

16. GRAS Substances

*A list of flavoring ingredient substances considered
generally recognized as safe by the Flavor & Extract
Manufacturers' Association Expert Panel*

R.L. Smith and R.A. Ford

□ THE FLAVOR INDUSTRY IS MOTIVATED PRIMARILY by the need to better duplicate natural flavors. This is especially true today because of two major dietary trends: (1) the "gourmet revolution," resulting in a demand for a wide variety of easy-to-prepare foods with increasingly complex and sophisticated flavors, and (2) the "health revolution," resulting in a demand for foods with lower fat and salt, with no decrease in flavor intensity.

Despite the availability of a large number of flavor ingredients, there is still a need to continue to develop new ones. New flavor development is generally driven by research into the composition of raw and cooked traditional foods as well as into the chemistry of the cooking process.

The Expert Panel of the Flavor and Extract Manufacturers' Association (FEMA) has continued to review flavor ingredients for evaluation of GRAS (Generally Recognized As Safe) status under the provisions in the 1958 Food Additives Amendment. This is the latest in a series of articles reporting the results of its review over the past two years. A list of 22 new flavor ingredients determined to be GRAS is presented in Table 1.

While the conditions of use and the resulting potential exposure played a critical role in the Panel's conclusions, careful consideration was given to all relevant data. A review of all the data considered and the detailed reasoning that led to the GRAS decisions are beyond the scope of this article. However, the data are generally available from the published literature either from the FEMA Scientific Literature Reviews (SLRs) or elsewhere, and the principles used to reach a GRAS conclusion have been clearly described (Woods and Doull, 1991).

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Conditions of Use

The conditions of use are reported as usual and maximum levels in various categories of food in Table 2. The technology inherent in flavor formulations typically involves the use of flavoring materials over a wide range of use levels. While the reported usual levels reflect the median or most common uses, some special applications require the higher levels. Just as it is obvious that all foods in any given category do not necessarily contain the flavoring material at any level, it should be obvious that the higher levels would be used in only a few specialized flavor applications within any category.

As has been reported in previous FEMA GRAS articles (Oser and Ford, 1979; Hall and Oser, 1965) these use levels are not intended to be either rigid limits or the highest acceptable (safe) exposures. Rather, they reflect only the proposed uses in the application for GRAS determination and therefore are better viewed as good manufacturing practice (GMP) guidelines. They are, however, the levels of use reviewed by the Panel in their consideration of GRAS status and any other uses resulting in significantly higher exposure should be carefully evaluated to insure that they still meet the criteria of GRAS.

In keeping with that philosophy, two substances previously determined to be GRAS were reviewed with new proposed usages. Additional maximum use levels were 150 ppm for sodium 2-(4-methoxyphenoxy) propanoate (FEMA No. 3773) in breakfast cereals and 0.5 ppm for 5-methyl-2-hepten-4-one (FEMA No. 3761) in both alcoholic and nonalcoholic beverages. These uses were concluded not to affect the GRAS status of these two materials.

Safety Assessments

Increased toxicological testing of the components of natural foods has made it obvious that many of these natural components will prove to be carcinogenic to rats and/or mice when tested according to traditional protocols (Ames et al., 1990). The relevance of the results of these tests to human health has been hotly debated (Gori, 1991) especially where the dose that causes the effects exceed the human exposure by many orders of magnitude. It is inevitable that some flavor ingredients would fall into this class because of their very low consumption in food (Oser and Ford, 1990) and their inherently low toxicity which allows for a very high

—Continued on page 106

16. GRAS Substances (continued)

maximum tolerated dose in traditional bioassays.

The results of such tests are often more a function of the unique experimental conditions than of the substance being tested. Human health assessment is not possible in tests where a broad range of structurally unrelated substances is associated with a specific adverse effect in a particular organ often in only one sex of a single species (EPA, 1991). It is these types of results which engender terms such as "some evidence" or "equivocal evidence" of carcinogenicity—descriptions which signify the completion of the test but serve little to evaluate human health.

