EVALUATION OF THE HEALTH ASPECTS OF CORN SILK
AS A FOOD INGREDIENT

1977

Prepared for

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

Contract No. FDA 223-75-2004
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Life Sciences Research Office
Federation of American Societies’
for Experimental Biology
9650 Rockville Pike
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NOTICE

This report is one of a series concerning the health aspects of using the Generally Recognized as Safe (GRAS) or prior sanctioned food substances as food ingredients, being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-75-2004 with the Food and Drug Administration (FDA), U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshalling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office (LSRO), established by FASEB in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to review and evaluate 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. The Select Committee's evaluations are being made independently of FDA or any other group, governmental or nongovernmental. The Select Committee accepts responsibility for the content of each report. Members of the Select Committee who have contributed to this report are named in Section VII.

Tentative reports are made available to the public for review in the Office of the Hearing Clerk, Food and Drug Administration, after announcement in the Federal Register, and opportunity is provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the substances covered by the report. The data, information, and views presented at the hearing are considered by the Select Committee in reaching its final conclusions. Reports are approved by the Select Committee and the Director of LSRO, and subsequently reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the reports are approved and transmitted to FDA by the Executive Director of FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of all of the individual members of its constituent societies.

Kenneth D. Fisher, Ph.D., Director
Life Sciences Research Office
FASEB
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I. INTRODUCTION

This report concerns the health aspects of using corn silk as a food ingredient. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (1), which summarizes the world's scientific literature from 1920 through 1974.* To assure completeness and currency as of the date of this report this information has been supplemented by searches of over 30 scientific and statistical reference sources and compendia that are generally available; use of new, relevant books and reviews and the literature citations contained in them; consideration of current literature citations obtained through computer retrieval systems of the National Library of Medicine; recent literature searches by the Toxicology Information Response Center, Oak Ridge, Tennessee; searches for relevant data in the files of FDA; and by the combined knowledge and experience of members of the Select Committee and the LSRO staff. In addition, an announcement was made in the Federal Register of September 2, 1977 (42 FR 44284-44285) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the health aspects of using corn silk as a food ingredient. The Select Committee received no requests for such a hearing on corn silk.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321 (s)], GRAS substances are exempt from the premarketing clearance that is required for food additives. It is stated in the Act and in the Code of Federal Regulations (2) [21 CFR 170.3 and 170.30] 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. These sections of the Code also indicate 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. FDA (2) recognizes further that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

*The document (PB-234 900/9) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.

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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 accordance 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. While the Select Committee realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited, it recognizes that there can be instances where, in the judgment of the Select Committee, there are insufficient data upon which to base a conclusion. The Select Committee is aware that its 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 corn silk and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of this substance under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

The Code of Federal Regulations (2) lists corn silk among the essential oils, oleoresins, and natural extractives or distillates of plants that are GRAS for their intended use [21 CFR 182.20]. Thus, the material added to food is not corn silk itself but a product derived from it. In this report the term corn silk refers to this derived product. The Food Chemicals Codex (3) provides no specifications for corn silk. The Select Committee has found no information concerning the process or solvent(s) used to derive it and no data on its composition.

There are few clues as to the possible composition of corn silk. The so-called "silk" of the ear of Indian corn, Zea mays L. (4) is composed of a variety of substances, most of which have not been characterized. Gross analytical studies conducted in 1931 showed the presence of about 2 percent crude fat, 19 percent crude protein, 52 percent soluble nitrogen-free compounds, and a remainder consisting largely of crude fiber and pentosans (5). Somewhat later, Berger (6) found the silk of corn to contain about 2 percent fatty oil, 0.1 percent essential oil, 12 to 13 percent tannin, up to 0.05 percent alkaloid, and about 2 to 3 percent each of saponins, resins, rubber-like products, and reducing sugar. One reducing sugar was identified as arabinose. More recent analyses indicate the presence of about 4 to 13 percent tannin; 2.5 percent resin; 2 to 3 percent saponins, flavones, and pigments; 2 percent
of a fraction containing arachidic acid, linoleic acid, pentoses, and pentosans; 1 percent glucoside; up to 0.05 percent unidentified alkaloid; and 0.1 to 0.2 percent essential oils. The essential oil fraction was reported to contain 18 percent carvacrol (7). Using chromatographic methods, Granada et al. (8) detected four alkaloids, several flavones, and about 0.2 percent essential oil containing α-terpineol, menthol, carvacrol, thymol, and a thymol ester.

