## Recent Progress in the Consideration of Flavoring Ingredients Under the Food Additives Amendment

## 13. GRAS Substances

BERNARD L. OSER, RICHARD A. FORD, AND BRUCE K. BERNARD

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☐ IT IS NOW more than a quarter of a century since the passage of the Food Additives Amendment of 1958. At that time, the Flavor and Extract Manufacturers' Association (FEMA) initiated usage surveys and other steps toward evaluating the GRAS (Generally Recognized as Safe) status of flavoring substances under their conditions of use. The early results of this program were published in three articles (Hall, 1959, 1960; and Hall and Oser, 1961) and included the following issues among others; (a) the unique problems, methodologies, and approaches required in evaluating the safety of flavoring substances employed in the total diet at a few parts per billion or less; (b) the importance of obtaining accurate usage data (total poundage and concentration levels) for flavoring substances; and (c) the method by which FEMA would review the GRAS status of flavors.

#### **EXPERT PANEL**

By 1960, FEMA convened a panel of independent experts, toxicologists, and pharmacologists to review all data relevant to the safety of flavoring substances. This process was undertaken with the knowledge and encouragement of the Food and Drug Administration (FDA). The decision to create this panel, the qualifications required of potential participants, the names of the initial members, and the methods to be employed in review of flavors were previously reported (Hall and Oser, 1961; Oser and Hall, 1977).

A significant portion of the work of the expert panel during the early years involved reviewing information on the more than 1,400 flavoring substances reported to be in use prior to 1958.

The results of these deliberations and their relationship to the provisions of the 1958 Food Additives Amendment were published by Hall and Oser (1965).

In succeeding years, the expert panel has dealt less with substances already in use and more with new substances intended for use as flavors and additional uses for previously listed substances. It has been the policy of FEMA to encourage the industry to submit these additions and alterations to the expert panel for review of their GRAS status.

The results of these deliberations have been published as a series of articles (GRAS lists) in Food

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Technology (Hall and Oser, 1965, and 1970; Oser and Hall, 1972; Oser and Ford, 1973a, 1973b; 1974; 1975; 1977; 1978; 1979). It has been the consistent policy of FEMA to publish, or require the publication of the background data and usage levels relevant to safety evaluation. Since the mid-1970s, these have been in the form of Scientific Literature Reviews (SLR) initially performed under contract with the FDA. All of this has resulted in the wide recognition of FEMA GRAS lists. The FDA adopted, with very few exceptions, the first such list of substances in the form of two Food Additive Regulations (Code of Federal Regulations Title 21). It is the view of all those involved with the GRAS concept, including FDA and FEMA, that only by publication can the scientific community have the opportunity to comment on or take issue with the opinion of other specialists in the field of food safety evaluation. The purpose of this report is to present the conclusions reached by the expert panel with respect to the substances submitted for GRAS consideration during the period 1979-1983. Release of GRAS 13 has been delayed pending completion of the SLR revisions. This process is now complete, and FEMA is exploring means by which these updated SLRs can be made available to the

The rationale for selection of the original panel has been previously described. The current panel consists of scientists who are qualified by training and years of experience in pharmacology, toxicology, nutrition, organic chemistry, metabolism, and animal and comparative pathology as related particularly to the safety evaluation of flavors. Panel members involved with decisions presented herein and their most recent institutional affiliation were: Dr. Ambrose, retired, Medical College of Virginia; Dr. John M. Doull, University of Kansas Medical Center; Dr. David W. Fassett, retired, Eastman Kodak Company; Dr. Paul M. Newberne, Massachusetts Institute of Technology; Professor Robert L. Smith, St. Mary's Hospital Medical School, University of London; Dr. Howard C. Spencer, retired, Dow Chemical Corporation; Mr. Carrol S. Weil, retired, Bushy Run Research Center; and Dr. Lauren A. Woods, Virginia Commonwealth University. Dr. Bernard L. Oser, consultant to FEMA, served as chairman. Dr. Anthony Ambrose, a long-time member of the panel, participated in nearly all of the deliberations but is since deceased. Professor R. Tecwyn Williams, St. Mary's Hospital Medical School, University of London, also deceased, had been unable to participate in the GRAS evaluations in this report. Dr. Spencer, an original panel member, participated in all GRAS 13 decisions and has recently retired from the panel. Each of these three members made extensive and substantial contributions to the workings of the panel. Dr. Bernard M. Wagner, Overlook Hospital, Columbia College of Physicians and Surgeons, a recent addition to the panel, did not participate in the evaluations reported herein.

#### **REAFFIRMATION OF GRAS STATUS**

The importance of reevaluation at reasonable intervals, taking into account any new and relevant data on substances previously determined to be GRAS, has been discussed by FDA, FEMA, and others involved in the flavor and food industries. Such reexaminations are based on knowledge of changes in current usage levels and consumption patterns, pertinent toxicological data reported in the literature, and results of significant but not yet published studies. To this end, the process of GRAS reaffirmation of flavoring substances previously determined to be GRAS was undertaken by the expert panel several years ago. The process will be completed following a comprehensive review of past, current, and projected studies and updated usage and consumption data.

FEMA continues to sponsor studies on the safety evaluation of structural classes of flavor substances. A current example is the series of metabolism studies underway at St. Mary's Hospital Medical Center, University of London, on the species and dose-dependent metabolism of the substituted propyl benzene family (Zangouras et al., 1981; Caldwell et al., 1982, 1983; Sangster et al., 1983). Such work has direct application to the validity of employing animal data to evaluate potential risk in man.

