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Report to Congressional Requesters

August 1994

FOOD AND DRUG ADMINISTRATION

Carrageenan Food Additive From the Philippines Conforms to Regulations

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GAO

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Health, Education, and
Human Services Division

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Congressional Requesters

This report responds to your joint request for information on the Food and Drug Administration's (FDA) regulation of carrageenan—a food additive derived from red seaweed. (Requesters are listed at the end of this letter.) At issue is whether a less refined, less expensive carrageenan manufactured in the Philippines should be imported and sold in the United States as carrageenan. U.S. carrageenan manufacturers estimate that their revenue losses to Philippine carrageenan could exceed $170 million over 4 years.

Commercial food manufacturers use carrageenan to control moisture and modify texture in products such as ham, deli meats and turkey products, ice cream, and chocolate milk. FDA first approved the use of carrageenan in foods in 1961. During the late 1970s, processed Eucheuma seaweed[1] (PES) was introduced for use as carrageenan. The major difference between traditionally refined carrageenan and PES is the way in which it is processed. Traditionally refined carrageenan is produced by extracting the carrageenan from the seaweed and filtering the carrageenan extract to remove the cellulose and other substances, a process used for more than 3 decades. To produce PES, the process is modified in that the other substances are extracted and the remaining seaweed containing carrageenan and cellulose is processed as PES. In 1990, FDA determined that PES (now called Philippine natural grade (PNG) carrageenan) meets its criteria to be classified as carrageenan in the United States. (We are using the term PNG in our response to distinguish between PNG carrageenan and traditionally refined carrageenan.)

Congressional concerns have been heightened by allegations that PNG is different from traditionally refined carrageenan because of the way in which it is processed and by safety considerations arising from the difference in processing. You asked us to provide information on FDA's basis for (1) classifying PNG as carrageenan and (2) determining that PNG is safe for use in foods. In subsequent discussions with your offices, you also asked us to provide information on FDA's plans to investigate recent allegations that some PNG could be unsafe because it is processed with an illegal pesticide.

[1]Eucheuma cottonii and Eucheuma spinosum are FDA-approved red seaweed sources for carrageenan that abound in the warm waters surrounding the Philippines.

The results of our work are summarized in the following sections and discussed more fully in appendix I.

Results in Brief

Based on FDA's food additive regulations for traditionally refined carrageenan, FDA classified PNG as carrageenan. Because FDA determined that PNG is carrageenan—an approved food additive, PNG manufacturers were not required to submit a food additive petition to FDA. A new food additive petition would have required FDA to approve conditions under which PNG could be used in foods.

FDA's determination that PNG complied with its food additive regulations included a determination that there were no significant qualitative differences between PNG and traditionally refined carrageenan, including the safety of processing procedures. Based on FDA's original evaluation of the safety of traditional carrageenan and information about PNG, FDA looked at the safety of PNG processing and concluded that there is no inherent safety difference between PNG and traditionally refined carrageenan. Allegations about illegal pesticide use on PNG have led FDA to begin testing carrageenan for the presence of unapproved pesticide residues of ethylene oxide.

Background

FDA's food additive regulations (21 C.F.R. 172.620) define carrageenan as a "refined hydrocolloid that is prepared by aqueous extraction from" specific red seaweeds.[2] Carrageenan must be processed from one of eight red seaweeds listed in the regulations. Carrageenan has been produced in the United States and Europe for more than 30 years by chemically extracting the carrageenan from red seaweeds. Traditionally refined carrageenan is produced through a process that extracts the carrageenan from the seaweed, discarding the cellulose, impurities, and other substances along with the seaweed. In producing PNG, however, the impurities and other substances are extracted, and the carrageenan and cellulose are retained in the seaweed, which is processed as PNG. While PNG has a high level of cellulose, according to FDA officials, cellulose is not considered a safety concern.

Manufacturers of "new" food additives must submit a petition to obtain FDA's approval before the additives can be used in foods. In response to a petition for approval of a proposed use of a new food additive, the Federal

[2]Hydrocolloids, also known as industrial gums, thickeners, stabilizers, and gelling agents, have a variety of uses in food, beverages, and pharmaceuticals. The primary function of hydrocolloids is to control moisture within a product or substance.

