FEMA Expert Panel: 30 Years of Safety Evaluation for the Flavor Industry

A history of the Flavor and Extract Manufacturers Association's Expert Panel and their endeavor to evaluate the safety of flavoring materials

Bernard L. Oser and Richard A. Ford

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☐ AN INDEPENDENT PANEL of expert toxicologists, pharmacologists, and biochemists has served the flavor industry, and thereby the public and the Food and Drug Administration (FDA), for more than 30 years by acting as the primary body for evaluation of the safety of flavor ingredients. This group, known as the Expert Panel of the Flavor and Extract Manufacturers Association (FEMA) is well recognized for this activity, not only throughout the flavor industry, but throughout the toxicology community.

The Panel owes its origin to its founder Bernard L. Oser, who served as its Chairman from the beginning until 1985, and to the foresight of those in the industry, especially Richard L. Hall and the members of FEMA, who understood the need for an independent panel of experts as provided for in the Food Additives Amendment of 1958, to review and oversee the many substances used in flavor formulations. Hall's knowledge, experience, and persuasive oratory greatly facilitated the support and cooperation of the flavor industry in this effort. The FEMA program, and particularly the role of the Expert Panel, is the main subject of this article.

The enactment, in 1958, of the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act created a completely new set of requirements for both FDA and the regulated industries. The Amendment defined a food additive as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not **generally recognized,** among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (. . . or experience based on common use in food) to be safe under the conditions of its intended use . . . " (emphasis added). The latter part of this definition exempted a large number of substances which were generally recognized as safe (GRAS) under conditions of intended use, from the rigorous requirements for evidence of safety for food additives. There existed not only the problems created by the increased requirements for new food additives, but also the problem of determining which substances, among the large backlog then thought to be in use should be considered as food additives and which should be considered GRAS.

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Backlog of Substances

FDA began to deal with this backlog beginning in 1958 by publishing in the *Federal Register* partial lists of substances believed to be GRAS. These covered many common natural flavors including several hundred spices, and only 27 well known synthetic flavors. The contrast between these lists and the well over one thousand flavoring substances known to have been in use at the time illustrates the difficulty FDA had when it came to flavors.

Flavors are a numerous but highly specialized group of food ingredients. Hundreds of naturally occurring chemicals, and many others, are made synthetically and thousands are normal components of food. Knowledge of their identity and conditions of use was not generally available outside the food and flavor industries or to those asked to judge the safety of substances on the FDA lists. The large, disparate group of people directly or indirectly invited to comment through the *Federal Register* publications either could not do so or provided a mixed and not very useful response.

By 1960, dealing with the backlog came to a standstill. It was clear that the FDA effort at GRAS determination and publication could not continue in the same direction. Neither was it conceivable that the small flavor industry could meet the literal requirements of a food additive petition for all, or even a significant percent, of the flavoring substances then in use.

At this point the flavor industry's trade association, FEMA guided by Oser, decided to utilize the

missing pages and ads.

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Table 1—**FEMA Expert Panel**—*Past and Present*

Anthony A. Ambrose, Ph.D.
Member, 1971-83 (deceased)
Professor, Medical College of Virginia

Bruce K. Bernard, Ph.D.
Executive Secretary, 1983-85
President, Scientific Research Associates, Inc.

Frank R. Blood, Ph.D.
Member, 1969-70 (deceased)
Professor, Vanderbilt University School of Medicine

George A. Burdock, Ph.D.
Executive Secretary, 1986-present
Director, Scientific Affairs, FEMA

John Doull, M.D., Ph.D.
Member, 1978-present
Professor, University of Kansas Medical Center

David W. Fassett, M.D.
Member, 1960-83 (retired)
Director, Eastman Kodak Health and Safety Laboratory

Richard A. Ford, Ph.D.
Executive Secretary, 1970-82
Liaison Member, 1982-present
President, Research Institute for Fragrance Materials

Horace W. Gerarde, Ph.D., M.D.
Member, 1960-74 (deceased)
Medical Director, Becton Dickinson and Co.

Richard L. Hall, Ph.D.
Executive Secretary, 1960-66 (retired)
Vice President, McCormick & Co.