#### ALTERATIONS FOR PREVIOUSLY LISTED SUBSTANCES

As has been the practice of FEMA, this publication lists the substances and their maximum use levels in various food categories as most recently reported to the panel and determined to be GRAS. With the passage of time, new uses (either in other food categories or at changed use levels) for substances previously listed are developed. Categories and levels of use reported in GRAS lists reflect current usage and are intended as a guide to good manufacturing practice (GMP), not as rigid limitations or tolerances. A more detailed discussion of the interpretation of this point by FEMA and FDA was previously published by Oser and Ford in 1979.

The panel recognizes, however, that any such increase in use levels should be evaluated to ensure continued GRAS status. With this in mind, the food categories and usage levels for D,L-valine (FEMA no. 3444) were reviewed and the subsequent changes can be found in the Table 2 of this report. New analytical data presented on FEMA no. 2804 indicated that the proper name for this substance should be 3-(hydroxymethyl)-2-heptanone. The panel reviewed the data and reaffirmed its GRAS status.

Three substances, 2-methyl-5-vinylpyrazine (FEMA no. 3211, GRAS 4), o-vinylanisole (FEMA no. 3248, GRAS 4), and musk ambrette (FEMA no. 2758, GRAS 3) were reviewed by the expert panel and found to require additional data including toxicological testing for the continuation of their GRAS status. As interest in these substances is insufficient to support the acquisition of the data required for futher safety evaluation, these flavoring substances were dropped from the GRAS list.

#### **NOTES TO THE READER**

GRAS 13 includes D,L-phenylalanine as a newly listed substance (FEMA no. 3726). It should not be confused with L-phenylalanine (FEMA no. 3585) previously listed in GRAS 11 (Oser and Ford, 1978). Readers should be aware of use limitations on specific substances or groups of substances as well as the more general GMP guidelines.

Table I of this report is an alphabetical cross reference list. Substances with cis-trans stereochemical designations have also been named according to the more recent and less ambiguous IUPAC (E)-(Z)

nomenclature system.

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- —"Primary Names and Synonyms Alphabetical Cross Reference List" is on pp. 70-72
- —"GRAS Flavoring Ingredients and Usage Levels" are on pp. 74-89

## GRAS 13—Primary Names and Synonyms<sup>a</sup> Alphabetical Cross Reference List

FEMA I	Vo. Substance	FEMA	No.	Substance
3651	6-ACETOXYDIHYDROTHEASPIRANE	3662	DIHYDROXYACETOR	PHENONE
	1-Acetoxy-2-methoxybenzene (see Guaiacyl acetate, no. 3687)		1-(x,y-Dihydroxypheroxy) (see Dihydroxy)	nyl)ethanone acetophenone, no. 3662)
	1-Acetoxy-2-(2,2,3-trimethyl-3-cyclopentenyl)ethane (see Campholene acetate, no. 3657)		2,6-Dimethoxy-p-cre (see 4-Methyl-	esol 2-6-dimethoxyphenol, no. 3704)
3652	4-(p-ACETOXYPHENYL)-2-8UTANONE		2,6-Dimethylbenzen	ethiol
3653	4-ACETYL-6-t-BUTYL-1,1-DIMETHYLINDANE			thylthiophenol, no. 3666)
	1-Acetylcyclohexyl acetate		2,6-DIMETHYL-6-HE	
	(see Methyl 1-acetoxycyclohexyl ketone, no. 3701)		•	ETHOXY-3(2H)-FURANONE
	Acetyl guaiacol	3665	2,2-DIMETHYL-5-(1 YL)TETRAHYDROFU	
	(see Guaiacyl acetate, no. 3687)	3666	2,6-DIMETHYLTHIO	
3654	4-ACETYL-2-METHYLPYRIMIDINE	3000	Dioxyacetophenone	FHENOL
3655	4-ALLYL-2,6-DIMETHOXYPHENOL		• • •	acetophenone, no. 3662)
	4-Allylsyringol	3667	DIPHENYL ETHER	
	(see 4-Allyl-2,6-dimethoxyphenol, no. 3655)		Diphenyl oxide	
	α-Amino-4-imidazolepropionic acid (see L-Histidine, no. 3694)			ether, no. 3667)
	2-Amino-3(4-imidazyl)propionic acid	3668	DISODIUM 5-GUAN	YLATE
	(see L-Histidine, no. 3694)	3669	DISODIUM 5-INOSIN	NATE
	lpha-Amino- $eta$ -phenylpropionic acid	3670	trans, trans-2,4-DOD	ECADIENAL
	(see D,L-Phenylalanine, no. 3726)		(E,E)-2,4-Dodecadier	
	2-Aminobutanedioc acid			s-2,4-Dodecadienal, no. 3670)
	(see L-Aspartic acid, no. 3656)		1,4-Epoxy-p-mentha (see 1,4-Cineol	
	2-Aminoglutaramic acid		4-Ethenylphenol	e, 110. 3056)
	(see L-Glutamine, no. 3684) $\alpha$ -Aminohydrocinnamic acid		(see p-Vinylphe	enol, no. 3739)
	(see D,L-Phenylalanine, no. 3726)		1-Ethoxy-4-hydroxyb	
	2-Aminosuccinic acid			one monoethyl ether, no. 3695)
	(see L-Aspartic acid, no. 3656)		p-Ethoxyphenol	
8656	L-ASPARTIC ACID			one monoethyl ether, no. 3695)
	lpha-Benzylidene methional		4-ETHYL-2,6-DIMET	
	(see 2-(Methylthiomethyl)-3-phenylpropenal, no. 3717)		2-ETHYL-4,5-DIMET	HYLOXAZOLE
	Benzyl isoeugenol	3673	2-ETHYLFURAN	
	(see Isoeugenyl benzyl ether, no. 3698)		Ethyl $\beta$ -furfuryl- $\alpha$ -thi	opropionate irfurylthio) propionate, no. 3674)
	Benzyl 2-methoxy-4-propenylphenyl ether (see Isoeugenyl benzyl ether, no. 3698)	3674	ETHYL 3-(FURFURY	
	1-Benzyloxy-2-methoxy-4-propenylbenzene	3074	Ethyl $\beta$ -ketohexanoa	
	(see Isoeugenyl benzyl ether, no. 3698)		* 1	ohexanoate, no. 3683)
	Bois de rose oxide	3675	ETHYL trans-2-HEXE	
	(see 2,6,6-Trimethyl-2-vinyltetrahydropyran, no. 3735)		Ethyl (E)-2-hexenoate	
3657	CAMPHOLENE ACETATE		(see Ethyl trans	s-2-hexenoate, no. 3675)
	3-Carbomethoxypyridine (see Methyl nicotinate, no. 3709)		1-Ethylhexyl 2-methylhex	yl-2-butenoate xyl tiglate, no. 3676)
3658	1,4-CINEOLE		1-Ethylhexyl 2-methy	•
-	2,4-Cresotaldehyde		•	kyl tiglate, no. 3676)
	(see 2-Hydroxy-4-methylbenzaldehyde, no. 3697)		1-ETHYLHEXYL TIGI	
	p-Cresyl octanoate		ETHYL 3-MERCAPTO	
	(see p-Tolyl octanoate, no. 3733)		ETHYL 2-METHYL-3	
	o-Cresyl salicylate		ETHYL 3-METHYLPE	
DCE O	(see o-Tolyl salicylate, no. 3734)		2-ETHYL-4-METHYL	
3659	α-DAMASCONE	3681	ETHYL 4-(METHYLT	
3000	9-DECENOIC ACID		Ethyl 3-methylvalera	te ethylpentanoate, no. 3679)
	6-Deoxy-L-mannose (see L-Rhamnose, no. 3730)	3682	ETHYL cis-4,7-OCTA	
	,	5552		
3661	3,6-DIHYDRO-4-METHYL-2-(2-METHYLPROPEN-1-YL)-2H-		Ethyl (Z)-4,7-octadie	noate

