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GRAS

FLAVORING SUBSTANCES 23

The 23rd publication by the FEMA Expert Panel presents safety and usage data on 174 new generally recognized as safe flavoring ingredients.

The Expert Panel of the Flavor and Extract Manufacturers Association continues to perform its primary function of evaluating the safety of flavoring substances under the conditions of intended use.

For more than four decades, the FEMA Expert Panel has maintained a safety evaluation program to respond to the provision in the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act—Public Law 85-929, 72 Stat. 1784 (1958), codified at 21 USC Sec. 348 (1988)—that exempted from food additive status those substances "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." Substances "generally recognized as safe" (GRAS) by the FEMA Expert Panel under the conditions of their intended use are not considered to be food additives and are excluded from mandatory premarket approval by the U.S. Food and Drug Administration.

In May 2010, the FEMA Expert Panel will have completed 50 years of continuous operation evaluating the safety of flavoring substances. During this time, the Panel has rigorously supported the meaning and intent of the GRAS provision. First, the Panel has been and is now composed of well-recognized experts from academic scientific disciplines that are related to the safety evaluation of flavoring substances. The disciplines of toxicology, pathology, biochemistry, organic chemistry, pharmacology, and medicine are well represented on the Panel. Second, the Panel members are not only well-recognized in their respective disciplines but they are experienced in applying that expertise and scientific judgment to the safety evaluation of flavor ingredients. Currently, the duration of membership on the Panel is in the range from two to more than 25 years, with a mean Panel tenure of 11 years. Third, consistent with the "generally recognized as safe" evaluation process, the Panel regularly publishes its GRAS decisions in the peer-reviewed literature. To this end,

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the Panel not only publishes articles identifying substances newly determined as GRAS (e.g., Newberne et al., 2000; Smith et al., 2001, 2003, 2005), but also publishes the scientific data supporting the GRAS determination for these substances (Adams et al., 1996, 1997, 1998, 2002, 2004, 2005a, b, c, 2007; Newberne et al., 1999; Smith et al., 2002). In addition, the Panel periodically evaluates and publishes the criteria and scientific procedures it applies in reaching its GRAS decisions (Hall and Oser, 1977; Woods and Doull, 1991; Smith et al., 2005a, b).

In 1996, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) initiated a systematic program to evaluate the safety of flavoring substances. Based on the evaluation of the available safety data, JECFA has reached conclusions consistent with those of the Panel; namely, that more than 1,700 GRAS flavoring substances are considered "no safety concern under current conditions of intake." In a similar program in the European Union begun in 2001, the European Food Safety Authority has reached similar conclusions on substances structurally related to flavoring substances evaluated by JECFA.

Further confirmation of the key role that the Expert Panel plays in the global safety evaluation of flavoring substances is that non-U.S. flavor companies and trade associations have reached out to the Panel for its scientific evaluation expertise. Beginning in 2005, the Japanese Flavor and Fragrance Materials Association (JFFMA) joined with the International Organization of Flavor Industries (IOFI) and FEMA to sponsor the GRAS evaluations of more than 300 substances previously used in flavorings only in Japan and other Asian countries. The program's goals are (1) to have Asian-specific flavor ingredients evaluated by the FEMA Expert Panel for GRAS status for use as flavoring substances in the United States; and (2) subsequently submit the data supporting the GRAS substances to JECFA for a second safety evaluation. As expected, some groups of flavor ingredients scheduled for review are specific to an Asian diet. For example, the Panel concluded that a group of substituted isothiocyanates »»

In May 2010, the FEMA Expert Panel will have completed 50 years of continuous operation evaluating the safety of flavoring substances.

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(Nos. 4414–4427) used in "wasabi-type" flavors are GRAS.

In this, the 23rd GRAS publication, 174 new GRAS flavoring substances—Nos. 4254–4429, except 4378–4379—are identified (Tables 1 and 2). In addition, the Panel determined that new use levels and food categories for five flavoring substances are consistent with their current GRAS status (Table 3). Of these 174 new flavoring substances, four are Natural Flavor Complexes (Nos. 4265, 4266, 4283, and 4385) while one (No. 4385) is a flavor carrier used in the preparation of finished food flavors. The Panel also comments on the expanding list of GRAS evaluations for substances with non-flavor functions that are added to finished flavorings.

FEMA GRAS Evaluation of Substances with Non-Flavor Function

Flavorings are typically mixtures of substances, most of which impart flavor (e.g., menthol and cinnamaldehyde) or, on a more limited basis, modify flavor (e.g., neohespiridin dihydrochalcone and (-)-homoeriodictyol, sodium salt). Compounded flavorings also include substances that act as preservatives (butylated hydroxyanisole, BHA), solvents (ethyl alcohol), encapsulating agents (*beta*-cyclodextrin), and emulsifiers (carrageenan) (Table 4). Often, substances that act as emulsifiers, solvents, and preservatives in the preparation of compounded flavors serve the same function in the food supply. In these instances, the Panel evaluates the substance for its GRAS status based strictly on its intended use as a component of a food flavor. In order to complete the GRAS evaluation, the applicant must demonstrate that the substance provides the specified function in flavors under conditions and at levels of use that do not serve other non-flavor functions in the finished food. For example, neohesperidin dihydrochalcone (FEMA No. 3811) provides a sweetening effect at levels >300 ppm in a finished food product. However, it was recently evaluated by the Panel and received GRAS status to be added as a flavor modifier at 30 ppm, where it does not display a sweetening effect. Fundamentally, these substances are GRAS for their function in modifying, preserving, emulsifying,

etc., the flavoring that is added to food. They are not GRAS for their direct addition to modify, preserve, emulsify, etc., the food. Based on the fact that flavorings are added to food in such minute quantities, normally 1% or less, the function of the substances added to flavorings occurs at a concentration that is far below that required to exert the same function in food.

This criterion is entirely consistent with Section 201(s) of the Federal Food, Drug, and Cosmetic Act, which states that in order for a substance to be considered GRAS it must be "safe under conditions of intended use." It is also consistent with past Panel decisions in which substances possessing non-flavor functions (solvents, modifiers, antioxidants, etc.) have been recognized as GRAS for their intended use in compounded flavors (Table 4). For example, methyl paraben (FEMA No. 2710) is FEMA GRAS for its intended use as a preservative for flavorings. It is not GRAS for its use in food as an antimicrobial agent.

Anticipated Annual Volumes of Use for New Flavoring Substances

In its early years of operation, the Expert Panel evaluated the safety of approximately 1,000 flavoring substances that had been in use prior to the 1958 GRAS regulation. This created an initial list of flavorings that was published in the peer-reviewed literature in 1965 (Hall and Oser, 1965). Under contract to the U.S. FDA, the National Academy of Sciences-National Research Council (NAS-NRC) (NAS, 1970, 1975, 1982 and 1987) and later FEMA (Lucas et al., 1999) conducted a series of surveys on the use of FEMA GRAS flavoring substances and food additives used in the preparation of compounded flavors. These surveys collected data related to exposure, including the volume of flavoring substances that disappeared into the U.S. food supply on an annual basis. Together with a

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CALCULATION OF INTAKE

$$\mu g/person/day = \frac{(\text{annual volume, kg/year})(10^9\ \mu g/kg)}{(\text{population} \times \text{survey correction factor})(365\ \text{days/year})}$$

where:
U.S. population (10%, "eaters only") = 28×10^6.

Correction factor = 0.6 for NAS (1970, 1982, 1987) surveys, representing the assumption that only 60% of the annual flavor volume was reported in the poundage surveys.

Correction factor = 0.8 for the Lucas et al. (1999) survey, representing the assumption that only 80% of the annual flavor volume was reported in the poundage survey.

$$\mu g/kg\ bw/day = \frac{\mu g/person/day}{60\text{-kg body weight}}$$

Slight variations may occur from rounding.

more comprehensive analysis of the intake of a restricted number of flavoring substances (Hall and Oser, 1977), these data were the basis for estimating the exposure of U.S. consumers to these flavoring substances.

When a new flavoring substance is developed and evaluated for GRAS under conditions of intended use, there is no survey data available upon which to initially estimate exposure. In the absence of such data and until a survey is performed, the Expert Panel requires the company applying for GRAS status for a flavoring substance to provide anticipated poundage for the substance that the company expects to sell into the food and beverage market during the first year. The applicant company is also asked to provide data on potential patterns of use of the flavoring substance in different food categories (e.g., baked goods, soft candy, seasonings, and flavors) and concentrations at which the substance is detected and tolerated by a taste test panel. These data, in conjunction with data on biological and chemical properties of the substance and metabolism and toxicity for the GRAS candidate and structurally related substances, serve the Expert Panel in its safety assessment (Smith et al., 2005b).

In order to assess the relationship of anticipated annual poundage information to actual survey reported poundage data, anticipated poundage reported by GRAS applicants for flavoring agents from FEMA GRAS Lists 6–19 was compared with the results of NAS and FEMA industry-wide poundage surveys performed during the 25-year period from 1970 to 1995. From this analysis, it is apparent that in the vast majority of cases, anticipated poundage (i.e., the amount of a flavoring substance that a flavor company expects to sell in the first year of use) is not realized. Approximately 84% (296/351) of the materials surveyed had reported poundage that averaged less than the anticipated poundage reported in the GRAS application, while roughly 15% (51/351) of the materials averaged more. Therefore, for the vast majority (84%) of flavoring agents the anticipated poundage is an overestimation. Since these anticipated poundages are used to calculate the per capita intake times 10 (PCI x 10) values until surveyed poundage is reported, these PCI x 10 values are, in most cases, overestimates of intake. Of the overestimates, more than one-third of the materials have annual poundage of less than 1 kg reported in recent surveys. For another third of the flavorings substances, anticipated volumes overestimate actual poundage by greater than 90%.

Less than 10% (32/351) of the substances surveyed showed anticipated poundages that underestimated by two-fold or greater the reported annual volumes from later surveys. However, in all of these cases, the anticipated and survey-reported poundages were within the same order of magnitude, providing confidence that intakes calculated using either data would not be significantly different and still provide enormous margins of safety (10,000–1,000,000) when compared to the no-observable-adverse effect level in relevant animal studies. Additionally, the majority of these substances are naturally occurring in traditional food, and intake from food sources far exceeds that from added flavor use.

These data clearly demonstrate that for the vast majority (84%) of FEMA GRAS flavoring substances, the use of anticipated poundage to calculate PCI x 10 values is indeed

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CORRECTION & CHANGES

In Table 3 of "GRAS Flavoring Substances 19" (Newberne et al., 2000), the synonym for FEMA No. 3933 was incorrectly listed as *trans*-2-hexenyl propionate. The correct synonym is *cis*-2-hexenyl propionate.

Jay I. Goodman, Professor of Pharmacology and Toxicology at Michigan State University, retired from the FEMA Expert Panel in October 2005 after 10 years of continuous dedicated service.

Ivonne M.C.M. Rietjens, Professor of Biochemistry and Food Toxicology at Wageningen University, joined the Panel in January 2006.

