

United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet

<https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances>

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.

Ozone

Handling/Processing

Identification

Chemical Names:	Trade Names:¹
Ozone	Ozonator; Ozone Systems; Sorbal; Villa 3000
Other Names:	CAS Numbers:
2-Trioxiden-2-ium-1-ide; Triatomic oxygen; Triooxygen; Triooxygene	10028-15-6
	Other Codes:
	EINECS: 233-069-2

Summary

This full scope technical report provides updated and new information to the National Organic Standards Board (NOSB) to support the sunset review of ozone, listed at 7 CFR 205.605(b)(21). This report focuses on the uses and applications of ozone in organic processing and handling.

The only review to include ozone on the National List was conducted in 1995 (NOP, 1995). The NOSB recommended listing the substance without annotation in 1995 (NOSB, 1995a). Ozone was included on the National List of Allowed and Prohibited Substances (hereafter referred to as the “National List”) with the first publication of the National Organic Program (NOP) Final Rule ([65 FR 80548](#), December 21, 2000). The NOSB has since continued to recommend its renewal in 2007, 2010, 2017, and 2020 (NOSB, 2007, 2010, 2015, 2020a). Representatives from fruit producers and organic trade or business organizations expressed support for the continued listing of ozone, prior to the Fall 2020 NOSB meeting (NOSB, 2020b). They noted that ozone was very effective as a sanitizer/disinfectant and pest control agent in packing houses, helping producers meet requirements of the Food Safety Modernization Act.

Ozone is listed at § 205.605(b)(21) as a nonagricultural synthetic substance and may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” without any annotation that limits its source or use.

Characterization

Composition of the Substance:

Ozone is a molecule composed of three oxygen atoms (O₃) (National Center for Biotechnology Information, 2024). It is often represented with the central oxygen atom connected by a double bond with one oxygen atom and connected by a single bond with another oxygen atom (see [Figure 1](#)). However, in nature, the electrons are shared equally between the two bonds.

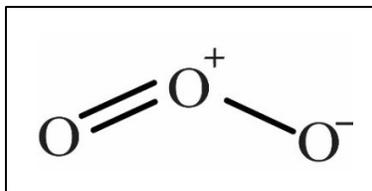


Figure 1: Chemical structure of O₃

Source or Origin of the Substance:

Ozone occurs naturally, mostly in the upper atmosphere. Naturally occurring ozone is often the product of ultraviolet radiation on atmospheric oxygen (O₂) (National Center for Biotechnology Information, 2024).

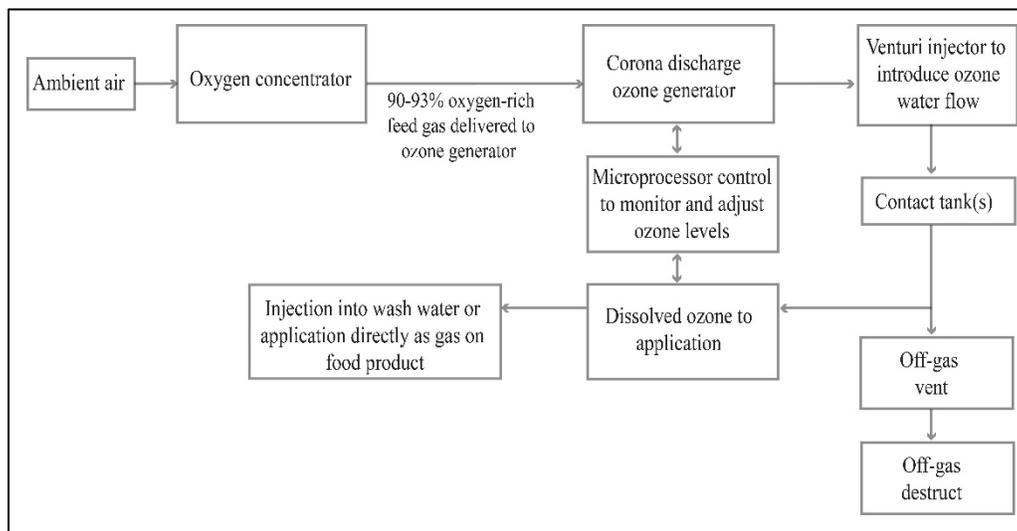
- Producers generate most ozone by applying a low-current electrical discharge (“corona discharge”) to atmospheric oxygen (Foley & Kirschner, 2022).
- Increasingly, producers generate ozone through the electrolysis of water (Okada & Naya, 2012).
- Producers can also generate ozone photochemically by exposing oxygen in air or water to ultraviolet light (UV) (Horvath et al., 1985; Wojtowicz, 2005).

¹ Trade names are for equipment used to generate ozone on site.

56
 57 The UV method produces relatively low ozone concentrations compared to corona discharge (Wojtowicz, 2005).
 58 However, it may be suitable for producers aiming to generate small amounts of ozone in combination with
 59 disinfection effects provided by ultraviolet light (Foley & Kirschner, 2022). We found references to an older method
 60 for synthesizing ozone by feeding liquid oxygen between two electrodes separated by an inert gas (such as helium),
 61 that forms a barrier that ionizes to form plasma (Grosse & Stokes, 1967; Stokes & Streng, 1965).
 62

63 Ozonation occurs in several steps (see [Figure 2](#)) (Tapp & Rice, 2012).

- 64 1. Most low-current electrical discharge systems used in food processing facilities first concentrate oxygen
- 65 from atmospheric gases to about 93% pure O₂.
- 66 2. The oxygen then passes through the corona discharge ozone generator.
- 67 3. The ozone generation process is monitored and adjusted to maintain concentration.
- 68 4. Producers may either apply the ozone directly to food, or inject it into wash water, depending on the food
- 69 and application. When applied directly, the generator releases ozone as a gas into the storage chamber or
- 70 directly on the product. In the latter case, producers dissolve ozone into water used to wash food.
- 71 5. Producers can off-gas ozone either directly or treat it to accelerate decomposition into O₂ before releasing it
- 72 into ambient air.
 73



74
 75 **Figure 2: Flow diagram of the generation, application, and control of ozone in a food processing plant. Adapted from**
 76 **Tapp & Rice (2012)**
 77

78 Nuclear reactors also generate large quantities of concentrated ozone. Ozone is a by-product of the irradiation of
 79 ambient oxygen with combined beta, gamma, and neutron radiation in the course of operation of the reactors
 80 (Horvath et al., 1985). However, a practical way of separating ozone from radioactive material has prevented
 81 commercialization of this source (Wojtowicz, 2005). Even if the operators of nuclear reactors overcome such
 82 technical barriers, nucleo-chemical ozone sources still present additional hazards if used to handle and process food
 83 (Guzel-Seydim et al., 2004).
 84

85 **Properties of the Substance:**

86 Ozone gas ranges from colorless to pale blue in appearance (see [Table 1](#)). In gaseous form, it is unstable and highly
 87 reactive. Ozone is heavier than air and rapidly decomposes into atmospheric oxygen.
 88

89 **Table 1: Physical and chemical properties of ozone** (Foley & Kirschner, 2022; National Center for Biotechnology Information,
 90 2024; Wojtowicz, 2005)

Property	Value
Physical state and appearance	Gas at 0 °C and 1 atm
Odor	Pungent
Color	Colorless to bluish in gas form; dark blue in liquid form; blue-black crystals in solid form
Molecular weight	47.998 g/mol
Specific gravity	1.61 at 21.1 °C and 1 atm (Compressed Gas Association, 1999)
Solubility	1.06 g L ⁻¹ in water at pH 3.5 at 0 °C and 1 atm
Boiling point	-112 °C
Melting point	-192 to -193 °C

Property	Value
Critical temperature	-12.1 °C
Vapor pressure	41,257 mm Hg at -12 °C
Stability	Unstable gas that rapidly decomposes to O ₂ at 0 °C and 1 atm
Reactivity	Reacts with virtually every element with the exceptions of most noble metals, fluorine, and inert gases

91
 92 Temperature, pressure, and ionic strength of a solution all influence the solubility of ozone (Wojtowicz, 2005).
 93 Solubility is increased by pressure and decreased by temperature (Wojtowicz, 2005). Ozone is pH neutral, but is
 94 more stable in solutions with low (acidic) pH (Galdeano et al., 2018). Specific gravities of gases are relative to air,
 95 with air having a value of 1.0 at standard temperature and pressure (Gordon, 2024). Thus, ozone is heavier than air.
 96

97 Ozone is a strong oxidizing agent with an oxidation potential of 2.07 eV (Foley & Kirschner, 2022). Only a few
 98 other oxidizing agents [such as fluorine (F₂), the hydroxyl radical (OH), and nascent or monoatomic oxygen (O)]
 99 have a greater oxidation potential (Foley & Kirschner, 2022). Oxygen and the hydroxyl radical are both produced as
 100 decomposition products of ozone in aqueous solution (Dubey et al., 2022; Khadre et al., 2001). While ozone has a
 101 distinct pungent odor, it has no flavor and leaves no taste in ozonated water (Wojtowicz, 2005).
 102

103 **Specific Uses of the Substance:**

104 Organic processors and handlers report that ozone is widely used as a sanitizer and to clean equipment (CCOF,
 105 2020; Organic Trade Association, 2020). Organic fresh produce handlers use it on food contact surfaces, in direct
 106 food contact, as an ethylene scavenger, and to control insects (Organic Produce Wholesalers Coalition, 2020).
 107 Ozone is also used to sanitize barrels used to make organic wine (CCOF, 2020). One organic handler cited the Food
 108 Safety Modernization Act ([Public Law 111-353](#), January 4, 2011) as creating the necessity for effective sanitizers in
 109 fresh fruit (Austin, 2020). While there are other options available, handlers may rotate different sanitizers as a
 110 strategy to prevent pathogen resistance (Austin, 2020). Specific examples include aqueous ozone to sanitize organic
 111 cherries prior to packing and gaseous ozone to prevent post-harvest diseases in bananas (Organic Produce
 112 Wholesalers Coalition, 2020).
 113

114 The primary use of ozone globally is as a water treatment (Wojtowicz, 2005). In this capacity, ozone oxidizes
 115 organic and inorganic compounds, improving water quality when used as a broad-scope disinfectant. In food
 116 production, handlers also apply ozone directly to food as an antimicrobial treatment (O'Donnell et al., 2012).
 117 Consequentially, ozone is also a preservative (see [Evaluation Question #3](#), below).
 118

119 Ozone can reduce decay and extend the storage life of a variety of foods (see [Table 2](#), below). Processors can apply
 120 ozone both as a wash water disinfectant that reduces the populations of spoilage organisms and as a gas discharged
 121 in controlled- or modified-atmosphere refrigeration chambers (Sarron et al., 2021; B. Tiwari & Muthukumarappan,
 122 2012). Sarron et al. (2021) found that most studies of lettuce and carrots involved treatment with ozonated wash
 123 water, while most studies of tomatoes involved treatment with gaseous ozone. Ozone gas is desirable as a non-
 124 thermal, dry antimicrobial for food products that need to avoid heat and moisture to preserve quality (Afsah-Hejri et
 125 al., 2020; Gyawali et al., 2024). Researchers identified that the most studied fresh vegetables treated with ozone are
 126 lettuce, carrots, and tomatoes (Sarron et al., 2021; B. Tiwari & Muthukumarappan, 2012).
 127

128 Ozone is also used as an alternative to sulfiting agents to make no-sulfite-added wines (Mostashari et al., 2022). A
 129 common use is to sanitize oak barrels between vintages (Stadler & Fischer, 2020). It can also be used for post-
 130 harvest treatment of the grapes to inactivate undesirable yeasts and microorganisms that are antagonistic to yeast
 131 fermentation and to sanitize clean-in-place systems (Mostashari et al., 2022).
 132
 133

Table 2: Food and beverages commonly treated with ozone

Food	Effect of ozone on pathogens and food products	References
Carrots	Ozonated wash water effectively extends carrot storage life.	(Sarron et al., 2021; N. Singh et al., 2002)
Dried fruit	Fumigation with ozone inhibits mold, controls insects, and extends the storage life of dates, figs, and other dried fruits.	(Boopathy et al., 2022; Prabha et al., 2015)
Fresh fruits and vegetables	The storage life of apples and oranges is prolonged by the degradation of ethylene by ozone in a controlled or modified atmosphere.	(Prabha et al., 2015; B. Tiwari & Muthukumarappan, 2012)
Fruit juices	Ozone can achieve a 5-log reduction of <i>E. coli</i> , <i>S. spp</i> , and <i>L. monocytogens</i> in apple, tomato, peach, orange, and other juices.	(Pandiselvam et al., 2019)
Grains	Ozone controls insects and mycotoxin-producing molds in stored corn, wheat, soybeans, flaxseed, and other grains and oilseeds.	(Jian et al., 2013; B. K. Tiwari et al., 2010)
Lettuce	Ozonated water extends the shelf life of fresh-cut lettuce.	(Beltrán et al., 2005)

Food	Effect of ozone on pathogens and food products	References
Milk and dairy products	Ozone gas is used to sterilize clean-in-place dairy equipment and as an atmospheric treatment in cheese storage/aging rooms to prevent unwanted molds.	(Pandiselvam et al., 2019)
Peanuts and tree nuts	Ozone inhibits <i>A. niger</i> and reduces aflatoxin and other mycotoxins in peanuts. Ozone gas is a dry processing technique also effective in decontaminating almonds, Brazil nuts, and pistachios.	(de Alencar et al., 2012; Gyawali et al., 2024)
Poultry	Ozone is used to treat poultry processing chill water.	(Pohlman, 2012)
Beef	Ozone spray can decontaminate pathogenic bacteria on beef carcasses; ozone gas in modified atmosphere refrigeration inhibits <i>Clostridium perfringens</i> .	(Pohlman, 2012)
Dried spices	Fumigation with ozone caused 100% mortality of insects in coriander and turmeric.	(Boopathy et al., 2022)
Tomatoes	Storage life is extended in modified atmosphere chambers with elevated levels of ozone gas.	(Sarron et al., 2021)
Wine	Ozone can be used as an alternative to sulfites as a sanitizer and antimicrobial in oak barrels, as a post-harvest treatment to inactivate undesirable yeasts and other microorganisms, and to sanitize equipment.	(Mostashari et al., 2022; Stadler & Fischer, 2020)

134

135 **Approved Legal Uses of the Substance:**

136 Food manufacturers use ozone as an antimicrobial and pest control agent. Therefore, the relevant legal uses of this
 137 substance are regulated by the FDA and EPA (US EPA, 2021; US FDA, 2023).

138

139 EPA

140 Pesticidal devices such as ozone generators do not have to be registered with the EPA, but they are still subject to
 141 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (US EPA, 2021). Manufacturers of ozone
 142 generating equipment are required to register with EPA and report to the agency the names and addresses of the
 143 establishments that install such devices (40 CFR 152.500; [41 FR 51065](#), November 19, 1976).

144

145 Ozone located in the lowest boundary of the stratosphere, or ground-level ozone, is classified as a pollutant by the
 146 U.S. Environmental Protection Agency (US EPA) under the Clean Air Act.

147

148 FDA

149 Ozone is Generally Recognized as Safe (GRAS) by the FDA without limitations other than current Good
 150 Manufacturing Practices. The FDA notes its use as an additive in contact with food, including:

- 151 • meat and poultry [21 CFR 173.368(d)]
- 152 • raw agricultural commodities [21 CFR 173.368(e)]
- 153 • bottled water (21 CFR 184.1563)

154

155 The FDA lists ozone as an antimicrobial agent that processors may use in contact with food, including meat and
 156 poultry [21 CFR 173.368(d)], unless such use is precluded by standards of identity established by the USDA’s Food
 157 Safety Inspection Services (FSIS) (9 CFR 319 or 9 CFR 321, subpart P).

