EVALUATION OF THE HEALTH ASPECTS OF BEESWAX
(YELLOW OR WHITE) AS A FOOD INGREDIENT

1975

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.

C. Jelleff Carr, Ph.D., Director
Life Sciences Research Office
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I. INTRODUCTION

This report concerns the health aspects of using beeswax 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 1973.* 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 Toxicological 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, announcement was made in the Federal Register of February 13, 1976 (41 FR 6787 and 6788) 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 beeswax as a food ingredient. The Select Committee received one request for such a hearing, but this request was withdrawn.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321 (s)], GRAS substances are exempt from the premaking clearance that is required for food additives. It is stated in the Code of Federal Regulations 21 CFR 121.1, revised April 1, 1975 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. FDA recognizes 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 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

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*The document (PB-223 854/1) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.
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, aware that biological testing is dynamic, bases its conclusions on information now available; it cannot anticipate the results of experiments not yet conducted or those of tests that may be reconducted, using new technologies. 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 beeswax 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

Beeswax is a secretory product of honeybees used as a structural material in honeycombs. Beeswax generally refers to wax of the domesticated honey bee, *Apis mellifica*, also referred to as *A. mellifera*, but other species found in Asia - *A. dorsata*, *A. florea*, and *A. indica* - also are sources of commercial beeswax. The Asiatic waxes are known as East Indian beeswax or Ghedda wax. Beeswax is produced domestically and also is imported from Latin America, Africa, Europe and Asia (2).

Crude beeswax is prepared from honeycombs emptied of honey by draining or centrifuging. The combs are melted in hot water or steam, or with solar heat and strained to remove bee and cocoon fragments and other foreign material. The crude wax is refined by melting in hot water to which sulfuric acid or alkali may be added to extract impurities. The resulting wax is referred to as yellow beeswax. White beeswax is produced by bleaching the constituent pigments, principally carotenones, of yellow beeswax with peroxides but preferably by sunlight (3-5).

The Food Chemicals Codex (6) specifications for white and yellow beeswax are given in Table I. Beeswax is insoluble in water and cold ethanol. Food Chemicals Codex specifications require it to be free of carnauba wax, Japan wax, rosin or soap adulteration.


<table>
<thead>
<tr>
<th></th>
<th>White</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific gravity</td>
<td>0.95</td>
<td>0.95</td>
</tr>
<tr>
<td>Melting range</td>
<td>62-65</td>
<td>62-65</td>
</tr>
<tr>
<td>Ester value</td>
<td>72-79</td>
<td>72-77</td>
</tr>
<tr>
<td>Acid value</td>
<td>17-24</td>
<td>18-24</td>
</tr>
<tr>
<td>Arsenic</td>
<td>≤3 ppm</td>
<td>≤3 ppm</td>
</tr>
<tr>
<td>Heavy metals (as Pb)</td>
<td>≤40 ppm</td>
<td>≤40 ppm</td>
</tr>
<tr>
<td>Lead</td>
<td>≤1 ppm</td>
<td>≤1 ppm</td>
</tr>
<tr>
<td>Color</td>
<td>Yellowish white</td>
<td>Yellow to grayish brown</td>
</tr>
</tbody>
</table>

Beeswax consists principally of esters, free fatty acids, and hydrocarbons. Approximate composition is given in Table II where the major components of the principal classes of compounds present are listed. The major fatty acid components of the esters are palmitic and 15-hydroxy palmitic acids which are esterified with C_{28}, C_{30}, and C_{32} alcohols. Acids and alcohols are principally even-numbered carbon compounds (7-9) whereas the hydrocarbons are mainly compounds that contain an odd number of carbon atoms (7-10). Cholesteryl esters of fatty acids and w-myristolactone have been reported (3) as minor constituents (1 percent or less).

*A. indica* (Indian) beeswax differs from *A. mellifica* wax in that the content of hydrocarbons is lower (8 vs 15 percent) and total alcohols are higher but the sum of the two is about the same. Also, the alcohols and hydrocarbons in *A. indica* wax appear to contain higher proportions of C_{24} to C_{28} compounds (11).

