## 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.

# Flavors Handling/Processing

Identification o	f Petitioned Substance
Chemical Names:	14 CAS Numbers:
See Appendix A - Natural Flavor Additives	15 See <i>Appendix A</i> - Natural Flavor Additives.
	16 FDA ID codes are included in lieu of CAS
Other Names:	17 Numbers where CAS numbers not assigned
See <i>Appendix A</i> - Natural Flavor Additives	18 the Chemical Abstract Service.
T 1 N	19
Trade Names:	20 Other Codes:
See <i>Appendix B</i> - Suppliers of Organic Flavors for a list of handlers identified as selling	<ul><li>21 See <i>Appendix A</i> - Natural Flavor Additives fo</li><li>22 FEMA Codes.</li></ul>
certified organic flavors.	22 FEMA Coues.
certifice of game navois.	
Summary	of Petitioned Use
	as requested a limited scope technical report on flave w of all substances on the National List of Allowed ar he USDA organic regulations every five years
This limited scope technical report supplies respo	onses to the following focus questions from the NOSB
1) What flavors are available in organic fo	
,	
2) What flavors could be certified organic	based on their source and manufacturing process, bu
are not?	÷.
3) What flavors cannot be certified organic	c based on their source and manufacturing?
In addition, this report includes information about	it the composition, sources, and manufacturing
	ternational allowances in organic and conventional
product formulations is also included.	<i>σ</i>
•	
	nagricultural nonsynthetic ingredients in processed
č i , č	ion: "Flavors - nonsynthetic flavors may be used whe
	ll flavors must be derived from organic or nonsynthe
	nthetic solvents and carrier systems or any artificial
preservative″ [7 CFR 205.605(a)].	
Elevene were one of the exhibit on each the second still and the	consideration by the NIOCD in the anising! Notice of
	consideration by the NOSB in the original National
List. On October 31, 1995, the NOSB (1995) recom	mended the following for flavors:
"Upon implementation, all manufacturers w	ill he required to have certification from the
producers of natural flavors that,	00 годиной ю ниос сонцисаной угони ние
producers of natarat fuctors that,	
For "organic food" (95%-100% organic in	igredients):
	natural flavor are from natural sources and have
	hich makes them different than their natural
chemical state.	
	l using any synthetic solvents and carrier systems
or any artificial preservatives.	

61	
62	For "foods made with organic ingredients" (50%-95% organic ingredients):
63	1) All of the flavor constituents used in the natural flavor are from natural sources and have
64	not been chemically modified in a way which makes them different than their natural
65	chemical state.
66	2) The natural flavor does not contain propylene glycol, any artificial preservatives, and is not
67	extracted with hexane.
68	
69	Additionally, manufacturers shall provide written documentation in their Organic Handling
70	Plan showing efforts made toward the ultimate production of an organic natural flavor as listed
71	in the stepwise progression below:
72	
73	Natural flavor constituents and non-synthetic carrier base and preservative agents (ex. grain
74	ethanol, non-synthetic glycerin and non-synthetic acetic acid).
75	
76	Organic flavor constituents, organic carrier base, and organic preservative agents.
77	organie jacor constituento, organie carrier sube, and organie preservatice agents.
78	Organic flavor constituents extracted using organically produced solvents, organic carrier base,
79	and organic preservative agents."
80	
81	The USDA National Organic Program (NOP) placed "Flavors" on the original National List on December
82	21, 2000, with the following annotation: "nonsynthetic sources only and must not be produced using
83	synthetic solvents and carrier systems or any artificial preservative" [65 FR 80547]. Flavors meeting the
84	annotation were classified as nonagricultural and nonsynthetic on 7 CFR 205.605(a). The NOSB's
85	recommendation of the stepwise progression to develop organic flavors was not included in the final
85 86	regulation. On November 6, 2014, the NOP received a petition to amend the National List annotation to
87	require the use of organic flavors when commercially available (OTA, 2014). On October 29, 2015, the
88	NOSB recommended amending the annotation in response to the petition (NOSB, 2015). The NOP acted
89	on that recommendation, ultimately revising the National List annotation for flavors on January 28, 2019
90 01	[83 FR 66779].
91	
92	Characterization of Petitioned Substance
93	
94	Composition of the Substance:
95	
96	Foods are complex matrices composed of hundreds of chemical constituents. There are many definitions
97	of what constitutes a "flavor" but one comprehensive description is given in a standard flavor reference
98	(Burdock, 2016):
99	
100	"Flavor is the sum of those characteristics of any material taken in the mouth, perceived principally by the
101	sense of taste and smell, and also the general pain and tactile receptors in the mouth, as received and
102	interpreted by the brain."
103	
104	Those constituents impart such sensory qualities that are referred to as "flavors," which in turn will have
105	different legal definitions depending on the jurisdiction. The legal status of flavors is further discussed in
106	the Approved Legal Uses of the Substance section below. Food science and flavor textbooks divide tastes
107	into five basic flavors: bitter, sour, sweet, salty, and savory or umami (Attokaran, 2017; DeMan et al.,
108	2018; Lindsay, 2007; Potter & Hotchkiss, 1998). Earlier guides listed only four flavors, excluding umami
109	(Walter, 1916). The historical introduction of umami or savory flavors to the North American palate has
110	
110	been the subject of study (Tracy, 2016).
	been the subject of study (Tracy, 2016).
111	
	been the subject of study (Tracy, 2016). Flavor is highly subjective and difficult to measure (Drew, 1994; Potter & Hotchkiss, 1998; Shepherd, 2005). The olfactory senses of smell and taste are regarded as the most primitive in human cognition

114 (Shepherd, 2005). Individuals subjectively perceive various combinations of these five basic flavors

differently for complex reasons. Those factors are all subjects of ongoing research in food chemistry,
 psychology, physiology, and anthropology. The perception of flavor by an eater will depend on several

different factors including, but not limited to, the chemical composition of the food (Attokaran, 2017;

- 118 Auvray & Spence, 2008). Cultural and psychological factors are as much the basis for flavor preferences
- as chemical sensory stimulation and physical gratification (Al Saqqa, 2022; Downey & Eiserle, 1970;
- 120 Myers & Sclafani, 2006).
- 121

122 The ability to detect and identify specific chemical substances played a role for evolutionary selection.

Studies have shown that flavor is the most fundamental determinant of food preferences, acceptance, and rejection (Baeyens et al., 2001; De Houwer et al., 2001; Myers & Sclafani, 2006; Papies et al., 2022).

125

126 Different flavors and other olfactory sensations are culturally and psychologically associated with

127 different foods and non-food substances (Al Saqqa, 2022; Baeyens et al., 2001; Downey & Eiserle, 1970;

128 Myers & Sclafani, 2006; Papies et al., 2022). The perception of flavor is also linked to the other senses, 129 such as feel or texture, sight or color, and sound of the food as it is being prepared or consumed

(Attokaran, 2017; Auvray & Spence, 2008; B. Smith, 2012). As such, flavor composition can be viewed

131 from a reductionist perspective of isolating and optimizing individual flavoring substances through

- 132 analytical and extraction methods. On the other hand, from a holistic perspective, flavor composition is
- 133 more than a collection of chemicals in a food or ingredient. The identification and naming of substances
- responsible for different attributes found in foods is confounded by the interactions between different
- 135 chemical components in the food. The same flavor component may be present in a wide variety of foods,
- 136 but will have different sensory qualities in each of those foods (Chambers & Koppel, 2013).
- 137

138 Over 3,000 different flavor ingredients are used in food (IOFI, 2022; U.S. FDA, 2022). These may be

characterized as individual molecular substances obtained from precursors extracted from agricultural

sources, or as concentrated foods. Individual flavors can range from simple single ingredients to

141 formulations that are often chemically complex. The International Organization of the Flavor Industry

142 (IOFI) identifies over 600 source materials or naturally complex substances used for flavoring (IOFI,

- 143 2022). Some complex flavorings may have over 100 different identifiable individual substances contained
- 144 within them (J. B. Hallagan et al., 2020; Somogyi, 2000). Their compositions vary widely depending on

145 their types, origins, precursors, extraction methods, and adjuncts.

146

147 The growth of the flavor industry in the second half of the 20<sup>th</sup> century was driven by several

148 technological advances (Berenstein, 2018). One was the advance in analytical chemistry. Isolating specific

149 flavor chemicals using the techniques available in the 1940s often took very large sample sizes of plant

sources (Haagen-Smit, 1949). The ability to identify specific substances that account for flavor is a

relatively recent development in food science, going back to the late 1950s with the advent of technology

152 involving gas chromatography and fast-scan mass spectrometry (Lindsay, 2007). These analytical

153 methods allowed for a more efficient and precise identification of specific flavor agents. The rapid

advances in the 1960s and 1970s made food scientists hopeful that they would be able to identify, isolate,

and extract pure aromas and flavors, despite apparent limitations (Teranishi et al., 1967). Analytical

chemistry is now capable of the identification of specific substances that can change a flavor profile at

- 157 concentrations down to parts per trillion (ppt or  $10^{-12}$ ) (Lindsay, 2007).
- 158

## 159 Source or Origin of the Substance:

160

161 Natural flavors can come from a wide variety of sources. The oldest sources are from wild plants and

162 animals. There is evidence that herbs and spices were wild crafted before being cultivated. Flavors can be

- extracted from wild-crafted plants, moss, algae, fungi, or lichens, as well as animals. Some naturally-
- 164 occurring algae are potential sources of flavoring compounds (Francezon et al., 2021). Lichens have been
- used as ingredients in traditional ayurvedic medicines for centuries, and have recently found markets as
- 166 fragrances and flavors (Upreti et al., 2005). These species also may be either wild-harvested or cultivated.

168 Most commercial sources of natural flavors originate from agriculturally produced crops and livestock. 169 Food consisted almost entirely of agricultural or wild-harvested ingredients prior to the industrial 170 revolution of the 19th century. The flavor manufacturing industry emerged as a separate entity in food 171 production about 150 years ago. Glucovanillin (imitation vanilla flavor) was first synthesized from coniferin, giving birth to the flavor industry (Guentert, 2007; Haarmann, 1884). Other flavors and 172 173 fragrances were chemically isolated and synthesized not long afterwards. Some flavors may have natural 174 precursors but are the products of chemical synthesis (van der Schaft, 2007). Flavors that are synthesized 175 but have a molecular structure that is analytically the same as their natural analogs are called "nature 176 identical" in some jurisdictions (Müller, 2007; Somogyi, 2000). The term is not legally recognized in the 177 U.S. by the FDA, and European legislation removed recognition in 2010 [EC 1334/2008]. The term 178 "nature identical" still appears in the Codex Guidelines on food labeling as a valid claim (FAO/WHO 179 Joint Standards Programme, 2018) and may be recognized in jurisdictions outside of North America and 180 Europe.

181

182 As methods to identify flavor chemicals improved, the processing methods to extract the identified

- 183 substances from natural sources evolved. Research and development also resulted in synthesis processes
- 184 using novel precursors that were intended to replicate the structures and performance of natural flavor
- 185 analogs. These synthetic chemicals were often chemically identical to their natural analogs, and may
- have a higher concentration, but were still seen as "impure" compared to the botanical sources. As the 186
- flavor industry grew and new synthetic products were introduced, the classifications of flavors as 187
- 188 "natural" or "artificial" were often arbitrary and not always consistent (Berenstein, 2018). The term
- 189 "semi-synthetic" was sometimes used to describe substances synthesized from natural origins (Jacobs, 190 1947). However, the term is rarely used in the current literature and has lost its original meaning.
- 191

192 From its very beginning, the flavor industry had to balance consumer expectations to make food with

- 193 familiar flavors derived from natural sources with food consistently produced at a reasonable cost
- 194 (Jacobs, 1947). The USDA organic regulations reflect the consumer preference for organic and natural
- 195 sources of ingredients. The demand for organic food took the food and flavor industries to a new level in
- 196 a search for organic flavors. A review of the literature indicates that those who buy organic food may
- 197 have a different set of quality preferences from other consumers, with flavor differences being one of the
- 198 main qualities identified (Schleenbecker & Hamm, 2013). A review of consumer demand for foods
- 199 labeled "100% organic" or that do not contain nonorganic flavors is beyond the scope of this limited
- 200 scope technical report.
- 201

202 Certified organic flavors are a relatively recent phenomenon. Flavors sold as "100% organic" consist 203 entirely of organic agricultural ingredients, excluding water and salt [7 CFR 205.301(a)].<sup>1</sup> Flavors labeled 204 as "organic" must contain a minimum of 95% organic ingredients, excluding water and salt, and may contain up to 5% nonorganic ingredients [§ 205.301(b)].<sup>2</sup> The nonorganic ingredients used in an organic 205

- 206 flavor may include natural flavors that are not organic [§§ 205.301(b) and 205.605(a)].<sup>3</sup> Certified organic
- 207 flavors that have flavoring agents other than those claimed on the label may be labeled as "[specific
- 208 flavor] type. WONF" (With Other Natural Flavors) [21 CFR 101.22(i)(1)(iii)].
- 209
- 210 Following the lawsuit, Harvey v. Veneman [396 F.3d 28 (1st Cir. 2005)], the deciding judge ordered the
- 211 USDA to clarify that the commercial unavailability of organic ingredients did not create a blanket
- 212 exemption allowing the use of nonorganic ingredients. The USDA issued that clarification on July 1, 2005
- [20 FR 38090]. Certified organic handlers and their certification agents who had misinterpreted the 213
- regulations were given until June 9, 2007 two years from the date of the judge's order to comply. The 214
- 215 court also required USDA to notify the public that all agricultural ingredients used in processed
- 216 products labeled as "organic" must be either organically produced or to appear on the National List of
- 217 allowed nonorganic ingredients, not to exceed the total amount by weight, net of water and salt. On

<sup>1 § 205.301</sup> Product composition. (a) Products sold, labeled, or represented as "100 percent organic."

<sup>&</sup>lt;sup>2</sup> § 205.301 Product composition. (b) Products sold, labeled, or represented as "organic."

<sup>&</sup>lt;sup>3</sup> § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." (a) Nonsynthetics allowed.

- 218 June 7, 2006, the USDA revised the regulations based on the court order to reflect this clarification 219 [71 FR 32803].
- 220

221 In that same clarification, the USDA initiated an emergency petition procedure to add agricultural 222 substances that had been approved by certifying agents for use in organic processed products but did

223 not appear on 7 CFR 205.606.<sup>4</sup> In response, various entities filed over 50 petitions for agricultural items

224 deemed necessary by the petitioners to be added to the National List. The NOSB began their 225 consideration of these materials at the March 2007 meeting [72 FR 10971]. Several agricultural sources of

226 flavors were petitioned, including a petition for "spices, dried" (Kopral & Twieg, 2006). The NOSB

- 227 recommended some – specifically celery powder, dillweed oil, frozen galangal, hops, frozen lemongrass,
- 228 chipotle chili peppers, and Turkish bay leaves - to be added to the National List. These substances were
- 229 added to § 205.606 of the National List on June 27, 2007 [72 FR 35137]. The NOSB did not recommend
- Poblano peppers, red peppers, or spices (NOSB, 2007). Some agricultural ingredients that serve as 230
- 231 flavorings were added as "colors," including saffron, paprika, blueberry, cherry, and turmeric 232 [72 FR 35137].
- 233

234 The NOSB heard testimony at the March 2007 meeting as to whether flavors as a group or individual

235 flavors would be more appropriate for addition to § 205.606 and subject to commercial availability, or if

- 236 they should otherwise remain on § 205.605. However, the NOSB made no recommendation at that
- 237 meeting to reclassify flavors as agricultural. Several members of the NOSB stated the opinion that
- 238 individual agricultural flavors needed to be petitioned to be used from nonorganic agricultural sources
- 239 in organic processed products (NOSB, 2007). Thus, there appeared to be a consensus that herbs, spices,
- 240 cultivated plants, and food animals were agricultural.
- 241

242 Table 1 provides a summary of the organic status of various conceptual sources, origins, production, and

243 processing methods of flavor ingredients based on NOP and FDA regulations. Sources can be

244 agricultural or nonagricultural. Production, handling, and processing methods can either comply with

- 245 the organic regulations or be noncompliant. The final products may be either synthetic or nonsynthetic.
- 246 Finally, there are methods that are excluded from all organic claims that need to be considered. These 247 combinations of conditions result in four different cases to be considered when evaluating flavor
- 248 ingredients for use in organic processed products. At one end, flavors that are 100% organic allow for
- 249 final food products to be labeled as 100% organic. At the other end, excluded flavoring agents prevent
- 250 processed products from making any organic claim, regardless of the percentage of organic content. The

251 cases presented may not reflect how certifying agents make actual certification decisions for specific

252 flavors or products. This technical report discusses certification best practices and how certifying agents classify ingredients in section Responses to NOSB Focus Questions.

253 254 255

## Table 1: Flavor Ingredients in Organic Processed Products by Sources and Processing Methods

Case # and Source / Origin	Processing Methods	Organic Status
	Processed compliant with organic handling standards (Extracted, isolated, and formulated using methods listed on 7 CFR 205.270—i.e., mechanical or biological methods; not combined/treated with volatile synthetic solvents, processing aids or ingredients not on § 205.605.). Produced and handled without excluded methods or ionizing radiation.	<ul> <li>Organic agricultural.</li> <li>Allowed in processed products labeled "Organic" or "Made with Organic [specific ingredient(s)]."</li> </ul>

<sup>&</sup>lt;sup>4</sup> § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Case # and	Processing Methods	Organic Statuc
Case # and Source / Origin	Processing Methods	Organic Status
2. Nonorganic crops and livestock	Processed compliant with organic handling standards (Extracted, isolated, and formulated using methods listed on 7 CFR 205.270 – i.e., mechanical or biological methods; not combined/treated with volatile synthetic solvents, processing aids or ingredients not on § 205.605.). Produced and handled without excluded methods or ionizing radiation. Produced and handled without excluded	<ul> <li>Nonorganic agricultural; Nonsynthetic.</li> <li>Allowed in processed products labeled "Organic" if on § 205.606 and not commercially available as organic, or in products labeled "Made with Organic [specific ingredient(s)]."</li> </ul>
3. Nonagricultural source	methods, ionizing radiation or sewage sludge. Processed compliant with organic handling standards (Extracted, isolated, and formulated using methods listed on 7 CFR 205.270 – i.e., mechanical or biological methods; not combined/treated with volatile synthetic solvents, processing aids or ingredients not on § 205.605). Produced and handled without excluded methods or ionizing radiation.	<ul> <li>Nonagricultural; Nonsynthetic.</li> <li>Allowed as a flavor in processed products labeled "Organic" if an organic source is not commercially available, or in products labeled "Made with Organic [specific ingredient(s)]."</li> </ul>
<ol> <li>All sources, precursors and derivatives, including organic agricultural ingredients</li> </ol>	Processed not compliant with organic handling standards. Extracted, isolated, and formulated using methods not listed on 7 CFR 205.270, combined/treated with volatile synthetic solvents, or made with processing aids or ingredients not on § 205.605. . Specifically, handled not consistent with the annotation at § 205.605(a), or declared "synthetic" by the FDA at 21 CFR 172.515 or § 182.60. Produced and handled using excluded methods, ionizing radiation or sewage sludge.	<ul> <li>Nonagricultural; Synthetic.</li> <li>Prohibited for use as an ingredient in processed products labeled "Organic" and "Made with Organic" [specific ingredients(s)].</li> </ul>

256 Sources: 7 CFR 205; 21 CFR 182.

#### 257

258 A growing number of compounds previously derived from wild sources are being produced

synthetically or through the fermentation of genetically modified microorganisms. Developments in

260 biotechnology have enabled aroma and flavor chemicals previously limited to a small number of

organisms to be expressed by a wide range of organisms through genetic engineering (R. G. Berger, 2009;

262 Y. H. Hui et al., 2010). The FDA has declined to address the identification and labeling of flavors

obtained from genetically modified sources (Hallagan, 2017). Most of these sources would be considered

264 excluded from organic production and handling by the excluded methods prohibition at § 205.105(e).

265 Individual cases are explored further in *Evaluation Question* #2.

266

Flavors are also derived from animals as both slaughter and non-slaughter products. Various dairybased flavorings are prepared from milk, which may come from cows, sheep, goats, buffalo, or other

269 mammals. Egg derivatives may be used as flavoring agents as well.

270

271 Historically, some animals were hunted, caught, or trapped for their fragrances and flavors. Musk deer

272 (Moschus moschiferus) and sperm whales are now protected species, and the muscone and ambergris

273 respectively harvested from them have not been commercially available in any form for many years

274 (Frey, 2005). Archeological evidence shows that First Nations people of Canada used castoreum from

275 276	beavers in pre-Columbian America (Helwig et al., 2021). Castoreum from beavers remains one of the few wild-animal derived substances that is GRAS and still used as a flavoring agent (Burdock, 2007).
277	
278	Two flavoring substances may have identical molecular formulas, but have different molecular
279	structures, known as isomers (Guentert, 2007). The standard textbook example is limonene, with a
280	molecular formula of $C_{10}H_{16}$ , but with two isomers or enantiomers. D-limonene, also known (R)-(+)-
281	limonene is the primary isomer extracted from citrus fruit. The L-limonene, otherwise known as (S)-(-)-
282	limonene, is largely absent from citrus fruit but found in other plant sources. Textbooks often claim that
283	one smells like lemons and the other smells like oranges, but recent empirical research showed that this
284 285	is not the case (Kvittingen et al., 2021).
285 286	Approved Legal Uses of the Substance:
280	<u>Approved Legar Oses of the Substance.</u>
287	Flavors and flavoring agents are regulated by the Food and Drug Administration (FDA) under the
288	authority given to them by the Food, Drug, and Cosmetic Act as amended. Most of the flavors within the
290	scope of this review would fall into the category of "natural flavors" or "natural flavorings" as defined
290	by the FDA:
292	by the 1DA.
293	"The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or
294	extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis,
295	which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or
296	vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood,
297	poultry, eggs, dairy products, or fermentation products thereof, whose significant function in
298	food is flavoring rather than nutritional. Natural flavors include the natural essence or
299	extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of
300	this chapter, and the substances listed in § 172.510 of this chapter." [21 CFR 101.22(a)(3)]
301	
302	Appendix A - Natural Flavor Additives includes the list of ingredients that are included in that regulatory
303	definition derived from the FDA's database "Substances in Food," formerly "Everything Allowed in
304	Food in the U.S. (EAFUS)." This report does not claim Appendix A to be an exhaustive list. The Flavor
305	and Extract Manufacturers Association (FEMA) and IOFI lists have substances included that do not meet
306	those criteria.
307	
308	By contrast, FDA defines artificial flavors and artificial flavorings as follows:
309	
310	"The term artificial flavor or artificial flavoring means any substance, the function of which is to
311	impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice,
312	edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy
313	products, or fermentation products thereof. Artificial flavor includes the substances listed in
314	§§ 172.515(b) and 182.60 of this chapter except where these are derived from natural sources."
315	[21 CFR 101.22(a)(1)]
316 317	FDA also considers spices to be a separate category from flavors:
318	FDA also considers spices to be a separate category noninnavors.
318	"The term spice means any aromatic vegetable substance in the whole, broken, or ground form,
320	except for those substances which have been traditionally regarded as foods, such as onions,
321	garlic and celery; whose significant function in food is seasoning rather than nutritional; that is
322	true to name; and from which no portion of any volatile oil or other flavoring principle has been
323	removed. Spices include the spices listed in § 182.10 and part 184 of this chapter, such as the
324	following:
325	
326	"Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon,
327	Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace,
328	Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white;

329 Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric." [21 CFR 101.22(a)(2)] 330 331 332 Flavors are largely industry self-regulated by the FEMA GRAS Panel (Hallagan et al., 2020; Hallagan & 333 Hall, 1995, 2009). The panel was established following the Food Additives Act (FAA) of 1958 [PL 85-929, 334 effective September 6, 1958]. The FAA established the basis for the FDA to declare food additives as 335 "Generally Recognized as Safe" or GRAS. Also included in the FAA was the Delaney clause, which 336 banned the use in food of any chemical found to induce cancer in people or test animals (Merrill, 1997). 337 FEMA formed its first expert panel to evaluate flavors as GRAS in 1960 (Hallagan & Hall, 1995). In the years since then, FEMA GRAS Panel assessments have resulted in over 800 flavor ingredients voluntarily 338 339 declared GRAS (Hallagan et al., 2020). While the FDA may issue a "No Questions" letter to the expert 340 panel claiming GRAS status, such action does not mean that the FDA has determined that the substance 341 is GRAS [81 FR 94959, August 17, 2016]. 342

#### 343 <u>Combinations of the Substance:</u>

Flavor delivery systems vary in their form, functionality, and complexity. Some compounded flavor
compositions may have over 100 constituents (Hallagan et al., 2020; Somogyi, 2000). They may come as
solid, liquid, or aromatic forms. The simplest flavors consist of a single flavor entity that corresponds to a
naturally present material in concentrated form. Some are basic combinations of flavoring agents. Many
if not most flavor products will contain non-flavor ingredients that are broadly referred to as "adjuvants"
(FEMA, 2011). Adjuvants include carriers, stabilizers, dispersants, emulsifiers, preservatives, and many

351 other substances with different functionalities to deliver, maintain, or enhance a flavor's performance.