Victor J. Feron, Professor Emeritus in the Dept. of Biological Toxicology at Utrecht University, retired from the Panel in July 2006 after more than seven years of continuous dedicated service.

a highly conservative approach. With the additional assumption that the company applying for GRAS status for a material will represent, at best, 60% of the volume of any material sold into the marketplace, the estimated daily per capita intakes calculated from these numbers are highly inflated and present an additional safety factor. As poundage surveys update the information available for flavoring substances, a more accurate estimate of intake is achieved, but in the interim the anticipated poundage results in a considerable margin of safety. **FT**

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TABLE 1: Primary Names & Synonyms

Primary names (in boldface, listed alphabetically) & Synonyms (in lightface)

FEMA No.	Substance primary names and synonyms
4254	***N*-Gluconyl ethanolamine** *N*-(2-Hydroxyethyl)-hexonamide 2,3,4,5,6-Pentahydroxy-*N*-(2-hydroxyethyl)-hexanamide Gluconic acid ethanolamine *N*-(2-Hydroxyethyl)-gluconamide
4255	***N*-Gluconyl ethanolamine phosphate** *N*-(2-Hydroxyethyl)-hexonamide phosphate 2-[(2,3,4,5,6-Pentahydroxyhexanoyl)-amino]ethyl dihydrogen phosphate 2,3,4,5,6-Pentahydroxy-*N*-(2-hydroxyethyl)hexanamide phosphate Gluconic acid ethanolamine phosphate
4256	***N*-Lactoyl ethanolamine** 2-Hydroxy-*N*-(2-hydroxyethyl)-propanamide (2*R*)-2-Hydroxy-*N*-(2-hydroxyethyl)propanamide *N*-(2-Hydroxyethyl)-lactamide Lactamide MEA Lactic acid monoethanolamide *N*-(*beta*-Hydroxyethyl)lactamide *N*-Hydroxyethyllactamide Lactoyl ethanolamine Lactonyl ethanolamine
4257	***N*-Lactoyl ethanolamine phosphate** *N*-(2-Hydroxy-1-oxopropyl)ethanolamine *o*-phosphate 2-[(2-Hydroxypropanoyl)amino]ethyl dihydrogen phosphate Phosphoric acid mono-[2-(2-hydroxypropionylamino)-ethyl] ester
4258	**Ethanethiol** Ethyl mercaptan Ethyl thioalcohol Mercaptoethane Thioethanol Thioethyl alcohol
4259	**Heptane-1-thiol** 1-Heptylthiol 1-Mercaptoheptane Heptyl mercaptan Heptylthiol *n*-Heptanethiol *n*-Heptyl mercaptan *n*-Heptylthiol
4260	***S*-Isopropyl 3-methylbut-2-enethioate**
4261	**3-Methylhexanal**
4262	**4-Pentenal** Pent-4-en-1-al
4263	**Propyl propane thiosulfonate** *S*-Propyl propane-1-sulfonothioate *S*-Propyl propanethiosulfonate
4264	***alpha*-Ionene** Raspbilene 1,2,3,4-Tetrahydro-1,1,6-trimethylnaphthalene Ionene Frambilene 1,1,6-Trimethyltetraline 1,1,6-Trimethyl-1,2,3,4-tetrahydronaphthalene
4265	***Gardenia gummifera* distillate** *Gardenia gummifera* L.
4266	***Piper longum* distillate** *Piper longum* Linn.
4267	***N*-3,7-Dimethyl-2,6-octadienylcyclopropylcarboxamide**
4268	**(+/-)-Ethyl 2-hydroxy-2-methylbutyrate** Ethyl 2-methyllactate 2-Hydroxy-2-methylbutyric acid ethyl ester
4269	**(+/-)-Ethyl 2-hydroxy-3-methylvalerate** Ethyl 2-ethyllactate 2-Hydroxy-3-methylpentanoic acid ethyl ester Ethyl 2-hydroxy-3-methylpentanoate
4270	**2-(2-Hydroxyphenyl) cyclopropanecarboxylic acid *delta*-lactone** 1a,7b-dihydrocyclopropa[c]-chromen-2(1*H*)-one Cyclopropylcoumarin
4271	**2-Decanone** Methyl *n*-octyl ketone Methyl octyl ketone Octyl methyl ketone
4272	**(+/-)-*trans*- and *cis*-2-Hexenal propylene glycol acetal** (+/-)-*E*- and *Z*-2-Hexenal propylene glycol acetal 4-Methyl-2-(1*E*)-1-pentenyl-1,3-dioxolane
4273	**(+/-)-*trans*- and *cis*-2-Hexenal glyceryl acetal** (+/-)-*E*- and *Z*-2-Hexenal glyceryl acetal
4274	***trans*-2-Hexenyl 2-methylbutyrate** (*E*)-2-Hexenyl 2-methylbutyrate
4275	**2-(4-Methyl-5-thiazolyl)ethyl formate**
4276	**2-(4-Methyl-5-thiazolyl)ethyl propionate**
4277	**2-(4-Methyl-5-thiazolyl)ethyl butanoate**
4278	**2-(4-Methyl-5-thiazolyl)ethyl isobutyrate**
4279	**2-(4-Methyl-5-thiazolyl)ethyl hexanoate**
4280	**2-(4-Methyl-5-thiazolyl)ethyl octanoate**
4281	**2-(4-Methyl-5-thiazolyl)ethyl decanoate**
4282	**(+/-)-3-(Ethylthio)butanol**
4283	***Decalepis hamiltonii* extract** *Decalepis hamiltonii*
4284	**2-(*trans*-2-Pentenyl)cyclopentanone** Jasminone (*E*)-2-(Pent-2-enyl)cyclopentan-1-one
4285	**3,9-Dimethyl-6-(1-methylethyl)-1,4-dioxaspiro[4.5]decan-2-one**
4286	***cis*- and *trans*-2-Isobutyl-4-methyl-1,3-dioxolane** *Z*- and *E*-2-Isobutyl-4-methyl-1,3-dioxolane *Z*- and *E*-3-methylbutyraldehyde propylene glycol acetal
4287	***cis*- and *trans*-2-Isopropyl-4-methyl-1,3-dioxolane** *Z*- and *E*-2-Isopropyl-4-methyl-1,3-dioxolane 4-Methyl-2-(1-methylethyl)-1,3-dioxolane *Z*- and *E*-isobutyraldehyde propylene glycol acetal
4288	**4-Aminobutyric acid** *gamma*-Aminobutanoic acid *gamma*-Aminobutryic acid *omega*-Aminobutyric acid 3-Carboxypropylamine 4-Aminobutanoic acid 4-Aminobutyric acid GABA
4289	**3-Mercaptoheptyl acetate**
4290	**Ethyl *trans*-2-methyl-2-pentenoate** Ethyl (*E*)-2-methyl-2-pentenoate
4291	**Methyl hexyl ether** *n*-Hexyl methyl ether 1-Methoxyhexane
4292	***trans*-2-*trans*-4-Nonadiene** (*E*,*E*)-2,4-Nonadiene
4293	**1-Octene** *alpha*-Octene *alpha*-Octylene Octylene Caprylene
4294	***cis*- and *trans*-Ethyl 2,4-dimethyl-1,3-dioxolane-2-acetate** *Z*- and *E*-Ethyl 2,4-dimethyl-1,3-dioxolane-2-acetate

FEMA No.	Substance primary names and synonyms
4295	**Citronellyl *trans*-2-methyl-2-butenoate** Citronellyl tiglate Citronellyl tiglinate 3,7-Dimethyl-6-octenyl *trans*-2-methyl-2-butenoate 3,7-Dimethyl-6-octenyl 2-methylcrotonate
4296	**5-Acetyl-2,3-dihydro-1,4-thiazine** 1-(3,4-Dihydro-2*H*-1,4-thiazin-5-yl)ethanone
4297	***Bis*(1-mercaptopropyl)sulfide** 1,1′-Thiobis-1-propanethiol
4298	**2,5-Dithiahexane** 1,2-*Bis*(methylmercapto)ethane
4299	**Pseudoionone** *phi*-Ionone *psi*-Ionone 2,6-Dimethyl-2,6,8-undecatrien-10-one 2,6-Dimethylhendeca-2,6,8-trien-10-one 2-Pseudoionone 6,10-Dimethyl-3,5,9-undecatrien-2-one Citrylidene acetone
4300	***cis*- and *trans*-*l*-Mercapto-*p*-menthan-3-one** *Z*- and *E*-l-Mercapto-*p*-menthan-3-one
4301	***trans*-2-Nonen-4-one** (*E*)-2-Nonen-4-one
4302	***trans*-4-Nonenal** (*E*)-4-Nonenal (*E*)-Non-4-enal
4303	**1,1′-(Tetrahydro-6*α*-hydroxy-2,3*α*,5-trimethylfuro[2,3-*d*]-1,3-dioxole-2,5-diyl)*bis*-ethanone** Diacetyl trimer 2,5-Diacetyl-3a,5,6,6a-tetrahydro-6a-hydroxy-2,3a,5-trimethylfuro[2,3-d]-1,3-dioxole Biacetyl trimer
4304	***trans*-2-Decenol** (*E*)-2-Decenol *trans*-2-Decen-1-ol (*E*)-2-Decen-1-ol
4305	***cis*-2-Pentenol** (*Z*)-2-Pentenol *cis*-2-Penten-1-ol (*Z*)-2-Penten-1-ol
4306	**2-Methylbutyl 3-methyl-2-butenoate** 2-Methylbutyl senecioate 2-Methylbutyl 3-methylbut-2-enoate
4307	**Citric and fatty acid esters of glycerol** Citric acid esters of mono- and diglycerides Citroglycerides
4308	***l*-Menthyl (*R,S*)-3-hydroxybutyrate** Menthyl methyllactate 2-Isopropyl-5-methylcyclohexyl-3-hydroxybutanoate Menthyl 3-hydroxybutanoate
4309	***N*-[(Ethoxycarbonyl)methyl]-*p*-menthane-3-carboxamide** [1*R*-(1.*alpha*.,2.*beta*.,5.*alpha*.)]-*N*-[[5-Methyl-2-(1-methylethyl)cyclohexyl]carbonyl glycine ethyl ester
4310	***N*-[2-(3,4-Dimethoxyphenyl)ethyl]-3,4-dimethoxycinnamic acid amide** 3-(3,4-Dimethoxyphenyl)-*N*-[2-(3,4-dimethoxyphenyl)ethyl]-2-propenamide
4311	**Mixture of methyl cyclohexadiene and methylene cyclohexene**
4312	**(+/-)-*cis*- and *trans*-1,2-Dihydroperillaldehyde** (+/-)-*Z*- and *E*-1,2-Dihydroperillaldehyde 4-Isopropenylcyclohexane-carboxaldehyde
4313	**5,7-Dihydroxy-2-(3-hydroxy-4-methoxy-phenyl)-chroman-4-one** (+/-)-Hesperetin (+/-)-5,7,3′-Trihydroxy-4′-methoxyflavanone Eriodictyol 4′-monomethyl ether
4314	**Phenethyl decanoate** *beta*-Phenylethyl caprate
4315	**3,6-Dimethyl-2,3,3*α*,4,5,7*α*-hexahydrobenzofuran** Dill ether
4316	**2-Methylacetophenone** 1-(2-Methylphenyl)ethanone 1-(2-Tolyl)ethanone 2-Acetyltoluene 2-Methylphenyl methyl ketone Methyl 2-methylphenyl ketone Methyl *o*-tolyl ketone *o*-Acetyltoluene *o*-Methylacetophenone
4317	**1-Ethyl-2-pyrrolecarboxaldehyde** Tea pyrrole 1-Ethyl-2-formylpyrrole 1-Ethyl-1*H*-pyrrole-2-carboxaldehyde 1-Ethyl-pyrrole-2-carboxaldehyde 1-Ethylpyrrole-2-aldehyde *N*-Ethyl-2-formylpyrrole *N*-Ethylpyrrole-2-carboxaldehyde
4318	***cis- and trans*-5-Ethyl-2,5-dihydro-4-methyl-2-(1-methylpropyl)-thiazole** *Z*- and *E*-5-Ethyl-2,5-dihydro-4-methyl-2-(1-methylpropyl)-thiazole
4319	***cis* and *trans*-5-Ethyl-4-methyl-2-(2-methylpropyl)-thiazoline** *Z*- and *E*-5-Ethyl-4-methyl-2-(2-methylpropyl)-thiazoline
4320	**2-Methyl-3-furyl methylthiomethyl disulfide**
4321	**Pyrrolidino-[1,2*E*]-4*H*-2,4-dimethyl-1,3,5-dithiazine** Tetrahydro-2,4-dimethyl-4*H*-pyrrolo[2,1-*d*]-1,3,5-dithiazine 2,4-Dimethyl-tetrahydro-pyrrolo[2,1-*d*][1,3,5] dithiazine
4322	***S*-Allyl-*L*-cysteine** 3-(Allylthio)-alanine (2*R*)-3-(Allylthio)-2-aminopropanoic acid (*R*)-Allylthio-2-aminopropionic acid *S*-Allylcysteine *S*-Allyl-*L*-cysteine (+)-*S*-Allylcysteine *S*-2-Propenylcysteine *S*-(2-Propenyl)-*L*-cysteine
4323	**5-Pentyl-3*H*-furan-2-one** 4-Hydroxy-3-nonenoic acid lactone 5-(1-Pentyl)-3*H*-furan-2-one 5-Amyl-3*H*-furan-2-one
4324	**3-Mercapto-3-methyl-1-butyl acetate** 3-Mercapto-3-methylbutyl acetate 3-Methyl-3-sulfanylbutyl acetate
4325	**(+/-)-3-Mercapto-1-butyl acetate** 3-Mercaptobutyl acetate 3-Thiobutyl acetate
4326	**5-Nonen-*trans*-2-one** 5-Nonen-(*E*)-2-one *trans*-5-Nonen-2-one (*E*)-5-Nonen-2-one *trans*-Non-5-en-2-one (*E*)-Non-5-en-2-one
4327	***l*-Menthyl acetoacetate** (-)-Menthyl acetoacetate
4328	**4-Octen-3-one** Oct-4-en-3-one
4329	**2,4,6-Trimethylphenol** Mesitol 1,3,5-Trimethylphenol 1-Hydroxy-2,4,6-trimethylbenzene 2-Hydroxymesitylene Hydroxymesitylene Mesityl alcohol

