NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: ____**November 2011**___ | **Substance:** Potassium Hydroxide

Committee: Crops ☐ **Livestock** ☐ **Handling** X **Petitioned for** annotation change from "Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process" to "Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches" **on the National List § 205.605(b)**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes X	No ☐	N/A ☐
2.	Essential & Availability Criteria	Yes X	No ☐	N/A ☐
3.	Compatibility & Consistency	Yes X	No ☐	N/A ☐
4.	Not or Inconsistently Available as Organic	Yes X	No ☐	N/A ☐

B. Substance Fails Criteria Category: _____ Comments: _____

_____

C. Proposed Annotation (if any): annotation change from "Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process" to "Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the canning or Individually Quick Frozen (IQF) production process"

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: The petition is to change the annotation for the current §205.605 (b) listing of potassium hydroxide to add the allowed use of lye peeling of peaches for canning, in addition to peaches for freezing. Citation:__

D. Recommended Committee Action & Vote (State Motion): __Recommend changing the annotation for potassium hydroxide from "Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process" – to "Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the canning or Individually Quick Frozen (IQF) production process" on the National List § 205.605(b)

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Motion by: DICKSON Seconded: MIEDEMA Yes: 6 No: 0 Absent: 1 Abstain: 0

Crops		Agricultural		Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling	X	Synthetic	X	Rejected[3]	
No restriction		Commercially Un-Available as Organic[1]		Deferred4	

1) Substance voted to be added as "allowed" on National List to § 205. X ___with Annotation (if any) prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches

2) Substance to be added as "prohibited" on National List to § 205._____with Annotation (if any) _____

_____

Describe why a prohibited substance:_____

_____

3) Substance was rejected by vote for amending National List to § 205. _____Describe why material was rejected:_____

_____

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

_____ _____

Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance** – Potassium Hydroxide

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		TAP lines 163-186: "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)."
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		See #1 above.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		See #1 above.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		TAP lines 193-194: "The petitioner has submitted experimental data showing no increase in potassium content of the fruit due to 193 the use of potassium hydroxide."
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		See #10 above.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			TAP lines 216-237: "Potassium Hydroxide is Generally Recognized As Safe under 21 CFR 184.1631. Federally approved food uses are 218 summarized in Table 1." Referenced table includes used in peeling of fruits and vegetables, allowed under 21 CFR 173.315(a)(1)
13. Does the substance contain		X		TAP lines 229-236

residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]				

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance - Potassium Hydroxide

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			The petition and the TAP describe the production method in detail. TAP lines 48-51: 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: $KCl + H_2O \rightarrow HCl + KOH$
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			According to the TAP, the source potassium chloride is natural, but the process renders the resultant potassium hydroxide synthetic (lines 138-139). Potassium chloride occurs naturally as sylvite, and it can be extracted from sylvinite or from salt water. Potassium hydroxide is also a by-product of the synthesis of nitric acid from potassium nitrate and hydrochloric acid.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See #2.
4. Is there a natural source of the substance? [§205.600 b.1]	X			Potassium hydroxide can be obtained naturally by the leaching of wood ash, but this method is not commercially practiced (TAP lines 136-140).
5. Is there an organic substitute? [§205.600 b.1]		X		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			Petitioner states that this substance is the only viable method of commercial peach peeling, and as such, is used to make products meet consumer expectations.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			TAP lines 141-143: 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).
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		Substance is synthetic.
9. Is there any alternative substances? [§6518 m.6]		X		See #7. The only natural alternative is not commercially viable.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance - Potassium Hydroxide

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X			
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	This substance is used as an ingredient in an organic processed food. It is not used in agriculture.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality of food is not degraded, and is in some cases improved over other processing methods.
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;				Petitioned material is not for use in production
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

[1]If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the agricultural substance inconsistently or not commercially available as organic?

Substance - Color, Beta-carotene extract, derived from carrots

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	This is not an agricultural substance.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

Additional Background

List: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (b) Synthetics allowed--Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Committee Summary

Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener and poultry scald agent. It is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide 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. In fruit and vegetable peeling, potassium hydroxide serves to weaken the glycolytic bonds of pectin, which is responsible for skin adhesion. Weakening these bonds allows the peeling of fruit and vegetable skins by water spray or other mechanical methods.

In 1995, the NOSB approved the addition of potassium hydroxide to 205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001, a petitioner sought to expand the use of potassium hydroxide by amending the annotation to read “prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.” The 2001 TAP review for that expansion noted that “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 2001 TAP review also noted that the environmental effects which had originally resulted in the restrictive annotation could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjusments buffer the alkalinity of the wastewater. Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of potassium hydroxide for the peeling of fresh peaches to be canned. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step.

Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Committee supports the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since

canning and freezing are the primary commercially processing methods used for peaches, we favor removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Committee Recommendation(s)

The handling committee recommends the expansion of the annotation of the following substance in this use category as published in the final rule:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (b) Synthetics allowed--Sulfur dioxide—Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.