EVALUATION OF THE HEALTH ASPECTS OF TALLOW, HYDROGENATED TALLOW, STEARIC ACID, AND CALCIUM STEARATE AS FOOD INGREDIENTS

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
Bethesda, Maryland 20014
This report is one of a series of evaluations of the health aspects of the Generally Recognized as Safe (GRAS) or prior sanctioned food substances 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
FASEB
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I. INTRODUCTION

This report concerns the health aspects of using tallow, hydrogenated tallow (including tallow flakes), stearic acid and calcium stearate as food ingredients. 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 1972.* 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; 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 February 10, 1976 (41 FR 5882 and 5863) 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 tallow, hydrogenated tallow, stearic acid and calcium stearate as food ingredients. The Select Committee received no requests for such a hearing on tallow, hydrogenated tallow, stearic acid and calcium stearate as food ingredients.

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 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

*The document (PB-223 859/0) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.
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, 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 reducted, 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 tallow, hydrogenated tallow (including tallow flakes), stearic acid and calcium stearate and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of these substances under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

In North America, tallow generally refers to fat rendered from cattle and sheep tissues; thus, in unrefined animal fat it is a natural constituent of foods. The major constituents of tallow are glycerides of oleic acid (36 to 50 percent), palmitic acid (23 to 37 percent), stearic acid (6.0 to 20 percent), myristic acid (1.0 to 8.0 percent), palmitoleic acid (1.5 to 6.0 percent) and linoleic acid (0.5 to 5.0 percent). Minor constituents include arachidic, linolenic and eicosenoic acids (2).

In hydrogenated tallow the content of oleic, linoleic and other unsaturated acids has been reduced by addition of hydrogen to the double bonds of these glyceridic acids. Tallow flakes are fully hydrogenated tallow in flaked form (3).

Stearic acid, or n-octadecanoic acid, \( \text{CH}_3(\text{CH}_2)_{16}\text{COOH} \), is naturally present in the glycerides of animal fats and most vegetable oils. Some is produced commercially by the hydrogenation of the unsaturated 18-carbon fatty acids of soybean or other vegetable oils. When obtained from animal fats by hydrolysis and fractional crystallization, commercial stearic acid is a mixture of solid organic acids, chiefly palmitic and stearic acids. Commercial products containing about 90 percent stearic acid are produced by the hydrolysis and crystallization of a completely hydrogenated vegetable oil or by the fractional distillation of fatty acid mixtures obtained from tallow (4). The Food Chemicals Codex (5) specifies acid, iodine and saponification values and solidification point range for food grade stearic acid and permits not more than 3 ppm of arsenic and 10 ppm of heavy metals (as lead).
Calcium stearate is a compound of calcium with variable proportions of stearic and palmitic acids. It is insoluble in water, in alcohol and ether. Food Chemicals Codex provides specifications for the food grade product (6).

Stearic acid, beef tallow, hydrogenated tallow, and tallow flakes appear in the FDA GRAS list among substances migrating to food from cotton and cotton fabrics used in dry food packaging [21 CFR 121.101(i)] (7). Calcium stearate is included on a partial listing of substances presumed to be GRAS by FDA but not published (8). Stearic acid also is included among regulated additives that are permitted in food (21 CFR 121.1070) with the provisos that it should contain not over 2 percent unsaponifiable matter, should contain no chick-edema factor, and should be used with suitable labeling as a lubricant, binder, or defoaming agent in accordance with good manufacturing practice, or as a component of other food-grade additives (7). Tallow and hydrogenated tallow are regulated additives permitted as components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 121.2526); beef tallow and fatty acids derived therefrom as defoaming agents in the manufacture of paper and paperboard for use in packaging, transporting and holding food (21 CFR 121.2519); hydrogenated tallow, fatty acids and calcium stearate as components of defoaming agents in the processing of beet sugar and yeast (21 CFR 121.1099); and calcium stearate and the aluminum, magnesium, potassium, and sodium salts of stearic acid conforming with 21 CFR 121.1070 are regulated additives permitted for use as binders, emulsifiers, or anticaking agents in food (21 CFR 121.1071)(7).

The present report concerns the health aspects of tallow, tallow flakes, hydrogenated tallow, and stearic acid only in their GRAS listing as used in cotton food packaging, and calcium stearate as a general purpose food additive.