158

159 When producers use ozone on raw agricultural commodities such as fruit, its use is limited as an antimicrobial agent
 160 provided for under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(q)(1)(B)(i)]. However, producers
 161 cannot use ozone [21 CFR 173.368(d)]:

- 162 • in the field [21 USC 321(q)(1)(B)(i)(I)],
- 163 • in a treatment facility that changes the status of the produce from a raw agricultural commodity to a
 164 processed one [21 U.S.C 321(q)(1)(B)(i)(II)], or
- 165 • during transportation from the field to the treatment or processing facility [21 U.S.C 321(q)(1)(B)(i)(III)].

166

167 Bottled water treated with ozone must meet the microbiological, physical, chemical, and radiological standards
 168 established by the FDA prior to its treatment (21 CFR 184.1563; 165.110).

169

170 The FDA states the following regarding the maximum acceptable level:

171

172 *Ozone is a toxic gas with no known useful medical application in specific,*
 173 *adjunctive, or preventive therapy. In order for ozone to be effective as a*
 174 *germicide, it must be present in a concentration far greater than that which can*
 175 *be safely tolerated by man and animals [21 CFR 801.415(a)].*

176

177 Food safety regulations related to meat, milk, eggs, dairy products, juices, and other foods that pose a risk of food-
178 borne pathogens require pathogens of human health concern to be reduced by 99.999% or 10^5 , commonly referred to
179 as a 5-log reduction (US FDA, 2007; US FSIS, 2021). After a review of numerous scientific studies, researchers
180 determined that ozone use consistently resulted in the industry standard of a 5-log reduction in pathogens (Prabha et
181 al., 2015). The FDA states that the Hazard Analysis and Critical Control Point (HACCP) Plan requires juice
182 manufacturers to monitor and validate that ozone and other non-thermal methods meet the 5-log standard
183 (21 CFR 120.25).

184

185 **Standard of identity for ozone under FDA:**

186 The FDA describes the standard of identity for ozone as follows (21 CFR 173.368):

187

188 Ozone (CAS Reg. No. 10028-15-6) may be safely used in the treatment, storage,
189 and processing of foods, including meat and poultry (unless such use is precluded
190 by standards of identity in 9 CFR part 319), in accordance with the following
191 prescribed conditions:

192

193 (a) The additive is an unstable, colorless gas with a pungent,
194 characteristic odor, which occurs freely in nature. It is produced
195 commercially by passing electrical discharges or ionizing radiation
196 through air or oxygen.

197

198 (b) The additive is used as an antimicrobial agent as defined in
199 §170.3(o)(2) of this chapter.

200

201 (c) The additive meets the specifications for ozone in the Food
202 Chemicals Codex, 7th ed. (2010), pp. 754-755, which is incorporated by
203 reference. ...

204

205 (d) The additive is used in contact with food, including meat and poultry
206 (unless such use is precluded by standards of identity in 9 CFR part 319
207 or 9 CFR part 381, subpart P), in the gaseous or aqueous phase in
208 accordance with current industry standards of good manufacturing
209 practice.

210

211 (e) When used on raw agricultural commodities, the use is consistent
212 with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic
213 Act (the act) and not applied for use under section 201(q)(1)(B)(i)(I),
214 (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act.

215

216 **GRAS affirmation for ozone under FDA:**

217 The FDA states that ozone is GRAS as an antimicrobial agent (21 CFR 173.368 and 21 CFR 184.1563) when used
218 in accordance with good manufacturing or feeding practices.

219

220 **Specifications for ozone in the Food Chemicals Codex:**

221 The 14th edition of the *Food Chemicals Codex* (U.S. Pharmacopeia, 2024) specifies the following for ozone:

222

223 **Description:** Ozone occurs as an unstable, colorless gas. It is produced *in situ*
224 from oxygen either by ultraviolet irradiation of air or by passing a high-voltage
225 discharge through air. It is a potent oxidizing agent that decomposes at ambient
226 temperature to molecular oxygen.

227

228 **Identification:** Laboratory procedure uses sodium hexametaphosphate,
229 ammonium chloride, and ammonium hydroxide as reagents. A sample of
230 ozonated water is compared to a blank water sample that has not been ozonated.
231 The assay uses an indigo stock solution, phosphoric acid, monobasic sodium
232 phosphate, and malonic acid as reagents.

233

234 **Assay:** Concentrations in ozonated water of between 0.01 and 0.5 mg/L of O₃.

235

236 **Arsenic (as As):** Not established.

237

Chloride: Not established.

237 **Heavy Metals (as Pb):** Not established.
238 **Nonvolatile Residue:** Not established.
239 **Sulfur Compounds:** Not established.

240
241 However, the FDA incorporates the standard of identity for ozone used by *Food Chemicals Code* 7th Edition
242 [21 CFR 173.368(c)].

243 244 **Action of the Substance:**

245 246 Ozone as an oxidizing agent

247 Ozone is a strong oxidizing agent. Its potential oxidizing capacity makes ozone a powerful antimicrobial substance
248 (Guzel-Seydim et al., 2004). Oxidizing agents typically contain electronegative atoms (such as oxygen) that strongly
249 attract electrons from other molecules. Oxidation damage is caused by oxidizing agents that chemically react with
250 biological components, disrupting their normal function.

251
252 More specifically, microorganisms are rapidly inactivated by a combination of reactions with intracellular enzymes,
253 nucleic materials, and components of their enveloping protein layer (e.g. spore coats, viral capsids, or cell
254 envelopes) (Khadre et al., 2001). Microbial inactivation by ozone is a complex process (Greene et al., 2012). Ozone
255 disintegrates the cell wall and causes it to rupture (lysis) under the high oxidation potential of ozone (Aslam et al.,
256 2020; Greene et al., 2012). Once exposed, the cell-content constituents (such as enzymes and nucleic acids) are
257 deactivated (Greene et al., 2012; Khadre et al., 2001).

258
259 Ozone may also interfere with respiratory function in some microorganisms (Khadre et al., 2001). Researchers think
260 that spores exposed to ozone are disrupted and degraded, exposing the core and cortex to further action by the ozone
261 (Aslam et al., 2020; Khadre et al., 2001). Ozone inactivates viruses by what appears to be a similar mode of action
262 of removing the viral outer coat (Khadre et al., 2001). Another hypothesis is that ozone damages viral RNA (Khadre
263 et al., 2001). Protozoan eggs (oocytes) are also susceptible to the effects of ozone (Guzel-Seydim et al., 2004).

264 265 Synergism with essential oils

266 Essential oils can work synergistically with ozone, achieving greater pathogen reduction for products that are not
267 appropriate for thermal processing methods such as carrots, lettuce, and other leafy greens (Dev Kumar &
268 Ravishankar, 2019; Floare et al., 2023; N. Singh et al., 2002).

269 270 Interaction with ethylene

271 Ozone's interaction with the ripening agent ethylene is controversial and inconsistent (Prabha et al., 2015; Tokala et
272 al., 2018). In some studies, researchers demonstrated that ethylene production increases when ozone is introduced, a
273 phenomenon believed to be related to increased oxidative stress (Forney et al., 2003). In another study, researchers
274 discovered that ethylene levels decreased in separate storage chambers containing table grapes and peaches,
275 delaying degradation caused by continued ripening (Palou et al., 2002).

276 277 **Combinations of the Substance:**

278 Processors do not typically combine ozone generated on-site for antimicrobial treatment with any substance other
279 than water, but research indicates that it may be used in conjunction with ultraviolet light, ultrasound, or cold plasma
280 as physical methods to increase efficacy (Fan & Song, 2020; O'Donnell et al., 2012). Ozone may also be used in
281 combination with essential oils that have antioxidant properties and antimicrobial activity (Floare et al., 2023; N.
282 Singh et al., 2002).

283
284 Combinations of ozone with UV light or hydrogen peroxide (H₂O₂) result in advanced oxidation processes (AOPs)²
285 that are effective against the most resistant organisms (Khadre et al., 2001). However, processors generally do not
286 use AOP techniques for direct food contact. Processors prefer to use these methods for wastewater treatment and
287 equipment sanitizing because of their non-selective reactions (Greene et al., 2012). Direct food application of AOPs
288 to reduce pathogens and maintain food quality remains a challenge for researchers (Fan & Song, 2020).

289
290 Ozone generation by corona discharge may produce other incidental gases, such as nitrogen oxides (NO_x) (Foley &
291 Kirschner, 2022; Horvath et al., 1985; Tapp & Rice, 2012). These other gases are considered air pollutants found in
292 conjunction with ozone (US EPA, 2024a).

293

² Advanced oxidation processes (AOPs) generate highly reactive intermediates—particularly the hydroxyl radical (OH[•])—in water to treat recalcitrant organic compounds (Khadre et al., 2001).

294

Status

295

296 **Historic Use:**

297 The word “ozone” is derived from the ancient Greeks’ description of the odor produced by lightning flash (Foley &
 298 Kirschner, 2022). Ozone was first described by Dutch scientist Martin van Marum as a phenomenon produced by
 299 passing electricity through air in 1786, but was not identified as a chemical substance until 1840 by German-Swiss
 300 chemist Christian Friedrich Schoenbein (Horvath et al., 1985). Nikola Tesla received one of the first patents for an
 301 ozone generator (Tesla, 1896).

302

303 Outside the U.S., ozone has been used extensively for water purification and other sanitizer and fumigant functions
 304 since the early 1900s (EPRI, 2001). The first practical use of ozone as a disinfectant began in 1903 as a treatment for
 305 drinking water systems in Europe (Wojtowicz, 2005). Between 1903 and 1906, Nice, France installed an ozone
 306 treatment system sufficient to disinfect the entire city water supply (Rice et al., 1981; Rideal, 1909). The earliest
 307 report of the successful use of ozone in the food industry was to increase the storage life of meat in cold storage at a
 308 facility in Cologne, Germany, in 1909 (Horvath et al., 1985). Early attempts to sterilize milk with ozone failed
 309 (Vosmaer, 1914). The French seafood industry began using ozone to treat shellfish in 1936 (EPRI, 2001). The dairy
 310 industry started to use ozone gas to remove unwanted molds from cheese storage facilities in the 1940s (EPRI,
 311 2001).

312

313 Compared to the early adoption and long history of use in Europe, the U.S. food industry was slow to adopt ozone as
 314 an antimicrobial treatment (EPRI, 2001; Sarron et al., 2021; B. Tiwari & Rice, 2012). The FDA declared ozone to be
 315 GRAS for use in bottled water in 1995 (50 FR 57130, November 13, 1995) and GRAS for use in food processing in
 316 1997. In 2001, the FDA recognized ozone as GRAS as a secondary direct food additive. Organic processing and
 317 handling operations used ozone as an alternative to chlorine products and other possibly compatible applications
 318 prior to the passage of the Organic Foods Production Act (NOP, 1995). We found no record in public comments or
 319 in the Technical Advisory Panel (TAP) review prior to the original NOSB recommendation explaining the specific
 320 uses and applications from early organic operations.

321

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

323 The Organic Foods Production Act of 1990 (OFPA) does not include any reference to ozone (Organic Foods Production
 324 Act of 1990, 1990).

325

326 The National List includes ozone for use in organic processing and handling at 7 CFR 605(b)(21). For crop production
 327 purposes, USDA organic regulations include ozone on the National List at 7 CFR 205.601(a)(5) with an annotation
 328 specifying that ozone is only for use as an irrigation water cleaner. Ozone for handling and processing was included on
 329 7 CFR 605(b) in the first publication of the NOP Final Rule ([65 FR 80548](#), December 21, 2000). Use of ozone as a
 330 disinfectant in organic crop production on 7 CFR 601(a) was added to the National List in 2003 ([68 FR 61987](#), October 31,
 331 2003). Synthetic ozone is not allowed for organic livestock production.

332

333 In *NOP 5023: Guidance, Substances Used in Post-Harvest Handling of Organic Products*, the NOP explains that materials
 334 on the National List at 7 CFR 205.605 (such as ozone) may be used for both post-harvest handling and pest control (NOP,
 335 2016c).

336

337 **International:**

338

339 **International Organic Food Standards: CODEX Alimentarius Commission—Guidelines for the Production,**
 340 **Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**

341 Ozone does not appear in Annex 2, Table 3, “Ingredients of non-agricultural origin referred to in section 3 of these
 342 guidelines” (FAO/WHO Joint Standards Programme, 2013).³

343

³However, Section 5 of the Codex Guidelines provides for member states “to evaluate new substances for use in organic production” based on the following criteria in §5.1 (FAO/WHO Joint Standards Programme, 2013):

- i) *they are consistent with principles of organic production as outlined in these Guidelines;*
- ii) *use of the substance is necessary/essential for its intended use;*
- iii) *manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;*
- iv) *they have the lowest negative impact on human or animal health and quality of life; and*
- v) *approved alternatives are not available in sufficient quantity and/or quality.*

All stakeholders should have the opportunity to be involved in the evaluation process of substances to be included on the lists (FAO/WHO Joint Standards Programme, 2013). Member states should make the list available to other countries upon request (FAO/WHO Joint Standards Programme, 2013).

344 International Organic Agriculture Standards: IFOAM – Organics International (International Federation of Organic
345 Agriculture Movements)

346 Ozone is allowed to clean equipment without limitations in Appendix 4, Table 2, “Indicative list of equipment
347 cleansers and equipment disinfectants” of the current IFOAM guidelines (IFOAM, 2014).

348
349 Canada: Organic production systems-General principles and management standards (CAN/CGSB-32.310). Organic
350 production systems-Permitted substances list (CAN/CGSB-32.311)

351 Ozone is allowed under §8.1.2(b) of the Canadian General Standards Board’s Organic Production Systems: General
352 principles and management standards for organic production (CAN/CGSB, 2021a). Ozone appears without a
353 limiting annotation in Table 6.5 “Processing aids” and Table 7.3 “Food-grade cleaners, disinfectants and sanitizers
354 permitted without a mandatory removal event” of the Canadian General Standards Board’s Organic production
355 systems: Permitted Substances List (CAN/CGSB, 2021b).

356
357 Europe and United Kingdom (Northern Ireland): European Economic Community (EEC) Council Regulation
358 (EC No. 2018/848 and 2021/1165)

359 Ozone does not appear in the EU organic standards. Article 24(1)(g) of EC 2018/848 says that the European
360 Commission may authorize products for cleaning and disinfection of processing and storage facilities (EU
361 Commission, 2018). Annex IV, Part C of the EC 2021/1165 contains the lists of products that can be used for
362 cleaning and disinfection of processing and storage facilities (EU Commission, 2021). As of November 1, 2024, that
363 list is empty.

364
365 The EU Expert Group for Technical Advice on Organic Production (EGTOP) considered ozone, among other
366 cleaning and disinfecting techniques, prior to the publication of the current regulations, but did not make a
367 conclusive recommendation about ozone and other specific substances (EGTOP, 2014, 2016). EGTOP
368 recommended that ozone be permitted to treat potable water, but that it not be permitted for direct contact with food
369 (EGTOP, 2014).

370
371 While the previous regulation addressed disinfection of livestock facilities, it did not explicitly address disinfection
372 of plant material, including post-harvest washing, or disinfectants used in processing and handling (EGTOP, 2016;
373 EU Commission, 2008a). EC 2018/848 authorizes the listing of such substances for the first time, but neither EC
374 2018/848 nor EC 2021/1165 established criteria to evaluate such substances (EU Commission, 2018, 2021). EGTOP
375 proposed such criteria, along with a list of unwanted substances for organic production, processing, and handling
376 (EGTOP, 2021). Ozone is not on any of the unwanted lists (EGTOP, 2021). The European Commission has not
377 acted on EGTOP’s recommendation as of December 2024.