<sup>&</sup>lt;sup>a</sup>Primary names, in capital letters, and synonyms, in lower case, are listed alphabetically. Synonyms are followed by reference to the primary name and FEMA number.

4-Isopropyl-3-cyclohexene-1-carboxylic acid (see 1,2,5,6-Tetrahydrocuminic acid, no. 3731)

FEMA .	No.	Substance	FEMA	NO.	Substance
3683	ETHYL 3-OXOHEXANOA	ΓE	3699	ISOPROPYL 2-MET	THYLBUTYRATE
	Ethyl 3-thiopropionate (see Ethyl 3-mercap	topropionate, no. 3677)		α-Ketobutyric acid (see 2-Oxobu	ityric acid, no. 3723)
	2-Ethyloxole (see 2-Ethylfuran, ne	o. 3673)		L-Mannomethylose (see L-Rhamn	nose, no. 3730)
	4-Ethylsyringol (see 4-Ethyl-2,6-din	nethoxyphenol, no. 3671)		$\alpha$ -Melonol (see 2,6-Dim	ethyl-6-hepten-1-ol, no. 3663)
	iso-Eugenyl benzyl ether (see Isoeugenyl benz	avlether no 3698)	3700	1-p-MENTHENE-8-	
	Glutamic acid-5-amide (see L-Glutamine, no			•	nethyl-3(2H)-furanone ethyl-4-methoxy-3(2H)-furanone, no.
8684	L-GLUTAMINE			6-Methoxyeugenol	
685	GLYCERYL 5-HYDROXYD	ECANOATE		•	,6-dimethoxyphenol, no. 3655)
686	GLYCERYL 5-HYDROXYD	ODECANOATE		6-Methoxyisoeuger (see 4-Proper	nyl-2,6-dimethoxyphenol, no. 3728)
687	GUAIACYL ACETATE			o-Methoxyphenyl a	
8688	cis-3-HEXENYL BENZOA	re .		•	acetate, no. 3687) enylphenyl benzyl ether
	(Z)-3-Hexenyl benzoate (see <i>cis</i> -3-Hexenyl b	enzoate, no. 3688) ·		(see Isoeugen	yl benzyl ether, no. 3698)
689	cis-3-HEXENYL cis-3-HEX	ENOATE			XYCYCLOHEXYL KETONE
	(Z)-3-Hexenyl (Z)-3-hexen	oate			CETATE (mixed o,m,p)
	(see <i>cis</i> -3-Hexenyl <i>c</i>	is-3-hexenoate, no. 3689)		3-METHYL-2-BUTA 4-METHYL-2,6-DIN	
	cis-3-Hexenyl 2-hydroxypi	•	0705	_2-METHYL-1,3-DIT	
c00	,	actate, no. 3690)		3-Methylene-2-octa	
690	cis-3-HEXENYL LACTATE				-1-buten-3-one, no. 3725)
	(Z)-3-Hexenyl lactate (see <i>cis</i> -3-Hexenyl la	actate, no. 3690)			B-cyclohexene-1-carboxylic acid Tetrahydrocuminic acid, no. 3731)
	HEXYL BENZOATE			Methyl 2,4-hexadie	
692	HEXYL trans-2-HEXENOA	TE		•	orbate, no. 3714)
	Hexyl (E)-2-hexenoate (see Hexyl <i>trans</i> -2-h	exendate, no. 3692)		Methyl (E,E)-2,4-he (see Methyl s	exadienoate orbate, no. 3714)
693	HEXYL 2-METHYL-3&4-P	ENTENOATE	3706	METHYL 2-HYDRO	XY-4-METHYLPENTANOATE
694	L-HISTIDINE			Methyl 2-hydroxyis	*
695	HYDROQUINONE MONOR	THYL ETHER			2-hydroxy-4-methylpentanoate, no. 370 orbinal
696	5-HYDROXY-2,4-DECADI	ENOIC ACID δ-LACTONE		Methyl isopropyl ca (see 3-Methyl	l-2-butanol, no. 3703)
	4-Hydroxy-3-methoxyben: (see Vanillyl alcohol,			Methyl 2-keto-3-me (see Methyl 2	ethylvalerate !-oxo-3-methylpentanoate, no. 3713)
	4-(4-Hydroxy-3-methoxyp (see Vanillylidene ac			Methyl 3-methyl-2- (see Methyl 2	-oxovalerate !-oxo-3-methylpentanoate, no. 3713)
	4-Hydroxy-3-methoxyphe		3707	METHYL 2-METHY	LPENTANOATE
	(see Vanillyl alcohol,		3708	METHYL 2-METHY	LTHIOBUTYRATE
697	2-HYDROXY-4-METHYLB			Methyl 2-methylval	
	$\beta$ -( $p$ -Hydroxyphenyl)alanin (see L-Tyrosine, no.		2700	•	2-methylpentanoate, no. 3707)
	4-Hydroxystyrene	<i></i>		METHYL NICOTINA	
	(see p-Vinylphenol,	no. 3739)	3710 3711	METHYL 3-NONEN 2-METHYL-2-OCTE	
	2-Isobutoxynaphthalene (see β-Naphthyl isob	outyl ether, no. 3719)		METHYL trans-2-0	
	Isobutyl $\beta$ -naphthyl ether	, 5, 2. 10,		Methyl (E)-2-octend	
		outyl ether, no. 3719)		(see Methyl ti	rans-2-octenoate, no. 3712)
	(see L-Rhamnose, no	o. 3730)			
698	ISOEUGENYL BENZYL ET	LICO			