352

Carriers are diluents and solvents for a flavor (Burdock, 2016). These are flavor-neutral and are used to standardize the amount of the active flavoring ingredient and facilitate handling. Liquid flavors are often

delivered within the solvent used for extraction. The most common solvent used in certified organic

355 derivered within the solvent used for extraction. The most common solvent used in certified organic 356 flavors reported by interviewed certifying agents was organic alcohol in the form of an extract or

357 tincture. Nonorganic liquid flavors often contain propylene glycol as the carrier (Burdock, 2016; Jacobs,

358 1947). The use of propylene glycol or other synthetic carriers does not comply with the current

annotation at 7 CFR 205.605(a). Similarly, the use of common synthetic preservatives: sodium benzoate,

potassium sorbate, and sulfites (FEMA, 2011), does not comply with the annotation for allowed flavors at \$ 205.605(a).

361 362

363 Solid formulations may use gums, dextrin, sugar, flour, or starches as carriers (Burdock, 2016; FEMA,

2011). Such carriers are generally agricultural and nonsynthetic. When used in a certified organic flavor,

they would also need to be organically produced and handled. When used in a nonorganic flavor they

366 would not need to be organically produced, but presumably would need to document that they are not

367 produced or handled using excluded methods, sewage sludge, or ionizing radiation. There is also a

368 growing interest in new techniques that use synthetic polymers to handle essential oils and other liquid

369 flavor ingredients in a solid form (Castro et al., 2016). Such synthetics carriers do not meet the annotation

describing allowed flavors at § 205.605(a).

371

The actual flavoring components may make up a small percentage of a given flavor delivery system.

373 Many if not most components of flavor delivery systems are prohibited by the annotation in § 205.605(a).

Even more are prohibited for use in the production of certified organic flavors. There are processing aids

and ingredients that may be used in formulating flavors that would meet the current annotation at
 § 205.605(a) but would not qualify for organic certification, even if an organic source is used to make the

376 § 205.605(a) but would not quality for organic certification, even if an organic source is used to make the 377 precursor or resulting flavor. For example, nonsynthetic carriers and preservatives would be compliant

with the \$ 205.605(a) annotation for flavors, but if they do not themselves appear on \$ 205.605(a), would

379 make a flavor ineligible for certification as organic. This is discussed in greater detail in the *Responses to* 

380 NOSB Focus Questions section. Flavors may also contain various impurities. For example, hexane-

381 extracted oleoresins may have residual hexane (Attokaran, 2017).

Handling/Processing

383 Even within certified organic flavors, certification agents interviewed reported that in many cases, over 384 95% of a certified organic flavor's formulation is the ingredient delivery system made up of flavor-neutral 385 carriers and less than 5% nonorganic flavoring agents. However, organic carriers may also be used to 386 dilute the nonorganic added components to below 5% net of water and salt to comply with the organic 387 labeling laws. 388 389 Status 390 391 International 392 393 Canada, Canadian General Standards Board – CAN/CGSB-32.311-2020, Organic Production Systems 394 **Permitted Substances List** 395 The Permitted Substances List (PSL) Table 6.4 – Ingredients not classified as food additives includes 396 (CAN/CGSB, 2021b): 397 398 Flavours: Derived from biological source (see Table 11 B (1) & (2) Origin and mode of 399 production of CAN/CGSB-32.310), and substances (see Table 6.3 Extraction solvents and 400 precipitation aids). 401 402 May contain permitted carriers (see Table 6.3 & 6.4 Carriers). 403 404 The publication appears to have a citation error in referring to Table 11 of the Canadian General 405 Principles and Management Standards for Organic Production (CAN/CGSB 32.310), which refers to the 406 substance review criteria for livestock inputs in Tables 5.2 and 5.3 of the PSL. It is Table 12 that refers to 407 substance review criteria for permitted substances in processing of organic food in Tables 6.3, 6.4, and 6.5 408 of the PSL. Table 12 Part B reads "Origin and mode of production: 1. Shall be found in nature. Substances 409 may be produced using physical (for example, extraction, precipitation), enzymatic or microbial (for 410 example, fermentation) processes, as well as through chemical extractions that do not alter the 411 substance's chemical structure. 2. Preferably from organic sources." (CAN/CGSB, 2021a). 412 413 The Table 6.3 listing for "Extraction solvents and precipitation aids" reads (CAN/CGSB, 2021b): 414 415 *The following may be used to derive (extract) substances listed in Tables 5.2, 6.3, 6.4 and 6.5:* 416 417 *a) water;* 418 *b) culinary steam, as described in 8.1.2 b) of CAN/CGSB-32.310;* 419 *c) fats, oils and alcohols other than isopropyl alcohol; d)* supercritical CO2; and 420 421 substances listed in Tables 6.3, 6.4 or 6.5 of this standard. e) 422 423 Precipitation aids derived from biological sources (such as plant proteins, albumin, casein, and 424 gelatin) may also be used. In addition, non-biological precipitation aids, such as bentonite, 425 silicon dioxide, etc., may be used if listed in Tables 6.3, 6.4 or 6.5. If listed in Tables 6.3, 6.4 or 6.5, precipitation aids shall meet any annotation restrictions therein. 426 427 428 The listings for "Carriers" in Tables 6.3 and 6.4 both read (CAN/CGSB, 2021b): 429 430 Carriers of non-agricultural origin may be used if listed in Tables 6.3, 6.4 or 6.5. Nonorganic 431 carriers of agricultural origin (such as wheat starch) may be used if ingredients or processing 432 aids containing organic carriers are not commercially available. 433 434 CODEX Alimentarius Commission – Guidelines for the Production, Processing, Labelling and 435 Marketing of Organically Produced Foods (GL 32-1999) 436 Table 3, Ingredients of non-agricultural origin referred to in Section 3 of these guidelines includes the

Flavors

437 listing (FAO/WHO Joint Standards Programme, 2008):

438	
439	3.2 Flavourings: Substances and products labelled as natural flavouring substances or natural
440	flavouring preparations are defined in the General Requirements for Natural Flavourings
441	(CAC/GL 29-1987).
442	
443	The organic guidelines refer to an obsolete set of guidelines that have been replaced with the Guideline
444	for the Use of Flavourings (FAO/WHO Joint Standards Programme, 2008).
445	
446	European Economic Community (EEC) Council Regulation – EC No. 2018/848
447	Flavoring substances in organic products must be natural or organic under European regulations.
448	
449	Article 16, Production rules for processed food states:
450	
451	"Operators that produce processed food shall comply, in particular, with the detailed production
452	rules The Commission is empowered to adopt delegated acts Those delegated acts shall not
453	include the possibility of using flavouring substances or flavouring preparations which are
454	neither natural, within the meaning of Article 16(2), (3) and (4) of Regulation (EC) No
455	1334/2008 nor organic" (EU Commission 2018).
456	
457	Part IV, Processed food production rules § 2.2.2 states:
458	
459	"In the processing of food, the following products and substances may be used: substances
460	and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008
461	that have been labeled as natural flavoring substances " (EU Commission 2018).
462	
463	The referenced regulation offers these definitions [EC 1169/2011, Article 3]:
464	
465	1) For the purposes of this Regulation, the definitions laid down in Regulations (EC) No 178/2002
466	and (EC) No 1829/2003 shall apply.
467	2) For the purposes of this Regulation, the following definitions shall also apply:
468	(a) 'flavourings' shall mean products:
469	(i) not intended to be consumed as such, which are added to food in order to impart or
470	modify odour and/or taste;
471	(ii) made or consisting of the following categories: flavouring substances, flavouring
472	preparations, thermal process flavourings, smoke flavourings, flavour precursors or
473	other flavourings or mixtures thereof;
474	(b) 'flavouring substance' shall mean a defined chemical substance with flavouring properties;
475	(c) 'natural flavouring substance' shall mean a flavouring substance obtained by appropriate
476	physical, enzymatic or microbiological processes from material of vegetable, animal or
477	microbiological origin either in the raw state or after processing for human consumption by
478	one or more of the traditional food preparation processes listed in Annex II. Natural
479	flavouring substances correspond to substances that are naturally present and have been
480	identified in nature;
481	(d) 'flavouring preparation' shall mean a product, other than a flavouring substance, obtained
482	from:
483	(i) food by appropriate physical, enzymatic or microbiological processes either in the raw
484	state of the material or after processing for human consumption by one or more of the
485	traditional food preparation processes listed in Annex II; and/or
486	(ii) material of vegetable, animal or microbiological origin, other than food, by appropriate
487	physical, enzymatic or microbiological processes, the material being taken as such or
488	prepared by one or more of the traditional food preparation processes listed in Annex II;
489	(e) 'thermal process flavouring' shall mean a product obtained after heat treatment from a
490	mixture of ingredients not necessarily having flavouring properties themselves, of which at
491	least one contains nitrogen (amino) and another is a reducing sugar; the ingredients for the
492	production of thermal process flavourings may be:
493	(i) food; and/or

494	(ii) source material other than food;
495	(f) 'smoke flavouring' shall mean a product obtained by fractionation and purification of a
496	condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived
497	smoke flavourings as defined in points (1), (2) and (4) of Article 3 of Regulation (EC) No
498	2065/2003;
499	(g) 'flavour precursor' shall mean a product, not necessarily having flavouring properties itself,
500	intentionally added to food for the sole purpose of producing flavour by breaking down or
501	reacting with other components during food processing; it may be obtained from:
502	(i) food; and/or
503	(ii) source material other than food;
504	(h) 'other flavouring' shall mean a flavouring added or intended to be added to food in order to
505	<i>impart odour and/or taste and which does not fall under definitions (b) to (g);</i>
506	(i) 'food ingredient with flavouring properties' shall mean a food ingredient other than
507	<i>flavourings which may be added to food for the main purpose of adding flavour to it or</i>
508	modifying its flavour and which contributes significantly to the presence in food of certain
509	naturally occurring undesirable substances;
510	(j) 'source material' shall mean material of vegetable, animal, microbiological or mineral origin
510	from which flavourings or food ingredients with flavouring properties are produced; it may
512	be:
512	<i>i) food; and/or</i>
514	(ii) source material other than food;
515	(k) 'appropriate physical process' shall mean a physical process which does not intentionally modify the
516	chemical nature of the components of the flavouring, without prejudice to the listing of traditional food
517	preparation processes in Annex II, and does not involve, inter alia, the use of singlet oxygen, ozone,
518	inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.
519 520	3) For the purpose of the definitions listed in paragraph $2(d)$ , (e), (g) and (j), source materials for which bits are discribed in the purpose of the pur
520	which hitherto there is significant evidence of use for the production of flavourings shall be
521	considered as food for the purpose of this Regulation.
522	Flavourings may contain food additives as permitted by Regulation (EC) No 1333/2008
523	and/or other food ingredients incorporated for technological purposes." [EC 1334/2008].
524	
525	The European Union's flavor regulations have a more limited number of processes that are acceptable
526	for the production of natural flavors (Müller, 2007; Sabisch & Smith, 2020). Certain processes in Europe
527	lead a substance to be classified as "artificial" that are considered "natural" in the U.S. (Müller, 2007).
528	
529	Japan Agricultural Standard (JAS) for Organic Production
530	The Japanese Agricultural Standard for Organic Processed Foods allows "Flavoring" with the
531	annotation: "Limited only to those that are not chemically synthesized" (Japanese Agricultural Standard
532	for Organic Processed Foods, 2020).
533	
534	IFOAM-Organics International
535	The IFOAM Standards Appendix 4, Table 1, List of Approved Additives and Processing/Post-harvest Handling
536	<i>Aids</i> includes "Flavoring Agents" with the following annotation (IFOAM, 2014):
537	
538	Operators may use:
539	<ul> <li>organic flavoring extracts (including volatile oils), and, if not available,</li> </ul>
540	<ul> <li>natural flavoring preparations approved by the control body. Such approval shall include</li> </ul>
541	assessment that natural flavors shall meet the following criteria:
542	- the sources are plant, animal or mineral;
543	<ul> <li>The process of production is in accordance with a recognized organic standard;</li> </ul>
544	<ul> <li>The process of production is in accordance with a recognized of game standard,</li> <li>They are produced by means of solvents such as vegetal oils, water, ethanol, carbon</li> </ul>
545	<i>dioxide and mechanical or physical processes."</i>
545 546	αιόλιας απα ποσιαπισαί οι μαθοίσαι μιοσούο.
540	

547	Evaluation Questions for Substances to be used in Organic Handling
548	
549	The authors of this report identified Evaluation question #2 from the Technical Report template as relevant
550	to addressing the three focus questions asked by the NOSB. That evaluation question, along with
551	response, is included below. Responses to the three focus questions follow.
552	
553	<b>Evaluation Question #2:</b> Discuss whether the petitioned substance is formulated or manufactured by
554	a chemical process or created by naturally occurring biological processes (7 U.S.C. 6502 (21)). Discuss
555	whether the petitioned substance is derived from an agricultural source.
556	
557	Flavors come from many origins and the nomenclature varies both by the context of the specific foods,
558	flavors, and labeling laws involved. For this review, the plants, animals, microorganisms, or minerals
559	from which the primary flavoring substances are derived are called "sources." The specific substances
560	derived from them are referred to as "precursors" and the final flavoring substances as "derivatives."
561	Precursors are legally defined in the European regulation but not by the FDA. Sources and precursors
562	are transformed into flavors by many different methods, some of which are biological, some
563	mechanical/physical, and some involve chemical synthesis that may or may not include a biological
564	intermediary.
565	
566	Some sources (NOP, 2005). Some herbal and fungal precursors are from sources that may be wild
567	harvested and may be eligible for organic certification under the USDA organic regulations for wild
568	crops [7 CFR 205.207].
569	
570	Flavors may be extracted from wild animals that are hunted or trapped. Examples include castoreum
571	from beavers (Burdock, 2007) and musk tonquin from musk deer (Clarke, 1922). Nonsynthetic,
572 573	nonagricultural ingredients may also be derived from microbial fermentation, such as yeast flavoring. As
575 574	discussed below, a growing number of fermentation flavor ingredients are produced using genetically modified organisms, which is prohibited in organic production and handling at § 205.105(e). Yeast and
574 575	potentially other fermentation organisms can be produced organically.
576	potentially other termentation organisms can be produced organically.
577	Some nonagricultural flavors and their formulations are produced from entirely synthetic sources
578	(Fischetti, 2010; Jacobs, 1947). One example is vanillin as a by-product of pulp and paper manufacturing
579	(Hocking, 1997) or from petrochemical-derived guaiacol (Bomgardner, 2016; Ciriminna et al., 2019).
580	Another is pineapple flavor including ethyl butyrate derived from petrochemical precursors (Berenstein,
581	2018). Such sources would be synthetic and therefore not allowed for use as ingredients in organic
582	processed food.
583	
584	Some flavors are derived from the fermentation of agricultural substrates using unmodified naturally
585	occurring organisms and are therefore agricultural according to the decision tree in NOP 5033-2 (NOP,
586	2016c). With that said, a growing number are from genetically modified organisms designed to express
587	flavor chemicals from donor organisms (Hanlon & Sewalt, 2021). One example is vanillin, originally
588	produced from vanilla orchids (Vanilla spp.), which can now be produced and extracted from fermented
589	genetically modified yeast (Saccharomyces cerevisiae) (Brochado et al., 2010; Ramaen et al., 2018). Another
590	example that may be from organic agricultural sources or from genetically modified organisms is Stevia.
591	Stevia refers generically to steviol glycoside sweeteners originating from a perennial shrub native to

- 592 South America, *Stevia rebaudiana*. A recently patented process shows that steviol glycosides may also be
- 593 produced by fermentation of various genetically modified bacterial or microfungal hosts (Philippe et al.,
- 594 2019, 2020). Meat flavors are also produced from genetically modified organisms (Vrljic et al., 2018).

#### 595 Extraction and Concentration Techniques

- 596 Flavors and their precursors may be extracted or isolated from natural, agricultural sources by several
- 597 different techniques. The processes used may be physical, mechanical, biological, or chemical.
- 598

#### 599 Cold pressing

One of the oldest and simplest methods used to extract flavors is using pressure. As the name suggests,

the liquids from a raw material – juices or oils – are forced through screens. The practice is still used to

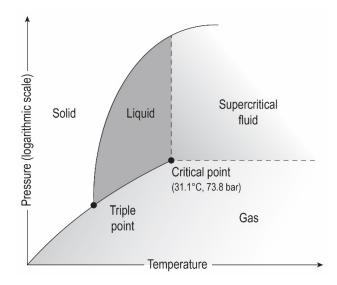
- 602 collect volatile oils from citrus fruits, for example, where flavor is lost through the use of high
- temperatures or the presence of solvents (R. G. Berger, 2007; Y. H. Hui et al., 2010). The solid mass is
- removed, and the liquid is collected using gravity. Some traditional processes used sponges to soak up
- 605 the oils (Arce & Soto, 2008). Enzymes may be used to increase yields (Cakaloglu et al., 2018). The liquid
- may be further concentrated through centrifugal force (Y. H. Hui et al., 2010). Technological advances
   have increased the amount of pressure that can be used and expanded the potential to use high-pressure
- filtration techniques. Cold pressing is receiving renewed attention as processors look for alternatives that
- require less energy than distillation, and do not involve toxic chemicals (Cakaloglu et al., 2018). Cold
- 610 pressing is a mechanical, non-chemical process.
- 611
- 612 Steam distillation and Water vapor stripping
- 613 The use of water vapor to extract various aroma and flavor chemicals goes back for centuries. Volatile
- oils have a higher vapor pressure than water, which means they can be stripped from plants through the
- 615 application of steam or water vapor (Y. H. Hui et al., 2010). Various apparatuses can use the difference in
- 616 evaporation temperatures and specific gravity to distill the oils and separate them from the water vapor
- as it cools. Stripping involves boiling water under pressure and the shooting of a jet of live steam
- 618 through a plant material matrix, while distillation generally refers to the immersion of the plant material
- 619 in boiling water (Y. H. Hui et al., 2010). Advances in vacuum technologies increased the effectiveness
- and yield of steam distillation in the latter half of the 19<sup>th</sup> century (Walter, 1916). Steam distillation can be
- 621 regarded as a physical process for extraction and concentration.
- 622
- 623 Solvent extraction
- Oils can be extracted by various solvents. Ethanol (sometimes called grain alcohol) was one of the first
- solvents used to extract essential oils from plants. An early technique involved refluxing ethanol over the
- raw material at elevated temperatures over a period of time, which was known as "infusion" (Burdock,
- 627 2016). A more refined technique involved the percolation of plant raw material in an ethanol solution
- through a series of vessels in either a continuous process or in batches (Attokaran, 2017). Alcohol
- 629 extraction with vacuum distillation would be an acceptable method for polar hydrocarbons. Non-polar
- 630 hydrocarbons are more difficult to extract with alcohol. Ethanol is an acceptable solvent to produce
- nonorganic flavors used in organic production. Organic flavors would need to be made using organicethanol, which is commercially available.
- 632 633

Various petroleum-derived solvents became preferred later in the 19<sup>th</sup> century because they could be used at ambient temperatures and resulted in higher yields of product with fewer off-flavors and impurities. Ethanol had a drawback in that the temperatures needed to effectively extract essential oils were relatively high and yields were relatively low. Early non-polar solvents used included ether and methylene dichloride (dichloromethane) (Y. H. Hui et al., 2010). Later, isopropanol, methanol, hexane, butane, acetone, ethyl acetate, ethylene dichloride, and methylene dichloride became preferred non-polar solvents (Attokaran, 2017; Burdock, 2016). The use of these solvents is considered chemical processing

and prohibited, both to make organic flavors per 7 CFR 205.105(c) and non-synthetic non-organic flavors

- 642 per the 7 CFR 205.605(a) annotation.
- 643
- 644 <u>Supercritical carbon dioxide</u>
- 645 A relatively new extraction technique involves the use of carbon dioxide at various temperatures and
- 646 pressures. Carbon dioxide is a gas at standard temperature and pressure. Above 73 bar and 31 degrees
- 647 Celsius (88°F), carbon dioxide becomes a supercritical fluid (Y. H. Hui et al., 2010) (*Figure 1*).
- 648

#### Figure 1: Phase Changes in Carbon Dioxide. Adapted from Bauer et al. (2013).



#### 650 651

As a supercritical fluid, carbon dioxide can penetrate solid masses like a gas and dissolve substances like a

liquid. Supercritical carbon dioxide can be used as a non-polar solvent to remove various essential oils

654 from plant material. The flavor profiles of supercritical extracted oils and oleoresins rival those of

hexane, but at a higher price (R. G. Berger, 2007). Significantly more carbon dioxide is used in the

656 supercritical process than in processes that use other conventional solvents (Attokaran, 2017).

657 Supercritical carbon dioxide has the advantage over hexane, ethylene dichloride, and other conventional

solvents, as it does not leave residual contamination. Because carbon dioxide is on the National List in
 7 CFR 205.605(b), supercritical extraction is acceptable for both organic flavors and nonorganic flavors

660 used in organic processed products.

661

### 662 Flavor Categories

Flavors can be categorized in many ways. The most fundamental is the distinction between "natural" and "artificial" flavors. These terms have legal meanings defined by the FDA in the U.S. and by other authorities with somewhat different definitions in other countries (Müller, 2007).

666

667 The literature often groups certain types of flavors with common characteristics. These groups include 668 spices, essential oils, fruit extracts, vegetable extracts, chocolate, dairy flavors, meat flavors, and coffee 669 flavors. Other specialty flavors are available as well that may have a small market share and difficulty in 670 obtaining organic sources due to the lack of volume.

671

#### 672 Herbs and Spices

673 Herbs and spices are among the oldest of the flavoring ingredients. Both herbs and spices are derived

674 from plants. Herbs consist of plant leaves, stems, and flowers. Spices are obtained from harvesting the

seeds, roots, bark, or other plant organs. Herbs are prehistoric in nature, believed by ethnobotanists to

- 676 originate from traditional pharmacological uses (Wrensch, 1992). Herbs have been wild-crafted or
- cultivated throughout recorded history. Spices used for culinary purposes were central to the
- development of various cuisines, and have a long history of cultivation going back to the origins of
- recorded history thousands of years ago (Parry, 1962). As such, most if not all herbs and spices may beconsidered agricultural in origin.
- 680 c 681
- 682 Herbs and spices may be used in various forms, such as dried leaf, flake, powder or frozen. Blends of
- herbs and spices are also prepared for market. Some of these involve proprietary recipes. Herbs and
- spices may also appear in various tinctures, hydrosols water-based fractions of aromatic plants
- resulting from steam distillation and infusions made with alcohol, water, vinegar, or culinary oils. Such
- preparations are noted throughout recorded history. Spice oleoresins were a more recent development,
- 687 with solvent extraction processes developed in the 1940s (Attokaran, 2017).