378
379 Japan: Japan Agricultural Standard (JAS) for Organic Production

380 Ozone is allowed with limitations under the JAS standard for organic food. Ozone appears on Annex A “Additives
381 (for Organic Processed Foods excluding Alcohol Beverages)” with the annotation “Limited to the use for
382 disinfecting the processed meat products, or cleaning of eggs” (Japanese Agricultural Standard for Organic
383 Processed Foods, 2022).

384
385 Korea: Republic of Korea (ROK) Korean Organic Act

386 Ozone is allowed with limitations under the ROK standard for organic food. Article 3 §1 of the Enforcement Rule
387 Of The Act On The Promotion Of Environment-Friendly Agriculture And Fisheries And The Management Of And
388 Support For Organic Foods” refers to permitted substances on Annex 1 (KMAFRA, 2020). “Ozone water” appears
389 in Annex I, Part C, Table 1, “Substances permitted for use as food additives or processing aids” with the following
390 annotation: “cleaning or disinfecting agent used on the surface of food” (KMAFRA, 2020).

391
392 Switzerland: Federal Office for Agriculture (FOAG), Switzerland Organic Ordinances, Organic Farming Ordinance
393 (SR 910.18), EAER Ordinance on Organic Farming (SR 910.181), FOAG Ordinance on Organic Farming
394 (SR 910.184)

395 Ozone does not appear in the Swiss Ordinances on organic farming (Swiss EAER, 1997; Swiss FOAG, 1997).
396 Switzerland participates in EGTOP. Consequently, the status of ozone appears to be similar to that in the European
397 Union and Great Britain, where ozone is allowed to disinfect water, but prohibited for direct food contact (EGTOP,
398 2014).

399
400 Taiwan: Organic Agriculture Regulations

401 Ozone appears in Chapter 2 “Substances allowed to be used in production, processing, packaging, distribution and
402 sale”, Part 1 “Processing, packaging, distribution, and sale”, Table 4, “Other substances allowed to be used” with the
403 condition, “Only for cleaning and infection (*sic*) purpose” (Organic Agricultural Promotion Act, 2018).

404
 405 United Kingdom (Great Britain): Organic Products Regulations (2009), Retained Council Regulations (EC)
 406 (834/2007, 889/2008, and 1235/2008)
 407 The standard for Great Britain is based on the retained European Council Regulations prior to the United Kingdom's
 408 exit from the European Union (EU Commission, 2007, 2008a, 2008b). As noted above for the EU regulation, ozone
 409 is not mentioned in the implementing regulation (EU Commission, 2008a). EGTOP recommended that ozone be
 410 allowed to treat potable water, but prohibited for direct contact with food (EGTOP, 2014).
 411

Evaluation Questions

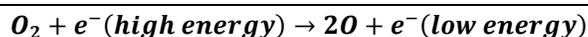
Classification of the Substance:

412
 413
 414 Evaluation Question #1(A): Describe if this substance is extracted from naturally occurring plant, animal, or mineral
 415 sources.

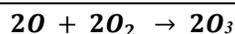
416 Ozone is not extracted from a naturally occurring plant, animal, or mineral source. Ozone (O₃) is produced by an
 417 electrochemical or photochemical reaction using diatomic oxygen (O₂). The oxygen used as a precursor to produce
 418 ozone is sourced from naturally occurring atmospheric oxygen (O₂).
 419

420
 421 Evaluation Question #1(B): Describe the most prevalent processes used to manufacture or formulate this substance.
 422 Include any chemical changes that may occur during manufacture or formulation of this substance.

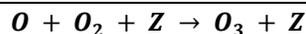
423 The primary process used to generate ozone is by electrical discharge of oxygen. The only feedstock is atmospheric
 424 oxygen (O₂), which is abundant in nature. The chemical reactions involved in corona discharge are outlined in
 425 [Equation 1](#), [Equation 2](#), and [Equation 3](#) (Brodowska et al., 2018; Foley & Kirschner, 2022):
 426
 427



Equation 1



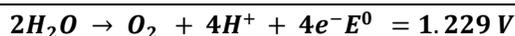
Equation 2



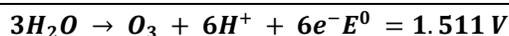
Equation 3

436 High-energy electrons (6-7 eV) break the oxygen double bonds (Foley & Kirschner, 2022). The oxygen *atoms* (O)
 437 attach to oxygen *molecules* (O₂) either by direct collision or by a three-body collision with another gas (Z), such as
 438 nitrogen or nitrogen oxides. These additional gases are also produced *in situ*, mainly by corona discharge (Foley &
 439 Kirschner, 2022; Horvath et al., 1985; Tapp & Rice, 2012).
 440

441
 442 Much of the ozone generated industrially is used for water treatments. Consequentially, researchers have been
 443 interested in the efficiencies that can be gained by generating ozone directly in water through an electrochemical
 444 reaction (Okada & Naya, 2012). The anode reactions are outlined in [Equation 4](#), [Equation 5](#), and [Equation 6](#) (Okada
 445 & Naya, 2012):
 446



Equation 4

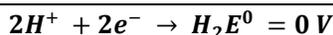


Equation 5



Equation 6

455
 456 The cathode balances the reaction in [Equation 7](#) (Okada & Naya, 2012):
 457



Equation 7

461 The cumulative reactions use significantly less electricity than corona discharge (Okada & Naya, 2012) and produce
462 hydrogen (H₂) as a co-product, which can be used to generate energy.

463
464 The third method processors used in commercial food production is photochemical, through ultraviolet (UV) light
465 radiation (Horvath et al., 1985; Tapp & Rice, 2012). Most UV generators use low-pressure mercury lamps that cause
466 oxygen atoms to dissociate at a wavelength of 185 nm (Tapp & Rice, 2012). The oxygen radicals formed by
467 photodecomposition readily attach to the surrounding O₂ molecules to form ozone (O₃) (Tapp & Rice, 2012).

468
469 Evaluation Question #1(C): Discuss whether this substance is agricultural or nonagricultural. If the substance is
470 nonagricultural, is it synthetic or nonsynthetic (natural) [7 U.S.C. 6502(22); NOP 5033-1 (Decision Tree for
471 Classification of Materials as Synthetic or Nonsynthetic); NOP 5033-2 (Decision Tree for Classification of
472 Agricultural and Nonagricultural Materials for Organic Livestock Production of Handling)]?

473
474 **Agricultural or nonagricultural classification**

475 Evaluation of ozone against Guidance NOP 5033-2 *Decision Tree for Classification of Agricultural and*
476 *Nonagricultural Materials for Organic Livestock Production or Handling* (NOP, 2016b) is discussed below.

477
478 1. *Is the substance a mineral or bacterial culture as included in the definition of nonagricultural substance at*
479 *section 205.2 of the USDA organic regulations?*

480 No. Ozone is produced from atmospheric oxygen and electrical discharge or UV light.

481
482 2. *Is the substance a microorganism (e.g., yeast, bacteria, fungi) or enzyme?*

483 No. Ozone is not a microorganism.

484
485 3. *Is the substance a crop or livestock product or derived from crops or livestock?*

486 No. Ozone originates from atmospheric oxygen using physical and electrochemical processes. Although crops
487 release oxygen as part of photosynthesis, it is not possible to separate “agricultural” oxygen from “non-agricultural”
488 sources of oxygen.

489
490 4. *Has the substance been processed to the extent that its chemical structure has been changed?*

491 Yes. The process of ozone generation involves the breaking of the oxygen double bonds of atmospheric oxygen (O₂)
492 by the energy produced from electrons. The chemical structure is changed from O₂ to O₃. This is a small, but
493 significant and essential change in chemical composition.

494
495 5. *Is the chemical change a result of naturally occurring biological processes such as fermentation or use of*
496 *enzymes; or a result of mechanical/physical/biological processes described under section 205.270(a)?*

497 No. The ozone generation process is electrochemical or photochemical, and not biological.

498
499 Therefore, ozone should be classified as a nonagricultural substance.

500
501 **Synthetic or nonsynthetic classification**

502 Evaluation of ozone against Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or*
503 *Nonsynthetic* (NOP, 2016a) is discussed below.

504
505 1. *Is the substance manufactured, produced, or extracted from a natural source?*

506 Yes. Ozone is composed entirely of oxygen, which comprises about 21% of the atmosphere. The other reactants are
507 electrons (from electricity), generated by human-created devices.

508
509 2. *Has the substance undergone a chemical change so that it is chemically or structurally different than how*
510 *it naturally occurs in the source material?*

511 Yes. For commercial applications, generators synthetically produce ozone from atmospheric oxygen. Diatomic
512 oxygen is changed to triatomic oxygen (ozone) by corona discharge, electrolysis, or photochemical reactions
513 produced by ultraviolet light.

514
515 2b. *At the end of the extraction process, does the substance meet all the criteria described at 4.6 of NOP 5033?*

516 This does not apply to ozone. The various chemical reactions do not involve an extraction process.

517

518 3. *Is the chemical change created by a naturally occurring biological process, such as composting,*
519 *fermentation, or enzymatic digestion; or, by heating or burning biological matter?*

520 No. The chemical change for all commercial food-grade ozone, as described in this report, is the result of
521 electrochemical reactions with either corona discharge, electrolysis, or photochemical by exposure to artificial
522 ultraviolet light.

523

524 Therefore, ozone should be classified as synthetic according to the decision tree.

525

526 Evaluation Question #1(D): Does this substance in its raw or formulated forms contain nanoparticles?

527 According to NOP Policy Memo 15-2 *Nanotechnology*, nanotechnology is conducted at the nanoscale, which is
528 about 1 to 100 nanometers (nm) (NOP, 2015). The NOP uses the term “incidental nanomaterials” to refer to
529 substances that are byproducts of other manufacturing (e.g., homogenization, milling) or that occur naturally. The
530 NOP uses the term “engineered nanomaterials” to refer to substances designed and manufactured to have unique
531 properties or behavior attributable to particle size. However, these terms are not mutually exclusive.

532

533 Ozone is a gas at standard temperature and pressure, and it is comprised of individual, disassociated O₃ molecules.
534 An ozone molecule is 1.26 Å or 0.126 nm (Bocci, 2011). This size falls below the NOP’s defined nanoscale range,
535 which goes down to 1 nm (NOP, 2015). Researchers are also investigating the use of ozone nanobubbles to improve
536 disinfection effectiveness by increasing the stability of ozone and its surface area coverage (Seridou & Kalogerakis,
537 2021).

538

539 Ozone fits the definition of an incidental nanomaterial because its nanoparticle scale is an aspect of its natural
540 occurrence. However, one could argue that it also fits the definition of an engineered nanomaterial because ozone’s
541 unique properties (for example, its effectiveness as a fumigant) are attributable to its particle size. In other words,
542 while ozone’s nano-scale size is naturally occurring, some of its unique and beneficial properties are a result of its
543 size.

544

545 Evaluation Question #1(E): Does this substance in its raw or formulated forms contain ancillary substances?

546 No. Food-grade ozone contains no ancillary substances as defined by the NOSB’s 2016 recommendation.

547

548 Evaluation Question #1(F): Is this substance created using excluded methods?

549 No. Ozone is a non-agricultural synthetic chemical. It is generated from a non-biological source—atmospheric
550 oxygen, and electricity or ultraviolet light.

551

552 Evaluation Question #2: Specify whether this substance is categorized as generally recognized as safe (GRAS) when
553 used according to FDA’s good manufacturing practices [7 CFR 205.600(b)(5)]. If not categorized as GRAS,
554 describe the regulatory status.

555 Ozone is GRAS as a secondary direct food additive permitted in food for human consumption (21 CFR 173.368). It
556 is also GRAS as an antimicrobial agent used to disinfect bottled water (21 CFR 184.1563). The water itself must
557 meet the microbiological, physical, chemical, and radiological quality standards established by the FDA
558 [21 CFR 165.110(b)(2) – (b)(5)]. Current good manufacturing practice requires a maximum residual level of
559 0.4 mg / L of ozone in the water, at the time of bottling [21 CFR 184.1563(c)].

560

561 **Purpose and Necessity of the Substance:**

562

563 Evaluation Question #3: Describe whether the primary technical function or purpose of this substance is a
564 preservative [7 CFR 205.600(b)(4)].

565 The FDA describes a chemical preservative as follows (21 CFR 101.22):

566

567 (a)(5) The term *chemical preservative* means any chemical that, when added to
568 food, tends to prevent or retard deterioration thereof, but does not include
569 common salt, sugars, vinegars, spices, or oils extracted from spices, substances
570 added to food by direct exposure thereof to wood smoke, or chemicals applied for
571 their insecticidal or herbicidal properties.

572

573 While this definition is somewhat ambiguous, we interpret it to mean that a chemical disinfectant, such as ozone,
574 would not be considered a chemical preservative. Ozone is not an ingredient incorporated into food, having a lasting
575 effect to prevent oxidation or other deterioration of food. Furthermore, ozone may be applied for insecticidal
576 purposes (such as when used as a fumigant), or microbial disinfection (a seemingly similar purpose).

577

578 The primary technical function of ozone in food handling is as an antimicrobial disinfectant (Brodowska et al., 2018;
579 Guzel-Seydim et al., 2004; O'Donnell et al., 2012). If other steps are taken to limit the recolonization of a treated
580 food product (such as vacuum sealing), the disinfection of decay-causing microorganisms can help to preserve some
581 agricultural products. Ozone also deactivates various enzymes that accelerate the degradation of various fruits,
582 vegetables, and fruit juices, effectively extending the shelf-life of those products (Mayookha et al., 2023).

583
584 Carrots are one of the most studied vegetables in association with ozone treatment. Scientists demonstrated in
585 numerous studies that microbial activity is decreased mainly by cellular disruption, as described in [Action of the](#)
586 [Substance](#), and storage life is extended via preserved quality after ozone treatment (Sarron et al., 2021). Scientists
587 also demonstrate consistently lower microbial counts, longer storage life, and better quality of lettuce and other
588 salad greens after treatment, when compared to untreated varieties of these crops (Sarron et al., 2021). Scientists
589 treating tomatoes with ozone gas in a modified atmosphere storage chamber prevented microbial degradation from
590 molds and fungi by inactivation of spores and vegetative fungi as described in [Action of the Substance](#) (Sarron et al.,
591 2021).

592
593 Scientists have demonstrated that ozone is effective at reducing pathogenic fungi that produce mycotoxins in grains
594 if applied when the grain is first stored, particularly if moisture levels are high (Afsah-Hejri et al., 2020; Tiwari et
595 al., 2010). Efficacy is a function of ozone concentration, moisture content, duration, and ozone dispersion (B. K.
596 Tiwari et al., 2010). Treatment lengths range from minutes to days and concentrations range from 50 ppm to 4%
597 with variable results (B. K. Tiwari et al., 2010). These include *Fusarium* spp., *Aspergillus* spp., and *Penicillium* spp.
598 In addition, the strong oxidizing properties of ozone degrades the mycotoxins produced by these organisms,
599 including aflatoxins, ochratoxin A, fumonisins, deoxynivalenol (DON), and zearalenone (Afsah-Hejri et al., 2020).

600
601 Ozone is also effective as an insecticide for various grain storage pests when used as a fumigant (Tiwari et al.,
602 2010). Grain damaged by insects is more prone to decomposition and molds that cause mycotoxins (Neme &
603 Mohammed, 2017). Gaseous ozone treatments at concentrations between 25 ppm and 50 ppm over a period ranging
604 from six hours to five days were able to achieve over 50% mortality of target pests with some treatments showing
605 100% efficacy against certain pests (B. K. Tiwari et al., 2010).

