

GRAS 30

Flavoring Substances

The 30th publication by the Expert Panel of the Flavor and Extract Manufacturers Association provides an update on recent progress in the consideration of flavoring ingredients generally recognized as safe under the Food Additives Amendment.

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FOR MORE THAN 60 years, the FEMA GRAS Program has operated to assess the safety of flavor ingredients for their intended use in human food. The GRAS provision of the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act defines a food additive as: “... *any substance ... which ... may ... [become] a component or... [affect] the characteristics of any food ... if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures ... to be safe under the conditions of its intended use...*” The FEMA GRAS program operates within the confines of the 1958 Food Additives Amendment using defined scientific procedures to assess the safety of flavoring ingredients under their conditions of intended use as published in Smith et al. 2005a and b, and Cohen et al. 2018a.



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This publication includes the results of the Expert Panel's review of 38 new flavorings under their conditions of intended use (Tables 1 and 2). In addition, the Expert Panel determined that new use levels and/or use in new food categories for 11 flavor ingredients are consistent with their current FEMA GRAS status (Table 3). The Expert Panel removed the FEMA GRAS status for the uses of one substance.

The Panel also describes recent progress evaluating natural flavor complexes for reaffirmation of GRAS status, releases its policy statement regarding cannabis-derived flavorings, addresses the consideration of new plant protein products within the food category classification system, and includes a discussion regarding the consideration of target tissue exposure in its review of *in vivo* genotoxicity study data.

Progress in the Reevaluation of Natural Flavor Complexes

In 2018, the FEMA Expert Panel published an updated safety procedure that it has used in its FEMA GRAS evaluation of natural flavoring complexes (NFCs), which are naturally occurring mixtures of chemicals

that are produced using physical separation methods starting from botanical and other natural sources. The updated procedure has been applied to new potential NFCs as well as for NFCs that already have uses that are considered FEMA GRAS (Cohen et al. 2018). Utilizing the procedure, the Panel has completed comprehensive reassessments of over 200 NFCs to date, reported in seven publications. Many of these were in the first FEMA GRAS list that was published in 1965 (Hall and Oser 1965). These seven publications include the results of comprehensive, constituent-based safety

EXPERT PANEL MEMBER CHANGE

The Expert Panel wishes to thank Dr. Samuel Cohen for the multiple terms that he has served as the FEMA Expert Panel Chair, including during the recent meetings that had to be held virtually due to the COVID-19 pandemic. Dr. Cohen continues in his role as an Expert Panel member. The Panel has appointed Dr. Ivonne Rietjens to serve as the FEMA Expert Panel Chair. Dr. Rietjens previously served as the Vice-Chair of the Panel. Dr. Nigel Gooderham has been appointed as the Panel's Vice-Chair.



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- evaluations of *Citrus*-derived NFCs (Cohen et al. 2019); mint, buchu, dill, and caraway-derived NFCs (Cohen et al. 2020); *Cinnamomum* and *Myroxylon*-derived NFCs (Rietjens et al. 2020); clove, cinnamon leaf, and West Indian bay leaf-derived NFCs (Gooderham et al. 2020a); lavender, guaiac, coriander-derived, and related NFCs (Fukushima et al. 2020); *Eucalyptus*-derived and other eucalyptol-containing NFCs (Eisenbrand et al. 2021); and origanum oil, thyme oils, and related phenol derivative-containing NFCs (Cohen et al. 2021). The Expert Panel continues preparing additional publications within the scope of this reevaluation program.

Potential Evaluation of Cannabis-derived Flavorings

The FEMA Expert Panel has considered the U.S. Food and Drug Administration's FDA Regulation of Dietary Supplement & Conventional Food Products Containing Cannabis and Cannabis-derived Compounds (FDA 2021) regarding the regulation of dietary supplements and conventional food products containing cannabis and cannabis-derived compounds. While FDA notes that "Ingredients derived from cannabis that do not contain CBD [cannabidiol] or THC [tetrahydrocannabinol] might be able to be used in foods and dietary supplements if all other FD&C requirements are met," the FEMA Expert Panel has concluded that it will not review cannabis derivatives for FEMA GRAS status under conditions of intended use as flavorings, including derivatives with only trace amounts of THC and CBD. The FEMA Expert Panel may review this policy in the event of new actions from the FDA on regulatory considerations of cannabis-containing and cannabis-derived ingredients.

Consideration of Plant Protein Food Products Within the Food Category System

The FEMA Expert Panel uses a food category classification system that is derived from the U.S. Code of Federal Regulations' (CFR) listing of food categories (21 CFR 170.3(n)) to establish conditions of intended use for FEMA GRAS determinations. Each main food category listed within 21 CFR 170.3(n) is accompanied by descriptions of the types of food products that would be included in that category, and these food products within each category typically have similar portion sizes. Recently, there has been increasing interest in the production and consumption of plant protein-derived food products that are used in substitution of some foods. These

plant protein-derived food products are generally not included within the food category descriptions (of the foods for which they substitute) that are provided in the CFR. For the purposes of their safety assessments, the Expert Panel has determined that imitation or substitute products belong to the same food product categories as the products they imitate or for which they are intended to substitute, as it is expected that the portion sizes will be very similar.

