, 2001.
†All CFR references are to Title 21 CFR unless noted otherwise.

6. *Its use is compatible with the principles of organic handling.*
The use of a synthetic substance to perform a mechanical function such as peeling can be seen as not consistent with objectives of minimizing synthetic substances in handling of organic food. However, use of this material will allow the availability of an organic product otherwise not available, as hand peeling of peaches will not be viable on a commercial scale. Pureed peach products can be produced without chemical peeling techniques, but canned and frozen peaches cannot.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
Apples and pears may be mechanically or steam peeled, as are carrots, potatoes, and sweet potatoes (Luh, 1988). Tomatoes are mechanically or steam peeled and also commonly lye peeled.

Peaches, nectarines, and apricots used in processing may be peeled by a number of methods. These include hand peeling, use of boiling water or steam, high pressure steam, chemical peeling using lye (sodium or potassium alkalis), dry caustic peeling that uses infrared heat and higher concentrations of lye, by freezing, and using acids (Woodroof, 1986).

Hand peeling uses less water and reduces enzyme effects that cause browning (heat and alkali), and wash water is not contaminated. However, this is offset by high cost and increased opportunity for microbial contamination (Woodroof, 1986). Boiling or steam peeling is used for riper peaches and especially for freestone (melting flesh) varieties. According to Woodroof, it is more suited for peaches for juicing and freezing, which are picked riper than those used for canning. However, the petitioner notes that peaches used for individual quick freezing (IQF) must be picked at a firmer stage in order to peel and then successfully slice or dice them. High pressure steam peeling combines steam with high pressure to create a high internal pressure of the fruit. When pressure is reduced, the skin separates from the softened tissue beneath it. The petitioner conducted studies to evaluate the use of steam under pressure for various time periods, but was unsuccessful in obtaining satisfactory results. A longer duration of steam was needed to remove the peel, which resulted in over softening and destruction of the flesh. The petitioner also conducted experiments that combined steaming and hand peeling (slip skinning) which is used in smaller operations. This procedure also requires a riper peach, was tested on freestones, and did not produce fruit that could be sliced or diced for the freezing tunnel.

Freezer peeling reportedly works on very ripe, melting flesh peaches, using equipment similar to those for steam peeling. The peach is frozen quickly to shallow depth, then thawed rapidly, so the skin is released easily. The fruit is then treated with ascorbic acid to prevent browning.

Lye peeling involves the application or dip of peaches into a heated solution of potassium hydroxide, ranging from 2—7% in strength. The lower rates are used on clingstone (non-melting flesh) varieties. Different rates, temperatures, and time of exposure are used for fruits destined for canning or freezing. Peaches for canning are generally exposed at lower concentrations at higher temperatures, which cooks the surface of the fruit. In the process described by the petitioner, peaches destined for freezing are sprayed with a solution maintained at 190 degrees for a period of 1-3 minutes and run through a scrubber machine that removes the fragments of peels by brushing. The peaches are subsequently rinsed with fresh water, treated with ascorbic acid, pitted, and then sliced or diced. The cut peaches then are run through freezing tunnels where they are rapidly frozen by high volume chilled air.

Enzyme peeling was also attempted by the petitioner, without success.

The alternative to chemical peeling, in the absence of commercially viable hand peeling or mechanical peeling, at the present time appears to having organic peaches limited in availability to the pureed forms.

TAP Reviewer Discussion[2]

Reviewer 1 *[West coast--Ph.D., Food Science and Nutrition professor with inspection and certification experience]*

Disclaimer: I have the following financial interest or conflict related to the use of this substance: I am conducting research on the acidification of alkali peeled tomatoes by-products in an effort to reduce the solid and liquid waste generated from conventional tomato processing plants.

[Agrees that the database is reasonably complete and accurate.]
[Agrees with the OFPA criteria evaluation with the following additional comments]

1. It cannot be produced from a natural source and has no organic ingredients as substitutes

I agree with the criteria evaluation.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.

