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

Document Type:

□ National List Petition or Petition Update

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

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

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

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

⊠ Technical Report

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

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

Contractor names and dates completed are available in the report.

Sodium Hydroxide Handling/Processing

1	Ident	ification of Petitioned Substance
2	Chemical Names:	CAS Numbers:
3	Sodium hydroxide	1310-73-2
4 5	Other Names:	Other Codes:
6	Caustic soda	EC No. 215-185-5
7	Sodium hydrate	ICSC No. 0360
8	Soda lye	NSC No. 135799
9	Ascarite	RTECS No. WB4900000
10		UNII No. 55X04QC321
11	Trade Names:	
	Commonly sold as a generic commodity a branded product	and not
12	*	Summary of Petitioned Use
13 14 15 16 17 18 19 20 21 22 23 24 25	as a nonagricultural (nonorganic) substa "made with organic," except for lye pee Regulations (CFR) Section 205.605(b). So amendment in the extraction of plant ma Sodium hydroxide is used in many hand including food, paper pulping, chemical agents (NRC 1984, ATSDR 2002, Flomer	dling and processing applications across various industries, l production and extraction, etching, and detergents and cleaning baum et al. 2006). This technical report will focus on the uses of l handling of organic food products and will update existing
26	Charac	terization of Petitioned Substance
27 28 29 30 31	in water, it dissociates into sodium catio	oound and strong base (Atkins et al. 2008). When the substance dissolves ons (Na ⁺) and hydroxide anions (OH ⁻) (ATSDR 2002, Atkins et al. 2008).
32 33	Sodium hydroxide is commercially avai	lable as a colorless to white solid with \geq 96% purity (SC 2016, LC 2018).
34 35 36 37 38	5	nce that is primarily produced through the electrolysis of aqueous 995, Simon et al. 2014, Du et al. 2018). See Evaluation Question #1
39 40 41 42 43 44 45 46	water and short-chain alcohols (methane Atkins et al. 2008, SC 2016, LC 2018). Th atmospheric carbon dioxide (CO ₂), form exothermic reaction. The exothermic nat	olving completely into Na ⁺ and OH ⁻ ions) with high solubility in ol [CH ₃ OH], ethanol [CH ₃ CH ₂ OH], etc.) (Silberberg 2003, PC 2005, e substance is hygroscopic (absorbs water) and highly reactive with ing sodium bicarbonate (NaHCO ₃) with water and acids in an ture may result in the potential for violent reactions, including the gases (Silberberg 2003, PC 2005, SC 2016, LC 2018). Specific below in Table 1.

Table 1: Properties of Sodium Hydroxide (NaOH)

Property	Sodium Hydroxide
Chemical Formula	NaOH
Molecular Weight	39.997 g/mol
CAS No.	1310-73-2
Appearance	Colorless to white solid
Melting Point	323 ° C
Boiling Point	1388 °C
Water Solubility	Soluble
Density	2130 kg/m ³
pН	14 (5%)
Reactivity	Undergoes exothermic reaction in with water and acids. Absorbs
	atmospheric carbon dioxide (CO2) to form sodium bicarbonate
	(NaHCO ₃). Absorbs water from the atmosphere (hygroscopic).

50

O Sources: (PC 2005, ATSDR 2002, Atkins et al. 2008, SC 2016, LC 2018)

5152 Specific Uses of the Substance:

- 53 Sodium hydroxide is used in many industries: soap-making, including "made with organic...soap-based
- 54 algicide/demossers, herbicides, animal repellents, and insecticidal soaps," as described in 7 CFR 205.601;
- 55 textile and paper production; glass and mineral production and extractions; in food processing as a
- 56 disinfectant, cleaning agent, and degreaser; and as a food additive and processing aid (NRC 1984, ATSDR
- 57 2002, Flomenbaum et al. 2006). Sodium hydroxide is also used in the handling and processing of organic
- 58 food products, such as poultry, olive processing, and as a production aid for pretzel manufacturing
- 59 (Humphrey et al. 1981, Brenes-Balbuena et al. 1992, Seetharaman et al. 2002, McKee et al 2008, Rombouts et al. 2012, Johnson and Mitchell 2019).
- 61

62 Sodium hydroxide has been used in conventional fruit processing, primarily in lye peeling processes

63 (Garcia and Barrett 2006, Rock et al. 2012). Despite the frequent use of sodium hydroxide for lye peeling in

64 conventional agricultural processing, lye peeling is not allowed under NOP guidelines due to the high

biological oxygen demand (BOD) in the resulting wastewater (Shi and LeMaguer 2000, Garcia and Barrett

- 66 2006, Rock et al. 2012, USDA 2016).
- 67

Sodium hydroxide is sometimes listed as an alternative alkali to lime (calcium oxide, CaO) and hydrated or
 slaked lime (calcium hydroxide, Ca(OH)₂) in corn products such as hominy and tortilla dough due to its

- 70 improved solubility over the calcium salts (Wagner 1940, Diez de Sollano and Berriozabal 1955, del
- 71 Carmen de Arriola et al. 1988). However, lime or slaked lime are the traditional sources of alkali for the
- 72 production of hominy and tortilla dough and remain the primary alkalis in commercial uses as well
- (Wagner 1940, Diez de Sollano and Berriozabal 1955, del Carmen de Arriola et al. 1988, Campus-Baypoli et
 al. 1999).
- 74 75

76 *Cleaning agent/degreaser*

- 77 Sodium hydroxide is the active ingredient in several commercial formulations of cleaning agents and
- 78 degreasers. Sodium hydroxide is commonly found in oven cleaners and products to unblock plumbing
- 79 (Silberberg 2003). Sodium hydroxide acts to break bonds that are commonly found in organic matter,
- 80 increasing water solubility of the organic matter, which facilitates its removal (Timberlake 2016).
 81
- 82 *pH adjuster*
- 83 Sodium hydroxide is a strong base that reacts with substances in acidic conditions (Silberberg 2003). Due to
- 84 the reactive nature of the base, it is commonly used to adjust the pH of water systems and can be applied to
- 85 other food and beverage systems for regulation of acidity (ODHS 1998, NHMRC 2011). The addition of
- sodium hydroxide results in an increased pH or alkalinity of the system.
- 87

