EVALUATION OF THE HEALTH ASPECTS OF PULPS AS THEY MAY MIGRATE TO FOOD FROM PACKAGING MATERIALS

December, 1973

Prepared for

Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D.C.

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Life Sciences Research Office
Federation of American Societies for Experimental Biology
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Bethesda, Maryland 20014
NOTICE

This report is one of a series of evaluations of the health aspects of the Generally Recognized as Safe (GRAS) food substances that are being made by the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) under contract with the Food and Drug Administration (FDA) of the U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and its resources are particularly suited to marshalling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office, established in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to make a continuing review, analysis, and evaluation of the available information on each of the GRAS substances. These scientists, designated the Select Committee on GRAS Substances, were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. Members of the Select Committee on GRAS Substances who have contributed to this report are named in Section VII. The Select Committee's evaluations are being made independently of FDA or any other governmental or nongovernmental group.

These reports are approved by the Select Committee prior to submission to FDA. Although most LSRO consultants are members of FASEB constituent societies, the reports do not necessarily reflect the views of the Federation as a corporate body or carry the endorsement of the members of its constituent societies.

C. Jelleff Carr, Ph.D., Director
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I. INTRODUCTION

Under terms of FDA Contract 72-85, FASEB's Life Sciences Research Office was requested to evaluate the health aspects of using pulps as food ingredients, primarily on the basis of information contained in a monograph furnished by FDA (1), summarizing the world's scientific literature from 1920 through 1970, and in certain supplemental documents, including current literature citations obtained through Toxline* and Medline*, available as of December, 1973. Certain pulps are food substances that have been generally recognized as safe (GRAS) under the provisions of Section 121.101 and Section 121.2546 of the Code of Federal Regulations (21 CFR 121.101 and 21 CFR 121.2546, revised April 1, 1973).

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321(s)], GRAS substances are exempt from the requirement of premarketing clearance for food additives. It is stated in 21 CFR 121.1 that GRAS means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of substances on the basis of scientific data derived from published literature. This section of the Code also indicates that expert judgment is to be based on the evaluation of results of credible toxicological testing or, for those substances used in food prior to January 1, 1958, on a reasoned judgment founded in experience with common food use, and is to take into account reasonably anticipated patterns of consumption, cumulative effects in the diet, and safety factors appropriate for the utilization of animal experimentation data. It is recognized further (21 CFR 121.3) that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

The Select Committee on GRAS Substances of LSRO is making its evaluations of these substances in full recognition of the foregoing provisions. In reaching its conclusions on safety the Select Committee, in accord with FDA's guidelines, is relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the public health, and realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited. The Committee is also aware that biological testing, like all of science, is dynamic. Accordingly, the Committee's conclusions, based as they are on the information now available, cannot anticipate and be guided by experiments

*Nationwide online bibliographic retrieval systems initiated by the National Library of Medicine, Bethesda, Maryland.
not yet done or by the results of tests that may be reconduted, using new technologies that are continually being evolved. These conclusions will need to be reviewed as new or better information becomes available.

In this context, the LSRO Select Committee on GRAS Substances has reviewed the available information on pulps and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of pulps under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

The term, "pulps", as cited in the Generally Recognized as Safe (GRAS) list, refers to materials in paper or paperboard, derived from wood, straw, bagasse, or other natural sources, that may migrate to foods from food packages or containers (2). In addition to its listing as GRAS, the Code of Federal Regulations also indicates that pulp from reclaimed fiber may be safely employed as a component of articles used in connection with food, provided it is free of poisonous or deleterious substances and is repulped with water to recover the fiber with the least possible amount of non-fibrous substances (3).

Accordingly, this report concerns paper and paperboard as made by conventional paper-making processes. Further, it concerns only such part of the constituents of paper and paperboard as may migrate from packages to the food contained therein.

The principal constituent of paper and paperboard is cellulose, the health aspects of which as a food ingredient have been evaluated in another report of the Select Committee (4). Other constituents, of variable nature and amount, can be present in paper and paperboard depending on the material pulped and the process used. Several of these possible non-fibrous constituents of paper and paperboard such as inorganic salts, are separately cited in the GRAS list (2) and have been, or will be, evaluated in other reports of the Select Committee.

III. CONSUMER EXPOSURE DATA

The Select Committee has not been successful in finding data that would provide an adequate basis for estimating the extent to which the constituents of paper and paperboard migrate to food from packages and
containers. A National Research Council subcommittee report (5) does not include consumer exposure data for materials from this source that may be present in food. Unlined paper and paperboard packages are not used for foods of high moisture content, making it unnecessary to consider the leaching into food of the water soluble, non-fibrous materials from such packages. This report considers only the amount of cellulosic pulp that might enter dry packaged foods as a result of abrasion of the container during marketing, storage, and use. The Select Committee has found no guidelines for estimating this amount. However, it seems logical to assume that the level of consumer exposure to pulps (primarily cellulose) from this source, can only be many fold lower than the amounts of cellulose estimated to be added to processed foods [152.3 mg per kg body weight for an average adult (4)], and orders of magnitude lower than the amounts of cellulose regularly consumed by man as a constituent of his vegetable fare.

IV. BIOLOGICAL STUDIES

The Select Committee is not aware of any toxicological tests on pulp per se. However, the available information on cellulose, the principal constituent of pulp, has been evaluated and found to be without hazard as a food ingredient at levels considerably higher than could conceivably be present in food as a result of the migration of pulp from food packages and containers (4). Experience also provides confirmation of the innocuousness of pulp as a food ingredient. As a natural ingredient of plant materials, pulp is eaten regularly in large amounts by livestock and other herbivorous animals. Pulp is present in most of the basic diets of laboratory test animals used for metabolic and toxicologic studies. Pulp is consumed by man as common constituents of the vegetable matter of his diet. No evidence of animal toxicity due to pulp has been reported.

V. OPINION

Since paper and paperboard packaging materials are not food but might be considered possible contaminants in food, it is not surprising that the Food Chemicals Codex (6) does not include specifications for such materials. However, inasmuch as pulp from paper and paperboard can conceivably migrate to foods and thus become a food ingredient, specifications for paper used in connection with food, including limits with respect to source, abradability, and content of heavy metals and other possible toxicants, could be a useful, additional safeguard of food wholesomeness. In the meantime it is assumed that
good manufacturing practice and quality control provide for adequate safeguards in the use of "food quality" cellulose and other pulp ingredients in the packaging materials used for food.

In light of all of the foregoing, the Select Committee concludes that:

There is no evidence in the available information on pulps that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used in food packaging materials as now practiced or as they might be expected to be used for such purposes in future.
VI. REFERENCES CITED


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January 23, 1974
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