Corn silk is reported to be an ingredient of maple, nut and root beer flavors (9). It has been suggested (1) that carvacrol is mainly responsible for the flavoring characteristics of corn silk. However, carvacrol is likely to be present only to the extent of 0.04 percent or less in the silk itself (7); hence, carvacrol could be a major constituent in corn silk as it is used in foods only if the product is derived by extraction and fractionation procedures that concentrate it. Carvacrol is known to occur in several other materials used for food flavoring purposes, among them lovage oil, oregano, thyme, and marjoram (9-11). In addition, the Code of Federal Regulations (2) lists carvacrol and its ethyl ether as synthetic flavoring substances and adjuvants [21 CFR 172.515] that may be safely used in foods. These two substances are not evaluated in this report.

III. CONSUMER EXPOSURE DATA

The Flavor and Extract Manufacturers' Association, as part of a survey of the food industry made by a National Research Council (NRC) subcommittee in 1970 (12), inquired concerning the food use of corn silk. Based on the responses, weighted means were calculated (Table I) for the usual percentage addition of corn silk to foods in several categories.

<table>
<thead>
<tr>
<th>Food category</th>
<th>Weighted mean</th>
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<tr>
<td>Baked goods, baking mixes</td>
<td>17.9 ppm</td>
</tr>
<tr>
<td>Frozen dairy desserts, mixes</td>
<td>4.9</td>
</tr>
<tr>
<td>Soft candy</td>
<td>10.6</td>
</tr>
<tr>
<td>Gelatins, puddings, fillings</td>
<td>1.3</td>
</tr>
<tr>
<td>Nonalcoholic beverages</td>
<td>11.1</td>
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<tr>
<td>Alcoholic beverages</td>
<td>0.2</td>
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The National Research Council subcommittee estimated possible average daily intakes from Market Research Corporation of America data on the mean frequency of eating foods by food category, U.S. Department of Agriculture data on mean portion size of foods in these categories, and the assumption that all food products within a category contain corn silk at the level shown in Table I. For persons over two years old the estimated average daily intake was 3.83 mg. However, the NRC subcommittee has recognized that such an assumption is likely to lead to overestimates of intake and that in most cases its calculations of possible intakes are overstated, often by considerable margins. Because of factors detailed in Section XI of the subcommittee's report (12), it stated that the average estimated total dietary intakes are likely to be much higher than would be the intakes achieved through consumption of a diet consisting totally of processed foods to which corn silk had been added at maximum levels. Accordingly, this estimate has been viewed in light of an estimate made by the same NRC subcommittee (12) concerning the total amount of corn silk (184 kg) reported by the manufacturers to be used annually in food. The daily per capita "intake" of corn silk (about 3 μg) calculated from this figure, is considerably smaller than the 3.83 mg estimated on the basis of the levels of addition given in Table I. The Select Committee believes that 3 μg is more likely to be typical of daily intakes of corn silk.

IV. BIOLOGICAL STUDIES

It is not possible to relate the few biological studies reported in the literature for various extracts or components of the silk of corn to possible consequences of using commercial corn silk in foods because of the absence of any information concerning the nature and composition of the commercial product. However, it is to be noted that administration of extracts or components of the silk of corn have been found to have no biological effects under some conditions and to elicit biological responses under others.

