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U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FEDERAL BUREAU OF INVESTIGATION
WASHINGTON, D.C. 20535

**The 1977 Survey of Industry on the
Use of Food Additives**

Volume 1 of 3

Description of the Survey

**Committee on GRAS List Survey--Phase III
Food and Nutrition Board
National Research Council**

**NATIONAL ACADEMY OF SCIENCES
Washington, D.C.
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16. Abstract (Limit 200 words) This report contains detailed information with regard to the data collected in the 1977 Survey of Industry on the Use of Food Additives undertaken by committees of the Food and Nutrition Board of the National Research Council under sponsorship of the Food and Drug Administration (FDA). The report consists of three volumes each presenting a discussion of (and in the case of Volumes 2 and 3, data from) the 1977 survey. Volume 1 provides an overview of the entire survey: background information, nature of the questionnaire and the rationale behind its development, and procedures for processing the data. The survey questionnaire document is reproduced as Appendix A of Volume 1. Volume 2 contains aggregated food additive data from the survey including annual poundage, reported technical effects, and use levels aggregated in greater than 200 food sub-categories. Volume 3 contains estimates of the daily intake of substances reported in the survey. Both Volume 2 and 3 contain sections on methodology and discussions concerning limitations on the interpretation of the data. The survey covered regulated direct food additives including food colors and "secondary direct" additives, flavoring ingredients not covered in previous surveys, and certain GRAS substances about which more information was desired.				
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NOTICE

The project that is the subject of this report was Approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for this report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The work on which this report is based was performed pursuant to contract number 223-77-2025 with the Food and Drug Administration.

PREFACE

Each volume of this report presents a discussion of (and in the case of Volumes 2 and 3, data from) the 1977 Survey of Industry on the Use of Food Additives.

Volume 1 is designed to provide an overview of the entire survey: background information, nature of the questionnaire and the rationale behind its development, and procedures for processing the data. Instructions designed to aid respondents in completing the questionnaire are dealt with only briefly. This information is covered in great detail in the survey instructions that are reproduced with the remainder of the survey questionnaire document as Appendix A of Volume 1. The organization of this introductory section parallels that of the survey document. In order to gain a better understanding of the survey, the reader should refer to the Appendix that contains the survey questionnaire.

The survey data are found in Volumes 2 and 3 of this report. Volume 2 contains the aggregated data from the survey, an explanation of the way in which some of the data were summarized, and some cautions concerning their interpretation. Volume 3 contains estimates of the daily intake of substances reported in the survey. It, too, includes a section on methodology and some discussion concerning limitations on the interpretation of the data.

The survey was administered by the Committee on GRAS List Survey--Phase III of the National Research Council's Food and Nutrition Board. This Committee, the members of which are listed on the following page, participated in all phases of the survey.

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ACKNOWLEDGEMENTS

The Committee wishes to express its appreciation to the many persons who assisted in the survey. Dr. John Aultan served as a member of the Committee until August, 1977, when his responsibilities as Dean of the College of Pharmacy at the University of the Pacific precluded further participation. The Committee is grateful for his help. Special thanks are due Edward F. Dodson, who acted as staff officer for this project in its early stages. Other members of the project staff who assisted in the survey and its follow-up are: Mrs. Doris E. Hester, of the College of Pharmacy, who was staff officer for the survey; and Mrs. Jane M. Hester, who was staff officer for the follow-up survey. The staff officers were assisted by Mrs. Mary Ann Hester, who was staff officer for the follow-up survey. The staff officers were assisted by Mrs. Mary Ann Hester, who was staff officer for the follow-up survey. The staff officers were assisted by Mrs. Mary Ann Hester, who was staff officer for the follow-up survey.

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BACKGROUND OF THE SURVEY

The 1977 Survey of Industry on the Use of Food Additives is the third in a series of food additive studies undertaken by committees of the Food and Nutrition Board of the National Research Council under the sponsorship of the Food and Drug Administration (FDA). The FDA initiated this effort in 1970 in response to a presidential directive issued the previous year. Prior to 1970 there had been no comprehensive attempt to ascertain the amounts of food additives used by industry and the amounts of these substances ingested by the U.S. population.

In 1958, drafters of the Food Additives Amendment to the Federal Food Drug and Cosmetic Act were faced with a large, undefined group of substances that were then added directly to food and chose to divide these substances into two basic groups. Some substances were recognized by experts on the basis of either "scientific procedures" or "experience based on common use in food," to be safe under the conditions of [their] intended use. This group included all components of food (including those that are generally thought of as food ingredients as well as food chemicals, per se) and was the basis for the category termed "generally recognized as safe" or "GRAS." It should be noted that this term applies to substances in use before January 1, 1958. Substances coming into use after that date are eligible for GRAS status only on the basis of "scientific procedure." The so-called GRAS list (actually a misnomer, as no single definitive list existed) was the focus of the first two surveys by the NAS. The first survey (Phase I) was a pilot study conducted in 1970 to field-test the practicality of the survey instrument. This was followed in 1971 by the Phase II

survey; the results of this survey were published in 1973.¹

The second group of chemicals added directly to food comprises all those that do not have GRAS status. Unlike GRAS substances, the number of these substances is known, and each has received specific approval for use in food. Food colors are included in this category and are regulated separately under the provisions of the Color Additive Amendments of 1960. It is this group that forms the nucleus of substances included in the Phase III survey. In addition to these "regulated food additives," the survey included a number of GRAS substances about which more information was desired. Whenever the term "food additive" is used in this report, it includes all substances that were covered by the survey, regardless of regulatory status.

The 1977 survey was designed to elicit from food processors (and, in some cases, manufacturers of food chemicals) information on the levels at which additives were used in foods and the products to which they were added. Combining use level data with estimates of food consumption made it possible to calculate the potential intake of these additives. This report contains detailed information with regard to the data collected.

¹A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe (GRAS), National Academy of Sciences, Washington, D.C., 1973. Available from National Technical Information Service, Springfield, Virginia (Publication No. PB 221-920).