TABLE 1 *CONTINUED*: Primary Names & Synonyms

Primary names (in boldface, listed alphabetically) & Synonyms (in lightface)

FEMA No.	Substance primary names and synonyms
4330	**4-Hydroxyacetophenone** 1-(4-Hydroxyphenyl)-1-ethanone 1-(4-Hydroxyphenyl)ethanone 4-Acetophenol 4-Acetylphenol 4-Hydroxyphenyl methyl ketone 4-Hydroxyphenylethanone Methyl 4-hydroxyphenyl ketone Methyl *p*-hydroxyphenyl ketone *p*-Acetophenol *p*-Acetylphenol *p*-Hydroxyacetophenone *p*-Hydroxyphenyl methyl ketone Piceol
4331	**(+/-)-[*R*-(*E*)]-5-Isopropyl-8-methylnona-6,8-dien-2-one** Virginione
4332	***1*-Methyl-1*H*-pyrrole-2-carboxaldehyde** 1-Methyl-2-formylpyrrole 2-Formyl-1-methylpyrrole 2-Formyl-*N*-methylpyrrole *N*-Methyl-2-formylpyrrole *N*-Methyl-2-pyrrolaldehyde *N*-Methyl-2-pyrrolylcarboxaldehyde *N*-Methylpyrrole-2-carbaldehyde *N*-Methylpyrrole-2-carboxaldehyde 1-Methylpyrrole-2-carboxaldehyde
4333	**1-Pentanethiol** Amyl mercaptan Pentyl mercaptan
4334	**Pentadecanoic acid** *n*-Pentadecanoic acid *n*-Pentadecoic acid Pentadecylic acid
4335	**Tridecanal**
4336	**Tridecanoic acid** *n*-Tridecanoic acid *n*-Tridecoic acid Tridecylic acid
4337	**Hexyl heptanoate** 1-Hexyl heptanoate Hexyl enanthate
4338	**Dodecyl propionate** Dodecyl propanoate *n*-Dodecyl propionate
4339	**Hexyl nonanoate**
4340	**Dodecyl butyrate** *n*-Dodecyl butyrate
4341	**Heptyl heptanoate** 1-Heptyl heptanoate Heptyl heptoate
4342	**Hexyl decanoate** Hexyl caprate
4343	**Ethyl 4-methylpentanoate** Ethyl 4-methylvalerate Ethyl isocaproate Ethyl isohexanoate
4344	**Ethyl 2-ethylbutyrate** Ethyl *alpha*-ethylbutyrate Ethyl 2-ethylbutanoate
4345	**Ethyl 2-ethylhexanoate** Ethyl 2-ethylcaproate Ethyl *alpha*-ethylcaproate
4346	**5-Methylhexyl acetate**
4347	**4-Methylpentyl isovalerate** 4-Methylpentyl 3-methylbutanoate
4348	**3,7-Dimethyloctanal** 3,7-Dimethyl-1-octanal 6,7-Dihydrocitronellal Dihydrocitronellal
4349	***cis*-4-Decenol** (*Z*)-4-Decenol
4350	***cis*-5-Octenoic acid** (*Z*)-5-Octenoic acid
4351	**5-Hexenol** 5-Hexene-1-ol 5-Hexen-1-ol Hex-5-en-1-ol
4352	**3-Isopropenylpentanedioic acid**
4353	**Methyl 4-pentenoate** Allylacetic acid methyl ester Methyl allylacetate Methyl pent-4-enoate
4354	***cis*-4-Octenol** *cis*-4-Octen-1-ol (*Z*)-4-Octenol (*Z*)-4-Octen-1-ol
4355	**11-Dodecenoic acid**
4356	***trans*-3-Hexenol** (*E*)-3-Hexen-1-ol (*E*)-3-Hexenol *trans*-3-Hexen-1-ol
4357	***trans*-4-Octenoic acid** (*E*)-4-Octenoic acid
4358	**Isobutyl 10-undecenoate**
4359	***cis*-9-Octadecenyl acetate** (*Z*)-9-Octadecenyl acetate *cis*-9-Octadecen-1-yl acetate Oleyl acetate Acetic acid oleyl ester
4360	**Ethyl 4-pentenoate** Ethyl allylacetate Ethyl pent-4-enoate
4361	**Ethyl 3-octenoate** Ethyl oct-3-enoate
4362	**3-Octenoic acid** 2-Heptene-1-carboxylic acid
4363	***cis*-9-Octadecenol**
4364	**Decanal propyleneglycol acetal** 2-Nonyl-4-methyl-1,3-dioxolane
4365	**Acetaldehyde hexyl isoamyl acetal**
4366	**Dodecanal dimethyl acetal** 1,1'-*Bis*(methoxy)dodecane 1,1-Dimethoxydodecane Dodecanal dimethyl acetal Lauryl aldehyde dimethyl acetal
4367	**Nonanal dimethyl acetal** 1,1-Dimethoxynonane Pelargonaldehyde dimethyl acetal Pelargonic aldehyde dimethyl acetal
4368	**Heptanal propyleneglycol acetal** 2-Hexyl-4-methyl-1,3-dioxolane
4369	**Hexanal hexyl isoamyl acetal**
4370	**Hexanal dihexyl acetal** 1,1-*Bis*(hexyloxy)hexane
4371	**Isovaleraldehyde diethyl acetal** 1,1-Diethoxy-3-methylbutane 1,1-Diethoxyisopentane
4372	**Valeraldehyde propyleneglycol acetal** 2-Butyl-4-methyl-1,3-dioxolane
4373	**Nonanal propyleneglycol acetal** 2-Octyl-4-methyl-1,3-dioxolane
4374	**Undecanal propyleneglycol acetal**
4375	**Valeraldehyde dibutyl acetal**
4376	**Acetaldehyde 1,3-octanediol acetal** 4-Methyl-2-pentyl-1,3-dioxane
4377	**Hexanal octane-1,3-diol acetal** 2,4-Dipentyl-1,3-dioxane
4380	**Isovaleraldehyde glyceryl acetal**
4381	**Acetaldehyde di-*cis*-3-hexenyl acetal**

FEMA No.	Substance primary names and synonyms
4382	**2,6-Dimethyl-5-heptenal propyleneglycol acetal** 2-(1,5-Dimethyl-4-hexenyl)-4-methyl-1,3-dioxolane
4383	**Octanal propyleneglycol acetal** 2-Heptyl-4-methyl-1,3-dioxolane
4384	**Hexanal butane-2,3-diol acetal** 4,5-Dimethyl-2-pentyl-1,3-dioxolane
4385	**Pecan shell flour**
4386	**Di-(1-propenyl)-sulfide (mixture of isomers)** 1-Propenylsulfanylpropene
4387	**2-Pentylthiophene** 2-*n*-Pentylthiophene
4388	**5-Ethyl-2-methylthiazole**
4389	**2,4-Dimethylpyridine** *alpha,gamma*-Dimethylpyridine
4390	**3-(4-Hydroxyphenyl)-1-(2,4,6-trihydroxyphenyl)-propan-1-one** Phloretin 2',4',6'-Trihydroxy-3-(*p*-hydroxyphenyl)propiophenone *beta*-(*p*-Hydroxyphenyl)-2,4,6-trihydroxypropiophenone *beta*-(*p*-Hydroxyphenyl)-phloropropiophenone 2',4',6'-Trihydroxy-3-(4-hydroxyphenyl)propiophenone 2',4',6'-Trihydroxy-3-(*p*-hydroxyphenyl)propiophenone Dihydronaringenin Naringenin dihydrochalcone Phloretol
4391	**(+/-)-Ethyl 3-hydroxy-2-methylbutyrate**
4392	**(+/-)-Ethyl 3-mercapto-2-methylbutanoate**
4393	**(+/-)-*cis*- and *trans*-2-Methyl-2-(4-methyl-3-pentenyl)cyclo-propanecarbaldehyde**
4394	**Trimethyloxazole** 2,4,5-Trimethyloxazole
4395	**2,5-Dimethyl-4-ethyloxazole** 4-Ethyl-2,5-dimethyloxazole
4396	**2-Propyl-4,5-dimethyloxazole** 2-*n*-Propyl-4,5-dimethyloxazole
4397	**2-Isobutyl-4,5-dimethyloxazole** 2-(2-Methylpropyl)-4,5-dimethyloxazole
4398	**2-Methyl-4,5-benzoxazole** 2-Methyl-1,3-benzoxazole 2-Methylbenzoxazole
4399	**2-Nonanone propyleneglycol acetal**