-Continued on page 73

FEMA	No. Substance	FEMA	No.	Substance
3713	METHYL 2-OXO-3-METHYLPENTANOATE	3723	2-OXOBUTYRIC ACID	
	2-Methylphenyl 2-hydroxybenzoate	3724	2-PENTADECANONE	
	(see o-Tolyl salicylate, no. 3734)	3725	2-PENTYL-1-BUTEN-3-C	DNE
	p-Methylphenyl octanoate (see $p$ -Tolyl octanoate, no. 3733)		6-Pentyl-α-pyrone (see 5-Hydroxy-2,4	-decadienoic acid $\delta$ -lactone, no.
	Methyl 3-pyridinecarboxylate		3696)	
	(see Methyl nicotinate, no. 3709)	3726	D,L-PHENYLALANINE	
	4-Methylsalicylaldehyde (see 2-Hydroxy-4-methylbenzaldehyde, no. 3697)		Phenyl ether (see Diphenyl ether	, no. 3667)
	4-Methylsalicylic aldehyde (see 2-Hydroxy-4-methylbenzaldehyde, no. 3697)		1-Phenyl-3 or 5-propyl-1 (see 1-Phenyl-3 or	,2-diazole 5-propylpyrazole, no. 3727)
3714	METHYL SORBATE	3727	1-PHENYL-3 or 5-PROP	YLPYRAZOLE
	4-Methylsyringol (see 4-Methyl-2,6-dimethoxyphenol, no. 3704)		4-Propenyl-1-(benzyloxy) (see Isoeugenyl ber	-2-methoxybenzene nzyl ether, no. 3698)
3715	7-METHYL-4,4a,5,6-TETRAHYDRO-2(3H)-NAPHTHALENONE	3728	4-PROPENYL-2,6-DIMET	HOXYPHENOL
3716	4-METHYLTHIAZOLE		4-Propenylsyringol	
	Methylthio 2-methylbutyrate			6-dimethoxyphenol, no. 3728)
	(see Methyl 2-methylthiobutyrate, no. 3708)	3729	4-PROPYL-2,6-DIMETHO	XYPHENOL
3717	2-(METHYLTHIOMETHYL)-3-PHENYLPROPENAL		4-Propylsyringol	
	Methyl tridecyl ketone			limethoxyphenol, no. 3729)
2710	(see 2-Pentadecanone, no. 3724)	3730	L-RHAMNOSE	
	3-METHYL-1,2,4-TRITHIANE		Ribotide	
3719	β-NAPHTHYL ISOBUTYL ETHER	0704	(see Disodium 5-gu	
	Neroloxide (see 3,6-Dihydro-4-methyl-2-(2-methylpropen-	3/31	1,2,5,6-TETRAHYDROCU	
	1-yl)-2H-pyran, no. 3661)		(2RS,5SR,6SR)-2,6,10,1 yl acetate (mixture of C2	O-Tetramethyl-1-oxaspiro[4,5]dec-6-
3720	cis-2-NONEN-1-OL		•	drotheaspirane, no. 3651)
	(Z)-2-Nonen-1-ol	3732	THAUMATIN	
	(see cis-2-Nonen-1-ol, no. 3720)	3733	ho-TOLYL OCTANOATE	
	Ocimen quintoxide	3734	o-TOLYL SALICYLATE	
0704	(see 2,2-Dimethyl-5-(1-methylpropen-1-yl)tetrahydrofuran, no. 3665)		$\alpha$ , $\alpha$ ,4-Trimethyl-3-cyclol (see 1-p-Menthene-	
3/21	trans, trans-2,4-OCTADIENAL (E,E)-2,4-Octadienal		4-(2,6,6-Trimethyl-2-cyc (see $\alpha$ -Damascone,	lohexenyl)-2-butene-4-one no. 3659)
3722	(see trans, trans-2,4-Octadienal, no. 3721) cis-5-OCTEN-1-OL		2-(2,2,3-Trimethyl-3-cycl (see Campholene ad	•
	(Z)-5-Octen-1-ol	3735	2,6,6-TRIMETHYL-6-VIN	YLTETRAHYDROPYRAN
	(see <i>cis</i> -5-Octen-1-ol, no. 3722)	3736	L-TYROSINE	
	3-Octyl 2-methyl-2-butenoate (see 1-Ethylhexyl tiglate, no. 3676)	3737	VANILLYL ALCOHOL	
	3-Octyl 2-methylcrotonate	3738	VANILLYLIDENE ACETOR	NE
	(see 1-Ethylhexyl tiglate, no. 3676)	3739	p-VINYLPHENOL	
	3-Octyl tiglate (see 1-Ethylhexyl tiglate, no. 3676)		2,6-Xylenethiol (see 2,6-Dimethylth	niophenol, no. 3666)