Food, Drug, and Cosmetic Act requires FDA to establish regulations prescribing conditions for the additive's safe use in food or to deny its use. Once FDA has approved a food additive, manufacturers or importers are generally free to use or modify any process to produce the ingredient without notifying FDA. The final ingredient must, however, comply with FDA's regulations and may not introduce contaminants that could render the food injurious to health or otherwise cause the adulteration of the food. Manufacturers or importers who are not certain whether a food additive complies with a relevant regulation may seek FDA's advice.

The Federal Food, Drug, and Cosmetic Act prohibits distribution in the United States, or importation, of food additives that are adulterated. To ensure that food additives are not adulterated, FDA relies on postmarket surveillance of domestic establishments and imported products. To conduct postmarket surveillance, FDA (1) inspects domestic food establishments to ensure compliance with federal laws, regulations, and good manufacturing practices; and (2) inspects imported food products at the port of entry to ensure compliance with the same safety and labeling requirements established for domestic foods. Under the act, a food additive is adulterated if, among other things, it contains either (1) any pesticide residue that is not subject to a tolerance (i.e., a legal limit for residues established by the Environmental Protection Agency (EPA) for use on or in that food or (2) a pesticide residue in an amount greater than the tolerance level established by EPA for that food.[3]

Principal Findings

FDA Determined That PNG Conformed to Carrageenan Regulations

FDA's classification of PNG as carrageenan is based on the carrageenan standards contained in FDA's food additive regulations. In 1990, FDA classified PNG as carrageenan because, first, it determined that (1) the modified process used to produce PNG met the aqueous extraction requirement in its regulations and (2) PNG conformed with FDA's food additive specifications for carrageenan. Second, FDA determined that PNG conformed with its detailed specifications for carrageenan adopted in

[3]A food substance is found adulterated if it is filthy, is produced under insanitary conditions, or contains unapproved food additives, unapproved color additives, or certain unapproved pesticide residues. FDA shares responsibility with EPA for regulating pesticide residues in food. EPA determines the pesticide residue levels (tolerances) allowed on food, and FDA monitors and enforces these levels.

1979.[4] Third, FDA determined that the uses and functions of PNG are similar to those of traditionally refined carrageenan. Some U.S. manufacturers contend that PNG should not be classified as carrageenan because the modified process used to produce PNG is not an aqueous extraction as FDA regulations require. Chemists from several scientific associations we contacted, however, agreed with FDA that the modified process used to produce PNG involves an aqueous extraction.[5]

FDA followed its regulations in classifying PNG as carrageenan without requiring a food additive petition. Because FDA determined that PNG conformed to the food additive regulations for carrageenan, FDA did not require a food additive petition for PNG. In the absence of an existing regulation covering a particular additive, a manufacturer or importer is required to submit a food additive petition to FDA containing adequate data, including the results of animal studies where necessary, to demonstrate that a food additive is safe and will accomplish its intended function.

FDA officials told us that in the absence of sufficient information about PNG, the agency initially requested additional data in the form of a food additive petition. When FDA received additional information about PNG, it decided that the information at hand was sufficient to classify PNG as carrageenan. Although manufacturers of traditionally refined carrageenan characterized this as a reversal of FDA's position, because FDA had determined that PNG conformed to its existing food additive regulations, FDA decided to rescind its earlier request for a food additive petition for PNG.

FDA Concluded PNG Was Safe Based on Its Classification as Carrageenan

FDA concluded that PNG conformed with its carrageenan food additive regulations and was safe. More specifically, FDA had determined that carrageenan was safe when it approved a new food additive petition for traditionally refined carrageenan in 1961. FDA determined that PNG was safe because PNG is produced from approved seaweed sources for carrageenan that have been considered safe without toxicological testing because these seaweeds have been used as food for many decades. Later, in the 1990s FDA reviewed PNG's modified manufacturing process and determined that it was effective in eliminating bacteria normally found in seaweed and was

[4]FDA adopted the detailed specifications for carrageenan contained in the Food Chemicals Codex, second edition, as amended by the second supplement (1975).

[5]We discussed FDA's interpretation of aqueous extract with chemists from the National Institute of Standards and Technology, the Association of Official Analytical Chemists, and the American Chemical Society.

not expected to introduce contaminants that could render the food injurious to health.