- 688 689 As noted above, the FDA recognizes herbs and spices as a separate category from natural and artificial flavors. Most of the certifying agents interviewed indicated that these ingredients are treated as 690 691 agricultural and thus required to be certified organic. However, many herb and spice derivatives are precursors to various natural flavors, in particular essential oils and various specific extracts and isolates. 692 The presence of precursors derived from organic herbs and spices is indicative that their downstream 693 694 flavor products may also be feasible to produce in a form, quality, and quantity to be commercially 695 available as organic. 696 697 The herbs and spices identified by the FDA in 21 CFR 101.22(a) are included here to identify them 698 separately from nonagricultural flavors and to link them to various flavoring agents. Organic cultivation 699 methods are documented for all of them (Kowalchik & Hylton, 1998; V. Parthasarathy et al., 2008). This 700 review is not intended to be an exhaustive list of flavor sources that can be considered agricultural or 701 produced agriculturally, but documents that all officially recognized major herbs and spices are 702 agricultural products that are feasible to produce organically. 703 704 Organic spices had sales of about \$499 million in 2021, which was about 4.5% less than the previous year 705 (OTA, 2022). The Organic Trade Association (OTA) attributed the decline to supply chain issues. The 706 global market for organic spices is forecasted to continue to grow, with many of the world's largest 707 conventional spice companies increasing their capacity to manufacture and handle organic spices (FMI, 708 2022). 709 710 Allspice 711 Seeds from the pimento plant (Pimenta dioica) are used to make allspice, also known as pimento (Attokaran, 2017; Burdock, 2016). It is an evergreen relative of the laurel that is native to Meso-America 712 713 (Machuca et al., 2020). It was a traditional crop of pre-Columbian native people in the Caribbean and in 714 the humid tropical forests between the Yucatan peninsula and Costa Rica. Grown there and elsewhere in 715 the tropics, it has complex flavors that bear resemblances to bay leaves, cinnamon, cloves, and nutmeg. It 716 shares many derivatives that can be precursors to flavors identified with other plants, although often in 717 lower concentrations. The wood and leaves may also be used to produce various isolates and extracts
- recognized as natural flavors by FDA. The primary isolate is eugenol, but others are also produced. A
   cooperative in Chiapas grows and exports certified organic allspice (Machuca et al., 2020).
- 720
- 721 Anise and star anise
- Licorice and related flavoring substances are derived from sweet anise (*Pimpinella anisum*) or from star anise (*Illicum verum*) (FCC, 2022; Khan & Abourashed, 2010; Kowalchik & Hylton, 1998). Anise also has a
- wide range of culinary uses. Flavors can be derived from the leaves as well. Anise and star anise are
- 725 grown in temperate and Mediterranean climates.
- 726 727 Basil
- Various species of basil may be used for flavoring (Kowalchik & Hylton, 1998). The main commercial
  source in the U.S. is sweet basil (*Ocimum basilicum*). Other species used for flavoring and flavor extracts
- 730 include lemon basil (*Ocimum americanum*), holy basil (*O. sanctum*), African basil (*O. gratissimum*) and
- 731 camphor basil (O. kilimandscharium) (Kowalchik & Hylton, 1998). Holy basil is used to prepare tulsi tea
- and its oil extract may be present in various herbal preparations. Camphor basil is not used for cooking
- but may be used as a tea (Kowalchik & Hylton, 1998). Basil oil may be produced by steam distillation
- (Burdock, 2016). The oleoresin is most commonly extracted by a mixture of acetone and hexane, or by
- hexane alone (Attokaran, 2017). It is not clear from the literature how basil oleoresins used in organic
- 736 processed products are extracted. Basil oil is soluble in propylene glycol, but is not soluble in glycerine
- (Burdock, 2016; FCC, 2022). A substitute for propylene glycol was not found in a search of the literature.
- 738739 Bay leaves
- The evergreen sweet bay laurel (*Laurus nobilis*) has been cultivated for bay leaves since antiquity
- 741 (Kowalchik & Hylton, 1998). The leaves consist of between 0.3-3.1% volatile oil. The primary constituents
- 742 of the oil are 1,8-cineole, α-pinene, linalool, and α-terpineol (Khan & Abourashed, 2010). Derivatives

- include infusions, fluid extracts, and oleoresins (Burdock, 2016). It is used mainly in soups and meat
- products, and is a standard in both French and Indian cuisines (Attokaran, 2017).
- 746 *Caraway seed*
- 747 Caraway seed is produced from *Carum carvi*, a biennial in the same family as carrots, fennel, cilantro, and
- 748 parsley (Kowalchik & Hylton, 1998). Carvone is the principle active component in caraway seed
- 749 (Attokaran, 2017). Derivatives include infusions, decoctions, alcoholic distillate, and water distillate
- 750 (Burdock, 2016). Caraway seed is seldom made into an oleoresin (Attokaran, 2017). Caraway seed is
- commonly used in rye bread. It is also used in other baked goods, cheeses, and liqueurs (Attokaran, 2017;
- 752 Parry, 1962).
- 753
- 754 *Cardamom*
- 755 Most commercial sources of cardamom are from the species *Elettaria cardamomum*, which is called true or
- 756 green cardamom (Attokaran, 2017). Black cardamom (*Amomum subulatum*) and white or Siamese
- cardamom (*Amomum krevanh*) are also cultivated and used as spices and natural flavor derivatives.
- "White cardamom" can also refer to green cardamom that has been chemically bleached or sulfured
- 759 (Parry, 1962). Cardamom can be processed into essential oils, tinctures, fluid extracts, and oleoresins
- 760 (Burdock, 2016).
- 761 762 *Celery seed*
- 763 While most celery (*Apium graveolens*) is cultivated as a vegetable, the seed of this biennial may also be
- visite most celefy (*Aprillin graveoliss*) is cultivated us a vegetable, the seed of this brential may also beused as a spice (Parry, 1962). The seed can be extracted into oil and flavorings, although sometimes
- rot a set us a spice (1 arry, 1702). The seed can be extracted into on and introducings, autologit sometimes celery leaves and roots are also used for flavor extraction. Pure celery seed extract is regarded as higher
- quality than extracts from other celery plant organs (Burdock, 2016). Celery seed oleoresin has a more
- 767 bitter flavor than celery seed extract and is used in some meats and soups (Attokaran, 2017).
- 768 769 *Chervil*
- French parsley or garden chervil (*Anthriscus cerefolium*) is a fine herb that can be grown in temperate
- climates (Kowalchik & Hylton, 1998). The primary constituent of chervil essential oil is estragole,
- followed by 1-allyl-2-dimethoxybenzene (K. Başer & DeMirci, 2007).
- 773
- 774 *Cinnamon and Cassia*
- Cinnamon sold in the U.S. comes from one of three sources. Most spice sold as "cinnamon" on the world
- market and in the U.S. comes from Chinese cinnamon or cassia (*Cinnamonum cassia*). Cassia accounts for
- 777 over 90% of what is traded as cinnamon (Madan & Kannan, 2004). Indonesia, China, Madagascar,
- 578 Seychelles, and Vietnam are the largest suppliers of cassia (Coppen, 1995). The aromatic bark of the true
- cinnamon tree (*Cinnamomum verum*), also known as Ceylon or Sri Lankan cinnamon (*C. zeylanicum*), is
- the next most common source. Sri Lanka is the only significant commercial source of true cinnamon. In
- the U.S., the common name cinnamon also applies to Indonesian cinnamon or korintji (*C. burmannii*)
- 782 (Khan & Abourashed, 2010) and Saigon cinnamon (*C. loureiroi*) (O'Neil, 2013).
- 783
- Steam distillation of cinnamon bark varies based on where it was produced and the duration of the
   distillation process. Distilling 40-50 kg of cinnamon bark for four to five hours yields approximately 0.5-
- 786 0.7% essential oil on a dry weight basis (Dayananda et al., 2004). Cassia essential oil more often uses
- twigs and leaves. Cassia leaves and twigs steam distilled in 60-kg batches for three to four hours will
- yield about 0.31-0.33% dry weight of essential oil (Dao, 2004). Cinnamon and cassia essential oils are both
- graded based on their cinnamaldehyde also known as cinnamic aldehyde content (Dayananda et al.,
- 2004). Cinnamaldehyde content from various cinnamon essential oil sources will range from 60-90%
- depending on the species, origin, extraction process, and handling (Burdock, 2016; Dao, 2004;
- 792 Dayananda et al., 2004). Cassia and cinnamon oleoresins are usually extracted by ethylene dichloride or
- an acetone-hexane mixture (Attokaran, 2017). Other extracts can be obtained using supercritical  $CO_2$
- (Attokaran, 2017). Cinnamaldehyde can also be synthesized from benzaldehyde and acetaldehyde
- 795 (Fischetti, 2010; Richmond, 1950).
- 796

- 797 Cloves
- 798 Cloves are native to Southeast Asia and produced from the tropical evergreen, *Syzygium aromaticum* (V.
- Parthasarathy et al., 2008). The tree is cultivated in tropical regions worldwide. The world's largest
- producer is Indonesia, followed by Madagascar, Tanzania, and Sri Lanka (FAO, 2015). The flower buds
- and twig tips are used as the spice (Attokaran, 2017). Stems and leaves may also be used to produce
- 802 essential oils, with the main components being eugenol, ß-caryophyllene, and eugenyl acetate
- 803 (Attokaran, 2017; Burdock, 2016).
- 804
- 805 *Coriander*
- 806 Coriander generally refers to the fruit and seeds of the cilantro (*Coriandrum sativum*) plant, but the term
- 807 may include cilantro leaves or flowers (Kowalchik & Hylton, 1998). Cilantro can be cultivated in a wide
- 808 range of climates and is organically produced. Cilantro fruit is a source of d-linalool (Khan &
- 809 Abourashed, 2010).
- 810
- 811 *Cumin seed*
- 812 Cumin (*Cuminum cyminum*) is a small annual that is extensively cultivated throughout the
- 813 Mediterranean region (Khan & Abourashed, 2010). Cumin was introduced to India about 1,000 years ago
- 814 (V. Parthasarathy et al., 2008). Black cumin yields about 1% essential oil with steam distillation
- 815 (Attokaran, 2017). Cumin can also be made into an alcohol tincture, infusion, fluid extract, and oleoresin
- 816 (Burdock, 2016). The principle component of cumin is cuminaldehyde, which is responsible for cumin's
- 817 distinct aroma and taste (V. A. Parthasarathy et al., 2008).
- 818
- 819 Dill seed
- 820 Dill (*Anethum graveolens*) is a temperate zone plant that is reported as simple to grow, but as a biennial
- the seeds are not produced until the second year (Kowalchik & Hylton, 1998). Dill may also refer to
- 822 Indian dill, A. sowa (Attokaran, 2017). Indian dill is grown as an intercrop in South Asian organic farming
- 823 systems (V. Parthasarathy et al., 2008). For both species of dill seed, the essential oil is obtained by steam
- distillation (Burdock, 2016). A. graveolens oil is over 50% dillapiole, 20% carvone, 16% trans-
- hydrocarvone, and almost 6% limonene (Burdock, 2016). Oil from A. sowa differs from A. graveolens oil in
- 826 physical properties, odor, and flavor (Burdock, 2016).
- 827828 Fennel seed
- 829 Fennel (*Foeniculum vulgare*) is another biennial from the Apiaceae (formerly Umbelliferae) family
- 830 (Kowalchik & Hylton, 1998). Within fennel species, varieties are divided between common or bitter
- fennel and sweet fennel based on the concentration of different flavor constituents. Myristicin and apiole
- are present in sweet fennel and absent in common fennel (Khan & Abourashed, 2010). Common fennel is
- also reportedly higher in fenchone and lower in anethole than sweet fennel. As with other biennials,
- fennel seed is produced in the second year. Fennel seed has a licorice flavor profile like anise but is
- 835 described by some sources as having a slight nut profile. Fennel and sweet fennel oil are used in baked
- 836 goods, meats, snack foods, gravies, and alcoholic beverages. Sweet fennel is also used in condiments and
- 837 relishes (Khan & Abourashed, 2010).
- 838
- 839 Fenugreek
- 840 Fenugreek (*Trigonella foenum-graecum*) is a legume that is native to the Mediterranean region, where it
- has been a staple of Middle Eastern cuisine for centuries (Kowalchik & Hylton, 1998). The main
- 842 constituent of fenugreek is anethole, but its characteristic flavor and texture comes from a couple of
- families of saponins (Burdock, 2016). Fenugreek flavor is described as burnt sugar. Fenugreek is a
- traditional ingredient in curry powders and its derivatives have also long been used as precursors for
- imitation maple flavoring (Burdock, 2016; Parry, 1962). Steam distillation results in poor yields; volatile
- hydrocarbon or hydroalcoholic extracts are variable in quality (Burdock, 2016). Ethanol may be used to
- 847 prepare a fenugreek oleoresin that disperses well without the use of propylene glycol (Attokaran, 2017).
- 848 Roasting fenugreek increases the yield and improves the flavor.
- 849

#### 850 Ginger

- 851 The rhizomes of the ginger (*Zingiber officinale*) plant are native to Southeast Asia and have been
- introduced to Africa, the West Indies, and Hawaii (V. Parthasarathy et al., 2008). Traditional cultivation
- 853 practices vary widely around the world (Parry, 1962). Ginger's characteristic aroma is primarily
- attributed to zingiberol volatile oil (Burdock, 2016). Ginger essential oil is prepared by coarsely grinding
- with a hammer mill, flattening with a roller mill, then steam distillation at low pressure, yielding about
- 856 2% essential oils (Attokaran, 2017). Ginger may be prepared into an alcohol tincture of 20:60-65 or as an
- 857 oleoresin (Burdock, 2016). Ginger, its derivatives, and its flavoring extracts are used in alcoholic and non-858 alcoholic beverages, baked goods, candies, confectionaries, sauces, and seafood (Attokaran, 2017; Khan &
- Abourashed, 2010). Soft drinks will usually be prepared from ginger oleoresin or extract (Khan &
- Abourashed, 2010). Soft driffks will usually be prepared from ginger ofeoresin or extrac 860 Abourashed, 2010).
- 860 Abourashed, 861
- 862 Horseradish
- 863 Horseradish is harvested from the root of a perennial crucifer, *Armoracia rusticana* (Kowalchik & Hylton,
- 1998). Horseradish is a relative of mustards and is a source of various pungent isothiocyanates (Burdock,
- 2016). Horseradish may be prepared into an alcohol tincture or steam distilled (Burdock, 2016). While
- 866 horseradish is related to wasabi or Japanese horseradish (*Wasabi japonica*) and has many of the same
- flavoring substance, it is a different genus and species with a distinct flavor and aroma profile.
- 868 Horseradish and wasabi have different ratios of various isothiocyanates they hold in common (Masuda
- et al., 1996).
- 870
- 871 Mustard
- 872 Several *Brassica* species are cultivated and sold as mustard (Kowalchik & Hylton, 1998). The main
- 873 commercial varieties are black mustard (*B. nigra*), brown mustard (*B. juncea*), and white or yellow
- 874 mustard (*B. alba* and *B. hirta*) (Attokaran, 2017). Both mustard seeds and leaves may be used to extract
- various isothiocyanates that have a characteristic sharp mustard flavor (Burdock, 2016). Allyl
- isothiocyanate makes up about 90% of mustard essential oil (K. Başer & DeMirci, 2007). Very little
- 877 mustard is processed into oleoresin, possibly because the extraction process can be difficult when so
- 878 much water is present in the slurry (Attokaran, 2017).
- 879
- 880 Nutmeg and mace
- 881 The evergreen laurel tree *Myristica fragrans* is cultivated for two spices, nutmeg and mace (V.
- Parthasarathy et al., 2008). The main producer in the world is Indonesia (Attokaran, 2017). Nutmeg is
- made from the seeds, which may be sold whole or ground. The seed coating or aril is used to make mace.
- 884 After the husk splits, the mace is carefully detached and processed separately from the nutmeg (Parry,
- 1962; Peter, 2001). While they have similar flavors, they are subtly different given their different
- quantities of aromatic substances. Mace yields about 10-13% essential oils depending on the variety and
- production region, and nutmeg yields about 6.5-8% essential oils (Burdock, 2016). Nutmeg can be
- pressed into a semi-solid fixed oil that is called a concrete (Sharangi, 2018). Nutmeg can be made into an
- ethanol tincture, expressed into a fatty oil, and extracted as an oleoresin. Mace can also be made as a
- tincture, extract, and oleoresin (Burdock, 2016). The leaf and pericarp of four different *Myristica* species –
- M. *fragrans*, M. *beddomei*, M. *fatua*, and M. *malabarica* are sometimes also steam distilled into mace
   volatile oil (Sharangi, 2018).
- 892 893
- 894 *Oregano and marjoram*
- 895 The term oregano may be used to refer to various species of *Origanum*, the most common being *O*.
- 896 *vulgare* (Kowalchik & Hylton, 1998). Common oregano is also sometimes called wild marjoram. Most
- 897 commercial marjoram is from the species O. majorana, also known as sweet marjoram (Kowalchik &
- 898 Hylton, 1998). Marjoram is called oregano in some regions. Both marjoram and oregano are dried as
- culinary herbs and may have extracts that are steam distilled, infused, or made into an alcohol tincture
- 900 (Burdock, 2016). The alcohol tincture obtained from *O. vulgare* and other *Origanum* species is specified in
- 901 the European Pharmacopoeia to contain at least 60% carvacrol (K. Başer & DeMirci, 2007). Thymol is also a
- 902 principal component, with many other terpenes and sesquiterpenes reported (Attokaran, 2017).
- 903 Carvacrol and thymol levels vary widely by species and cultivation conditions (Baser & Buchbauer,
- 904 2009).

#### 906 Paprika and red pepper

The red pepper (*Capsicum spp.*) is a solanaceous genus native to the Americas. The most commonly used form is *C. annuum*, that when used as a spice is best known for a hot, biting flavor (Kowalchik & Hylton,

1998). Paprika is associated with the milder cultivars of *C. annuum* adapted to cooler climates (Attokaran,

- 2017). There are many synonyms in English for the different *Capsicum* fruits that are grown as a spice.
- 911 The most used other names are cayenne, chili, and red pepper (Kowalchik & Hylton, 1998; Peter, 2001).
- 912 Other *Capsicum* species commercially grown in North America include *C. frutescens*, which includes the
- Tabasco cultivar, and *C. chinense*, which includes the habanero cultivar (Attokaran, 2017; USDA/ ARS /
   GRIN, 2022).
- 914 915

916 The chemical constituent most often attributed for the piquant flavor of various hot peppers is capsaicin

- 917 (Attokaran, 2017; Burdock, 2016). Capsaicin's capacity to deliver heat is measured in Scoville heat units
- 918 (SHUs) (Burdock, 2016; Sharangi, 2018). Capsaicin is a phenol that is not volatile with steam but it can be 919 made into ethanol tinctures (Burdock, 2016). Dried powdered and flaked chili peppers are the prevailing
- way that the flavor is used in most applications (Attokaran, 2017; Sharangi, 2018), and India accounts for
- about half of all global chili exports (Sharangi, 2018). However, the oleoresins are sometimes used
- 922 (Attokaran, 2017). *Capsicum* oleoresins are extracted using ethylene dichloride or a mixture of hexane and
- acetone, often after preparation with various other chemicals such as ethanol, methanol, and benzyl
- 924 peroxide (Attokaran, 2017).
- 925

Paprika is also used as a coloring agent. The USDA added "Paprika color – dried powder and vegetable

927 oil extract (CAS #68917-78-2)" to the National List [7 CFR 205.606] in 2007 [72 FR 35137]. Paprika was
 928 removed from the National List on March 30, 2022 [87 FR 10930].

- 929
- 930 Parsley

Parsley (*Petroselinum crispum*) is a hardy herb originating with use documented to Greek and Roman

antiquity (Kowalchik & Hylton, 1998). Parsley leaves are the most familiar for use as an herb, both fresh

and dried into flakes. Derivatives from parsley fruits and seeds may be used as flavor precursors and

parsley roots are also sometimes used (Khan & Abourashed, 2010). Parsley fruits are 3-6% essential oil

- consisting of 60-80% myristicin in some varieties, and up to 70% apiol in other varieties (Burdock, 2016).
- Another reported chemical is allyl tetramethoxy benzene, which in some varieties may be up to 75% of
- 937 the oil.

938939 Pepper (black and white)

940 Black pepper (*Piper nigrum*) is a woody tropical perennial climbing vine crop native to the evergreen

- 941 forest of the Western Ghat of India (Khan & Abourashed, 2010; Peter, 2001; Thankamani, 2008). Black
- 942 pepper is the most commonly used spice in the world, with a history of over 3,000 years of use
- 943 (Ravindran, 2003). India, Indonesia, and Vietnam account for about two-thirds of the world's production
- of black pepper. By volume, black pepper is the leading organic spice traded by India (Choudhuri et al.,
- 2018). Kerala is the state of India that produces the most black pepper (V. Parthasarathy et al., 2008). The
- ripe whole fruits of the black pepper plant are harvested, dried, cleaned, graded and packaged as black
- pepper (Balasubramanian et al., 2016). White pepper is made by removing the fruit wall (pericarp) of
- fully ripe black pepper (Ravindran, 2003). Black pepper oleoresin may be extracted using ethanol,
- acetone, ethylene dichloride, or ethyl acetate (Balasubramanian et al., 2016). Indian black pepper yields
- higher oleoresins and has a different flavor profile than black pepper harvested elsewhere (Peter, 2001).
- The main active constituent of black pepper is piperine (Attokaran, 2017; Balasubramanian et al., 2016; Burdock, 2016; V. A. Parthasarathy et al., 2008; Peter, 2001). Piperine levels in whole black pepper will
- 952 Burdock, 2010; V. A. Farmasaramy et al., 2008; Feter, 2001). Piperine levels in whole black pepper will
   953 vary by variety, soil, climate, and other local conditions (V. A. Parthasarathy et al., 2008; Peter, 2001).
- vary by variety, soil, climate, and other local conditions (V. A. Parthasarathy et al., 2008; Peter, 2001).
- 955 Rosemary
- 956 The hardy perennial evergreen, *Rosmarinus officinalis*, is the source of rosemary (Kowalchik & Hylton,
- 1998). It is commonly used in soups, meat dishes, and savory baked goods (Khan & Abourashed, 2010).
- Peak harvest for the rosemary plant is at the flowering top stage (Başer & Demirci, 2012). Rosemary oil is
- 959 made by steam distillation of the fresh flowering tops (Khan & Abourashed, 2010). Extraction is

960 improved by the superheating of water under pressure (Basile et al., 1998). Other solvents used in 961 extraction include acetone, hexane, and supercritical carbon dioxide (EFSA, 2008). The primary active

- 962 ingredients found in rosemary are carnosol, rosmanol, rosmarin and rosmarinic acid, with yields and
- 963 composition varying by cultivar, location, and seasonal conditions. Rosemary can be made into a fluid
- 964 extract, tincture, or oleoresin (Burdock, 2016). 965
- 966 Saffron
- 967 The stigmata of crocus (Crocus sativus) are the source of saffron (Kowalchik & Hylton, 1998). A native of
- Asia Minor, it has a broad cultivation range. Spain, Iran, and India are the main producers of saffron 968
- 969 (Attokaran, 2017; Peter, 2001). It is very labor intensive to produce, requiring the collection of stigmata
- 970 from tens or even hundreds of thousands of plants to make commercial quantities, with yields of
- 971 between 1.5 and 3.0 kg/ha (1.3-2.7 lb./A) (Peter, 2001). Saffron is mostly used whole in small quantities, and is not practical to make extractives (Attokaran, 2017). Specific applications may involve an alcohol 972
- 973 tincture, steam distillation, or solvent extraction (Burdock, 2016). Saffron is also used as a coloring agent.
- 974 "Saffron extract color (pigment CAS #1393-63-1)" was added to the National List [7 CFR 205.606] in 2007
- 975 [72 FR 35137]. In 2019, the annotation was amended to also say, "Derived from Crocus sativus"
- 976 [83 FR 66559].
- 977
- 978 Sage

979 Sage (Salvia spp.) is a genus of evergreen perennial that is hardy in a wide range of climates. The primary 980

- culinary sage is S. officinalis also called common or Dalmatian sage, but Clary sage (S. sclarea), pineapple
- sage (S. elegans), and Mexican bush sage (S. leucantha) are also cultivated for specific culinary uses 981 982 (Kowalchik & Hylton, 1998). Common sage is believed to have originated in the Mediterranean region.
- 983 Sage essential oil is produced by steam distillation, with yields and composition highly variable
- 984 depending on region, harvest season, and climatic conditions (Attokaran, 2017). Yields of 1-3% essential
- 985 oils are common. Sage essential oils contain a rich and variable mix of aromatic compounds, including
- 986 salvin, picrosalvin, carnosol, terpenes, tannins, phenolic acids, flavonoids, and ethers (Baser &
- 987 Buchbauer, 2009; Burdock, 2016; Khan & Abourashed, 2010). Some phenolic flavoring substances are
- 988 unique to sage (Burdock, 2016). The oleoresin is obtained by solvent extraction (Burdock, 2016). Sage
- 989 derivatives and isolates are used as flavoring ingredients in a wide range of foods, including meats,
- 990 candy, frozen dairy desserts, and alcoholic and non-alcoholic beverages (Khan & Abourashed, 2010).
- 991 992
- Savory

993 Two species from the genus *Satureja* are cultivated as herbs. One is the annual summer savory (S. 994 *hortensis*) and the other is the woody perennial winter savory (S. montana). They are both temperate herbs

- 995 originating in Europe (Kowalchik & Hylton, 1998). Summer savory is the more widely cultivated and
- 996 used herb (Attokaran, 2017). Greek savory (S. spinosa) is also used (Khan & Abourashed, 2010). Savory is
- 997 used as ingredients in condiments, sauces, meats, processed vegetables, and gravy, with the highest
- 998 levels reported in condiments (Khan & Abourashed, 2010). The main flavoring components of savory are
- 999 carvacrol and various terpenes, specifically y-terpinene (Attokaran, 2017; Khan & Abourashed, 2010).
- 1000 Most oleoresins and extracts are made from summer savory (Khan & Abourashed, 2010).
- 1001
- 1002 Tarragon
- 1003 Tarragon (Artemesia dracunculus) is a hardy perennial grown in temperate climates (Kowalchik & Hylton, 1004 1998). While believed to be Russian in origin, tarragon is most associated with French cuisine (Attokaran, 1005 2017). Tarragon is used in condiments, sauces, cooking vinegar, meat, fish, and egg preparations 1006 (Attokaran, 2017; Khan & Abourashed, 2010; Kowalchik & Hylton, 1998). The primary flavoring 1007 component is estragole, also known as methyl chavicol (Attokaran, 2017; Burdock, 2016; Khan & 1008 Abourashed, 2010). The Russian varieties have a different flavor profile and chemical composition from 1009 the French varieties (Attokaran, 2017). Tarragon may be prepared as an extract, alcohol tincture, essential
- 1010 oil, or oleoresin (Burdock, 2016). Tarragon essential oil is made from steam distillation (Burdock, 2016).
- 1011 Tarragon oleoresin is extracted with hexane (Attokaran, 2017).