FEMA No.	Substance primary names and synonyms
4400	**6-Methyl-5-hepten-2-one propyleneglycol acetal** 2,4-Dimethyl-2-(4-methyl-3-pentenyl)-1,3-dioxolane
4401	**2-Pentyl 2-methylpentanoate** 2-Methylpentanoic acid, 2-pentyl ester
4402	**3-Octyl butyrate** 1-(Ethylhexyl)butanoate 3-Octyl butanoate Butanoic acid, 1-ethylhexyl ester
4403	**Dimethylbenzyl carbinyl crotonate**
4404	**Dimethylbenzyl carbinyl hexanoate**
4405	**1,5-Octadien-3-one**
4406	**10-Undecen-2-one**
4407	**2,4-Dimethyl-4-nonanol**
4408	**8-Nonen-2-one**
4409	**8-*p*-Menthene-1,2-diol** 8,9-*p*-Menthen-1,2-diol *d*-Limonene-1,2-diol Limonene glycol (1*S*,2*S*,4*R*)-Limonene-1,2-diol
4410	**Caryophyllene alcohol** Decahydro-2,2,4,8-tetramethyl-4,8-methanoazulen-9-ol
4411	***d*-2,8-*p*-Menthadien-1-ol**
4412	***cis*-3-Nonen-1-ol** (*Z*)-3-Nonen-1-ol (3*Z*)-Nonenol *cis*-3-Nonenol
4413	***trans*-3-Hexenyl acetate** (*E*)-3-Hexen-1-ol acetate (*E*)-3-Hexen-1-yl acetate (*E*)-3-Hexenyl acetate Acetic acid *trans*-3-hexenyl ester
4414	**4-(Methylthio)butyl isothiocyanate** Erucin 1-Isothiocyanato-4-(methylthio)butane
4415	**6-(Methylthio)hexyl isothiocyanate** 1-Isothiocyanato-6-(methylthio)hexane
4416	**5-(Methylthio)pentyl isothiocyanate** 5-(Methylthio)pentyl isothiocyante 1-Isothiocyanato-5-(methylthio)pentane Berteroin
4417	**Amyl isothiocyanate** 1-Pentyl isothiocyanate *n*-Pentyl isothiocyanate Pentyl isothiocyanate 1-Isothiocyanatopentane

FEMA No.	Substance primary names and synonyms
4418	**3-Butenyl isothiocyanate** 1-Butene-4-isothiocyanate
4419	**2-Butylisothiocyanate** 1-Methylpropyl isothiocyanate 2-Isothiocyanatobutane *sec*-Butyl isothiocyanate
4420	**Ethyl isothiocyanate** Ethyl mustard oil Ethyl thioisocyanate Isothiocyanatoethane
4421	**5-Hexenyl isothiocyanate** 6-Isothiocyanato-1-hexene
4422	**Hexyl isothiocyanate** 1-Hexyl isothiocyanate 1-Isothiocyanatohexane Hexyl isothiocyanate n-Hexyl isothiocyanate n-Hexyl mustard n-Hexyl mustard oil
4423	**Isoamyl isothiocyanate** 1-Isothiocyanato-3-methylbutane 3-Methylbutyl isothiocyanate Isopentyl isothiocyanate
4424	**Isobutyl isothiocyanate** 2-Methyl-1-propyl isothiocyanate 2-Methylpropyl isothiocyanate 1-Isothiocyanato-2-methylpropane
4425	**Isopropyl isothiocyanate** 2-Propyl isothiocyanate 2-Isothiocyanatopropane Isopropyl mustard Isopropyl mustard oil
4426	**Methyl isothiocyanate** Isothiocyanatomethane Methyl isothiocyanide Methyl mustard Methyl mustard oil
4427	**4-Pentenyl isothiocyanate** 5-Isothiocyanatopent-1-ene
4428	**Benzyl isothiocyanate** Isothiocyanatomethylbenzene (Isothiocyanatomethyl)benzene Benzyl mustard Benzyl mustard oil
4429	**2,4-Dimethyl-3-oxazoline** 2,4-Dimethyl-2,5-dihydro-1,3-oxazole

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)

	N-Gluconyl ethanolamine	*N*-Gluconyl ethanolamine phosphate	*N*-Lactoyl ethanolamine	*N*-Lactoyl ethanolamine phosphate	Ethanethiol	Heptane-1-thiol	*S*-Isopropyl 3-methylbut-2-enethioate	3-Methyl-hexanal	4-Pentenal	Propyl propane thiosulfonate	*alpha*-Ionene	*Gardenia gummifera* distillate
Category	**FEMA No. 4254**	**4255**	**4256**	**4257**	**4258**	**4259**	**4260**	**4261**	**4262**	**4263**	**4264**	**4265**
Baked goods			5/40		0.2/1	0.2/1	0.4/2					
Beverages (nonalcoholic)	15/150		5/50	5/15				0.5/0.5			0.5/0.5	10/30
Beverages (alcoholic)	5/30		5/50	5/15				0.5/0.5			0.5/0.5	10/30
Breakfast cereal	5/50		10/100		0.1/0.5	0.1/0.5	0.2/1	0.5/0.5			0.5/0.5	
Cheese	5/40		5/30		0.2/1	0.2/1	0.4/2					
Chewing gum	3/20		3/20					0.5/0.5			0.5/0.5	20/50
Condiments/ relishes	10/50				0.1/0.5	0.1/0.5	0.2/1					10/40
Confectionery frostings	5/50		5/50	5/15	0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	
Egg products												
Fats/oils	5/75				0.1/0.5	0.1/0.5	0.2/1					
Fish products					0.1/0.2	0.1/0.2	0.1/0.4					
Frozen dairy	5/40		1/25	5/15	0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	
Fruit ices	15/75		1/25	5/15	0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	
Gelatins/ puddings	5/40		1/25	5/15	0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	
Granulated sugar												
Gravies	10/100	5/15	5/30	5/15	0.1/0.5	0.1/0.5	0.2/1		0.005/0.1	0.01/1		
Hard candy	10/75		10/75	5/15	0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	10/15
Imitation dairy	5/50		1/15	5/15	0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	
Instant coffee/tea	3/30		1/15									
Jams/jellies				5/15								
Meat products	10/100	5/15	20/100		0.1/0.2	0.1/0.2	0.1/0.4					
Milk products	5/50		1/15		0.2/1	0.2/1	0.4/2	0.5/0.5			0.5/0.5	
Nut products												
Other grains					0.1/0.5	0.1/0.5	0.2/1					
Poultry	20/100		20/100		0.1/0.2	0.1/0.2	0.1/0.4					
Processed fruits				5/15	0.2/1	0.2/1	0.3/1.5	0.5/0.5			0.5/0.5	
Processed vegetables												
Reconstituted vegetables												
Seasonings/ flavors	5/15	5/15	5/15	5/15	0.1/0.5	0.1/0.5	0.2/1	0.5/0.5	0.005/0.1	0.01/1	0.5/0.5	100/500
Snack foods	10/100	5/15	5/50		0.4/2	0.4/2	1/5	0.5/0.5	0.005/0.1	0.01/1	0.5/0.5	15/50
Soft candy	10/75		10/75	5/15	0.2/1	0.2/1	0.4/2					10/40
Soups	10/100	5/15	5/60		0.1/0.5	0.1/0.5	0.2/1		0.005/0.1	0.01/1		
Sugar substitutes	5/15											
Sweet sauces					01./0.5	0.1/0.5	0.2/1	0.5/0.5			0.5/0.5	

	Piper longum distillate	*N*-3,7-Dimethyl-2,6-octadienyl cyclopropyl-carboxamide	(+/-)-Ethyl 2-hydroxy-2-methyl butyrate	(+/-)-Ethyl 2-hydroxy-3-methylvalerate	2-(2-Hydroxy-phenyl) cyclopropane-carboxylic acid *delta*-lactone	2-Decanone	(+/-)-*trans*- and *cis*-2-Hexenal propylene glycol acetal	(+/-)-*trans*- and *cis*-2-Hexenal glyceryl acetal	*trans*-2-Hexenyl 2-methyl-butyrate	2-(4-Methyl-5-thiazolyl)-ethyl formate	2-(4-Methyl-5-thiazolyl)-ethyl propionate	2-(4-Methyl-5-thiazolyl)-ethyl butanoate
Category	**4266**	**4267**	**4268**	**4269**	**4270**	**4271**	**4272**	**4273**	**4274**	**4275**	**4276**	**4277**
Baked goods		0.2/1			11/20	5/25					1/2.7	2.7/2.7
Beverages (nonalcoholic)	20/100	0.4/2	10/25	10/25	2/4	2/10	0.5/7.7	1/10	3/15	0.1/0.25		
Beverages (alcoholic)	30/150		10/25	10/25	1/5							
Breakfast cereal			10/30	10/30		2/10						
Cheese		2/8										
Chewing gum	50/200		20/100	20/100			10/90	10/50	25/100			
Condiments/ relishes	30/120	4/20										
Confectionery frostings						4/20						
Egg products		2/10										
Fats/oils						2/10						
Fish products		2/10				1/5						
Frozen dairy			5/20	5/20	6/15	3/15				0.1/0.15		
Fruit ices			5/20	5/20		3/15					1/2.9	
Gelatins/ puddings			10/25	10/25	7/15		1/7.5	2/10	10/20			2.0
Granulated sugar												
Gravies	30/150	4/10										
Hard candy	20/200		20/50	20/50	11/40		0.8/7.6	2/20	5/25			
Imitation dairy		2/10								0.1/0.15		
Instant coffee/tea			10/25	10/25								
Jams/jellies												
Meat products		2/10				1/5						
Milk products						3/15				0.1/0.15		
Nut products		1/4										
Other grains												
Poultry		2/10										
Processed fruits			5/20	5/20		2/10						
Processed vegetables		1/5				2/10						
Reconstituted vegetables		1/4										
Seasonings/ flavors	100/500											
Snack foods	30/150	5/20										
Soft candy	20/200		10/25	10/25	10/20		1/2.5	1/5	5/20			2.7
Soups		2/10				2/10						
Sugar substitutes												
Sweet sauces		2/10										

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)