Dzhamalieva (13) intubated two dogs (breed and sex not indicated) with aqueous infusions of corn silk. The infusions were prepared by placing 3, 5, 10, or 20 g samples of corn silk (age and moisture not indicated) in 100 ml of water, autoclaving for 30 minutes, and filtering to provide what were regarded as 3, 5, 10, and 20 percent infusions of corn silk. One dog received 163 ml of the 10 percent infusion (20 ml per kg body weight) and the second the equivalent of 44 ml per kg. No disturbances in the dogs' behavior were noted after five hours. Thereafter, both dogs received an additional 60 ml per kg without adverse effects and they continued to be normal, with small weight gains, 10 days after intubation of the corn silk infusion was terminated. Total dose of the 10 percent infusion was 223 ml for one dog, 104 ml for the other. Parenteral studies were also conducted on guinea pigs and rabbits. Four guinea pigs injected subcutaneously with
a single dose of 7 to 10 ml of the 20 percent infusion (17 to 25 ml per kg body weight) followed by a similar dose after four days, showed no adverse effects when observed over a period of 12 days. Similarly, five rabbits given single intravenous doses of 5 ml per kg body weight of the 20 percent corn silk infusion, repeated after five hours, showed no ill effects when observed over a period of 10 days. It was also observed that none of the corn silk infusions exerted any in vitro bactericidal or bacteriostatic effect on Staphylococcus, Streptococcus and a number of other pathogenic microorganisms.

Wastl (14) studied the effects of corn silk extract on 12 normal, adult rats and on 28 adult rats with experimentally induced hypertension. Some animals in both groups were white Wistar and others were a piebald strain, not otherwise identified. The method of preparing the corn silk extract was not described but, in context, it appears that it was an aqueous or aqueous alcohol extract, subsequently dried. A dilute aqueous solution of the dried material was injected intraperitoneally for four consecutive days in daily doses of 0.1 mg of dried corn silk extract per kg body weight. Daily blood pressure measurements were made on each of four consecutive days prior to the dosing with corn silk extract, on each of the four consecutive experimental days, and on each of four consecutive days following the last dose. No effect on the blood pressure of normal rats was observed, but a decrease of 17 to 82 percent was observed in the hypertensive animals. Water injection under the same conditions had no effect on the blood pressure of either the normal or hypertensive rats. Blood pressure of the hypertensive rats injected with corn silk extract returned to pretreatment levels by the second day following cessation of the treatment. There was no evidence of adverse effects in any of the treated animals. The author indicated that the same blood pressure reducing effect on hypertensive animals could be elicited by oral administration of the corn silk extract.

Starks et al. (15) and subsequently McMillian et al. (16) found aqueous extracts of corn silk to contain a feeding stimulant for corn earworm larvae. The active principle was not identified but it was found to be heat stable, water soluble, and insoluble in organic solvents.

Corn silk and corn silk fluid extract have apparently long been among the folk medicines believed to be helpful in such disorders as diabetes, gout, edema, obesity, and kidney stones (4-7, 13), but the therapeutic values attributed to these materials are essentially without proof.

V. OPINION

The silk of corn contains a wide variety of compounds, many present in very small amounts; included are sugars, tannins, saponins, flavones, glucosides, fats, alkaloids, and various aromatic components of the essential
oil fraction. The composition of the commercial product (corn silk) that is added to foods will obviously depend on the procedures used for extraction of the silk of corn and the subsequent concentration and fractionation of the extract. The Select Committee has not been able to obtain any information concerning the method of preparation of the commercial product or its composition, or to find any reports of biological studies on the commercial product. In the absence of such information, it is not possible to relate the few reported biological studies on corn silk extracts and components to the possible consequences of using corn silk as a food ingredient.

There are no known specifications for food-grade corn silk. Considering the origin of the product, specifications are needed to establish limits for possible variations in its composition and for the presence of incidental contaminants such as pesticidal chemicals.

In light of the foregoing, and in spite of the fact that the amount of corn silk consumed as a result of its addition to foods is extremely small, the Select Committee concludes that:

In view of the lack of information on the identity of the product used in foods and of relevant biological studies concerning it, the Select Committee has insufficient data upon which to base an evaluation of corn silk when it is used as a food ingredient.
VI. REFERENCES CITED


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Report submitted by:

December 12, 1977
Date

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