After manufacturers of traditionally refined carrageenan raised questions about the propriety of FDA's classification of PNG as carrageenan and about PNG's safety, FDA reexamined its classification of PNG as carrageenan with particular attention to PNG's safety.[6] To facilitate its reexamination, FDA requested the trade associations representing traditional carrageenan and PNG manufacturers and their respective members to submit data on the safety of PNG. After reviewing the information provided, in August 1992, FDA reaffirmed its classification of PNG as carrageenan. Based on the results of assays of PNG, FDA determined that PNG was safe for use in food and that PNG's modified refining process does not affect the safety of the final product. Specifically, FDA determined that the only significant difference between PNG and traditional carrageenan is that PNG contains more cellulose as compared to traditionally refined carrageenan. FDA considers the cellulose contained in PNG to be generally recognized as safe and does not consider it to represent a safety concern.

Information on Pending Petitions and Alleged Safety Violations

Petitions to Amend FDA's Carrageenan Regulations Are Pending

Despite FDA's reaffirmation of its decision, manufacturers of traditionally refined carrageenan continue their efforts to have FDA rescind its determination that PNG should be classified as carrageenan and that PNG is safe for use in foods. Manufacturers of traditionally refined carrageenan have petitioned FDA to amend its carrageenan regulations. The petitions would permit PNG to be marketed as a food ingredient, but under a separate regulation and a different name that would clearly distinguish it from carrageenan. FDA also received results of a study performed by an independent chemist indicating that, among other things, PNG may contain contaminants from its manufacture or processing that may affect its safety

[6]Further, the Joint Explanatory Statement of the Committee of Conference to H.R. 5268, appropriations for Rural Development, Agriculture and Related Agencies for Fiscal Year 1991, said it "expected FDA to reexamine its decision on PNG carrageenan as a substitute for highly refined processed carrageenan in accordance with 21 CFR 172.620."

for food. As of April 1994, FDA was in the process of reviewing the petitions and study results before making its final decision.

Allegations of Illegal Pesticide Use in Some PNG

In June 1993 and February 1994, FDA received allegations from manufacturers of traditionally refined carrageenan that some PNG could be adulterated because it is processed with an illegal pesticide. Specifically, they alleged that a leading manufacturer of PNG used ethylene oxide as a pesticide on its product. Ethylene oxide is not approved for use on carrageenan.[7] When foods are decontaminated with ethylene oxide gas, the chemical ethylene chlorohydrin is formed. One of the traditional carrageenan manufacturers also alleged that certain hams were contaminated with ethylene chlorohydrin. The traditional carrageenan manufacturer stated that because the hams were processed with PNG that had been treated with ethylene oxide, they too contained residues of ethylene chlorohydrin.

FDA first received allegations of this illegal practice in June 1993. In August 1993, the leading manufacturer of PNG acknowledged in a letter to FDA that it had used ethylene oxide to process PNG, but that it ceased this practice once it learned ethylene oxide was not approved for use on carrageenan. FDA officials admitted that they did not follow the agency's standard procedures for handling industry allegations in that they did not refer the allegation to an FDA district office for follow-up. In February 1994, another manufacturer of traditionally refined carrageenan presented test results to FDA showing that PNG from the same manufacturer had been decontaminated with ethylene oxide because the PNG contained ethylene chlorohydrin. The traditional carrageenan manufacturer also provided test results showing that certain hams were contaminated with ethylene chlorohydrin because they were processed with PNG that had been treated with ethylene oxide. Although FDA has not completed its determination of whether ethylene oxide was used on PNG, FDA officials told us in May 1994 that based on its preliminary evaluation, they have determined that ethylene chlorohydrin, at the levels reported by the traditional carrageenan manufacturer, does not represent a safety concern.

The manufacturer of PNG stands by its earlier statement that it no longer uses ethylene oxide. The manufacturer speculates that the PNG tested could have been manufactured prior to August 1993 before it ceased using

[7]EPA regulations permit using ethylene oxide as a fumigant to decontaminate some food products, namely spices, herbs, and black walnuts.

ethylene oxide. To avoid further use of adulterated PNG, in February 1994, the manufacturer recalled all PNG that was treated with ethylene oxide.

FDA has the authority under the Federal Food, Drug, and Cosmetic Act to identify an imported food product containing an illegal pesticide residue as adulterated and to detain and subsequently refuse entry of that shipment into the United States. To determine if some PNG contains an illegal pesticide residue, FDA is collecting samples of imported carrageenan, both traditionally refined carrageenan and PNG, to test for ethylene chlorohydrin, the residue of ethylene oxide. If FDA's surveillance activities identify any imported carrageenan that contains the illegal pesticide residue ethylene chlorohydrin, FDA will consider the product adulterated and take appropriate regulatory action.