#### 1013 *Thyme*

- 1014 Thyme is an herb derived from the leaves of the *Thymus* spp. plants (Kowalchik & Hylton, 1998). There
- 1015 are estimated to be 215 species of thyme (Morales, 2003). The most commercially important one is *T*.
- 1016 *vulgaris* (Attokaran, 2017; Kowalchik & Hylton, 1998). Other species may be used (Burdock, 2016; Khan &
- Abourashed, 2010; Morales, 2003). Thyme is associated with Creole, Cajun, and French cuisines. Spain,
  France, and Portugal are the leading producers of thyme (Lawrence et al., 2002). Most thyme essential oil
- 1019 is produced through steam distillation of the flowering tops (Khan & Abourashed, 2010). Steam
- 1020 distillation of partially dried thyme tops yields about 0.5-1.2% oil (Burdock, 2016). Aromatic petroleum
- solvents, such as butane; alcohols, including methanol; acetone, and supercritical carbon dioxide may
- also be used to extract various flavoring compounds (Venskutonis, 2003). The main flavoring compound
- 1023 is thymol (Attokaran, 2017; Burdock, 2016; Khan & Abourashed, 2010). Thyme and thyme derivatives are
- 1024 used in salad dressings, soups, gravies, meat and poultry products, candy, and alcoholic and non-
- 1025 alcoholic beverages (Attokaran, 2017; Khan & Abourashed, 2010; Kowalchik & Hylton, 1998).
- 1026
- 1027 Turmeric
- 1028 Rhizomes of the turmeric (*Curcuma longa*) plant are native understory plants in tropical climates
- 1029 (Choudhuri et al., 2018). Turmeric is a major ingredient in Indian and Southeast Asian cuisines and India
- 1030 remains the main producer (Attokaran, 2017). One of the main uses is in prepared mustards (Khan &
- 1031 Abourashed, 2010). Turmeric is also used in other condiments. High-yielding turmeric cultivars
- 1032 performed well with organic trials in the northwestern Himalayas (Choudhary & Rahi, 2018). Turmeric
- 1033 is used mostly in dry powdered form (Attokaran, 2017). Turmeric essential oil is prepared by steam
- 1034 distillation (Burdock, 2016). The essential oil is about 60% turmerones (Khan & Abourashed, 2010). These
- 1035 are complex sesquiterpenes (Attokaran, 2017). Turmeric is also used for coloring, with its characteristic
- 1036 pigment mostly contributed by curcumin (Attokaran, 2017; Khan & Abourashed, 2010). Turmeric may
- 1037 also be prepared in an ethanol extract or tincture (Burdock, 2016). Ethylene dichloride is the preferred
- 1038 solvent for turmeric oleoresin extraction (Sharangi, 2018). Other solvents used include acetone, ethyl
- alcohol, hexane, isopropyl alcohol, methylene dichloride, and trichloroethylene (Burdock, 2016).
  Turmeric is also used as a coloring agent. In 2007, "Turmeric extract color (CAS #458-37-7)" was added
- to the National List [7 CFR 205.606, 72 FR 35137]. In 2019, the annotation was amended to add, "Derived
- from *Curcuma longa*" [83 FR 66559]. Turmeric was removed from the National List on March 30, 2022
- 1043 [87 FR 10930].
- 1044
- 1045 Essential Oils, Oleoresins, Extracts, and Isolates
- 1046 The volatile aromatic portions of plants can be extracted, isolated, and concentrated by various means.
- 1047 They are distinguished from herbal preparations by their concentration and purity, as well as the
- 1048 techniques used for extraction. These techniques often involve agriculturally produced herbs and spices.
- 1049 Analytical chemistry to identify the chemical constituents of plant organs harvested for fragrance and
- 1050 flavor was first recorded in the industrial production of essential oils beginning in 1833 (Baser &
- 1051 Buchbauer, 2009). As analytical techniques improved through the 19<sup>th</sup> century, various molecular
- structures and formulas associated with specific flavors became better known, and with them the ability
- 1053 to produce essential oils of a specific purity and standardized concentration of aromatic compounds. 1054
- 1055 Essential oils are a hydrophobic complex mixture of volatile hydrocarbons derived from plant material.
- 1056 Many of the chemical constituents are cyclic structures, such as terpenes, phenols, benzenoids, ring
- alcohols, and aromatic esters. Essential oils also contain non-aromatic hydrocarbons, and their
- 1058 functionality depends on the concentrations of specific constituents. Many of the essential oils are
- 1059 derived from herbs and spices, such as cinnamon, cloves, rosemary, thyme, and sage. As such, they may
- 1060 be considered agricultural products.
- 1061
- 1062 Essential oils can be extracted by many different methods. The oldest method is through steam, a process
- 1063 known as hydrodistillation. The volatile portions of the plant organs will evaporate at temperatures
- 1064 lower than the boiling point of water. The evaporated essence is captured and concentrated. Essential
- 1065 oils may also be extracted using aromatic petroleum solvents such as hexane. A relatively new technique 1066 for concentrating essential ails is to use supercritical earborn discide (CO)
- 1066 for concentrating essential oils is to use supercritical carbon dioxide (CO<sub>2</sub>).

- 1068 A comprehensive review of all essential oils, oleoresins, extracts, and isolates from nonorganic sources
- 1069 that are currently used in certified organic processed product is beyond the scope of this technical report.
- 1070 However, a few essential oils discussed below, serve as examples of how extracts, essential oils,
- 1071 oleoresins, and isolates are produced from herbs and spices.
- 1072 1073 Anise oil
- 1074 Anise oil is extracted from either anise or star anise (Khan & Abourashed, 2010). Anise oil may be
- 1075 extracted by steam distillation or supercritical carbon dioxide (Rodrigues et al., 2003), making organic
- 1076 sources feasible. The primary component of anise oil is anethole (Khan & Abourashed, 2010). Anise oil
- 1077 may be used as a source for the isolates 4-anisaldehyde, estragole and pseudoisoeugenyl-2-
- 1078 methylbutyrates. Sweet anise seeds are about 2.5% oil upon steam distillation, consisting of about 95%
- 1079 trans-anethole and 2% methyl chavicol (Burdock, 2016). Steam-distilled star anise has 3-3.5% volatile oil, with 85-90% anethole (Attokaran, 2017). Star anise can also be made into an alcohol tincture (Burdock,
- 1080 2016).
- 1081
- 1082
- 1083 Cinnamon oil
- 1084 Cinnamon oil is derived from the bark, leaves, and twigs of trees in the genus Cinnamomum (Coppen,
- 1085 1995). The bark is composed of approximately 4% volatile oils extractable by steam distillation
- (Dayananda et al., 2004; O'Neil, 2013). The principle active component is cinnamaldehyde or cinnamic 1086
- 1087 aldehyde, with camphor, coumarin, eugenol, and linalool also part of the flavor profile. C. osmophloeum
- has higher levels of the trans- isomer of cinnamaldehyde (Hussain et al., 1986), which is significantly 1088
- 1089 more reactive than the cis- isomer (Klibanov & Giannousis, 1982). Cinnamon oil can also be distilled from
- 1090 the leaves and twigs, but consists of between 80 and 88% eugenol, which is also the main constituent of
- 1091 clove oil. The root bark oil of C. zeylanicum has approximately 4-5% cinnamaldehyde and eugenol, and
- 1092 about 60% camphor (Wijesekera et al., 1974). Cinnamon oleoresins are mostly produced by extraction
- 1093 with a solvent, such as hexane (Dayananda et al., 2004). It is possible to produce cinnamon oil by use of 1094 supercritical fluid extraction, but that technique is rarely used because of the high cost and insignificant
- 1095 quality advantage. The literature reviewed and interviews conducted by the authors of this report did
- 1096 not clarify how nonorganic cinnamon isolates are extracted or produced, or why there are no organic
- 1097 sources of cinnamon oil.
- 1098
- 1099 Clove oil
- 1100 Clove essential oil is produced from the plant buds, but other constituents of the clove plant may be used
- 1101 for various extracts and isolates. Clove buds are approximately 15-21% volatile oil (Merck, 2015), with
- extraction yields averaging 15-18% (Khan & Abourashed, 2010). Eugenol is the primary active 1102
- 1103 constituent and main isolate. Other constituents present in clove buds include glucosides of sterols
- 1104 (sitosterol, stigmasterol, and campesterol), crategolic acid, methyl ester, oleanolic acid, quercetin,
- eugeniin, kaempferol, and rhamnetin (Khan & Abourashed, 2010). The chemical compositions of clove 1105
- 1106 oils will vary due to the differences in plant growing conditions, genetic traits, plant parts used, and the extraction methods (Alma et al., 2007). 1107
- 1108
- 1109 Clove bud and leaf oil are generally extracted by water distillation, while clove stem oil is extracted by
- steam distillation. The stems yield 4-6% and the leaves yield 2-3% volatile oils (Khan & Abourashed, 1110
- 1111 2010). Clove oil consists of 60-90% eugenol, 2-27% eugenyl acetate, 5-12%  $\beta$ -caryophyllene, and minor
- 1112 constituents such as methyl amyl ketone, methyl salicylate, and benzaldehyde (Bhuiyan, 2012; Bhuiyan
- et al., 2010; Khan & Abourashed, 2010; Merck, 2015). Clove stem oil usually contains 90-95% and clove 1113
- leaf oil 82-88% eugenol. Stem and leaf oil may have traces of naphthalene (Burdock, 2016; Khan & 1114
- 1115 Abourashed, 2010). 1116
- 1117 Mint oils
- 1118 Various species of the plant genus Mentha can be used as sources of mint oil and other mint derivatives
- 1119 (Baser & Buchbauer, 2009). Most commercial sources of mint oil are from cornmint (M. arvensis),
- peppermint (M. piperita), spearmint (M. spicata), bergamot mint (M. citrate), and horse mint (M. longifolia) 1120
- 1121 (Lawrence, 2007). Each of these species has a distinct flavor profile based on different chemical

compositions. Peppermint oil is one of the most produced essential oils in the world (Schmidt, 2009).
Cornmint and peppermint are the main sources of menthol (Lawrence, 2007). Menthol can also be

1123 Communication perpendition are the main sources of mention (Lawrence, 2007). Menthol can also be 1124 produced synthetically (Fischetti, 2010). Commint oil is sometimes blended with or even misrepresented

1125 as peppermint oil (Burdock, 2016). By comparison, the main aromatic component of spearmint oil is

1126 carvone (Lawrence, 2007). The mints all contain a rich, variable, and complex mixture of many other

- 1127 aromatic and flavoring compounds, including vindifloral, pulegone, piperitone, limonene, and various
- flavonoids, terpenoids, and carotenoids (Baser & Buchbauer, 2009; Burdock, 2016; Khan & Abourashed,
- 1129 2010; Lawrence, 2007).
- 1130

1131 Most mint oils are produced by high pressure steam distillation (Lawrence, 2007). The original

1132 processing method involved packing fresh mint into a chamber and passing steam through it. The 1133 moisture would be removed by condensation and the oil would float on top. The mint essential oil

1134 would then be removed by distillation using the different boiling points of oil and water (Russell, 1926).

1135 Advances in temperature control, vacuum distillation, and crystallization have resulted in higher yields

and a greater range of derivatives appropriate for various applications, but mint oil extraction remains

1137 mostly a physical and mechanical process (Denny & Lawrence, 2007). Mint oils and other derivatives are

- used in candy and frozen dairy desserts. Mint essential oils are used in many soaps, toothpastes, and
- 1139 other personal care products, as well as tobacco products (Burdock, 2016; Hayes et al., 2007; Khan &
- 1140 Abourashed, 2010; Lawrence, 2007).
- 1141

## 1142 Vanilla extract

1143 The pods from various species of orchids of the genus *Vanilla* are used to make an extract that is one of

1144 the most widely used flavoring agents in the world. The primary commercial species *V. planifolia* is native

1145 to the upland tropical rain forests of pre-Columbian Meso-America (Lubinsky et al., 2008). Most

references to vanilla are to this species, but where there is ambiguity, it may be called "Mexican" or

"Bourbon" vanilla. Other species cultivated for use as flavoring agents include *V. tahitensis* or Tahitian

1148 vanilla and *V. pompona*. The vanilla orchid is a shade-loving crop and organic farming systems generally

intercrop it with other perennial plantation crops, such as coconut, areca nut, and black pepper(Choudhuri et al., 2018). Vanillin, one of the flavoring constituents of natural vanilla, can be produced

from synthetic sources (Haarmann, 1884; Hocking, 1997) as well as from genetically modified yeast

1152 (*Saccharomyces cerevisiae*) (Brochado et al., 2010; Ramaen et al., 2018). Over 85% of the vanillin sold in the

- 1153 world uses petrochemical-derived guaiacol (Bomgardner, 2016; Ciriminna et al., 2019). Less than 1%
- 1154 comes from natural sources and organic sources are a fraction of that. The FDA classifies vanillin as a
- 1155 synthetic additive [21 CFR 182.60].

## 1156

## 1157 Types and WONF

1158

1159 Flavor that is obtained "From The Named Fruit" or "From The Named Flavor" may be labeled as FTNF

1160 (FEMA, 2011). Flavors labeled as "types" may contain ingredients other than the juices, extracts, or other

1161 derivatives within the identified precursors. If a food contains "both a characterizing flavor from the

- 1162 product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the
- characterizing flavor, the food shall be labeled [according to regulatory requirements with] the words
- "with other natural flavors" [21 CFR 101.22(i)(1)(iii)]. "With Other Natural Flavor" is often abbreviated
- 1165 "WONF." Most products that are made WONF are simulating or resembling fruit and vegetable flavors,
- 1166 but the term may also appear on labels to describe other flavors. A flavor described as a "strawberry

1167 flavor WONF" will have flavor components derived from strawberries but will also contain flavoring

1168 ingredients that come from other precursors. By contrast, a "strawberry type" natural flavor will contain

- 1169 flavorings derived from other fruit that mimic the taste of strawberries.
- 1170
- 1171 Fruit Concentrates and Extracts
- 1172 Fruit extracts and flavorings have a long history of being used as flavors in mineral waters and
- 1173 carbonated beverages (Berenstein, 2018; Walter, 1916). The 1920s in the U.S. saw numerous innovations
- 1174 in the use of fruit flavorings in beverages. The development of soft drinks to replace the market for
- alcoholic beverages made illegal by prohibition drove innovation in fruit flavors (Berenstein, 2018), as

- 1176 did the invention of the cocktail and novel flavoring agents that could be used in illicit alcoholic 1177 beverages to make them more palatable (A. F. Smith, 2013). 1178 1179 Because high heat can damage fruit flavors, lower temperatures are used. Sugar solutions become solid 1180 at a lower temperature than water, and the water can be removed by freezing, so the concentrate can be poured off. Vacuum distillation has a long history of use in capturing and concentrating various fruit 1181 1182 flavors (Cruess, 1924, 1948; Guadagni & Dimick, 1953; Walter, 1916). A third method is removal of water 1183 by osmosis through a semi-permeable membrane. These methods would be mechanical or physical 1184 processes and would not involve the use of processing aids that are prohibited for organic production. 1185 Ion exchange can be used to remove various polar substances. 1186 1187 As noted above, fruit flavoring ingredients that come exclusively from the named flavor may be labeled as "From The Natural Fruit" or "From The Natural Flavor" abbreviated FTNF (FEMA, 2011). These may 1188 1189 be formulated with non-flavoring adjuvants. However, label claims may be more restrictive. 1190 1191 Fruit flavors can be categorized by plant taxonomy or origin (Jiang & Song, 2010). Within the 1192 classification of fruit concentrates and extracts, the category can be further divided into types of fruit. 1193 This report will look at berries, citrus, grape, pome fruit, stone fruit, and tropical fruit. Based on 1194 interviews of accredited certifying agents, WONF flavor ingredients comprise a large portion if not most 1195 of the certified organic fruit flavors in the Organic Integrity Database (OID) (NOP, 2022). 1196 1197 Berries 1198 Berries are characterized as "soft fruits" because they are highly perishable and difficult to ship without 1199 special care in handling. Many have a narrow harvest window that limits sales as fresh fruit. Over 1,800 1200 certified organic berry flavors were listed in the OID. The predominant certified organic berry flavors are strawberry, raspberry, blueberry, and cranberry (NOP, 2022). The database also includes unspecified 1201 1202 berry flavor blends. Many of these are modified by the word "type" or "WONF." Extracting berry 1203 flavors is considered a value-added proposition. 1204
- 1205 Citrus

Citrus fruits (*Citrus spp.*) are grown in tropical and subtropical regions and have a distinct flavor profile that is considered desirable in many foods. Species produced for flavors are oranges (*C. sinensis*), lemons (*C. limon*), limes (*C. aurantifolia*), grapefruit (*C. paradisi*), tangerines (*C. reticulata*), and bitter lemon; these all have different distinct flavor profiles (Burdock, 2016; Hui et al., 2010). Flavorings may be extracted from various parts of the fruit that are not usually consumed. For example, lemon flavor may originate from peels or seeds. The most basic form of a fruit flavoring is a juice concentrate. Concentrates have had

- 1212 the water removed from them by various methods. While citrus greening disease has set back organic
- 1213 production in the U.S. and elsewhere, most organic citrus fruits are still commercially available.
- 1214 1215 *Grapes*

1216 Grapes (Vitis vinifera) are grown in a broad range of temperate, subtropical, and Mediterranean climates

- 1217 (Winkler, 1974). The fruit is versatile in that it can be consumed fresh as table grapes, dried as raisins,
- 1218 pressed into non-alcoholic juice, or fermented into wine. Grapes were one of the first crops to be
- 1219 produced organically on a large scale (NRC / NAS, 1989). Grape concentrate is one of the main flavor
- 1220 components of fruit flavors that are labeled as [specific fruit] "Type" or "WONF." Determination of the
- 1221 flavors contributed from various organic and nonorganic grape sources in such organic products would
- 1222 require further investigation.
- 1223
- 1224 Pome fruit

1225 Apples (*Malus domestica*) and pears (*Malus persica*) are the predominant pome fruits, but other pome

- 1226 fruits are used to derive precursors that create other natural flavors and flavoring agents (Y. H. Hui et al.,
- 1227 2010). Organic apples and pears are extensively cultivated. Organic sources of apple derivatives appear
- 1228 to have the potential to be commercially available, particularly if fruit that does not meet table-grade
- standards can be used to derive precursors. Apples and pears like grapes also appear to be used as
- 1230 sources of flavor components identified in flavor products labeled as "WONF." It was not possible to

- determine which flavors use organic apples as precursor sources or are made from nonorganic applesand pears given the data available on the OID (NOP, 2022).
- 1233 1234 Stone fruit
- 1235 Various members of the genus *Prunus* are classified as stone fruits based on the presence of a pit found in
- 1236 the center that protects a single seed. The most widely cultivated stone fruits are peaches, plums,
- 1237 apricots, and cherries. Almonds are technically a stone fruit, with the fruit considered the hull and the pit
- 1238 containing the shell and nutmeat. Certified organic sources of all stone fruits considered are listed on the
- 1239 OID, possibly making their derivatives commercially available from organic sources (NOP, 2022).
- 1240 1241 Tropical fruit
- Bananas (*Musa* spp.) are the primarily consumed tropical fruit and with that, the main tropical fruit
- 1243 flavoring used. Most bananas used for fresh fruit are *M. acuminata* var. "Cavendish." However, for
- 1244 flavoring, other varieties and species may be used. More often other fruits are used to make "banana
- 1245 type" flavors. The other tropical fruits that are used as precursors for natural flavors are pineapple
- 1246 (Ananas comosus), mango (Manfifera spp.), papaya (Carica papaya), starfruit (Averrhoa caramboloa), and
- 1247 passionfruit (*Passiflora edulis*) (Y. H. Hui et al., 2010). Replication of tropical fruit flavors became a focus
- 1248 of research during the shortages of World War II (Berenstein, 2018). Artificial pineapple flavor was one
- 1249 of the first flavors isolated using a distillation / fractionation process (Haagen-Smit, 1949).
- 1250
- 1251 <u>Vegetable Extracts</u>
- 1252 Vegetable flavors are also used in certain foods. The main vegetable flavors used are garlic, onion,
- 1253 tomato, and peppers. These all appear on the OID, as does carrot extract, sweet potato flavoring, and
- 1254 mixed vegetable flavor or vegetable broth (NOP, 2022). Celery and peppers are covered in the section on
- 1255 herbs. Most of these concentrated forms would be agricultural in origin and minimally processed. Some
- 1256 of the isolated chemicals from hot pepper, e.g., capsaicin, or allicin from garlic, may require additional
- 1257 processing steps that may not be acceptable in organic handling.
- 1258
- 1259 Garlic

Garlic (*Allium sativum*) is a vegetable with a recognizable pungent flavor profile. It is well adapted for
organic production throughout the temperate U.S. (Bachmann & Hinman, 2008). The characteristic flavor
of garlic is largely from the sulfur-containing compounds, primarily diallyl disulfide and the related
compounds allicin, allyl disulfide, and triallyl disulfide (Block, 2010). Diallyl disulfide comprises about
60% of garlic oil by weight (Khan & Abourashed, 2010). Diallyl disulfide readily decomposes into the

- 1265 other two allyl sulfide molecules (Block, 2010). Allicin is the main odor component (Khan & Abourashed,
- 1266 2010). When garlic cloves are cut or crushed, the cysteine-related amino acid alliin is enzymatically
- 1267 converted to allicin, making it a secondary metabolite (Block, 1985).
- 1268