III. CONSUMER EXPOSURE DATA

Stearic acid is regularly consumed as a glyceride component of the fat in meat, table spreads, and other foods. Tallow is eaten as a constituent of the fat in beef and as an ingredient in oleomargarine and shortening. In 1972, 495 million pounds (220 million kg) of tallow were used in the manufacture of shortening and 10 million pounds (4.5 million kg) in the manufacture of oleomargarine (9). Daily per capita intake of these products would provide approximately 30 grams of tallow containing about 4 grams stearic acid. No data are available on the use of tallow flakes in food or on the intake of stearic acid, tallow or tallow flakes from the consumption of foods packaged in cotton fabrics containing these products. However, for comparative purposes a survey of the food industry by a National Research Council (NRC) subcommittee (10), indicated 26,198 kg of stearic acid were used by the food industry in 1970. Although the NRC survey questionnaire did not request information on stearic acid, three or fewer companies volunteered information on the poundage they used in 1970. Based on a U.S. population of 205 million, this quantity would provide 0.35 mg stearic acid per capita daily. It is the opinion of the Select
Committee, however, that the daily intake of stearic acid, tallow or hydrogenated tallow from that which may migrate to food from packaging materials is small in comparison to the intake of these substances from meat, margarine, and shortening.

The NRC subcommittee survey of the food industry indicated 280,000 kg of calcium stearate were used in 1970 (10). This was 2.8 times that used in 1960 based on reports of those respondents who submitted information for both 1960 and 1970. Reported functions of calcium stearate in food products were as an emulsifier, flavoring agent adjuvant, formulation aid, lubricant and stabilizer or thickener. Table I lists the level of addition of calcium stearate to foods in several food categories. Based on information supplied by those manufacturers who reported adding calcium stearate to at least one food in a category, the NRC subcommittee calculated a weighted mean for the usual addition level of this substance to food products in each category.

**TABLE I**

<table>
<thead>
<tr>
<th>Food category</th>
<th>Weighted mean percent</th>
</tr>
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<tbody>
<tr>
<td>Baked goods, baking mixes</td>
<td>1.03</td>
</tr>
<tr>
<td>Fats and oils</td>
<td>0.06</td>
</tr>
<tr>
<td>Meat products</td>
<td>0.02</td>
</tr>
<tr>
<td>Poultry products</td>
<td>0.02</td>
</tr>
<tr>
<td>Eggs, egg products</td>
<td>0.02</td>
</tr>
<tr>
<td>Fish products</td>
<td>0.02</td>
</tr>
<tr>
<td>Soft candy</td>
<td>0.92</td>
</tr>
<tr>
<td>Soups, soup mixes</td>
<td>0.02</td>
</tr>
<tr>
<td>Snack foods</td>
<td>0.02</td>
</tr>
<tr>
<td>Gravies, sauces</td>
<td>0.03</td>
</tr>
<tr>
<td>Hard candy</td>
<td>0.08</td>
</tr>
<tr>
<td>Chewing gum</td>
<td>***</td>
</tr>
<tr>
<td>Seasoning and flavors</td>
<td>0.64</td>
</tr>
</tbody>
</table>

Asterisks (*** in the table mean that there were insufficient data on which to base an estimate. Level of addition of calcium stearate 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 10.
The NRC subcommittee estimated possible average daily intakes of calcium stearate (Table II) 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 contained the substance at the levels shown in Table I. Such an assumption is likely to lead to overestimation of intake. The NRC subcommittee has recognized that in most cases its calculations of possible intake are overstated, often by considerable margins.*

### TABLE II

<table>
<thead>
<tr>
<th>Age group</th>
<th>Intake mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 mo</td>
<td>38</td>
</tr>
<tr>
<td>6-11 mo</td>
<td>290</td>
</tr>
<tr>
<td>12-23 mo</td>
<td>610</td>
</tr>
<tr>
<td>2-65+ yr</td>
<td>1500</td>
</tr>
</tbody>
</table>

Because of factors detailed in Section XI of the NRC report (10), the subcommittee stated that the possible average estimated dietary intakes (Table II) are likely to be much higher than would the intake achieved through consumption of a diet consisting totally of processed foods to which the substance had been added at maximum levels reported. That the values in Table II are probably generous overestimates of intake is indicated by computation of per capita daily intake, 4 mg, from the estimated food industry usage (280,000 kg) of calcium stearate in 1970 and a U.S. population of 205 million. The Select Committee considers the latter value as a more realistic estimate of the intake of calcium stearate by the 2 to 65+ year age group.