Tissue Exposure for an *In Vivo* Genotoxicity Study

The FEMA Expert Panel recently published on the use of genotoxicity information within the context of flavor safety evaluations (Gooderham et

CORRECTIONS AND ERRATA TO PREVIOUS GRAS PUBLICATIONS

Primary names of FEMA 2121, 2122, and 2123.

In GRAS 3 (Hall and Oser 1965), the botanical name for FEMA 2121 (Bay Leaves West Indian Extract), FEMA 2122 (Bay Leaves West Indian Oil), and FEMA 2123 (Bay Leaves West Indian Oleoresin) was listed as *Pimenta acris* Kostel. The botanical *Pimenta racemosa* is also considered FEMA GRAS for FEMA 2121, 2122, and 2123, as published in a FEMA GRAS assessment of clove, cinnamon leaf, and West Indian bay leaf–derived flavoring ingredients (Gooderham et al. 2020a).

Use levels for FEMA 2288. In GRAS 28 (Cohen et al. 2018b), there was a clerical error, and the Anticipated Usual and Maximum Use Levels for FEMA 2288 in Baked Goods should read 233/384 ppm.

Primary names of FEMA 2829 and 2830. In GRAS 3 (Hall and Oser 1965), the botanical name for FEMA 2829, Orris concrete liquid oil, and FEMA 2830, Orris root extract, was listed as *Iris Florentina* L. The botanicals *Iris pallida* and *Iris germanica* are also considered FEMA GRAS under the identities of FEMA 2829 and FEMA 2830.

Primary name of FEMA 2973. The primary name of FEMA 2973, Quillaia [*Quillaja saponaria* Molina], has been corrected to Quillaia extract (*Quillaja saponaria* Molina).

Synonym for FEMA 3812. In reference to the FEMA Expert Panel's consideration of the GRAS status of neutral, hydrated, and salt forms of

GRAS substances as described in GRAS 25 (Smith et al. 2011), ferulic acid was added as a synonym for FEMA 3812, Sodium 3-methoxy-4-hydroxycinnamate.

Use levels for FEMA 4601. In GRAS 28 (Cohen et al. 2018b), there was a clerical error, and the Anticipated Usual and Maximum Use Levels for FEMA 4601 in Baked Goods should read 20/30 ppm.

Primary name of FEMA 4666. In GRAS 24 (Smith et al. 2009), the primary name for FEMA 4666 was listed as *alpha*-Bisabolol. The primary name has been amended to (\pm)-*alpha*-Bisabolol.

Identity Description of FEMA 4796. In Supplementary Information 1 for GRAS 27, the identity description for FEMA 4796 erroneously included rebaudioside E under "other steviol glycosides."

Identity Description of FEMA 4845. In Supplementary Information 1 for GRAS 28, the identity description for FEMA 4845 erroneously omitted "maltodextrin <20%."

Identity Description of FEMA 4876. In Supplementary Information 1 for GRAS 28, the identity description for FEMA 4876 erroneously included "other individual steviol glycosides not further glucosylated each less than 1%" and should have said "other individual steviol glycosides not further glucosylated each less than 6%."

BASIS FOR SAFETY EVALUATION DECISIONS FOR GRAS 30

Key findings of the FEMA Expert Panel GRAS determinations, including identity statements for natural flavoring complexes, are available on femaflavor.org.

al. 2020b). During the development of that publication, the Panel considered the role that target tissue exposure would play in drawing conclusions about the validity of *in vivo* genotoxicity studies for which negative results are reported.

Standard guidelines, such as those developed by the Organization for Economic Cooperation and Development (OECD), provide recommendations for the criteria for determining that a study has produced a clear negative result. As an example, for *in vivo* micronucleus studies, the four criteria are that:

- a) None of the treatment groups exhibits a statistically significant increase in the frequency of micronucleated immature erythrocytes compared with the concurrent negative control,
- b) There is no dose-related increase at any sampling time when evaluated by an appropriate trend test,
- c) All results are inside the distribution

of the historical negative control data (e.g., Poisson-based 95% control limits), and

d) Bone marrow exposure to the test substance(s) occurred” (OECD 474 2016).

Additionally, the OECD *in vivo* micronucleus study guideline states that, “In cases where the response is not clearly negative or positive and in order to assist in establishing the biological relevance of a result (e.g., a weak or borderline increase), the data should be evaluated by expert judgement and/or further investigations of the existing experiments completed” (OECD 474 2016).

The Panel notes that while it is desirable to obtain clear positive or clear negative outcomes from *in vivo* genotoxicity studies, in many cases evidence of target tissue exposure is not available. On that basis, the Panel relies upon its use of expert judgment in concluding whether the data from an *in vivo* genotoxicity study, even in the absence of direct evidence of target tissue exposure, do not indicate a concern for genotoxicity.