Ian Munro, Ph.D.
Member, 1986-present
Canadian Centre for Toxicology

Paul M. Newberne, Ph.D., D.V.M.
Member, 1979-present
Professor, Boston University School of Medicine

Bernard L. Oser, Ph.D.
Founder and Nonvoting Chairman, 1960-86
Chairman Emeritus, 1987-present (retired)
Bernard L. Oser and Associates

Philip S. Portoghese, Ph.D.
Member, 1984-present
Professor, University of Minnesota, College of Pharmacy

Maurice H. Seevers, Ph.D., M.D.
Member, 1960-74 (deceased)
Professor, University of Michigan Medical School

Robert L. Smith, Ph.D., D.Sc.
Member, 1981-present
Professor, St. Mary's Hospital Medical School, University of London

Howard C. Spencer, Ph.D.
Member, 1960-84 (retired)
Toxicologist, Dow Chemical Co. Biomedical Laboratory

Jakob A. Stekol, Ph.D.
Member, 1960-69 (deceased)
Fels Institute for Cancer Research

Frank M. Strong, Ph.D.
Member, 1970-76 (deceased)
Professor, University of Wisconsin

Bernard M. Wagner, M.D.
Member, 1983-present
Deputy Director, Nathan Kline Institute, Research Professor, New York University School of Medicine

Carrol S. Weil, M.A.
Member, 1981-present (retired)
Corporate Research Fellow, Bushy Run Research Center, Mellon Institute

R. Tecwyn Williams, Ph.D., M.D.
Member, 1975-80 (deceased)
Professor, St. Mary's Hospital Medical School, University of London

Lauren A. Woods, Ph.D., M.D.
Member, 1960-present
Professor Emeritus, Medical College of Virginia, Virginia Commonwealth University

FEMA Expert Panel (continued)

only feasible method for evaluating flavor materials by employing the statutory exclusion from the definition of food additive of any substance that was "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use".

It was recognized that two problems had to be addressed for this effort to be successful. First the experts that would be asked to determine if the flavoring substances in use were GRAS must not only be shown to be qualified by training and experience, they must also have no connection with the food or flavor industry that might instill any bias. Additionally, before such a determination could be made, the "conditions of its intended use" must be determined for each of these flavoring materials.

On the advice of Oser, FEMA urged its members to cooperate by making available their unique knowledge and data concerning usages of flavoring substances and common practice in the food industry. FEMA began by conducting, in 1959–60, the first comprehensive survey of the identity and uses of all known flavoring substances in the United States. This set a pattern for later surveys of other food ingredients, conducted by the National Academy of Sciences under contract with the Food and Drug Administration. FDA not only encouraged the FEMA program but supplied its own list of several hundred natural flavor substances including spices, herbs, essential oils, etc. as well as extracts and derivatives thereof.

Creation of an Expert Panel

FEMA also agreed to sponsor the creation of a panel of eminently qualified experts, and supply them with all available information related to safety-in-use of each flavoring substance. The original Panel was selected by Oser as were the subsequent replacements due to the normal processes of attrition. Oser's experience included membership in the Food Protection Committee of the National Academy of Science/National Research Council, the World Health Organization/Food and Agriculture Organization of the United Nations, and the International Union of Pure and Applied Chemistry. It was his personal influence and preeminence in the field that persuaded the members to serve in this innovative effort for an organization of which most of them had never heard. That first Panel consisted of Oser as the nonvoting chairman, David W. Fassett, Horace W. Gerarde, Maurice H. Seevers, Howard C. Spencer, Jakob A. Stekol, and Lauren A. Woods (Table 1). Richard L. Hall served as the Panel's Executive Secretary.

While one original member of the Panel (Woods) still serves, others have been replaced over the years by a few highly qualified individuals who have served for varying terms (Table 1). The current members of the Panel are John Doull, Ian Munro, Paul Newberne, Phil Portoghese, Robert Smith, Bernard Wagner, Carrol Weil, and Lauren Woods. Robert Smith is the current Chairman of the Panel, Paul Newberne its Cochairman, and Richard Ford is the Liaison member to the similar Expert Panel

of the Research Institute for Fragrance Materials. George Burdock serves as the Executive Secretary.

The Panel was asked not only if they considered each substance to be safe, but whether their conclusions could reasonably be expected to be shared by other qualified experts, provided they were equally well informed of the data. From the beginning, policy required that all GRAS decisions of the Panel be unanimous, not merely consensual, and published in the open literature for comment by the scientific community at large. It is also important to note that all decisions on GRAS status were and are made in executive session with no employees of the flavor or food industry present.