Since the U.S. Department of Agriculture (USDA) is responsible for inspecting meat and poultry products, USDA tested processed hams for ethylene chlorohydrin. USDA found ethylene chlorohydrin in some hams, but decided not to recall the hams because it believes the levels found do not represent a safety concern.

Agency Comments

We discussed the information in this report with officials in FDA and have included their comments where appropriate.

To obtain information used in this report, we reviewed FDA regulations relating to food additives in general and to carrageenan specifically. We also reviewed FDA records on its decision to classify PNG as carrageenan and on its determination concerning the safety of PNG. We discussed the basis for these decisions with FDA officials. We also discussed FDA's decisions with manufacturers of both traditional carrageenan and PNG as well as representatives of trade associations, the World Health Organization, and the National Academy of Sciences to obtain their perspectives on the issues involved. We discussed FDA's interpretation of aqueous extraction with scientists from the National Institute of Standards and Technology, the Association of Official Analytical Chemists, and the American Chemical Society. In addition, we discussed FDA and USDA plans for sampling and testing to assure that carrageenan and hams processed with carrageenan, respectively, do not contain illegal pesticide residues. We also discussed with EPA officials the health implications of potential pesticide contamination of carrageenan.

We conducted our work from October 1993 to March 1994 in accordance with generally accepted government auditing standards.

As we arranged with your offices, we will send copies of this report to appropriate congressional committees and subcommittees, the Secretary of Health and Human Services, and the Commissioner of Food and Drugs. We will also make copies available to other interested parties upon request.

If you or your staffs have any questions about this report, please call me on (202) 512-7119. Other major contributors to this report are listed in appendix II.

Mark V. Nadel
Associate Director, National
and Public Health Issues

List of Requesters

The Honorable William V. Roth, Jr.
United States Senate

The Honorable Robert E. Andrews
House of Representatives

The Honorable Roscoe G. Bartlett
House of Representatives

The Honorable Sherwood L. Boehlert
House of Representatives

The Honorable Frederick C. Boucher
House of Representatives

The Honorable Michael N. Castle
House of Representatives

The Honorable Bill Emerson
House of Representatives

The Honorable Vic Fazio
House of Representatives

The Honorable Elizabeth Furse
House of Representatives

The Honorable Dean A. Gallo
House of Representatives

The Honorable Benjamin A. Gilman
House of Representatives

The Honorable Robert W. Goodlatte
House of Representatives

The Honorable James V. Hansen
House of Representatives

The Honorable Steny H. Hoyer
House of Representatives

The Honorable Don Johnson
House of Representatives

The Honorable Jack Kingston
House of Representatives

The Honorable Richard H. Lehman
House of Representatives

The Honorable Jerry Lewis
House of Representatives

The Honorable John Linder
House of Representatives

The Honorable Robert T. Matsui
House of Representatives

The Honorable John T. Myers
House of Representatives

The Honorable Bill Orton
House of Representatives

The Honorable Richard J. Santorum
House of Representatives

The Honorable Karen Shepherd
House of Representatives

The Honorable Norman Sisisky
House of Representatives

The Honorable Joe Skeen
House of Representatives

The Honorable Robert G. Torricelli
House of Representatives

The Honorable Fred Upton
House of Representatives

The Honorable Curt Weldon
House of Representatives

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Abbreviations

AIM	acid-insoluble matter
ECH	ethylene chlorohydrin
EPA	Environmental Protection Agency
EtO	ethylene oxide
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
JECFA	Joint Expert Committee on Food Additives
PES	processed Eucheuma seaweed
PNG	Philippine natural grade
SIAP	Seaweed Industry Association of the Philippines
USDA	U.S. Department of Agriculture

Information on the Food and Drug Administration's Regulation of Carrageenan

FDA's Basis for Classifying PNG as Carrageenan

The Food and Drug Administration determined that Philippine natural grade carrageenan complied with its regulations and should be classified as carrageenan. While the extraction processes used to produce PNG and traditionally refined carrageenan are different, FDA determined that the process used for PNG meets the extraction requirement called for in FDA regulations and that the function of both products is similar.

The following chronology describes FDA's approval of traditionally refined carrageenan for use in food and its classification of PNG as carrageenan.