- 88 Cocoa processing
- 89 Sodium hydroxide is used to refine the color and flavor profiles of chocolate and cocoa powders (Eggen
- 90 1980, Ellis 1990, Rodriguez at al. 2009, Moser 2015). Sodium hydroxide is specifically used in Dutched
- 91 chocolate products (Dutch processing is the treatment of cocoa with sodium hydroxide or other alkalis)
- 92 and is associated with enhanced flavors and darker colors (Ellis 1990, Miller et al. 2008, Li et al. 2014, Moser
- 2015). Sodium hydroxide reacts with compounds associated with bitter or sour tastes in the raw or partially
 processed cocoa, and promotes darker color development by promoting oxidation processes and Maillard
- 95 reactions at elevated pHs (7-9) (Miller et al. 2008, Rodriguez et al. 2009, Moser 2015). The alkali treatment of
- 96 cocoa products also improves their ability to be dispersed in water and milk, an important feature when
- 97 used in the production of beverages, icings, and creams (Eggen 1980, Miller et al. 2008, Moser 2015).
- 98
- 99 Sugar processing
- 100 Sodium hydroxide is used at several stages of sugar manufacturing (Chaji et al. 2010, Prati and Moretti
- 101 2010, Doherty 2011, Xu and Cheng 2011, Yoo et al. 2011, Laksameethanasan et al. 2012). Sodium hydroxide
- 102 applications include as an alkali pretreatment of plant matter to digest lignin and hemicellulose to increase
- 103 the efficiency of enzymes that break down complex sugar polymers (Chaji et al. 2010, Xu and Cheng 2011,
- 104 Yoo et al. 2011). Sodium hydroxide is also used to regulate pH and clarify the sugar juices that are
- 105 produced following the extrusion of plant materials (Prati and Moretti 2010, Doherty 2011,
- 106 Laksameethanasan et al. 2012).
- 107
- 108 Poultry processing
- 109 Sodium hydroxide is used as an additive to scald water in poultry processing (Humphrey et al. 1981,
- 110 Brotsky and Bender 1990, Bender and Elfstrum 1995, McKee et al. 2008). In the scalding process, the poultry
- 111 is immersed in hot water, which is meant to loosen feathers and facilitate the defeathering and evisceration
- 112 processes (Barbut 2001, Zhuang et al. 2013). The addition of sodium hydroxide increases the pH of the
- 113 scald water and reduces bacterial populations that might be present in a water-only scald (Humphrey et al.
- 114 1981, Brotsky and Bender 1990, Bender and Elfstrum 1995, McKee et al. 2008).
- 115
- 116 Olive processing
- 117 Sodium hydroxide is used in olive processing to remove the bitter taste from ripe olives (Cruess and
- 118 Alsberg 1934, Johnson and Mitchell 2019). This process typically includes soaking the olives in a sodium
- 119 hydroxide solution for 12 hours, with soaks being carried out on three successive days. Between soaking
- 120 periods, the olives are suspended in water or a diluted brine solution (Brenes-Balbuena et al. 1992). In
- addition to removing bitter tastes from ripe olives, sodium hydroxide treatment also prevents undesired
- 122 discoloration (Angel and Ben-Shalom 1979, Brenes-Balbuena et al. 1992).
- 123
- 124 The use of sodium hydroxide in organic olive production is difficult to gauge. Several producers of organic
- 125 olives have stated that their olives are not produced with sodium hydroxide (Acropolis, Odysea).
- 126 However, several articles discussing conventional and organic olives mention the use of lye (sodium
- 127 hydroxide) curing, without discrimination between conventional and organic processing (Superfoodly
- 128 2017, George Meteljan Foundation).
- 129
- 130 Pretzel production
- 131 Sodium hydroxide is used in pretzel production as an alkaline dip applied to the shaped dough prior to
- 132 baking (Kurzius 1975, Walsh 1992). The alkaline dip chemically changes the surface starch and proteins,
- 133 resulting in a smooth surface (Kurzius 1975, Walsh 1992, Seetharaman et al. 2002, Rombouts et al. 2012).
- 134 The products of the chemical transformations brought about by sodium hydroxide treatment result in
- 135 improved browning by promoting the Maillard reaction (Seetharaman et al. 2002, Rombouts et al. 2012).
- 136

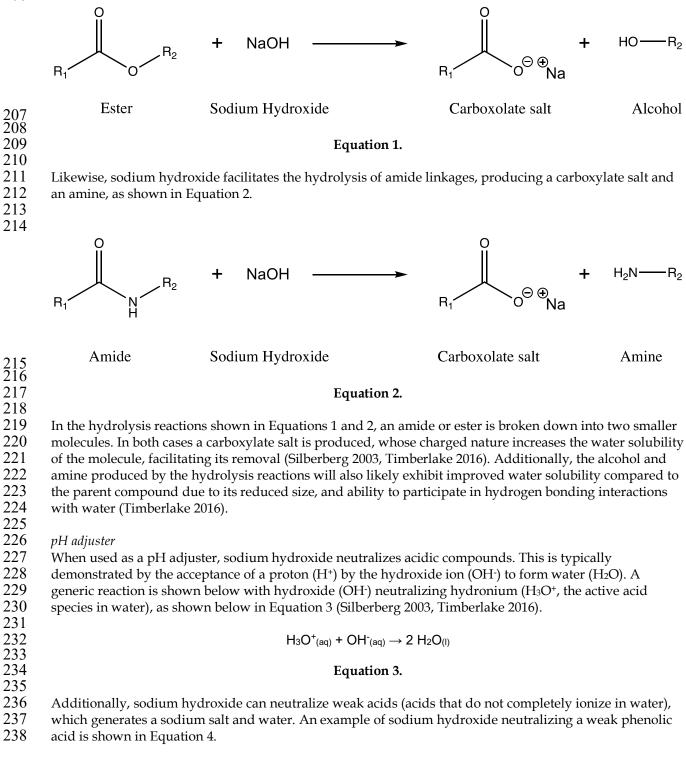
137 Approved Legal Uses of the Substance:

- 138 The USDA has approved synthetic sources of sodium hydroxide as a "nonagricultural (nonorganic)
- 139 substance allowed as an ingredient in or on processed products labeled as "'organic' or 'made with organic
- (specified ingredients or food group(s)^{$\prime\prime\prime$} with the stipulation that the substance is "prohibited for use in lye
- 141 peeling of fruits and vegetables," at 7 CFR 205.605(b). Sodium hydroxide is also approved by the USDA for
- 142 use as plant or soil amendments in the extraction of plant material at 7 CFR 205.601(j).

- 143 144 The United States Food and Drug Administration (FDA) has granted sodium hydroxide GRAS (generally 145 recognized as safe) status "when used in accordance with good manufacturing or feeding practice," at 21 146 CFR 582.1763 and as a "direct human food ingredient," at 21 CFR 184.1763. In addition, the FDA has 147 approved the use of sodium hydroxide for the production of a range of GRAS substances such as benzoyl 148 peroxide, magnesium hydroxide, rapeseed oil, propylene glycol, sodium benzoate, sodium citrate, sodium 149 lactate, sodium propionate, zein, sodium chlorite, sodium formate, sodium oleate, sodium palmitate, and 150 sodium sulfate. 151 152 The FDA has approved the substance for use in the production of "modified hop extract," which is a 153 "flavoring agent," at 21 CFR 172.560. Sodium hydroxide has been approved by the FDA to produce 154 "hydroxylated lecithin," which is used as a "multipurpose additive," at §172.814. The FDA has also 155 approved using sodium hydroxide to modify food starch with the stipulation that the amount of sodium 156 hydroxide used for the modification is "not to exceed 1 percent," at §172.892. Additionally, the FDA has 157 approved sodium hydroxide in the production of "canned green beans and canned wax beans," at 158 §155.120, "tomato concentrates," at §155.191, and "catsup," at §155.194. Sodium hydroxide has also been 159 approved by the FDA for use in caramel coloring additives at §73.85. 160 161 The FDA has approved sodium hydroxide as an "indirect food additive" to make "sanitizing solutions" for 162 food processing equipment, utensils, or contact articles at 21 CFR 178.1010. In this instance, it is approved 163 when it is combined (as a part of sodium salt reaction products) with the following substances: elemental 164 iodine, hydriodic acid, dodecylbenzene sulfonic acid, phosphoric acid, isopropyl alcohol, and calcium 165 chloride. However, there are specific ratios that are required by the regulation for the sanitizing solutions. 166 167 The FDA has approved sodium hydroxide as an "antistatic and/or antifogging agent in food-packaging 168 materials," at §178.3130. The FDA has also approved sodium hydroxide as an additive for boiler water 169 used in the preparation of steam that will contact food, at §173.310. The FDA has approved the substance 170 as a "component of paper and paperboard in contact with aqueous and fatty foods," with the stipulation 171 that the mixture containing sodium hydroxide is "for use only as a retention aid employed prior to the 172 sheet-forming operation in the manufacture of paper and paperboard," at §176.170. Sodium hydroxide and 173 resulting soaps are approved by the FDA for use as a "defoaming agent used in the manufacture of paper 174 and paperboard," at §176.210. 175 176 The FDA has approved sodium hydroxides for use in the production of "polymer substances and polymer 177 adjuvants for food treatment," specifically for "acrylate-acrylamide resins," at 21 CFR 173.5, and "sodium 178 polyacrylate," at §173.73. The FDA has also approved sodium hydroxide for use in the production 179 'polymers for use as indirect food additives," specifically "polyethylene resins, carboxyl modified," at 180 §177.1600. 181 182 The United States Environmental Protection Agency (EPA) has identified sodium hydroxide as a 183 "hazardous substance," at 40 CFR 116.4. The EPA has also designated sodium hydroxide as a "neutralizer," 184 with an "exemption from the requirement of a tolerance," as an "inert ingredient used pre- and 185 post-harvest," at 40 CFR 180.910, and as an "inert ingredient applied to animals," at §180.930. The EPA has 186 granted a "tolerance exemption for active and inert ingredients for use in antimicrobial formulations 187 (food-contact surface sanitizing solutions)," for sodium hydroxide applied to "dairy processing equipment, 188 and food-processing equipment and utensils," at §180.940. 189 190 The EPA regulates the use of sodium hydroxide in industrial paper production, including in a "kraft pulp 191 mill," or "soda pulp mill," which use sodium hydroxide solutions to "produce pulp from wood by cooking 192 (digesting) chips," as defined at 40 CFR 63.861. Within the paper pulping industry, the cellulose ether 193 process and the viscose process use sodium hydroxide in a "reaction of cellulose (e.g., wood pulp or cotton 194 linters) ... to produce alkali cellulose," as stated at §63.5610. The viscose process also reacts "sodium 195 cellulose xanthate with additional sodium hydroxide to produce viscose solution," as defined at §63.5610.
- 196