—"Gras Flavoring Ingredients and Usage Levels" start on page 74

### **GRAS FLAVORING INGREDIENTS AND USAGE LEVELS**

Flavor and Extract Manufacturers' Association average maximum levels (in ppm) on which the Expert Panel based its judgements that the substances are generally recognized as safe for their intended uses

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
<i>3651</i> 6-ACETOXYDIHYDROTHEASPIRANE	0.5	-	0.5			0.2	0.5	-		0.2	Condiments & relishes—0.3; Instant coffee and tea—0.05; Seasonings & flavorings—
3652 4-(p-ACETOXYPHENYL)-2- BUTANONE		_	_	2.0	2.0			0.5	-	_	Fruit ices—1.0; Confectionery & frosting— 1.0; Jams & jellies—1.0; Imitation dairy—1.0; Hard
					t <sub>m</sub>						candy—2.0; Chewing gum—10.0
3653 4-ACETYL-6-t-BUTYL-1,1- DIMETHYLINDANE	_			8.0	_	_			_		
3654 4-ACETYL-2-METHYLPYRIMIDINE	10.0	5.0	1.0	5.0	5.0	3.0	10.0	2.0	5.0	3.0	Breakfast cereals—5.0; Milk products—1.0; Egg products—0.5; Confectionery & frosting— 5.0; Nut products—5.0; Hard candy—5.0; Chewing
<i>3655</i> 4-ALLYL-2,6-DIMETHOXYPHENOL	_		0.5		_	0.2	0.5	-	<del></del>	0.5	cheese—0.5; Seasonings & flavorings—5.0; Poultry—0.2; Condiments & relishes—5.0
3656 L-ASPARTIC ACID	250	_	250	_	-	_		150		_	Condiments & relishes—250; Seasonings & flavorings—
3657 CAMPHOLENE ACETATE			_	3 .	3		_	3	3	<del></del>	Hard candy—3; Chewing gum—3
3658 1,4-CINEOLE	12.14	9.62	8.29	11.49	9.91	<del></del> .		9.21	4.71		Hard Candy—50.0; Chewing Gum—25.0

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings			Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3659 α-DAMASCONE	_		_	0.5	0.5	_		0.5	0.5	_	Confectionery & frosting— 0.5; Hard candy—0.5; Chewing gum—0.5
3660 9-DECENOIC ACID			_	_		_	_	_		_	Fats & oils—100
3,6-DIHYDRO-4-METHYL-2-(2- METHYLPROPEN-1-YL)-2H- PYRAN	0.2	0.1	_	0.2	0.1	-	_	0.1	_		Milk products—0.1; Processed fruit—0.1; Fruit ices—0.1; Jams & jellies—0.1; Hard candy—0.2; Instant coffee & tea—0.1
3662 DIHYDROXYACETOPHENONE	_		0.2	_			_	_	_	_	
<i>3663</i> 2,6-DIMETHYL-6-HEPTEN-1-OL	_	0.2	-	0.5	0.5	_	_	0.2		_	Fruit ices—0.2; Confectionery & frosting— 0.5; Imitation dairy—0.4; Hard candy—0.5; Chewing gum—2.0
3664 2,5-DIMETHYL-4-METHOXY-3 (2H)-FURANONE	12.0	3.0	_	2.5	5.0	. –	_	0.5	1.0	_	Milk products—2.5; Fruit ices—3.0; Confectionery & frosting— 2.5; Jams and jellies—2.5; Hard candy—5.0; Chewing gum—10.0
3665 2,2-DIMETHYL-5-(1- METHYLPROPEN-1-YL)- TETRAHYDROFURAN	~		_	0.5	0.5	_		_		<del></del>	Confectionery & frostings— 0.5; Hard candy—0.5; Chewing gum—0.5
3666 2,6-DIMETHYLTHIOPHENOL	3.0	_	1.0	1.5	0.25	2.0	5.0	0.05	0.05	0.5	Confectionery & frosting— 0.5; Breakfast cereals—3.0; Milk products—0.5; Egg products—0.5; Condiments & relishes—0.5; Nut products—0.5; Hard candy—2.5; Chewing gum—5.0

