EVALUATION OF THE HEALTH ASPECTS OF CAROB BEAN GUM

AS A FOOD INGREDIENT

DECEMBER 1972

Prepared for

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

Contract No. FDA 72-85
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Life Sciences Research Office
Federation of American Societies
for Experimental Biology
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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 of the Federation of American Societies for Experimental Biology under contract with the Food and Drug Administration 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 competence 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
Life Sciences Research Office
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I. INTRODUCTION

Under the terms of FDA Contract 72-85, dated March 30, 1972, FASEB's Life Sciences Research Office was requested to evaluate the health aspects of using carob bean gum as a food ingredient, primarily on the basis of information contained in a monograph summarizing the world's scientific literature from 1920 through 1970, and in certain supplemental documents available as of December 1972. The LSRO Select Committee on GRAS Substances has reviewed these materials and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of carob bean gum under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

Carob bean gum (also called locust bean gum) is the material separated and variously refined from the endosperm of the seed of the carob tree, Ceratonia siliqua, a large leguminous evergreen that is widely cultivated in the Mediterranean area. Cyprus, Spain, Italy, Greece, and Syria are the most important producing countries, but Algeria, Portugal, Turkey, and Morocco also are sources (1, 6).

The carbohydrate component of carob bean gum is considered to be a neutral galactomannan polymer consisting of a main chain of 1, 4-linked D-mannose units with a side-chain of D-galactose on every fourth or fifth unit, attached through 1, 6-glycosidic linkages to the polymannose chain. It has been variously reported to contain from 73 to 86 percent D-mannose units and from 27 to 14 percent D-galactose units. An average molecular weight of 310,000 has been reported (1, 6).

In its specifications for carob bean gum, the Food Chemicals Codex sets a minimum of 73 percent galactomannans, and maximum limits for protein, starch, ash, heavy metals, and other impurities or minor components (5).

In the food industry, carob bean gum is reported to be used principally as an emulsion stabilizer, in proportions ranging from 0.77 to 0.0006 percent. It is currently used in the following food categories, arranged in decreasing order of carob bean gum content: cheese, imitation dairy products, fruit ices, gravies, sweet sauce, condiments and relishes, processed fruit, frozen dairy products, jams and jellies, confectionery.
and frosting, alcoholic and nonalcoholic beverages, gelatin puddings, fats and oils, meat products, milk products, and baked goods (4).

Carob bean gum is reported to have been first used as a food product in the United States in 1925 (4). The total amount used in foods approximately doubled between 1960 and 1970 (4). However, the Select Committee has no information to indicate whether the carob bean gum content of the foregoing food categories has changed significantly in recent years.

III. CONSUMER EXPOSURE DATA

A comprehensive survey by a National Academy of Sciences sub-committee has provided information on the possible daily human intake of carob bean gum in the total diet, as shown in the following table for individuals in various age groups (4). The Select Committee has converted these figures to possible intake per kilogram of body weight.

<table>
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<th>Age group</th>
<th>Possible daily intake</th>
<th>Per kilogram of body weight*</th>
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<tbody>
<tr>
<td></td>
<td>Total Average mg</td>
<td>Maximum mg Average mg</td>
</tr>
<tr>
<td>0-5 months</td>
<td>31 mg</td>
<td>64 mg</td>
</tr>
<tr>
<td></td>
<td>6 mg</td>
<td>13 mg</td>
</tr>
<tr>
<td>6-11 months</td>
<td>352 mg</td>
<td>1062 mg</td>
</tr>
<tr>
<td></td>
<td>44 mg</td>
<td>133 mg</td>
</tr>
<tr>
<td>12-23 months</td>
<td>628 mg</td>
<td>1455 mg</td>
</tr>
<tr>
<td></td>
<td>57 mg</td>
<td>132 mg</td>
</tr>
<tr>
<td>2-65+ years</td>
<td>1021 mg</td>
<td>2232 mg</td>
</tr>
<tr>
<td></td>
<td>17 mg</td>
<td>37 mg</td>
</tr>
</tbody>
</table>

*Calculations based on an average weight of 60 kg for an adult (13) and the following estimated weights of infants by age groups: 0-5 mos., 5 kg; 6-11 mos., 8 kg; and 12-23 mos., 11 kg (14).