No adverse nutritional consequences of using lye peeling

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown produces do not have adverse effects on human health as defined by applicable Federal regulations.*

Lye peeling maintains by removing the skin, the visual (sensory) quality of the fruit and also acts to help reduce the rate of polyphenyloxidase enzyme activity that reduces the rate of enzymatic browning of the flesh (a notable loss in quality).

4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.

It has broad FDA approval when used according to GMP's.

5. Is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.

I agree with the criteria evaluation.

6. Its use is compatible with the principles of organic handling.

I agree with the criteria evaluation.

7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

I agree with the criteria evaluation.

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

My conclusions for this review will be based solely on the basis of consistency and scientific reasoning. Since both KOH and NaOH are approved ingredients according to the NOSB, this means their addition in food products is permanent. They can be directly incorporated into the product formulation and still are approved. With KOH or NaOH use in lye peeling, both KOH and NaOH are prohibited even when rinsed with clean potable water so no residue remains on the product. Therefore, both KOH and NaOH when used in lye peeling should be viewed as a processing aid not an ingredient. It is very difficult to understand how either KOH or NaOH can be approved as direct ingredient and not as a processing aid. This is logically inconsistent with sound reasoning.

Therefore on the basis of consistency the fact that both KOH and NaOH are washed off from the food matrix (no residue) I will recommend that KOH and NaOH be approved for lye peeling of both fruits and vegetables with the annotation that it be used according to FDA CFR regulations and that there be no residual KOH left

[2] *OMRI's information is enclosed is square brackets in italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are edited for any identifying comments, redundant statements, and typographical errors. Text removed is identified by ellipses […].Additions to the TAP review text were incorporated into the review. Statements expressed by reviewers are their own and do not reflect the opinions of any other individual or organizations.*

on the product. Therefore the processor must show that KOH is being used as a processing aid and that resulting fresh water washes or rinses are sufficient to remove KOH (or NaOH) residue.

Recommendation Advised to the NOSB:

a. The substance is: ___X___Synthetic ____Not Synthetic

b. The substance __X_ Should ____Should not be added to the National List of Allowed Non-organic Ingredients (includes processing aids).

c. *Annotation suggested, including justification:* Must be used in accordance with FDA CFR and when used for lye peeling, no residue must remain on the fruit.

Additional commentary

This has been a very difficult review as I have been torn 50% for not approving and 50% for approval. However, the major issues that I feel decision making should be built upon is consistency in organic integrity. Every time I ask myself why is KOH approved for direct usage as a food ingredient according to the NOP and not as a process aid where it can be removed from the product, I seem to come up with the same conclusion- that KOH also be approved as a process aid for lye peeling of fruits and vegetables.

Reviewer 2 [*A Midwest based consultant in organic handling and processing with extensive background in organic certification and policy development*]

[Agrees that the database is accurate and complete with the following comments]

Another synonym is potassium hydrate.

[Agrees with the Processing Criteria Evaluation with the following comments]

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
   Leached wood ashes, while capable of saponifying animal fats, cannot give the functionality required of modern industry.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*
   As an industrial chemical whose manufacture does employ the use of other toxic materials, i.e., mercury cells, by-products of chlorine production, etc., KOH does impact the environment. The mere transportation of these chemicals poses a risk. Note the restrictions placed on facilities using this technology based on waste water requirements. In the textile industry, there is growing concern about the disposal of bleaching products and more and more communities are requiring closed systems for KOH & NaOH bleaching.

   The product itself, being highly caustic and corrosive, requires special handling as a hazardous material. It is arguable that this product and its sister product, NaOH, are the two most hazardous and toxic materials currently allowed as ingredients on the National List. There is an extensive medical database on the corrosive and toxic effects of this substance. The petitioner's argument that the waste matter is not a concern because of the need to actually acidify the effluent is faulty logic. By not allowing use of this product, not only are we reducing the amount of toxic chemical production (KOH) and the toxic waste issues that entails, but we also reduce the amount of such materials as muriatic acid entering into the water supply.

   Although the final rules list both KOH and NaOH as approved, I feel these products do not satisfy the criteria listed above

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
   I agree with the criteria evaluation.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
   I agree with the criteria evaluation.