606
607 Ozone has antibacterial and antifungal properties, as demonstrated by experiments with almonds, Brazil nuts, and
608 pistachios (Gyawali et al., 2024). Almonds and other shelled tree nuts are required to be heat treated or have another
609 validated method that achieves a 4-log (99.99%) reduction in *Salmonella* (USDA Specialty Crops Program, 2022).
610 However, in the studies we reviewed and cited in a recent literature review article (Gyawali et al., 2024), ozone
611 failed to meet the target 4-log reduction of the pathogen of concern of the different nuts (de Oliveira et al., 2020;
612 Gyawali et al., 2024; Perry et al., 2019).

- 613 • Brazil nuts inoculated with *A. flavus* and were treated with ozone gas for four hours at concentrations
614 between 2.42 and 13.24 mg/L (de Oliveira et al., 2020). The treatment of 8.88 mg/L achieved a 3.1 log
615 reduction of *A. flavus* and was not significantly different from the higher treatment (de Oliveira et al.,
616 2020). The *A. flavus* colonies displayed a distinct change in color and shape that showed oxidation of the
617 morphological structure (de Oliveira et al., 2020).
- 618 • Almonds and pistachios in the shell were inoculated with *Salmonella enterica*, placed in a vacuum
619 chamber, and treated with ozone at 160 mg/m³ for 30 minutes (Perry et al., 2019). The pistachios were also
620 soaked in brine (Perry et al., 2019). The almonds showed a 2.9 log reduction in *Salmonella*, but the
621 pistachios had only a 0.8 log reduction (Perry et al., 2019). The relative lack of efficacy was attributed to
622 the ability of *S. enterica* to survive in dry environments (Perry et al., 2019).

623
624 Evaluation Question #4: Will this substance primarily be used to recreate or improve flavors, colors, textures, or
625 nutritive values lost in processing (except when required by law)? If so, describe how [7 CFR 205.600(b)(4)].
626 No. We found no evidence that processors apply ozone treatments to recreate or improve flavors or colors, as it is an
627 odorless, colorless gas that leaves no aftertaste.

628
629 Regarding nutritive value, most scientists explore whether ozone degrades nutrients rather than enhances them.
630 Scientists observed that several foods treated with ozone lost color compared to untreated foods. Ozone treatment
631 had this particular effect on the following agricultural products (Brodowska et al., 2018):

- 632 • apple juice
- 633 • blackberries
- 634 • broccoli
- 635 • carrots
- 636 • grapes
- 637 • lettuce

- 638 • oranges
- 639 • pistachios
- 640 • tomato juice

641

642 Evaluation Question #5: Describe any effect or potential effect on the nutritional quality of the food or feed when
643 this substance is used [7 CFR 205.600(b)(3)].

644 After harvest, vitamin content begins to decline in fresh fruits and vegetables (Kader, 2002). However, ozone
645 treatment of wash water and in storage atmospheres can have a measurable impact on nutritional quality (Aslam et
646 al., 2020; Botondi et al., 2021; Sarron et al., 2021). Fruit and vegetable nutrient content can be preserved by
647 inhibiting the decay process, which can lead to the loss of specific vitamins and other nutrients. Scientists observed
648 higher vitamin A and β -carotene (beta carotene) in carrots treated with ozone compared to untreated carrots (Sarron
649 et al., 2021). On the other hand, the strong oxidizing potential can reduce the content of certain vitamins and
650 ancillary nutrients. Vitamin B₁ (thiamine) and vitamin C (ascorbic acid) are the most vulnerable to loss by oxidation
651 (Aslam et al., 2020).

652

653 Researchers who have analyzed the negative impacts on nutrient content in fresh-cut fruits and vegetables assume
654 nutrient loss or degradation to be limited only to plant surfaces and infected cut areas (Aslam et al., 2020; Botondi et
655 al., 2021). Studies that empirically validate this hypothesis are limited. We found one simulation that used cut leafy
656 greens that were then washed in ozonated water and exposed to ozone gas (Shynkaryk et al., 2015). The researchers
657 found that leaf uptake of ozone through the stomata and cut surfaces was limited to only a few millimeters
658 (Shynkaryk et al., 2015).

659

660 In a study of strawberries, Pérez et al. (1999) reported that ozonated fruit had three times the vitamin C content
661 compared to the untreated fruit after three days. The researchers concluded that any short-term nutrient loss from
662 ozonation was negated by the observed increase in biosynthesis of vitamin C from stored carbohydrates (Pérez et al.,
663 1999). By day 7 post-treatment, the ozonated fruit had slightly lower (but statistically significant) vitamin C content
664 than the untreated fruit (Pérez et al., 1999). Scientists in another study demonstrated that ozone-treated potatoes had
665 higher vitamin C content than untreated potatoes (Rice, 2012).

666

667 Environment and Human Health Effects

668

669 Evaluation Question #6: List any reported residues of heavy metals or other contaminants in excess of FDA
670 tolerances that are present or have been reported in this substance [7 CFR 205.600(b)(5)].

671 The FDA establishes “action levels” for poisonous or deleterious substances that are unavoidable in human food and
672 animal feed (U.S. FDA, 2000). These include aflatoxin, cadmium, lead, polychlorinated biphenyls (PCBs), and
673 many other substances. The FDA uses different action level tolerances for these substances, depending on the
674 commodity. Commodities are largely food items; however, the FDA also includes tolerances for ceramic and metal
675 items, such as eating vessels and utensils. FDA guidance does not identify any action levels for these contaminant
676 substances in ozone (US FDA, 2000).

677

678 As a gas, ozone is unlikely to be contaminated with heavy metals. We found no evidence of food-grade ozone
679 contaminated by heavy metals or any other contaminants subject to FDA tolerances or action levels. Ozone
680 generation by nuclear power reactors may be radioactive. However, the contamination risks associated with this
681 production method prevent commercial applications from such sources, including food and water treatment (Guzel-
682 Seydim et al., 2004; Wojtowicz, 2005). The current *Food Chemicals Codex* also does not specify limits on
683 impurities in ozone for arsenic, lead, or other elemental contaminants (U.S. Pharmacopeia, 2024).

684

685 Evaluation Question #7: Discuss and summarize findings on whether the manufacture and use of this substance may
686 be harmful to the environment or biodiversity [7 U.S.C. 6517(c)(1)(A)(i) and 7 U.S.C. 6517(c)(2)(A)(i)].

687 While ozone in the upper stratosphere is vital to shielding the lower atmosphere from solar radiation, at ground
688 level, it is regarded as a pollutant (US EPA, 2024a).

689

690 Ozone generator systems produce waste ozone that needs to be vented because they are not 100% efficient in mass
691 transfer from the carrier gas stream (Foley & Kirschner, 2022). The generator systems may include sodium bisulfite
692 or activated carbon filters to scrub the excess ozone, but such systems add to the operational costs (Foley &
693 Kirschner, 2022). Ozone generator systems can also use transition metals and their oxides to catalyze the
694 decomposition of ozone to oxygen prior to venting (Foley & Kirschner, 2022). Some ozone generator systems will
695 also heat the vent to 300 °C (572 °F) using electric or natural gas heaters to accelerate decomposition (Foley &
696 Kirschner, 2022).

697

698 Effects on plants

699 Ozone is toxic to plants and animals (terrestrial and aquatic) (Wojtowicz, 2005). Ozone damage to agricultural crops
700 caused by smog was first observed in California grapes in the 1950s (Richards et al., 1958). The impacts of ozone
701 pollution on plant growth and health have received considerable attention from scientists worldwide (Jimenez-
702 Montenegro et al., 2021; W. H. Smith, 1992). Ozone damage causes visible yellowing of the leaves (chlorosis) and
703 leaf death at higher levels (Grulke & Heath, 2020; Richards et al., 1958). Exposure to 0.2 ppm ozone results in a
704 reduction of photosynthesis by a factor of 2 (Wojtowicz, 2005).

705
706 Airborne ozone causes environmental stress in forest plants irrespective of their species (Günthardt-Goerg et al.,
707 2023). In one experiment, exposure of forest plants to elevated ozone levels caused visible tissue damage to the
708 leaves and other organs exposed (Grulke & Heath, 2020; Günthardt-Goerg et al., 2023). Leaves exposed to ozone
709 also showed signs of interference with gas exchange and respiration (Günthardt-Goerg et al., 2023). Forests in the
710 U.S. with elevated levels of ozone grew more slowly compared with forests with lower levels of ozone (Grulke &
711 Heath, 2020). Little is known about ozone's effects on ecosystem processes, such as water, carbon, and nutrient
712 cycling (Grulke & Heath, 2020).

714 Effects on aquatic animals

715 The adverse impacts on wildlife caused by air pollution in general and ozone in particular have been studied less
716 than the impacts on plant life (Newman et al., 1992). Studies of the toxicity of ozone-treated wastewater
717 demonstrate mixed results of impacts on fish and other aquatic animals. Some studies show that ozone reduces the
718 toxicity of effluent, while other studies show the opposite (Lim et al., 2022). The results varied by the species and
719 age of the model, and the other pollutants in the effluent. Increased toxicity could not be solely attributed to ozone
720 exposure (Lim et al., 2022). The lethal concentrations of ozone (96 hr LC₅₀) for rainbow trout, channel catfish, and
721 striped bass are 9.3, 30, and 80 ppb, respectively (Wojtowicz, 2005).

722

723 Effects on terrestrial animals

724 A review of the literature on air pollution's impact on biodiversity found only one study specific to ozone's impacts
725 on terrestrial wildlife and biodiversity (Newman et al., 1992). The researcher documented a genetic change in the
726 sensitivity to ozone in deer mice (Newman et al., 1992; Richkind, 1979). Deer mice collected in Los Angeles that
727 were exposed to elevated levels of ambient ozone showed greater resistance to ozone exposure in experimental
728 conditions than laboratory mice, but still suffered adverse health effects (Richkind & Hacker, 1980). Ozone causes
729 lung damage and impaired respiratory function in laboratory animals (Lippmann, 1989; Menzel, 1984; NTP, 1994).
730 Ozone caused lesions in the lungs, noses, and larynxes of exposed rats and mice in both short- and long-term studies
731 (NTP, 1994). The lethal dose for half the experimental animals (4-h LD₅₀) for albino mice is 3.8 ppm (Wojtowicz,
732 2005).

733

734 Effects on environment

735 The U.S. EPA classifies ground-level ozone as a greenhouse gas, but notes that it is different from other greenhouse
736 gases in several ways (US EPA, 2016). Ozone's impact on global warming and climate change depends on its
737 placement (NASA, 2015). Stratospheric ozone has a net warming effect that is balanced by preventing harmful
738 ultraviolet radiation from reaching the earth. Ozone causes atmospheric warming by absorbing solar radiation
739 (Wojtowicz, 2005). Ground-level ozone is a greenhouse gas that contributes to climate change by the same pathway
740 of trapping heat (UCAR, 2024).

741

742 Ground-level ozone varies by season and location (US EPA, 2016). More ozone is produced from both natural
743 sources and human activity during periods of high temperatures and long day lengths (Guicherit & Roemer, 2000;
744 US EPA, 2024c). The amount of human activity (anthropogenic) causing air pollution and altitude are also factors
745 that influence ozone levels (Guicherit & Roemer, 2000). More NO_x and VOC pollution causes higher ozone levels,
746 making urban areas more likely to have high ozone levels than rural areas (Guicherit & Roemer, 2000; US EPA,
747 2024a).

748

749 Ozone generators use electricity. The environmental impact of electricity is related to how the electricity is
750 generated (US EPA, 2024b). Electricity produced from the burning of coal, oil, or natural gas will have a larger
751 carbon footprint than locations that rely primarily or entirely on renewable energy (Davis et al., 2016; Schivley et
752 al., 2018).

753

754 Evaluation Question #8: Describe and summarize any reported effects upon human health from use of this substance
755 [7 U.S.C. 6517(c)(1)(A)(i), 7 U.S.C. 6517(c)(2)(A)(i), and 7 U.S.C. 6518(m)(4)].

756 Ozone is considered a hazardous chemical substance (NIOSH, 2019). When used as an antimicrobial substance,
757 ozone has a beneficial effect on human health through the reduction of foodborne pathogens to safe levels

758 (Brodowska et al., 2018; Kim et al., 2003; O'Donnell et al., 2012; Suslow, 2004). The same chemical properties that
759 make ozone a powerful and effective antimicrobial agent used to control food-borne pathogens also make it toxic to
760 all living organisms, including humans (Menzel, 1984; Rice, 2012). Residual exposure in food is not an issue
761 because ozone decomposes rapidly into oxygen after it is applied either to wash water or in the controlled/modified
762 atmosphere chambers where food is stored (Brodowska et al., 2018; Guzel-Seydim et al., 2004; Pandiselvam et al.,
763 2019; Tapp & Rice, 2012).

764
765 Exposure to ozone is known to induce various toxic effects on both humans and experimental animals (Beckett,
766 1991; Klaassen, 2001; Menzel, 1984; Rice, 2012; Seagle, 1973). It has been described as “one of the most toxic and
767 ubiquitous air pollutants” (Menzel, 1984). Ozone’s toxicity is a direct result of its strong oxidizing properties that
768 are toxic to the cells of all living organisms (Klaassen, 2001). Exposure to ozone also increases a person’s
769 susceptibility to infections (Menzel, 1984). Researchers believe that interactions between particulate matter and
770 ozone contribute to respiratory system damage (Beckett, 1991; Jerrett et al., 2009).

771
772 The primary human health concern of ozone treatment of food and water is worker safety. Food handling and
773 processing plant workers in close proximity to ozone generators in water treatment and food handling facilities are
774 exposed to higher levels of ozone than the general public (Rice, 2012; Seagle, 1973). Ozone is an irritant to the eyes,
775 nose, mouth, and upper respiratory system. In the U.S., the permissible exposure limit (PEL) for ozone set by the
776 Occupational Health and Safety Administration (OSHA) is 0.1 ppm or 0.2 mg/m³ over an eight-hour time-weighted
777 average (29 CFR 1910.1000).

778
779 Air pollution from off-gassed excess ozone in the proximity of handling facilities is also a health and safety concern
780 (Rice, 2012). Scrubbing systems that capture the excess ozone reduce the levels of ozone released and are mostly
781 used by very large ozone systems that generate tons of the material daily. Some smaller systems also utilize this
782 device (Rice, 2012). Many researchers have examined the adverse health effects of ozone pollution (Bell et al.,
783 2014; Orellano et al., 2020; Zhang et al., 2021).

784
785 Jerret et al. (2009) correlated ozone pollution levels with respiratory mortality based on data collected from a large
786 population in the U.S. between 1977 and 2000. In 96 metropolitan statistical areas, scientists observed that for every
787 10 ppb increase in exposure to ozone, there was a 2.9% increase in the risk of death from respiratory causes. The
788 researchers concluded that the risk of dying from a respiratory cause is three times more likely in metropolitan areas
789 with the highest ozone levels compared to places with the lowest ozone concentrations (Jerrett et al., 2009).

790
791 The elderly, women, and those living in poverty are particularly susceptible to the adverse impacts of ozone
792 pollution (Bell et al., 2014). Pediatricians have linked high levels of ozone with near-fatal and fatal asthma attacks in
793 children (Varghese et al., 2024). Scientists conducting related research have also observed a similar pattern of
794 elevated health risks internationally from ozone pollution (Orellano et al., 2020; Zhang et al., 2021).

795
796 Ozone demonstrates the capacity to reduce pesticide residues in various foods (Diksha et al., 2023). In one
797 experiment, bok choy (pak choi) with residues of the organophosphorus pesticide malathion and the carbamate
798 pesticide carbosulfan was treated with ozonated water (Wang et al., 2021). The researchers found that as ozone
799 concentration increased, pesticides degraded more rapidly (Wang et al., 2021). These resulting decomposition
800 products were further broken down through hydrolysis, releasing H⁺ and OH⁻ ions in the water (Wang et al., 2021).
801 Ozone disrupts specific types of hydrocarbons (unsaturated aliphatic moieties like alkynes and alkenes) by breaking
802 carbon chains and releasing benzene rings in the molecular structure of pesticides (Diksha et al., 2023). The released
803 smaller molecules are largely water soluble and can be further decomposed by hydrolysis (Diksha et al., 2023).