Beeswax (yellow wax) and bleached beeswax (white wax) are listed as GRAS substances in the Code of Federal Regulations (12) as miscellaneous and/or general purpose food additives [21 CFR 121.101(d)(8)]. White beeswax also is listed among natural flavoring substances and natural substances used in conjunction with flavors [21 CFR 121.1163]. Non-food applications include use in cosmetics, pharmaceuticals, polishes and church candles (13).

Beeswax as a component of comb honey has been ingested since ancient times. Modern processing separates honey from the comb, so that incidental intake of beeswax with honey is uncommon. The average import of crude beeswax for the years 1960 to 1964 was 4.864 million pounds (2,209,000 kg) and, in 1970, 3.697 million pounds (1,680,400 kg). In 1970 the United States produced 4.648 million pounds of the crude product (2).
### TABLE II

Composition of Yellow Beeswax (7)

<table>
<thead>
<tr>
<th>Esters</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monoesters:</td>
<td>35</td>
</tr>
<tr>
<td>[ C_{15}H_{31}CO_2CH_2(CH_2)_nCH_3 ]</td>
<td></td>
</tr>
<tr>
<td>[ n = 22 - 32 ]</td>
<td></td>
</tr>
<tr>
<td>Diesters</td>
<td>12</td>
</tr>
<tr>
<td>[ C_{15}H_{31}CO_2CH(CH_2)_{13}CO_2CH_2(CH_2)_nCH_3 ]</td>
<td></td>
</tr>
<tr>
<td>[ n = 22 - 30 ]</td>
<td></td>
</tr>
<tr>
<td>Hydroxy esters</td>
<td>24</td>
</tr>
<tr>
<td>[ C_{15}H_{30}(OH)CO_2CH_2(CH_2)_nCH_3 ]</td>
<td></td>
</tr>
<tr>
<td>[ n = 22 - 32 ]</td>
<td></td>
</tr>
<tr>
<td>[ CH_3(CH_2)<em>{n_1}CO_2(CH_2)</em>{n_2}CH(OH)CH_3 ]</td>
<td></td>
</tr>
<tr>
<td>[ n_1 = 14 \text{ or } 22 ]</td>
<td></td>
</tr>
<tr>
<td>[ n_2 = 22 - 32 ]</td>
<td></td>
</tr>
<tr>
<td>Hydroxy diesters and triesters of [ C_{16} \text{ and } C_{24} - C_{34} ] acids and hydroxy acids and [ C_{24} - C_{30} ] diols.</td>
<td></td>
</tr>
<tr>
<td>Free acids</td>
<td>8</td>
</tr>
<tr>
<td>[ C_{24} - C_{34} ] aliphatic acids</td>
<td></td>
</tr>
<tr>
<td>Hydrocarbons</td>
<td>15</td>
</tr>
<tr>
<td>[ C_{25} - C_{30} ] alkanes</td>
<td></td>
</tr>
<tr>
<td>[ C_{31} - C_{33} ] olefins</td>
<td></td>
</tr>
<tr>
<td>Not identified</td>
<td>6</td>
</tr>
</tbody>
</table>

### III. CONSUMER EXPOSURE DATA

A survey of the food industry conducted by a National Research Council (NRC) subcommittee reported that the total amount of yellow and white beeswax used in all food products was 48,500 pounds (22,140 kg) in 1960 and 16,360 pounds (7,370 kg) in 1970, a decrease of approximately fourfold over 10 years' time (14). The 1970 figure was estimated to represent about 60 percent of actual consumption; on this basis, actual 1970 consumption was 12,300 kg or 0.16 mg per person per day.
The NRC survey also provided information on the level of addition of beeswax to foods in several food categories as given in Table III. The NRC subcommittee surveyed manufacturers by questionnaire concerning the usual and maximal levels of addition of yellow and white beeswax to foods. Based on information supplied by those manufacturers who reported adding a beeswax to at least one food in a category, a weighted mean was calculated for the usual and maximal percentage addition of these substances to food products in the categories. Only the weighted mean usual level of addition is reported in Table III.