197 Action of the Substance:

- 198 The action of the substance varies based on the application in food processing. Given this variation in mode 199 of action, each application will be addressed separately.
- 200
- 201 *Cleaning agent/degreaser*
- 202 The effectiveness of sodium hydroxide as a cleaning agent and/or degreaser is due to its ability to promote
- 203 hydrolysis of amide and ester linkages, functionalities that are commonly found in organic matter
- 204 (Timberlake 2016). The result of the basic hydrolysis of esters is the formation of a carboxylate salt and an 205 alcohol, as shown in Equation 1.
- 206



239 240 Cocoa processing

241 Sodium hydroxide is used in cocoa and chocolate manufacture, specifically in the Dutching process.

- 242 Sodium hydroxide reacts with acidic components of raw or partially processed cocoa products that are 243 associated with sour and bitter tastes through hydrolysis and neutralization reactions (shown above in 244 Equations 1 and 2, and below in Equation 4) (Rodriguez et al. 2009, Moser 2015). These neutralization and 245 hydrolysis reactions raise the pH of the cocoa from an acidic 5-6 to a basic 7-9 (Rodriguez et al. 2009, Moser 246 2015).
- 247

248 The hydrolysis of large molecular structures upon alkalization, or Dutching, results in the formation of 249 charged molecules. These smaller, more polar molecules have increased interactions within aqueous solutions, resulting in improved solubility and uniform dispersion (Eggen 1980, Moser 2015).

250 251

252 The Dutching process produces darker brown and red colors upon treatment with sodium hydroxide. The 253 more intense colors following alkali treatment are associated with the formation of polyphenolic polymers 254

- and Maillard reactions, both of which are promoted at high pH (Ellis 1990, Rodriguez et al. 2009, Li et al. 255
- 2014, Miller et al. 2014, Moser 2015). The polymerization process that gives chocolate its characteristic color 256
- is catalyzed by the polyphenol oxidase (PPO) enzyme, which operates most effectively under a pH of ~8 257
- (Rodriguez et al. 2009). Moreover, the neutralized phenolate molecules (see Equation 4 below) are better 258 suited to these polymerization reactions than their neutral and acidic phenolic counterparts, and deeper
- 259 colors have been associated with increased polymerization of these phenolic compounds (Miller et al. 2008,
- 260 Rodriguez et al. 2009, Li et al. 2014, Moser 2015).
- 261 262 Sugar processing

263 Sodium hydroxide is used as a pretreatment to promote the digestion of plant material. Sodium hydroxide 264 facilitates the basic hydrolysis of ester linkages present in hemicellulose (shown in Equation 1), removing 265 natural plant structure and allowing for increased access to the sugar polymers of interest (Chaji et al. 2010,

266 Xu and Cheng 2011, Yoo et al. 2011). The reactive nature of the base results in the neutralization of phenolic

267 functionalities present in both lignin and hemicellulose (shown in Equation 4), making the structures and

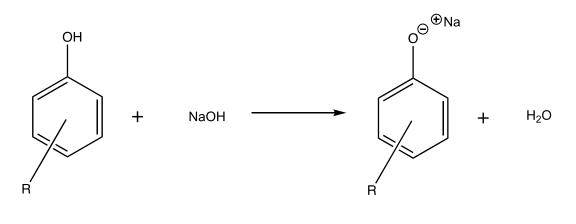
- 268 digested portions of hemicellulose more water soluble and easier to remove from the sugar polymers
- 269 (Chaji et al. 2010, Xu and Cheng 2011, Yoo et al. 2011).
- 270

271 Sodium hydroxide is also used following the extrusion of plant material. The sugar juices produced in the 272

extrusion process are a complex mixture of compounds including chlorophyll, polyphenolic compounds, 273 organic acids, salts, amino acids, proteins and sugar polymers (Prati and Moretti 2010, Doherty 2011,

- 274 Laksameethanasan et al. 2012). Acids are typically used to remove chlorophyll and similar compounds to
- 275 prevent discoloration, which leads to a low, acidic pH (Prati and Moretti 2010). Sodium hydroxide is added
- 276 to raise the pH to 8-11, which prevents the undesired isomerization of sugar molecules (Prati and Moretti
- 277 2010, Doherty 2011, Timberlake 2016). Sodium hydroxide is applied as a clarifying agent by breaking the
- 278 amide linkages (shown in Equation 2) that hold together amino acids and proteins (Laksameethanasan et 279 al. 2012, Timberlake 2016).
- 280 281 Poultry processing
- 282 Sodium hydroxide is used in poultry processing as an antimicrobial, specifically as an anti-salmonella
 - 283 agent (Humphrey et al. 1981, Brotsky and Bender 1990, Bender and Elfstrum 1995, McKee et al. 2008). It is
 - 284 used as an additive in the scalding process and has been reported to reduce bacterial populations
 - 285 compared to a water only scald (Humphrey et al. 1981, Brotsky and Bender 1990, Bender and Elfstrum
 - 286 1995, McKee et al. 2008). The addition of sodium hydroxide improves the efficacy of the scalding process as
 - 287 the strong base denatures the proteins of the undesired substances, allowing for their more efficient feather
 - 288 removal, while also denaturing bacterial proteins and reducing colony populations (Humphrey et al. 1981,
 - 289 McKee et al. 2008). The alkaline environment is reported to specifically target microbial enzymes, resulting
 - 290 in the inability of bacteria to transport essential nutrients (Jay 2000).