Change in GRAS Status of Mintlactone

The FEMA GRAS status of mintlactone (5,6,7,7a-tetrahydro-3,6-dimethyl-2(4H)-benzofuranone, CAS No. 13341-72-5; formerly FEMA No. 3764) under its conditions of intended use as a flavor ingredient was reviewed by the FEMA Expert Panel. After reviewing the available information relevant to the FEMA GRAS status of mintlactone, including recent studies kindly provided to the FEMA Expert Panel

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by the Research Institute for Fragrance Materials (RIFM), the Expert Panel concluded that additional data are required to support the continuation of its GRAS status. Such data should include OECD- and

GLP-compliant *in vitro* and *in vivo* genotoxicity testing, and confirmation from the industry that the commercial substance will not degrade to mutagenic impurities. Until such data are available for review by the Expert Panel, the flavor ingredient mintlactone has been removed from the FEMA GRAS list. **ii**

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GRAS FLAVORING SUBSTANCES 30

Table 1 - Primary Names & Synonyms

Primary names (in boldface) & synonyms (in lightface)

FEMA NO.	SUBSTANCE PRIMARY NAME AND SYNONYMS	FEMA NO.	SUBSTANCE PRIMARY NAMES AND SYNONYMS
4943	Decanedioic acid 1,8-Octanedicarboxylic acid 1,10-Decanedioic acid Sebacic acid Decanedicarboxylic acid	4959	9-Dodecen-12-olide Yuzu lactone Oxacyclotridec-10-en-2-one 1-Oxacyclotridec-10-en-2-one
4944	trans-2-Dodecenedioic acid (E)-Dodec-2-enedioic acid Dodec-2-enedioic acid Traumatic acid trans-Traumatic acid	4960	trans-alpha-Bergamotene alpha-Bergamotene, trans- 2-Norpinene, 2,6-dimethyl-6-(4-methyl-3-pentyl)-, trans-(-) Bicyclo(3.1.1)hept-2-ene, 2,6-dimethyl-6-(4-methyl-3-penten-1-yl)-, (1S,5S,6R)- Bicyclo(3.1.1)hept-2-ene, 2,6-dimethyl-6-(4-methyl-3-pentyl)-, (1S-(1.alpha.,5.alpha.,6.alpha.))- alpha-trans-Bergamotene alpha-Bergamotene, (-)-trans- (-)-trans-alpha-Bergamotene (-)-exo-alpha-Bergamotene
4945	cis-8-Decenal 8-Decenal, (8Z)- (8Z)-Dec-8-enal	4961	4-Methyltrideca-2E,4-dienal
4946	2-Amino-2-deoxy-poly-D-glucosamine Chitosan	4962	Lepidium meyenii root extract Lepidium peruvianum root extract
4947	Glucosylated stevia extract 40% with 14% Rebaudioside A	4963	Pandan leaf (Pandanus amaryllifolius) distillate extract
4948	2-Hexylpyridine 2-(n-Hexyl)pyridine	4964	Corynebacterium glutamicum cell free fermentation product C. glutamicum dried fermentation broth
4949	Corynebacterium ammoniagenes fermentation product C. ammoniagenes dried fermentation broth	4965	N-(1-((4-Amino-2,2-dioxido-1H-benzo[c][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide
4950	Stevia rebaudiana extract with Rebaudiosides AM and M	4966	4-Methylheptan-3-one
4951	Glucosylated steviol glycosides 90% supraglucosylated rebaudioside A	4967	delta-Cadinene delta-Cadinene Cadina-1(10),4-diene
4952	Glucosylated steviol glycosides 91% supraglucosylated rebaudioside D	4968	Stevia rebaudiana extract with Rebaudioside M ≥90%
4953	Glucosylated steviol glycosides 58% supraglucosylated stevioside	4969	Yerba mate extract (Ilex paraguariensis A. St.-Hil.) Mate absolute Ilex paraguariensis A. St.-Hil. extract
4954	Blue agave inulin (Agave tequilana)	4970	2-Methyl-1-(2-(5-(p-tolyl)-1H-imidazol-2-yl)piperidin-1-yl)butan-1-one
4955	Emblica officinalis fruit extract Phyllanthus emblica extract Amla extract Indian gooseberry extract	4971	beta-Farnesene 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (6E)- 1,6,10-Dodecatriene, 7,11-dimethyl-3-methylene-, (E)- (6E)-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene (E)-7,11-Dimethyl-3-methylene-1,6,10-dodecatriene (E)-beta-Farnesene trans-beta-Farnesene
4956	Boehmeria niven leaf extract Ramie leaf extract	4972	Diethyl mercaptosuccinate
4957	Rebaudioside M 85% Rebaudioside X 85%	4973	3-Mercapto-3-methyl-1-pentyl acetate
4958	4-Formyl-2-methoxyphenyl 1-menthyl glutarate 4-Formyl-2-methoxyphenyl-(1R,2S,5R)-2-isopropyl- 5-methylcyclohexyl pentanedioate Pentanedioic acid, 1-(4-formyl-2-methoxyphenyl) 5-[(1R,2S,5R)- 5-methyl-2-(1-methylethyl)cyclohexyl] ester		