	2-(4-Methyl-5-thiazolyl)-ethyl isobutyrate	2-(4-Methyl-5-thiazolyl)-ethyl hexanoate	2-(4-Methyl-5-thiazolyl)-ethyl octanoate	2-(4-Methyl-5-thiazolyl)-ethyl decanoate	(+/-)-3-(Ethylthio)-butanol	*Decalepis hamiltonii* extract	2-(*trans*-2-Pentenyl)-cyclopentanone	3,9-Dimethyl-6-(1-methyl-ethyl)-1,4-dioxaspiro[4.5]-decan-2-one	*cis*- and *trans*-2-Isobutyl-4-methyl-1,3-dioxolane	*cis*- and *trans*-2-Isopropyl-4-methyl-1,3-dioxolane	4-Aminobutyric acid	3-Mercapto-heptyl acetate
Category	**4278**	**4279**	**4280**	**4281**	**4282**	**4283**	**4284**	**4285**	**4286**	**4287**	**4288**	**4289**
Baked goods	5/30	0.5/0.9	1.0	5/45	10/50	10/50	1/20	10/30	15/50	15/30	50/300	3/5
Beverages (nonalcoholic)		0.1/0.1			1/10	5/50	1/20	20/40	5/50	5/50	20/100	1/3
Beverages (alcoholic)					1/10	10/50	1/20	20/40	5/10	5/10	30/200	5/10
Breakfast cereal					5/10	10/50	0/5	10/20	1/50		30/100	2/5
Cheese	0.1/0.16				1/10		0/5	20/40	1/50			
Chewing gum						10/100	1/20	40/60	1/100		100/500	5/10
Condiments/ relishes					2/10	10/25	0/5	5/10	10/50			
Confectionery frostings						10/50	1/20	40/60	1/50	10/20	30/100	0.5/2
Egg products							0/1	2/10	1/50			
Fats/oils							1/20	2/20	1/100		30/100	2/5
Fish products				1/4.8			0/5	1/10				
Frozen dairy						5/25	1/20	20/40	5/20	5/10		2/5
Fruit ices				1/3.8			1/20	20/40	0.5/20	0.5/2.5	20/100	
Gelatins/ puddings	10/42					10/50	1/20	5/10	5/20	5/10	20/100	2/4
Granulated sugar							0/5	5/10				
Gravies					2/10		0/5	2/10	1/50			
Hard candy					10/20	10/50	1/20	40/60	20/100	20/50	40/300	2/4
Imitation dairy						10/50	1/20	20/40	1/100			2/4
Instant coffee/tea						10/50	0/5	20/30	2/10	1/5	20/100	1/4
Jams/jellies							1/20	20/40	0.1/20			2/5
Meat products					3/20		0/5	5/10	1/100		20/200	
Milk products					2/10	5/25	1/20	20/40	5/50	5/10	30/100	0.5/3
Nut products							0/5	20/40	1/100			
Other grains							0/5	10/20	1/50			
Poultry							0/5	10/20	1/50			
Processed fruits							1/20	20/40	0.1/20			
Processed vegetables					2/10		0/5	5/10	0.1/20			
Reconstituted vegetables							0/5	5/10				
Seasonings/ flavors					5/30	200/1,000	1/5	2/5	1/100			50/100
Snack foods					5/30		1/20	5/10	1/100		10/100	
Soft candy	0.1/0.15		0.5/1.5	20/32	2/10	5/25	1/20	40/60	10/100	10/30	20/200	2/4
Soups				0.8/0.8	1/10		0/5	5/10	1/50		30/200	
Sugar substitutes							0/5	5/10				
Sweet sauces							1/20	20/40	0.8/20			

	Ethyl *trans*-2-methyl-2-pentenoate	Methyl hexyl ether	*trans*-2-*trans*-4-Nonadiene	1-Octene	*cis*- and *trans*-Ethyl 2,4-dimethyl-1,3-dioxolane-2-acetate	Citronellyl *trans*-2-methyl-2-butenoate	5-Acetyl-2,3-dihydro-1,4-thiazine	*Bis* (1-mercapto-propyl) sulfide	2,5-Dithiahexane	Pseudo-ionone	*cis*- and *trans*-*l*-Mercapto-*p*-menthan-3-one	*trans*-2-Nonen-4-one
Category	**4290**	**4291**	**4292**	**4293**	**4294**	**4295**	**4296**	**4297**	**4298**	**4299**	**4300**	**4301**
Baked goods			0.25/0.5	0.08/0.15	10/50	10/50	5/20			5/25	0.1/0.5	
Beverages (nonalcoholic)	2/20	5/20	0.25/0.5	0.08/0.15			1/10			2/10	1/5	1/10
Beverages (alcoholic)	2/20	5/20	0.25/0.5	0.08/0.15			2/10				1/5	2/10
Breakfast cereal	10/20	10/20	0.25/0.5	0.08/0.15	5/25	5/25	5/20			2/10		
Cheese				0.08/0.15	7/35	7/35	1/5	0.5/2		3/15	0.01/0.05	2/5
Chewing gum			0.25/0.5	0.08/0.15								5/15
Condiments/ relishes					5/10	5/25	5/25	0.2/1	0.02/0.2	2/10	0.01/0.05	5/25
Confectionery frostings			0.25/0.5	0.08/0.15	10/50	10/50	2/10			4/20	1/5	2/10
Egg products							1/5	1/5	0.02/0.2			
Fats/oils					5/25	5/25		1/5		2/10	0.01/0.05	
Fish products			0.25/0.5		2/10	2/10		1/5	0.02/0.2	1/5	0.01/0.05	
Frozen dairy	2/10	5/20	0.25/0.5	0.08/0.15	7/35	7/35	1/5		0.02/0.1	3/15	0.01/0.05	
Fruit ices	2/15	10/25	0.25/0.5	0.08/0.15	10/50	10/50				3/15	0.1/0.5	1/5
Gelatins/ puddings	5/25	10/25	0.25/0.5	0.08/0.15			2/10			5/25	0.01/0.05	2/10
Granulated sugar							2/10					
Gravies				0.08/0.15	20/100	20/110		0.5/2	0.02/0.2	2/10	0.01/0.05	
Hard candy	10/25	10/25	0.25/0.5	0.08/0.15			2/10					2/10
Imitation dairy				0.08/0.15	7/35	7/35	2/10			3/15	0.01/0.05	
Instant coffee/tea	5/20	5/20					2/10					2/10
Jams/jellies			0.25/0.5	0.08/0.15		20/110				5/25		
Meat products					2/10	2/10	1/5	1/10	0.02/0.2	1/5	0.01/0.05	
Milk products			0.25/0.5	0.08/0.15	7/35	7/35	2/5		0.01/0.1	3/15	0.01/0.05	1/5
Nut products								0.2/1	0.01/0.1			
Other grains					5/25	5/25	2/5			2/10		
Poultry					2/10	2/10		1/5	0.02/0.2	1/5	0.01/0.05	
Processed fruits	2/10	5/20	0.25/0.5	0.08/0.15	7/35	7/35				2/10	0.01/0.05	
Processed vegetables			0.25/0.5	0.08/0.15			1/5	1/5	0.01/0.1		0.01/0.05	
Reconstituted vegetables				0.08/0.15				0.2/1	0.01/0.1			
Seasonings/ flavors	100/1,000	100/1,000	0.25/0.5	0.08/0.15	5/10	5/25	50/1,000	50/1,000	10/50	2/10	0.01/0.05	50/1,000
Snack foods				0.08/0.15			2/10	0.5/2.5	0.02/0.1			2/10
Soft candy	5/25	10/25	0.25/0.5	0.08/0.15			2/10					2/10
Soups				0.08/0.15	5/10	5/25		0.5/2	0.02/0.1	2/10	0.01/0.05	
Sugar substitutes			0.25/0.5				10/25					10/25
Sweet sauces					5/10	5/25				2/10	0.01/0.05	

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)

	trans-4-Nonenal	1,1′-(Tetrahydro-6*a*-hydroxy-2,3*a*,5-trimethylfuro[2,3-*d*]-1,3-dioxole-2,5-diyl)*bis*-ethanone	*trans*-2-Decenol	*cis*-2-Pentenol	2-Methylbutyl 3-methyl-2-butenoate	Citric and fatty acid esters of glycerol	*l*-Menthyl (*R,S*)-3-hydroxybutyrate	*N*-[(Ethoxycarbonyl)methyl)-*p*-menthane-3-carboxamide	*N*-[2-(3,4-Dimethoxyphenyl)ethyl]-3,4-dimethoxycinnamic acid amide	Mixture of methyl cyclohexadiene and methylene cyclohexene	(+/-)-*cis*- and *trans*-1,2-Dihydroperillaldehyde	5,7-Dihydroxy-2-(3-hydroxy-4-methoxyphenyl)-chroman-4-one
Category	**4302**	**4303**	**4304**	**4305**	**4306**	**4307**	**4308**	**4309**	**4310**	**4311**	**4312**	**4313**
Baked goods		20/50	10/50	10/50		0.8/1.5	20/100	20/200	10/50	0.0025/1	1/5	200/500
Beverages (nonalcoholic)	1/10	5/10	5/25	5/25	2/8	0.2/0.3	15/50	10/50	3/20	0.0025/1	1/5	100/800
Beverages (alcoholic)	2/10	10/20			4/10		30/150	10/400	5/25	0.0025/2	2/10	200/800
Breakfast cereal		20/50	5/25	5/25	5/10		5/20	10/50		0.0001/1	1/5	150/600
Cheese		20/100	7/35	7/35			5/20	20/100		0/1		200/600
Chewing gum	5/15	50/200			10/20	45/90	1,000/2,000	100/1,000	50/100	0.0001/1	2/20	200/1,000
Condiments/relishes	5/25		5/25	5/25		0.2/0.4	30/150	20/300		0/2	1/5	
Confectionery frostings	2/10	10/50	10/50	10/50	5/10	4.5/9	150/700	10/200	10/20	0.1/1	2/10	100/500
Egg products								10/150		0/1		
Fats/oils		10/50	5/25	5/25				10/200		0.1/2		100/500
Fish products			2/10	2/10		0.03/0.06		10/100		0/1		100/500
Frozen dairy		5/20	7/35	7/35	5/10		10/40	10/300		0/1	1/5	100/500
Fruit ices	1/5	5/10	10/50	10/50	2/8		30/150	10/150	5/10	0.1/2	1/2	
Gelatins/puddings	2/10	10/30			2/8	2.5/5	70/250	5/100		0/1	1/5	100/500
Granulated sugar								15/100		0/1		100/800
Gravies			20/100	20/100		0.1/0.2	10/30	10/100		0/1		100/500
Hard candy	2/10	10/50			20/50	2/4	150/700	50/350	10/30	0.1/2	5/20	100/800
Imitation dairy		10/50	7/35	7/35			5/20	10/100		0/1		100/600
Instant coffee/tea	2/10	10/20				0.6/1.3	30/150	10/65	5/10	0/1	1/5	100/400
Jams/jellies		10/50	20/100	20/100	5/10			10/65		0.1/1		100/800
Meat products			2/10	2/10		0.002/0.004		10/100		0/1		100/600
Milk products		5/20	7/35	7/35	2/5	0.3/0.6	70/300	10/100	3/10	0/1	1/5	100/400
Nut products								10/200		0/1		
Other grains			5/25	5/25				10/300		0/1		
Poultry			2/10	2/10		0.003/0.006		10/100		0/1		
Processed fruits			7/35	7/35	4/10		30/150	10/200		0.1/1		
Processed vegetables								10/200		0/1		
Reconstituted vegetables								10/100		0/1		
Seasonings/flavors	50/1,000	20/100	5/25	5/25		0.1/0.2		20/200	5/20	0.1/1	100/1,000	200/1,000
Snack foods	2/10						10/30	20/300	5/20	0.1/1	2/10	200/800
Soft candy	2/10	10/50			5/10	3/6	150/700	10/150	5/20	0.1/2	1/5	
Soups		10/50	5/25	5/25		0.1/0.2	10/30	10/100		0/1		100/600
Sugar substitutes	10/25							5/100		0/1		100/1,000
Sweet sauces		10/50	5/25	5/25	5/10			10/100		0/1		100/800