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
I agree with the criteria evaluation

6. *Its use is compatible with the principles of organic handling.*
I agree with the opinion that the use of KOH, as a toxic, synthetic chemical, is not compatible with organic production principles. While it is true that perhaps this product cannot be produced in any other manner with current technology, I don't believe that has been historically a basic criterion for acceptance in the organic production system. The organic industry has used prohibitions on products and processes to drive innovation and invention to replace the environmentally harmful practices often found on conventional farms and in processing facilities. More on this in § 7.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
If by a similar product, one means other fruits, then, yes there are alternative methods of peeling. But it appears to be also true that to peel peaches for freezing, no other technology offers the economy and effectiveness of lye peeling. In fact, the two other peach processors I found, one in California and one in Michigan, actually use NaOH. But the question of acceptability seems to hinge on the commercial availability of this one product, as produced by one processor, the petitioner. While the petitioner has developed a number of persuasive and accurate arguments to support his case, the fact remains that the process is inherently synthetic.

Additionally, the NOSB has wrestled with the issued posed by the use of these products for years and placed the restriction on lye peeling now noted in the final rule. And although the department (NOP) dropped part of the annotation for the two caustics listed, the restriction prohibiting lye peeling was kept. Allowing this use of KOH will also be seen as inconsistent with the same restriction placed on NaOH and be hard to defend.

One historical perspective – Hirzel Canning successfully defended an OCIA standards change for use of this material for tomato peeling. They claimed KOH was preferable to NaOH and developed a questionable evaporation process for the spent caustic, placing large amounts in solid form on land outside the cannery. Soon after, this use was disallowed by IFOAM upon accreditation of OCIA's program and has not been allowed since.

Other methods of peeling attempted to date (but also found unacceptable) have been the use of liquid nitrogen, oxygen and Freon 12. Liquid oxygen use was dangerous around flammable materials, liquid nitrogen did not work well around unripe portions of the fruit and Freon 12 was unacceptable for obvious environmental concerns (fluorocarbon release.)

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.
While it is true that this processor does provide a market for organic IQF peaches and that no one to date has developed a large scale commercial process for peeling peaches without synthetic materials, the material itself and past review history support continuing the restriction on the use of KOH as a lye peeling agent. The rule should not be used to concretize current synthetic processes just so one large conventional processor can take advantage of the market potential for frozen organic peaches. One of the overarching principles of organic processing is the development of new, environmentally sensitive and functionally appropriate technologies to replace the ubiquitous use of food grade *chemicals* in our food supply.

Recommendation Advised to the NOSB:

a. The substance is: __X__Synthetic _____Not Synthetic

b. The substance ____Should ___X__Should not be added to the National List of Allowed Non-organic Ingredients (includes processing aids).

c. Annotation Suggested, including justification:

None.

Additional Commentary - Response to additional questions:

1. *It appears that canning is not commercially possible without lye peeling also. Do reviewers have knowledge of steam or pressure-steam systems for canning operations as well?*
   I have no additional knowledge about steam or pressure steam systems except as presented in the review and literature. The companies I spoke with and the literature I researched were essentially reprints or duplications of the food science currently published and employed. Very little in new developments for processing fruits and vegetables (except with drying technologies) seems to have occurred in the last 10-15 years.

2. *Much of the fruit processing references used are dated. Please add any new sources or info about discounted alternatives as well as any other new and promising technologies.*
   In my literature search, I could find no newer references than those cited. As the food industry has grown concentrated with fewer and larger companies, there seems to be less incentive to spend large amounts of money on new equipment and processes, when the use of functional materials has been shown to be much cheaper and easier to achieve the desired processing and organoleptic properties.

3. *Is there any new information on enzyme peeling? Does anyone do freezer peeling?*
   I don't know.

4. *Are you familiar with any independent studies that look at either hand-peeling, scalding, infrared treatment, or dry-peeling with sodium carbonate or sodium bicarbonate as alternatives to lye peeling?*
   No.

5. *Are there any designs for mechanical peelers?*
   Only on small scale, as best as I can learn.

6.