FEMA NO.	SUBSTANCE PRIMARY NAME AND SYNONYMS
4974	Germacrene D ≥85%
4975	Scutellaria baicalensis root extract Chinese skullcap extract Baikal skullcap extract
4976	Lemon seed (<i>Citrus limon</i>) oil <i>Citrus limon</i> seed oil <i>Citrus medica limonum</i> seed oil <i>Citrus medica</i> seed oil
4977	10-Hydroxy-4,8-dimethyldec-4-enal 4-Decenal, 10-hydroxy-4,8-dimethyl-
4978	Rebaudioside B 95%
4979	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane
4980	Mixture of (8Z,11Z)-heptadeca-8,11-dienal and (Z)-heptadec-8-enal



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GRAS FLAVORING SUBSTANCES 30

Table 2 - Average Usual Use Levels/Average Maximum Use Levels

Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) for new FEMA GRAS Flavoring Substances on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)

	Decanedioic acid	trans-2-Dodecenedioic acid	cis-8-Decenal	2-Amino-2-deoxy-poly-D-glucosamine	Glucosylated stevia extract (40% with 14% Rebaudioside A	2-Hexylpyridine	<i>Corynebacterium ammontagenes</i> fermentation product	<i>Stevia rebaudiana</i> extract with Rebaudiosides AM and M	Glucosylated steviol glycosides 90% supraglucosylated rebaudioside A
CATEGORY/FEMA No.	4943	4944	4945	4946	4947	4948	4949	4950	4951
BAKED GOODS	40/200	40/200	0.004/0.2	1,500/2,000	50/60	1/5	1,000/7,500	50/150	70/70
BEVERAGES, NON-ALCOHOLIC	20/50	10/50	0.0002/0.01	1,500/2,000	50/60	1/5		50/50	70/70
BEVERAGES, ALCOHOLIC	15/30	15/50	0.0002/0.01	1,500/2,000	50/60	1/5		50/50	70/70
BREAKFAST CEREALS	50/100	50/200	0.002/0.1		50/60		1,000/5,000	50/50	70/70
CHEESES	40/100	50/200	0.0004/0.02	1,500/2,000		1/5	2,000/7,500	50/50	70/70
CHEWING GUM	100/300	100/500	0.004/0.2	1,500/2,000				50/50	70/70
CONDIMENTS AND RELISHES	30/100	30/200	0.002/0.1	1,500/2,000		1/5	3,000/20,000	50/50	70/70
CONFECTIONS AND FROSTINGS	40/100	40/200	0.002/0.1	1,500/2,000	50/60			50/50	70/70
EGG PRODUCTS	50/100	40/300	0.001/0.05			1/5	1,000/10,000	50/50	
FATS AND OILS	50/100	40/100	0.004/0.2	1,500/2,000	50/60	1/5		50/50	
FISH PRODUCTS	50/100	50/300	0.001/0.05	1,500/2,000		1/5	3,000/10,000	50/50	
FROZEN DAIRY	40/100	40/300	0.0004/0.02		50/60			50/50	70/70
FRUIT ICES	30/60	15/100	0.0004/0.02		50/60			50/50	70/70
GELATINS AND PUDDINGS	30/60	15/100	0.0004/0.02	1,500/2,000	50/60			50/50	70/70
GRANULATED SUGAR		40/200	0.001/0.05		50/60				
GRAVIES	40/100	40/200	0.001/0.05	1,500/2,000		1/5	3,000/20,000	50/50	70/70
HARD CANDY	50/200	50/300	0.001/0.05		50/60			50/50	70/70
IMITATION DAIRY PRODUCTS	40/100	40/200	0.0004/0.02	1,500/2,000	50/60		2,000/10,000	50/50	70/70
INSTANT COFFEE AND TEA	30/100	15/100	0.001/0.05	1,500/2,000	50/60			50/50	70/70
JAMS AND JELLIES	50/100	15/100	0.0004/0.02	1,500/2,000	50/60			50/50	70/70
MEAT PRODUCTS	50/100	50/300	0.001/0.05	1,500/2,000		1/5	2,000/15,000	50/50	
MILK PRODUCTS	40/100	40/100	0.0004/0.02	1,500/2,000	50/60			50/50	70/70
NUT PRODUCTS	40/100	40/200	0.001/0.05		50/60		1,000/10,000	50/50	70/70
OTHER GRAINS	50/200	50/200	0.0004/0.02	1,500/2,000	50/60			50/50	70/70
POULTRY PRODUCTS	50/100	50/300	0.001/0.05			1/5	2,000/10,000	50/50	
PROCESSED FRUITS	50/100	50/200	0.0004/0.02	1,500/2,000	50/60			50/50	
PROCESSED VEGETABLES	50/100	50/300	0.001/0.05	1,500/2,000		1/5		50/50	
RECONSTITUTED VEGETABLE PROTEIN	50/100	50/300	0.001/0.05	1,500/2,000		1/5		50/50	
SEASONINGS AND FLAVORS	50/100	50/300	0.001/0.05	1,500/2,000	50/60	1/5	5,000/50,000	50/50	70/70
SNACK FOODS	50/100	50/300	0.0004/0.02		50/60	1/5	1,000/10,000	50/50	70/70
SOFT CANDY	50/200	50/300	0.001/0.05	1,500/2,000	50/60			50/50	70/70
SOUPS	50/300	50/200	0.0004/0.02	1,500/2,000	50/60	1/5	3,000/20,000	50/50	70/70
SUGAR SUBSTITUTES	30/60	30/100	0.002/0.1	1,500/2,000	50/60				
SWEET SAUCES	40/100	40/100	0.001/0.05	1,500/2,000	50/60			50/50	70/70