1269 While fresh and powdered garlic are used for domestic cooking, food processing applications use the oil 1270 form of garlic extensively as a flavor ingredient (Khan & Abourashed, 2010). Because it is heavier than

- 1270 nonit of game extensively as a navor ingredient (retain & rebotrastica, 2010). Because it is neavier main 1271 most essential oils, garlic oil is produced by a special water and pressurized steam distillation process,
- 1272 with enzymes frequently used in preparations to increase yields (Attokaran, 2017). The oleoresin may be
- 1273 produced either through hexane extraction or the use of supercritical carbon dioxide (Attokaran, 2017).
- 1274 Over 20 different garlic oil volatiles are also isolated and produced by supercritical extraction
- 1275 (Attokaran, 2017). Various derivatives of the amino acid cysteine are extracted from garlic (Burdock,
- 1276 2016). Garlic is a common flavor in many savory foods, and its derivatives are used as flavoring agents in
- 1277 condiments, relishes, snack foods, soups, dressings, meat, gravies, and many other processed foods
- 1278 (Attokaran, 2017; Khan & Abourashed, 2010).
- 1279
- 1280 Tomatoes
- 1281 Tomatoes (*Lycopersicum esculentum*) are the second most consumed vegetable in the U.S. after potatoes
- 1282 (USDA / ERS, 2022). Lycopene provides tomatoes with a distinct flavor and color profile (Attokaran,
- 1283 2017). Tomato lycopene extract can be made from the whole fruit, the ripe tomato pulp, or the skins
- 1284 removed in the canning process. Most processes will include some ß-carotene. Various techniques may

- 1285 be used, including dehydration, solvents such as ethyl acetate, hexane, ethanol, or supercritical CO<sub>2</sub>
- 1286 (Attokaran, 2017).
- 1287
- 1288 Animal-derived flavors
- 1289 Flavoring agents associated with various animal products are used to enhance or recreate flavors in
- certain products. Most are related to dairy products such as cheeses, frozen desserts, and vogurts. Meat 1290
- 1291 flavor is also desired in certain products. Fish and shellfish flavors are used in some specialty products.
- Insects are also a source of flavors. Honeybees are the main insect source of flavors, but other insects are 1292
- 1293 being explored for potential future use.
- 1294 1295 Dairy Flavors
- 1296 Most milk and dairy flavors consumed in the U.S. are derived from milk and milk products of cattle (Bos 1297 *taurus*), such as milk, butter, cheese, whey, and other dairy products. Organic milk is commercially 1298 available. The final uses for these flavors are often in non-dairy products where butter or cheese flavor 1299 may be advantageous. The introduction of dairy flavor isolates to imitation dairy products has a long 1300 and sometimes controversial history. These may be marketed as lactose-free products to the lactose 1301 intolerant. Growing interest in the market for vegan dairy substitutes has increased interest in finding dairy flavor substitutes. Partial-dairy or hybrid products that are predominately plant-based but contain 1302
- 1303 animal-derived flavoring components extracted from casein and whey from dairy animals offer a middle
- 1304 ground between animal-based products and those that are completely plant-derived. Such hybrids face
- 1305 ambiguous regulatory status (Kamath et al., 2022).
- 1306
- 1307 Meat, Seafood, and Umami Flavors
- 1308 Meat flavoring is a relatively new development compared to herbs, spices, and essential oils. The science
- 1309 is rapidly changing. Most meat flavoring agents were historically extracted or concentrated from
- 1310 slaughtered and cooked livestock by freeze-drying and concentrating a ground meat slurry from cuts of
- 1311 meat that were edible but not otherwise marketable. Beef bouillon served as a flavoring agent to
- 1312 introduce savory flavors to preparations that were largely plant-based when meat was in short supply. 1313
- One of the earliest patents for flavorings intended to resemble meat involved the processing of milk and
- 1314 dairy products (Eberhard, 1902). A later invention used whey treated with hydrochloric acid as a meat
- 1315 analog flavor for textured vegetable protein products (Baugher, 1975).
- 1316
- 1317 The introduction of the amino acid salt monosodium glutamate (MSG) changed the flavor industry, 1318 particularly for savory flavors (Marshall, 1948). MSG was first isolated in 1908 from the Japanese sea 1319 vegetable Laminaria japonica (Lindemann et al., 2002). MSG introduced the word "umami" as a fifth 1320 flavor to common English usage (Tracy, 2016). Other ingredients, mostly L-a-amino acid salts and 5'-1321 ribonucleotides, were introduced to the market as meat and seafood flavorings. The original sources of
- 1322 MSG were considered to be nonsynthetic in the early literature (Marshall, 1948). Most commercial
- 1323 production of MSG is from bacterial fermentation of Cornyebacterium glutamicum, Brevibacterium
- 1324 lactofermentum, and Brevibacterium flavum (Sano, 2009).
- 1325
- 1326 It is unclear whether it would be possible to produce MSG in a way that would meet the criteria
- 1327 specified in the annotation for flavors in § 205.605(a). There are no certified organic sources of MSG.
- 1328 Amino acids in general, particularly MSG, have been the subject of debate within the organic
- 1329 community. Amino acids were included in the original set of NOSB recommendations. Prior to the
- 1330 Natural Flavors recommendation made in 1994, the NOSB tabled the petition. NOSB members voiced the
- 1331 opinion that amino acids should be petitioned separately on a case-by-case basis, although no formal 1332 vote appears to have been taken.
- 1333
- 1334 More recent inventions involve the genetic modification of microorganisms to recreate the flavor, aroma,
- 1335 texture and colors of meat in predominantly plant-based and fermentation-produced foods through the
- 1336 expression of proteins, amino acids, and fatty acids previously found either exclusively or in higher
- 1337 concentrations in animal tissue (Fraser et al., 2019; Vrljic et al., 2018). These patents disclose the 1338
- organisms used and DNA sequences responsible. Such techniques could be considered excluded
- 1339 methods under § 205.105, and thus impossible to produce organically.

#### 1340 1341 Bees and other insects 1342 Honeybees (Apis mellifera) provide various flavors. Honey, propolis, and beeswax are recognized as 1343 flavoring agents or may be used as precursors (IOFI, 2022; U.S. FDA, 2022). Other invertebrates produce chemical substances that are potential precursors to natural flavors. Insect protein and chitin are being 1344 explored as potential sources for replicating meat and shellfish flavors in plant-based food (Melgar-1345 1346 Lalanne et al., 2019). Without specific invertebrate standards, the organic certification of insects and other 1347 invertebrate animals as agricultural flavor sources remains ambiguous. 1348 1349 **Beverage Flavors** 1350 Flavors associated with specific non-alcoholic and alcoholic beverages are another category that requires 1351 special consideration. Some of these flavors are also used in candies and confectionaries. Alcoholic beverages fit into a separate category and are subject to a different set of regulations from food and non-1352 alcoholic beverages. Flavorings used for beer, wine, and spirits are briefly reviewed here. 1353 1354 1355 Chocolate 1356 The seeds of the cacao plant (Theobroma cacao) are used to make the base for the beverage cocoa as well as 1357 the flavor component for chocolate. Cocoa extract is made by curing and fermentation of cacao beans, which are then dried and roasted (Burdock, 2016). 1358 1359 1360 Coffee 1361 Fruit of various Coffea species are roasted to make coffee. The two main species cultivated are C. arabica 1362 and C. robusta, sometimes called C. canephora (Khan & Abourashed, 2010). Roasted coffee is known to contain over 1,000 volatile flavor components (Burdock, 2016). Coffee flavor is mostly associated with the 1363 1364 beverage but may also be used as a flavoring agent in some food applications. Powdered coffee is an extract that is sold as instant coffee, but may also be used as a flavoring ingredient (Attokaran, 2017). 1365 Coffee flavor may also be extracted using ethanol (Attokaran, 2017; Burdock, 2016). 1366 1367 1368 Tea 1369 Tea is usually associated with the beverage made from the leaves of *Camellia sinensis* (Attokaran, 2017; Khan & Abourashed, 2010). The unfermented leaves that are used to make green tea are treated by either 1370 1371 steaming or dry heat processes (Khan & Abourashed, 2010). Black tea is fully fermented after heat 1372 treatment (Attokaran, 2017). Enzymes for fermentation are contained in the leaves (Burdock, 2016). 1373 White tea and oolong tea are also derived from Camellia sinensis through specific traditional treatments 1374 and processing. Certain teas are grown and harvested at specific times for specific flavor profiles, with 1375 teas grown at high altitudes in India, such as Darjeeling, particularly prized for their quality (Attokaran, 1376 2017). Tea is known for its tannin, which comprises about 13% of the dried leaves (Burdock, 2016). It is also a natural source of flavonoids, anthocyanins, and aldehydes (Khan & Abourashed, 2010). A growing 1377 number of ready-to-drink teas are being marketed, many of which rely on various added tea flavorings. 1378 1379 Many certified organic flavors are classified as tea, which may be *Camillia sinensis*, but flavors labeled as 1380 tea may also refer to uncaffeinated herbal tea blends. Examples include chamomile (mostly Matricaria chamomilla and Chamaemeium nobile but may be from other sources); rooibos (Aspalathus spp.); and 1381 1382 hibiscus (Hibiscsus spp.). Chai tea – more properly called "masala chai" is made from Camillia sinensis and the blend of spices that comprise garam masala. Tea extracts are prepared by several different 1383 methods. The most common is steeping in hot water. Tea derivatives can also be made by solvent 1384 extraction of the cured leaves by alcohol or other solvents (Burdock, 2016). In addition to use in ready-to-1385 1386 consume shelf-stable tea beverages, tea extracts may be found in baked goods, candy, and frozen desserts, with some baked goods consisting of up to 3% tea extracts (Khan & Abourashed, 2010). 1387 1388

1389 Hops

1390 The main flavoring component of beer is hops (*Humulus lupulus*) (Attokaran, 2017). Hops come from a

1391 vigorous climbing perennial vine that has male and female flowers on separate plants. The female

1392 flowers, known as cones, are used for flavors. The active flavoring components are found in volatile oils

- that comprise 0.3-1.0% of the flowers, and 3-12% resinous bitter principles (Khan & Abourashed, 2010).
- 1394 Hops have a complex range of aromas and flavors that reflect a diversity of chemical constituents. Hops

have two types of acids that are responsible for imparting bitterness and aroma. The α-acids include
humalone and its related compounds that contribute to bitterness. On the other hand, β-acids include
lupulone and allied chemicals responsible for aroma (Attokaran, 2017). Historically, U.S. brewers
preferred milder varieties with lower levels of bitters and aroma (Attokaran, 2017). Craft brewing has
changed the preferences for hops that are stronger and have a broader palate of flavors. Hops can be
made into an infusion, fluid extracts, tinctures, concretes, and absolutes (Burdock, 2016). Hop oil can be
made by steam extraction (Burdock, 2016; Khan & Abourashed, 2010).

1402

Hops were added to 7 CFR 205.606 on June 21, 2007 [72 FR 35137]. In 2009, the USDA received a petition
to remove hops from the National List because organic hops were commercially available from multiple
sources (Quinn, 2009). Hops were subsequently removed from the National List on October 30, 2014
[79 FR 58655]. However, it is not clear from either the *Federal Register* notice [79 FR 58655] or Policy
Memo 11-1 (NOP, 2011) whether the removal of hops from § 205.606 applies to the various hops extracts,
or if nonorganic hops extracts are allowed under § 205.605(a).

- 1409
- 1410 Wine

1411 The literature on wine flavors is vast, varied, and difficult to summarize. Wood chips may be used to

- 1412 impart an "oak" or other flavor consistent with being wooden barrel-fermented when fermentation takes
- 1413 place in steel tanks.
- 1414
- 1415 <u>Maple Flavor</u>
- 1416 Maple syrup is produced from the sugar maple (*Acer saccharum*). Maple flavor, on the other hand, may
- 1417 be extracted from various spices, such as fenugreek (Burdock, 2016).
- 1418
- 1419 <u>Mushrooms and Fungi</u>

1420 Various mushrooms and other members of the fungal kingdom are used to produce flavors. The NOSB

1421 recommended standards on October 17, 2001 for organic mushroom production, which are still pending

action from the USDA (NOSB, 2001). Although the USDA has not established separate standards for

mushrooms and other fungi, certified organic mushroom producers appear in the OID, as do mushroomderived flavors such as mushroom distillates (NOP, 2022). Mushroom and yeast derivatives are used to

1424 derived havois such as mushioon distinates (NOT, 2022). Mushioon and yeast derivatives are used t

- 1425 produce umami or meat-like flavors (Holtz, 1998).
- 1426
- 1427 <u>Smoke Flavor</u>

1428Many foods are identified by a flavor that reminds the eater of food being prepared over an open wood1429fire. The invention of liquid smoke allowed for recreation of the flavor without preparing the food over a

- 1430 wood fire. Wood smoke is forced into a kettle or chamber filled with water, which is then steam distilled
- through a conduit. The smokey liquid is then condensed. An early patent used wood from sugar maple
- 1432 (Chase, 1893). Other sources of wood used may be agricultural or wild harvested in origin. Subsequent
- 1433 improvements were made in processes to removed undesirable flavors and odors, and to formulate
- 1434 products with various ancillary ingredients that improve the dispersion of the flavor through the food
- 1435 matrix (Goblik et al., 1974; Hollenbeck, 1963; Melcer & Sair, 1975; Underwood, 2000). Acetic acid, which
- 1436 may be produced from vinegar or synthesized, was the preferred stabilizer for earlier processes (Goblik
- 1437 et al., 1974; Hollenbeck, 1963). Phosphoric acid may also be added as a stabilizer (Underwood, 2000).
- 1438
- 1439 Most smoke flavor comes from combustion or pyrolysis of industrial timber into charcoal. It may be
- 1440 possible to use wood gathered from certified organic fruit trees, but there is no evidence that this is
- 1441 currently done.
- 1442

1443	Focus Areas Requested by the NOSB
1444	
1445	The NOSB requested responses to three focus questions within this technical report:
1446	
1447	1) What flavors are available in organic form?
1448	2) What flavors could be certified organic based on their source and manufacturing, but are not?
1449	3) What flavors cannot be certified organic based on their source and manufacturing?
1450	
1451	These questions are answered below based on information gathered from documents published by $USDA$ and has the A area dited Cartifican Accessible (ACA) the literature (with variable sizes to access
1452 1453	USDA and by the Accredited Certifiers Association (ACA), the literature (with weight given to peer- reviewed journal articles), from data downloaded from the USDA's Organic Integrity Database (OID),
1454	and from interviews conducted with personnel working with USDA Accredited Certifying Agents
1455	(certifying agents) that have expertise in organic and nonorganic flavors.
1456	()
1457	USDA and ACA Documents
1458	
1459	Official guidance and industry best practices formed the baseline to answer the focus questions. The
1460	most relevant official document is the NOP USDA's Policy Memo 11-1 on the Use of Natural Flavors
1461	(NOP, 2011). That memo superseded an earlier Guidance document titled <i>NOP Guidance for Certifiers on</i>
1462 1463	<i>Flavors</i> (NOP, 2007). Prior to that, the USDA prepared an <i>Overview of Flavor Additives</i> (NOP, 2005). Other relevant NOP documents are the <i>Classification of Materials</i> (NOP, 2016a) along with the decision tree to
1464	classify substances as synthetic or nonsynthetic (NOP, 2016c). Also relevant is the Accredited Certifier
1465	Association's ACA Best Practices for Review of Nonorganic Flavors (ACA, 2021a) and ACA Best Practices for
1466	Commercial Availability of Nonorganic Flavors (ACA, 2020).
1467	
1468	While these documents are not legally binding, they serve as guides for the certifiers to implement the
1469	regulation consistently.
1470	
1471	Organic Integrity Database
1472 1473	To answer the focus questions, OMRI downloaded records of all products identified in the Organic
1474	Integrity Database (NOP, 2022) by keywords associated with flavors and status of Certified Organic that
1475	were current between November 3 and November 10, 2022. Keywords used included "flavor,"
1476	"essence," "essential oil," "extract," "WONF," "oleoresin," "distillate," "fortifier," "masker," and
1477	"modifier." All certified organic products from processors and handlers that appeared to exclusively
1478	make or sell flavors were also downloaded. Many of the certifying agents, particularly those based
1479	outside the U.S., identified operations as certified organic only for "flavors" sometimes with modifiers
1480	such as "spices" or "extracts" but no specific product identification. These resulted in null fields for
1481	specific products. Other operations appeared to be distributors or re-packers that did not process flavors.
1482 1483	After removing null records and apparent duplicates, there were approximately 14,877 certified organic flavor products produced by about 154 certified organic handling operations contained in the OID. These
1485	operations were certified by 25 of the USDA accredited certifying agents. These are estimates; the exact
1485	numbers could not be fully verified with the certifying agents by the deadline for this technical report.
1486	Appendix B - Suppliers of Organic Flavors includes a list of operations certified organic for products that
1487	could be considered "flavors" using the above search criteria, along with their certifying agents and the
1488	number of certified organic products identified as "flavors" that they carry.
1489	

## 1490 <u>Certifier Interviews</u>

- 14911492 OMRI requested interviews with certifying agent personnel familiar with the review of organic flavors
- and evaluation of the use of nonorganic natural flavors in certified organic processed products.
- 1494 Personnel for seven ACAs were interviewed between November 21 and December 15, 2022, in
- 1495 chronological order: QAI, OTCO, CCOF, Pennsylvania Certified Organic, ACO Certification Ltd, and

1496 Washington State Department of Agriculture. The individuals interviewed were either reviewers or 1497 supervisors. Most of the interviews were conducted by videoconference. In four of the seven interviews, 1498 a supervisor and a reviewer specializing in the review of processing operations were both present.

1499

1500 Experience with organic certification under the NOP ranged from less than one to over ten years. Several 1501 had worked for multiple certifiers. Collectively, the certifying agents that agreed to be interviewed 1502 account for the certification of 79% of the estimated number of operations that are certified to handle or 1503 process organic flavors and 96% of the estimated number of organic flavors certified. The interview 1504 questions are included in Appendix D - Flavors Technical Report - Certifier Interview Questions. The 1505 responses are anonymous and not attributed to any single certifying agent or individual. Aggregate 1506 responses are summarized in response to the questions. Exceptions are noted but are not further 1507 explained to maintain anonymity. The certifying agents and interviewees were told that the information 1508 that they provided would be made public, so no confidential business information was divulged.

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#### **Responses to NOSB Focus Questions**

#### 1. What flavors are available in organic form?

1512 1513 Between November 4 and 10, 2022, OMRI identified over 14,000 different products that are listed as 1514 certified organic flavor ingredients on the USDA's Organic Integrity Database (OID). The certifying 1515 agents for these products believe that an undetermined number of these products contain less than 5% 1516 nonorganic flavor ingredients. If carriers or delivery systems make up over 95% of the ingredients net of 1517 water and salt, and the nonorganic ingredients are on the National List, a flavor ingredient is considered 1518 eligible to be certified organic. Certifying agents interviewed stated that many products identified as 1519 certified organic flavors on the OID contain a nonorganic flavor component or components at less than 1520 5%. The OID does not distinguish between 100% organic natural flavors and those that are a minimum of 1521 95%. Only two products identified as organic flavors in the OID have "100% organic" in the product 1522 name, both of which are orange essences. Cold-pressed citrus extracts in general should be commercially 1523 available. The certifiers that account for the most certified organic flavors stated that few certified 1524 organic flavors – if any – would be 100%. The certifiers that certified only a few flavor manufacturers 1525 were more likely to certify 100% organic flavor ingredients, many of which were single ingredients that 1526 were mechanically extracted or concentrated.

1527

1528 Order of words on the label of the certified organic product matter. By comparison, 4,563 of the certified 1529 organic flavors in the OID are identified as "WONF" or "With Other Natural Flavors." Accredited 1530 Certifying Agent review staff familiar with these products indicated that these other natural flavors are 1531 more often nonorganic natural flavors meeting the annotation of § 205.605(a). They may be made from 1532 nonorganic sources, or the precursors may have been extracted using solvents or other processing aids 1533 that are acceptable under the annotation but that are not acceptable to produce a certified organic flavor. 1534 The "other natural flavors" may also be certified organic, so WONF is not, by itself, an indication of a

- 1535 nonorganic flavoring agent in an organic flavor.
- 1536

1537 All ACAs interviewed reported that they allowed nonorganic flavors that were available in organic form, 1538 but the word "form" has other meanings besides organic or nonorganic. Specifically, when referring to 1539 flavors, the word "form" often refers to the physical characteristics, such as liquid or solid. Within the physical state, there may be functional differences related to the way that they are extracted or delivered. 1540 1541 Solids may be in powder, flake, or granular form. Some concentrated solids or semi-solids are called 1542 "concrete" forms. Liquids may be presented as extracts, essential oils, or oleoresins. Thus, a processor 1543 may not be able to find a certified organic flavor to be commercially available in the form required for a 1544 specific application in an organic processed product. Questions regarding functionality and quality may 1545 require greater documentation. By definition, a flavor is limited only to that functionality, but as discussed above, flavoring agents may be multifunctional. Quality is inherently subjective. Certifying 1546 1547 agents may ask for the results from flavor panels or other supporting empirical evidence, but none was 1548 able to provide specific examples where they deemed such evidence unacceptable.

The nonorganic flavoring components in an organic flavor, or a nonorganic flavor that a processor uses in lieu of an organic flavor, may involve chemical processing steps that would not be obvious if the nonorganic flavoring agent is supported by an affidavit, rather than the certifier independently verifying its extraction or isolation process. Several of the certifiers acknowledged that they do not evaluate every nonorganic agent in a certified organic flavor that they certify using Guidance 5033-2 (NOP, 2016b) in order to confirm that the ingredient is nonagricultural and thus permitted under § 205.605(a), and that it has not undergone a chemical change and is thus nonsynthetic.

- 1557
- 1558 1559

# 2. What flavors could be certified organic based on their source and manufacturing process, but are not?

1560 Certifying agents reported in interviews that when added up between them all, they have reviewed
1561 thousands of nonorganic flavor ingredient declarations. None could give a precise number of how many
1562 they have reviewed over the years, although the smaller certifiers interviewed thought that the
1563 information could be retrieved without much effort. The larger ones would take more time, and they do
1564 not archive withdrawn product applications that they never certified.

1565

1566The interviewees said that they consistently followed the ACA's Best Practices for Commercial Availability1567of Natural Flavors (ACA, 2020) and indicated that they mostly followed the ACA's Best Practices for the1568Review of Organic Flavors (ACA, 2021a), but with some variations in interpretation. The ACA Best1569Practices and the accompanying forms are included in Appendix C - ACA Best Practices.

1570

1571 The procedures in both best practices rely mostly on documentation provided by the entity seeking to 1572 use a nonorganic flavor. While the Best Practices for the Review of Natural Flavors document indicates that 1573 additional verification steps may be taken, the follow-up is done to varying degrees. Those interviewed 1574 acknowledged that in most cases they do not follow up with the vendors of the flavors to investigate 1575 whether specific nonorganic flavors used by their clients could potentially be produced and handled in a 1576 way that would make them eligible for organic certification. A complicating factor in some cases occurs 1577 when multiple operations and suppliers are involved, such as when a brand owner is purchasing the 1578 ingredients and setting the specifications, and a co-packer or toll processor is doing the actual processing 1579 for a private label product.