It is recognized that the figures calculated for the daily intake of carob bean gum per kg of body weight in the age group 2-65+ years could be deceptively low, since the majority of individuals from age 2 to maturity will probably weigh less than 60 kg. Thus the daily intake of carob bean gum for children could be significantly higher than the figures indicated. For example, a child weighing 20 kg could consume, on the average, 51 mg per kg per day rather than 17 mg, and at a maximum, 112 mg per kg per day, rather than 37 mg.
However, such deviations from the figures in the table must also be considered in respect to total production and use of carob bean gum. The data developed by the National Academy of Sciences subcommittee are based on (a) a survey of the frequency of eating various food products, (b) a determination of the portion size of these food products, and (c) a survey of food producers to determine the percentage use of carob bean gum in these food products (4). The National Academy of Sciences subcommittee has pointed out that its calculations of intakes in most cases are overstated, often by considerable margins.* That human intakes are undoubtedly overstated in the case of carob bean gum is borne out by the following calculation: The NAS subcommittee has also provided data (4) to show that the use of carob bean gum for food purposes in the United States was 2,606,150 pounds (1.18 million kg) in 1970. This figure is reported to comprise between 60 and 70 percent of the total actual poundage used in food. On the basis of 60 percent adjusted to 100 percent (4.3 million pounds or 1.97 million kg), and a U.S. population of 200 million, the per capita per day average intake would be 27 mg. The derived total of 4.3 million pounds of carob bean gum used in foods per annum appears reasonable, since Census Bureau import statistics (15) show that only 10,887,757 pounds (4.94 million kg) of carob bean gum were imported for all uses in 1970. These figures suggest that not nearly enough carob bean gum is imported, even if all were used in food, to reach daily intakes as high as is indicated in the foregoing table.

On the basis of these considerations, therefore, the Select Committee regards the figures in the table as levels that are highly unlikely to be achieved by any of the age groups, but more likely, are generous overestimates of the carob bean gum content of the daily diet.

*An explanation for such overstatements is detailed in Section XI, "Significance and Use of Data in Safety Evaluations," of the NAS subcommittee's report (4). The Select Committee finds this explanation reasonable, and concurs in the first recommendation in Section XII of the same report, that "In order to conduct a more accurate survey on the intake of substances used in food processing, food consumption data collected specifically for this purpose are needed."
IV. BIOLOGICAL STUDIES

There are no reported long-term animal feeding studies (extending for more than half of the life span of the species) on carob bean gum. Relevant short-term animal studies and studies on man are summarized below.

Two chick experiments are pertinent. In the first, 10 one-day-old Arbor Acres chicks were fed a stock diet; another comparable group was fed the stock diet plus a 2 percent cellulose supplement; and a third comparable group was fed a 2 percent carob bean gum supplement (10). The third group showed a 30 percent depressed feed intake after three weeks, with a corresponding decrease in weight as compared to the cellulose-fed group. Each chick consumed about 340 mg of carob bean gum per day, or in excess of 2 g per kg per day. The degree of nitrogen retention and metabolizable energy content were about the same, as in the cellulose group, although the fat absorption was about 8 percent higher.

In the second test, similar groups of chicks were fed stock diets supplemented with 0.25, 0.5, 1.0, and 2.0 percent of carob bean gum (12). After three weeks, the chicks fed at the 2 percent level showed a 27 percent growth depression as compared to the controls, while those at the lower levels of supplement showed an average 6 percent growth depression. However, the authors provided no data on food intakes in this experiment. Others working with carob bean pods (7) have shown that tannins depress appetite and growth. In addition, carob beans contain trypsin inhibitors (16), which are known to have growth-inhibiting properties. Since tannins and trypsin inhibitors could be naturally present in the carob bean gum used in the chick studies, either or both could have accounted for the growth depression reported. From the data given, it is not possible to ascribe depression in growth to toxicity of the gum.

A 10 percent dietary supplement of carob bean gum does not significantly affect the growth of rats (8). Three groups of 8 rats averaging 44 g each were fed for 28 days on a stock diet, stock diet plus 1 percent cholesterol, and stock diet plus 1 percent cholesterol and 10 percent carob bean gum. Differences in weight gain among the three groups were not significant and no adverse effects were reported. While feed consumption was not reported, it is estimated that a 44-g rat would consume no less than 10 g per day of the 10 percent carob bean gum diet, which would be equivalent to 1 g of the gum per day. For a 44-g rat this intake rate would be about 23 g per kg per day.
No evidence of carcinogenic or allergenic activity of carob bean gum has been found in the literature surveyed.

V. OPINION

The available information reveals that there are no short-term toxicological consequences in chicks, rats, mice, hamsters, rabbits, and man of consuming carob bean gum in amounts exceeding those currently consumed in the normal diet of the U.S. population. There is no evidence that consumption of carob bean gum by man since 1925, when it was first used in the United States, has had adverse effects. It is to be noted, however, that no long-term feeding studies of carob bean gum have been reported. While the available information does not suggest long-term toxicity, it may be advisable in due course to conduct adequate feeding studies in several animal species, including pregnant animals, at dosage levels that approximate and exceed the current estimated maximum daily load in humans.

Carob bean gum, fed at relatively high levels, is reported to be toxic to pregnant animals of some species. Because the toxic levels reported are well in excess of the highest levels now consumed by man, the Select Committee is of the opinion that there are no adverse health aspects of consuming carob bean gum at current levels. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard.

The Select Committee has weighed the foregoing and concludes that:

The available information contains no evidence demonstrating that carob bean gum constitutes a hazard to the public when used in the manner and quantity now practiced.
VI. REFERENCES CITED


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Report submitted by:

December 19, 1972

Date

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Select Committee on GRAS Substances