EVALUATION OF THE HEALTH ASPECTS OF LARD AND LARD OIL AS THEY MAY MIGRATE TO FOODS FROM PACKAGING MATERIALS

1976

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
FASEB
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I. INTRODUCTION

This report concerns the health aspects of lard and lard oil as they may migrate to foods from packaging materials. 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; 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 April 1, 1977 (42 FR 17526 to 17529) 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 lard and lard oil as they may migrate to foods from packaging materials. The Select Committee received no requests for such a hearing on lard and lard oil.

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 (2) [21 CFR 170.3] 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 (2) recognizes further [21 CFR 170.30] that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

*The document (PB-234 891/0) 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, 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 reconduted, 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 lard and lard oil 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

Lard, one of the principal animal fats, has been a part of the human diet for many years. According to the FAO/WHO Recommended International Standard for lard (3), it is the fat rendered from fresh, clean, sound, fatty tissues of swine (Sus scrofa) in good health at the time of slaughter, and fit for human consumption as determined by a competent authority recognized in national legislation. The tissues do not include bones, detached skin, head skin, ears, tails, organs, windpipes, large blood vessels, scrap fat, skim-mings, settlings, and pressings, and are reasonably free from muscle tissues and blood.

Lard is a soft, white, unctuous mass that melts over a range of about 39° to 48°C; it readily undergoes oxidation but stability of the fat to development of rancid flavors and odors may be improved by deodorization and addition of antioxidants (4). The saponification number of lard ranges from 192 to 203, and the iodine number from 45 to 70 (3).

The fatty acid components of the triglycerides comprising lard vary somewhat in nature and amount, depending on the diet of the animal, but generally are about as follows: oleic, 35 to 60 percent; palmitic, 20 to 32 percent; stearic, 5 to 18 percent; linoleic, 3 to 15 percent; palmitoleic, 2 to 4 percent; myristic, 0.5 to 2.5 percent. All other fatty acid components are less than 2 percent each (5). The free fatty acid content of lard is very
low (0.2 to 0.7 percent expressed as oleic acid) (4). Little difference was found in fatty acid values between commercially-rendered lard, a laboratory-rendered lard and a solvent-extracted lard, all produced from the same batch of swine tissue (6).

Lard oil is a low melting fraction that has been expressed from lard. Its saponification number is from 195 to 197, its iodine value is 56 to 74, and it solidifies at -2° to +4°C (7). It is more often used for industrial purposes, e.g., as a cutting oil, than for food purposes (8).

Lard and lard oil are GRAS under the Code of Federal Regulations (2) as substances migrating to food from cotton and cotton fabrics used in dry food packaging [21 CFR 182.70]. Lard and lard oil are also regulated under 21 CFR 175.105 as components of adhesives intended for use in packaging, transporting, or holding food; under 21 CFR 178.3120 they may be safely used as components of animal glue for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food. Lard oil is regulated under 21 CFR 176.210 as a substance that may be used safely in the manufacture of paper and paperboard intended for use in the packaging, transporting, or holding food. A National Research Council (NRC) subcommittee on review of the GRAS list (Phase II) (9) ascertained in its survey that hydrogenated lard is used as a mastic substance in chewing gum.

III. CONSUMER EXPOSURE DATA

Other than the use cited for hydrogenated lard in chewing gum, there are no data presented in the NRC report (9) on the uses of lard or its consumption. No consumption data on lard and lard oil were included in that report because the GRAS substances used only as packaging material ingredients were not included in the NRC survey.

Because this report considers lard and lard oil only as they might enter packaged foods as a result of abrasion or contact with the container during marketing, storage, and use, the Select Committee has sought means for estimating this amount and has found no guidelines. However, it seems logical to assume that the level of consumer exposure to lard and lard oil from this source can only be manyfold lower than the amounts regularly consumed by man as a fatty component of his diet in such foods as margarine and shortenings. Data (Table I) on the quantity of lard used as food, are provided for comparison.
TABLE I

Total Quantity of Lard Used Annually in Foods in the United States (10)

<table>
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<tr>
<th>Use category</th>
<th>1960 million kg</th>
<th>1973 million kg</th>
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<tr>
<td>Margarine</td>
<td>25</td>
<td>33</td>
</tr>
<tr>
<td>Shortening</td>
<td>218</td>
<td>151</td>
</tr>
<tr>
<td>All other food uses</td>
<td>618</td>
<td>324</td>
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</table>

The data in Table I show a decline in total U.S. use of lard in foods from 4.8 kg per capita annually for 1960 (population 180 million) to 2.4 kg per capita annually in 1973 (population 210 million). The latter figure is equivalent to 6.6 g per person per day or 110 mg per kg body weight per day.