1580

1581 Certifying agents that agreed to be interviewed reported that answering the question, "What flavors 1582 could be certified organic based on their source and manufacturing process, but are not?" would require a manual search to identify what nonorganic flavors have been approved and a further investigation into 1583 1584 the factors that rendered them nonorganic. Such a project requires investigation of each individual 1585 nonorganic flavor that is currently used, going back to the production of the agricultural source, each 1586 isolated flavor precursor, and each final flavor. The data that is required is supposed to be on file with 1587 the certifiers and can be requested through the accreditation process. Each nonorganic flavor used would 1588 need to be evaluated to determine whether the source is agricultural or nonagricultural, whether 1589 isolation or extraction of the flavor precursor maintains organic integrity under § 205.270, and whether

- transformation of the precursor into the final flavoring agent renders it synthetic or maintains it asnonsynthetic. This includes nonorganic flavors used as ingredients in certified organic flavors. For
- 1592 certifiers, this might take a few hours of personnel time. For others, such a review could take hundreds of
- 1593 hours of file review and in some cases may still lead to inconclusive results.
- 1594
- 1595 Given that the suppliers of nonorganic flavors are not required to disclose the production and handling
- techniques, it is not possible to determine whether the obstacles to organic certification are
- 1597 insurmountable. The obstacles may be related to production, handling, or both. Some of the certifiers
- 1598 interviewed indicated that supply chain disruptions and changing international conditions (e.g., the
- 1599 revocation of India's recognition agreement) have created shortages of previously available organic
- 1600 ingredients. These may be seen as temporary but could be long-term if facilities have closed or will have
- 1601 difficulties with the changed regulatory environment. Several certifiers interviewed indicated that they
- 1602 believed the new Strengthening Organic Enforcement [88 FR 3548] regulation will make the certification

1604 drafting of this report on January 19, 2023.

1605 1606 Coming up with an exhaustive list of what flavors could be certified organic would require a case-by-1607 case review of every source of every flavor identified by IOFI and the Flavor Extract Manufacturers 1608 Association (FEMA) using the definitions in OFPA and the NOP regulations for both 1609 agricultural/nonagricultural and synthetic/nonsynthetic. Under current guidance, that would mean 1610 applying Policy 5033 (NOP, 2016) to multiple sources of the same flavor ingredient (NOP, 2016a). Some 1611 flavors may be considered both natural and synthetic by FDA, and even a natural source according to the 1612 FDA definition could be considered synthetic under the NOP. An example given in the ACA Best 1613 Practices for the Review of Organic Flavors is the derivative ethyl acetate (ACA, 2021a). Ethyl acetate is 1614 considered synthetic by the FDA in 21 CFR 182.60, though some certifying agents have reviewed it as 1615 nonsynthetic. Even if it were technically possible to produce a currently nonorganic flavor as certified 1616 organic, further research would be required in each case to determine the form needed to meet quality 1617 standards, and sufficient quantity would be needed for it to be considered commercially available. 1618 1619 When asked whether nonorganic flavors used in organic products could feasibly be certified organic, 1620 most certifying agents interviewed either had no opinion or thought it was not possible. However, at 1621 least two interviewees thought that it would be technologically possible to replicate any flavor currently 1622 used in an organic product in organic form. The certifying agents did not express a consensus about 1623 what it would be required for organic products to be made only with certified organic flavors if flavors 1624 were sunset from 7 CFR 205.605(a). The question of what nonorganic nonagricultural flavors that are

1625 currently permitted under § 205.605(a) would no longer be permitted if flavors were removed from the 1626 National List was also not possible to answer based on the available data in the published literature. The 1627 data would need to be collected from the processors and the certifying agents that certify them. Further 1628 investigation of the consequences of removing flavors from § 205.605(a) is needed. The feasibility of 1629 replacing specific individual nonorganic flavors used in organic processed products with organic ones 1630 that are commercially available is outside the scope of this technical report.

1631

### 3. What flavors cannot be certified organic based on their source and manufacturing?

1632 1633 Flavors that are synthetic, made with excluded methods, or made with ingredients and processing aids that do not appear on the National List cannot be certified organic. These are represented in Case #s 2, 4, 1634 1635 6, and 7 on *Table 1* of this report. Such flavors are currently not allowed for use under 7 CFR 205.605(a) and the sunset of natural flavors would not change that. This includes most if not all artificial flavors as 1636 defined by the FDA in 21 CFR 101.22(a)(1) The FDA has also listed some flavors as "synthetic" at 1637 1638 21 CFR 101.60 (Table 2). These presumably cannot be certified organic or be used as a natural flavor in an 1639 organic product under 7 CFR 205.605(a) because they are synthetic and not included on § 205.605(b). The 1640 ACA Best Practices for the Review of Non-Organic Flavors refer to the FDA sections relevant for the review 1641 of natural flavors, but do not outline steps for the verification that flavors identified as synthetic by the 1642 FDA are not used. The Best Practices appear to allow some artificial flavors that may be derived from 1643 natural sources. Thus, a precautionary approach would be to assume that the flavors are synthetic in the 1644 absence of a thorough evaluation of the source and manufacturing process of each using NOP Guidance 1645 5033 (NOP, 2016a).

I able 1: Flavors considered "synthetic" by the FDA.
Acetaldehyde (ethanal)
Acetoin (acetyl methylcarbinol)
Anethole (parapropenyl anisole)
Benzaldehyde (benzoic aldehyde)
N-Butyric acid (butanoic acid)
d- or l-Carvone (carvol)
Cinnamaldehyde (cinnamic aldehyde)
Citral (2,6-dimethyloctadien-2,6-al-8, gera-nial, neral)
Decanal (N-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde,
aldehyde C-10)
Ethyl acetate
Ethyl butyrate
3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate,
so-called strawberry aldehyde, C-16 aldehyde)
Ethyl vanillin
Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-ol)
Geranyl acetate (geraniol acetate)
Limonene (d-, l-, and dl-)
Linalool (33lorenti, 3,7-dimethyl-1,6-octadien-3-ol)
Linalyl acetate (bergamol)
Methyl anthranilate (methyl-2-aminobenzoate)
Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin)
Vanillin
Source: 21 CFR 182 60

1647

Source: 21 CFR 182.60

1650 More artificial flavors are listed in the FDA regulations in 21 CFR 172.515(b). While most presumably are 1651 prohibited for use as ingredients in organic food products based on 7 CFR 205.105(c), there may be 1652 exceptions. It was not possible to determine from secondary sources or from interviews with certifying 1653 agents which, if any, of these substances are used as flavoring agents in certified organic flavors, or as nonorganic flavors permitted for use in organic processed products under § 205.605(a). To make that 1654 1655

determination would require identification and declaration of each ingredient in a flavor, and a case-by-1656 case review using NOP Guidance 5033 to determine whether they are agricultural or nonagricultural 1657 and, if nonagricultural, whether they are synthetic or nonsynthetic (NOP, 2016a). A safe assumption is 1658 that most, if not all of these substances are nonagricultural and synthetically produced unless sources 1659 and manufacturing processes are fully documented and verified to be nonagricultural and nonsynthetic, 1660 which is the conclusion of Case 6 in *Table 1* above. However, from the interviews, it does not appear that 1661 certification agents currently take that approach.

1662

1663 Every interviewee indicated that they did not have the information or expertise to determine what 1664 certified organic flavors are infeasible. None of the certifiers interviewed use NOP Decision Tree for the 1665 Classification of Substances as Agricultural or Non-Agricultural or the Decision Tree for the Classification of 1666 Substances as Synthetic or Non-synthetic when evaluating flavors (NOP, 2016b, 2016c). Although they acknowledged that doing so would be consistent with best practices, they indicated that it was not 1667 required under NOP Policy Memo on the Use of Natural Flavors (NOP, 2011). Doing so would add 1668 1669 significantly to the time required to evaluate flavor components. Some certification personnel questioned 1670 whether such an approach was consistent with a sound and sensible approach to organic certification. 1671 The ACA Best Practices for the Review of Non-Organic Flavors document and NOP Policy Memo on the Use of 1672 Natural Flavors do not explain the conditions under which a flavor ingredient from an agricultural source would be transformed into a nonagricultural ingredient (ACA, 2021a; NOP, 2011). Most, if not all, 1673 1674 natural flavors are agricultural in origin. Most of the processing techniques that would render them to be 1675 nonagricultural would likely render them synthetic as well, and thus not allowed for use in an organic

1676 processed food product [7 CFR 205.105(c)].

1678 Certification decisions to allow specific flavor ingredients as nonagricultural and nonsynthetic were not 1679 made available in the interviews. In many cases, these involve proprietary techniques or trade secrets.

- 1680 One approach to answering this focus question would be to conduct a manual search of organic
- handling plan statements and investigate the sources, manufacturing processes, processing aids, andancillary ingredients used to make certified organic food products.
- 1683

1684 With respect to *Table 1* above, the certifiers presented differing interpretations of what was meant to be 1685 agricultural and nonagricultural, what made a specific isolate or derivative synthetic or nonsynthetic, 1686 what qualified under § 205.605(a), and what was prohibited based on § 205.105. While most said they 1687 followed the ACA Best Practices for the Review of Non-Organic Flavors (ACA, 2021a), the degree that they 1688 followed up with additional questions beyond what is provided in the application varied. Certifying 1689 agents do not perform inspections of uncertified flavor manufacturers to verify sources, extraction 1690 methods, and formulation procedures, consistent with other non-organic processing ingredients. In 1691 general, flavor ingredients are not third party verified for compliance with the annotation.

1692

1693 Nonorganic flavoring agents produced in-house by certified organic flavor producers also posed a 1694 dilemma, and there was no consensus among the interviewees about the appropriate procedures to

1695 pursue verifying the validity of claims of compliance in such situations. The prevailing approach was to

1696 continue to request more information for a questionable ingredient rather than deny certification or issue

- a noncompliance. None could provide a specific publicly disclosed case of a noncompliance or
- suspension based on the use of a nonorganic flavor that did not comply with § 205.605(a). All certifiers
- interviewed acknowledged that the review of flavors was difficult, complicated, and time-consuming to
- 1700 verify under the current regulations.
- 1701

1702 A growing number of flavors are not possible to be certified organic based on their origin from 1703 genetically modified organisms. Given the exclusion set by § 205.105, these also do not meet the 1704 requirements to be used as nonorganic, nonagricultural ingredients allowed in organic processed 1705 products. Vegetable, bacterial, and fungal-based meat flavorings are a prominent recent example, as 1706 discussed above. Natural flavors from genetically modified fermentation organisms are also being 1707 introduced to replace vanilla and citrus fruits.

1708

1709 Flavors that are derived from certified organic sources and precursors but do not have specific organic 1710 standards – yeast, for example – offer a challenge. Yeast appears separately on § 205.605(a) with a similar 1711 annotation to flavors. Given that there are no specific standards for fungi or invertebrate animals, other 1712 possible ingredients that may be nonorganic include derivatives from honeybees and edible mushrooms, 1713 though certified organic distilled honey, propolis extract, yeast flavors, and distilled mushroom flavors 1714 are all found in the OID (NOP, 2022). The NOP does not have aquaculture standards, making flavors 1715 derived from fin fish, shellfish, and aquatic plants a challenge. While aquatic animals are not certified 1716 organic, there are some aquatic plants certified under the current USDA organic standards. 1717

1718 Various flavors derived from forest and timber products may not be possible to certify as organic.

1719 Several natural flavor extracts come from pine or fir needles. One source flavoring that is outside the

- 1720 jurisdiction of the FDA is wood chips used for the aging of wine, whiskey, and other beverages that
- 1721 contain alcohol. Processors may use oak chips to flavor wines, for example. While it is hypothetically
- 1722 possible to certify organic oak trees, in practice it is not done. Other nonorganic, nonagricultural
- 1723 flavoring agents permitted for alcoholic beverages and tobacco products may not be possible to produce1724 organically.
- 1724 1725
- 1726 Five examples of non-certifiable flavors are:
- 1727 1) Castoreum derived from beavers.
- 1728 2) Tonquin musk oil from musk deer.
- 1729 3) Wood chips from nonorganic forest products.
- 1730 4) Distilled liquid smoke.
- 1731 5) Fish flavors.

1732 1733 1734 1735 1736 1737 1738 1739	Salt (sodium chloride) is in a unique category as a flavoring agent in that it is excluded from the calculation of organic percentage, along with water. There have been attempts to develop standards for certified organic salt in other countries. Other minerals may have functionality as flavoring agents, but none are as recognizable or primary as salt. Other minerals already on the National List at § 205.605 have some influence over flavor, but they are used as additives with other primary functionalities. Examples include calcium chloride, potassium chloride, and magnesium sulfate.
1740	Report Authorship
1741 1742 1743 1744	The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:
1745 1746 1747 1748 1749 1750 1751	<ul> <li>Brian Baker, Ph.D., Consultant, OMRI</li> <li>Jarod Rhoades, Senior Technical Coordinator, OMRI</li> <li>Tina Jensen Augustine, Senior Bilingual Technical Coordinator, OMRI</li> <li>Amy Bradsher, Deputy Director, OMRI</li> <li>Doug Currier, Technical Director, OMRI</li> <li>Ashley Shaw, Technical Assistant, OMRI</li> </ul>
1752 1753 1754	All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11–Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.
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Name	CAS Number or Other ID	FEMA Number
Alfalfa, Extract (Medicago sativa L.)	84082-36-0	2013
Alfalfa, Herb And Seed (Medicago sativa L.)	977092-93-5	
Allspice (Pimenta officinalis Lindl.)	977051-72-1	2017
Allspice, Oil (Pimenta officinalis Lindl.)	8006-77-7	2018
Allspice, Oleoresin (Pimenta officinalis Lindl.)	977017-87-0	2019
Almond, Bitter, Oil (ffpa) (Prunus spp.)	8013-76-1	2046
Aloe, Extract (Aloe spp.)	84837-08-1	2047
Althea Flowers (Althea officinalis L.)	977052-71-3	
Althea Root (Althea officinalis L.)	977005-75-6	2048
Ambergris, tincture	977023-08-7	2049
Ambrette, Absolute, Oil (Hibiscus abelmoschus L.)	977017-79-0	2050
Ambrette Seed (Hibiscus abelmoschus L.)	977052-20-2	
Ambrette Seed, Oil (Hibiscus abelmoschus L.)	8015-62-1	2051
Ambrette, Tincture (Hibiscus abelmoschus L.)	977017-78-9	2052
Amyris (Amyris balsamifera L.)	977059-69-0	
Amyris, Oil (Amyris balsamifera L.)	8015-65-4	
Angelica (Angelica spp.)	977050-05-7	
Angelica Root (Angelica spp.)	977050-06-8	2087
Angelica Root, Extract (angelica Archangelica L.)	977032-49-7	2087
Angelica Root, Oil (angelica Archangelica L.)	8015-64-3	2088
Angelica Seed (Angelica spp.)	977050-07-9	
Angelica Seed, Extract (Angelica archangelica L.)	977032-50-0	2089
Angelica Seed, Oil (Angelica archangelica L.)	977050-08-0	2090
Angelica Stem, Oil (Angelica archangelica L.)	977032-48-6	2091
Angola Weed (Roccella fuciformis Ach.)	977038-44-0	
Angostura (Galipea offincinalis Hancock)	977000-22-8	
Angostura, Extract (Galipea officinalis Hancock)	68916-12-1	2092
Anise (Pimpinella anisum L.)	977007-65-0	2093
Anise, Oil (Pimpinella anisum L.)	8007-70-3	2094
Anise, Star (Illicium verum Hook, F.)	977052-16-6	2095
Apricot Kernel, Oil (Prunus armeniaca L.)	72869-69-3	2105
Arnica Flowers (Arnica spp.)	977000-27-3	
Artemisia (Artemisia spp.)	977052-73-5	3114
Artemisia Extract	977032-37-3	3115
Artemisia Oil	8008-93-3	3116
Artichoke Leaves (Cynara scolymus L.)	977038-45-1	
Asafetida, Fluid Extract (Ferula assafoetida L.)	977038-46-2	2106
Asafetida, Gum (Ferula assafoetida L.)	9000-04-8	2107
Asafetida, Oil (Ferula assafoetida L.)	72869-70-6	2108
Balm (Melissa officinalis L.)	977051-08-3	2111
Balm Leaves (Melissa officinalis L.)	977090-74-6	
Balm Leaves, Extract (Melissa officinalis L.)	84082-61-1	2112

Name	CAS Number or Other ID	FEMA Number
Balm, Oil (Melissa officinalis L.)	8014-71-9	2113
Balsam, fir needles and twigs (Abies balsamea (l.) Mill.)	977107-97-3	
Balsam, Peru, Oil (Myroxylon pereirae Klotzsch)	977136-92-7	2117
Basil (Ocimum basilicum L.)	977050-14-8	2118
Basil Bush (Ocimum minimum L.)	977051-55-0	
Basil, Extract (Ocimum basilicum L.)	84775-71-3	
Basil, Oil (Ocimum basilicum L.)	8015-73-4	2119
Basil, Oleoresin (Ocimum basilicum L.)	977017-82-5	2120
Bay (Laurus nobilis L.)	977050-15-9	2124
Bay Leaves, Sweet, Extract (Laurus nobilis L.)	84603-73-6	2613
Bay Leaves, Sweet, Oil (Laurus nobilis L.)	8007-48-5	2125
Bay Leaves, West Indian, Oil (Pimen46aponariosa (mill.) J.w. Moore)	8006-78-8	2122
Carrot, Oil (Daucus carota L.)	8015-88-1	2244
Dog Grass, Extract (Agropyron repens (l.) Beauv.)	977038-73-5	2403
Dra'on's Blood, Extract (Daemonorops spp. or other botanical sources)	9000-19-5	2404
Benzoin, Resin (Styrax spp.)	9000-05-9	2133
Bergamot, Oil (Citrus aurantium L. Subsp. Bergamia Wright Et Arn.)	8007-75-8	2153
Blackberry Bark, Extract (Rubus, spp. Of section Eubatus)	977047-53-2	2155
Bois De Rose, Oil (Aniba rosaeodora Ducke)	8015-77-8	2156
Boldus Leaves (Peumus boldus Mol.)	977052-75-7	
Boronia, Absolute (Boronia megastigma Nees)	8053-33-6	2167
Bryonia Root (Bryonia spp.)	977000-49-9	
Buchu Leaves (Barosma betulina46aponariaata)	977000-50-2	
Buchu Leaves Extract	977009-82-7	
Buchu Leaves, Oil (Barosma spp.)	68650-46-4	2169
Buckbean Leaves (Menyanthes trifoliata L.)	977038-51-9	
Buckbean Leaves, Extract (Menyanthes trifoliata L.)	977038-52-0	
Cajeput, Oil (Melaleu46aponaria46onron L.)	8008-98-8	2225
Calumba Root (Jatrorrhiza palmata (lam.) Miers)	977000-55-7	
Calumba Root, Extract (Jatrorrhiza palmata (lam.) Miers)	977000-74-0	
Camphor, Japanese, White, Oil (Cinnamomum camphora (l.) Nees Et Eberm.)	8008-51-3	2231
Cananga, Oil (Cananga odorata Hook. F. And Thoms.)	68606-83-7	2232
Capers (Capparis spinosa L.)	977050-25-1	
Capsicum (Capsicum spp.)	977007-72-9	
Capsicum Extract (Capsicum spp.)	977018-42-0	2233
Capsicum, Oleoresin (Capsicum spp.)	8023-77-6	2234
Caraway (Carum carvi L.)	977001-27-6	2236
Caraway, Black (Nigella sativa L.)	977017-84-7	2237
Caraway, Oil (Carum carvi L.)	8000-42-8	2238
Cardamom (Elletaria cardamomum (I.) Maton)	977005-95-0	2240
Cardamom oleoresin	977090-82-6	
Cardamom Seed, Oil (Elletaria cardamomum (l.) Maton)	8000-66-6	2241
Haw Bark, Black, Extract (Viburnum prunifolium L.)	84929-54-4	2538

Name	CAS Number or Other ID	FEMA Number
Hemlock (Tsuga spp.)	977074-62-6	Number
Hemlock Needles And Twigs, Oil (Tsuga spp.)	8008-10-4	
Carob Bean, Extract (Ceratonia siliqua L.)	84961-45-5	2243
Cascara, Bitterless, Extract (Rhamnus purshiana Dc.)	977090-83-7	2253
Cascarilla Bark, Extract (Croton spp.)	977083-53-6	2254
Cascarilla Bark, Oil (Croton spp.)	8007-06-5	2255
Cassia Buds (Cinnamomum cassia Blume)	977091-24-9	2259
Cassie, Absolute (Acacia farnesiana (l.) Willd.)	977017-58-5	2260
Castoreum, Extract (Castor spp.)	8023-83-4	2261
Castoreum, Liquid (Castor spp.)	977016-89-9	2262
Castor Oil (Ricinus communis L.)	8001-79-4	2263
Catechu, Black, Extract (Acacia catechu Willd.)	8001-76-1	2264
Catechu, Black, Powder (Acacia catechu Willd.)	977090-84-8	2265
Cedar Leaf, Oil (Thuja occidentalis L.)	8007-20-3	2267
Celery Seed (Apium graveolens L.)	977007-75-2	2268
Celery Seed, Extract (Apium graveolens L.)	89997-35-3	2269
Celery Seed, Extract Solid (Apium graveolens L.)	977038-53-1	2270
Celery Seed, Oil (Apium graveolens L.)	8015-90-5	2271
Celery Seed, Oleoresin	977090-86-0	
Centaury (Centaurium umbellatum Gilib.)	977052-77-9	
Chamomile Flower (Anthemis nobilis L.)	977007-26-3	
Chamomile Flower, Hungarian, Oil (Matricaria chamomilla L.)	8002-66-2	2273
Chamomile Flower (Matricaria chamomilla L.)	977001-96-9	
Chamomile Flower, Oil (Anthemis nobilis L.)	8015-92-7	2272
Chamomile Flower, Roman, Extract (Anthemis nobilis L.)	84649-86-5	2274
Cherry Bark, Wild, Extract (Prunus serotina Ehrh.)	84604-07-9	2276
Cherry-laurel Leaves (Prunus laurocerasus L.)	977052-78-0	
Cherry Laurel, Oil (Prunus laurocerasus L.) (ffpa)	8000-44-0	2277
Cherry-laurel Water (Prunus laurocerasus L.)	977038-56-4	
Cherry Pits, Extract (Prunus spp.)	977038-54-2	2278
Chervil (Anthriscus cerefolium (l.) Hoffm.)	1338-80-3	2279
Chervil, Extract (Anthriscus cerefolium L.)	85085-20-7	
Chestnut Leaves (Castanea dentata (marsh.) Borkh.)	977052-79-1	
Chestnut Leaves, Extract (Castanea dentata (marsh.) Borkh.)	977023-21-4	
Chestnut Leaves, Extract Solid (Castanea dentata (marsh.) Borkh.)	977038-58-6	
Chicory, Extract (Cichorium intybus L.)	68650-43-1	2280
Chirata (Swertia chirata Buchham.)	977052-80-4	
Chirata, Extract (Swertia chirata Buchham.)	90604-50-5	
Chives (Allium schoenoprasum L.)	977050-37-5	
Cinchona Bark, Red (Cinchona succirubra Pav. Or Its Hybrids)	977052-81-5	2281
Cinchona Bark, Red, Extract (Cinchona succirubra Pav. Or Its Hybrids)	977038-61-1	2282
Cinchona Bark, Yellow (Cinchona spp.)	977052-82-6	2283
Cinchona Bark, Yellow, Extract (Cinchona spp.)	977083-24-1	2284