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*An explanation for such overstatements is detailed in Section XI, "Significance and Use of Data in Safety Evaluations," of the NRC subcommittee report (10). The Select Committee finds this explanation reasonable and concurs in the first recommendation of 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."

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IV. BIOLOGICAL STUDIES

Absorption, metabolism, excretion

Several studies have been reported in the literature on the use of tallow in animal feed, especially for poultry. Depending upon the age of the chicken, feeding tests have suggested that about one-half to four-fifths of the tallow is absorbed (11-14). When chicks were fed 10 to 20 percent beef tallow (estimated to be 12.5 to 25 g per kg body weight) in the diet, the apparent absorbability increased from about 53 percent at 1 week of age to about 76 percent at 12 weeks (11). Similar results were obtained in another test involving chicks on diets containing 21.7 percent tallow (12). Absorbability of beef tallow increased from 70 percent at 2 weeks to 80 percent in 8-week-old chicks. At 8 weeks, chicks were able to utilize tallow as well as adult hens. The metabolizable energy for tallow was found to be 6.56 to 7.32 kcal per g in 2- to 8-week-old chicks (12,14).

Digestibility of hydrogenated animal fat, m.p. 55 °C, fed at 12 percent level in the diet of chicks was 44 percent for one sample and 23 percent for another as determined after feeding for 2 to 4 weeks (13).

The digestibility of tallow was 87.6 percent when fed to calves at a level of 5 percent in an all-concentrate diet. When hay was added so that the proportion of hay to concentrates containing 5 percent tallow was 1:2, the digestibility of the tallow increased to 90.5 percent (15). In 60-pound pigs fed 5 percent beef tallow in a barley-soy meal ration, apparent digestibility of tallow was 65 percent (16). Apparent digestibility of tallow was 47 percent in pigs 2 to 3 weeks old fed 10 percent tallow in a basal ration consisting of corn starch, dextrose, and soy protein concentrate plus vitamin and mineral supplements (17).

In contrast to tallow, the digestibility of stearic acid is quite low. It was reported as zero for stearic acid, 90 percent purity, in 3- to 4-week-old chicks (18), 31 percent (apparent digestibility) for 70 percent purity stearic acid in 60-pound pigs (16), and 9.4 to 21 percent for rats fed a diet supplemented with 5 percent stearic acid-olive oil mixtures containing 5 and 15 percent stearic acid, respectively (19). Bayley and Lewis (16) found no significant difference in digestibility between stearic acid in the free form and as tristearin in the pig but Carroll and Richards (20) reported that tristearin was less well digested than free stearic acid in the rat. It has been suggested that the apparent low digestibility of stearic acid and the apparent high digestibility of oleic and linoleic acids when present together in a diet may result from the hydrogenating activity of the microflora in the lower digestive system which converts unsaturated acids to stearic acid rather than the relative absorbability of fatty acids in the intestines (17).
The digestibility of stearic acid fed to adult female rats as a mixture of calcium stearate and the free acid was less than when fed as the free acid in semi-synthetic rations. Digestibility was 9.5 percent for stearic acid in a ration containing 10.47 percent calcium stearate and 5.21 percent stearic acid (equivalent to 14.94 percent stearic acid) as compared to 15.8 percent digestibility in a ration containing 15 percent stearic acid and free of both calcium and magnesium. Inclusion of the Osborne-Mendel salt mixture in the stearic acid ration to provide 0.6 percent calcium and 0.09 percent magnesium reduced the digestibility to 14.4 percent suggesting interaction of these minerals with stearic acid during digestion. Fecal fat excreted in the form of soaps was greater for the rations containing calcium than for the calcium-free ration (21).

In man, after ingestion, fat glycerides separate in the intestine into two phases: one is an oil phase containing diglycerides, triglycerides, and some fatty acids; the other is a micellar phase consisting of bile salts, free fatty acids, and monoglycerides. The monoglycerides and free fatty acids from the micellar solutions are absorbed through the intestinal wall, leaving the bile salts within the intestinal lumen to form additional micelles. In rats, free fatty acids of less than 12 carbon atoms in length are preferentially absorbed directly into the portal blood (19). The longer chain fatty acids are primarily incorporated into triglycerides and appear in lymph chylomicrons (22).