804 805 **Alternatives**

806 The following three sections explore possible alternatives to ozone that are non-synthetic, non-agricultural
807 substances, organic agricultural products, and other methods that are physical, mechanical, or otherwise non-
808 chemical in their mode of action. When considering alternatives for pathogen reduction, organic handlers and
809 processors are required to meet all relevant food safety requirements in addition to the organic standards. These
810 include the Food, Drug, and Cosmetic Act as amended by the Food Safety Modernization Act of 2011 (FSMA)
811 (21 CFR 301 *et seq.*), the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), and the implementing regulations of
812 the FSMA ([80 FR 55908](#), September 17, 2015). While the FSMA does not require any specific performance
813 standard for pathogen reduction, it requires all food handling facilities to have a Food Safety
814 Plan (21 CFR 117.126), conduct a hazard analysis (21 CFR 117.130), and implement preventive controls
815 appropriate for food safety (21 CFR 117.135).

816

817 Some food groups have specific performance standards that handlers are required to meet. FDA guidance requires
818 non-thermal deactivation of microorganisms in juices to be equivalent to thermal pasteurization to be considered
819 acceptable substitutes for food safety, which is a 5-log₁₀ or 99.999% reduction of the most resistant microorganism
820 of public health significance [21 CFR 120.24(b)]. The guidance for the industry to implement the juice
821 pasteurization requirement has become an industry-wide standard (US FDA, 2004). The standard is to achieve a 5-
822 log decrease or 99.999% inactivation of a microorganism's colony-forming units (Režek Jambrak et al., 2018).
823 Almonds are required to meet a 4-log decrease or 99.99% inactivation for *Salmonella* spp. (USDA Specialty Crops
824 Program, 2022).

825
826 Alternative methods are sometimes used in combination with ozone to increase efficacy and reduce ozone use (Fan
827 & Song, 2020; Floare et al., 2023; Khadre et al., 2001; O'Donnell et al., 2012). The alternative methods presented
828 below may not always meet the 5-log reduction by themselves, but when combined, they can verify and validate that
829 their HACCP Plan meets the standard (Režek Jambrak et al., 2018). Combining different technologies has the
830 potential to protect food safety and optimize quality for a wide range of specific practical applications (Chiozzi et
831 al., 2022; Noci, 2017; Rawson et al., 2011; Režek Jambrak et al., 2018; Singla & Sit, 2021).

832
833 Evaluation Question #9: Are there alternative nonsynthetic (natural) source(s) of the substance
834 [7 CFR 205.600(b)(1)]?

835 We found no evidence of commercial or practical sources that offer nonsynthetic ozone. Recovery of nonsynthetic
836 ozone appears to be unattainable with existing technologies.

837
838 Evaluation Question #10: Describe all nonagricultural nonsynthetic (natural) substances or products which may be
839 used in place of this substance [7 U.S.C. 6517(c)(1)(A)(ii)]. Identify which of those are currently allowed under the
840 NOP regulations.

841

842 **Acids**

843 Various nonsynthetic acids (e.g., acetic acid, lactic acid, and citric acid) have antimicrobial properties (Bermúdez-
844 Aguirre & Barbosa-Cánovas, 2013; In et al., 2013; Mani-López et al., 2012; Ricke, 2003). Both citric acid
845 (produced by microbial fermentation of carbohydrate substances) and lactic acid are on the National List of
846 nonagricultural nonorganic substances allowed as ingredients in or on processed products labeled as “organic” or
847 “made with organic (specified ingredients or food groups) [7 CFR 205.605(a)(1)].

848

849 The mechanisms by which organic acids are thought to reduce microbial activity take place by multiple modes of
850 action, including acidification inside the cell (cytoplasm) with subsequent uncoupling of energy production and
851 regulation, and accumulation of the undissociated acid to toxic levels (Mani-López et al., 2012). The undissociated
852 acid molecules flow through the cell membranes of the microorganisms and are ionized inside, deforming the cell
853 structure and interfering with enzymatic activities, disrupting proteins and DNA structures, and ultimately damaging
854 the extracellular membrane (In et al., 2013; Mani-López et al., 2012). The acidity inhibits cell division and decreases
855 viability by damaging the RNA and DNA (Mani-López et al., 2012). Cells are not instantly destroyed, but are
856 instead fatally injured (In et al., 2013).

857

858 When used at 0.5% concentration in a microbial broth, citric acid, lactic acid, and acetic acid all were effective in
859 inhibiting the growth and reducing the populations of four *Shigella* species (*S. sonnei*, *S. boydii*, *S. flexnari*, and *S.*
860 *dysenteriae*), all foodborne pathogens, by between 1 and 2 logs (In et al., 2013). Lactic acid was able to achieve a 5-
861 log reduction of *S. sonnei* after two hours and a 2-log reduction of *S. boydii* in the same amount of time. The
862 researchers inoculated lettuce with *Shigella* cultures and submerged them in water with a no-treatment control and a
863 0.5% solution of each of the three acids over a 10-hour period. While cells were not destroyed in the same way that
864 ozone works, the various acids injure the cell to reduce its viability (In et al., 2013). Acetic acid was the most
865 effective against *S. dysenteriae* with 100% injury after 8 hours. Lactic acid was the most effective against the other
866 three species. (In et al., 2013). Further research is needed to determine whether these acids can achieve comparable
867 and predictable broad-spectrum pathogen reduction and validate whether they can be a viable substitute for ozone.

868

869 Citric acid treatment of nutrient broths inoculated with *E. coli*, *S. aureus*, and *C. albicans* reduced the populations of
870 all three species, with *C. albicans* showing the greatest sensitivity (Eliuz, 2020). Spinach inoculated with *E. coli*, *S.*
871 *typhimurium* and *L. monocytogenes* had its pathogen load reduced by approximately 4-log by synergistic treatment
872 of 1% citric acid and pulsed broad-spectrum xenon light (Cho & Ha, 2021). Citric acid achieved less than a one-log
873 reduction of all three of the pathogens, and xenon light by itself achieved a 4-5 log reduction with a 60-minute
874 treatment time, a 60-minute treatment time using both xenon light and citric acid achieved greater than a six-log
875 reduction in all cases (Cho & Ha, 2021). Another experiment involved romaine lettuce, grape tomatoes, and baby
876 carrots inoculated with *E. coli* and compared the results of treatment with ozone, citric acid, UV-light, and chlorine

877 solutions (Bermúdez-Aguirre & Barbosa-Cánovas, 2013). Citric acid was ineffective on lettuce and carrots, and
878 resulted in less than a 1-log reduction in tomatoes, performing significantly worse than ozone as a disinfectant
879 (Bermúdez-Aguirre & Barbosa-Cánovas, 2013).

880

881 **Microorganisms**

882 Microorganisms appear on the National List at 7 CFR 205.605(a)(19). Beneficial microorganisms are another well-
883 established, nonsynthetic strategy that can be used to reduce risks from foodborne pathogens, maintain product
884 quality, and extend the shelf life of food (Bogsan et al., 2015; Devlieghere et al., 2004). Researchers observed that
885 *Lactobacillus* spp. and other lactic acid bacteria (LAB) applied to the surface of various fresh fruits and vegetables
886 inhibits the growth of foodborne pathogens such as *Salmonella* spp., *Listeria monocytogenes*, and *E. coli* O157:H7,
887 by the excretion of lactic acid and competitive exclusion, production of bacteriocins, and other complex modes of
888 action that are not fully understood (Agriopoulou et al., 2020).⁴ Efficacy varied by species of beneficial bacteria,
889 process duration, temperature, target species, and food matrix (Agriopoulou et al., 2020). As noted above, lactic acid
890 produced by LAB inhibits and ultimately renders microorganisms non-viable (Mani-López et al., 2012). The
891 presence of the LAB also effectively extends the shelf-life of the crops and maintains product quality (Agriopoulou
892 et al., 2020).

893

894 **Bacteriocins**

895 Toxins produced by bacteria, known as bacteriocins, are another possible alternative for ozone (Devlieghere et al.,
896 2004; Schneider et al., 2018; Yang et al., 2014). As noted above, LAB produces bacteriocins, and other microbial
897 species commonly used in food handling and processing also produce bacteriocins (Devlieghere et al., 2004; Yang
898 et al., 2014). Bacteriocins can be classified as colicins or microcins, based on their specific activity against target
899 pathogens and by their mode of action (Yang et al., 2014). Colicins are high molecular weight antibacterial proteins
900 produced by bacteria that kill closely related species to reduce competition for space and nutrients (Yang et al.,
901 2014). The colicin-producing species also produces immunity proteins that inactivate the colicins to avoid
902 committing suicide (Kleanthous, 2010). Microcins are low molecular weight peptides that have more diverse modes
903 of action and a broader range of activity than colicins (Yang et al., 2014). Some microcins have an antibiotic mode
904 of action or are used as precursors to synthetic antibiotics (Yang et al., 2014). One such bacteriocin petitioned for
905 inclusion on the National List of nonagricultural ingredients allowed for use in organic processing and handling was
906 nisin (NOSB, 1995b). The NOSB did not recommend that it be added to the National List (NOSB, 1995a).

907

908 **Bacteriophages**

909 Another newer strategy is to use viruses that infect bacteria, or bacteriophages (O'Sullivan et al., 2019; Wei et al.,
910 2019). Bacteriophages are the most abundant organisms on earth (O'Sullivan et al., 2019; Yusuf, 2018). These
911 viruses attach and inject themselves into their specific bacterial host and replicate as a parasite, ultimately causing
912 cellular death (O'Sullivan et al., 2019; Yusuf, 2018). This is referred to as the lytic cycle (O'Sullivan et al., 2019).
913 Phages are host-specific and are unable to propagate without a bacterial cell (O'Sullivan et al., 2019). Scientists
914 have studied phages and their derivatives for *Listeria monocytogenes* (Misiou et al., 2018), *Salmonella* spp. (Wei et
915 al., 2019), and *E. coli* O157:H7 (Rozema et al., 2009) for their efficacy in reducing those foodborne pathogens.
916 Pathogen reductions are generally within the 90-95% range, far short of the target 5-log reduction (Mahony et al.,
917 2011; O'Sullivan et al., 2019). Phages generally do not achieve sufficient target pathogen reduction to qualify as
918 alternatives to pasteurization, but show promise as a preharvest intervention when used as part of an integrated
919 pathogen program combined with various physical techniques, such as high-pressure processing (Mahony et al.,
920 2011; Misiou et al., 2018; O'Sullivan et al., 2019). The FDA has approved *Listeria* specific phages for use in meat
921 and poultry products (21 CFR 172.785).

922

923 **Essential Oils**

924 Essential oils are potential antimicrobial alternatives to ozone. We discuss essential oils as organic agricultural
925 substances in further detail later in this report (see *Evaluation Question #11*, [below](#)). However, many of these
926 biological active components also serve as flavors (Burt, 2004; FEMA Expert Panel, 2022). Nonagricultural
927 nonsynthetic flavors appear on the National List at 7 CFR 605(a)(12).

928

929 Evaluation Question #11: Provide a list of organic agricultural products that could be alternatives for this substance 930 [7 CFR 205.600(b)(1)].

931 Various essential oils are effective antibacterials for various food applications (Burt, 2004; Laranjo et al., 2017;
932 Yusuf, 2018). Producers use approximately 300 essential oils commercially as flavors and fragrances (Burt, 2004;
933 Ríos, 2016). Farmers and ranchers use essential oils as biopesticides in organic crop and livestock production (Baker
934 & Grant, 2018; Chang et al., 2022; Rawat, 2021). However, essential oils are not yet a widely accepted material in

⁴ Bacteriocins are toxins produced by bacteria that inhibit or kill other bacteria.

935 post-harvest handling (Chang et al., 2022; Laranjo et al., 2017). Essential oils are not explicitly included on the list
936 of allowed non-organic agricultural ingredients (7 CFR 205.606). As such, they would be required to be from
937 organic sources if used as ingredients or processing aids for products labeled as “organic” [7 CFR 205.301(b)] or
938 “100% organic” [7 CFR 205.301(a)].
939

940 The European Pharmacopoeia identifies 29 different essential oils that have antimicrobial effects on bacteria (both
941 gram positive and gram negative), fungi, and yeast (Pauli & Schilcher, 2009). Scientists consider most of these
942 materials weak-to-moderate antimicrobials, and they are not consistently active across all targeted species of
943 foodborne pathogens (Pauli & Schilcher, 2009). As such, most would not achieve disinfection results comparable to
944 ozone. However, concentrating the active components of essential oils can increase their efficacy as antimicrobials.
945 The main foodborne pathogens studied for the antimicrobial efficacy of various essential oils are (Burt, 2004):

- 946 • *Listeria monocytogenes*
 - 947 • *Salmonella typhimurium*
 - 948 • *Escherichia coli* O157:H7
 - 949 • *Shigella dysenteria*
 - 950 • *Bacillus cereus*
 - 951 • *Staphylococcus aureus*
- 952

953 Among the fungi studied are *Aspergillus* spp., *Fusarium* spp., *Penicillium* spp., and other mycotoxin-producing
954 species (Dwivedy et al., 2016; Pauli & Schilcher, 2009). In one study, scientists directly compared the antimicrobial
955 activity of ozone with various essential oils in preserving ancient Egyptian archeological objects from *Aspergillus*
956 spp. and other microorganisms responsible for decay. They concluded that the essential oils provided “aesthetically
957 acceptable” results with “negligible toxicity to human health and the environment” (Geweely, 2022).
958

959 While essential oils clearly demonstrate antimicrobial activity, their effects on microorganisms are usually weaker
960 than those of synthetic compounds (Wińska et al., 2019). However, essential oils often work synergistically with
961 each other and with other preservation methods (Burt, 2004; Hyldgaard et al., 2012). Essential oil components also
962 have antioxidant activity (Lis-Balchin et al., 1998).⁵ Essential oils do vary in quality and potency based on the
963 concentration of their biologically active components (Burdock, 2016; Burt, 2004). Isolating or concentrating the
964 biologically active components of essential oils can improve the efficacy and reduce the variability of the results
965 (Lis-Balchin et al., 1998). However, consumer acceptance of the flavors of essential oils at concentrations sufficient
966 to reduce pathogens is a limitation to their practical application as an antimicrobial (Targino de Souza Pedrosa et al.,
967 2021).
968

969 While a comparison of all the essential oils reported to have antimicrobial activity comparable to ozone is beyond
970 the scope of this report, we selected cinnamon oil, peppermint oil, and thyme oil as model essential oils to examine
971 based on the following criteria (NOP, 2024; US FDA, 2020):

- 972 (1) Commercial availability of organic sources identified through the Organic Integrity Database (OID).
 - 973 (2) Available data and studies on essential oils’ human health and environmental effects.
 - 974 (3) Available scientific literature reviews that include an extensive range of uses and applications of essential
975 oils.
 - 976 (4) In the cases of peppermint oil and thyme oil, the availability of peer-reviewed journal articles that directly
977 compare the efficacy of those essential oils with ozone.
 - 978 (5) The essential oils selected are FDA GRAS.
- 979

980 We found that the available data and research rarely specified that the essential oils under review were organic.
981 Similarly, we found few studies of essential oil antimicrobial efficacy related directly to organic food processing.
982

983 **Commercial availability**

984 Many certified organic essential oils are currently available on the market. A keyword search of “essential oils” on
985 the OID identified approximately 219 certified organic handlers (NOP, 2024). Additional keyword searches on the
986 OID for “cinnamon oil” yielded 54 certified organic handlers, “peppermint oil” yielded 141 certified organic
987 handlers, and “thyme oil” yielded 65 certified organic handlers (NOP, 2024). In total, we identified 239 handlers
988 that have at least one of the three specific essential oils used as models or that handle generic essential oils. Handling
989 operations may be distributors and not primary manufacturers. Furthermore, some handlers are certified by multiple
990 agents, with agents certifying different specific essential oils sold by a given operation.
991

⁵ An antioxidant is a substance that counteracts deterioration of food by inhibiting its oxidation.