TABLE III

Level of Addition of Beeswax to Foods by Food Category (14)

<table>
<thead>
<tr>
<th>Food category</th>
<th>Beeswax, yellow ppm</th>
<th>Beeswax, white ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baked goods, baking mixes</td>
<td>***</td>
<td>3</td>
</tr>
<tr>
<td>Frozen dairy desserts, mixes</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Processed fruits, juices and drinks</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Soft candy</td>
<td>440</td>
<td>486</td>
</tr>
<tr>
<td>Sugar, confections</td>
<td></td>
<td>32</td>
</tr>
<tr>
<td>Sweet sauces, toppings, syrups</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Gelatins, puddings, fillings</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Beverages, nonalcoholic</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Beverages, alcoholic</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Hard candy</td>
<td>115</td>
<td></td>
</tr>
<tr>
<td>Chewing gum</td>
<td>***</td>
<td>339</td>
</tr>
</tbody>
</table>

Blanks in the table mean that the substance is not added to the foods indicated; asterisks (***)) in the table mean that (a) the substance is used in a processing phase of the foods indicated but residual levels in the final food product are negligible or unknown, or (b) the substance is used in the foods indicated but usage levels were not furnished by industry, or (c) the substance is in the foods indicated but the levels were considered to be reported incorrectly. Level of addition of yellow beeswax and white beeswax is the weighted mean of the levels reported by manufacturers as their usual addition to one or more products in a food category. For discussion of weighted mean see Section X and Exhibit 50 of reference 14.
Possible average daily intakes of yellow and white beeswax (Table IV) were estimated by the NRC subcommittee (14) from Market Research Corporation of America data on 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 foods within a category contain the substance at the level shown in Table III. Such an assumption is likely to lead to overestimates of intake. The NRC subcommittee has recognized that in most cases its calculations of possible intakes are overstated, often by considerable margins. Because of factors detailed in Section XI of the NRC subcommittee report, it was stated that the average estimated dietary intakes are likely to be much higher than would be the intakes achieved through consumption of a diet consisting totally of processed food to which the substance had been added at maximum levels. That the values in Table IV are overestimates of average intake is supported by comparison of daily intake of yellow or white beeswax for the 2 to 65+ year age group, 4 mg, with the national per capita daily intake, 0.16 mg, calculated above from poundage of beeswax used by industry in food products. The Select Committee regards the figures in Table IV as levels that are unlikely to be achieved by any of the age groups.

**TABLE IV**

Possible Average Daily Intake of Added Beeswax by Age Group (14)

<table>
<thead>
<tr>
<th>Substance</th>
<th>0-5 months</th>
<th>6-11 months</th>
<th>12-23 months</th>
<th>2-65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg</td>
<td>mg/kg*</td>
<td>mg</td>
<td>mg</td>
</tr>
<tr>
<td>Yellow beeswax</td>
<td>0.13</td>
<td>0.03</td>
<td>1.50</td>
<td>0.19</td>
</tr>
<tr>
<td>White beeswax</td>
<td>0.11</td>
<td>0.02</td>
<td>1.22</td>
<td>0.15</td>
</tr>
</tbody>
</table>

*Calculations based on an average weight of 60 kg for an adult (15) and the following estimated weights of infants by age group: 0-5 mo, 5 kg; 6-11 mo, 8 kg; 12-23 mo, 11 kg (16).

**IV. BIOLOGICAL STUDIES**

Beeswax is considered indigestible in mammals due to the structure of its component compounds which are not susceptible to hydrolysis by enzymes of the alimentary tract and to its insolubility and high melting point which prevent dissolution at body temperature. However, it has been reported that an avian species found in Africa eats beeswax as part of its natural diet and can digest the wax through the action of microflora.
found in this species and also present in wild African honeycomb (17, 18).

Solutions of beeswax in oils such as peanut and sesame have been used as vehicles for injection of drugs (19). Finely powdered heparin was suspended in a 10 percent solution of beeswax in sesame oil and the mixture was injected intramuscularly into 13 dogs (20). The beeswax was readily phagocytized. One week after injection the beeswax could be easily recognized on dissection of the muscle. Two months later, however, when numerous sections of the muscle were examined to find the site of injection, the beeswax could seldom be positively identified. The areas of injection had become small nodules composed largely of disintegrating phagocytic cells surrounded by a thin capsule.