- 292 Olive processing
- 293 Sodium hydroxide is used in olive processing to remove bitter tastes and prevent undesirable discoloration
- 294 (Cruess and Alsberg 1934, Angel and Ben-Shalom 1979, Brenes-Balbuena et al. 1992). Sodium hydroxide is
- alkaline and neutralizes the weakly acidic phenolic compounds in the olives. The phenolic compounds,
- which are composed of acidic aromatic alcohols, are responsible for the bitterness and discoloration found
- in untreated olives (Brenes-Balbuena et al. 1992, Andrews et al. 2003, Johnson and Mitchell 2019). Equation
 4 shows phenolic compounds neutralized by the alkaline sodium hydroxide.
- 299



300 301	Phenol compound	Sodium hydroxide	Sodium phenolate
301 302 303		Equation	4.
304 305 306 307	1	n reactions that are responsi	aste. Moreover, the phenolates are no longer able ble for undesirable brown spots (Brenes-Balbuena
308	Pretzel production		
309	,	an alkaline dip of formed pr	etzel dough prior to the baking process (Kurzius
310	1975, Walsh 1992). The sodium	m hydroxide dip denatures s	urface proteins to provide a smooth and uniform
311	0 1	5	l quaternary protein structure (unfolding),
312	specifically by disruption of t	he hydrogen and disulfide b	onding networks that provide this structure in

- the native protein state (Rombouts et al. 2012). Additionally, sodium hydroxide acts to gelatinize the
- 314 pretzel surface by hydrolysis of α-1,4-glycosidic bonds found within starch (Seetharaman et al. 2002,
- 315 Rombouts et al 2012).
- 316

The combination of protein denaturation and gelatinization of starch molecules provides a smooth surface that gives pretzels their characteristic texture (Seetharaman et al. 2002, Rombouts et al 2012). Moreover, the cleavage of glyosidic bonds within the surface starch molecules increases the number of sugar molecules

- 319 cleavage of gryosial bonds within the surface starch molecules increases the number of sugar molecules 320 present on the pretzel surface for participation in the Maillard reaction responsible for browning
- 321 (Rombouts et al. 2012).
- 321 322

323 Combinations of the Substance:

324 Sodium hydroxide is commercially available in high purity (≥96%) as an ionic compound consisting of

- 325 sodium (Na⁺) and hydroxide (OH⁻) ions (Aktins et al. 2008). The hygroscopic nature (propensity to absorb
- water) of sodium hydroxide results in its ability to form stable hydrates through incorporation of water
- 327 molecules into the ionic crystal lattice (Pickering 1893, Atkins et al. 2008). Common sodium hydroxide
- 328 hydrates are the mono, di, tri, tetra, penta, and hepta-hydrated compounds, correlating to the
- incorporation of 1, 2, 3, 4, 5, and 7 molecules of water, respectively (Pickering 1893, Mraw and Giauque
- 330 1962, Murch and Giauque 1962, Siemens and Giauque 1969, Giauque 1974).

332 333

Status

334 **Historic Use:**

335 Sodium hydroxide has been historically used in many industries, including soap-making, textile and paper

336 production, glass and mineral production and extractions, as a disinfectant, cleaning agent and degreaser,

337 and as a food additive and processing aid (NRC 1984, ATSDR 2002, Flomenbaum et al. 2006). Using

338 sodium hydroxide or lye in soap production was especially important for historical production of hard

339 soaps, which were preferred because they were easy to store and transport (Thorpe 1913, Stapleton et al. 340 1927). In early applications, sodium hydroxide was sourced as lye, or caustic soda, a relatively impure and

341 alkaline mixture isolated from the ashes of burned plant material (Thorpe 1913, Stapleton et al. 1927).

342

343 In specific relation to this report, the substance has historically been used in the processing of cocoa,

344 pretzels, and olives (Cruess and Alsberg 1934, Brenes-Balbuena et al. 1992, Rodriguez et al. 2009, Moser 345 2015, Johnson and Mitchell 2019). The use of alkali treatment in cocoa and chocolate manufacture dates

346 back to 1828 when Van Houten used a mixture of alkali salts to treat cocoa beans (Rodriguez et al. 2009,

347 Moser 2015). The "Dutch" process has become popular with chocolate manufacturers since then to improve

348 the flavors and colors of treated cocoa products (Moser 2015). The production of pretzels is documented

349 back to the 13th century. Dipping pretzels in an alkaline dip before baking was introduced in the 20th

350 century and has become a standard across the industry, with sodium hydroxide being the most prominent

351 substance (Seetharaman et al. 2002). In the 20th century, sodium hydroxide was used to treat olives to

352 reduce bitterness and avoid undesirable discoloration (Cruess and Alsberg 1934, Brenes-Balbuena et al. 353 1992, Johnson and Mitchell 2019).

354

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

356 Sodium hydroxide is not listed in the Organic Foods Production Act of 1990 (OFPA).

357

358 The USDA National Organic Program has approved synthetic sources of sodium hydroxide as a

359 "nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as

360 "'organic' or 'made with organic (specified ingredients or food group(s)," with the stipulation that the

361 substance is "prohibited for use in lye peeling of fruits and vegetables," at 7 CFR 205.605(b). Sodium

362 hydroxide is also approved by the USDA in the extraction of aquatic plant material for use as plant or soil

363 amendments at 7 CFR 205.601(j). Sodium hydroxide is also allowed as an alkali for the extraction of humic

- 364 acids (USDA 2012).
- 365

366 International:

367

368 Canadian General Standards Board Permitted Substances List -

369 Sodium hydroxide is listed in the Canadian General Standards Board Permitted Substances List 370 (CAN/CGSB-32.311-2015) in Table 4.2 as allowed for "soil amendments and crop nutrition," for the

371 "extraction of aquatic plants and aquatic plant products" and "plant extracts, oils, and preparations with

- 372 synthetic solvents," with the condition that "the manufacturer shall prove the need to use sodium hydroxide."
- 373
- 374

375 Sodium hydroxide is listed in Table 5.3 as a "health care product and production aid for use in dehorning 376 paste."

377

378 Sodium hydroxide is listed in Table 6.3 "ingredient classified as a food additive" and in Table 6.5 as a

379 "processing aid," with the condition that the substance is "prohibited for use in lye peeling of fruits and 380 vegetables."

381

382 Table 7.3 lists sodium hydroxide as a "food-grade cleaner, disinfectant, and sanitizer permitted without a 383 mandatory removal event."

385 386	CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) –
387	Sodium hydroxide is listed in the CODEX (GL 32-1999) in Table 3.1 as a "food additive, including carriers
388	for cereal products." The substance is also listed in Table 4 as a "processing aid which may be used for the
389	preparation of products of agricultural origin," with the specific condition that sodium hydroxide is to be
390	used for "pH adjustment in sugar production."
391	used for priradjustment in sugar production.
392	European Economic Community (EEC) Council Bogulation EC No. 824/2007 and 880/2008
	European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 –
393	Sodium hydroxide is not listed in EC No. 834-151 2007.
394	
395	Sodium hydroxide is listed in section A of EC No. 889/2008 as a "food additive, including carriers" and is
396	approved for "preparation of foodstuffs of plant origin," specifically "surface treatment of 'Laugengeback
397	[lye or pretzel breads].'"
398	
399	Japan Agricultural Standard (JAS) for Organic Production –
400	Sodium hydroxide is listed in the JAS for Organic Production Notification No. 1608 as an "agent for
401	cleaning or disinfecting of housing for livestock."
402	
403	Sodium hydroxide is listed in the JAS for Organic Production Notification No. 1606 as a "food additive
404	limited to be used for processing sugar as pH adjustment agent or used for grain processed foods."
405	
406	International Federation of Organic Agriculture Movements (IFOAM) -
407	Sodium hydroxide is listed in IFOAM as an "approved additive and processing/post-harvest handling
408	aid," with the limitation on use "for sugar processing and the surface treatment of traditional bakery
409	products." Sodium hydroxide is listed in IFOAM as an "equipment cleanser and equipment disinfectant,"
410	with the stipulation that "an intervening event or action must occur to eliminate risks of contamination."
411	Sodium hydroxide is listed as a "substance for pest and disease control and disinfection in livestock
412	housing and equipment."
413	
<i>4</i> 1 <i>4</i>	Evaluation Questions for Substances to Be Used in Organic Handling
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415	
415 416	Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the
415 416 417	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
415 416 417 418	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,
415 416 417 418 419	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
415 416 417 418 419 420	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)).
415 416 417 418 419 420 421	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)). Since the USDA has approved synthetic sources of sodium hydroxide as a nonagricultural (nonorganic)
415 416 417 418 419 420 421 422	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)). Since the USDA has approved synthetic sources of sodium hydroxide as a nonagricultural (nonorganic) substance that can be used in or on products labeled as "organic" or "made with organic," the most
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415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436	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)). Since the USDA has approved synthetic sources of sodium hydroxide as a nonagricultural (nonorganic) substance that can be used in or on products labeled as "organic" or "made with organic," the most prevalent synthetic method of sodium hydroxide production the is electrolysis of sodium chloride (Lindstrom 1974, Atkins et al. 2008). In this reaction, there are two separate half-reactions that take place to give the overall electrolysis reaction shown in Equation 5. $2 \text{ NaCl}_{(aq)} + 2 \text{ H}_2\text{ O}_{(i)} \rightarrow 2 \text{ NaOH}_{(aq)} + \text{H}_{2(g)} + \text{Cl}_{2(g)}$ Equation 5. At the cathode, electrons are added to water molecules, resulting in their reduction to form a molecule of dihydrogen and two hydroxide ions, shown in Equation 6 (Atkins et al. 2008, Simon et al. 2014). The hydrogen gas produced evaporates from the cathode and is often burned or discarded as waste (Lindstrom 1974).