	Glucosylated steviol glycosides 91% supraglucosylated rebaudioside D	Glucosylated steviol glycosides 58% supraglucosylated stevioside	Blue agave inulin (<i>Agave tequilana</i>)	<i>Emblica officinalis</i> fruit extract	<i>Boerhavia rivea</i> leaf extract	Rebaudioside M 85%	4-Formyl-2-methoxyphenyl L-menthyl glutarate	9-Dodecen-12-olide	trans-alpha-Bergamotene	4-Methyltrideca-2E,4-dienal
CATEGORY/FEMA No.	4952	4953	4954	4955	4956	4957	4958	4959	4960	4961
BAKED GOODS	50/50	100/100	1,400/14,000	50/200	60/120	15/20	5/50	0.5/2	269/269	0.004/0.2
BEVERAGES, NON-ALCOHOLIC	50/50	100/100	350/3,500	30/100	40/80	15/20		0.01/0.2	24/24	0.0002/0.01
BEVERAGES, ALCOHOLIC	50/50	100/100		30/100	15/30	15/20		0.01/0.2		0.0002/0.01
BREAKFAST CEREALS	50/50	100/100		50/200	50/150	15/20	1/10	0.3/1	34/34	0.002/0.1
CHEESES	50/50	100/100		50/200	80/160			0.1/0.5		0.0004/0.02
CHEWING GUM	50/50	100/100	700/7,000	100/300	100/200	15/20		1/4	465/465	0.004/0.2
CONDIMENTS AND RELISHES	50/50	100/100		50/200	40/100	15/20		0.3/1	2/20	0.002/0.1
CONFECTIONS AND FROSTINGS	50/50	100/100		50/200	40/100	15/20	1/10	0.3/1	56/56	0.002/0.1
EGG PRODUCTS				50/200	50/100			0.1/0.5		0.001/0.05
FATS AND OILS				50/100	40/100			2/10		0.004/0.2
FISH PRODUCTS				50/200	20/80			0.1/0.5		0.001/0.05
FROZEN DAIRY	50/50	100/100		50/150	40/120	15/20		0.1/0.5		0.0004/0.02
FRUIT ICES	50/50	100/100		20/100	15/30	15/20		0.1/0.5	16/147	0.0004/0.02
GELATINS AND PUDDINGS	50/50	100/100		20/100	30/60	15/20		0.1/0.5	83/83	0.0004/0.02
GRANULATED SUGAR										0.001/0.05
GRAVIES	50/50	100/100	1,400/14,000	50/200	50/120	15/20		0.2/2		0.001/0.05
HARD CANDY	50/50	100/100	1,400/14,000	100/300	20/30	15/20		0.2/2	93/93	0.001/0.05
IMITATION DAIRY PRODUCTS	50/50	100/100		50/300	40/120	15/20		0.5/3		0.0004/0.02
INSTANT COFFEE AND TEA	50/50	100/100		50/200	20/60	15/20		0.1/0.5		0.001/0.05
JAMS AND JELLIES	50/50	100/100		20/150	10/50	15/20		0.1/0.5		0.0004/0.02
MEAT PRODUCTS			700/7,000	50/300	40/120			0.1/0.5	6/10	0.001/0.05
MILK PRODUCTS	50/50	100/100		50/150	40/120	15/20		0.1/0.5		0.0004/0.02
NUT PRODUCTS	50/50	100/100		50/200	40/100	15/20				0.001/0.05
OTHER GRAINS	50/50	100/100		50/300	50/100	15/20				0.0004/0.02
POULTRY PRODUCTS			420/4,200	50/300	50/100			0.1/0.5		0.001/0.05
PROCESSED FRUITS		100/100		30/200	15/30	15/20		0.1/0.5		0.0004/0.02
PROCESSED VEGETABLES		100/100		50/300	15/100	15/20				0.001/0.05
RECONSTITUTED VEGETABLE PROTEIN		100/100		50/300	15/100	15/20				0.001/0.05
SEASONINGS AND FLAVORS	50/50	100/100	700/7,000	50/200	40/80	15/20				0.001/0.05
SNACK FOODS	50/50	100/100	1,400/14,000	50/200	50/150	15/20		0.3/1		0.0004/0.02
SOFT CANDY	50/50	100/100	1,400/14,000	100/300	15/30	15/20		0.3/2	93/93	0.001/0.05
SOUPS	50/50	100/100	1,400/14,000	50/200	40/80	15/20		0.05/0.5		0.0004/0.02
SUGAR SUBSTITUTES				20/100	10/40					0.002/0.1
SWEET SAUCES	50/50	100/100		20/200	40/80	15/20		0.1/1		0.001/0.05