	Phenethyl decanoate	3,6-Dimethyl-2,3,3*a*,4,5,7*a*-hexahydro-benzofuran	2-Methyl-acetophenone	1-Ethyl-2-pyrrolecarbox-aldehyde	*cis- and trans-* 5-Ethyl-2,5-dihydro-4-methyl-2-(1-methyl-propyl)-thiazole	*cis* and *trans-* 5-Ethyl-4-methyl-2-(2-methyl-propyl)-thiazoline	2-Methyl-3-furyl methylthio-methyl disulfide	Pyrrolidino-[1,2*E*]-4*H*-2,4-dimethyl-1,3,5-dithiazine	*S*-Allyl-*L*-cysteine	5-Pentyl-3*H*-furan-2-one	3-Mercapto-3-methyl-1-butyl acetate	(+/-)-3-Mercapto-1-butyl acetate
Category	**4314**	**4315**	**4316**	**4317**	**4318**	**4319**	**4320**	**4321**	**4322**	**4323**	**4324**	**4325**
Baked goods	10/15	100/500	5/25	1.2/3.6	0.4/2	0.4/2	0.002/0.1	0.02/0.1	2/25	2/10	0.5/3	0.5/3
Beverages (nonalcoholic)	4/9		2/10	0.3/0.9	0.2/1	0.2/1				1/3	0.2/1	0.2/1
Beverages (alcoholic)	1/4			1.5/4.5						2/10	0.2/1	0.2/1
Breakfast cereal			2/10	0.6/1.8	0.4/1	0.4/1	0.002/0.1		2/25	2/10	0.2/2	0.2/2
Cheese		25/125					0.002/0.2	0.02/0.1	2/25	2/10	0.5/2	0.5/2
Chewing gum				3/9						2/10	0.2/2	0.2/2
Condiments/ relishes		25/125					0.002/0.1	0.02/0.1	2/25	2/10	0.2/1	0.2/1
Confectionery frostings			4/20	1.2/3.6	0.4/2	0.4/2				1/5	0.2/1	0.2/1
Egg products												
Fats/oils		50/250	2/10		0.2/1	0.2/1	0.002/0.1	0.02/0.1	2/25	2/10		
Fish products			1/5		0.1/0.4	0.1/0.4	0.002/0.1	0.02/0.1	2/25			
Frozen dairy	10/15			0.6/1.8						1/5	0.1/1	0.1/1
Fruit ices			3/15	0.6/1.8	0.4/2	0.4/2					0.1/1	0.1/1
Gelatins/ puddings	7/14			0.6/1.8						1/5	0.2/1	0.2/1
Granulated sugar												
Gravies		50/250					0.002/0.1	0.02/0.1	2/25			
Hard candy				1.2/3.6						2/10	0.5/2	0.5/2
Imitation dairy		50/250							2/25	1/5	0.2/1	0.2/1
Instant coffee/tea				0.3/0.9			0.002/0.1		2/25	2/10	0.2/1	0.2/1
Jams/jellies				0.6/1.8						1/5	0.2/1	0.2/1
Meat products		25/125	1/5		0.1/0.4	0.1/0.4	0.002/0.1	0.02/0.1	2/25			
Milk products			3/5	0.6/1.8	0.4/2	0.4/2				1/5	0.1/1	0.1/1
Nut products			2/10		0.4/2	0.4/2	0.002/0.1		2/25	0.2/0.2	0.2/1	0.2/1
Other grains												
Poultry		25/125					0.002/0.1	0.02/0.1	2/25			
Processed fruits					0.3/1.5	0.3/1.5					0.1/1	0.1/1
Processed vegetables		25/125			0.3/1.5	0.3/1.5	0.002/0.1		2/25			
Reconstituted vegetables		25/125					0.002/0.1		2/25			
Seasonings/ flavors		500/5,000					0.002/0.1	0.02/0.1	2/25	100/1,000	10/1,000	10/1,000
Snack foods		50/250		0.3/0.9			0.002/0.1	0.02/0.1	2/25	1/5	0.2/1	0.2/1
Soft candy	10/20			0.6/1.8						1/5	0.2/1	0.2/1
Soups		25/125	2/10		0.2/1	0.2/1	0.002/0.1	0.02/0.1	2/25			
Sugar substitutes												
Sweet sauces				0.6/1.8						1/5	0.2/1	0.2/1

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)

	5-Nonen-*trans*-2-one	*l*-Menthyl acetoacetate	4-Octen-3-one	2,4,6-Trimethyl-phenol	4-Hydroxy-acetophenone	(+/-)-[*R*-(*E*)]-5-Isopropyl-8-methylnona-6,8-dien-2-one	*1*-Methyl-1*H*-pyrrole-2-carbox-aldehyde	1-Pentanethiol	Pentadecanoic acid	Tridecanal	Tridecanoic acid	Hexyl heptanoate
Category	**4326**	**4327**	**4328**	**4329**	**4330**	**4331**	**4332**	**4333**	**4334**	**4335**	**4336**	**4337**
Baked goods	2/10	100/200	1/5	0.1/0.5	0.1/0.5	0.1/0.5	0.1/0.5	0.06/0.5	0.5/5	0.05/0.5	0.02/0.2	
Beverages (nonalcoholic)	2/10	50/200	1/5	1/5	1/5	1/5	1/5			1/10		0.2/1
Beverages (alcoholic)	5/10	50/300	2/10	1/5	1/5	1/5	1/5					0.4/2
Breakfast cereal	2/10	100/200	1/5									
Cheese				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05				
Chewing gum	2/10	1,000/6,000	2/20									
Condiments/ relishes			1/5	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					
Confectionery frostings	2/10	50/100	1/5	1/5	1/5	1/5	1/5					
Egg products												
Fats/oils									1/5			
Fish products				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.1/0.5				
Frozen dairy	2/10	100/200	1/5	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					
Fruit ices	2/10	100/200	1/5	0.1/0.5	0.1/0.5	0.1/0.5	0.1/0.5					0.5/2.5
Gelatins/ puddings	2/10	100/200	1/5	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					
Granulated sugar												
Gravies				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.05/0.5				
Hard candy	2/10	200/1,000	2/10									1/5
Imitation dairy				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05		0.2/1			
Instant coffee/tea	2/10	25/100	2/20									
Jams/jellies	2/10		1/5									0.5/2.5
Meat products				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.1/0.5				
Milk products	1/5			0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.1/0.5	0.1/0.5			
Nut products												
Other grains												
Poultry				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					
Processed fruits	2/10	100/200	1/5	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					
Processed vegetables				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					
Reconstituted vegetables												
Seasonings/ flavors	100/1,000	100/1,000	100/1,000	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.4/2	1/5			
Snack foods		100/200	1/5	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05		0.2/1			
Soft candy	2/10	300/1,000	1/5									
Soups				0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05	0.1/0.5				
Sugar substitutes												
Sweet sauces	2/10		1/5	0.01/0.05	0.01/0.05	0.01/0.05	0.01/0.05					

	Dodecyl propionate	Hexyl nonanoate	Dodecyl butyrate	Heptyl heptanoate	Hexyl decanoate	Ethyl 4-methyl-pentanoate	Ethyl 2-ethylbutyrate	Ethyl 2-ethyl-hexanoate	5-Methylhexyl acetate	4-Methylpentyl isovalerate	3,7-Dimethyl-octanal	*cis*-4-Decenol
Category	4338	4339	4340	4341	4342	4343	4344	4345	4346	4347	4348	4349
Baked goods	5/10	0.4/10	2/20				2/200					
Beverages (nonalcoholic)	10/100	10/100	10/100	3/15	0.3/1.5	5/50	2/50		10/100		0.1/0.5	0.3/1.5
Beverages (alcoholic)					0.5/2.5							0.5/2.5
Breakfast cereal							2/200					
Cheese							2/200					
Chewing gum	50/250	10/200	50/250	25/100			10/500	4/20				
Condiments/ relishes							2/200					
Confectionery frostings							1/50					
Egg products							2/200					
Fats/oils	5/100	0.4/10	2/20				2/200					
Fish products							2/200					
Frozen dairy	0.2/3	0.2/2	0.2/3				1/50					
Fruit ices					0.5/2.5		2/50	1/5			0.2/1	0.5/2.5
Gelatins/ puddings				10/20			1/50					
Granulated sugar												
Gravies							1/50					
Hard candy	20/40	0.4/10	5/20	5/25	1/5		10/500	2/10	5/10		0.5/2.5	1.5/7.5
Imitation dairy							1/50					
Instant coffee/tea											0.5/2.5	
Jams/jellies					0.5/2.5		1/50	1/5			0.2/1	0.8/4
Meat products							2/200			0.2/1		
Milk products	5/30						2/200					
Nut products							2/200					
Other grains							2/200					
Poultry							2/200					
Processed fruits							2/200	0.01/0.04				
Processed vegetables							1/50			0.2/1		
Reconstituted vegetables												
Seasonings/ flavors							5/500			0.05/0.25		
Snack foods	5/20						1/50			0.1/0.5		
Soft candy				5/20			5/500	2/10				
Soups							1/50			0.01/0.5		
Sugar substitutes												
Sweet sauces							2/200	0.01/0.04				

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)

	cis-5-Octenoic acid	5-Hexenol	3-Isopropenyl-pentanedioic acid	Methyl 4-pentenoate	*cis*-4-Octenol	11-Dodecenoic acid	*trans*-3-Hexenol	*trans*-4-Octenoic acid	Isobutyl 10-undecenoate	*cis*-9-Octadecenyl acetate	Ethyl 4-pentenoate	Ethyl 3-octenoate
Category	4350	4351	4352	4353	4354	4355	4356	4357	4358	4359	4360	4361
Baked goods	1/2	0.25		2/5		0.2/9	15/30	0.1/0.2	20/46	50/150	2/5	
Beverages (nonalcoholic)		0.04			1/5		5/15		0.5/3	3/15		0.3/1.5
Beverages (alcoholic)					1.5/7.5		0.1/15		2/10			0.5/2.5
Breakfast cereal												
Cheese												
Chewing gum			0.2/1				200/1,000		0.1	50/250		
Condiments/relishes												
Confectionery frostings							10/40					
Egg products												
Fats/oils							5/50			20/100		
Fish products												
Frozen dairy							10/20			10/30		
Fruit ices					1.5/7.5		0.5/20					0.5/2.5
Gelatins/puddings									2/3	5/20		
Granulated sugar												
Gravies												
Hard candy		0.04/0.2	0.1/0.5		4/20		10/50		7/20	2/20		1.5/7.5
Imitation dairy												
Instant coffee/tea							1/5					
Jams/jellies					2/10		0.01/2					0.8/4
Meat products												
Milk products						0.01/0.2						
Nut products												
Other grains												
Poultry												
Processed fruits												
Processed vegetables												
Reconstituted vegetables												
Seasonings/flavors												
Snack foods												
Soft candy		0.04	0.2/1				10/50		5			0.5
Soups							1/20			10/30		
Sugar substitutes												
Sweet sauces									3			