Sodium Hydroxide

440 441 442 443 444	The current flow in the electrolytic cell is completed by the oxidation of chloride ions at the anode to form chlorine gas (Cl ₂), shown in Equation 5 (Lindstrom 1974, Atkins et al. 2008, Simon et al. 2014). Unlike the production of hydrogen at the cathode, the chlorine produced at the anode is isolated as a commercially important by-product (Lindstrom 1974, Atkins et al. 2008). The isolated chlorine is used in a range of industrial applications, predominantly in the production of polyvinyl chloride (PVC) (Atkins et al. 2008).
445 446 447	$2 \text{ Cl}_{(aq)} \rightarrow \text{Cl}_{2 (g)} + 2 \text{ e}^{-}$
448 449	Equation 7.
450 451 452 453 454	After the electrochemical transformations described in Equations 6 and 7, the process yields an aqueous solution that is easily separated from the gas products (Equation 5). Solid sodium hydroxide is isolated from the manufacturing process by the evaporation of water, leaving a white to colorless solid (Lindstrom 1974, Atkins et al. 2008).
455 456 457 458 459	Sodium hydroxide was historically produced industrially as the metathesis reaction (a reaction in which the cations and anions salts are exchanged) of aqueous calcium hydroxide (Ca(OH) ₂) with sodium carbonate (Na ₂ CO ₃), shown in Equation 8, or by the electrolysis of an aqueous solution of sodium chloride (NaCl, salt) shown in Equation 5, Lindstrom 1974, Atkins et al. 2008).
460 461	$Ca(OH)_{2(s)} + Na_2CO_{3(aq)} \rightleftarrows CaCO_{3(s)} + 2 NaOH_{(aq)}$
461 462 463	Equation 8.
463 464 465 466 467 468 469	In the metathesis reaction shown in Equation 8, the reaction occurs through the exchange of the calcium (Ca^{2+}) and sodium (Na^+) cations with carbonate (CO_3^{2-}) and hydroxide (OH^-) anions, respectively. The reaction is driven to completion due to the greater solubility of the calcium hydroxide compound compared to the calcium carbonate product (Atkins et al. 2008). The resulting sodium hydroxide-rich solution is evaporated to yield sodium hydroxide solids.
470 471 472 473	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.
473 474 475 476 477	Sodium hydroxide is not a naturally occurring substance. Modern commercial production of sodium hydroxide occurs through the electrolysis of sodium chloride to produce sodium hydroxide and hydrogen and chlorine gases (Equation 5) (Lindstrom 1974, Atkins et al. 2008, Simon et al. 2014).
478 479 480	Sodium hydroxide was historically produced as lye, or caustic soda, as a relatively impure and alkaline mixture isolated from the ashes of burned plant material (Thorpe 1913, Stapleton et al. 1927).
481 482 483	Evaluation Question #3: If the substance is a synthetic substance, provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).
484 485	Sodium hydroxide does not occur naturally and has only been isolated through chemical transformations.
486 487 488 489	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.
489 490 491 492 493 494	Sodium hydroxide has GRAS status as a "general purpose food additive," at 21 CFR 582.1763 and as a "direct food substance," at §184.1763. In addition, the FDA has approved using sodium hydroxide for the production of a range of GRAS substances: benzoyl peroxide at §184.1157, magnesium hydroxide at §184.1428, rapeseed oil at §184.1555, propylene glycol at §184.1666, sodium benzoate at §184.1733, sodium citrate at §184.1751, sodium lactate at §184.1768, sodium propionate at §184.1784, zein at §184.1984, sodium

chlorite at §186.1750, sodium formate at §186.1756, sodium oleate at §186.1770, sodium palmitate at
§186.17771, and sodium sulfate at §186.1797.
Evaluation Question #5: Describe whether the primary technical function or purpose of the patitione

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)).

501

When sodium hydroxide is used as a scald additive in poultry processing, it may be viewed as a
preservative because the scald additive process reduces salmonella populations on processed poultry
(Humphrey et al. 1981, Brotsky and Bender 1990, Bender and Elfstrum 1995, Jay 2000, McKee et al. 2008).
Reduced bacterial populations means that processed poultry has a longer shelf life (Brotsky and Bender 1990, Bender and Elfstrum 1995). The bacterial populations are reduced because the pH in the sodium
hydroxide scalds is high, which disrupts bacterial enzymes and prevents bacteria from getting essential
nutrients (Jay 2000).

509

510 Sodium hydroxide does not act as a preservative when used in cocoa processing, olive processing, pretzel 511 production, pH adjustment, or sugar processing.

512

513 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

516 (b)(4)).

517518 Sodium hydroxide is not used to improve flavors that are lost during processing. However, sodium

519 hydroxide has many applications within the food industry, including as a processing aid to improve flavor, 520 color, and texture (Cruess and Alsberg 1934, Angel and Ben-Shalom 1979, Brenes-Balbuena et al. 1992,

color, and texture (Cruess and Alsberg 1934, Angel and Ben-Shalom 1979, Brenes-Balbuena et al. 1992,
Seetharaman et al. 2002, Rodriguez et al. 2009, Rombouts et al. 2012, Moser 2015). Using the substance in

521 Seetharaman et al. 2002, Rodriguez et al. 2009, Rombouts et al. 2012, Moser 2015). Using the substance in 522 organic food processing, specifically in cocoa processing, olive processing and pretzel production, to

522 organic root processing, specifically in cocou processing, once processing and precising production, to 523 improve flavors, colors, and textures. The results of each application are discussed in more detail below.

524

525 *Cocoa processing*

526 Sodium hydroxide is primarily used to improves flavors and colors of Dutch processed cocoa and

527 chocolate products (Moser 2015). This is achieved by the hydrolysis and neutralization of compounds

528 associated with bitter tastes (Rodriguez et al. 2009, Moser 2015). Additionally, the neutralization of

529 phenolic compounds, and optimization of the PPO enzyme under basic conditions improves the colors of

the treated cocoa products (Ellis 1990, Miller 2008, Rodriguez et al. 2009, Moser 2015).