GRAS FLAVORING SUBSTANCES 30

Table 2 CONTINUED - Average Usual Use Levels/Average Maximum Use Levels

Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) for new FEMA GRAS Flavoring Substances on which the FEMA Expert Panel based its judgments that the substances are generally recognized as safe (GRAS)

	<i>Lepidium meyenii</i> root extract	Pandan leaf (<i>Pandanus amaryllifolius</i>) distillate extract	<i>Corynebacterium glutamicum</i> cell free fermentation product	<i>N</i> -(1-(4-Amino-2,2-dioxido-1 <i>H</i> -benzol[<i>c</i>][1,2,6]thiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide	4-Methylheptan-3-one	<i>delta</i> -Cadinene	<i>Stevia rebaudiana</i> extract with Rebaudioside <i>M</i> ≥90%	Yerba mate extract (<i>Ilex paraguariensis</i> A. St. -Hil.)	2-Methyl-1-(2-(5-(<i>p</i> -tolyl)-1 <i>H</i> -imidazol-2-yl) piperidin-1-yl)butan-1-one
CATEGORY/FEMA No.	4962	4963	4964	4965	4966	4967	4968	4969	4970
BAKED GOODS	35/70	4/40	1,000/11,000	10/22	1/5	0.9/0.9	70/70		
BEVERAGES, NON-ALCOHOLIC	15/35			15/22	0.5/2		35/35	400/1,000	
BEVERAGES, ALCOHOLIC	5/20			10/22	0.5/2		35/35	400/1,000	
BREAKFAST CEREALS	35/70	2/40	1,000/11,000	20/22	1/5		100/100		
CHEESES	30/60	1/20	3,000/11,000		0.5/2		35/35	400/1,000	
CHEWING GUM				22/22			35/35		100/300
CONDIMENTS AND RELISHES	25/50	2/40	3,000/18,000	20/22	0.5/2	0.3/0.3	35/35	400/1,000	
CONFECTIONS AND FROSTINGS				22/22			35/35	400/1,000	
EGG PRODUCTS	40/80		1,000/7,000				35/35		
FATS AND OILS	10/50	2/40			2/8		35/35		
FISH PRODUCTS	40/80	2/40	3,000/9,000				35/35		
FROZEN DAIRY	40/80			15/22	1/5		35/35	400/1,000	
FRUIT ICES	10/30			15/22	0.5/2		35/35	400/1,000	
GELATINS AND PUDDINGS	30/80			15/22	0.5/2		35/35	400/1,000	
GRANULATED SUGAR									
GRAVIES	25/50	2/40	3,000/11,000		1/5		35/35	400/1,000	
HARD CANDY				22/22	1/5	0.9/0.9	35/35	400/1,000	
IMITATION DAIRY PRODUCTS	50/120		3,000/11,000	15/22	0.5/2		35/35	400/1,000	
INSTANT COFFEE AND TEA	10/30	2/40		10/22	0.5/2		35/35	400/1,000	
JAMS AND JELLIES				15/22			35/35	400/1,000	
MEAT PRODUCTS	50/100	1/20	3,000/11,000		1/5		35/35		
MILK PRODUCTS	35/70	0.5/10		15/22	0.5/2		45/45	400/1,000	
NUT PRODUCTS	35/70	1/20	1,000/4,000		0.5/2		35/35		
OTHER GRAINS	35/80	1/20			0.5/2		35/35		
POULTRY PRODUCTS	50/100	2/40	3,500/7,500		1/5		35/35		
PROCESSED FRUITS	10/30				0.5/2		35/35	400/1,000	
PROCESSED VEGETABLES	50/100	1/20			0.5/2		35/35	400/1,000	
RECONSTITUTED VEGETABLE PROTEIN	50/100	1/20			0.5/2		35/35	400/1,000	
SEASONINGS AND FLAVORS	100/200	2/40	20,000/150,000				35/35		
SNACK FOODS	50/100	1/20	7,500/20,000		1/5		35/35		
SOFT CANDY				20/22	1/5		35/35	400/1,000	
SOUPS	35/70	1/20	3,500/18,500		0.5/2		35/35	400/1,000	
SUGAR SUBSTITUTES									
SWEET SAUCES	35/70			15/22			35/35	400/1,000	