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3667 DIPHENYL ETHER	_	_	_	7.5	_	_	_	2.5		_	
3668 DISODIUM 5-GUANYLATE	143	3000	200	3000	2000	720	50	2000	_	240	Fats and oils—2000; Other grains—240; Milk products—46; Cheese—0.4; Poultry—200; Fish products—10.0; Processed vegetables—140; Condiments & relishes—3200 Reconstituted vegetables—150; Main dishes, NEC—0.15; Seasonings & flavorings—1000
3669 DISODIUM 5-INOSINATE	141	3000	314	3000	_	660	50	220		660	Other grains—240; Fats and oils—2000; Milk products— 46.0; Cheese—0.4; Poultry—200; Fish products— 10.0; Processed vegetables— 220; Condiments & relishes—3200 Reconstituted vegetables— 50.0; Seasonings & flavorings—
3670 trans, trans-2,4-DODECADIENAL	1.0	÷	0.5			0.5	0.5	_		0.5	Condiments & relishes—0.5
<i>3671</i> 4-ETHYL-2,6-DIMETHOXYPHENOL	-	_	1.0	_	_	0.5	1.0	-	_	1.0	Cheese—1.0; Poultry—0.5; Condiments & relishes—5.0; Seasonings & flavorings—5.0
<i>3672</i> 2-ETHYL-4,5-DIMETHYLOXAZOLE	1.5		0.5	1.0	1.0	0.2	_	_	-	0.5	Breakfast cereals—0.5; Confectionery & frosting— 1.0; Chewing gum—2.5; Instant coffee & tea—0.2

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3673 2-ETHYLFURAN	42.5	21.5		22.5	21.0		<del></del>	11.5	3.0	_	
3674 ETHYL 3-(FURFURYLTHIO)- PROPIONATE	2.0	_		_	0.2	0.5	2.0	0.1	_	0.2	Breakfast cereals—0.2; Fats & oils—20.0; Confectionery and frosting—0.2; Sweet sauce—0.1; Nut products—5.0 Imitation dairy—0.1; Hard candy—0.2; Chewing gum—1.0
3675 ETHYL trans-2-HEXENOATE	12.0	_	-	_	5.0	_	— <del>v</del>	0.5	1.0	_	Milk products—2.5 Fruit ices—3.0; Confectionery & frosting— 10.0; Hard candy—5.0
<i>3676</i> I-ETHYLHEXYL TIGLATE	_		20.0	_		20.0	20.0	÷	<u>-</u>	50.0	Condiments & relishes—20.0 Seasonings & flavorings—
<i>3677</i> ETHYL 3-MERCAPTOPROPIONATE	7.5	_	_		_	_		0.5	<b>-</b> _	_	Fruit ices—0.5; Hard candy—6.0
3678 ETHYL 2-METHYL- 3,4-PENTADIENOATE	_		_	1.0	2.0	_	_	1.0	_	_	Confectionery & frosting— 2.0; Imitation dairy—1.0; Hard candy—2.0; Chewing gum—5.0
<i>3679</i> ETHYL 3-METHYLPENTANOATE	0.1	0.1	_	0.5	0.1	_	-	0.1	0.1	_	Breakfast cereals—0.1; Fruit ices—0.1; Confectionery & frosting— 0.5; Imitation dairy—0.1; Hard candy—0.1; Chewing gum—0.5
3680 2-ETHYL-4-METHYLTHIAZOLE	_	1.0	_	1.0	1.0			1.0	_	_	Confectionery & frosting— 1.0; Hard candy—1.0

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3681 ETHYL 4-(METHYLTHIO)-BUTYRATE			_	0.2	0.2	_	_	0.2	0.2		Confectionery & frosting— 0.2; Hard candy—0.2; Chewing gum—0.2
3682 ETHYL cis-4,7-OCTADIENOATE	20.0	15.0	_	15.0	15.0	-	20.0	10.0	10.0	_	Breakfast cereals—25.0; Milk products— 10.0; Fruit ices—15.0; Confectionery & frosting— 10.0; Jams & jellies—5.0; Sweet sauce—5.0; Imitation dairy—10.0; Hard candy—20.0; Chewing gum—25.0
<i>3683</i> ETHYL 3-OXOHEXANOATE	5.0	_	-		3.0	_		1.5	3.0	-	Fats & oils—2.5; Fruit ices—2.5; Confectionery & frosting—3.0; Hard candy—7.5
3684 L-GLUTAMINE	350	_	350	350	-	_	_	<del></del>	_		Nut products—350; Seasonings & flavorings— 350
3685 GLYCERYL 5-HYDROXYDECANOATE	50.0		~-	_	_			_	_	_	Fats & oils—50.0; Imitation dairy—10.0
3686 GLYCERYL 5-HYDROXYDODECANOATE	50.0	_	_		_	_		_	_	_	Fats & oils—50.0; Imitation dairy—10.0
<i>3687</i> GUAIACYL ACETATE	15.2	9.59	_	11.2	10.0			10.0	<del></del>	_	
3688 cis-3-HEXENYL BENZOATE	3.0	_	_	1.0	1.0	_	_	1.0	2.0	_	Milk products—1.0; Confectionery & frosting— 1.0; Jams & jellies—1.0; Sweet sauce—1.0; Hard candy—3.0; Chewing gum—10.0