Name	CAS Number or Other ID	FEMA Number
Cinchona, Extract (Cinchona spp.)	68990-12-5	2285
Cinnamon (Cinnamomum spp.)	977000-66-0	2289
Cinnamon Bark, Extract (Cinnamomum spp.)	977038-60-0	2290
Cinnamon Bark, Oil (Cinnamomum spp.)	8007-80-5	2291
Cinnamon Bark Oleoresin, Ceylon, Chinese, Or Saigon (Cinnamomum spp.)	977091-23-8	
Cinnamon Leaf, Oil (Cinnamomum spp.)	8015-96-1	2292
Cinnamon Leaf Oil, Rectified	977184-45-4	
Citronella, Oil (Cymbopogon nardus Rendle)	8000-29-1	2308
Citrus Peels, Extract (Citrus spp.)	977038-62-2	2318
Civet, Absolute (Viverra civetta Schreber & Viverra zibetha Schreber)	68916-26-7	2319
Clary (Salvia sclarea L.)	977051-94-7	2320
Clary, Oil (Salvia sclarea L.)	8016-63-5	2321
Clary Sage, Absolute	8022-75-1	
Clary Sage, Concrete	977183-97-3	
Clover (Trifolium spp.)	977002-83-7	
Clover, Extract (Trifolium spp.)	977070-51-1	
Clover, Oil (Trifolium spp.)	977042-18-4	
Clover Tops, Red, Extract Solid (Trifolium pratense L.)	977038-65-5	2326
Coca Leaf, Extract (decocainized) (Erythroxylon coca Lam.)	977073-62-3	2329
Coffee Concentrate, Pure	977091-25-0	2525
Coffee Extract, Solid	977091-26-1	
Cognac, Green, Oil	8016-21-5	2331
Cognac, White, Oil	977050-49-9	2332
Copaiba (South American spp. Of Copaifera L.)	8001-61-4	2332
Copaiba, Oil (South American spp. Of Copaifera L.)	8013-97-6	
Coriander (Coriandrum sativum L.)	977007-81-0	2333
	977183-62-2	2355
Coriander Leaf Oil (Coriandrum sativum L.)		2334
Coriander, Oil (Coriandrum sativum L.)	8008-52-4	2334
Cork, Oak (Quercus spp.)	977038-68-8	
Costmary (Chrysanthemum balsamita L.)	977017-86-9	2226
Costus Root, Oil (Saussurea lappa Clarke)	8023-88-9	2336
Cubeb (Piper cubeba L. F.)	977000-82-0	2338
Cubeb, Oil (Piper cubeba L. F.)	8007-87-2	2339
Cumin (Cuminum cyminum L.)	977050-55-7	2340
Cumin, Oil (Cuminum cyminum L.)	8014-13-9	2343
Currant Buds, Black, Absolute (Ribes nigrum L.)	68606-81-5	2346
Currant Juice, Black	977038-70-2	
Currant Leaves, Black (Ribes nigrum L.)	977032-41-9	
Damiana Leaves (Turnera diffusa Willd.)	977000-85-3	
Dandelion, Fluid Extract (Taraxacum spp.)	977038-71-3	2357
Dandelion Root, Extract Solid (Taraxacum spp.)	977038-72-4	2358
Davana Oil (Artemesia Pallens Wall.)	8016-03-3	2359
Dill Seed, Indian (Anethum spp.)	977082-99-7	2384

Name	CAS Number or Other ID	FEMA Number
Dill Seed Oil (Anethum sowa Roxb.)	8016-05-5	
Dittany Of Crete (Origan49aponarianus L.)	977017-92-7	2399
Dittany (fraxinella) Roots (Dictamnus albus L.)	977047-65-6	
Elder Flowers (Sambucus canadensis L. Or Sambucus nigra L.)	977002-47-3	2406
Elder Flowers, Extract (Sambucus canadensis L. Or Sambucus nigra L.)	977010-39-1	
Elder Tree Leaves (Sambucus nigra L.)	977038-74-6	
Elecampane Root, Extract (Inula helenium L.)	84012-20-4	
Elecampane Root, Oil (Inula helenium L.)	1397-83-7	
Elemi, Gum	9000-75-3	2407
Elemi, Oil (Canarium spp.)	8023-89-0	2408
Erigeron, Oil (Erigeron canadensis L.)	8007-27-0	2409
Eucalyptus, Oil (Eucalyptus globulus Labille)	8000-48-4	2466
Fennel, Common (Foeniculum vulgare Mill.)	977001-13-0	2481
Fennel, Sweet (Foeniculum vulgare Mill. Var. Dulce (d.c.) Alef.)	977007-85-4	2482
Fennel, Sweet, Oil (Foeniculum vulgare Mill. Var. Dulce (d.c.) Alef.)	8006-84-6	2483
Fenugreek (Trigonella foenum-graecum L.)	977155-29-5	2484
Fenugreek, Extract (Trigonella foenum-graecum L.)	84625-40-1	2485
Fenugreek, Oleoresin (Trigonella foenum-graecum L.)	977018-53-3	2486
Fir (pine) Needles And Twigs (Abies sibirica Ledeb.)	8021-29-2	2905
Fir Needles And Twigs, Oil (Abies spp.)	8021-28-1	2905
Galanga, Greater (Alpinia Galanga Willd)	977050-77-3	
Galangal Root (Alpinia spp.)	977038-75-7	2498
Galangal Root, Extract (Alpinia spp.)	977038-76-8	2499
Galangal Root, Oil (Alpinia spp.)	8024-40-6	2500
Galbanum, Oil (Ferula spp.)	8023-91-4	2501
Galbanum, Resin (Ferula spp.)	9000-24-2	2502
Gambir (Uncaria gambir Roxb.)	8001-48-7	
Genet, Absolute (Spartium junceum L.)	977161-78-6	2504
Genet, Extract (Spartium junceum L.)	90131-21-8	2505
Gentian Root, Extract (Gentiana lutea L.)	72968-42-4	2506
Gentian, Stemless (Gentiana acaulis L.)	977088-41-7	
Geranium (Pelargonium spp.)	977001-35-6	
Geranium, East Indian, Extract (Cymbopogon martini Stapf.)	977091-47-6	
Geranium, East Indian, Oil (Cymbopogon martini Stapf.)	8014-19-5	2831
Geranium Extract (Pelargonium spp.)	977091-46-5	
Geranium, Oil (Pelargonium spp.)	8000-46-2	
Geranium, Rose, Oil (Pelargoni49lorentinalen' L'her.)	977143-78-4	2508
Germander, Chamaedrys (Teucrium chamaedrys L.)	977081-08-5	
Germander, Chamaedrys, Extract (Teucrium chamaedrys L.)	977091-51-2	
Germander, Chamaedrys, Extract Solid (Teucrium chamaedrys L.)	977091-52-3	
Germander, Golden (Teucrium polium L.)	977088-44-0	
Ginger (Zingiber officinale Rosc.)	977001-38-9	2520
Ginger, Extract (Zingiber officinale Rosc.)	84696-15-1	2020

Name	CAS Number or Other ID	FEMA Number
Ginger, Oil (Zingiber officinale Rosc.)	8007-08-7	2522
Ginger, Oleoresin (Zingiber officinale Rosc.)	8002-60-6	2523
Grains Of Paradise (Aframomum melegueta (rosc.) K. Schum.)	977050-87-5	2529
Grapefruit Essence, Natural	977091-55-6	
Grapefruit, Extract	90045-43-5	
Grapefruit, Juice	977038-26-8	
Grapefruit, Oil (Citrus paradisi Macf.)	8016-20-4	2530
Grapefruit Oil, Conc.	977083-05-8	
Grapefruit, Oil, Terpeneless (Citrus paradisi)	68916-46-1	
Guaiac Gum (Guaiacum spp.)	9000-29-7	
Guaiac Gum, Extract (Guaiacum spp.)	84650-13-5	2531
Guaiac Wood, Extract (Guaiacum spp.)	977083-52-5	2533
Guaiac Wood, Oil (Guaiacum spp.)	8016-23-7	2534
Guarana, Gum (Paullinia cupana Hbk)	84929-28-2	2536
Guarana Seed, Extract	977145-75-7	
Guava Extract	90045-46-8	
Hickory Bark, Extract (Carya spp.)	977023-22-5	2577
Hops, Extract Solid (Humulus lupulus L.)	977083-25-2	2579
Hops, Oil (Humulus lupulus L.)	8007-04-3	2580
Horehound Extract (Marrubium vulgare L.)	84696-20-8	2581
Horehound (Marrubium vulgare L.)	977001-59-4	
Horehound Solid, Extract	977089-41-0	
Horsemint Leaves, Extract (Monarda spp.)	8006-85-7	2582
Horseradish (Armoracia lapathifolia Gilib.)	977050-94-4	
Hyacinth, Absolute (Hyacinthus orientalis L.)	977086-46-6	
Hyacinth Flowers (Hyacinthus orientalis L.)	977047-90-7	
Hyssop, Extract (Hyssopus officinalis L.)	84603-66-7	2590
Hyssop (Hyssopus officinalis L.)	977001-63-0	2589
Hyssop, Oil (Hyssopus officinalis L.)	8006-83-5	2591
Iceland Moss (Cetraria islandica Ach.)	977017-63-2	
Immortelle, Absolute (Helichrysum angustifolium Dc)	977060-66-4	
Immortelle, Extract (Helichrysum angustifolium Dc.)	90045-56-0	2592
Imperatoria (Peucedanum ostruthium (l.) Koch (Imperatoria ostruthium L.))	977002-32-6	
Iva (Achillea moschata Jacq.)	977091-61-4	
Iva, Extract (Achillea moschata Jacq.)	977091-62-5	
Jasmine, Absolute (Jasminum spp.)	977146-68-1	2598
Jasmine, Concrete (Jasminum spp.)	977125-38-4	2599
Jasmine, Oil (Jasminum grandiflorum L.)	8022-96-6	2600
Jasmine, Spiritus (Jasminum grandiflorum L.)	977038-79-1	2601
Juniper, Extract (Juniperus communis L.)	84603-69-0	2603
Juniper Oil (Juniperus communis L.)	8002-68-4	2604
Kola Nut, Extract (Cola acuminata Schott Et Endl.)	68916-19-8	2607
Labdanum, Absolute (Cistus spp.)	977046-98-2	2608

Name	CAS Number or	FEMA
Labdanum, Oil (Cistus spp.)	<b>Other ID</b> 8016-26-0	Number 2609
Labdanum, Oleoresin (Cistus spp.)	977092-72-0	2610
Lavandin Absolute	977183-98-4	2010
Lavandin, Concrete	977183-99-5	
Lavandin, Oil	8022-15-9	2618
Lavender, Absolute (Lavandula officinalis Chaix)	977126-26-3	2620
Lavender, Concrete (Lavandula officinalis Chaix)	977089-32-9	2620
Lavender (Lavandula officinalis Chaix)	977001-82-3	2619
Lavender, Oil (Lavandula officinalis Chaix)	8000-28-0	2619
Lavender, Spike (Lavandula latifolia Bill.)	977051-05-0	2022
Lavender, Spike, Oi51aponariaula spp.)	8016-78-2	3033
Lemon Essence	977091-76-1	5055
Lemon, Extract (Citrus limon (I.) Burm. F.)	84929-31-7	2623
Lemon Grass, Oil (Cymbopogon citratus Dc. & Cymbopogon flexuosusstapf)	8007-02-1	2623
Lemon, Oil, Terpeneless (Citrus limon (l.) Burm. F.)	68648-39-5	2624
	68916-88-1	2626
Lemon, Juice		
Lemon Peel Extract	977091-77-2	
Lemon-verbena (Lippia citriodora Hbk.)	977047-96-3	
Lemon Verbena, Oil (Lippia citriodora)	8024-12-2	
Lime, Essence	977164-71-8	
Lime, Juice	977026-98-4	
Lime Juice, Dehydrated	977091-78-3	
Lime Oil, Expressed	977059-80-5	
Lime, Oil, Terpeneless (Citrus aurantifolia (Christman) Swingle)	68916-84-7	2632
Linaloe Wood, Oil (Bursera delpechiana Poiss. & other Bursera spp.)	977051-12-9	2634
Linden Flowers, Extract (Tilia spp.)	84929-52-2	
Linden Flowers (Tilia glabra Vent.)	977009-77-0	2647
Linden Leaves (Tillia spp.)	977073-42-9	
Lovage, Extract (Levisticum officinale Koch)	977091-63-6	2650
Lovage (Levisticum officinale Koch)	977048-47-7	2649
Lovage, Oil (Levisticum officinale Koch)	8016-31-7	2651
Lungmoss (Sticta pulmonacea Ach.)	977022-85-7	
Mace (Myristica fragrans Houtt.)	977051-14-1	2652
Mace, Oil (Myrstica fragrans Houtt.)	977051-15-2	2653
Mace, Oleoresin (Myrstica fragrans Houtt.)	977010-60-8	2654
Maidenhair Fern (Adiantum capillus-veneris L.)	977070-30-6	
Mandarin, Oil (Citrus reticulata Blanco)	8008-31-9	2657
Marigold, Pot (Calendula officinalis L.)	977001-93-6	2658
Marjoram, Oleoresin (Marjorana hortensis Moench (Origanum majorana L.))	977038-85-9	2659
Marjoram, Pot (Majorana onites (l.) Benth. (Origanum vulgare L.))	977051-22-1	2660
Marjoram Seed (Majorana hortensis Moench (Origanum majorana L.))	977038-86-0	2661
Marjoram, Sweet (Majorana hortensis Moench (Origanum majorana L.))	977051-23-2	2662
Marjoram, Sweet, Oil (Majorana hortensis Moench (Origanum majorana L.))	8015-01-8	2663

Name	CAS Number or Other ID	FEMA Number
Mate, Absolute (Ilex paraguariensis St. Hil.)	977146-67-0	
Mimosa, Absolute (Acacia decurrens Willd. Var. Dealbata)	977092-60-6	2755
Mimosa Concrete (Acacia decurrens Willd. Var. Dealbata)	977184-00-1	
Molasses, Concentrate	977083-12-7	
Molasses, Extract (Saccharum officinarum L.)	977091-60-3	
Mountain Maple (Acer spicatum Lam.)	977048-48-8	
Mountain Maple Bark (Acer spicatum Lam.)	977089-64-7	
Mountain Maple, Extract Solid (Acer spicatum Lam.)	977089-65-8	2757
Mullein Flowers (Verbascum spp.)	977048-46-6	
Musk Tonquin (Moschus moschiferus L.)	8001-04-5	2759
Mustard, Brown (Brassica spp.)	977051-38-9	2760
Mustard, Brown, Extract (Brassica spp.)	977091-79-4	
Mustard, Yellow (Brassica spp.)	977051-39-0	2761
Mustard, Yellow, Extract (Brassica spp.)	977091-80-7	
Myrrh, Extract	100084-96-6	
Myrrh, Gum (Commiphora spp.)	9000-45-7	2765
Myrrh, Oil (Commiphora spp.)	8016-37-3	2766
Myrtle Leaves (Myrtus communis L.)	977070-85-1	
Myrtle, Oil (Myrtus communis L.)	8008-46-6	
Naringin, Extract (Citrus Paradisi Macf.)	977038-87-1	2769
Neroli, Bigarade Oil (Citrus aurantium L.)	8016-38-4	2771
Nutmeg (Myrstica fragrans Houtt.)	977051-44-7	2792
Nutmeg, Oil (Myrstica fragrans Houtt.)	8008-45-5	2793
Nutmeg Oleoresin	8007-12-3	
Oak Chips, White, Extract (Quercus Alba L.)	977083-13-8	2794
Oak Moss, Absolute (Evernia spp.)	977059-15-6	2795
Oak Moss, Concrete (Evernia prunasti spp.)	977183-63-3	
Oak Wood, English (Quercus robur L.)	977089-90-9	
Olibanum, Absolute (Boswellia spp.)	977184-03-4	
Olibanum, Gum, Resin (Boswellia spp.)	8050-07-5	
Olibanum, Oil (Boswellia spp.)	8016-36-2	2816
Olibanum, Resinoid (Boswellia spp.)	977184-02-3	
Onion, Oil (Allium cepa L.)	8002-72-0	2817
Opopanax, Gum	9000-78-6	
Opopanax, Non-specific	977136-06-3	
Opopanax, Oil	8021-36-1	
Opopanax Tincture	977091-81-8	
Orange Essence, Natural	977091-85-2	
Orange Essence Oil, Natural	68514-75-0	
Orange, Extract	977130-92-9	
Orange Flowers, Absolute (Citrus aurantium L.)	977049-65-2	2818
Orange, Juice	977059-38-3	
Orange Leaf, Absolute (Citrus aurantium L.)	977091-84-1	2820

Name	CAS Number or Other ID	FEMA Number
Orange, Oil, Distilled (Citrus sinensis (l.) Osbeck)	977091-83-0	2821
Orange, Oil, Terpeneless (Citrus sinensis (l.) Osbeck)	68606-94-0	2822
Orange Peel, Bitter, Extract (Citrus aurantium L.)	977081-87-0	2344
Orange Peel, Bitter, Oil (Citrus aurantium L.)	68916-04-1	2823
Orange Peel, Sweet, Extract (Citrus sinensis (l.) Osbeck)	977091-82-9	2824
Orange Peel, Sweet, Oil, Terpeneless (Citrus sinensis (l.) Osbeck)	977154-09-8	2826
Oregano (Lippia spp., Usually L. graveolens Hbk)	977138-70-7	2827
Origanum Oil, Extract (Thymus Capitatus Hoff. Et Link)	8007-11-2	2828
Orris, Concrete, Liquid, Oil (Ir53lorentinaina L.)	977086-43-3	2829
Orris Root, Extract (Ir53lorentinaina L.)	977096-43-7	2830
Pansy (Viola tricolor L.)	977068-82-8	
Paprika Oleoresin (Capsicum annuum L.)	68917-78-2	2834
Parsley, Oil (Petroselinum spp.)	8000-68-8	2836
Parsley, Oleoresin (Petroselinum spp.)	8025-95-4	2837
Parsley (Petroselinum spp.)	977051-58-3	2835
Passion Flower Extract	8057-62-3	
Passion Flower (Passiflora incarnata L.)	977001-53-8	
Patchouly, Oil (Pogostemon spp.)	8014-09-3	2838
Peach Kernel, Extract (Prunus persica Sieb Et Zucc.)	8023-98-1	
Peach Leaves, Extract (Prunus persica (l.) Batsch)	977183-61-1	
Peach Leaves (Prunus persica (l.) Batsch)	977009-83-8	
Peanut Stearine (Arachis hypogaea L.)	977051-59-4	
Pennyroyal, Oil, American (Hedeoma pulegiodes (l.))	8007-44-1	2839
Pennyroyal, Oil, European (Mentha pulegium L.)	8013-99-8	
Pepper, Black, Oil (Piper nigrum L.)	8006-82-4	2845
Pepper, Black, Oleoresin (Piper nigrum L.)	8002-56-0	2846
Pepper, Cayenne	977071-33-2	2266
Peppermint Leaves (Mentha Piperita L.)	977018-19-1	2847
Peppermint Plant	977001-36-7	
Pepper, Red	977184-01-2	2849
Pepper, White, Oil (Piper nigrum L.)	977018-20-4	2851
Pepper, White, Oleoresin (Piper nigrum L.)	977018-21-5	2852
Pepper, White (Piper nigrum L.)	977051-63-0	2850
Petitgrain, Lemon, Oil (Citrus limon (l.) Burm. F.)	8048-51-9	2853
Petitgrain, Mandarin, Oil (Citrus reticulata Blanco Var. Mandarin)	977051-67-4	2854
Petitgrain, Oil (Citrus aurantium L.)	8014-17-3	2855
Silver Fir, needles & twigs, Oil (abies Alba Mill.)	8021-27-0	
Simaruba Bark (Simaruba amara Aubl.)	977029-60-9	
Sloe Berries, Extract (Prunus spinosa L.)	90105-94-5	3021
Sloe Berries, Extract Solid (Prunus spinosa L.)	977029-61-0	3022
Snakeroot, Canadian, Oil (Asarum canadense L.)	8016-69-1	3023
Locust (carob) Bean Gum	9000-40-2	2648
Pimenta Leaf, Oil (Pimenta officinalis Lindl.)	977157-17-7	2901
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Name	CAS Number or Other ID	FEMA Number
Pine Bark, White, Extract Solid (Pinus strobus L.)	977089-63-6	
Pine Bark, White, Oil (Pinus strobus L.)	977089-62-5	
Pine Bark, White (Pinus strobus L.)	977002-91-7	
Pine Needle, Dwarf, Oil (Pinus mugo turra Var. Pumilio (haenke) Zenari)	8000-26-8	2904
Pine, Scotch, Oil (Pinus sylvestris L.)	8023-99-2	2906
Pine, White, Oil (Pinus spp.)	977019-44-5	
Pipsissewa Leaves, Extract (Chimaphi54aponariaata Nutt.)	89997-56-8	2914
Pomegranate Bark, Extract (Punica granatum L.)	977018-22-6	2918
Poplar Buds (Populus spp.)	977002-20-2	
Poppy Seed (Papaver somniferum L.)	977051-77-6	2919
Prickly Ash Bark Extract (Xanthoxylum spp.)	977018-23-7	2110
Prickly Ash Bark, Oil	977018-24-8	
Quassia, Extract (Picrasma excelsa (sw.) Planch Or Quassia amara L.)	68915-32-2	2971
Quebracho Bark Extract	977092-71-9	2972
Quillaia Extract (Quilla saponariaria Molina)	68990-67-0	2973
Quillaia (Quilla saponariaria Molina)	977002-27-9	2973
Quince Seed, Extract (Cydonia spp.)	977018-25-9	2974
Rhatany, Extract (Krameria spp.)	84775-95-1	2979
Rhubarb, Garden Root (Rheum rhaponticum L.)	977035-94-1	
Rhubarb Root (Rheum spp.)	977039-94-3	
Rose, Absolute (Rosa spp.)	977091-93-2	2988
Rose Hips, Extract (Rosa spp.)	977021-37-6	2990
Roselle (Hibiscus sabdariffa L.)	977017-88-1	
Rosemary, Extract (Rosmarinus officinalis L.)	84604-14-8	
Rosemary, Oil (Rosemarinus officinalis L.)	8000-25-7	2992
Rosemary, Oleoresin	977029-68-7	4705
Rosemary (Rosemarinus officinalis L.)	977002-36-0	2991
Rose, Oil (Rosa spp.)	8007-01-0	2989
Rose Water, Stronger (Rosa Centifolia L.)	8030-26-0	2993
Rosin (Pinus spp.) And Rosin Derivatives	8050-09-7	
Saffron (Crocus sativus L.)	977051-90-3	2998
Saffron, Extract (Crocus sativus L.)	84604-17-1	2999
Sage, Greek (Salvia Triloba L.)	977051-95-8	
Sage, Oil (Salvia officinalis L.)	8022-56-8	3001
Sage, Oleoresin (Salvia officinalis L.)	977029-66-5	3002
Sage (Salvia officinalis L.)	977002-44-0	3000
Sage, Spanish, Oil (Salvia lavandulaefolia Vahl.)	977125-77-1	3003
Sandalwood, Red (Pterocarpus santalinus L.f.)	98225-55-9	
Sandalwood, White (Santalum album L.)	977020-85-1	
Sandalwood, Yellow, Oil (Santalum album L.)	8006-87-9	3005
Sandarac (Tetraclinis articulata (Vahl.) Mast.)	9000-57-1	
Sarsaparilla, Extract (Smilax spp.)	977022-67-5	3009
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Name	CAS Number or Other ID	FEMA Number
Savory, Summer, Oil (Satureja hortensis L.)	8016-68-0	3013
Savory, Summer, Oleoresin (Satureja hortensis L.)	977029-75-6	3014
Savory, Summer (Satureja hortensis L.)	977051-98-1	3012
Savory, Winter, Oil (Satureja montana L.)	977029-74-5	3016
Savory, Winter, Oleoresin (Satureja montana L.)	977029-76-7	3017
Savory, Winter (Satureja montana L.)	977051-99-2	3015
Schinus Molle, Oil (Schinus molle L.)	68917-52-2	3018
Senna, Alexandria (Cassia acutifolia Delile)	977083-19-4	
Serpentaria (Aristolochia serpentaria L.)	977002-55-3	
Sesame (Sesamum indicum L.)	977052-01-9	
Spearmint, Extract (Mentha spicata L.)	84696-51-5	3031
Spearmint (Mentha spicata L.)	977002-61-1	3030
Spruce Needles And Twigs, Extract (Picea spp.)	977062-73-9	
Spruce Needles And Twigs, Oil (Picea spp.)	8008-80-8	3034
St. Johnswort Leaves, Flowers And Caulis (Hypericum perforatuml.)	977092-96-8	
Storax Extract (Liquidambar spp.)	977029-80-3	3037
Storax (Liquidambar spp.)	8046-19-3	3036
Storax Oil	8024-01-9	
Tagetes, Oil (Tagetes spp.)	8016-84-0	3040
Tamarind Extract (Tamarindus indica L.)	84961-62-6	
Tangerine, Essence	977029-78-9	
Tangerine, Extract (Citrus reticulata Blanco)	90063-83-5	
Tangerine, Oil (Citrus reticulata Blanco)	8016-85-1	3041
Tansy, Oil (Tanacetum vulgara L.)	8016-87-3	
Tansy (Tanacetum Vulgara L.)	977032-44-2	
Tarragon (Artemisia dracunculus L.)	977052-32-6	3043
Tarragon Extract (Artemisia dracunculus L.)	977029-81-4	
Tarragon Oil (Artemisia dracunculus L.)	8016-88-4	2412
Tea Extract (Thea sinensis L.)	84650-60-2	
Thistle, Blessed (Cnicus benedictus L.)	977023-13-4	
Thistle, Blessed, Extract (Cnicus benedictus L.)	977048-22-8	
Thistle, Blessed, Extract Solid (Cnicus benedictus L.)	977048-24-0	
Thistle, Blessed, Oil (Cnicus benedictus L.)	977048-23-9	
Thyme, Extract	84929-51-1	
Thyme Oil (Thymus vulgaris L. And T. zygis Var. Gracilis Boiss.)	8007-46-3	3064
Thyme Oleoresin	977029-72-3	
Thyme (Thymus serpyllum L.)	977052-37-1	
Thyme (Thymus vulgaris L.)	977052-36-0	3063
Thyme, Wild Or Creeping, Extract (Thymus aerpyllum L.)	84776-98-7	
Tolu, Balsam, Extract (Myroxylon spp.)	977075-28-7	3069
Tolu, Balsam, Gum (Myroxylon spp.)	9000-64-0	3070
Tuberose, Oil (Polianthes tuberosa L.)	8024-05-3	3084
Turmeric (Curcuma longa L.)	977052-44-0	3085