The Expert Panel was faced with two such reports from the National Toxicology Program (NTP) on flavor ingredients:

• **α -Methylbenzyl Alcohol.** In 1989 the National Toxicology Program (NTP) published a report on the carcinogenicity bioassays of α -methylbenzyl alcohol (FEMA No. 2685) in rats and mice (NTP, 1990a) which concluded:

"Under the conditions of these 2-year gavage studies, there was some evidence of carcinogenic activity of alpha-methylbenzyl alcohol for male F344/N rats, as shown by increased incidences of renal tubular cell adenomas and adenomas or adenocarcinomas (combined), and no evidence for carcinogenic activity for female F344/N rats administered 375 or 750 mg/kg. Renal toxicity characterized by severe nephropathy and related secondary lesions was observed in the dosed rats, and excessive mortality occurred during the last quarter of the studies. Poor survival reduced the sensitivity of the studies for detecting the presence of a carcinogenic response in both chemically exposed groups of male rats and in the high dose group of female rats. There was no evidence of carcinogenic activity of alpha-methylbenzyl alcohol for male or female B6C3F₁ mice administered 375 or 750 mg/kg for 2 years."

After careful review of this report and all other data relevant to the determination of safety under the conditions of use as a flavor ingredient, the FEMA Expert Panel came to the following conclusion: The NTP study of α -methylbenzyl alcohol was inadequate for a number of reasons. Reduction in body weight was excessive and survival was poor. There was an unexplained cluster of gavage-related losses between weeks 48–53 and excessive mortality occurred in the last quarter of the study.

Although α -methylbenzyl alcohol is a food flavoring agent, it was administered to the rats by gavage in this study. The method of administration was chosen because the chemical was not readily accepted when mixed in the feed and difficulty was encountered in maintaining constant dietary concentration. The bioassay doses of 375 and 750 mg/kg/day provided the equivalent of 23 million and 46 million times, respectively, the daily per capita intake of humans. Administration of more reasonable levels in the diet, such as some realistic multiple of expected human consumption, would probably have allowed for better survival and a more interpretable result.

The factors noted above provide sufficient evidence that the dosage of α -methylbenzyl alcohol was excessive, and probably accounted for the severe nephropathy and secondary lesions in the kidney as well as the excessive mortality. For these reasons, and after careful consideration, the Panel concluded that under the conditions of use as a flavor ingredient, α -methylbenzyl alcohol continues to be generally recognized as safe under conditions of use as a flavor ingredient.

• **Benzaldehyde.** The NTP also published a report

on the carcinogenicity bioassays of benzaldehyde (FEMA No. 2127) in rats and mice (NTP, 1990b) which concluded:

"Under the conditions of these 2-year gavage studies, there was no evidence of carcinogenic activity of benzaldehyde for male or female F344/N rats receiving 200 or 400 mg/kg per day. There was some evidence of carcinogenic activity of benzaldehyde for male or female B6C3F₁ mice, as indicated by increased incidences of squamous cell papillomas and hyperplasia of the forestomach."

The NTP conclusion, "some evidence of carcinogenic activity," of benzaldehyde was based solely on the increased incidence of squamous cell papillomas in the forestomach of male or female B6C3F₁ mice. This is a benign lesion in the forestomach of mice, an organ which has no human counterpart.

These benign lesions of epithelial surfaces are observed on the skin and other surfaces covered with squamous epithelium. Papillomas are also sometimes observed in the urinary bladder where they arise from transitional epithelium which often undergoes metaplasia to squamous epithelium. A majority of papillomas arise as a result of chronic irritation or, less frequently, from infection with some strains of viruses. The lesions which arose in the forestomach of the mice in the benzaldehyde NTP study were associated with the delivery by gavage of benzaldehyde, dissolved in corn oil, five days a week for two years. The introduction of a dosing needle into the stomach over this long period of time is sufficient to create a chronic irritation. This, combined with the corn oil which itself is a mild irritant and mitogen, was the likely etiology of the papillomas in the forestomachs of mice, a species which appears to be uniquely susceptible to the development of such lesions.