In a similar study, penicillin suspended in 0.05 to 0.1 ml of 3 percent beeswax in peanut oil was given to 10 hamsters intramuscularly twice daily for 5 days (21). Typical response was inflammation without necrosis and invasion by polymorphonuclear lymphocytes with progressive removal of beeswax particles by phagocytosis. The mixture was injected into the buttocks of 12 patients without reaction to the vehicle.

Penicillin suspended in corn or cottonseed oil was mixed with 5 percent beeswax and placed in gelatin capsules (22). No untoward reactions were observed in patients to whom these capsules were administered orally.

Beeswax contaminated with pollen has been presumed to be antigenic (23). Beeswax shown by microscopic examination to be pollen-free elicited no response in scratch or intracutaneous tests in known pollen sensitive patients. Beeswax to which pollen extract had been added produced typical allergic responses in susceptible patients (24).

The Select Committee is not aware of any reports demonstrating carcinogenicity of beeswax that has resulted from its use as a vehicle for other substances tested as carcinogens. No carcinogenic effects developed in male Donrym rats in which beeswax was immobilized in contact with the mucosa of the glandular stomach for 3 to 4 weeks when the rats were examined after 45 weeks (25). Implantation of 0.05 ml of a 1:1 beeswax tricaprylic mixture in the lungs of 105 Osborne-Mendel female rats resulted, during a period of 1 year after treatment, in the development of a bland granulomatous infiltrate limited to the surface of the solidified pellets except for two rats in which keratinizing squamous metaplasia were observed. In contrast, 101 rats injected with the wax mixture containing 0.05 mg 3-methylcholanthrene had a 13 percent incidence of keratinizing squamous metaplasia, and 6 percent incidence of
keratinizing squamous dysplasia with localized extension, overt squamous cell carcinoma and undifferentiated neoplasms (26). In a study of the carcinogenicity of tobacco and cigarette smoke condensate by the same technique, 66 female Osborne-Mendel rats (controls) that were injected with 0.05 ml of 1:1 beeswax-tricaprylin mixture developed no metaplastic epithelium surrounding the pellet after periods up to 107 weeks whereas 77 of 96 positive controls injected with 0.05 ml wax mixture containing 0.05 mg 3-methylcholanthrene developed keratinizing squamous metaplasia and 16 developed epidermoid carcinomas during the 55 week-period after treatment (27). Threads impregnated with beeswax implanted into the cervical canal and the uterine horns of 35 six-week-old control mice showed the development of invasive squamous carcinoma in one animal after 4 to 6 weeks whereas 59 of 102 mice developed this type carcinoma after implantation of threads impregnated with beeswax containing 20-methylcholanthrene (28). No observation has been reported of a tumor developing in thousands of instances of injection of beeswax intramuscularly or subcutaneously when beeswax was used as a vehicle for the administration of drugs in human patients.

White beeswax at 0.5 and 1.0 percent concentration was not mutagenic to Salmonella typhimurium strains TA-1535, -1537 or -1538 or to Saccharomyces cerevisiae, strain D-4, in plate and suspension tests with or without the addition of mouse, rat, or monkey tissue metabolic activation preparations (29).

No reports on the teratogenicity of beeswax were available to the Select Committee.

V. OPINION

There is a paucity of experimental data on the digestion, absorption, metabolism, and short-term or long-term toxicity of beeswax after oral intake by humans or animals; but as a component of comb honey, beeswax has been ingested since ancient times without evidence of harm. Although the composition of beeswax is complex, present knowledge of the processes of digestion suggests that beeswax is not digested or absorbed from the alimentary tract in most animals or man.

Beeswax containing pollens or oleoresins may be allergenic to sensitive individuals but beeswax alone has not been reported to be allergenic. No studies designed to show teratogenic effects of beeswax have been reported. Numerous injections of beeswax as a vehicle for drugs have not led to reports of tumors at the injection site.
Relatively little comb honey is used as a food in the U.S. The use of beeswax in processed food products decreased fourfold in the decade from 1960 to 1970 and presently is very small, amounting to an average estimated per capita daily intake of about 0.16 mg.

On the basis of the above considerations the Select Committee concludes that:

There is no evidence in the available information on beeswax (yellow or white) that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current or might reasonably be expected in the future.
VI. REFERENCES CITED


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June 3, 1976
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