- In October 1961, in response to a petition for approval of a "new" food additive, FDA issued regulations permitting the use of carrageenan in foods. The regulations provided standards for the description and use of carrageenan. FDA regulations also restricted the seaweed sources of carrageenan to eight red seaweeds that were determined to be safe.[8]
- In July 1979, FDA stated in a Federal Register notice that all food-grade carrageenan must comply with FCC's carrageenan standards.[9] The specifications in the FCC standards effectively precluded degraded carrageenan for use in food.[10]
- In 1984, FCC drafted revised standards for carrageenan. The extraction process described in the revised standards is the one used to extract traditionally refined carrageenan from seaweeds and is different from the process used for producing PNG. The standard would also allow the use of seaweeds that are not authorized in the FDA regulations and would require that carrageenan not include more than 2 percent acid-insoluble matter (AIM).[11] JECFA standards that were also revised were similar to FCC standards. Before 1984, FCC and JECFA standards did not address the AIM

[8]In addition to the standards in FDA regulations, the Committee on Food Chemicals Codex (FCC) and the Joint Expert Committee on Food Additives (JECFA) each have standards for carrageenan. FCC is an activity of the National Academy of Sciences' Institute of Medicine and works under a contract with FDA. FCC's objective is to develop minimum identity and purity requirements for food-grade chemicals based on safety and good manufacturing practices that are published in the "Food Chemicals Codex." JECFA is an activity of the World Health Organization and the Foreign and Agriculture Organization of the United Nations. JECFA is composed of an international group of experts and assists in developing International Food Standards (the Codex Alimentarius) for the purity and identity of food additives and contaminants. However, the marketing and use of carrageenan in the United States is subject only to FDA regulations. FCC and JECFA standards do not have the force of regulations in the United States unless they are adopted by FDA.

[9]Food Chemicals Codex, second edition, as amended by the second supplement (1975).

[10]FDA considers carrageenan whose composition does not conform to certain chemical specifications to be degraded.

[11]AIM is insoluble seaweed residue (primarily cellulose (crude fiber), sand, and shells) that does not dissolve during the chemical extraction process employed in producing traditionally refined carrageenan. In producing traditionally refined carrageenan, the carrageenan extract is filtered to remove all insoluble seaweed residues.

content of carrageenan. In 1986, FCC and JECFA issued their revised standards.

PNG does not comply with the revised FCC or JECFA standards for carrageenan because its manufacturing process does not follow the process used to extract traditionally refined carrageenan, and PNG contains as much as 18 percent AIM (consisting mainly of fibrous cellulose).[12]

- FDA did not adopt either the FCC or JECFA revised standards for carrageenan because they would allow the use of seaweeds that were not approved by FDA.[13]
- In 1985, concerned that FDA would adopt FCC and JECFA specifications, representatives from the Embassy of the Philippines asked FDA's opinion on whether PNG complied with FDA's carrageenan regulations. Since FDA lacked data on PNG, agency officials advised the embassy to submit a food additive petition containing information on the identity and safety of the PNG.
- In July 1989, the Philippine embassy requested FDA to review a protocol prepared by the Seaweed Industry Association of the Philippines (SIAP) to study the effects of PNG fed to rats for 90 days.[14] According to FDA, however, the protocol was submitted because SIAP apparently believed that review of the protocol was the initial step to gain both JECFA and FDA clearance for the use of PNG.
- In September 1989, to determine whether toxicity testing was required for approval of PNG as a food additive, FDA requested the Philippine embassy to provide data on (1) the seaweeds from which PNG is obtained, (2) the process used to isolate or extract the carrageenan, (3) the procedures used to assure the purity and quality of PNG produced, and (4) the uses and specifications for PNG. FDA advised embassy representatives that the extent of the similarity between PNG and traditionally refined carrageenan would determine if a new food additive regulation would be needed for PNG.
- In January 1990, the Philippine embassy submitted the data FDA requested.

[12]FCC has formed an ad hoc group to review its monograph for carrageenan and plans to publish any needed revision in July 1995. JECFA has temporarily given PNG a separate monograph, under the name "processed Eucheuma seaweed," and an identification number that is distinct from carrageenan. JECFA plans to reconsider its classification of PES (PNG) at its next meeting in February 1995.