7. *The petitioner claims to be the only source of IQF organic peaches. Do you know of any other firms processing organic peaches?*
   JR Woods appears to be correct about their peach processing data. I could only find two other plants processing conventional IQF peaches as noted in §7 and none doing organic.

8. *Do you think NOSB should reconsider the blanket allowance for some of the other uses of KOH? What would be the rationale to accept KOH for lye peeling and continue to prohibit NaOH?*
   I personally feel the use of KOH and NaOH is inappropriate for organic handling operations. Only two certifiers currently allow its use, and neither material appears as approved in either the IFOAM or EU list. There is no rationale for accepting one and not the other, since the differences in use, manufacture, and disposal are a matter of degree, not substance.

Reviewer 3 *[East Coast--Ph.D. in biochemistry with food industry experience]*
[Agrees that the database is accurate and complete with the following comments]

Potassium hydroxide is not an "oxidizer." See 21CFR184.1631.

Comment: Potassium hydroxide in food processing can be used in exceedingly minute amounts such as for pH control or in major amounts that trigger CERCLA reporting requirements. Some applications uniquely require potassium hydroxide whereas any alkali hydroxide can be used for lye peeling. The NOSB should get some 'flavor' for the quantitative and qualitative aspects of potassium hydroxide use in food processing. The supporting information does a fair job of communicating some aspects of this dimension. (Lye essentiality for black olives is clear but the reference describes use of sodium hydroxide not potassium hydroxide.)

[Agrees with the Processing Criteria Evaluation with the following comments and amendments]

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
   White ashes from wood have been used traditionally in America as a source of "lye." Wood ash is a crude form of potassium hydroxide. "Potash" ["pot" + "ash"] is defined in the dictionary as the crude potassium hydroxide obtained from wood ash. A solution formed by passing water through wood ashes may comply with the Food Chemicals Codex requirement of a minimum 85% of total alkali as KOH.

According to an internet document (Lerner, 2000), wood ash is about 25% calcium carbonate and contains about 10% potash (K_2O), 1% phosphate and trace amounts of micronutrients. Calcium hydroxide would not be appreciably soluble in the strongly alkaline lye water.

[The criteria evaluation needs to be corrected or amended as follows:]

The FDA regulation for potassium hydroxide specifically states: "Potassium hydroxide **is obtained commercially** from the electrolysis of potassium chloride solution" [21CFR184.1631(a)]. I do not read this statement as equivalent to: "21CFR **specifies** that it **be derived** from potassium chloride." Another manufacturing process – commercial or non-commercial – could provide acceptable material.
The statement controlling identity is 21CFR184.1631(b): "The ingredient meets the specifications of the Food Chemicals Codex:"
"Dutch-process cocoa" is preferably prepared with potassium carbonate or sodium carbonate. 21CFR163 may list several alternatives including potassium hydroxide but the carbonates are most commonly used according to several web pages (Intl Cocoa, Ency. Brittanica).

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*
The documentation provided by the petitioner (and vetted by the local water treatment agency) indicates that this petitioner has an environmentally benign system that results in a potassium-rich, pH-neutral solution being returned to cropland with no negative impact on the local hydrology.

This suggests that a condition upon use of an ingredient such as sodium hydroxide or potassium hydroxide is an appropriate and independently vetted waste treatment plan. However, local and State environmental authorities tightly regulate U.S. food processors of all stripes, so such a condition might pose an additional requirement only for an offshore processor.

[The criteria evaluation needs to be corrected or amended as follows:]

The EPA evaluated dry caustic peeling systems for peaches as a means of reducing water usage about 25 or 30 years ago. The reference and an abstract of this study are given at the end. The critical amendment is that water usage may be more important that alkali disposal in considering the environmental effects of any lye peeling process.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
I had not been aware that peeling peaches reduced the allergenicity so effectively.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
It is important to delete the "oxidizer" allegation under "Specific Uses."

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
I agree with the criteria evaluation.

6. *Its use is compatible with the principles of organic handling.*
Peach puree is routinely produced from intact peaches without peeling. Suitable equipment exists to remove the peels and pits by mechanical means.