The treatment had no effect on body weights or on survival. There was only a small increase in the hyperplasia of the forestomach and a trend for an increase in papillomas in those gavaged for two years. Thus, there was only a minor effect even after the relatively severe treatment over a period of two years.

There were discrepancies in the design and conduct of the studies and in the interpretation of the results. Benzaldehyde is a natural constituent of several species of edible plants and, as such, has been consumed orally on a continuous basis by large segments of the human population for centuries with no indication of adverse effects. The study therefore should have used the diet as the route of exposure rather than repeated gavage in corn oil. This in itself as noted above results in chronic gastric irritation and, sometimes, in hyperplasia and papillary proliferation of the forestomach of rodents. Second, there were no squamous cell carcinomas observed which, if present, might have suggested a continuum from hyperplasia to malignancy. Thus, only a proliferative benign lesion was associated with repeated gavage for two years. Third, the human does not possess a squamous forestomach similar to the rodent. There were no lesions in the glandular stomach of the mice which is similar to the glandular stomach of the human. These observations strongly suggest that the NTP studies have no significance for humans. After careful review of all the data, the FEMA Expert Panel concluded that, under conditions of intended use as a flavor ingredient, benzaldehyde continues to be generally recognized as safe under conditions of intended use as a flavor ingredient.

—Continued on page 108

16. GRAS Substances (continued)

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—Continued on page 112

16. GRAS Substances (continued)

GRAS 16—Primary Names and Synonyms^a

FEMA No	Substance	FEMA No	Substance
3775	ACETALDEHYDE ETHYL (Z)-3-HEXENYL ACETAL Acetaldehyde ethyl cis-3-hexenyl acetal cis-1-(1-Ethoxyethoxy)-3-hexene Ethyl cis-3-hexenyl acetal 3-Hexene, 1-(1-ethoxyethoxy)-, (Z)-	3786	gamma-METHYLDECALACTONE Dihydrojasnone lactone 2(3H)-Furanone, 5-hexyldihydro-5-methyl- 4-Methyldecanolide
3776	DIHYDRONOOTKATONE 2(1H)-Naphthalenone, octahydro-4, 4a-dimethyl-6-(1-methylethenyl)-, [4R(4.alpha.,4a.alpha.,6.beta.,8a.beta.)]-	3787	2-METHYL-3-TETRAHYDROFURANTHIOL
3777	1-ETHOXY-3-METHYL-2-BUTENE 2-Butene, 1-ethoxy-3-methyl- Ethyl 3-methyl-2-butenyl ether Prenyl ethyl ether	3788	METHYLTHIO 2-(ACETYLOXY) PROPIONATE Acetyl lactic acid thiomethyl ester S-Methyl-2-(acetyloxy) propanethioate Propanethioic acid, 2-(acetyloxy)-, S-methyl ester
3778	(Z)-3 & (E)-2-HEXENYL PROPIONATE Green note propionate cis-3 & trans-2-Hexenyl propionate Propanoic acid, cis-3 & trans-2-hexenyl ester	3789	3-(METHYLTHIO) HEXYL ACETATE
3779	HYDROGEN SULFIDE	3790	METHYLTHIO 2-(PROPIONYLOXY) PROPIONATE S-Methyl-2-(propionyloxy) propanethioate Propionyl lactic acid thiomethyl ester
3780	(Z)-4-HYDROXY-6-DODECENOIC ACID LACTONE gamma-Dodecen-6-lactone 1,4-Dodec-6-enolactone cis-6-Dodecen-4-olide 2(3H)-Furanone, dihydro-5(2-octenyl)-, (Z)-	3791	OCTAHYDROCOUMARIN 2H-1-Benzopyran-2-one, octahydro- Bicyclononalactone Cyclohexyl lactone
3781	2(4)-ISOBUTYL-4(2), 6-DIMETHYLDIHYDRO-4H-1,3,5-DITHIAZINE Dimethyl isobutyl dihydro-1,3,5-dithiazine	3792	2-PENTANETHIOL sec-Amylmercaptan 2-Mercaptopentane 1-Methylbutanethiol
3782	2(4)-ISOPROPYL-4(2),6-DIMETHYLDIHYDRO-4H-1,3,5-DITHIAZINE Dimethyl isopropyl dihydro-1,3,5-dithiazine	3793	D-RIBOSE D-Ribo-2,3,4,5-tetrahydroxyvaleraldehyde
3783	JAMBU OLEORESIN Spilanthes acmelia (oleracea) oleoresin	3794	SCLAREOLIDE Decahydro tetramethyl naphtho-furanone Naphtho[2,1-b]furan-2(1H)-one, decahydro-3a,6,6,9a-tetramethyl-, [3aR-(3a.alpha.,5a.beta.,9a.alpha.,9b.beta.)] Norambrienolide
3784	3-1-MENTHOXYPROPANE-1,2-DIOL 3-1-(p-Menthane-3-yloxy)-1,2-propanediol	3795	1,3,5-UNDECATRIENE
3785	4-METHOXY-2-METHYL-2-BUTANETHIOL 2-Butanethiol, 4-methoxy-2-methyl-	3796	VANILLYL BUTYL ETHER 4-(Butoxymethyl)-2-methoxyphenol Phenol, 4-(butoxymethyl)-2-methoxy-