Fatty acids can be both lengthened and shortened during metabolism. When labeled palmitic acid is fed to rats, appreciable amounts of the tagged carbon are found in the stearic and myristic acids of the body. Conversely, when labeled stearic acid is fed, labeled carbon is found in the palmitic acid fraction. It is also found in oleic acid (23).

There is some evidence that tallow and stearic acid may be thrombogenic when included in hyperlipemic diets of rats. Stearic acid fed at 3 to 6 percent in such diets exerted strong thrombotic and atherogenic effects. Bovine tallow was relatively less thrombogenic (24-26).

The Select Committee is aware of the concern over the role of saturated versus polyunsaturated fatty acids in the etiology of arteriosclerosis and associated vascular diseases. There is no consensus on this point. Nutrition is considered only one of the risk factors of this complex of diseases; a cause and effect relationship is not clearly established. While it is reasonable for some physicians and nutrition scientists to recommend curtailment of fat intake and control over the type of fatty acids ingested, the present state of knowledge is such that the term "toxicity" is not appropriate in describing the relationship between saturated fatty
acids and arteriosclerosis or cardiovascular disease.

The status of knowledge has been interpreted in a joint statement of the Food and Nutrition Board, National Academy of Sciences, National Research Council, and the Council on Foods and Nutrition of the American Medical Association which states that "In 'risk categories' it is important to decrease substantially the intake of saturated fat and to lower cholesterol consumption. In practice this entails substituting polyunsaturated vegetable oils for part of the saturated fat in the diet" (27). This issue has been reviewed by Reiser (28) and a vigorous challenge has been made by Keys et al. (29). These opposing views from responsible investigators reflect the difference in interpretation of present knowledge.

**Short-term studies**

The LD₉₅ of a stearic acid emulsion was 23 mg per kg body weight when it was injected intravenously into mice (30).

Day-old chicks were fed 5 percent prime tallow, No. 1 tallow, hydrogenated fat or stearic acid in the diet for 4 weeks. This is estimated to be about 6 g of these substances per kg body weight per day. No deleterious effects were noted. Feed utilization was improved by tallow, but not by hydrogenated fat or stearic acid (31). Newly hatched cockerels were fed diets containing 5 percent tallow for 12 weeks; there was no effect on growth rate, but feed conversion when measured as pounds of feed consumed per pound of gain was improved over that of controls (32).

Chicks were fed from 1 day to 8 weeks of age on rations containing 4 or 8 percent of animal tallow. At 8 weeks, the consumption of tallow was approximately 1.5 g and 3 g per kg body weight per day respectively, for the 4 percent and 8 percent dietary levels. Increased weight gain and feed efficiency were observed at the 8 percent level but not at the 4 percent level (33).

Groups of 25 one-week-old chicks were fed for 9 weeks on diets containing 7, 11, and 15 percent tallow; at the end of this time they were consuming about 5.9, 9.3, and 12.7 g per kg body weight per day, respectively. Tallow increased the feed efficiency but did not affect the rate of growth (34).

A few reports of short-term feeding studies have been published in which dogs, pigs, and rats were the experimental animals. Anorexia, constipation, listlessness and fever were observed in dogs given 5 percent stearic acid in the diet (35).

Feeding beef tallow at a level of 15 percent of the diet to miniature pigs for a year significantly decreased the blood clotting time as compared
to pigs fed 15 percent safflower oil in the same basal diet. The maximum effect on blood clotting occurred 3 hours after feeding (36).

When rats were kept on a diet containing 0.3 percent stearic acid for 209 days, anorexia, severe pulmonary infections, and high mortality were observed. The mean survival time of five male rats, which consumed an average of about 15 g of the diet per day including about 45 mg stearic acid (about 0.3 g per kg body weight) was 107 days. That of five female rats, which consumed an average of about 13.5 g of the diet per day including about 41 mg stearic acid, was 127 days. No gross or microscopic pathological lesions attributable to the stearic acid were found (37). Pulmonary infections also occurred in rats fed octadecylamine in concurrent experiments and it is unlikely that these infections and high mortality rates were associated with stearic acid in the diet.

When half of the total food given to young white rats consisted of stearic acid (about 50 g per kg of body weight) with the other half as casein, glucose, cellulose, and salt and vitamin mixtures, the males died within an average of 8.2 days and the females after 10.2 days. Death was considerably delayed when the stearic acid was reduced to three-tenths of the initial dose. When as little as 5 percent corn oil was added to the diet, the deleterious effects of the high concentrations of stearic acid were markedly reduced (38).

