

American

Paper 
Institute

serving the pulp, paper and paperboard industry

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December 21, 1973

Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Md. 20852

SUBJECT: Notice of Proposed Rulemaking published September 28, 1973,
38 Federal Register, 27076--27081 (1972)
Comments of American Paper Institute, Inc.

Dear Sirs:

The American Paper Institute, Inc. ("API") is the national trade association of more than 200 companies producing pulp, paper and paperboard. The members of API supply 90 percent of the wood pulp, paper and paperboard produced domestically for all uses, including the packaging of food products. They operate approximately 750 pulp, paper and paperboard mills, using both virgin and recycled fibers as a raw material, and over 5000 converting plants which produce such packaging products as folding cartons, corrugated boxes, composite cans, multi-pack carriers and other containers.

Under date of October 10, 1972 the API submitted comments relative to the proposal concerning asbestos fibers in talc as published August 12, 1972, 37 Federal Register 16407-08 (1972).

The members of the API, as producers of food packaging, are interested persons respecting the rulemaking proposal entitled, "Asbestos Particles in Food and Drugs, Notice of Proposed Rulemaking," which was published in the Federal Register of September 28, 1973 at pages 27076-27081. Under the proposal, and pursuant to certain provisions of the Federal Food, Drug and Cosmetic Act (secs. 402, 502, 701, 52 Stat. 1046-1047, as amended, 1055-1056, as amended; 21 U.S.C. 342, 352, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner of Foods and Drugs proposes to amend Title 21 of the Code of Federal Regulations, Part 121.101, Paragraphs (d) (8), (h), and (i) and to add a new Section 121.2006 paragraphs (a), (b), and (c).

Insofar as these proposed amendments and new sections relate to food packaging materials, API is opposed to the adoption of the same for the following reasons:

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I

The proposed amendment to Section 121.101 (h) which would require that talc used in paper and paperboard for food packaging be "free of asbestos fibers as determined in Sec. 121.2006" prescribes an unnecessary and illogical limitation on talc which limitation will yield nothing in the way of protection of the public health.

In the production of paper and paperboard the only significant use of talc is what may be described as a trace amount added to the wire screen at sheet forming to prevent pitch from sticking to the screen. The extent to which such talc may bear or contain asbestos particles which may become a part of the paper sheet which in turn may contaminate food when the sheet becomes food packaging is highly speculative. Essentially a trace amount of talc bearing a trace contaminant of asbestos fibers which may become a trace component of paper or paperboard, a trace of which may migrate to food, defies any quantitative estimate.

In view of the trace exposure from paper and paperboard and the following observations, the requirement "free of asbestos fibers as determined in Sec. 121.2006" would appear to have no legal or scientific basis and should be deleted.

- (1) There is no scientific evidence which will support the conclusion that an occasional asbestos fiber ingested from paper or paperboard used as food packaging presents a hazard to the consumer. As indicated in the prologue to the proposed order, the scientific evidence concerning the hazards from ingestion of asbestos is contradictory and inconclusive.¹ In fact, as indicated in the prologue to the proposed order, hamsters fed a diet containing 1% asbestos fibers for life had no tumors as a result of the diet.²
- (2) The fact that asbestos fibers from paper or paperboard, in some infinitesimal amount, present no hazard is manifestly apparent in that humans tolerate massive numbers of such fibers from other sources in their

¹"The evidence concerning the possible hazard from ingestion of asbestos particles is contradictory and inconclusive: "Federal Register, Vol. 38 No. 188--Friday, September 28, 1973, p. 27077, Col. 2, Line 66.

²"In a published study by W. E. Smith, et al. (Ref. 41), hamsters maintained on a diet of 1 percent chrysotile or amosite through life had no gastrointestinal tumors." Ibid. p. 27077, Col. 3, Line 7.