	3-Octenoic acid	*cis*-9-Octadecenol	Decanal propylene-glycol acetal	Acetaldehyde hexyl isoamyl acetal	Dodecanal dimethyl acetal	Nonanal dimethyl acetal	Heptanal propylene-glycol acetal	Hexanal hexyl isoamyl acetal	Hexanal dihexyl acetal	Isovaler-aldehyde diethyl acetal	Valer-aldehyde propylene-glycol acetal	Nonanal propylene-glycol acetal
Category	4362	4363	4364	4365	4366	4367	4368	4369	4370	4371	4372	4373
Baked goods		20/100	10/50							5/50	1/50	1/50
Beverages (nonalcoholic)			1/10	1/10	2/10	1/10	3/15	0.2/2	1/10	10/100	1/20	1/20
Beverages (alcoholic)					4/20		4/20			1/5		
Breakfast cereal			1/30							1/100	1/50	1/50
Cheese			1/30							1/100	1/50	0.1/20
Chewing gum			10/50						5/30	5/500	1/100	2/10
Condiments/ relishes			0.2/40							1/100	1/50	1/50
Confectionery frostings			0.2/40							1/100	1/50	1/50
Egg products			1/30							1/100	1/50	1/50
Fats/oils	2/10		1/100							1/30	1/100	1/50
Fish products			0.2/40							1/50		
Frozen dairy			0.2/40					0.5/3	0.5/3	2/50	0.1/20	0.1/20
Fruit ices			2/40		4/20		6/30			1/50	0.1/20	1/20
Gelatins/ puddings			0.2/40		2/10			0.5/3		2/50	0.1/20	0.1/20
Granulated sugar												
Gravies			1/30							1/100	1/50	1/50
Hard candy			1/100				5/25		2/10	10/500	1/100	1/50
Imitation dairy	0.5/2.5		1/30							5/500	1/100	1/50
Instant coffee/tea										2/10		
Jams/jellies							6/30			1/50	0.1/20	0.1/20
Meat products	0.5/2.5		0.2/40							1/100	1/100	1/50
Milk products			2/30							1/100	1/50	1/50
Nut products			1/30							1/100	1/100	0.1/20
Other grains			1/30							1/50	1/50	
Poultry			1/30							1/100	1/50	0.1/20
Processed fruits										1/50	0.1/20	
Processed vegetables										0.1/20	0.1/20	
Reconstituted vegetables												
Seasonings/ flavors	5/25		1/100							5/500	1/100	1/50
Snack foods	1/5		1/30							1/100	1/100	0.1/20
Soft candy			1/100		10/50		5.0			5/500	1/100	1/50
Soups			0.2/40							1/50	1/50	0.1/20
Sugar substitutes												
Sweet sauces										1/50	0.1/20	0.1/20

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)

	Undecanal propylene-glycol acetal	Valeraldehyde dibutyl acetal	Acetaldehyde 1,3-octanediol acetal	Hexanal octane-1,3-diol acetal	Iso-valeralde-hyde glyceryl acetal	Acetaldehyde di-*cis*-3-hexenyl acetal	2,6-Dimethyl-5-heptenal propylene-glycol acetal	Octanal propylene-glycol acetal	Hexanal butane-2,3-diol acetal	Pecan shell flour	Di-(1-propenyl)-sulfide (mixture of isomers)	2-Pentyl-thiophene
Category	4374	4375	4376	4377	4380	4381	4382	4383	4384	4385	4386	4387
Baked goods		1/50			8/40	2/300	0.2/1	10/50			0.2/0.5	0.2/1
Beverages (nonalcoholic)	0.5/2.5		0.2/1	0.3/1.5	10/50	5/300	5/25	1/10	0.4/2		0.05/0.1	
Beverages (alcoholic)			0.4/2	0.5/2.5					0.6/3		0.1/0.2	
Breakfast cereal		1/50				2/300						
Cheese		1/50				2/300					0.2/0.4	0.01/1
Chewing gum	5/25	0.1/20			50/250	5/500	40/200	10/50				
Condiments/ relishes		0.1/20				2/300					0.5/2.5	0.1/1
Confectionery frostings		1/50				5/500						
Egg products		1/50				2/300						0.3/1
Fats/oils		1/50				5/500	0.5/2	0.5/10			0.2/0.4	0.1/1
Fish products											0.1/0.3	0.2/1
Frozen dairy		0.1/20				5/500		1/10				
Fruit ices	1/5	0.1/20	0.5/2.5	0.5/2.5		5/500	6/30		0.6/3			
Gelatins/ puddings					3/15	5/500		2/10				
Granulated sugar												
Gravies		0.1/20				5/500					0.1/0.3	0.2/1
Hard candy	1/5	1/50	1/5	1.5/7.5	10/50	5/500	20/100	1.6/10	2/10		0.5/1	
Imitation dairy		1/50				5/500						
Instant coffee/tea												
Jams/jellies		0.1/20	0.5/2.5	0.8/4		5/500			1/5			
Meat products		1/50				2/300				2,000/3,000	0.5/2	0.1/1
Milk products		1/50						2/10			0.2/0.5	
Nut products		0.1/20										
Other grains		0.1/20				5/500						
Poultry		1/30									0.5/1	0.1/1
Processed fruits						5/500						
Processed vegetables						5/500					0.5/1	0.01/1
Reconstituted vegetables												0.01/1
Seasonings/ flavors		1/100				5/500					0.5/2	1/50
Snack foods		1/50				2/300					0.4/1	0.1/1
Soft candy		1/50				5/500	20/100	1.6/10	2.0			
Soups		0.1/20				2/300					0.2/0.4	0.2/1
Sugar substitutes												
Sweet sauces		0.1/20				5/500						

	5-Ethyl-2-methylthiazole	2,4-Dimethyl-pyridine	3-(4-Hydroxy-phenyl)-1-(2,4,6-trihydroxy-phenyl)-propan-1-one	(+/-)-Ethyl 3-hydroxy-2-methyl-butyrate	(+/-)-Ethyl 3-mercapto-2-methyl-butanoate	(+/-)-*cis*- and *trans*-2-Methyl-2-(4-methyl-3-pentenyl)-cyclopropane-carbaldehyde	Trimethyl-oxazole	2,5-Dimethyl-4-ethyloxazole	2-Propyl-4,5-dimethyl-oxazole	2-Isobutyl-4,5-dimethyl-oxazole	2-Methyl-4,5-benzoxazole	2-Nonanone propylene-glycol acetal
Category	**4388**	**4389**	**4390**	**4391**	**4392**	**4393**	**4394**	**4395**	**4396**	**4397**	**4398**	**4399**
Baked goods		0.1/0.3	30/300	2/10	0.2/1	133/178	0.4/2	0.4/2	0.4/2	2/10	0.4/2	0.2/2
Beverages (nonalcoholic)		0.1/0.3	20/300	2/10	0.1/1	17/28	0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	0.05/0.2
Beverages (alcoholic)		0.1/0.3	40/300	5/10	0.2/2	3/6						0.05/0.5
Breakfast cereal		0.5/1	30/300	2/10	0.2/1		0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	
Cheese		0.5/1	40/300				0.4/2	0.4/2	0.4/2	0.4/2	0.4/2	0.1/1
Chewing gum		0.1/0.3	40/400	2/10		147/430						
Condiments/ relishes	0.01/2	10/40			0.1/0.3	10/10	0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	
Confectionery frostings	0.01/1	3/10	20/200	2/10	0.1/0.3		0.4/2	0.4/2	0.4/2	1/5	0.4/2	
Egg products		0.1/0.3										
Fats/oils		20/40	40/200				0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	0.1/1
Fish products		0.1/0.3	30/200				0.1/0.4	0.1/0.4	0.1/0.4	0.2/1	0.1/0.4	
Frozen dairy	0.01/2	0.1/0.3	20/200	2/10	0.1/0.5	22/34	0.4/2	0.4/2	0.4/2	0.4/2	0.4/2	0.05/0.2
Fruit ices		0.1/03	30/300	2/10			0.4/2	0.4/2	0.4/2	0.4/2	0.4/2	
Gelatins/ puddings		0.1/0.3	20/200	2/10	0.1/0.4	174/210	1/5	1/5	1/5	1/5	1/5	0.1/0.5
Granulated sugar		0.1/0.3	20/300		0.2/1							
Gravies		3/10	20/300			1/1	1/5	1/5	1/5	1/5	1/5	
Hard candy	0.01/1	0.1/0.3	20/300	2/10	0.2/2	8/115						0.1/1
Imitation dairy		0.5/1	20/400		0.2/1		0.4/2	0.4/2	0.4/2	0.4/2	0.4/2	
Instant coffee/tea		5/10	20/400	2/10	0.2/1							
Jams/jellies		0.1/0.3	20/400	2/10			1/5	1/5	1/5	1/5	1/5	
Meat products		30/40	20/200			1/2	0.1/0.4	0.1/0.4	0.1/0.4	0.2/1	0.1/0.4	
Milk products		0.1/0.3	20/300	1/5	0.1/0.3		0.4/2	0.4/2	0.4/2	0.4/2	0.4/2	
Nut products		5/10	20/300									
Other grains		5/10			0.2/1		0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	
Poultry		20/40					0.1/0.4	0.1/0.4	0.1/0.4	0.2/1	0.1/0.4	
Processed fruits		0.1/0.3		2/10			0.3/1.5	0.3/1.5	0.3/1.5	0.4/2	0.3/1.5	
Processed vegetables		1/3			0.1/0.3							
Reconstituted vegetables		1/3										
Seasonings/ flavors		0.1/0.3	30/300	100/1,000	20/200		0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	
Snack foods		1/3	30/300		0.1/0.5		0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	0.1/1
Soft candy	0.01/1	0.1/0.3	30/300	2/10	0.1/0.3	142.3/.181.1						0.1/1
Soups	0.01/2	20/40	10/100				0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	
Sugar substitutes		0.1/0.3	20/200		0.2/2							
Sweet sauces		0.1/0.3	20/200	2/10			0.2/1	0.2/1	0.2/1	0.2/1	0.2/1	

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)