992 Cinnamon oil

993 Cinnamon oil is extracted from the bark of trees from the genus *Cinnamomum* (Ravindran et al., 2004). Most
994 cinnamon in the world is from *Cinnamomum cassia*, also known as cassia (Madan & Kannan, 2004). Sri Lankan or
995 true cinnamon (*C. zeylanicum* also known as *C. verum*) accounts for most of the rest of the oil, which can also be
996 extracted from the leaves and twigs of this species (Ravindran et al., 2004). Another minor source is korintji or
997 Indonesian cinnamon (*Cinnamomum burmanii*) (Khan & Abourashed, 2010). Cinnamaldehyde—also known as
998 cinnamic aldehyde—is a flavonoid and secondary plant metabolite that makes up between 60-90% of cinnamon oil
999 and is the principal biologically active component (Dayananda et al., 2004).

1000

1001 Cinnamon oil from *C. cassia* is effective against a large number of yeasts, fungi, and bacteria (both gram-positive
1002 and gram-negative) including (Pauli & Schilcher, 2009):

- 1003 • *Campylobacter jejuni*
- 1004 • *Candida albicans*
- 1005 • *E. coli* O157:H7
- 1006 • *Staphylococcus aureus*
- 1007 • *Shigella* spp.

1008

1009 Researchers studying different *Cinnamomum* species found that cassia oil was the most effective in inhibiting
1010 *Salmonella* spp., and cinnamon oil had the highest efficacy against *B. cereus* (Ezzaky et al., 2023). However, both
1011 oils were relatively ineffective against *E. coli* and *S. aureus*.

1012

1013 Scientists concluded that cinnamon oil was the most effective of 51 different essential oils against *Pseudomonas*
1014 *aeruginosa*, with an 85.8% reduction in growth, and *Torulopsis utilis*, with a 100% reduction in growth. Fasake et
1015 al. (2022) compared fresh-cut cauliflower (*Brassica oleracea* var. *botrytis*) treated with either ozonated water,
1016 cinnamon oil, oregano (*Origanum* spp.) oil, or left untreated, wrapped in modified atmosphere packaging, and
1017 refrigerated. The researchers reported that ozone and cinnamon oil each inhibited the total bacterial count (TBC) on
1018 the cauliflower stored for 21 days. The cauliflower with the ozonated water treatment had a slightly lower TBC than
1019 the one treated with cinnamon oil, but the difference was not statistically significant (Fasake et al., 2022). The TBC
1020 for cauliflower treated with oregano oil was higher than ozonated water or cinnamon oil, but still lower than the
1021 untreated control (Fasake et al., 2022).

1022

1023 Cinnamon oil combined with salt (sodium chloride) effectively inhibited the infection, growth, and aflatoxin
1024 production by *Aspergillus flavus* and *A. glaucus* grown on corn (*Zea mays*), but cinnamon oil alone was less
1025 effective (Chatterjee, 1989). Montes-Belmont and Carvajal (1998) concluded that cinnamon oil was the most
1026 effective of the 11 essential oils tested for control of *A. flavus* on corn without phytotoxicity.⁶ Other foodborne
1027 pathogens inhibited by cinnamon oil include (Gupta et al., 2008; G. Singh et al., 2007):

- 1028 • *Aspergillus flavus*
- 1029 • *Aspergillus ochraceus*
- 1030 • *Aspergillus terreus*
- 1031 • *Penicillium citrinum*
- 1032 • *Panicillium viridicatum*
- 1033 • *Bacillus* sp.
- 1034 • *Listeria monocytogenes*
- 1035 • *E. coli* sp.
- 1036 • *Klebsiella* sp.
- 1037 • *Rhizomucor* sp.

1038

1039 Cinnamon and its derivatives, including the essential oil, are FDA GRAS (21 CFR 180.20). The Joint FAO/WHO
1040 Expert Committee on Food Additives (JECFA) concluded that cinnamon derivatives do not pose food safety
1041 concerns at the current estimated levels of intake (JECFA, 2001). While cases of acute toxicity are rare,
1042 pediatricians reported this occurring in young children either accidentally or intentionally ingesting relatively large
1043 amounts (Schwartz, 1990).

1044

1045 Cinnamon oil is used to control Varroa mites (*Varroa jacobsoni*) (Kraus et al., 1994), and American foulbrood
1046 (*Paenibacillus larvae*) (Gende et al., 2009) in bees (*Apis mellifera*). At the doses effective to control foulbrood
1047 (50 µg/ml), cinnamon oil was reported to be virtually non-toxic (Gende et al., 2009). However, a much higher

⁶ Phytotoxic: Toxic to plants.

1048 10% solution was fatal to almost 99% of the bees treated (Kraus et al., 1994). We found no evidence that cinnamon
1049 oil has adverse effects on aquatic organisms.

1050

1051 **Peppermint oil**

1052 Processors extract mint oil from plants of the genus *Mentha* by steam distillation (Burdock, 2016; Denny &
1053 Lawrence, 2007; Khan & Abourashed, 2010). The most common species used for the production of mint essential
1054 oils are corn mint (*Mentha arvensis*), peppermint (*Mentha piperata*), and spearmint (*Mentha spicata*) (Denny &
1055 Lawrence, 2007). Menthol is a simple monoterpene that is the primary active substance in peppermint oil and corn
1056 mint oil. Spearmint oils are often over 50% carvone (Lawrence, 2007).

1057

1058 Peppermint oil inhibits the growth of many different bacteria, fungi, and yeasts (Khan & Abourashed, 2010; Pauli &
1059 Schilcher, 2009; Shah & D'Mello, 2004). It is also an antiviral agent (Alankar, 2009). Ezzaky et al. (2023)
1060 concluded that mint oil was the most effective against *E. coli* and *S. aureus* in a study comparing the efficacy of
1061 essential oils in *Cinnamomum* spp, *Mentha* spp., and *Salvia* (sage) spp. Argawal et al. (2008) reported that of 30
1062 plant oils tested, peppermint oil showed the greatest inhibition of *C. albicans* after eucalyptus oil.

1063

1064 Peppermint oil showed a synergistic effect with ozone treatment on the following microorganisms (Floare et al.,
1065 2023):

- 1066 • *Candida albicans*
- 1067 • *E. coli*
- 1068 • *P. aeruginosa*
- 1069 • *S. aureus*
- 1070 • *S. mutans*

1071

1072 The addition of peppermint oil increased the efficiency of ozone and decreased the effective exposure time of ozone
1073 from 120 seconds to 55 seconds (Floare et al., 2023). The inhibitory rates obtained by the mixture increased when
1074 compared with the inhibitory rates of ozone or essential oils when applied as single compounds (Floare et al., 2023).
1075 The essential oils increased the potency of the ozone (Floare et al., 2023).

1076

1077 Peppermint oil and spearmint oil are FDA GRAS (21 CFR 182.200). Cornmint oil is also GRAS, based on a
1078 declaration from the Flavors Extract Manufacturers Association Expert Panel (R. Smith et al., 2005). Some
1079 individuals are allergic to mint (Tran et al., 2010; Woolf, 1999). Symptoms reported by allergic individuals include
1080 the following (Malekmohammad et al., 2021; Tran et al., 2010; Woolf, 1999):

- 1081 • contact dermatitis (itchy rash including from exposure to peppermint oil in lip balm)
- 1082 • ataxia
- 1083 • hot flashes
- 1084 • drowsiness
- 1085 • shortness of breath
- 1086 • abdominal pain
- 1087 • metabolic acidosis
- 1088 • hyperextension of the extremities
- 1089 • tremors
- 1090 • unconsciousness

1091

1092 Large doses of peppermint oil can be nearly fatal and can cause organ damage when ingested or injected (Behrends
1093 et al., 2005; Nath et al., 2012). Peppermint oil is frequently used in herbal medicines. Some patients receiving these
1094 therapeutics have reported drug interactions and side effects, including apnea or bronchial and/or laryngeal spasms
1095 (Malekmohammad et al., 2021). Peppermint oil is also contraindicated as herbal medicine in patients with bile duct
1096 obstruction, gall bladder inflammation, and liver disorders (Malekmohammad et al., 2021). We found no reports of
1097 adverse environmental impacts of peppermint oil.

1098

1099 The primary active substance in peppermint oil, menthol, has been widely studied for its effects on human health
1100 and non-target species (Hayes et al., 2007; Malekmohammad et al., 2021). Much of the research on the human
1101 health effects of menthol is related to its use as an additive to cigarettes. However, some research involves candies
1102 and personal care products such as toothpaste (Hayes et al., 2007; Malekmohammad et al., 2021). Menthol has a low
1103 potential for toxicity to humans (Hayes et al., 2007). While it is safely used in food, some sensitive people reported
1104 heartburn, irritation, contact dermatitis, slowed heartbeat (bradycardia), and abdominal pain (Malekmohammad et
1105 al., 2021). Menthol is commonly used to treat tracheal mites (*Acarapis woodie*) in honeybees (*Apis mellifera*).

1106 Scientists concluded that menthol had the greatest margin of safety for bees of all the essential oil isolates tested
1107 (Ellis & Baxendale, 1997).

1108

1109 **Thyme oil**

1110 Processors extract thyme oil by water and steam distillation of the flowering tops of common thyme (*Thymus*
1111 *vulgaris*), creeping thyme (*T. serpyllum*), and red or Spanish thyme (*Thymus zygis*) (Burdock, 2016; Khan &
1112 Abourashed, 2010; Lawrence et al., 2002). The primary active constituent is thymol, a monoterpene phenol
1113 (Coimbra et al., 2022; Lawrence et al., 2002; Zarzuelo & Crespo, 2003). Other biologically active components
1114 include linalool and p-cymene (Coimbra et al., 2022).

1115

1116 Scientists reported that thyme oil in aqueous suspension reduced the population of *E. coli* O157:H7 bacteria on
1117 lettuce to a level not significantly different from the population reduction achieved by ozonated water (Singh et al.,
1118 2002). In contrast, thyme oil was slightly, but significantly, less effective than ozonated water in treating baby
1119 carrots inoculated with *E. coli* O157:H7 bacteria (Singh et al., 2002). Researchers concluded that the most effective
1120 treatment was sequential washing with thyme oil, ozonated water, and aqueous chlorine dioxide (ClO₂) (Singh et al.,
1121 2002).

1122

1123 While most studies of essential oils do not specify whether organic sources were used, we found data from one study
1124 of organic thyme. Organic thyme oil from four species in a chitosan film inhibited the growth of the foodborne
1125 pathogens *Serratia marcescens*, *Listeria innocua*, and *Alcaligenes faecalis*. However, it was ineffective in inhibiting
1126 *Enterobacter amnigenus* (Ballester-Costa et al., 2016). Scientists also demonstrated that thyme oil inhibits the
1127 growth of methicillin-resistant *S. aureus* at a relatively low dose (Shukr & Metwally, 2014).

1128

1129 In another study, scientists treated minced pork inoculated with four subspecies of *Salmonella* with thyme oil and
1130 refrigerated it for 15 days (Boskovic et al., 2017). The thyme oil treatment reduced the pathogens at all levels;
1131 however, the most effective dose of 0.9% had a flavor that was unacceptable to the professional food science
1132 sensory panel (Boskovic et al., 2017).

1133

1134 Thyme oil extracted from *Thymus vulgaris*, *T. serpyllum*, and *T. zygis* var. *gracilis* is FDA GRAS (21 CFR 182.20).
1135 We found no evidence of thyme oil reported as a food allergen or indicated with other adverse human health effects.

1136

1137 Honeybees tolerate thyme oil with few fatalities when treated for Varroa mites (*Varroa destructor*) at doses between
1138 6 and 30 grams (g) in powdered form over a period of 8 to 49 days (Imdorf et al., 1999). Efficacy increased with
1139 both dose and duration (Imdorf et al., 1999). Honey bees had a 50% mortality (LC₅₀) when exposed in a Petri dish to
1140 a concentration of 8.05 μL thymol in an alcohol solution for 72 hr (Damiani et al., 2009). Honeybees treated with
1141 12.5 and 25 g of thymol powder for 28 days suffered no significant mortality losses, although losses were not
1142 quantified (Calderone et al., 1997). Queen bees appear to be more susceptible to thymol toxicity than worker bees
1143 (Whittington et al., 2000). Thyme oil is not toxic to the beneficial predator *Atheta coriaria*, known as the rove beetle
1144 (Echegaray & Cloyd, 2012).

1145

1146 Evaluation Question #12: Describe if there are any alternative practices that would make the use of this substance
1147 unnecessary [7 U.S.C. 6518(m)(6)].

1148 Heat is one of the oldest practices used to reduce microbial activity in food (Potter & Hotchkiss, 1998). Thermal
1149 technologies are defined as those that use temperatures in excess of 80 °C (176 °F) to reduce foodborne pathogens to
1150 safe levels (Chiozzi et al., 2022). However, heat degrades most fresh fruits and vegetables (Kader, 2002). Therefore,
1151 thermal technologies are not a practical alternative to antimicrobial treatment by ozone for these applications. Non-
1152 thermal processing refers to techniques that operate at temperatures less than 30 °C (86 °F) (Chiozzi et al., 2022).
1153 Ozonation is a non-thermal process, along with ultraviolet (UV) light, ultrasound, pulsed electric fields, and high
1154 hydrostatic pressure processing (Chiozzi et al., 2022; Rawson et al., 2011). Pulsed electric fields and cold plasma are
1155 proposed as other non-thermal options (Chiozzi et al., 2022; Režek Jambrak et al., 2018), but they are omitted
1156 because, at present, they do not appear to be in widespread commercial use and their status in the organic standards
1157 is not clear. These alternative methods are all in commercial use at present and may be used to disinfect foods that
1158 are not appropriate for thermal processing (Chiozzi et al., 2022).

1159

1160 **Ultraviolet light**

1161 UV light has germicidal properties between 200-280 nm in the electromagnetic spectrum, known as UV-C
1162 (Choudhary & Bandla, 2012). The FDA does not classify UV as “ionizing radiation” at 21 CFR 179.26, which is
1163 prohibited for use in organic production and handling [7 CFR 205.105(f)]. The FDA allows UV to be used on food
1164 and food products for surface microorganism control, to sterilize water used in food production, and to reduce
1165 human pathogens and other microorganisms in juice products [21 CFR 179.39(b)]. The FDA specifies that the UV

1166 light is from low-pressure mercury lamps emitting 90% of the emission at a wavelength of 253.7 nm
1167 [21 CFR 179.39(a)]. However, the FDA regulations specify UV used to treat food, food products, and water used as
1168 a food ingredient to be generated without ozone production [21 CFR 179.39(b)]. Ozone is produced by UV light
1169 from oxygen under standard temperature and pressure exposed to wavelengths below 240 nm on the electromagnetic
1170 spectrum (Horvath et al., 1985; SCHEER, 2017).