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lifetime. The prologue to the proposed order relates that scientific workers found that tap water for the city of Ottawa contained 2 million asbestos fibers per liter and soft drinks the same order of magnitude.³ Since potable water and beverages are food, the hazards attendant on consumption must be considered acceptable, i.e., these foods with massive numbers of asbestos fibers are not regarded as adulterated.

- (3) The most persuasive evidence of the deleterious nature of asbestos fibers is associated with inhalation and the effect on the lungs. Long time exposures of humans has made possible real life observations of the onset and progress of disease. There is a definitely greater incidence of lung cancer and malignancies of the body lining tissues among workers in asbestos mines after 10-14 years of exposure.⁴

It is apparent, however, that a lifetime exposure to the usual air borne concentrations of asbestos fibers, air breathed, is not significantly hazardous. The prologue to the proposed order indicates that human lungs generally harbor thousands or millions of asbestos fibers, though most people do not have asbestosis, a fibrous disease of the lungs.⁵ Further justification for the concept that the limitations required by law be determined as the safe level rather than an achievable level is apparent in recent regulations promulgated under the Williams-Steiger Occupational Safety and Health Act of 1970. In establishing standards or

³"These workers found that, whereas the tap water in Ottawa (having a filter plant) contained about 2 million fibers per liter, the quality (quantity) of fibers in soft drinks and alcoholic beverages purchased in the Ottawa area ranged from 1 to 12 million fibers per liter." Ibid. p. 27077, Col. 3, Line 25.

⁴"In these workers in asbestos mines, malignancies of the lung and of the body lining tissues, namely lung cancer and mesothelioma, occur at rates greater than in persons not so occupationally exposed. There is a 5 to 7 fold increase in lung cancer in asbestos workers which is noted as early as 10 to 14 years after onset of exposure and is significant at 20 years." Ibid. p. 27077, Col. 1, Line 75.

⁵"There is considerable evidence that most human lungs harbor thousands or millions of asbestos fibers although most people do not have asbestosis." Ibid. p. 27077, Col. 2, Line 17. (Refs. 35 through 37)

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limits for the amount of asbestos fibers in ambient air for workers exposed to asbestos dust, the Department of Labor, Occupational Safety and Health Administration has amended the appropriate regulations in Part 1910 of Title 29, Code of Federal Regulations. The prologue to the order is most informative in that the objective of the legal limit was the specific level below which exposure is safe. There is no requirement that the work atmosphere be free of asbestos fibers nor as free as the technology will permit. The requirement, in brief, presently limits occupational exposure to an 8-hour time weighted (TWA) airborne concentration of asbestos dust not exceeding 5 fibers longer than 5 micrometers per milliliter of air. With an initial allowable concentration of 5 fibers per cubic centimeter of air, the maximum possible aspiration of asbestos particles would be 100,000 per minute for each 8-hour day. With an allowable concentration of 2 fibers per cubic centimeter of air, the standard which will become effective July 1, 1976; the maximum possible aspiration of asbestos particles would be 40,000 per minute for each 8-hour day. The fibers of reference, 5 micrometers or larger are the same size as those considered in the proposed FDA order.⁶ To estimate the practical effect of this limit the assumption may be made that a standard man at light activity breathes 20 liters per minute.

The OSHA order submits as a basis for its standard that the best scientific evidence available as to a safe level has been selected subject to such reconsideration as new knowledge may provide.⁷

⁶"(b) Permissible exposure to airborne concentrations of asbestos fibers-
(1) Standard effective July 7, 1972. The 8-hour time-weighted average airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed five fibers, longer than 5 micrometers, per cubic centimeter of air, as determined by the method prescribed in paragraph (e) of this section. (2) Standard effective July 1, 1976. The 8-hour times-weighted average airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed two fibers, longer than 5 micrometers, per cubic centimeter of air, as determined by the method prescribed in paragraph (e) of this section."
Federal Register, Vol. 37, No. 110-Wednesday, June 7, 1972, p. 11320, Col. 1.