- 531
- 532 Sugar processing

533 One application of sodium hydroxide in sugar processing is to clarify sugar juices following plant

- extrusion. Juice clarification occurs by promoting the hydrolysis of proteins, amino acids, and enzymes
- found within the sugar mixture (Prati and Moretti 2010, Doherty 2011, Laksameethanasan et al. 2012). The
- 536 enzymes found in the sugar mixture promote oxidative processes, which result in the darkening of the
- 537 mixture. Cleavage of ester and amide linkages (shown in Equations 1 and 2) work to shut down and digest
- 538 oxidative enzymes, preventing discoloration of the sugar mixture (Laksameethanasan et al. 2012).
- 539
- 540 Olive processing
- 541 The strongly basic nature of sodium hydroxide produces a high pH solution that neutralizes the acidic
- 542 compounds that create the bitter taste found in ripe olives (Cruess and Alsberg 1934, Angel and Ben-
- 543 Shalom 1979, Brenes-Balbuena et al. 1992). Additionally, the alkaline conditions produced by sodium
- 544 hydroxide result in the neutralization of a range of phenolic compounds, and the neutralized phenolates
- 545 are no longer able to undergo the polymerization processes that result in undesirable brown spots formed 546 in olive processing (Brenes-Balbuena et al. 1992).
- 547
- 548 Pretzel production

549 Sodium hydroxide is used in pretzel production to create the specific color and texture that is associated 550 with pretzels, which result from an alkaline dip in sodium hydroxide solution prior to baking (Kurzius

- with pretzels, which result from an alkaline dip in sodium hydroxide solution prior to baking (Kurzius
 1975, Walsh 1992). As a high pH/basic solution sodium hydroxide, produces chemical changes on the
- solution sol
- 553 bonding networks responsible for tertiary and quaternary protein structure (Rombouts et al. 2012).
- Additionally, because the solution is basic, hydrolysis occurs in the α -1,4-glycosidic bonds present in starch
- 555 (Rombouts et al. 2012). Starch hydrolysis is responsible for the smooth surface of the characteristic pretzel
- texture, and an increased number of sugar molecules promotes browning via the Maillard reaction(Seetharaman et al. 2002, Rombouts et al. 2012).
- 558

559 Sodium hydroxide is not used to improve or recreate color, flavor, texture, or nutritional value lost during 560 processing in poultry processing or as a pH adjuster.

561

562 Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or 563 feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

564

565 When used as approved for organic processing applications, sodium hydroxide is used in low

566 concentrations (~1-2%) and is not expected to affect the nutritional quality of the processed food/feed in

- terms of sodium content. Sodium hydroxide is used as a pH regulator in many food applications, which
- 568 may result in loss of some proteins and organic acids, including vitamins, due to degradation and
- 569 neutralization at high pH.
- 570
- 571 *Cocoa processing*

The neutralization of phenolic compounds (see Equation 4) improves their water solubility. This actively works to remove compounds associated with bitter and sour tastes; however, these reactions also occur with beneficial molecules, facilitating their removal as well. Chief among these compounds are flavonols, a subcategory of flavonoids, which have been associated with beneficial antioxidant character (Katsube et al. 2006, Miller et al. 2008, Li et al. 2014, Nakabayashi et al. 2014). The polymerization of these compounds is

- also improved under the alkaline conditions, which contributes to the darkened color profile (Rodriguez et
- al. 2009, Li et al. 2014). The oxidation and polymerization processes that occur in the Dutch process greatly
- 579 reduce their antioxidant character and nutritional value (Miller et al. 2008, Li et al. 2014).
- 580
- 581 Pretzel processing
- 582 The alkaline dip in pretzel manufacture appears to have no effects on the nutritional quality of the finished 583 pretzel. The dips result in changes to the protein structure on the surface of the dough, and hydrolysis of
- amide bonds aids in the gelatinization process (Seetharaman et al. 2002, Yao et al. 2006, Rombouts et al.
- 585 2012, Timberlake 2016). However, these changes are primarily to the three-dimensional structure of the
- 586 protein, which maintains its composition of amino acids. When hydrolysis reactions occur within the
- 587 protein, they appear to be limited to the formation of relatively large peptides that remain on the dough 588 surface, which is reported to have no statistically significant changes to the protein content of the dough
- 588 surface, which is reported 589 (Yao et al. 2006).
- 590

591 Starch and sugar molecules on the surface of the dough appear to diminish in content following the

alkaline dip. However, the mechanism of this change, and the resulting change to overall nutritional

593 content, is not well established (Yao et al. 2006). Reports show that starches and small sugar molecules

- (e.g., amylose) are likely to undergo hydrolysis, and that the resulting smaller sugar molecules may have
- 595 improved solubility in the alkaline solution (Lai et al. 2004, Yao et al 2006). This would result in the loss of 596 starches and sugars on the dough surface, which may negatively affect nutritional quality. However, other
- 596 starches and sugars on the dough surface, which may negatively affect nutritional quality. However, other 597 literature reports state that these hydrolyzed starches and sugars likely undergo polymerization, which is
- 597 literature reports state that these hydrolyzed starches and sugars likely undergo polymerization, which is 598 favorable at high pH (Baunsgaard et al. 2001, Coca et al. 2004, Yao et al. 2006, Rombouts et al. 2012). These
- polymerization and gelatinization products remain on the surface of the dough to give the smooth surface
- and golden color associated with pretzels and would not result in significant nutritional changes. Given the
- 601 uncertainty of the outcome for hydrolysis products, and that the hydrolysis of starches and sugars "does
- 602 not penetrate the dough piece significantly," make it difficult to analyze the extent of nutritional changes in
- 603 pretzels, if present at all (Yao et al. 2006).

605 Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of 606 FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 607 (b)(5)).

608

604

609 There are no known reports of heavy metal contaminants present in sodium hydroxide. Due to the

610 electrolytic manufacturing process, the most likely contaminants would be the remaining starting material,

611 sodium chloride. Most salt (NaCl) is isolated from natural sources and is primarily mined or isolated via 612 the evaporation of sea, or other high-salinity water sources (EUSALT 2020). The natural sources of salt give

613 the possibility for contamination by heavy metals found within the environment where the salt was

614 isolated from (mine or aquatic system). Studies have shown that trace amounts of heavy metals may be

615 present in food or technical grade salt, although they are present well below the maximum standards set

616 forth by the Codex for food grade salt, as shown in Table 2 below (FAO 2001, Heshmati et al. 2014, SPEX

617 2020). Many heavy metals are insoluble as hydroxide salts, making handling the substance the most likely source of contamination (Atkins et al. 2008).

- 618
- 619 620

Table 2. Contaminants in Sodium Chloride (NaCl)

Contaminant	Amount detected (ppm)	Codex maximum limit (ppm)
Arsenic (As)	not detected	0.5
Copper (Cu)	1.23, 0.03	2
Lead (Pb)	0.852, 0.44	2
Cadmium (Cd)	0.229, not detected	0.5
Mercury (Hg)	0.054, not detected	0.1
Sources: EAO 2001 Heshmati et al. 2014 SPEX 2020		

621 622

ources: FAO 2001, Heshmati et al. 2014, SPEX 2020

623 Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the 624 petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) 625 and 7 U.S.C. § 6517 (c) (2) (A) (i)).

626

627 Sodium hydroxide is a strongly basic and reactive substance. In addition to food processing applications, 628 sodium hydroxide has been used as an herbicide to control tree root growth, adding some risk to the 629 environment in the event of a spill or improper use (EPA 1992). Using sodium hydroxide in water 630 treatment applications has limited the use of resulting effluent "which may not be discharged into lakes,

631 streams, ponds, estuaries, oceans, or public waters" (EPA 1992).

632

633 Manufacturing sodium hydroxide produces chlorine gas (Equations 5 and 7) (Lindstrom 1974, Atkins et al. 634

2008, Simon et al. 2014). Chlorine is a highly reactive substance that can combine with many different 635 chemicals to form chlorinated products. Due to the high reactivity of chlorine, it is not long-lived in the

636 environment and is unlikely to cause environmental damage in its natural gas form (ATSDR 2010).

637 However, the various chlorinated products formed from the release of chlorine gas to the environment

638 could result in the potential for damage to the environment and biodiversity.

639

640 Lye peeling is a historically important method of processing fruits and vegetables and is still in use for

641 some peeling processes in non-organic agriculture (Rock et al. 2012, USDA 2016). However, the use of

642 sodium hydroxide in peeling processes for fruits and vegetables results in basic wastewater, which also

643 includes organic matter liberated from the treated fruits and vegetables (Garcia and Barrett 2006, Rock et al.