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings		Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3689 cis-3-HEXENYL cis-3-HEXENOATE	-	-		-	1.0		-	0.5	_	-	Fruit ices—0.2; Confectionery & frosting— 0.5; Jams & jellies—1.0; Reconstituted vegetables— 1.0; Imitation dairy—0.5; Hard candy—1.0; Chewing gum—2.0
3690 cis-3-HEXENYL LACTATE	20.0	5.0	_		5.0	_		1.0	5.0	_	Jams and jellies—10.0; Hard candy—10.0
3691 HEXYL BENZOATE	10.0	7.5	_	10.0	7.5		-	7.5	5.0		
3692 HEXYL trans-2-HEXENOATE	5.0		_		3.0		_	1.5	3.0	-	Milk products—2.5; Fruit ices—2.5; Confectionery & frosting— 3.0; Hard candy—7.5
3693 HEXYL 2-METHYL-3&4-PENTENOATE	_	_		0.4	0.4		-	0.4	0.4	-	Confectionery & frosting— 0.4; Hard candy—0.4; Chewing gum—0.4
3694 L-HISTIDINE	150	-	150		_	_	-	-			Milk products—150; Confectionery & frosting— 150
3695 HYDROQUINONE MONOETHYL ETHER	5.0	5.0	0.5	5.0	5.0	_		5.0	_	_	
3696 5-HYDROXY-2,4-DECADIENOIC ACID δ-LACTONE	0.2	_	-	0.1	0.05	_	-	0.2		0.2	Cheese—0.2; Condiments & relishes—0.5; Confectionery & frosting— 0.2; Reconstituted vegetables— 0.2; Imitation dairy—0.1; Hard candy—0.2; Chewing gum—0.5

Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3697 2-HYDROXY-4-METHYL- BENZALDEHYDE	2.0	0.5	_	0.5	1.0	_	_	-	-		Milk products—1.0 Processed fruit—0.5; Confectionery & frosting— 0.5; Nut products—0.5 Hard candy—0.5
3698 ISOEUGENYL BENZYL ETHER	13.0	5.0	_	5.0	5.66		_	8.66	*******	_	
3699 ISOPROPYL 2-METHYLBUTYRATE	10.0	10.0		15.0	10.0		20.0	5.0	_		Breakfast cereals—10.0; Fruit ices—15.0; Confectionery & frosting— 10.0; Jams & jellies—5.0; Sweet sauce—5.0; Imitation dairy—10.0; Hard candy—15.0; Chewing gum—20.0; Seasonings & flavorings—1.0
3700 1-p-MENTHENE-8-THIOL	_	_		0.002	0.001	_	_	0.001			Chewing gum—0.004; Processed fruit—0.001; Fruit ices—0.001; Confectionery & frosting—0.002; Jams & jellies—0.001; Hard candy—0.002
3701 METHYL 1-ACETOXYCYCLOHEXYL KETONE	0.2	_	<del></del>	0.5	0.2			0.2	0.2	-	Breakfast cereals—0.5; Processed fruit—0.1; Fruit ices—0.1; Confectionery & frosting— 0.2; Jams & jellies—0.1; Hard candy—0.5; Chewing gum—0.5
3702 METHYLBENZYL ACETATE (mixed o,m,p)	_		-	· <u></u>	_	_		1.0		_	
3703 3-METHYL-2-BUTANOL	20.0	5.0	-	_	5.0		_	1.0	5.0	_	Jams & jellies—10.0; Hard candy—10.0

Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Use
3704 4-METHYL-2,6-DIMETHOXYPHENOL	_		1.0	. —	_	0.5	1.0	_	_	1.0	Cheese—1 Poultry—0 Condiments relishes—5 Seasonings flavorings—
<i>3705</i> 2-METHYL-1,3-DITHIOLANE	0.5	-	0.5	-	_	0.1	3.0	-		0.1	Breakfas cereals—0 Cheese—0 Condiment relishes—0. Nut products— Instant cof & tea—0.0 Egg products—
3706 METHYL 2-HYDROXY-4- METHYLPENTANOATE	10.0	2.5	_		2.5	_	•	0.5	2.5	_	Jams & jellies—5 Hard candy—5
3707 METHYL 2-METHYLPENTANOATE	_	0.5		0.25	0.25		0.5	0.25	0.25		Confection & frosting 0.25; Na products-0.25; Har candy—0. Chewing gum—1.0
3708 METHYL 2-METHYLTHIOBUTYRATE	_	0.3	-	0.3	0.5	_	_	_	0.5		Confection & frosting 0.3; Imitat dairy—0. Hard candy—0
3709 METHYL NICOTINATE	40.0	10.0	_	_	10.0	_	_	2.0	10.0	-	Jams & jellies—20 Hard candy—20
3710 METHYL 3-NONENOATE	15.0	_	-	15.0	···· <u> </u>	_		2.0	_	-	Fruit ices—5.0 Confection & frosting 15.0; Han candy—15 Chewing gum—25
3711 2-METHYL-2-OCTENAL	1.0	1.5	1.5	_	_	1.0	1.5	_		1.0	Breakfas cereals—( Fats & oils—0.5; M products— Cheese—I Fish products— Condiment relishes—( Nut products— Imitatio Dairy—0 Seasonings

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3712 METHYL trans-2-OCTENOATE	7.5		_		3.0			1.5	3.0	<del></del>	Milk products—2.5; Fruit ices—2.5; Confectionery & frosting— 3.0; Hard candy—7.5
3713 METHYL 2-OXO-3-METHYLPENTANOATE	100	50.0	_	50.0		_	25.0	25.0	50.0	_	Breakfast cereals—50.0; Other grains—50.0; Fats & oils—50.0; Milk products— 25.0; Confectionery & frosting— 50.0; Imitation dairy—25.0; Hard candy—100; Chewing gum—100
3714 METHYL SORBATE	10.0	2.5		_	2.5	_		0.5	2.5	_	Jams & jellies—5.0; Hard candy—5.0
3715 7-METHYL-4,4a,5,6-TETRAHYDRO- 2(3H)-NAPHTHALENONE	1.0	_	_	1.0	0.5		_	0.2	-		Breakfast cereals—1.0; Confectionery & frosting— 1.0; Nut products—0.5; Imitation dairy—0.5; Hard candy—1.0; Chewing gum—2.0
3716 4-METHYLTHIAZOLE	5.0		5.0	5.0	_	5.0	5.0		-	5.0	Breakfast cereals—5.0; Fats & oils—3.0; Milk products—3.0; Cheese—5.0; Condiments & relishes—1.5; Confectionery & frosting— 5.0; Nut products—5.0; Reconstituted vegetables— 5.0; Imitation dairy—2.5; Hard candy—5.0; Chewing gum—5.0; Instant coffee & tea—2.0

Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3717 2-(METHYLTHIOMETHYL)-3- PHENYLPROPENAL	_		_		-	1.0	-	_	_	1.0	Nut products—1.0; Reconstituted vegetables— 0.5; Imitation dairy—0.5
3718 3-METHYL-1,2,4-TRITHIANE	1.5	0.5	1.0	0.5	0.3	0.5	1.5	0.15	0.5	0.5	Breakfast cereals—0.5; Egg products— 0.05; Confectionery & frosting— 0.5; Nut products—0.5; Hard candy—1.0; Chewing gum—5.0
3719 $\beta$ -NAPHTHYL ISOBUTYL ETHER	5.0	5.0	-	5.0	5.0	_	_	5.0	1.0	_	
3720 cis-2-NONEN-1-OL	0.15	0.15	0.1	0.1	0.15	0.05	0.2	0.05		0.05	Breakfast cereals—0.2; Fats & oils—0.35; Milk products—0.1; Cheese—0.1; Fruit ices—0.05; Condiments & relishes—0.05; Confectionery & frosting— 0.15; Jams & jellies—0.05; Sweet sauce—0.1; Nut products—0.1; Imitation dairy—0.05; Hard candy—0.15; Chewing gum—0.2; Instant coffee & tea—0.05
3721 trans,trans-2,4-OCTADIENAL	2.0	_	2.0	_	_	2.0		_	_	2.0	
3722 cis-5-OCTEN-1-OL	15.0	15.0	_	15.0	20.0	_	30.0	10.0	15.0	_	Breakfast cereals—15.0; Milk products— 10.0; Processed fruit—5.0; Fruit ices—20.0; Confectionery & frosting— 10.0; Jams & jellies—10.0; Sweet sauce—5.0; Nut products—5.0; Reconstituted vegetables— 1.0; Hard candy—25.0; Chewing gum—25.0

Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3723 2-OXOBUTYRIC ACID	2.0	12.0			****		_	1.0	_	_	
3724 2-PENTADECANONE		_	***************************************	-	_		_	_	_	_	Fats & oils—75.0
3725 2-PENTYL-1-BUTEN-3-ONE····· —	0.01—				<u></u>	0.01	0.01			0.01	Cheese—0.01; Egg products— 0.01; Condiments & relishes— 0.005; Reconstituted vegetables— 0.01; Seasonings & flavorings—0.1
3726 d,l-PHENYLALANINE	300		300	-	_		_	_	_	- Constant	Nut products—300; Condiments & relishes—300; Seasonings & flavorings—5.0
3727 1-PHENYL-3 or 5-PROPYLPYRAZOLE	1.0	1.0		1.0	1.0			1.0	_	_	
3728 4-PROPENYL-2,6- DIMETHOXYPHENOL	_		1.0	_	_	0.5	1.0	_	_	1.0	Cheese—1.0; Poultry—0.5; Condiments & relishes—5.0; Seasonings & flavorings—
3729 4-PROPYL-2,6-DIMETHOXYPHENOL	_		1.0			0.5	1.0	_	-	1.0	Cheese—1.0; Poultry—0.5; Condiments & relishes—5.0; Seasonings & flavorings—5.0
3730 L-RHAMNOSE	500	-	200	500	_	_	100	500			Milk products— 50.0; Confectionery & frosting— 100; Chewing gum—100; Sugar substitutes— 10.0; Instant coffee & tea—10.0
3731 1,2,5,6-TETRAHYDROCUMINIC ACID	2.5		5.0	_	-	2.5	5.0	_	_	5.0	Cheese—1.0; Poultry—5.0; Egg products—2.5; Fish products—5.0; Condiments & relishes—5.0; Imitation dairy—0.5; Seasonings & flavorings—

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other Uses
3732 FHAUMATIN	_	_		_		_	_		_		Chewing gum—300
3733 p-TOLYL OCTANOATE	5.0	5.0	5.0	5.0	5.0		_	5.0	_	_	
3734 p-TOLYL SALICYLATE			_			_		-	-	_	Hard candy—15.0; Chewing gum—100
3735 2,6,6-TRIMETHYL-6-VINYL- TETRAHYDROPYRAN			-	0.5	2.0	_		0.5	-		Confectionery & frosting— 1.0
3736 TYROSINE	250		250	_	_	_	250	-	_	_	Condiments & relishes—250; Seasonings & flavorings—
3737 VANILLYL ALCOHOL	12.0	12.0	_	12.0	12.0	_	_	12.0	_	_	
3738 ANILL YLIDENE ACETONE	8.0	8.0		8.0	8.0	_		8.0		_	
3739 o-VINYLPHENOL	5.0	2.5	5.0	_	2.0	-	_	1.5	0.5	5.0	Confectionery & frosting— 2.0; Sweet sauce—2.5; Nut products—2.0; Imitation dairy—3.0; Hard candy—2.0; Chewing gum—10.0

# Changes in Categories and Use Levels for Substances that Previously Received GRAS Status

3444 d,l-VALINE	300	40.0ª	300	_	80.0ª	-	_	15.0ª	0.9*	-	Breakfast cereals—0.9a; Milk products— 40.0a; Condiments & relishes—300; Confectionery & frosting— 300; Chewing gum—200a; Seasonings & flavorings— 300
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<sup>&</sup>lt;sup>a</sup>Usage levels are identical to those in GRAS 8