⁷"No one has disputed that exposure to asbestos of high enough intensity and long enough duration is causally related to asbestosis and cancers. The dispute is as to the determination of a specific level below which exposure is safe. Various studies attempted to establish quantitative relations between specific levels of exposure to asbestos fibers and the appearance of adverse biological manifestations, such as asbestosis, lung cancers and mesothelioma, have given rise to controversy as to the validity of

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- (4) There is no scientific evidence to show that talc will transfer from paper or paperboard to food. Most food in direct contact with a paper or paperboard surface is dry food, and transfer of a substance from the paper or paperboard can only be by abrasion. With the trace amounts of talc used in the paper industry, there is no scientific evidence to show that talc transfers to dry food by abrasion. Wet or oily foods are normally separated from the paper or paperboard package by a barrier coating or barrier film, and there is no scientific evidence to show that talc and/or asbestos fibers migrate from the paper or paperboard through the barrier to the food.

II

The addition of the new section, Sec. 121.2006, Talc, should be abandoned for the reasons cited above and for the reason that there is no intent nor purpose in the Food, Drug and Cosmetic Act to justify the Commissioner's requirement that food and food packaging be free of asbestos fibers to the maximum extent practical nor that food and food packaging not complying with that requirement shall be deemed to be adulterated within the meaning of Sec. 402.⁸ On the other hand it is clear that Sec. 301 and Sec. 402 of the F D & C Act require that talc used in food or in food packaging be free from asbestos fiber (or any other foreign material) to the extent necessary to protect the public health. Sec. 301 (a) of the Act prohibits introduction into interstate commerce of food (et.al) which is adulterated.

⁷the measuring techniques used and the reliability of the relations attempted to be established. Because of the long lapse of time between onset of exposure and biological manifestations, we have now evidence of the consequences of exposure, but we do not have, in general, accurate measures of the levels of exposure occurring 20 or 30 years ago, which have given rise to these consequences. There are also controversies concerning the relative toxicity of the various kinds of asbestos, and varying hazards in different workplaces.

"It is fair to say that the controversy has centered in the area between a two fiber TWA concentration and five-fiber TWA concentration, with variations on the time needed for compliance. Many employers support a five-fiber TWA. Most medical opinion is divided between a two-fiber standard and a five-fiber standard.

"In view of the undisputed grave consequences from exposure to asbestos fibers, it is essential that the exposure be regulated now, on the basis of the best evidence available now, even though it may not be as good as scientifically desirable. An asbestos standard can be re-evaluated in the light of the results of ongoing studies, and future studies, but cannot wait for them. Lives of employees are at stake." Federal Register, Vol. 37, No. 110-Wednesday, June 7, 1972, p. 11318, Col. 2, Line 71

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Sec. 402 in turn provides that food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. Thus, an association with the possibility of injury to health is essential if a substance is to be identified as poisonous or deleterious. No substance is of itself poisonous or deleterious in any amount and conversely all substances are poisonous or deleterious in some amount. To adulterate, to be poisonous or deleterious, the amount of the contaminating substance must be sufficient that it may render the food injurious to health, when all ways in which the substance is being consumed are considered. Sec. 406 provides that any substance added to food in an amount which is poisonous or deleterious shall be deemed to be unsafe for the application of Sec. 402, i.e., an adulterated food. However, when such substance is required in the production of the food or cannot be avoided by good manufacturing practice, Sec. 406 provides that the Secretary shall, to the extent as he finds necessary for the protection of the public health, promulgate regulations limiting the substance. Any quantity exceeding the limit shall be deemed to be unsafe, adulterated food for the purpose of Sec. 402.

Thus, under the F D & C Act the Secretary may limit or may be required to limit the quantity of a contaminant substance in food as he finds necessary for the protection of the public health. Whereas it may be desirable to limit a contaminant substance in food to the least possible amount, the Act clearly provides that such substance shall be limited to the extent necessary to prevent adulteration within the meaning of Sec. 402.