Male and female weanling rats were fed a diet containing 50 percent stearic acid (about 50 g per kg of body weight at start of the experiment) for 8 weeks. Microscopic examination of their fatty tissues showed a foreign body reaction. The lesion was usually located within the fat cell membrane. No evidence of acute inflammatory reactions, hemorrhages, or birefringent material was noted. No foreign body reactions were observed in the controls whose diets contained 50 percent lard (39).

Long-term studies

No long-term animal studies on the feeding of tallow, hydrogenated tallow, stearic acid or calcium stearate were available to the Select Committee.

Special studies

In a carcinogenicity test, 92 mice divided into seven test groups of 10 to 16, received subcutaneous injections of 0, 0.05, 0.5, and 1.0 mg of stearic acid (estimated to be 2.5, 25, and 50 mg per kg body weight per day) once, twice, or three times weekly. The number of injections per test group varied from 26 to 114. Only one group of 10 mice developed four subcutaneous sarcomas in the 18-month experimental period, as compared to one sarcoma in one of the control groups. This reacting treatment group had been given 0.05 mg twice a week for a total of 114 injections. No mouse in the other six groups developed any sarcomas, including those
given 0.5 mg twice a week for a total of 114 injections or 1.0 mg twice a week for a total of 82 injections. There was no explanation for the apparently anomalous finding of four sarcomas in the one test group (40).

To clarify the picture, the investigators conducted a joint study with another laboratory. Stearic acid was tested for carcinogenicity in mice, again by subcutaneous injections once weekly for 26 weeks at concentrations of 0.05 to 0.5 mg. No sarcomas were observed at the site of injection. The authors concluded that stearic acid was noncarcinogenic under the conditions of their tests (41).

Other tests on carcinogenicity also were negative. No tumors were found in ten rats fed 0.3 percent of stearic acid in the basal diet for 209 days (37).

A recent epidemiological study suggests an association between colon cancer and saturated fat and cholesterol in the diet, but the authors caution against incrimination of particular dietary factors until further studies are conducted (42).

No reports have been found on the mutagenicity and teratogenicity of tallow, hydrogenated tallow, stearic acid or calcium stearate or on the carcinogenicity of tallow, hydrogenated tallow and calcium stearate.

The Joint FAO/WHO Expert Committee on Food Additives considered salts of myristic, palmitic and stearic acids (including calcium salts) to be equivalent to normal products of digestion of fats with cations that are normally encountered in the diet; consequently the Joint Committee considered it unnecessary to establish an acceptable daily intake (43).

V. OPINION

Tallow and stearic acid, one of its chemical components, are consumed as part of normal human diets primarily in meats and in smaller quantities as ingredients of shortening and oleomargarine. Calcium stearate appears to be a normal product of digestion of diets containing calcium and stearic acid. Hydrogenated tallow, including tallow flakes, is used to some extent in the manufacture of shortening.

Feeding tests with animals show a high utilization of tallow as an energy source, but a relatively low digestibility of hydrogenated tallow, stearic acid, and calcium stearate. None of the feeding tests involving amounts of these substances comparable to those estimated to be consumed as food additives showed any toxic effects. Furthermore, the toxicity of stearic acid at very high concentrations is markedly reduced by the presence in the diet of glycerides of substantially lower melting point, such as those containing unsaturated fatty acids. Carcinogenicity tests of stearic acid have shown negative results.
This report is directed toward the GRAS status of tallow, hydrogenated tallow, and stearic acid as given in the Code of Federal Regulations 121.101(i) as substances migrating to food from cotton and cotton fabrics used in dry food packaging and calcium stearate as a GRAS substance (unpublished). Even at the levels estimated as being consumed by man from all added sources of these substances there is no evidence to demonstrate a hazard to the public.

In light of these observations, the Select Committee concludes that:

As substances that may migrate to foods from cotton or cotton fabrics, there is no evidence in the available information on tallow, hydrogenated tallow, or stearic acid that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public, when they are used at levels that are now current or that might reasonably be expected in the future.

There is no evidence in the available information on calcium stearate that demonstrates, or suggests reasonable grounds to suspect a hazard to the public, when it is used as a direct food additive at levels that are now current or that might reasonably be expected in the future.
VI. REFERENCES CITED


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April 30, 1976
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