[The criteria evaluation needs to be corrected or amended as follows:]

The OFPA [7 USC 6510(a)(1)] states that a person "shall not . . **add** any synthetic ingredient during the processing or any post harvest handling of the product." The scientific literature clearly indicates that the action of "lye" is to dissolve a layer of peel, enabling a water rinse to remove the peel. The FDA regulation [21CFR173.315(c)] requires rinsing to remove residues of the lye peeling agent. Thus, the lye peeling agent is not **added** to the food.

The precedent in organic food processing for direct contact between lye (a synthetic substance) and an organic product being an acceptable practice is the acceptance of the use of sodium hydroxide in pretzel manufacture. In pretzel manufacture, dough is exposed to a lye solution prior to baking to achieve the typical brown glaze of the pretzel. The lye is **not** rinsed off prior to baking and thus lye is "**added**" to the food in the sense of 7 USC 6510(a)(1).

The non-synthetic substance sodium carbonate is an acceptable substitute for the synthetic substance sodium hydroxide in pretzel manufacture. Nonetheless, both the NOSB and the NOP saw fit to accept sodium hydroxide for lye treatment of and lye addition to "organic" pretzels.

In the present case, potassium hydroxide is a superior source of lye compared to sodium hydroxide, since the neutralized plant effluent adds an essential plant nutrient rather than saline to the cropland to which it is applied.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*

[Additional supporting information or comments.]

Based on the documentation supplied and additional searching in library and on internet, I conclude that peaches for halves or frozen peaches cannot be satisfactorily peeled in a commercial operation except by lye peeling. However, "lye" includes at least four substances, both the hydroxides and the carbonates of sodium and potassium. Sodium carbonate is a non-synthetic substance. It would be desirable for a manufacturer to test sodium carbonate to determine if non-synthetic "lye" would work. However, the saline wastewater disposal problem might make this unfeasible and less consistent with sustainable agriculture.

The economics of supply and disposal of lye force the food processor to use the minimum quantity possible.

The USDA/AMS Grading Manual for Canned Clingstone Peaches [see reference list; pages 1-7 enclosed] indicates that peaches for canning must be properly peeled and discusses only lye peeling as the method to remove the peel.

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

In previous reviews of lye peeling, this reviewer has opposed use of lye peeling of fruits and vegetables, in as much as sodium and potassium hydroxides are synthetic substances and contact between such a substance and an organic food was held to violate the organic integrity of that food. I now have a different view.

The OFPA [7 USC 6517(c)(1)(A)(ii)] permits the use of a synthetic substance in food processing when the "substance is necessary to the production and handling of the agricultural product because of unavailability of wholly natural substitute products."

Based on the documentation supplied and additional searching in library and on the internet, I conclude that peaches for halves or frozen peaches cannot be satisfactorily peeled in a commercial operation except by lye peeling. Thus lye peeling is "necessary to the. . . handling of the agricultural product."

The "wholly natural substitute product" is wood ash, a crude form of potassium hydroxide, which has been traditionally used in lye treatment of food (e.g., hominy - see reference, Mountain Laurel). To my knowledge, wood ash is unavailable in adequate quantity and of sufficient and consistent quality to satisfy the commercial need.

The ultimate question then is whether exposure of an organic food to a lye solution constitutes an irreversible degradation of the organic integrity of the food. Both the NOSB and the NOP answered this question in the negative when they accepted sodium hydroxide for lye treatment of and lye addition to "organic" pretzels.

The precedent in organic food processing for the acceptability of direct contact between lye (a synthetic substance) and an organic product is the allowance of the use of sodium hydroxide in pretzel manufacture. In pretzel manufacture, dough is exposed to a lye solution prior to baking to achieve the typical brown glaze of the pretzel. The lye is **not** rinsed off prior to baking and thus this lye is "**added**" to the food in the sense of 7 USC 6510(a)(1). Recall that the OFPA [7 USC 6510(a)(1)] states that a person "shall not . . **add** any synthetic ingredient during the processing or any post harvest handling of the product."