It may be noted that the authority to set limits or tolerances provided in Sec. 406 was originally intended to include pesticides. In the application of economic poisons to agricultural crops it is desirable to limit the poison to the minimum feasible level. The Act, however, provides as discussed above only for such limit as is necessary to protect the public health, i.e., to prevent the raw agricultural commodity from bearing an amount which is unsafe or adulterated or which must be deemed to be unsafe or adulterated when all other sources of ingestion of the pesticide are considered.

As an example, it is probable that a raw agricultural commodity with a pesticide tolerance of 10 parts per million can, in a given year, readily be produced with no more than 2 parts per million of residual pesticide, minimum feasible level. This makes it desirable under those circumstances that producers so use the economic poison as to leave as a residual no more than that amount. However, concerning the crop of the producer who ignorantly or carelessly uses five-fold quantities which leave a residual of more than that amount, up to 10 parts per million, there is no violation and no adulteration since the tolerance identifies the level above which the raw agricultural commodity is to be deemed unsafe, considering all other ways in which the economic poison is concurrently being ingested by the consumer. However, strongly we may feel against the producer who

⁸"(b) Good manufacturing practice requires that talc be free from asbestos fibers to the maximum extent practicable. Accordingly, any food or food-packaging material containing talc that is not free from asbestos fibers as determined by the method set out in paragraph (c) shall be deemed to be adulterated in violation of Section 402 (a) (1) of the act." Federal Register, Vol. 38, No. 188, September 28, 1973, p. 27079, Col. 3, Line 72.

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wastefully used more pesticide than necessary, the offense against the law depends on the adulteration of food. Other means than the threat of criminal prosecution must be used to persuade and educate that the least possible amount should be used as may be dictated by wind, rain, insect population and the like.

It would, therefore, appear that in view of:

- (1) the absence of clear cut evidence of any danger to health from the ingestion of a trace of asbestos fibers,
- (2) the massive numbers of asbestos fibers which can be found in potable water of municipal systems,
- (3) the massive numbers of asbestos fibers which may safely be air aspirated by workmen exposed daily to dusts,

no regulation concerning asbestos in talc used for food packaging is required. Talc as produced and refined for use in the production of paper and paperboard requires no limitation on asbestos fibers. The possibility that ingestion of asbestos fibers resulting from the use of talc in food packaging will be injurious to health is so remote that scientific evidence thereof is needed before any regulation is adopted.

III

The Commissioner of Food and Drugs proposes to amend Title 21 of the Code of Federal Regulations, in part, by adding the new section 121.2006 to Subpart E. In 121.2006 (b), it is stated that:

"Accordingly, any food or food-packaging material containing talc that is not free from asbestos fibers as determined by the method set out in paragraph (c) shall be deemed to be adulterated in violation of section 402 (a) (1) of the act."

(emphasis added).

Once again, as it did in its written comments of October 10, 1972 on the proposed subject regulation, API submits that food-packaging may not be regulated as "food" under Section 402 (a) (1) of the Federal Food, Drug and Cosmetic Act. The term "food" is defined in Section 201 (f) of the Act; food-packaging is not included within that definition.

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Section 402 (a) (1) of the Act states that a "food" shall be deemed "adulterated" if it bears or contains any poisonous or deleterious substance which may render the "food" injurious to health. Since food-packaging material is not includible within the Act's definition of "food," it is respectfully submitted that there is no basis in law for the proposed regulation of food-packaging material under Section 402 (a) (1) of the Act. Food-packaging material cannot lawfully be deemed adulterated under Section 402 (a) (1) of the Act by reason of its containing talc which is not free from asbestos fibers.

For the above reasons, the American Paper Institute, Inc. opposes the Proposal as it relates to the regulation of food packaging and the use of talc in food-packaging materials.

The American Paper Institute, Inc. requests a copy of the Environmental Impact Statement upon which this Proposal is based, and further requests that it be granted at least 60 days after receipt of such Statement within which time to prepare meaningful comments thereto.

Respectfully,



Edwin A. Locke, Jr.
President

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