644 2012). Unless properly treated, this wastewater increases the pH of soils, and contributes to water pollution

645 (Garcia and Barrett 2006, Rock et al. 2012). The presence of organic matter and remaining base results in a 646

high biological oxygen demand (BOD), which is a measure of the amount of oxygen required for the 647 breakdown of the organic matter via aerobic microorganisms (Sawyer et al. 2003, Garcia and Barrett 2006,

648 Rock et al. 2012). For these reasons, the NOP has prohibited the use of sodium hydroxide for peeling fruits

649 and vegetables at 7 CFR 205.605(b). However, these peeling processes use a much higher concentration of

650 sodium hydroxide (8-25%) than the approved uses (1-2%) (Shi and LeMaguer 2000, Rock et al. 2012). At the

651 time of this report, the author did not find any reports of adverse environmental effects from the relatively

- 652 low concentrations of sodium hydroxide used in approved organic processes, including increases BOD of 653 aquatic systems. 654 655 Evaluation Question #10: Describe and summarize any reported effects upon human health from use of 656 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 657 (m) (4)). 658 659 Sodium hydroxide is a strong base and is a highly reactive and corrosive compound that has been placed 660 into Toxicity Category I by the EPA (EPA 1992). Upon dissociation from the sodium cation (Na⁺), the 661 reactive hydroxide (OH-) begins to disrupt biological tissue. These disruptions occur in many forms 662 including in protein denaturation and dissolution, collagen disruption, saponification (hydrolysis) of fat 663 molecules, emulsification of cellular membranes, and cell death (EPA 1992, Flomenbaum et al. 2006, SC 664 2016, LC 2018). 665 666 Sodium hydroxide is especially hazardous when consumed, although all reported cases of poisoning from 667 sodium hydroxide in adults are from intentional ingestion, most of which are reported in developing 668 countries (Chang et al. 2011). Cases of accidental sodium hydroxide in children are often fatal (NRC 1984, 669 Chang et al. 2011). The reactive and strongly basic nature of sodium hydroxide makes the substance 670 particularly disruptive to the gastrointestinal tract (NRC 1984, ATSDR 2002, Flomenbaum et al 2006, Chang 671 et al. 2011). When sodium hydroxide is ingested, abdominal pain is frequent due to the necrosis and 672 stricture of the esophagus, stomach, and gastrointestinal tract (ATSDR 2002, Chang et al. 2011). 673 674 Sodium hydroxide is severely damaging to lung tissue and can result in degradation and dissolution of the 675 lungs (NRC 1984, ATSDR 2002). Most reported deaths from sodium hydroxide are due to a combination of 676 effects from ingestion, shock, infection of corroded tissues, and lung damage (ATSDR 2002). 677 678 In addition to the dangers from ingestion, the substance is also highly corrosive to surface tissue. Severe 679 ocular degeneration has been reported to occur upon contact with the substance, resulting in possible 680 severe pain, irritation, and blindness (EPA 1992, ATSDR 2002, Flomenbaum et al. 2006, SC 2016, LC 2018). 681 Sodium hydroxide can penetrate skin, resulting in the potential for deep and slow-healing chemical burns 682 (EPA 1992, ATSDR 2002, Flomenbaum et al. 2006, SC 2016, LC 2018). 683 684 Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned 685 substance unnecessary (7 U.S.C. § 6518 (m) (6)). 686 687 *Cleaning agent/degreaser* 688 As discussed in the action of the substance section, the strongly basic nature of sodium hydroxide allows 689 for the dissolution and removal of organic matter. While strong bases, and sodium hydroxide specifically, 690 are most used in commercial cleaning agents and degreasers, amide and ester functionalities can be 691 hydrolyzed under acidic conditions as well (Timberlake 2016). Under acidic conditions, amides and esters 692 are hydrolyzed to carboxylic acids rather than carboxylate salts, and ammonium salts are produced in 693 place of amines for amides (Timberlake 2016). Despite the slight change in products, acidic hydrolysis 694 reactions yield smaller molecules with enhanced water solubility to facilitate the dissolution and removal
 - 695 of organic matter.
 - 696
 - 697 Poultry processing
 - 698 The scalding process is ubiquitous in poultry processing. However, sodium hydroxide is not a necessary
- 699 additive for the scalding process. While the alkaline nature of sodium hydroxide scalds reduces salmonella,
- 700 populations compared to normal scalding conditions, a common alternative is to use higher temperatures
- 701 (McKee et al. 2008). However, while the higher temperature scald helps to facilitate bacterial removal, it
- 702 also removes cuticle from the poultry, resulting in a pale appearance and reducing the quality of the
- 703 poultry products (McKee et al. 2008).

705 Olive processing

Sodium hydroxide treatments are the predominant industry practice for removing the bitter taste from ripe

- 707 olives (Brenes-Balbuena et al. 1992, Johnson and Mitchell 2019). However, there are several curing
- alternatives, that include soaking in water, brine (saturated salt solution), or with the application of dry
- salt. (ANR 2007). However, water-curing olive processes yield a more bitter product due to the relatively
 low water solubility of the bitter phenolic compounds. Likewise, dry salt processing results in increased
- 710 low water solubility of the bitter precion compounds. Encewise, any sait processing results in increased 711 bitterness compared to sodium hydroxide treatments (ANR 2007). Brine processing of olives offers an
- alternative that is based on natural fermentation processes, although it requires a longer cure time of up to
- 713 six months (ANR 2007).
- 714

715 Recent reports have offered alternatives to the basic neutralization provided by applying sodium

716 hydroxide. The use of enzyme (protein) catalysts has been reported to effectively remove the phenolic

717 compounds associated with olive bitterness (Johnson and Mitchell 2018). According to Johnson and

718 Mitchell (2018), the bitter phenol compounds are hydrolyzed by the applied enzyme, resulting in products 719 that have either no bitterness or at least a reduced bitterness. (Mitchell and Johnson 2018).

720

Additionally, using polymeric chromatography, specifically Amberlite resin columns, has been reported to remove phenols responsible for bitter tastes. In this alternative method, the brined olives are processed through an Amberlite resin, to which the phenols adsorb and are then removed from the brine solution (Johnson and Mitchell 2019). The Amberlite resin material can be washed with ethanol for regeneration and reuse (Johnson and Mitchell 2019). While new alternatives to sodium hydroxide neutralization of phenols are promising, they have yet to be applied on a large scale (Johnson and Mitchell 2019).

There are no suitable alternatives for sodium hydroxide in alkaline dough dips for pretzel production, pHadjustment, or sugar processing.

730

727

Final Formation F

734

735 Potassium hydroxide is the best alternative to sodium hydroxide within all the applications below.

736 However, potassium hydroxide has the same negative aspects as sodium hydroxide. Potassium hydroxide

737 is more reactive than sodium hydroxide, making it a more dangerous chemical to work with and store, and

738 offer increased hazards to aquatic life (USDA 2016). Additionally, potassium hydroxide is a more

expensive base than sodium hydroxide, limiting its commercial appeal as an alternative to sodiumhydroxide (USDA 2016).

- 741
- 742 *Cleaning agent/degreaser*

743 There are several substances that are alternatives to sodium hydroxide for use as a cleaning agent or

degreaser. Calcium hydroxide (Ca(OH)₂) is also a strong base, with the potential to promote hydrolysis

reactions (Silberberg 2003, Timberlake 2016). However, unlike sodium hydroxide, calcium hydroxide is

- 746 limited by low water solubility (Silberberg 2003). The low solubility of calcium hydroxide limits its
- maximum hydroxide (OH) concentration, and therefore its capacity as a cleaning agent or degreaser.
- 748 Sodium carbonate (Na₂CO₃) and sodium bicarbonate (baking soda, NaHCO₃) are also alternatives that are
- vised in commercial cleaning agents (Silberberg 2003). However, the reduced basicity to carbonate (CO₃²⁻)
- and bicarbonate ($HCO_{3^{-}}$) have reduced reactivity. This is especially important in some cleaning
- applications, where the strongly basic nature of soluble hydroxide sources is required for the removal of
- 752 organic matter. 753

754 The ability of acids to catalyze the hydrolysis of amides and esters, thereby breaking up and removing

- view of the second seco
- acids, although all are weak acids (do not dissociate completely when dissolved in water) (Silberberg 2003).
- 757 These acids include citric acid, lactic acid, L-malic acid, tartaric acid, alginic acid, ascorbic acid,
- hypochlorous acid, and phosphoric acid. Due to the weak strength of these approved acids, they would
- need to be used in a higher concentration than sodium hydroxide to produce the same hydrolysis results.