IV. BIOLOGICAL STUDIES

Digestion and metabolism

In chickens, the digestibility coefficients (percent of ingested fat that is digested) have been reported by various workers to range from 84 to 95 percent (11-13). The energy value was found by Peterson and Vik-Mo (11) to be 7.92 kcal per g and by Renner and Hill (12) to be 8.8 kcal per g. Hydrolysis of lard to the form of free fatty acids before administration reduced the digestibility coefficient of lard to 65 percent (12). Carlson and Bayley (14) determined the digestibility coefficient of lard to be 81 percent when fed to young pigs as 10.7 percent of the diet (about 3.7 g per kg body weight). In tests with human volunteers who consumed 50 to 115 g of lard daily (about 0.8 to 1.9 g per kg body weight), Langworthy (15) found lard to be digested to the extent of 97 percent. Three-day metabolic balance studies with normal, full-term infants five to nine days old on the first day of study, indicated that fecal excretion of fat averaged only 0.30 g per kg per day when intake of lard averaged 6.37 g per kg body weight per day, indicating that about 95 percent of the ingested lard was digested (16).

Acute toxicity

Acute toxicity studies have not been reported. Toxicity studies on the products of digestion of lard – the fatty acids and glycerol – have been described in other reports of the Select Committee, including glycerin and
glycerides (17), tallow and stearic acid (18), coconut oil, peanut oil, oleic acid and linoleic acid (19), and hydrogenated soybean oil (20). None of these substances is toxic even in doses in excess of usual intakes. It should be borne in mind in considering the data that follow, that all of these studies involved doses of lard or lard oil that are vastly larger than would be expected to occur in foods due to the migration of lard from the packaging materials containing them.

**Short- and long-term studies**

In a six-week feeding study in which lard was fed to 12 twenty-one-day-old male Wistar rats at dietary levels providing from 10 to 73 percent of the calories (about 5 to 40 g per kg per day), Thomasson (21) found that the food-efficiency of lard was comparable to that of summer butterfat and that feeding lard at these levels did not decrease survival.

Silberberg and Silberberg (22) found that a 24 percent lard diet, (about 30 g lard per kg body weight) fed from weaning to death, significantly increased the mortality and shortened the life span of male (50 percent dead at a mean age of 447 days compared to 559 days in controls), but not female mice of the C57 strain. Male DBA mice were similarly affected, but to a lesser degree (50 percent dead at a mean age of 325 days compared to 373 days in controls). Subsequently, the same authors (23) fed a 25 percent (about 30 g lard per kg body weight) lard diet to C57 mice for five months beginning at ages one month, seven months or twelve months after which they were fed the control diet for life. The life span of the animals fed lard during the period of growth (starting at one month or seven months old) was as long as or longer than the controls (655 days and 694 days, respectively, as compared to 653 days for controls). Mean age at death of animals fed lard from weaning through life was 546 days.

**Reproductive effects**

In research by Santyan y Velasco and Pancaldi (24), 2 two-month-old female rats were maintained on a bread, milk, and water diet and three female litter mates were given, in addition, 4 to 5 g of lard daily (some 80 g of lard or more per kg body weight). This extraordinarily high proportion of fat in the diet would be expected to diminish the intake of nutrients provided by the control ration. A few days after the experiment was begun, the rats fed the lard supplement began to lose their appetites and became emaciated. This was accompanied by edema of the snout, eyes, and external genital organs. As the lard feeding continued, these disturbances diminished until they disappeared after 9 to 10 days to "recur periodically, and in a progressively more attenuated form." All five females produced litters. The pups from the rats fed lard were stunted (average weight 4 g compared to 5.7 g for pups from control dams), sickly, poorly nourished, cyanotic, and had dry, wrinkled skin. Livers were small, yellowish, and soft in consistency,
indicative of a state of adiposis. These results were confirmed by repeating the lard feeding using three other females and examination of their offspring.