	<i>beta</i> -Farnesene	Diethyl mercaptosuccinate	3-Mercapto-3-methyl-1-pentyl acetate	Germacrene D ≥85%	<i>Scutellaria bicolor</i> root extract	Lemon seed (<i>Citrus limon</i>) oil	10-Hydroxy-4,8-dimethyldec-4-enal	Rebaudioside B 95%	2-(furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	Mixture of (8Z,11Z)-heptadeca-8,11-dienal and (Z)-heptadec-8-enal
CATEGORY/FEMA No.	4971	4972	4973	4974	4975	4976	4977	4978	4979	4980
BAKED GOODS	10/50	1/10	0.001/0.05	0.5/0.5	200/300	10/100		20/30	0.0025/0.005	0.2/0.5
BEVERAGES, NON-ALCOHOLIC	5/20	0.1/1	0.0001/0.002	0.2/0.2	100/200	5/50	0.5/5	20/30	0.0001/0.005	0.02/0.05
BEVERAGES, ALCOHOLIC	5/20	0.1/1	0.0001/0.002		100/200	5/50	0.5/5	20/30	0.0002/0.005	0.02/0.05
BREAKFAST CEREALS	10/50				200/300	10/100		20/30		
CHEESES	2/10		0.0005/0.005			5/100				0.2/0.5
CHEWING GUM	30/90	1/10	0.0005/0.01	3.4/4.8	100/200		2/20	25/30		
CONDIMENTS AND RELISHES	5/15	1/10	0.0001/0.01		100/200	5/100		20/30	0.0001/0.0025	
CONFECTIONS AND FROSTINGS	20/60	1/10	0.0005/0.005		100/200		2/20	20/30	0.0001/0.0025	
EGG PRODUCTS			0.0002/0.001		100/200	5/100			0.0001/0.0025	0.1/0.3
FATS AND OILS	5/30					5/100				0.2/0.5
FISH PRODUCTS	1/5					10/100			0.0001/0.0005	
FROZEN DAIRY	5/40	1/10	0.0002/0.003		200/300	5/50		20/30	0.001/0.005	
FRUIT ICES	5/20	1/10	0.0002/0.003	0.3/0.3	100/200		0.5/5	20/30	0.0001/0.0005	
GELATINS AND PUDDINGS	2/10	1/10	0.0002/0.003		100/200			20/30	0.0001/0.0005	
GRANULATED SUGAR										
GRAVIES	5/20	0.1/1	0.0005/0.005		200/300	10/100		20/30	0.0001/0.001	0.2/0.5
HARD CANDY	10/50	1/10	0.0005/0.01	0.5/0.5	200/300		1/10	20/30	0.002/0.005	0.05/0.2
IMITATION DAIRY PRODUCTS	1/5				200/300	5/100		20/30	0.002/0.005	
INSTANT COFFEE AND TEA	5/20	1/10	0.0003/0.005		100/200	5/50	0.5/5	20/30	0.0001/0.005	
JAMS AND JELLIES	2/10	1/10			100/200		1/10	20/30		
MEAT PRODUCTS	1/5	1/10	0.001/0.01		100/200	10/100			0.0001/0.005	0.1/0.3
MILK PRODUCTS	10/30		0.0001/0.001		200/300	5/100		20/30	0.0001/0.005	
NUT PRODUCTS	5/20	1/10			200/400	5/100		20/30	0.0001/0.005	
OTHER GRAINS	10/50	0.1/1			200/300	5/100		20/30		
POULTRY PRODUCTS	1/5	0.1/1				10/100			0.0001/0.001	0.1/0.3
PROCESSED FRUITS	5/30	0.1/1			100/200	5/50		20/30		
PROCESSED VEGETABLES	5/10	0.1/1			100/200	10/100				0.05/0.2
RECONSTITUTED VEGETABLE PROTEIN	5/20				200/400	10/100			0.001/0.005	0.05/0.2
SEASONINGS AND FLAVORS	10/50	0.1/1	0.01/0.5		300/500	10/100		20/30	0.001/0.005	0.1/0.3
SNACK FOODS	5/20		0.001/0.05		100/200	10/100		20/30	0.0001/0.005	0.05/0.2
SOFT CANDY	10/30	1/10	0.001/0.1		200/300		1/10	20/30	0.0001/0.001	0.05/0.2
SOUPS	5/20	1/10	0.0003/0.003		200/300	10/100		20/30	0.0001/0.0005	0.1/0.3
SUGAR SUBSTITUTES	1/10				200/300					
SWEET SAUCES	2/10		0.001/0.01		200/400			20/30	0.0001/0.005	

GRAS FLAVORING SUBSTANCES 30

Table 3 - Updated Average Usual Use Levels/Average Maximum Use Levels

Average Usual Use Levels (ppm)/Average Maximum Use Levels (ppm) for flavoring substances previously recognized as FEMA GRAS. ^a represents a change from previous FEMA GRAS publications.

^c represents a correction and errata to previous GRAS publications.