[13]The Food Chemicals Codex, second edition, third supplement (1978), list of red seaweeds was expanded to include additional red seaweeds as sources of carrageenan. FDA did not agree with the expansion because FCC standards allow the use of seaweeds for which a history of safe use as food has not been demonstrated and which are not approved in the United States. FDA has not adopted any Food Chemicals Codex edition published after 1975.

[14]SIAP is the trade association representing seaweed manufacturers in the Philippines. SIAP's members represent 95 percent of the worldwide production of PNG carrageenan.

- Based on its review of the information submitted, FDA determined that PNG was produced from approved seaweeds and that the product conformed with the description for carrageenan in FDA regulations. Because FDA determined that PNG should be classified as carrageenan and was not a new food additive, the Philippines believed it did not need to submit a food additive petition for FDA's approval.
- In July 1990, FDA informed SIAP and the Philippine embassy that PNG satisfied the requirements of FDA's carrageenan regulations and could be used in food.
- Traditional carrageenan manufacturers and trade associations representing the manufacturers questioned FDA's decision to classify PNG as carrageenan. One issue raised by traditional carrageenan manufacturers was that the production process used to produce PNG is not an aqueous extraction and therefore does not conform to FDA's regulations.
- The Joint Explanatory Statement of the Committee of Conference to H.R. 5268, appropriations for Rural Development, Agriculture and Related Agencies for Fiscal Year 1991, expected FDA to reexamine its July 1990 decision concerning PNG. In conducting a review of its decision, FDA requested all interested parties to submit any information relevant to the decision.
- In July 1991, based on FDA's review of information submitted in response to its request, FDA affirmed its previous decision. FDA determined that PNG was, as specified in the FDA regulations, "a refined hydrocolloid prepared by aqueous extraction" from FDA-approved red seaweeds. FDA's rationale for its classification is that (1) PNG meets the functional definition of a "hydrocolloid" in that the functions of PNG are the same as those of traditionally refined carrageenan, i.e., they are used in foods as thickeners, stabilizers, and gelling agents; (2) the process by which PNG is prepared (extracting the impurities and soluble material while retaining the carrageenan in the seaweed) constitutes one form of aqueous extraction;[15] and (3) PNG is "refined" because water and soluble materials are removed from the seaweed. FDA also determined that the only significant difference between PNG and traditional carrageenan is that PNG contains more cellulose (as much as 18 percent), compared to the traditional carrageenan product that is expected to contain less than 2-percent cellulose.
- At various times in 1991, in accordance with agency regulations that set out procedures for review of agency decisions, carrageenan trade associations again requested that FDA review its decision to classify PNG as carrageenan. In August 1992, FDA reaffirmed its decision.

[15]There is no standard definition of "aqueous extraction." We contacted scientists from the National Institute of Standards and Technology, the Association of Official Analytical Chemists, and the American Chemical Society. They agreed that the process used to produce PNG involves an aqueous extraction.

- Since FDA's decision, traditional carrageenan manufacturers have filed three petitions with FDA. The petitions request that FDA amend its regulations for carrageenan. Petitions range from requests to exclude PNG from use in human food to permitting PNG to be marketed as a food ingredient, but under a separate regulation and a different name that would clearly distinguish it from traditionally refined carrageenan. FDA is in the process of reviewing the various petitions and does not have an estimate on when it will complete its review and make its decision.

FDA Has Determined That PNG Is Safe for Use in Foods

FDA has acknowledged that there are differences in the extraction processes used to manufacture PNG and traditionally refined carrageenan but has concluded that these differences have no significance with respect to the safety of the final products. In July 1991, based on information submitted to FDA for its use in reexamining its classification of PNG as carrageenan, including the safety of PNG, FDA was not given any evidence that PNG contains contaminants from its manufacture or processing that would affect its suitability for food use.

In February 1993, however, FDA received study results as part of the comments on the petitions indicating that PNG may contain contaminants from its manufacture or processing that may affect its suitability for food. A study done by Dr. D.M.W. Anderson of the University of Edinburgh, United Kingdom, has raised concerns about the safety of PNG. SIAP disagrees with Dr. Anderson's study. SIAP's assays and an animal toxicity study of PNG, which were submitted to FDA, did not find any harmful substances in PNG or raise any toxicity concerns with the product. Based on the assays and animal study, JECFA, like FDA, has determined that PNG is safe for human consumption.