	6-Methyl-5-hepten-2-one propylene-glycol acetal	2-Pentyl 2-methyl-pentanoate	3-Octyl butyrate	Dimethyl-benzyl carbinyl crotonate	Dimethyl-benzyl carbinyl hexanoate	1,5-Octadien-3-one	10-Undecen-2-one	2,4-Dimethyl-4-nonanol	8-Nonen-2-one	8-*p*-Menthene-1,2-diol	Caryophyll-ene alcohol	*d*-2,8-*p*-Menthadien-1-ol
Category	**4400**	**4401**	**4402**	**4403**	**4404**	**4405**	**4406**	**4407**	**4408**	**4409**	**4410**	**4411**
Baked goods		0.02/0.1			1/10			10/50			1/10	
Beverages (nonalcoholic)	0.1/1		1/10	1/2	0.5/1	0.05/0.5		2/10		0.1/0.5	0.1/1	0.1/0.5
Beverages (alcoholic)	0.1/2				0.5/1			2/20		0.2/1	0.3/5	0.2/1
Breakfast cereal									0.00002/0.0001			
Cheese											0.2/3	
Chewing gum	2/10	0.1/0.5			30/100			30/300		1/5	3/20	1/5
Condiments/ relishes												
Confectionery frostings												
Egg products												
Fats/oils												
Fish products												
Frozen dairy		0.01/0.05		2/3	1/10			5/30	0.00002/0.0001		0.3/3	
Fruit ices	0.1/2			2/3	1/10			2/20			0.2/3	
Gelatins/ puddings	0.1/2			2/3	1/10			2/20		0.2/1	0.2/3	0.2/1
Granulated sugar												
Gravies												
Hard candy	0.5/3	0.02/0.1	10/100	10/20	30/100	0.5/5	0.00001/0.0001	5/30		0.5/2.5	1/5	0.5/2.5
Imitation dairy									0.002/0.005			
Instant coffee/tea												
Jams/jellies					1/10							
Meat products												
Milk products		0.01/0.05					0.00001/0.0001		0.002/0.005			
Nut products												
Other grains												
Poultry												
Processed fruits												
Processed vegetables												
Reconstituted vegetables												
Seasonings/ flavors												
Snack foods		2.5/10										
Soft candy	0.1/2	0.02/0.1		10/20	30/100						1/5	
Soups												
Sugar substitutes												
Sweet sauces												

	cis-3-Nonen-1-ol	*trans*-3-Hexenyl acetate	4-(Methylthio) butyl isothio-cyanate	6-(Methylthio)-hexyl isothio-cyanate	5-(Methylthio)-pentyl isothio-cyanate	Amyl isothio-cyanate	3-Butenyl isothio-cyanate	2-Butyl-isothio-cyanate	Ethyl isothio-cyanate	5-Hexenyl isothio-cyanate	Hexyl isothio-cyanate	Isoamyl isothio-cyanate
Category	**4412**	**4413**	**4414**	**4415**	**4416**	**4417**	**4418**	**4419**	**4420**	**4421**	**4422**	**4423**
Baked goods	0.02/0.2							2/20				
Beverages (nonalcoholic)	0.1/1	2/10	1/10	1/10	1/10		1/10	1/10		1/10	1/10	
Beverages (alcoholic)	0.1/1	2/10	1/10	1/10	1/10		1/10	1/10		1/10	1/10	
Breakfast cereal												
Cheese			0.5/5	0.5/5	0.5/5		0.5/5	0.5/5		0.5/5	0.5/5	
Chewing gum	0.2/2	5/25	5/50	5/50	2/20		5/50	5/50		5/50	5/50	
Condiments/ relishes			2/20	5/50	2/20	5/25	40/400	15/80		50/500	1/10	2/10
Confectionery frostings												
Egg products												
Fats/oils								1/10	0.1/0.5			
Fish products								1/5				
Frozen dairy	0.1/1							1/5				
Fruit ices												
Gelatins/ puddings												
Granulated sugar												
Gravies								1/10				
Hard candy	0.2/2	5/25	2/20	2/20	2/20		2/20	2/20		2/20	2/20	
Imitation dairy								1/10				
Instant coffee/tea												
Jams/jellies												
Meat products								0.5/5	0.5/2.5			
Milk products	0.1/1											
Nut products			0.5/5	0.5/5	0.5/5		0.5/5	0.5/5		0.5/5	0.5/5	
Other grains				0.5/2.5	1/5	0.1/0.5						0.1/0.5
Poultry												
Processed fruits												
Processed vegetables							0.5/2.5	0.5/5				
Reconstituted vegetables								0.5/5				
Seasonings/ flavors				0.8/4	1/5	0.1/0.5	10/100	5/50	0.2/1	10/100	5/50	0.1/0.5
Snack foods			0.5/5	0.5/5	1/5	0.1/0.5	1/10	1/10	0.1/0.5	2/20	0.5/5	0.1/0.5
Soft candy	0.2/2	5/25	2/20	2/20	2/20		2/20	2/20		2/20	2/20	
Soups			0.5/5	0.8/5	1/5	0.1/0.5	1/5	0.5/5	0.1/0.5	1/5	0.5/5	0.1/0.5
Sugar substitutes												
Sweet sauces												

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)

	Isobutyl isothiocyanate	Isopropyl isothiocyanate	Methyl isothiocyanate	4-Pentenyl isothiocyanate	Benzyl isothiocyanate	2,4-Dimethyl-3-oxazoline
Category	**4424**	**4425**	**4426**	**4427**	**4428**	**4429**
Baked goods		2/20			0.4/2	0.4/2
Beverages (nonalcoholic)	1/10			1/10	0.2/1	0.2/1
Beverages (alcoholic)	1/10			1/10		
Breakfast cereal					0.2/1	0.2/1
Cheese	0.5/5	0.5/5		0.5/5	0.4/2	0.4/2
Chewing gum	2/20			5/50		
Condiments/ relishes	5/25	10/50		100/700	0.2/1	0.2/1
Confectionery frostings					0.4/2	0.4/2
Egg products						
Fats/oils		1/10	0.05/0.25		0.2/1	0.2/1
Fish products					0.1/0.4	0.1/0.4
Frozen dairy					0.4/2	0.4/2
Fruit ices					0.4/2	0.4/2
Gelatins/ puddings					1/5	1/5
Granulated sugar						
Gravies		1/10			1/5	1/5
Hard candy	1/10			3/30		
Imitation dairy		1/10			0.4/2	0.4/2
Instant coffee/tea						
Jams/jellies					1/5	1/5
Meat products		0.5/5	0.25/2		0.1/0.4	0.1/0.4
Milk products					0.4/2	0.4/2
Nut products	0.5/5			0.5/5		
Other grains	0.1/0.5	0.5/5		0.5/2.5	0.2/1	0.2/1
Poultry					0.1/0.4	0.1/0.4
Processed fruits					0.3/1.5	0.3/1.5
Processed vegetables		0.5/5				
Reconstituted vegetables		0.5/5				
Seasonings/ flavors	0.5/2.5	5/50	0.1/0.5	10/100	0.2/1	0.2/1
Snack foods	0.5/5	1/10	0.05/0.25	2/20	0.2/1	0.2/1
Soft candy	1/10			3/30		
Soups	0.5/5	1/5	0.05/0.25	0.5/5	0.2/1	0.2/1
Sugar substitutes						
Sweet sauces					0.2/1	0.2/1

TABLE 3: Updated Average Usual Use Levels/Average Maximum Use Levels

Updated average usual use levels (ppm)/average maximum use levels (ppm) for flavoring substances previously recognized as FEMA GRAS

	Cardamom seed oil	Cinnamic acid	Sodium 2-(4-methoxy-phenoxy) propanoate	Neo-hesperidine dihydro-chalcone	Iso-quercitrin, enzymatic-ally modified
	FEMA 2241	**2288**	**3773**	**3811**	**4225**
Category	**GRAS List 3**	**3**	**15**	**17**	**22**
Baked goods	51.5/70[a]	232.88/383.67	100/150	4/4	
Beverages (nonalcoholic)	2.29/4.04	300[a]/400[a]	80/130	5[a]/10[a]	150/200
Beverages (alcoholic)	111.14/120[a]	570/712	150[a]/250[a]	5[a]/10[a]	150[a]/200[a]
Breakfast cereal			100/150	3/3	
Cheese			50/80	3/4	
Chewing gum	50[a]/4500[a]		80/130	200/200	1,500/2,000
Condiments/ relishes	61.84/70[a]		100/150	2/3	
Confectionery frostings			70/100	3/3	
Egg products				2/3	
Fats/oils				4/4	
Fish products				2/3	
Frozen dairy	5.62/10[a]	191.68/262.82	100/150	2/3	150/200
Fruit ices			75/125	1/2	
Gelatins/ puddings	12.91/15[a]	265/290	85/135	2/3	150/200
Granulated sugar					
Gravies	5/10		90/140	3/4	
Hard candy	50[a]/3500[a]	0.01/0.01	100/150	5[a]/15[a]	
Imitation			80/130	3/4	
Instant coffee/tea				2/3	
Jams/jellies			85/135	2/3	
Meat products	36.18/55[a]		70/100	2/3	
Milk products			5/50	3[a]/6[a]	
Nut products				3/4	
Other grains			70/100	3/4	
Poultry				2/3	
Processed			50/80	2/3	
Processed vegetables			50/80	2/3	
Reconstituted vegetables				2/3	
Seasonings/ flavors			100/150	3/4	
Snack foods			100/150	3/3	
Soft candy	6.74/8.03	249.38/356.04	100/150	2/3	150/200
Soups				5[a]/10[a]	
Sugar substitutes				4/4	
Sweet sauces			90/140	2/3	

[a]*New use level.*

TABLE 4: Examples of FEMA GRAS Substances with Non-Flavor Functions

Substance	FEMA No.	Function in flavorings	Other food-related functions
Acetone	3326	Flavor/solvent	Extraction solvent
Butylated hydroxytoluene	2184	Antioxidant	Antioxidant
Disodium 5′-guanylate	3668	Modifier	Flavor enhancer
Disodium 5′-inosinate	3669	Enhancer	Flavor enhancer
Ethanol	2419	Flavor/solvent	Extraction solvent/vehicle
Guar gum	2537	Emulsifier	Stabilizer/thickener/ emulsifier
Lactisole	3773	Modifier	
Methyl paraben	2710	Preservative	Antimicrobial agent
Neohespiridin dihydrochalcone	3811	Modifier	Sweetener
Propyl gallate	2947	Antioxidant	Adhesive/coatings
Thaumatin	3732	Modifier	Sweetener
Triacetin	2007	Solvent/humectant/adjuvant	Plasticizer
Beta-cyclodextrin	4028	Flavor inclusion complex	
Grape seed extract	4045	Flavor modifier	
Diacetyl tartaric acid esters of mono- and diglycerides	4092	Flavor modifier	Emulsifier/ emulsifier salt
Tomato lycopene	4110	Antioxidant/stabilizer	Color
Glyceryl-lacto esters of fatty acids	4124	Flavor modifier	Emulsifier/ plasticizer
Lactylated fatty acid esters of glycerol and propylene glycol	4153	Flavor modifier	Emulsifier/ plasticizer
Betaine	4223	Flavor modifier	Nutrient
Adenosine monophosphate	4224	Flavor modifier	
Isoquercitrin, enzymatically modified	4225	Antioxidant/preservative	
Glycerol ester of rosin	4226	Adjuvant/emulsifier	Chewing gum base
Gum arabic, hydrogen octenylbutane dioate	4227	Flavor encapsulating agent/emulsifier	Stabilizer/adjuvant/ formulation aid
(-)-Homoeriodictyol, sodium salt	4228	Flavor modifier	
(+-)-N,N-Dimethyl menthyl succinamide	4230	Flavor modifier	
5,7-Dihydroxy-2-(3-hydroxy-4-methoxy-phenyl)-chroman-4-one	4313	Flavor modifier	