Developing Criteria

The Panel spend a substantial amount of time in their earlier days developing criteria to be used in reaching a conclusion as to the GRAS status of flavoring substances. This was a particularly challenging task because the majority of these substances had little or no classical toxicological data. Yet the levels and volumes of use were so low and the chemical structures so innocuous that intutition would dictate that there was no reason to be concerned about health effects under the conditions of use. Of course, intuition hardly meets the definition of scientific procedures called for in the GRAS exemption. On the other hand, many of these materials did meet the provision of "experience based on common use in food" since they were natural constituents of food and/or had been used as flavors for many years. The Panel considered both the history of use and scientific procedures in devising a set of criteria to be used to establish the GRAS status of flavor substances. While these criteria were developed in the early 60's, they were first published in 1973 (Gerarde, 1973). The list of 20 criteria is too long to be discussed in detail, but some of the important points should be mentioned.

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Where classical toxicity data are available, these can be used with an adequate safety factor. But what was the Panel to do in those many cases where such data are not available? Chemicals normally present in food and consumed by man through the ages without any apparent adverse effects, can be presumed to be safe at the concentrations found in these foods. The Panel also developed several general principles based on the chemical structures of the substances.

While it was recognized that minor changes in structure may be accompanied, in some cases, by profound changes in toxicity, there are several trends that are obvious such as: in a homologous series of aliphatic organic compounds such as the hydrocarbons, alcohols, aldehydes, carboxylic acids, esters, and ketones, there is usually a stepwise change in toxicity accompanying stepwise changes in chemical structure. Thus, the toxicity of a member of a homologous series can be predicted from the toxicity of the immediately adjacent congeners. Also the introduction of double or triple bonds in the carbon chain of a homologous series increases the toxicity while increasing the molecular weight tends to decrease the toxicity. It was recognized that the functional group or groups in a molecule determines not only the nature and quality of the toxic action inherent in a chemical, but also the chemical structure of biotransformation products. Such biotransformation can lead either to increased toxicity (activation) or serve as a detoxication mechanism. Therefore, metabolism must be considered along with the chemical structure.

It was well recognized that such generalizations do not provide precise predictions and cannot be used in isolation but when combined with the very low levels of use (Tables 2 and 3) of most flavor materials, provide considerable help in reaching a decision on the safety under the conditions of use.

Key to many of the Panel's deliberations was the consideration of the low levels of use along with the chemical considerations mentioned above. This prompted the definition of Toxicologically Insignificant Usage, TIU (Hall, 1960) signifying simultaneous fulfillment of all the following qualifications: (1) use for at least 10 years by more than one company, (2) average maximum use level in any finished food not in excess of 10 ppm, (3) annual national consumption of less than 1,000 lb, (4) absence of any unfavorable indications from structure, composition, or experience in use, which would cast doubt on its safety.

The Panel, with the considerable assistance of FEMA, proceeded to gather and review all of the available data on (1) toxicity, (2) metabolism, (3) natural occurrence in foods, (4) analogies with chemically related substances, the toxicity or metabolism of which were known, (5) the nature, level and volume of use in foods, and (6) the toxicological significance of the levels in use for more than 800 substances. This review resulted in the conclusion that 662 chemically defined flavoring substances were GRAS under the conditions of use.

A list of GRAS flavoring substances representing the Panel's early conclusions was published in *Food Chemical News* in 1961. In 1960 and 1961 *Food Technology* published two articles dealing with the evolving FEMA program (Hall, 1960; Hall and Oser, 1961). These early lists were greeted at first with tacit, and then explicit acceptance by FDA, and later by many foreign governmental and intergovernmental agencies.

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Reviewing Natural Flavors

In 1962 the Expert Panel, at the suggestion of FDA personnel, began to review botanically derived natural flavors in addition to the single chemical substances that had been the Panel's focus. Since many of the criteria used in evaluating single substances did not apply to natural flavors, the Panel developed special criteria for this class of flavors. Such substances were required to (1) have been in use by at least two firms, one of which must have used it for at least 20 years and there must have been at least 40 "firm-years" (number of firms times years of common use), (2) be used in a range of food categories, presumably resulting in relatively wide consumption or in specific products widely used, and (3) be absent of any information suggesting possible hazard under conditions of use. Additionally, the Panel looked for knowledge of the structure, toxicity, or metabolic fate of the principal and significant constituents, the toxicological insignificant use (less than 10 ppm in any food category and less than 1,000 lb/year), and any experience in drug use that provides an indication of safety, specific experience in human consumption or the dosage necessary to produce physiological effects. In cases where the constituents were largely unknown only the presence of toxicological data and a basis for an assumption of uniform composition permitted a conclusion of GRAS.