760 761 *pH adjustment*

- The basic character of sodium hydroxide allows it to be used to regulate pH and increase the alkalinity of applied systems. The National List includes many basic substances that are possible alternatives for pH regulation applications. These include calcium carbonate (CaCO₃), calcium sulfate (CaSO₄), magnesium sulfate (MgSO₄), sodium carbonate (Na₂CO₃), sodium bicarbonate (NaHCO₃), calcium citrate, calcium hydroxide (Ca(OH)₂), potassium carbonate (K₂CO₃), potassium citrate, potassium lactate, potassium
- phosphate (K₃PO₄), sodium citrate, and sodium lactate.
- Among the possible alternatives listed above, only calcium hydroxide (Ca(OH)₂) is also a strong base.
- 770 However, calcium hydroxide has low water solubility, which reduces its usefulness as a pH adjuster
- 771 (Silberberg 2003). Calcium carbonate (CaCO₃) also has low solubility, which coupled with the weak
- strength of the base, makes it a poor substitute for sodium hydroxide. The remaining weak bases have
- adequate water solubility to allow for their use as pH regulators and may be appropriate alternatives to
- sodium hydroxide in specific processing applications.
- 776 Cocoa processing
- 777 Sodium hydroxide (NaOH) and potassium carbonate (K₂CO₃) are the predominant alkali salts used in the
- 778 Dutch process (Miller et al. 2008, Li et al. 2014). However, the literature includes many alternatives for
- cocoa alkalization, specifically potassium carbonate (K₂CO₃), sodium carbonate (Na₂CO₃), ammonium
- 780 carbonate ((NH₄)₂CO₃), magnesium carbonate (MgCO₃), potassium bicarbonate (KHCO₃), sodium
- 781 bicarbonate (NaHCO₃), ammonium bicarbonate (NH₄HCO₃), ammonium hydroxide (NH₄OH), and
- magnesium oxide (MgO) (Moser 2015). However, all of the above alkali salts are weaker bases than sodium
- 783 hydroxide and would likely require increased concentrations to achieve a similar pH change and alkaline
- 784 conditions.
- 785
- 786 *Poultry processing*
- 787 There are several approved substances that are alternatives for sodium hydroxide in poultry processing,
- 788 including tartaric acid, citric acid, lactic acid, L-malic acid, potassium iodide (KI), calcium chloride (CaCl₂),
- 789 magnesium chloride (MgCl₂), potassium chloride (KCl), and calcium carbonate (CaCO₃) potassium
- real carbonate (K₂CO₃), and calcium hydroxide (Ca(OH)₂). Calcium carbonate, potassium carbonate, and
- calcium hydroxide offer the same mode of action as sodium hydroxide by increasing the pH of the scald
- solution. However, both calcium carbonate and calcium hydroxide have poor water solubility, which limits
- their ability to raise the pH of the scald solution. The carbonate (CO_{3^2}) anions found in calcium carbonate
- and potassium carbonate are weakly basic, especially compared to sodium hydroxide. The reduced
- alkalinity of calcium carbonate and potassium carbonate make them poor substitutes for sodium hydroxide
- in poultry processing applications.
- 797
- 798 The acids (tartaric, citric, lactic, and L-malic) offer a similar mode of action to sodium hydroxide, although
- with reduced solution pH. The reduced pH results in denaturation of proteins, especially at the increased temperatures employed during the scalding process (Barbut 2001, Zhuang et al. 2013, Timberlake 2016).
- 801
- 802 Potassium iodide (KI), potassium chloride (KCl), magnesium chloride (MgCl₂) and calcium chloride
- 803 (CaCl₂) additions would increase the salinity of the scald as an alternative mode of action to pH
- adjustment. The increased scald salinity promotes cellular crenation, a dehydration that results in the
- 805 diffusion of water from the cell to the solution to establish a concentration equilibrium (Timberlake 2016).
- 806 However, the increased salt content in of the scald solution may result in altered organoleptic properties
- 807 and nutritional content of the poultry products.
- 808 800 OI
- 809 Olive processing
- 810 Given the strongly basicity required to achieve the neutralization of phenolic compounds, there are no
- 811 natural alternatives to sodium hydroxide for olive processing for either reducing bitterness, or preventing
- 812 discoloration.
- 813

Pretzel production

814 815 Given the high pH required for the alkaline dip in pretzel production, alternatives to sodium hydroxide are 816 unlikely to be commercially viable. Calcium carbonate (CaCO₃), sodium carbonate (Na₂CO₃), potassium 817 carbonate (K₂CO₃) and sodium bicarbonate (NaHCO₃) are approved basic compounds, but the anions in 818 these compounds (CO_3^{-2-} and HCO_3^{--}) are weakly basic which do not make them feasible replacements for 819 the denaturation and hydrolysis of surface proteins and starch molecules in pretzel production (Kurzius 820 1975, Walsh 1992, Seetharaman et al. 2002, Rombouts et al. 2012). Calcium hydroxide (Ca(OH)₂) is a strong 821 base; however, it has limited value for use in pretzel production due to its poor water solubility. 822 823 Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for 824 the petitioned substance (7 CFR § 205.600 (b) (1)). 825 826 There are no organic agricultural products that could serve as an alternative for sodium hydroxide. 827 828 **Report Authorship** 829 830 The following individuals were involved in research, data collection, writing, editing, and/or final 831 approval of this report: 832 833 Philip Shivokevich, Visiting Assistant Professor of Chemistry, University of Massachusetts 834 Amherst 835 Anna Arnold, Technical Editor, Savan Group 836 837 All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing 838 Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions. 839 840 References 841 842 [Acropolis] Acropolis Organics. Olives. [accessed May 2020]. 843 https://www.acropolisorganics.com/services/olives/ 844 845 Andrews P, Busch JL, De Joode T, Groenewegen A, Alexandre A. 2003. Sensory properties of virgin olive 846 oil polyphenols: identification of deacetoxy-ligstroside aglycon as a key contributor to pungency. 847 Journal of Agricultural and Food Chemistry. 51: 1415-1420. 848 849 Angel S, Ben-Shalom N. 1979. Research on olive quality in Israel for processing, i, prevention of brown 850 spotting in green olives for pickling. Confructa. 24: 79-84. 851 852 [ANR] University of California Division of Agriculture and Natural Resources. 2007. Olives: safe methods 853 for home pickling. [accessed Jan 2020] https://anrcatalog.ucanr.edu/pdf/8267.pdf 854 855 [ATSDR] Agency for Toxic Substances and Disease Registry (US). 2010. Chlorine. Washington (DC): 856 Department of Health and Human Services, Public Health Service. [accessed Nov 2019]. 857 https://www.atsdr.cdc.gov/phs/phs.asp?id=683&tid=36. 858 859 [ATSDR] Agency for Toxic Substances and Disease Registry (US). 2002. Sodium hydroxide. Washington 860 (DC): Department of Health and Human Services, Public Health Service. [accessed Oct 2019]. 861 https://www.atsdr.cdc.gov/toxfaqs/tfacts178.pdf. 862 863 Atkins P, Overton T, Rourke J, Weller M, Armstrong F. 2008. Inorganic chemistry. 4th ed. New York (NY): 864 Oxford University Press. 865 866 Barbut S. 2001. Poultry products processing: an industry guide. Boca Raton (FL): CRC Press.

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