Name	CAS Number or Other ID	FEMA Number
Turmeric, Extract (Curcuma longa L.)	84775-52-0	3086
Turmeric, Oleoresin (Curcuma longa L.)	129828-29-1	3087
Turpentine	8052-14-0	
- Turpentine, Gum (Pinus spp.)	9005-90-7	3088
Turpentine, Rectified	977022-00-6	
Turpentine, Steam Distilled (Pinus spp.)	8006-64-2	3089
Valerian Root, Extract (Valeriana officinalis L.)	8057-49-6	3099
Valerian Root, Oil (Valeriana officinalis L.)	8008-88-6	3100
Vanilla, Absolute (Vanilla spp.)	977189-04-5	
Vanilla, Extract (Vanilla spp.)	8024-06-4	3105
Vanilla, Oleoresin (Vanilla spp.)	8023-78-7	3106
Vanilla (Vanilla spp.)	977004-06-0	3104
Veronica (Veronica officinalis L.)	977000-83-1	
Vervain, European (Verbena officinalis L.)	977000-41-1	
Vetiver, Oil (Vetiveria zizanioides Stapf)	8016-96-4	
Vetiver (Vetiveria zizaniodes Stapf)	977059-70-3	
Violet Leaves Absolute (Viola odorata L.)	8024-08-6	3110
Violet, Swiss (Viola calcarata L.)	977089-10-3	
Walnut Hull, Extract (Juglans spp.)	977014-38-2	3111
Walnut Leaves, Extract (Juglans spp.)	977091-98-7	
Woodruff, Sweet (Asperula odorata L.)	977070-09-9	
Yarrow, Herb (Achillea millefolium L.)	977000-16-0	3117
Yarrow, Oil (Achillea millefolium L.)	8022-07-9	
Yerba Santa, Fluid Extract (Eriodictyon californicum (hook And Arn) Torr)	977092-73-1	3118
Ylang-ylang, Oil (Cananga odorata Hook. F. And Thomas)	8006-81-3	3119
Yucca, Joshua-tree (Yucca brevifolia Engelm.)	977083-21-8	3120
Yucca, Mohave, Extract (Yucca spp.)	977083-20-7	3121
Zedoary Bark, Extract (Curcuma zedoaria (berg.) Rosc.)	84961-49-9	3123
Zedoary (Curcuma zedoaria (berg.) Rosc.)	977052-57-5	3122

Certifier Name	Operation Name	Number of Certified Flavors
QAI	Flavor Producers, LLC	1891
~ QAI	Gold Coast Ingredients, Inc.	925
QAI	FONA International, LLC	669
QCS	Earth Supplied Products, LLC	628
QAI	Allen Flavors, Inc.	591
OTCO & QAI	Kerry Ingredients & Flavours	469
CCOF	Primal Essence, Inc.	431
QAI	WILD Flavors, Inc.	406
QAI	OSF Flavors, Inc.	398
ОТСО	Custom Ingredients, Inc	377
QAI	Citromax Group Inc.	341
QAI	International Flavors & Fragrances, Inc.	296
ОТСО	FlavorFocus, LLC	290
CCOF	Synergy Flavors, Inc.	286
CCOF	Sovereign Flavors Inc.	280
OTCO	Abelei, Inc.	266
QAI	Sensient Flavors, LLC	262
ОТСО	Sentrex Ingredients	255
OTCO	Mother Mur'hy's Laboratories	254
QAI	Blue Pacific Flavors, Inc.	249
CUC	Bell Flavors and Fragrances	234
QAI	Givaudan Flavors Corporation	221
QAI	Scisorek & Son Flavors, Inc.	214
QAI	Tastepoint Inc. dba Tastepoint by IFF	197
OTCO	Robertet Flavors, Inc.	191
OTCO	Brand Aromatics, Inc.	163
OTCO	Ungerer and Company	149
QAI	Symrise Inc	140
QAI	Virginia Dare Extract Co. Inc.	131
QCS	CAS Organics, LLC	130
QAI	T. Hasegawa USA, Inc.	130
QAI	Flavorchem Corporation	128
QAI	Flavor Manufacturing Center	126
QCS	Green Line Botanicals	122
QAI	Jogue Inc.	122
QAI	Sh'nk's Extracts LLC	119
OTCO	Medicine Flower LLC	110
ОТСО	Target Flavors, Inc.	110
OTCO	Sapphire Flavors and Fragrances	109
QAI	Comax Manufacturing Corp.	108
QAI	Frutarom USA Inc.	108
OTCO	Metarom USA, LLC	104

Certifier Name	Operation Name	Number of Certified Flavors
MOSA	Edgar A Weber & Company, dba Weber Flavors	94
QAI	Flavor & Fragrance Specialties	91
QAI	Aromatech Flavorings Inc.	86
ОТСО	DairiConcepts L.P.	86
QAI	Alfrebro LLC	76
OTCO	H.B. Taylor Co.	72
WFCFO	Trilogy Essential Ingredients, Inc	72
OTCO	Savoury Systems International, LLC, Brookside Flavors & Ingredients	70
OTCO	Flavor Dynamics, Inc	68
QAI	California Custom Fruits & Flavors, Inc.	65
QAI	Jogue, Incorporated	65
OTCO	AMT Group, LLC (DBA Imbibe)	60
OTCO	Revela Foo-s - New Berlin, LLC	54
OTCO	Vigon International, LLC	53
QAI	Lassonde Pappas and Company Inc.	43
QCS	Vidya Herbs, Inc	43
OTCO	Callisons, Inc.	40
OTCO	Kalsec, Inc.	40
OTCO	Centrome, Inc./DBA Advanced Biotech	39
QAI	Flavors of Origin dba Flavor Materials International	38
OTCO	Butter Buds Inc.	35
QAI	Flavor Insights, LLC	35
CCOF	Silesia Flavors, Inc.	35
MOSA	Fontana Flavors	34
OTCO	Prinova Flavors LLC	34
OTCO	Spray-Tek LLC	33
OTCO	Phoenix Flavors, LLC	32
OTCO	eSense, LLC.	31
QAI	OC Flavors, Inc.	29
OTCO	Bluegrass Ingredients, Inc.	25
CCOF	Cook Flavoring Co./RR Lochhead Mfg. Co.	25
OTCO	Green Mountain Flavors, Inc.	25
TDA	Lineage Logistics LLC	25
QAI	Sensapure, Inc.	25
CCOF	Guayaki SRP	24
WFCFO	Lemur International	22
QAI	The Edlong Corporation	20
QCS	Treatt USA	19
QCS	Garden of Life, LLC	16
ОТСО	Marsh'll's Flavor House, Inc.	16
QAI	Mission Flavors & Fragrances, Inc.	16
QAI	Jean Niel Inc	15
MOSA	Beck Flavors	14

Certifier Name	Operation Name	Number of Certified Flavors
QAI	Nielsen-Massey Vanillas, Inc.	14
QAI	All American Foods, Inc.	13
OTCO	Continental Flavors, LLC	13
OTCO	Mane, Inc.	13
QAI	ZoomEssence, Inc	13
OTCO	Elan, Inc.	11
PJRFSI	Arylessence, Inc.	10
OTCO	Dutch American Foods, Inc.	10
WSDA	Fruitsmart, Inc.	10
QAI	Quality Ingredients Corporation	10
CCOF	Essential Flavors & Fragrances, Inc.	9
CDA	Rodelle Inc.	8
OTCO	The Lebermuth Company, Inc.	8
QCS	Citrus Extracts, LLC	7
QAI	Jedwards International, Inc.	7
OTCO	Pharmachem Laboratories LLC	7
QCS	Phyto-Plus, Inc.	7
QAI	S&D Coffee, Inc.	7
<i>Transitioning to a new certifier</i>	Templar Food Products	7
OTCO	Agropur MSI, LLC	6
ACO	Dr. Oetker Queen Australia Pty Ltd	6
BCS	Konfrut Gida Sanayi ve Ticaret A.Ş.	6
MOSA	Northwestern Extract Co	6
CCOF	Campbell Soup Supply Co.	5
MOSA	First Choice Ingredients	5
OTCO	IFC Solutions Inc.	5
OTCO	Kalsec Southwest	5
MOSA	Lan' O' Lakes	5
MOSA	QualiTech, Inc	5
ONE	SensoryEffects Inc.	5
QAI	Takasago International Corp. (US-) - Flavor Division	5
QAI	American Fruits and Flavors, LLC	4
OTCO	Cloud Top Organics, Inc.	4
РСО	Homesweet Homegrown, LLC	4
QCS	Nutranomy, LLC	4
QAI	Premier Specialties, Inc.	4
QAI	Agropur, Inc Le Sueur Food Ingredients Facility	3
QAI	Eatem Foods Company	3
UDAF	Aspen Copak	2
GOA	Dr. Vanilla LLC	2
QAI	Fruitcrown Products Corporation	2
CMEX	Industria Mexicana de Sabores S.A. de C.V.	2
ACO	Intec Vanilla Niugini Ltd	2

Certifier Name	Operation Name	Number of Certified Flavors
PJRFSI	Lorann Oils, Inc	2
QAI	MetaBev, Inc.	2
QAI	Refresco Beverages USA	2
BAC	4Care Co., Ltd.	1
MOSA	Brolite Products Inc.	1
OC	Carmi Flavors & Fragrances Company	1
OC	Cvista, LLC	1
CUC	E-Silk Route Ventures (Pvt) Ltd	1
BCS	Gaya Vanilla y Especies, SA.	1
CU	Holly Oak Chemical, Inc.	1
OCIA	Jeneil Biotech, Inc.	1
ONE	L.O.D.C. Group, Ltd. DBA Lily of the Desert	1
GOA	Meridian Flavors, Inc	1
SCS	Native Vanilla, Inc.	1
OC	Newport Flavours & Fragrances, Ltd, Nat're's Flavors, Select, Inc.	1
WSDA	Northwest Naturals LLC	1
ACO	Organic Lemon Myrtle Plantations Sdn. Bhd	1
ОТСО	OS Holdings	1
QAI	SciTech International dba SciTech Ingredients	1

2241 Source: Organic Integrity Database, November 2022. See the database for certifier name abbreviations.

2243	Appendix C - ACA Best Practices
2244	
2245	Commercial Availability of Natural Flavors
2246	<u></u>
2247	According to 7 CFR 205.2, commercial availability is the ability to obtain a production input in an
2248	appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or
2249	handling, as determined by the certifying agent in the course of reviewing the organic plan. The working
2250	group agreed to the following when determining commercial availability of organic natural flavors and
2251	flavoring substances:
2252	0
2253	• Operators must contact at least three valid suppliers, with exceptions considered on a case-by-
2254	case basis.
2255	• An operator sourcing natural flavors products or flavoring substances to be used in an
2256	organic flavor must contact flavor houses that may have an organic version of the flavor/
2257	flavoring substance or the ability to create an organic version.
2258	<ul> <li>Operators should check with different suppliers of flavors year-to-year.</li> </ul>
2259	• Having a contract in place with a flavor manufacturer is not sufficient justification to
2260	contact fewer than three valid suppliers. Additional documentation must be submitted
2261	and may be considered on a case-by-case basis.
2262	• A contract in place with a non-organic flavor manufacturer working towards certification or with
2263	a certified organic flavor manufacturer working to develop an organic version may be sufficient
2264	justification for contacting fewer than three valid suppliers, provided that documentation is
2265	submitted to verify the anticipated date of certification and/or organic system plan.
2266	<ul> <li>Claiming that a flavoring substance cannot be certified organic is not sufficient</li> </ul>
2267	justification for contacting fewer than three valid suppliers. Additional documentation
2268	must be submitted justifying the lack of ability to certify the ingredient, which may be
2269	considered on a case-by-case basis, or three valid suppliers must be contacted.
2270	• Operators must verify and document commercial availability annually for each non-organic
2271	flavor or flavoring substance used, with exceptions considered on a case-by-case basis.
2272	• An ordering or manufacturing schedule can be considered if part of the company's
2273	Standard Operating Procedure (SOP).
2274	• The use of otherwise compliant non-organic flavors in made-with-organic products does not
2275 2276	invoke a commercial availability search (as long as it meets the requirements of made with organic products)
2276 2277	organic products). The use of mode with examinations as an ingradient in an examination reduct does invoke a
2277	<ul> <li>The use of made-with-organic flavors as an ingredient in an organic product does invoke a commercial availability search since not "organic."</li> </ul>
2278	
2279	<ul> <li>Using the flavor name alone may not be sufficient evidence to verify lack of commercial availability of an organic flavor.</li> </ul>
2280	<ul> <li>Price cannot be a consideration for determination of the commercial availability.</li> </ul>
2281	
2282	<i>Source: ACA, 2020.</i>
2283	

2285	Criteria for Verification of Allowed Flavors
2286	
2287	Non-organic flavors, in accordance with 7 CFR 205.605(a), must:
2288	Be derived from organic or nonsynthetic sources only
2289	<ul> <li>Be produced without synthetic solvents and carrier systems or any artificial preservative</li> </ul>
2290	• Be in compliance with § 205.105 Allowed and prohibited substances, methods, and ingredients in
2291	organic production and handling, including being produced and handled without genetic
2292	modification.
2293	<ul> <li>Function as a flavor within the product labeled as "organic" or "made with organic (specified</li> </ul>
2294	ingredients or food group(s))"
2295	Only be used if organic versions are not commercially available - see separate ACA best practices
2296	document on assessing commercial availability of flavors
2297	
2298	Additional verification steps may include:
2299	<ul> <li>Verification that all other ingredients (ingredients besides flavors, solvents, carrier systems, and</li> </ul>
2300	preservatives) are allowed
2301	<ul> <li>Verification that all flavor component ingredients are allowed</li> </ul>
2302	<ul> <li>Verification that the flavor is non-agricultural</li> </ul>
2303	<ul> <li>Verification that the flavor is non-synthetic according to NOP 5033-1</li> </ul>
2304	<i>Source:</i> (ACA, 2021a, 2021b)
2305	

## 2306 <u>Natural Flavor Declaration Form</u>2307

See following page.

CICCIC A	Accredited Certifiers Association PO Box 332 Port Richey, FL 34673 (844) 783-7974 www.accreditedcertifiers.org
Natural Flavo	or Declaration
The USDA National Organic Program (NOP) regula CFR 205.605(a):	tions allow for non-synthetic natural flavors at 7
"Flavors –nonsynthetic flavors may be used when organi be derived from organic or nonsynthetic sources only an carrier systems or any artificial preservative."	-
In addition, non-organic flavors must be produced in substances, methods, and ingredients in organic pr	
food group(s))," the product must be produced a (a) Synthetic substances and ingredients (b) Nonsynthetic substances prohibited i (c) Nonagricultural substances used in o §205.605; (d) Nonorganic agricultural substances u provided in §205.606; (e) Excluded methods, except for vaccin accordance with §205.600(a);	;, except as provided in §205.601 or §205.603; n §205.602 or §205.604; r on processed products, except as otherwise provided in sed in or on processed products, except as otherwise es: Provided, That, the vaccines are approved in od and Drug Administration regulation, 21 CFR 179.26;
<ul> <li>Be derived from a non-synthetic source. Flar confirmed to be derived from non-synthetic s</li> <li>Function as a flavor in the "organic" or "made</li> <li>Not be produced using synthetic solvents an extraction solvents include natural ethanol, s</li> </ul>	vors that meet the FDA definition of natural flavor are ources. e with organic <sup>*</sup> product d carrier systems or any artificial preservatives. Allowed uper-critical carbon dioxide, authentic essential oil, and rinated, or halogenated solvents may be used. Propane,
The following form must be completed by the manu operations in products labeled as "organic" or "mad	-

<b>ICA</b>	Natural	Flavors	Decla	ration
			May	2021

Ma	nufacturer Name:		
Fla	vor name and code on technical data she	eet.	
1.	Do this natural flavor and all of its flavor co	nstituents meet the following FD/	A definition of a natural flavor?
	🗆 Yes 🗆 No	-	
	A natural flavor or natural flavoring is the essent of roasting, heating or enzymolysis, which contai vegetable juice, edible yeast, herb, bark, bud, ro fermentation products thereof, whose significant natural essence or extractives obtained from pia the substances listed in 172.510 of this chapter.	ins the flavoring constituents derived from ot, leaf or similar plant material, meat, see function in food is flavoring rather than ni nts listed in §§ 182.10, 182.20, 182.40, a	n a spice, fruit or fruit juice, vegetable o afood, poultry, eggs, dairy products, or utritional. Natural flavors include the
2.	List all specific sources of the flavor constit	uents (e.g., spice, plant part, ess	ential oil, etc).
3.	Describe the function(s) of this product		
4	Does the flavoring agent(s) in this material	only consist of substances that d	o not impart a specific
	characteristic flavor, such as flavorings with	-	
	the material is Luo Han Guo (Monk Fruit) d		
	similar the response should be Yes.		
	a. If Yes, attach documentation detail	ing the maximum usage rate for	the overall flavor material to
	qualify as a natural flavor: 🛛 Attac	hed 🗆 NA	
5.	Can the material legally be labeled as a "na	atural flavor" on the finished prod	uct labels per the applicable
	regulatory body? Yes No FDA labeling regulations, <u>https://www.accessdat</u> states that a natural flavor must be identified in to on the principal display panel the name of the fla followed by the word "flavored".	he ingredient statement as a natural flavo	r, and sections 101.22(I)(1)(I) includes
	<ul> <li>a. If the flavor consists of a natural fla</li> </ul>	-	its common or usual name on t
	label, list the name here:	🗆 NA	
6.	Do you sell an organic version of this flavor	? 🛛 Yes 🗋 No	
7.	List any non-flavor constituents, including b	out not limited to solvents, carrier	systems, and preservatives, u
		each constituent. Attach any rele	
	ingredients, such as a specification sheet.	Additional information may be rec	quested to verify the complianc
	these non-flavor ingredients.	1	1
	Non-Flavor Ingredient/ Adjuvant	Function in the Flavor	Documentation Attached?
			•
			Dage 2 of 5
			Page 2 of 5

ACA Natural Flavors Declaration May 2021

- 8. If alcohol/ethanol is used, please attach documentation describing the manufacturing process 
  Attached
  NA
- 9. If maltodextrin is used, please attach documentation describing the manufacturing process and GMO status

  Attached
  NA
- 10. If glycerin is used, please provide its organic certificate and/or a attach a full manufacturing description

  Attached
  NA
- 11. If citric acid is used, please attach documentation describing the manufacturing process 
  Attached 
  NA
- 12. Excluded methods, including genetic modification/GMOs, are prohibited for use at any stage in the process of making natural flavor products for use in products certified under the NOP. Please see the following pages for the definition and examples of excluded methods.
- 13. Ionizing radiation is prohibited for the treatment of organic products and inputs used to produce organic products. Other forms of radiation, including those used for food inspection, are permitted providing the uses meet applicable regulations that establish limitations pertaining to all (organic and non-organic) food products.
- 14. Materials produced or processed using nanotechnology or technologies intentionally manipulating matter at atomic, molecular, or macromolecular dimensions typically between 1 and 100 nm to create materials, devices and systems with fundamentally new properties and functions, are prohibited for all uses and as materials used in organic products. Naturally occurring nano-sized particles or those produced incidentally are permitted.
  - a. This natural flavor has been handled without the use of nanotechnology as described in NOP Policy Memo 15-2 as applicable. □ Yes □ No

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ACA Natural Flavors Declaration May 2021

To be signed by a qualified, technical representative of the manufacturer. Any operation that makes a false statement under The Organic Foods Production Act of 1990 to an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code (205.100(c)(2)).

Pursuant to applicable regulations, I, on behalf of the manufacturer, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge.

Signature:		Date:
Printed Name:	Title:	
Address:		
City:	State:	Zip:
Phone:	Email:	

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ACA Natural Flavors Declaration May 2021

## Other relevant definitions:

- A nonsynthetic (natural) substance is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). (7 CFR 205.2)
- A synthetic substance is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. (7 CFR 205.2)
- Excluded methods are defined as a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.(7 CFR 205.2) Prohibited excluded methods include, but are not limited to:

Method and synonyms	Турез
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via Oligonucleotides CRISPR-Cas system (Clustered regularly Interspaced short palindromic repeats) and associated protein genes TALENs (Transcription activator-like effector nucleases) Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System
Gene Sliencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAI pathway RNAI pesticides
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering
Synthetic biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems
Cioned animals and offspring	Somatic nuclear transfer
Plastic transformation	
Cisgenesis	The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.
Intragenesis	The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.
Agro-inflitration	
Transposons – Developed via use of In vitro nucleic acid techniques	
Induced mutagenesis	Developed through In vitro nucleic acid techniques

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2314		Appendix D - Flavors Technical Report - Certifier Interview Questions
2315		
2316	1.	What flavors are available in organic form?
2317		a. What flavors does your ACA certify?
2318		b. Are these all on the OID?
2319		c. How many are labeled 100% organic and contain only organic ingredients, other than
2320		water and salt?
2321		d. How many of these certified organic flavors contain non-organic ingredients?
2322		e. Are any of those non-organic ingredients themselves considered flavor components,
2323		including flavor enhancers or potentiators?
2324		f. If so, would all certified organic flavors still comply if "natural flavors" was sunset from
2325		the National List?
2326		g. If not, which currently certified flavors would be non-compliant?
2327		h. What components would be non-compliant?
2328		
2329	2.	What flavors could be certified organic based on their source and manufacturing process, but
2330		are not?
2331		a. What is the procedure to determine whether a flavor is commercially available?
2332		b. Has your agency reviewed and approved any non-organic flavors for use in organic
2333		products that <i>do not appear</i> in certified organic form at all on the OID?
2334		c. If so, which ones?
2335		d. What, were the reasons given for the unavailability of organic flavors?
2336		e. Has your agency reviewed and approved non-organic flavors for use in organic products
2337		that <i>do appear</i> in certified organic form at all on the OID?
2338		f. If so, what factors were considered valid reasons to determine that organic flavors were
2339		not required?
2340	2	What flavors connect he cartified arganic heard on their secures and many fasturing?
2341 2342	3.	QQ
2342		a. Have any flavors applied for certification and have been denied certification?
2343		b. What does your agency require to determine whether all the ingredients in a non-organic flavor or flavoring agent are non-organic synthesis or produced with evoluted methods?
2344		flavor or flavoring agent are non-synthetic or produced with excluded methods?
2345		c. Are there any flavors that have either applied for certification or for use as a non-organic flavor in an organic processed product your accord has determined to be per
2340		flavor in an organic processed product your agency has determined to be non- agricultural?
2347		d. If so, which ones?
2348		
2349		e. Has your agency reviewed any natural (non-synthetic) flavors with agricultural precursors that are not possible to produce or handle organically?
2350		f. If so, which ones?
2351		
2332		g. What is it about their source or processing that disqualifies them from certification?