The first comprehensive list of GRAS flavoring substances including both chemically defined and botanically derived materials appeared in *Food Technology* in February 1965 with an accompanying explanation of the Panel's conclusions. This list was designated as "GRAS III" (Hall and Oser, 1965), since it followed the first two preliminary lists. All subsequent FEMA GRAS lists have also appeared in *Food Technology*.

GRAS III declared 1,124 flavoring substances to be GRAS, with 267 others being reported as dropped from use because they did not meet the criteria for GRAS status. This program received wide public and interagency comment, and was later adopted nearly in its entirety by FDA in two food additive regulations, one covering natural and the other synthetic flavoring substances (21 CFR 172.510 and 172.515). The effect of the separation is to lend support to the myth that "natural" is better or safer than the artificial or synthetic.

As the backlog of substances already in use began to diminish, FEMA and the Panel began to address the preclearance of new substances. While the criteria that had been used in the early days of the Panel were, for the most part, applicable to the evaluation of new substances, it was obvious that these criteria should be reviewed.

The history of use criteria and TIU, as it was originally defined by the Panel, did not apply to new materials unless they were natural constituents of food and the intended conditions of use resulted in exposures that were similar to or lower than those from consuming the food in which they were a constituent. The Panel (Hall and Oser, 1972) turned to the definition of TIU that was developed by the National Academy of Sciences/National Research Council (NAS/NRC, 1970) and defined as follows: If a substance meets all the following criteria, it may be presumed to be toxicologically insignificant at a level of 1.0 ppm or less in the human diet: (1) the substance in question is of known structure and purity, (2) it is structurally simple, (3) the structure suggests that the substance will be readily handled through known metabolic pathways, and, (4) it is a member of a closely related group of substances, that, without known exception, are or can be presumed to be low in toxicity. This differs only slightly from the Panel's original version. It does not include the requirements of at least 10 years of use and a maximum limit on annual volume. The 10 ppm used by the Panel is equivalent to the NAS limit of 1.0 ppm in the human diet only when the food in which the flavor is used constitutes 10% of the diet, obviously not a likely situation.

The Panel concluded that substances not meeting these criteria would require stronger evidence of safety in the form of metabolic and/or toxicological data.

As a foundation for assessing the safety of flavoring substances under the conditions of use, companies are required to submit all pertinent and available information concerning chemical structure, volume of production, levels of use in foods, occurrence in nature, analogy to similar or related substances. Assurance is given of strict observance of confidentiality by the Panel. In the event that the available data are deemed insufficient to permit a

Table 2—**Annual Usage Volumes** *of GRAS flavoring substances*[a]

Usage (Kg/Yr)	No. of substances	Percent of total	Percentile
0-1	663[b]	38	38
>1-10	203	11	49
>10-100	272	16	65
>100-1,000	272	16	81
>1,000-10,000	153	9	90
>10,000	178	10	100
Total	1,741	100	

[a]Through GRAS list No. 14 based on 1987 survey
[b]401 Substances have no reported usage

Table 3—**Ranges of Average Maximum Use Levels** *of GRAS flavoring substances in foods*

Usage range (ppm)	No. of substances	Percent of total	Percentile
0-0.99	166	9	9
1-9.9	449	26	35
10-99	738	42	77
100-499	222	13	90
>500	166	10	100
Total	1,741	100	

determination of GRAS status, submitters are asked to develop the additional data needed to fill the gaps.

Another important concept adopted by the Panel addresses the fact that new substances are not widely known and while their proposed use might be easily concluded to be safe, the general recognition referred to in the Food Additives Amendment would be difficult to establish. Thus, the Panel decided that part of the criteria for GRAS status was publication of the Panel's conclusions in the open literature for comment and general knowledge. Only after a suitable interval with no challenges to the Panel's decisions, could it be truly said that the substances are GRAS.

The first of the publications of new substances (GRAS IV) appeared in 1970 (Hall and Oser, 1970). Over the years, almost 1,800 substances have appeared on FEMA GRAS lists (see references). Several hundred have been dropped from use, or not determined to be GRAS, largely because of inadequate data, or new evidence, and insufficient potential commercial value to justify acquiring the information the Panel required.