1171
1172 Microbial inactivation and protein damage are caused by UV-C light being absorbed by the organism's DNA
1173 (Chiozzi et al., 2022). The waves cause the formation of DNA photoproducts that result in mutation and cell death
1174 (Chiozzi et al., 2022). Applications of UV light for food disinfection include:

- 1175 • juices (Basak et al., 2023; Koutchma et al., 2016; Rawson et al., 2011)
- 1176 • fresh fruits and vegetables (Bermúdez-Aguirre & Barbosa-Cánovas, 2013; Chiozzi et al., 2022)
- 1177 • milk and dairy products (Chawla et al., 2021; Chiozzi et al., 2022)
- 1178 • meat and poultry products (Chiozzi et al., 2022)
- 1179 • nuts (Gyawali et al., 2024)

1180
1181 The efficacy of UV-C is a function of radiant energy and exposure time, with greater intensity and longer exposure
1182 times causing more cell death (Bermúdez-Aguirre & Barbosa-Cánovas, 2013; Chiozzi et al., 2022; Koutchma et al.,
1183 2016). Microorganisms of concern also vary in their susceptibility, with gram negative bacteria being more sensitive
1184 (Bermúdez-Aguirre & Barbosa-Cánovas, 2013). Results vary widely by food type, target organism, radiant energy,
1185 and exposure time (Bermúdez-Aguirre & Barbosa-Cánovas, 2013; Chiozzi et al., 2022; Noci, 2017). Most studies
1186 reported a greater than 1- but less than 5-log reduction in the organism of public health concern with UV-C as the
1187 only treatment, with some studies reporting less than a 1-log reduction (Chiozzi et al., 2022; Koutchma et al., 2016;
1188 Noci, 2017).

1189
1190 One disadvantage is that UV-C can disinfect only transparent foods and the food surface of opaque foods; it is
1191 ineffective where target organisms are shielded from the light (Bermúdez-Aguirre & Barbosa-Cánovas, 2013; Noci,
1192 2017). Another disadvantage is that UV can reduce vitamin C (ascorbic acid) content in juices (Basak et al., 2023;
1193 Chiozzi et al., 2022; Koutchma et al., 2016).

1194 1195 **Ultrasound**

1196 Ultrasound is another physical process used with modest success in controlling various spoilage organisms (Chiozzi
1197 et al., 2022; Režek Jambrak et al., 2018; Singla & Sit, 2021; Welti-Chanes et al., 2017). The term “ultrasound”
1198 refers to acoustic waves that are above the maximum frequency audible to human, which is approximately 20 kHz
1199 (Lacefield, 2014). Food treated with ultrasound is divided into two categories: low intensity with low energy and
1200 frequency higher than 100 kHz and high intensity with high energy and low frequency between 20 and 100 kHz
1201 (Welti-Chanes et al., 2017). Ultrasound's mode of action is known as “cavitation” or the formation of gas bubbles
1202 caused by the sound frequencies (Lacefield, 2014). Cavitation acts on microbes by removing the cells from the food
1203 surface, rendering them less resistant to sanitizers (Arvanitoyannis et al., 2017).

1204
1205 Ultrasound is the most commonly used medical diagnostic tool in the 21st century, and is considered one of the
1206 safest for humans (Lacefield, 2014). Most food industry applications are low-intensity and used in inspections for
1207 quality and detection of foreign matter (Welti-Chanes et al., 2017). High-intensity ultrasound was first used
1208 commercially for emulsification in 1960, with food applications among the first group of industrial applications
1209 (Mason, 2003). Manufacturers of food-grade ultrasound transducers for cleaning and sanitation include Parsonics
1210 (Parsonics, 2024), Kemet (Kemet, 2024), Christeyns (Christeyns, 2024), and Hielscher (Hielscher, 2024).

1211 1212 **High-pressure processing**

1213 Processors use high-pressure processing (HPP), also known as high hydrostatic pressure (HHP) processing to
1214 inactivate microorganisms in juices, milk and dairy products, fruit and vegetable preparations, and meat and poultry
1215 products (Aganovic et al., 2021; Cano-Lamadrid & Artés-Hernández, 2022; Chiozzi et al., 2022). For this method,
1216 processors put food products in packaging that can withstand high pressure and subject them to hydrostatic pressure
1217 between 100 and 1,000 MPa and temperatures between 0 °C and 120 °C (32 °F-248 °F) (Aganovic et al., 2021).
1218 Efficacy varies depending on characteristics of the food including (Aganovic et al., 2021):

- 1219 • pH
- 1220 • moisture content
- 1221 • physical composition
- 1222 • entrapment of microorganisms in the food matrix

1223
1224 The most common application of HPP is decontamination of meat and meat products (Huang et al., 2017). The US
1225 Food Safety Inspection Service (US FSIS) recognizes that HPP can achieve a 5-log reduction in *E. coli* O157:H7

1226 and *Salmonella* in ready-to-eat meat and poultry products, but notes that some strains are pressure-resistant (US
1227 FSIS, 2012). For that reason, inspection personnel are required to verify that the Hazard Analysis and Critical
1228 Control Point (HACCP) plan is effective in achieving the 5-log reduction (US FSIS, 2012). Other pathogenic strains
1229 of *E. coli* in beef may be controlled, as well (Sheen et al., 2015).

1230
1231 Fruit and vegetable juice matrices are particularly amenable to HPP and account for a large number of commercial
1232 applications of this technology (Huang et al., 2017; Roobab et al., 2021). HPP treated carrot juice had sensory
1233 characteristics of color, appearance, aroma, taste, and overall acceptability that were more similar to fresh juice
1234 when compared to thermally-treated juice, with approximately the same level of microbial inactivation (Zhang et al.,
1235 2016). Compared with UV light and thermal processing, HPP shows excellent retention of vitamin content in
1236 various fruit and vegetable juices, particularly vitamin C (Koutchma et al., 2016; Rawson et al., 2011). Thermal
1237 processing is sufficient, as long as the processing controls are documented (US FDA, 2004). HPP is not likely to
1238 require prior FDA approval because it is a physical process and not a chemical additive or exposure to radioactive
1239 substances, unlike ionizing radiation or chemical treatment, but it still needs to be verified and validated by a
1240 process authority with expertise in food safety (US FDA, 2004).

1241
1242 Processors can also use HPP in wine production (Bañuelos et al., 2020). While ozone is a substitute for sulfur
1243 dioxide and other sulfiting agents, HPP also shows promise as a substitute for no-sulfite-added wines (Bañuelos et
1244 al., 2020).

1245
1246 Dairy processors first used HPP to preserve unrefrigerated fluid milk in 1899 (Hite, 1899). Sensory and quality
1247 panelists have rated HPP treated milk and plant-based milk substitutes as having superior sensory quality and
1248 nutritional content compared to thermally processed versions. Researchers also reported that the HPP treated milk
1249 and plant-based milk substitutes achieved comparable levels of pathogen reduction and shelf stability compared to
1250 thermally processed versions (Andrés et al., 2016; Goyal et al., 2013; Huppertz, 2010; Rendueles et al., 2011).
1251 However, dairy processors have been reluctant to replace thermal pasteurization with HPP pasteurization for various
1252 reasons (*e.g.*, cost, regulatory uncertainty, and lack of familiarity with the technology) despite documented benefits
1253 in quality and functionality (Huppertz, 2010).

1254
1255 The most frequently mentioned barrier to adoption is the cost. HPP equipment is relatively expensive to purchase
1256 when compared with alternative antimicrobial technologies (Aganovic et al., 2021; Chiozzi et al., 2022; Huppertz,
1257 2010). HPP is also more scale-limited than thermal processing because it requires batch processing, and the largest
1258 vessels reported to withstand the high pressure have a 600 L (~160 gal) capacity (Huppertz, 2010). The regulations
1259 of HPP are also not as clearly defined as with thermal technology, leading to some resistance to its adoption (Huang
1260 et al., 2017). Processors in the U.S. that use HPP are responsible for the verification and validation of its efficacy
1261 (21 CFR 120.25). High-pressure processing is not likely to require FDA prior approval, but any such assumption
1262 should be verified by the process authority specified in the HACCP Plan (US FDA, 2004).

1263

1264

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1265

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1272

1273 All individuals comply with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of
1274 Interest for Contractor Employees Performing Acquisition Functions.

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Appendix A

Sources of Organic Essential Oils

Table 3 contains a list of USDA NOP certified organic essential oil handlers downloaded from the USDA Organic Integrity Database (OID) on November 4, 2024. The database is a union of the search for “Essential oils”, “Cinnamon oil”, “Peppermint oil”, and “Thyme oil” certified as organic under the handler scope. Handling operations may be distributors and not primary manufacturers. Some operations are certified by more than one agent, with certification agents certifying different essential oils handled by the same handler.

Table 3: Sources of Organic Essential Oils

Operation name ^a	Certified essential oil(s)	Certifier ^b	Country ^c
A G Organica Private Limited	Cinnamon oil, Peppermint oil, Thyme oil	ECO	India
A To Z Beauty, Llc DbA Cliganic	Peppermint oil, Essential oils (other)	QAI	USA
AAC Natural Products Private Limited	Cinnamon oil, Peppermint oil, Thyme oil	MAYA	India
Aadroit Indulgence Pvt. Ltd.	Cinnamon oil, Peppermint oil, Thyme oil	MAYA	India
Aaron Thomas Company, Inc.	Cinnamon oil	QAI	USA
Abdullah Inan-inan Tarim Ürünleri Ticaret	Thyme oil	ECO	Turkey
Actionpak Inc.	Peppermint oil, Essential oils (other)	PCO	USA
Agrinsa Agroindustrial S.a.	Essential oils (other)	OIA	Argentina
Agropecuária Gavião Ltda	Essential oils (other)	IBD	Brazil
Al Dahlia For Import & Export	Peppermint oil, Thyme oil, Essential oils (other)	BIOI	Egypt
All-One-God-Faith, Inc. DbA Dr. Bronner’s Magic Soaps, DbA Dr. Bronner’s	Cinnamon oil, Peppermint oil	OTCO	USA
Alpha Research & Development Ltd	Peppermint oil, Thyme oil	ECO	USA
Amrita Aromatherapy, Inc.	Essential oils (other)	OTCO	USA
Apple Food Industries	Peppermint oil	ECO	India
Arasa Gida Perakende Yatirim Ve Isletme San. Tic. A.s	Essential oils (other)	OIA	Turkey
Aroma Source Sarl Sarl	Essential oils (other)	ECO	Madagascar
Aromatics Llc	Essential oils (other)	MTDA	USA
Aryan Food Ingredients Ltd	Cinnamon oil, Peppermint oil, Thyme oil	MAYA	India
Aryan International Fzc	Cinnamon oil, Peppermint oil, Thyme oil	BIOI	UAE
ATS Trade Llc	Essential oils (other)	OIA	Argentina
Auburndale Plant Holdings, Llc	Peppermint oil	OTCO	USA
Australian Botanical Products	Peppermint oil, Essential oils (other)	ACO	Australia
Ayanda African Oils	Essential oils (other)	ECO	South Africa
Azafran Innovacion Ltd.	Cinnamon oil, Peppermint oil	ECO	India
Azure Farm	Peppermint oil	OTCO	USA
B D Aromatics Pvt. Ltd.	Peppermint oil	ECO	India
B&B Family Farm	Essential oils (other)	WSDA	USA
B&P Via Pack Brasil Produtos Alimentícios Ltda	Essential oils (other)	IBD	Brazil
Bigaflo Sa	Essential oils (other)	ECO	Tunisia
Bio Extracts (pvt) Ltd.	Essential oils (other)	CUC	Sri Lanka
Bio- Logic Sarl	Essential oils (other)	ECO	Madagascar
Biolandes Maroc Sarl	Essential oils (other)	ECO	Morocco
Bleroch S.a.	Essential oils (other)	OIA	Uruguay
Bonnie House Co., Ltd	Peppermint oil, Essential oils (other)	ACO	Taiwan
Bonnie House Pty Ltd	Peppermint oil, Essential oils (other)	ACO	Australia
Botanic Healthcare Llc	Cinnamon oil, Peppermint oil	ONE	USA
Botanika Tarim Ürünleri Kozmetik Gida Yag San. Tic. Ltd. Sti.	Thyme oil	ECO	Turkey
Bothota Organic Growers	Cinnamon oil	CUC	Sri Lanka
Brasil Citrus Indústria E Comércio Ltda	Essential oils (other)	IBD	Brazil
Bulk Cart (the)	Peppermint oil, Thyme oil	ONE	USA
C & A Service, Inc. - Abington, Md	Peppermint oil, Thyme oil	WFCFO	USA
Callisons, Inc.	Peppermint oil	OTCO	USA
Calosur Industrial S.a.	Essential oils (other)	OIA	Uruguay
Celebration Holdings Private Limited	Peppermint oil, Essential oils (other)	CUC	Sri Lanka
Charasmatic Trading & Consulting	Cinnamon oil, Peppermint oil, Thyme oil	OTCO	USA
Citrus & Allied Essences Ltd - Belcamp	Peppermint oil, Thyme oil	WFCFO	USA

Operation name ^a	Certified essential oil(s)	Certifier ^b	Country ^c
Clear Petroleum S.a.	Essential oils (other)	OIA	Argentina
Colombo Export & Import Agencies (pvt) Ltd	Essential oils (other)	CUC	Sri Lanka
Cosmetik Lab	Essential oils (other)	ECO	Morocco
Cupi Essential	Essential oils (other)	BIOI	Albania
Cvista, Llc	Essential oils (other)	OC	USA
Daily Harvest, Inc.	Peppermint oil	QAI	USA
Delbia Do Company	Essential oils (other)	NFC	USA
Ditco Dis Ticaret Gida San. Ltd. Sti.	Thyme oil	ECO	Turkey
Earthstar Farms, Llc	Essential oils (other)	CDA	USA
Ecocitrus - Cooperativa Dos Citricultores Ecologicos Do Vale Do Cai Ltda.	Essential oils (other)	IBD	Brazil
Ecodab Gida Tarim Kozmetik Yag Yem San.ve Tic.ltd.sti.	Thyme oil	ECO	Turkey
Elaga Sa	Essential oils (other)	ECO	Burundi
Elmar Limité	Essential oils (other)	ECO	Bosnia and Herzegovina
Eoas Organics (pvt) Ltd	Essential oils (other)	CUC	Sri Lanka
Espar S.r.l.	Essential oils (other)	OIA	Argentina
Essenceworks Pty Ltd	Thyme oil, Essential oils (other)	ACO	Australia
Ethereal Ingredients Private Limited	Cinnamon oil, Peppermint oil, Thyme oil	IBD	India
Excellentia Flavours Llc Dbá Excellentia International	Peppermint oil, Thyme oil	OTCO	USA
Expo Ceylon	Essential oils (other)	CUC	Sri Lanka
Extracts-unlimited, Llc	Peppermint oil, Thyme oil	OTCO	USA
Fairoils Madagascar Sarl	Essential oils (other)	ECO	Madagascar
Fdb Agroexport S.a.	Essential oils (other)	OIA	Argentina
Filaroma Ltd	Cinnamon oil, Peppermint oil	ECO	Mauritius
Firmenich Inc	Peppermint oil	ECO	USA
Fitzgerald's Organic Farm	Essential oils (other)	WSDA	USA
Flatiron Fields Llc	Essential oils (other)	WSDA	USA
Flavor Producers Llc	Peppermint oil	OTCO	USA
Flavorchem Corporation	Peppermint oil	QAI	USA
Flavorfocus, Llc Dbá Brookside Flavors & Ingredients	Peppermint oil	OTCO	USA
Floribis Sarl	Essential oils (other)	ECO	Madagascar
Forest Farmstead	Essential oils (other)	WSDA	USA
Fragrant Garden Sa	Essential oils (other)	ECO	Madagascar
Fuerte Del Bañado S.a.	Essential oils (other)	OIA	Argentina
G R Davis Pty Ltd	Essential oils (other)	ACO	Australia
Galowin S.a.	Essential oils (other)	OIA	Uruguay
Gie Targanine	Essential oils (other)	ECO	Morocco
Global Essence, Inc.	Peppermint oil, Thyme oil	QAI	USA
Going Natural S.r.l.	Essential oils (other)	OIA	Argentina
Gold Coast Ingredients, Inc.	Cinnamon oil, Peppermint oil, Thyme oil	QAI	USA
Golden Grove Naturals Pty Ltd	Peppermint oil, Essential oils (other)	ACO	Australia
Grain Millers, Inc.	Peppermint oil	OTCO	USA
Green Mountain Flavors, Inc.	Cinnamon oil, Peppermint oil	OTCO	USA
Greenleaf Extractions Pvt Ltd	Peppermint oil	BIOI	India
H2ea Sarl	Essential oils (other)	ECO	Morocco
Halilovic D.o.o.	Essential oils (other)	ECO	Bosnia and Herzegovina
Hangzhou Natur Foods Co., Ltd.	Essential oils (other)	IBD	China
Hashem Brothers For Essential Oils And Aromatic Products	Peppermint oil	CUC	Egypt
Hddes Extracts (pvt) Ltd	Cinnamon oil, Peppermint oil, Thyme oil, Essential oils (other)	CUC	Sri Lanka
Ideal Providence Farm Sole Proprietorship	Essential oils (other)	ECO	Ghana
Il Health & Beauty Natural Oils Co., Inc.	Peppermint oil, Thyme oil, Essential oils (other)	ONE	USA
Imcd Us Llc	Peppermint oil	QAI	USA
Inducitrica S.a.	Essential oils (other)	OIA	Argentina
Indus Cosmeceuticals Pvt. Ltd.	Cinnamon oil, Peppermint oil, Thyme oil, Essential oils (other)	ECO	India