^aPrimary names, in capital letters, and synonyms, in lower case, are listed alphabetically.

GRAS Flavoring Ingredients and Usage Levels

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

FEMA No.	Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Other uses
3775	Acetaldehyde ethyl (Z)-3-hexenyl acetal					0.04/0.4			0.04/0.3		Milk Products—0.08/0.4 Fruit Ices—0.02/0.1 Hard Candy—2.0/5.0 Chewing Gum—3.0/7.0
3776	Dihydronootkatone	1.5/4.0	0.7/2.0		1.0/3.0	1.0/3.0			0.2/0.3	0.5/1.5	Milk Products—0.5/1.5 Fruit Juice—0.5/1.5 Fruit Ices—0.6/1.8 Confectionary & Frosting—0.5/1.5 Jams & Jelly—0.8/2.5 Hard Candy—1.0/3.0 Chewing Gum—5.0/10 Granulated Sugar—0.5/1.5 Instant Coffee & Tea—0.2/0.5 Seasonings & Flavors—1.0/3.0

—Continued on page 114

16. GRAS Substances (continued)

FEMA No.	Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Other uses
3777	1-Ethoxy-3-methyl-2-butene		0.3/1.5		1.0/5.0	0.8/3.0			0.1/0.5	0.5/3.0	Milk Products—0.3/1.5 Fruit Juice—0.5/2.0 Fruit Ices—0.6/2.2 Confectionery & Frosting—0.7/2.5 Jams & Jelly—0.8/3.0 Hard Candy—2.0/5.0 Chewing Gum—5.0/15 Granulated Sugar—1.0/5.0 Sugar Substitutes—1.0/5.0 Instant Coffee & Tea—0.1/0.5 Seasonings & Flavors—1.0/5.0
3778	(Z)-3 & (E)-2-Hexenyl propionate	5.0/5.0			10/20				10/20	20/30	Breakfast Cereals—10/20 Frozen Dairy—10/20 Fruit Juice—10/20 Fruit Ices—10/20 Processed Vegetables—10/20 Condiments & Relish—10/20 Confectionery & Frosting—10/20 Jams & Jelly—10/20 Gelatins & Puddings—10/20 Reconstituted Vegetables—15/25 Hard Candy—15/25 Chewing Gum—15/30 Instant Coffee & Tea—15/20 Seasonings & Flavors—20/30
3779	Hydrogen sulfide	1.0/10	0.7/2.0	50/150		1.0/3.0	10/50		0.5/1.5	0.7/2.0	Breakfast Cereals—1.0/10 Fats & Oils—2.0/50 Milk Products—1.0/5.0 Cheese—3.0/20 Fruit Juice—2.0/5.0 Fruit Ices—0.5/1.5 Poultry—20/100 Egg Products—50/150 Fish Products—10/50 Processed Vegetables—10/50 Confectionery & Frosting—1.0/3.0 Gravies—10/50 Imitation Dairy—1.0/5.0 Hard Candy—1.0/5.0 Chewing Gum—0.5/1.0 Instant Coffee & Tea—5.0/50
3780	(Z)-4-Hydroxy-6-dodecenoic acid lactone	3.0/10									Milk Products—2.0/10 Fruit Ices—0.2/1.0 Imitation Dairy—1.0/5.0
3781	2(4)-Isobutyl-4(2), 6-dimethylidihydro-4H-1,3,5-dithiazine	0.5/5.0		0.5/5.0	0.5/5.0		0.1/2.0	0.5/5.0			Breakfast Cereals—0.5/5.0 Milk Products—0.05/1.0 Confectionery & Frosting—0.5/5.0 Nut Products—0.5/5.0 Hard Candy—0.5/5.0 Chewing Gum—1.0/20
3782	2(4)-Isopropyl-4(2), 6-dimethylidihydro-4H-1,3,5-dithiazine	0.5/5.0		0.5/5.0	0.5/5.0		0.1/2.0	0.5/5.0			Breakfast Cereals—0.5/5.0 Milk Products—0.05/1.0 Confectionery & Frosting—0.5/5.0 Nut Products—0.5/5.0 Hard Candy—0.5/5.0 Chewing Gum—1.0/20
3783	Jambu oleoresin						5.0/10	5.0/20			Fish Products—10/30 Processed Vegetables—5.0/20 Condiments & Relish—10/30 Sweet Sauce—10/30 Reconstituted Vegetables—5.0/20 Chewing Gum—20/100 Seasonings & Flavors—20/100
3784	3-1-Methoxypropane-1,2-diol				100/500	500/1,000			300/500	300.0/500.0	Confectionery & Frosting—100/500 Imitation Dairy—100/500 Hard Candy—500/500 Chewing Gum—3,000/4,000