Vinson and Cerecedo (25) raised Evans-Long rats through three generations and Wistar strain rats through four generations on diets containing 2, 5, and 10 percent lard (2, 5, and 10 g per kg body weight, respectively, at the start of feeding after weaning). Growth in both strains in all generations at all lard levels was excellent. There were four parent females of the Evans-Long strain, and 15 females in each of the $F_1$ and $F_2$ generations. There were 27 parent females of the Wistar strain and 35, 13, and 7 females, respectively, in the $F_1$, $F_2$, and $F_3$ generations. The dams lost considerable weight during lactation but regained it rapidly when litters were separated. Provision of lard ad libitum (up to 8 g per day consumed), in addition to the above diet, failed to improve lactation performance. The addition of 500 mg of brewer's yeast per day prevented weight loss of lactating dams. The authors concluded the lard diet was inadequate in some essential constituent or that the large amounts of fat interfered with ingestion of adequate amounts of other food constituents.

**Arthritis**

Silberberg and Silberberg (26) maintained more than 100 male C57 black mice throughout life on a stock diet containing 5 percent fat and supplemented with 25 percent lard (about 25 g lard per kg of body weight). Articular aging was hastened in the test animals as compared to that in a similar number of control animals. In general, the incidence of osteoarthritis was doubled. However, some mice remained free of articular changes even in old age. The test animals were considerably heavier than the controls (mean weight 31 to 40 g compared to 25 to 32 g in controls). These investigators (27) compared their results with C57 mice to those observed with a DBA strain. The mice on the same high lard diet gained only 8 percent more weight than did the controls and with hardly any increase in fat deposits. These results were related by the authors to the more rapid growth rate of the DBA mice. In a similar study (28), three groups of C57 black mice were fed a diet enriched with 25 percent lard (about 25 g per kg body weight) or 23 percent lard plus 3 percent linoleic acid. The linoleic acid supplement partly reversed the osteoarthritic effect of the high fat diet. The animals on the 25 percent lard diet showed the fastest growth to 12 months of age (mean maximum weight 36.4 g), but thereafter lost weight more rapidly (to mean weight of 26.7 g) than the mice receiving 3 percent linoleic acid or the controls. In contrast, Sokoloff and Mickelsen (29) found DBA/2 JN male mice maintained on a 25 percent lard diet (more than 30 g per kg body weight at the start of the experiment) to be more obese than those on a cottonseed oil diet at the same level, but found no evidence of the development of degenerative joint disease.
Carcinogenicity

No oral studies of the carcinogenicity of lard have been reported. However, lard was used as a vehicle for parenteral testing of various compounds for carcinogenicity in early work. Andervont (30) injected subcutaneously each of 190 mice of five pure strains and one mixed stock with 1 ml of lard given in three doses over a four week period. After 27 weeks no animals had developed tumors. Barry and Cook (31) injected 20 mice and 20 rats (strain not indicated) subcutaneously with a lard fraction that was liquid at 37°C. The dose in mice was 0.5 cc weekly at first and later 1 cc "at longer intervals"; in rats 1 cc at first and later 3 cc "at longer intervals." The mice observed after 40 weeks, and the rats after 124 weeks, showed no malignant injection-site tumors. Burrows et al. (32) reported that of 143 rats (strain not indicated) subjected to weekly subcutaneous injections of 1 ml of lard to maintain a depot of lard under the skin, seven had spindle-cell tumors at the site of injection when examined after one year of treatment.

Atherogenicity

A number of studies have been conducted of the effects of dietary lard at doses up to 23 g per kg body weight on increasing the level of plasma lipids and the appearance of atherosclerotic signs in man and laboratory animals (33-39). However, considering the limited uses for lard and lard oil covered in this report, it is improbable that the very small intakes that would be expected could be significant factors in influencing serum cholesterol or fat levels. Other reports of the Select Committee, such as that on hydrogenated soybean oil (20), will consider the possible atherosclerotic impact of dietary fat.

V. OPINION

Lard has been consumed in pork, as an ingredient in foods, or has been added to food as the result of frying, for centuries. Aside from the implication of all animal fats as contributors to atherosclerosis, no deleterious effects have been recorded. Some adverse effects observed in experimental animals can be ascribed to very high levels of fat in the diet rather than to specific effects of lard. Such high dietary levels of lard or lard oil are unlikely to occur in the diet of man. Moreover, the amount of lard or lard oil transferable to food from lard-treated cotton fabrics used in packaging, is obviously minute compared to the amounts of lard ingested in food.
In light of these considerations, the Select Committee concludes that:

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


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