	Ethyl palmitate	Oak chips extract (<i>Quercus alba</i> L.; <i>Quercus petraea</i>)	Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran	L-Histidine	N-(Heptan-4-yl)benzo[d[1,3]dioxole-5-carboxamide	3-(4-Hydroxyphenyl)-1-(2,4,6-trihydroxyphenyl)propan-1-one	Rebaudioside A	Glutaryl-valyl-glycine	Erythritol	<i>Cordyceps sinensis</i> fermentation product	Sodium gluconate
FEMA NO.	2451	2794	3236	3694	4232	4390	4601	4709	4819	4878	4934
GRAS PUBLICATION	29	3	4	13	27	26	28	29	29	28	29
CATEGORY											
BAKED GOODS	20/20	72/90	2/4	10/150	1/2	50*/150 ^a	20*/30 ^a	15/30		30/50	5,000*/20,000 ^a
BEVERAGES, NON-ALCOHOLIC	0.02*/0.2 ^b	550*/1,000 ^a	0.5/0.8	200*/200 ^a	2/5	50*/100 ^a	20/30	20/50	5,000*/25,000 ^a	30*/1,000	1,500*/3,500 ^a
BEVERAGES, ALCOHOLIC	0.3/5	1,000/1,000	1*/1 ^a		2/5	15/50	20/30	20/50	5,000*/25,000 ^a	10*/1,000	1,500*/3,500 ^a
BREAKFAST CEREALS						50*/100 ^a	20/50 ^a	80/160	12,500*/25,000 ^a	10*/100 ^a	2,500*/5,000 ^a
CHEESES					1/3	10/50		20/50			5,000*/20,000 ^a
CHEWING GUM	0.1/0.1	115/200	5/10				200/200	10/30	5,000*/25,000 ^a	20*/100 ^a	10,000*/20,000 ^a
CONDIMENTS AND RELISHES					2/4	10/100	20/30	30/60	5,000*/25,000 ^a	1*/30 ^a	2,500*/5,000 ^a
CONFECTIONS AND FROSTINGS	0.05*/0.2 ^b			20/150		20/100	20/30	15*/40 ^a	5,000*/25,000 ^a	1*/30 ^a	1,500/2,500
EGG PRODUCTS					2/5			15/45		1*/30 ^a	2,500*/5,000 ^a
FATS AND OILS					2/4			30/60			5,000*/10,000 ^a
FISH PRODUCTS					1/3			15/45		1*/30 ^a	5,000*/20,000 ^a
FROZEN DAIRY	20/20	52/200 ^a	1/2		2*/5 ^a	10/50	20/30	20/50	12,500*/25,000 ^a	10*/100 ^a	1,500/2,500
FRUIT ICES						20/50	20/30	20/50	5,000*/25,000 ^a		1,500/2,500
GELATINS AND PUDDINGS		1*/1 ^a	1/2			10/100	20/30	15*/40 ^a	5,000*/25,000 ^a		1,500*/2,500 ^a
GRANULATED SUGAR						20/100					
GRAVIES			0.02/0.05		2/4	10/100	20/30	30/60	5,000*/25,000 ^a	10*/100 ^a	2,500*/5,000 ^a
HARD CANDY	40/40	2/200 ^a	2/2			20/100	20/30	20*/50 ^a	5,000*/25,000 ^a	1*/30 ^a	10,000*/20,000 ^a
IMITATION DAIRY PRODUCTS					2*/5 ^a	50*/100 ^a	20/30	20/50	12,500*/25,000 ^a	10*/150 ^a	5,000*/10,000 ^a
INSTANT COFFEE AND TEA	0.1*/0.3 ^a				2*/5 ^a	15/50	20/30	10/30	5,000*/25,000 ^a	10*/150 ^a	1,500/2,500
JAMS AND JELLIES						20/50	20/30	20*/50 ^a	5,000*/25,000 ^a	10*/100 ^a	1,000/2,500
MEAT PRODUCTS				30/150	1/3		20/75	15/45		16*/40 ^a	5,000*/20,000 ^a
MILK PRODUCTS				10/150	2*/5 ^a	10/50	20/45 ^a	15/45	12,500*/25,000 ^a	15/100	2,500*/5,000 ^a
NUT PRODUCTS	3/5				2/5	20/50			12,500*/25,000 ^a	10*/150 ^a	2,500*/5,000 ^a
OTHER GRAINS						50*/100 ^a			12,500*/25,000 ^a	50/150	1,500*/5,000 ^a
POULTRY PRODUCTS					1/3		20/75	15/45		10*/150 ^a	5,000*/20,000 ^a
PROCESSED FRUITS						20/50	20/30		5,000*/25,000 ^a	20*/50 ^a	1,500/2,500
PROCESSED VEGETABLES					1/3	20/50	20/30	15/45	5,000*/25,000 ^a	10*/150 ^a	2,500*/5,000 ^a
RECONSTITUTED VEGETABLE PROTEIN					2/5	50*/150 ^a		15/45		10*/150 ^a	5,000*/20,000 ^a
SEASONINGS AND FLAVORS					5/10	10/100	20/30	80/160		10*/150 ^a	2,500/20,000 ^a
SNACK FOODS					5/10	50*/100 ^a	20/30	80/160		10*/150 ^a	2,500*/5,000 ^a
SOFT CANDY		60/200 ^a	3/7			20/100	20/30	15*/40 ^a	5,000*/25,000 ^a	1*/30 ^a	1,500*/2,500 ^a
SOUPS					2/4	10/100	20/30	20/50	5,000*/25,000 ^a	10*/100 ^a	2,500*/5,000 ^a
SUGAR SUBSTITUTES						20/100		80/160		1*/30 ^a	1,500*/3,500 ^a
SWEET SAUCES						10/100	20/30	30/60	5,000*/25,000 ^a	1*/30 ^a	1,500*/3,500 ^a