—Continued on page 116

16. GRAS Substances (continued)

FEMA No.	Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Other uses
3785	4-Methoxy-2-methyl-2-but-anethiol		0.0001/0.01	0.02/0.05	0.02/0.05	0.0001/0.01			0.01/0.02	0.01/0.03	Milk Products—0.001/0.01 Fruit Juice—0.01/0.03 Fruit Ices—0.02/0.05 Poultry—0.001/0.01 Fish Products—0.001/0.01 Confectionery & Frosting—0.001/0.01 Jams & Jelly—0.001/0.01 Sweet Sauces—0.001/0.01 Gravies—0.02/0.03 Hard Candy—0.02/0.05 Chewing Gum—0.02/0.1 Instant Coffee & Tea—0.001/0.01 Seasonings & Flavors—0.001/0.01
3786	gamma-Methyl-decalactone	1.0/3.0	0.5/1.0		0.5/1.5	1.0/3.0			1.0/3.0	1.0/5.0	Milk Products—0.5/1.0 Fruit Juice—0.5/1.0 Hard Candy—0.5/1.5 Chewing Gum—1.0/2.0
3787	2-Methyl-3-tetrahydro-furanthiol			0.5/2.0			0.3/1.0	5.0/15			Gravies—0.5/2.0
3788	Methylthio 2-(acetyloxy) propionate	0.5/2.3	0.2/0.6		0.2/0.6	0.02/0.2		0.5/1.2	0.02/0.2		Fats & Oil—0.2/0.6 Milk Products—0.2/0.6 Cheese—0.2/0.6 Condiments & Relish—10/23 Imitation Dairy—0.2/1.0 Seasonings & Flavors—10/23
3789	3-(Methylthio) hexyl acetate				0.1/0.5	0.1/0.3			0.01/0.1	0.01/0.1	Hard Candy—0.1/0.5 Chewing Gum—0.5/1.0
3790	Methylthio 2-(propionyl-oxy)propion-ate	0.7/3.5	0.3/0.5		0.4/1.2	0.02/0.2		0.75/1.7	0.02/0.3		Fats & Oils—0.3/0.7 Milk Products—0.3/0.7 Cheese—0.3/0.7 Poultry—0.1/0.5 Condiments & Relish—15/34 Imitation Dairy—0.3/0.7 Seasonings & Flavors—15/34
3791	Octahydro-coumarin	15/25	2.0/10		5.0/15	2.0/10			1.0/3.0		Milk Products—1.0/5.0 Nut Products—5.0/20 Imitation Dairy—1.0/5.0 Hard Candy—2.0/20 Chewing Gum—10/55
3792	2-Pentanethiol	0.06/0.1	0.02/0.06	0.005/0.05	0.05/0.1	0.01/0.05	0.001/0.01	0.01/0.05	0.02/0.04	0.01/0.03	Breakfast Cereals—0.02/0.05 Fats & Oils—0.005/0.02 Milk Products—0.001/0.01 Cheese—0.001/0.01 Fruit Juice—0.005/0.05 Fruit Ices—0.02/0.04 Condiments & Relish—0.02/0.1 Confectionery & Frosting—0.02/0.1 Jams & Jelly—0.005/0.05 Sweet Sauce—0.01/0.05 Gravies—0.005/0.05 Imitation Dairy—0.02/0.06 Hard Candy—0.03/0.1 Chewing Gum—0.01/0.1 Instant Coffee & Tea—0.005/0.05