Using a synthetic 'lye' to make pretzels is a greater threat to organic integrity than using the same lye to peel fruit. The scientific literature clearly indicates that the action of "lye" is to dissolve a layer of peel, enabling a water rinse to remove the peel. The FDA regulation [21CFR173.315(c)] requires rinsing to remove residues of the lye peeling agent. Thus, lye **is not added** to the peeled fruit. Lye **is added** to the baked pretzel.

Based on this precedent, peeling peaches with potassium hydroxide should be acceptable.

The potassium-rich wastewater from a KOH lye peeling operation should be returned to the land where it provides an essential nutrient (potassium). This is consistent with a system of sustainable agriculture.

Recommendation Advised to the NOSB:

a. The substance is: __X__Synthetic _____Not Synthetic

b. The substance __X__Should _____Should not be added to the National List of Allowed Non-organic Ingredients (includes processing aids).

c. Annotation Suggested, including justification:

FDA regulations [21CFR173.315] require rinsing to remove residues of the lye peeling agent. A certified wastewater disposal (recycling) plan must be in place.

Additional Commentary - Response to additional questions:

(1) It appears that canning is not commercially possible without lye peeling also. Do reviewers have knowledge of steam or pressure-steam systems for canning operations as well?
Not for peach halves or IQF peaches.

(2) Much of the fruit processing references used are dated. Please add any new sources or info about discounted alternatives as well as any other new and promising technologies.
The Del Monte website has a discussion of canned fruit processing that states exactly what the old literature does. See references.

(3) Is there any new information on enzyme peeling? Does anyone do freezer peeling?
I do not know.

(4) *Are you familiar with any independent studies that look at either hand-peeling, scalding, infrared treatment, or dry-peeling with sodium carbonate or sodium bicarbonate as alternatives to lye peeling?*
Yes; the EPA worked with Del Monte about 30 years ago on dry caustic peeling of peaches. A 1974 report is available. See references.

(5) *Are there any designs for mechanical peelers?*
I do not know.

(6) There appears to be some data that suggests that lye peeling can reduce pesticide residues in fruit. Is there any data to support this? If so, please provide the citation, preferably with a copy of the study. Yes. National Food Processors Association documents show reduced pesticide residues after peeling fruit. A sentence in an EPA document [HED DOC. NO. 013584; 21 JULY 1999; page 3] states: "Some processing studies indicate that phosmet residues will be reduced through washing and peeling (peach and apple processing studies), and residues are reduced in processing fruits into juices (apples, grapes)." No reference to the original work is given. I have personal knowledge that peeling fruits reduces pesticide levels (unless the pesticide is a systemic one).

(7) The petitioner claims to be the only source of IQF organic peaches. Do you know of any other firms processing organic peaches?
I do not know.

(8) Do you think NOSB should reconsider the blanket allowance for some of the other uses of KOH? What would be the rationale to accept KOH for lye peeling and continue to prohibit NaOH?
Potassium hydroxide is the more sustainable alternative. The major difference between KOH and NaOH is the environmental disposal issue. Potassium-rich wastewater from a KOH lye peeling operation can be returned to the land where it provides the essential nutrient potassium and water. The wastewater from a NaOH operation would make the soil saline. KOH costs more than NaOH per pound and more KOH is required (its higher molecular weight). But people use KOH to minimize the environmental effect (and total overall system costs).

Conclusion

Two of the three reviewers find it inconsistent that the NOSB recommendation and USDA final rules permit the use of potassium hydroxide as an ingredient, but not as a processing aid for peeling fruits and vegetables. The environmental impact of the use of caustics in chemical peeling can be mitigated through careful waste water management practices, and the allowance of potassium rather than sodium hydroxides is defensible based on the environmental impact of the waste water. The third reviewer finds that the principle of minimizing the use of synthetics should be considered more fundamental than the need for a particular form of a product, and is concerned about lack of international acceptance. The NOSB needs to consider whether it wants to amend the annotation to permit the use of potassium hydroxide only for peaches or stone fruit where there appear to be no alternatives, or to permit for all fruits and vegetables including tomatoes, apples, pears, and potatoes that are currently peeled using steam or mechanical methods.

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*Note: * = included in packet sent to NOSB*

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