Operation name ^a	Certified essential oil(s)	Certifier ^b	Country ^c
Intercit Inc DbA Firmenich	Peppermint oil	ECO	USA
Intraflavors	Essential oils (other)	ECO	Madagascar
Jall - Extração E Comercialização De Óleos Essenciais Ltda (aka Oleos Essenciais)	Essential oils (other)	IBD	Brazil
Jardin Du Soleil	Essential oils (other)	WSDA	USA
Jedwards International, Inc.	Peppermint oil	QAI	USA
Joh. Vögele Kg	Peppermint oil, Thyme oil	ECO	Germany
Jsh Farms, Inc. DbA Sunwest Ingredients	Essential oils (other)	ODA	USA
Kerry Ingredients & Flavours	Peppermint oil, Thyme oil	OTCO	USA
La Moraleja S.a.	Essential oils (other)	OIA	Argentina
Labbeemint, Inc.	Essential oils (other)	WSDA	USA
Laboratorio Elea Phoenix S.a.	Essential oils (other)	OIA	Argentina
Lake Alfred Holdings, Llc DbA Florida Caribbean Distillers Lake Alfred, Llc	Peppermint oil	OTCO	USA
Las Frutas Global Gida San. Ve Tic. Ltd. Sti.	Peppermint oil, Thyme oil	ECO	Turkey
Latin Lemon S.a.	Essential oils (other)	OIA	Argentina
Lavender Hill Farm	Essential oils (other)	WSDA	USA
Lebermuth Company (the), Inc.	Peppermint oil, Thyme oil	OTCO	USA
Lemur International, Inc	Essential oils (other)	WFCFO	USA
Lermond Company (the), Llc	Peppermint oil	OTCO	USA
Lihini Nature Products (pvt) Ltd	Essential oils (other)	CUC	Sri Lanka
Litoral Citrus S.a.	Essential oils (other)	ECO	Argentina
Lotus Brands, Inc	Essential oils (other)	WFCFO	USA
M3r International Llc	Essential oils (other)	OIA	Argentina
Mada Perfect Choice (mapec)	Essential oils (other)	ECO	Madagascar
Madamanag Sarl	Essential oils (other)	ECO	Madagascar
Makingcosmetics Inc.	Peppermint oil, Essential oils (other)	WSDA	USA
Mane Kancor Ingredients Private Ltd	Peppermint oil	ECO	India
Maple Holistics Llc	Essential oils (other)	NFC	USA
Marshall's Flavor House, Inc. DbA Avron Resources	Peppermint oil, Thyme oil	OTCO	USA
Matha Exports International Llp	Peppermint oil, Thyme oil	ECO	India
Mava Sa Société Anonyme	Essential oils (other)	ECO	Madagascar
Meabeauty	Peppermint oil	ECO	Tunisia
Mel-co	Essential oils (other)	OC	USA
Metarom Usa, Llc	Peppermint oil	OTCO	USA
Milky Way Trading DbA Get Natural Essential Oils	Peppermint oil, Thyme oil, Essential oils (other)	PCO	USA
Millot Aromatiques Bio	Essential oils (other)	ECO	Madagascar
Moksha Lifestyle Products	Cinnamon oil, Peppermint oil, Thyme oil	MAYA	India
Moksha Organics	Cinnamon oil, Peppermint oil, Thyme oil	ECO	India
Morechem Co., Ltd.	Peppermint oil	CUC	Korea (the Republic of)
Morning Myst Botanics	Essential oils (other)	WSDA	USA
Most Wise International Limited	Peppermint oil	CUC	Hong Kong
Mountain Valley Organics, Llc DbA Mountain Valley Botanics DbA Mountain Valley Garlic	Essential oils (other)	WSDA	USA
Mudar India Exports	Peppermint oil	CUC	India
Nap Naturally Australian Products Pty Ltd	Essential oils (other)	ACO	Australia
Nathan's Naturals Llc	Essential oils (other)	WSDA	USA
Natural Farms Llc	Essential oils (other)	OIA	Argentina
Naturally Australian Products (nap), Inc. DbA Nap Global Essentials	Cinnamon oil, Peppermint oil	OTCO	USA
Navada Imports, Llc	Thyme oil	OTCO	USA
Neikim S.a.	Essential oils (other)	OIA	Uruguay
New Directions Australia	Essential oils (other)	ACO	Australia
Niche Naturals Llc	Essential oils (other)	OIA	USA
Nisarga Biotech Pvt. Ltd.	Peppermint oil	ECO	India
Nishant Aromas Private Limited	Peppermint oil	CUC	India
Norwest Ingredients, Llc	Peppermint oil	OTCO	USA
Noushig, Inc. DbA Amoretti	Peppermint oil	OC	USA
Now Canada (division Of Puresource Corporation)	Peppermint oil	ECO	Canada

Operation name ^a	Certified essential oil(s)	Certifier ^b	Country ^c
Now Foods, Inc.	Peppermint oil, Essential oils (other)	QAI	USA
Nutpro S.r.l.	Essential oils (other)	OIA	Argentina
Nutrin S.a.	Essential oils (other)	OIA	Argentina
Oc Flavors, Llc Dba Mosaic Flavors	Peppermint oil	QAI	USA
Oh, Oh Organic, Inc.	Peppermint oil	OTCO	USA
Onsibon S.a.	Peppermint oil, Essential oils (other)	OIA	Argentina
Organic Botanicals, Llc	Essential oils (other)	WSDA	USA
Organic India Private Limited	Peppermint oil	CUC	India
Organic Infusions Inc	Cinnamon oil, Thyme oil	OC	USA
Organic Suppliers S.r.l	Essential oils (other)	OIA	Argentina
Origines Sarl	Essential oils (other)	ECO	Madagascar
Paclantic Naturals Llc.	Peppermint oil	ECO	USA
Panisal S.a.	Essential oils (other)	OIA	Uruguay
Pearl Banyan Capitol Llc Dba Banyan Botanicals Formerly Known As Banyan Trading Co	Cinnamon oil	QAI	USA
Pehuajo Prome S.a.	Essential oils (other)	OIA	Argentina
Phalada Agro Research Foundations Pvt. Ltd.	Peppermint oil	CUC	India
Phoenix Flavors, Llc	Cinnamon oil, Thyme oil	OTCO	USA
Pikes Peak Organic Manufacturing	Essential oils (other)	WFCFO	USA
Plant Lipids Private Limited	Cinnamon oil	BIOI	India
Plantus Industria E Comércio De Óleos Extratos E Saneantes Ltda	Essential oils (other)	IBD	Brazil
Plenty Foods Pty Ltd	Essential oils (other)	ACO	Australia
Pompeii Street Soap Co.	Essential oils (other)	PCO	USA
Positively Aromatic, Llc	Essential oils (other)	WSDA	USA
Proagri Solutions Llc	Cinnamon oil, Peppermint oil	OTCO	USA
Pt. Tripper Nature	Essential oils (other)	CUC	Indonesia
Pure Essential Oils & Herbs	Peppermint oil, Thyme oil, Essential oils (other)	BIOI	Egypt
Purple Path Farm	Essential oils (other)	WSDA	USA
Quantum Fulfillment And Support Llc	Essential oils (other)	NFC	USA
Quintis Sandalwood Pty Ltd	Essential oils (other)	ACO	Australia
Rakesh Products	Cinnamon oil, Peppermint oil, Thyme oil	CUC	India
Rakesh Sandal Industries	Cinnamon oil, Peppermint oil, Thyme oil	ECO	India
Randriampenomaro Harimanana	Essential oils (other)	ECO	Madagascar
Reliable Products Inc. Dba Reliable Products Inc. / Pure Farms Organic	Thyme oil	OTCO	USA
Reroot Organic Pvt.ltd	Peppermint oil	ECO	India
Robertet, Inc.	Peppermint oil	OTCO	USA
Rocky Mountain Oils	Essential oils (other)	UDAF	USA
Romonti, Inc.	Essential oils (other)	WFCFO	USA
S.a. San Miguel A.g.i.c.i. Y F	Essential oils (other)	OIA	Argentina
S.a. Treated Poles & Timber T/a Windy Ridge Oils Cc	Essential oils (other)	ECO	South Africa
S.a. Veracruz	Essential oils (other)	OIA	Argentina
Santis Sarl	Essential oils (other)	ECO	Morocco
Shemen Tov Corp. Dba Chandean Oils	Peppermint oil, Thyme oil	OTCO	USA
Sigma Services Corporation - Zion	Essential oils (other)	QAI	USA
South American Grain S.a.	Essential oils (other)	OIA	Argentina
Soyatech Pty Ltd	Essential oils (other)	ACO	Australia
Stabril S.a.	Essential oils (other)	OIA	Uruguay
Sterling Speciality Ingredients Llc	Essential oils (other)	OIA	USA
Sugrain S.a.	Essential oils (other)	OIA	Uruguay
Sunatura Exports Private Limited	Cinnamon oil, Peppermint oil, Thyme oil	CUC	India
Sundale S.a.	Essential oils (other)	OIA	Uruguay
Sunflag Agrotech 2	Peppermint oil	MAYA	India
Sustainable Botanicals International	Peppermint oil, Thyme oil	NFC	USA
Switch Supply Pty Ltd	Cinnamon oil, Peppermint oil, Essential oils (other)	ACO	Australia
Tech-vina Joint Stock Company	Essential oils (other)	CUC	Viet Nam
Tecnodesierto S.a.	Essential oils (other)	OIA	Argentina

Operation name ^a	Certified essential oil(s)	Certifier ^b	Country ^c
Ten Days Manufacturing Db a Daily Manufacturing	Essential oils (other)	OC	USA
Tks Co-pack Manufacturing, Llc	Essential oils (other)	UDAF	USA
Topical Pharmaceuticals Inc	Peppermint oil	ECO	USA
Tribal Medicinals	Peppermint oil	ECO	India
Trustee For Hornshaw Family Trust (the)	Essential oils (other)	ACO	Australia
Tsp Agro S.a.	Essential oils (other)	OIA	Argentina
Türer Tarım Ve Orman Ürünleri İth. İhr. San. Ve Tic. Ltd. Şti.	Thyme oil	ECO	Turkey
Uncle Harry's Natural Products	Essential oils (other)	WSDA	USA
Ungerer And Company	Peppermint oil	OTCO	USA
Ute Bv S.a.	Essential oils (other)	OIA	Argentina
Uyar Tarım Ürünleri Gıda San. Ve Tic. A.s.	Thyme oil	BIOI	Turkey
Vicente Trapani S.a.	Essential oils (other)	OIA	Argentina
Vietnam Staranised Cassia Manufacturing And Exporting Joint Stock Company (vina Samex ., Jsc)	Cinnamon oil, Essential oils (other)	CUC	Viet Nam
Vital Mark Pty Ltd	Essential oils (other)	ACO	Australia
Vlakbult Farming T/a Highland Essential Oils Vlakbult Plaas Boerdery Pty Ltd	Thyme oil	ECO	South Africa
Wee Hoe Cheng Chemicals Pte Ltd	Essential oils (other)	CUC	Singapore
Wholesale Botanics, Inc.	Essential oils (other)	ONE	USA
Wishbone Organics Inc	Essential oils (other)	OIA	USA
Wishbone S.r.l.	Essential oils (other)	OIA	Argentina
Zara Voyages Sarl	Essential oils (other)	ECO	Madagascar

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^a Operation names may be truncated. Note that some essential oils represented as certified organic under the USDA NOP standard may be produced by standards other than the USDA NOP and recognized as equivalent under an international arrangement before it is repackaged under the supervision of a USDA Accredited Certifying Agent.

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- ^b USDA Accredited Certifying Agents:
- [ACO] ACO Certification Ltd.
 - [AI] Americert International
 - [BAC] BioAgriCert
 - [BCS] Kiwa BCS Öko-Garantie GmbH
 - [BIOI] Bio.Inspecta
 - [CAAE] Servicio de Certificación CAAE S.L.U.
 - [CCOF] CCOF
 - [CDA] Colorado Department of Agriculture
 - [CERES] CERES
 - [CMEX] Certificadora Mexicana de Productos y Procesos Ecologicos SC
 - [CUC] Control Union Certifications
 - [ECO] Ecocert SAS (formerly Ecocert SA)
 - [IBD] IBD Certifications
 - [IDA] Idaho Department of Agriculture
 - [IDALS] Iowa Department of Agriculture and Land Stewardship
 - [IMOC] IMOcert Latinoamerica LTDA
 - [LETIS] LETIS S.A.
 - [MAYA] Mayacert S.A.
 - [MTDA] Montana Department of Agriculture
 - [MOSA] Midwest Organic Services Association, Inc.
 - [NFC] Natural Food Certifiers
 - [OEFFA] Ohio Ecological Food and Farm Association
 - [OCI] OneCert, International Private Limited
 - [ONE] OneCert, Inc.
 - [ODA] Oregon Department of Agriculture
 - [OTCO] Oregon Tilth Certified Organic
 - [OC] Organic Certifiers, Inc.
 - [OCIA] Organic Crop Improvement Association

- 1320 • [OIA] Organización Internacional Agropecuaria
- 1321 • [PCO] Pennsylvania Certified Organic
- 1322 • [QAI] Quality Assurance International
- 1323 • [QCS] Quality Certification Services
- 1324 • [SCS] SCS Global Services, Inc.
- 1325 • [SRS] SRS Certification GmbH
- 1326 • [TDA] Texas Department of Agriculture
- 1327 • [TNC] Transitioning to a New Certifier
- 1328 • [UDAF] Utah Department of Agriculture and Food
- 1329 • [WSDA] Washington State Department of Agriculture
- 1330 • [WFCFO] Where Food Comes From Organic (formerly A Bee Organic)

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° Physical location of the operation where given:

- 1333 • China = The People's Republic of China
- 1334 • Laos = Lao People's Democratic Republic
- 1335 • Netherlands = The Netherlands
- 1336 • Russia = The Russian Federation
- 1337 • UAE = United Arab Emirates
- 1338 • UK = The United Kingdom of Great Britain and Northern Ireland
- 1339 • USA = The United States of America.

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