Continuing Efforts

The Panel has continued to review flavoring substances for GRAS status to this day. The results have been published in a series of lists in *Food Technology* (Hall and Oser, 1970, 1972; Oser and Ford, 1973a, b, 1974, 1975, 1977, 1978, 1979; Oser et al., 1984, 1985; Burdock et al., 1990) with 1,761 substances currently considered GRAS by the Panel. Publication of the next GRAS list (GRAS 16) covering substances reviewed by the Panel over the past two years is planned for publication in this journal in the near future.

The sound basis for the GRAS decisions is reflected in the fact that only 10 substances have been removed from the GRAS list: alkanet root extract, brominated vegetable oil, calamus, calamus oil, 2-hexyl-4-acetoxytetrahydrofuran, 4-methylquinoline, musk ambrette, 3-nonanon-1-yl acetate, 2-methyl-5-vinylpyrazine and o-vinylanisole. Only two challenges to the Panel's decisions have been made over the years. The first was for saccharin where it must be kept in mind that the Panel only considered the use of saccharin as an ingredient in flavors, not as general purpose sweetener. Also, it could be maintained that Congress has determined saccharin to be generally recognized as safe. The other challenge was for cinnamyl anthranilate which, despite the industry's voluntary agreement not to use this substance, remains on the GRAS list while further testing proceeds. The results of this testing to date completely support the Panel's conclusion.

In 1968, the Panel decided that since it would shortly be 10 years since they had started their review of flavor materials, a second GRAS review should be undertaken. This review would take into account any changes in the pattern of usage along with increased knowledge in toxicology, especially where it might have an effect on assumptions about metabolic fate and structural analogy.

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The Panel called for a second industry-wide survey of flavor materials. This was later combined with the NAS/NRC 1970 survey of food additives (the first sponsored by FDA). The need to refine intake estimates by reducing the cumulative exaggerations involved in previous estimates led to the probabilistic intake method (Hall, 1976) which provided, for the first time, a categorization of intakes by age groups. This concept was subsequently adopted by the NAS/NRC in their 1977 survey of food additives.

In preparation for the project, the Panel called not only for a new survey of usage but also for a complete updating and review of the scientific literature for each of the flavoring substances. The Panel considered that the only practical method for gathering and presenting all of the relevant data on the approximately 1300 chemically defined flavoring substances then in use, was to group them by similar chemical structures in a group of Scientific Literature Reviews (SLRs). They designed these SLRs to include abstracts of reports on metabolism and toxicology, exposure data in the form of levels of use in particular food categories as well as total annual volume of use, chemical structures, physical properties, and a summary section where the data are discussed.

Preparation for this SLR project was well under way when FDA called for a "cyclic" review of all food additives and began its own GRAS review. As in 1960, when FDA came to the review of flavors, they found the task overwhelming, especially considering the very low priority they put on this class of food ingredients. After considerable discussion between FEMA and FDA, it was decided that mutual interest would be served if FDA contracted with FEMA to produce the SLRs that FDA would then use to complete its review. The result of this was the preparation of 69 SLRs with 28 supplements reviewing the data on approximately 1300 chemically defined flavor ingredients (Ford, 1974–77).

During the discussions with FDA, it was pointed out that the criteria that the Panel used were not generally known. This led to a publication with a detailed discussion of these criteria (Oser and Hall, 1977). This publication has recently been updated by a discussion of the evolution of the Panel's GRAS evaluation process and their current criteria (Woods

and Doull, 1991).

Another problem presented by the large number of substances was where to start and in what order to proceed with the review. This concern led to the development of the so-called FEMA Decision Tree (Cramer et al., 1978). This decision tree, through a series of 33 questions, mostly about chemical structure, classifies substances into one of three classes; low, intermediate, and high presumed toxicity. These three classifications, when combined with exposure lead clearly to a priority classification. Thus, high presumed toxicity combined with high volume of use results in the highest priority for review while low presumed toxicity combined with low usage results in the lowest priority. Other combinations are in between.

The Panel has now completed its second review of flavor materials in use in the USA except for the botanical extracts, oils, and others. Methods are being developed for a review of these "naturals." The Panel has begun another review calling for a much needed update of the SLRs to include the latest usage data as well as an update of other relevant data.

The Expert Panel that has performed the central role in the FEMA GRAS program is still, after 30 years, without parallel. Its efforts have been of inestimable value to the flavor industry and to the food, drug, and related industries so dependent on its products. It is difficult to conceive of where these industries would now be without the successful accomplishment of the Panel's continuing efforts.

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—Edited by James Giese, Associate Editor