3793	D-Ribose	200/1,000		500/1,000			500/1,000	200/1,000			Poultry—500/1,000 Fish Products—500/1,000 Gravies—500/1,000
3794	Sclareolide	2.0/3.0	1.0/3.0	1.0/4.0	1.0/3.0	1.0/2.0	1.0/2.0	2.0/4.0	1.0/5.0	1.0/5.0	Breakfast Cereals—1.0/3.0 Fats & Oils—1.0/2.0 Milk Products—2.0/4.0 Cheese—1.0/3.0 Fruit Juice—1.0/3.0 Fish Products—1.0/2.0 Processed Vegetables—1.0/2.0 Sweet Sauce—1.0/2.0 Reconstituted Vegetables—1.0/2.0 Gravies—1.0/2.0 Imitation Dairy—3.0/10 Hard Candy—1.0/3.0 Sugar Substitutes—1.0/3.0 Seasonings & Flavors—1.0/3.0

FEMA No.	Substance	Baked Goods	Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Other uses
3795	1,3,5-Undecatriene	0.02/0.5	0.015/0.4	0.05/1.2	0.03/0.7	0.01/0.3	0.01/0.3	0.04/1.0	0.004/0.1	0.02/0.5	Breakfast Cereals—0.01/0.25 Other Grain—0.01/0.25 Fats & Oils—0.05/1.0 Milk Products—0.01/0.25 Cheese—0.015/0.4 Fruit Juice—0.02/0.5 Fruit Ices—0.01/0.25 Poultry—0.05/1.2 Egg Products—0.02/0.5 Fish Products—0.03/0.7 Processed Vegetables—0.01/0.25 Condiments & Relish—0.02/0.5 Confectionery & Frosting—0.02/0.5 Jams & Jelly—0.02/0.5 Sweet Sauce—0.02/0.5 Nut Products—0.01/0.25 Reconstituted Vegetables—0.01/0.25 Gravies—0.03/0.7 Imitation Dairy—0.02/0.5 Hard Candy—0.02/0.5 Chewing Gum—0.5/5.0 Granulated Sugar—0.02/0.5 Sugar Substitutes—0.02/0.5 Instant Coffee & Tea—0.004/0.1 Seasonings & Flavors—0.2/5.0
3796	Vanillyl butyl ether	5.0/20		2.0/10	2.0/10		5.0/10	5.0/20	2.0/10	2.0/10	Breakfast Cereals—5.0/20 Other Grain—5.0/20 Egg Products—5.0/10 Processed Vegetables—5.0/20 Condiments & Relish—5.0/10 Reconstituted Vegetables—5.0/10 Gravies—5.0/10 Hard Candy—5.0/10 Chewing Gum—5.0/10