- Dr. Anderson tested six samples of PNG and found that two samples contained contaminants, including coliforms and faecal streptococci as well as large (up to 25 percent) quantities of unidentified impurities. The results of Dr. Anderson's study are part of the comments on the petitions that are before FDA to amend its carrageenan regulations. They will be considered in FDA's disposition of the petitions.
- SIAP speculates that the characteristics of the PNG that was tested could indicate that it was a grade of PNG that is used for pet food or that the PNG was contaminated during shipping and handling after it was manufactured.
- FDA's determination that PNG is safe is supported by the results of assays conducted by SIAP. SIAP conducted assays of 30 samples of PNG to obtain

JECFA clearance of PNG for use in foods. The assays showed that none of the samples contained harmful contaminants.

- Additionally, SIAP conducted a 90-day toxicity study involving the feeding of PNG to rats. The results of SIAP's study did not find evidence of toxicity.
- FDA is not alone in permitting the use of PNG as a food additive. Based on the assays and animal toxicity study, in February 1993 JECFA determined that PNG was safe for human consumption. JECFA allocated a temporary acceptable daily intake to PES. The acceptable daily intake was made temporary pending submission of the complete details from the 90-day toxicity study in rats. JECFA will consider allocating a permanent acceptable daily intake to PES after reviewing the requested data when JECFA reconvenes in 1995.
- Canada also is currently reviewing PNG's use as a food additive. Canada adopted the Food Chemicals Codex as part of its food additive regulations. Since PNG does not comply with the AIM requirement for carrageenan contained in FCC, PNG was not authorized for use in food. Subsequently, SIAP has petitioned the Canadian government to approve PNG as a food additive. Pending the completion of its review, the Canadian government agreed to allow manufacturers to use PNG until all stocks were exhausted. Although the agreement expired, the government is not rigorously enforcing its ban on the use of PNG in foods.

FDA's Plans to Detect Illegal Pesticide Use in PNG

Recently, FDA received allegations from the industry that a leading PNG manufacturer was distributing PNG that had been processed with an illegal pesticide that could cause the food additive to be adulterated. Specifically, in February 1994, a manufacturer of traditionally refined carrageenan provided test results indicating that PNG had been treated with an illegal pesticide, ethylene oxide (EtO). It was alleged that treatment by EtO resulted in a chemical residue, ethylene chlorohydrin (ECH), in PNG. Furthermore, the manufacturer's test results showed that certain hams were contaminated with ECH. The manufacturer stated that the hams were contaminated because they had been processed with PNG that had been treated with EtO.

The chemical ECH is formed when PNG is decontaminated using EtO gas. At certain exposure levels, ECH is toxic when it is ingested orally, inhaled, or comes in contact with skin. Although U.S. Environmental Protection Agency regulations permit using EtO in manufacturing some food products, the regulations do not permit using EtO to manufacture carrageenan. EPA has not established a tolerance level for ECH residue in carrageenan. FDA has evaluated the relevant toxicity tests on ECH and the analytical and

exposure data on the PNG that the traditional carrageenan manufacturer provided in February 1994. FDA has determined that the levels of ECH residues in PNG reported by the traditional carrageenan manufacturer do not represent a safety concern.

FDA Tests of Carrageenan

To determine if some PNG contains an illegal pesticide residue, FDA is collecting samples of imported carrageenan, both traditionally refined carrageenan and PNG, to test for ECH residues and other contaminants. Because it was alleged that PNG could also become contaminated with ECH through further processing after it is imported, FDA also will be collecting samples of carrageenan for analysis from domestic firms that process or repackage carrageenan or who may be importers or distributors of the product.

FDA will use the test results as a basis to determine what action to take. If FDA identifies that an imported food product contains an illegal pesticide residue, FDA will consider the product adulterated. FDA has the authority to detain and subsequently refuse entry of that shipment into the United States. In this case, for example, if FDA identifies an import shipment of carrageenan containing ECH, FDA has the authority to deny entry of that shipment.

USDA Tested Hams

Because the U.S. Department of Agriculture has responsibility for regulating the safety of meat and poultry products, and the allegations were against hams processed with PNG, USDA tested hams for the ECH residue. The allegations stated that processed hams had been manufactured using the ECH-contaminated PNG. USDA collected samples of processed hams from retailers in several states to test for ECH residue. However, USDA agreed with FDA that ECH in hams at the levels reported by the traditional carrageenan manufacturer is not a safety concern. In April 1994, USDA decided not to recall the hams containing ECH residues.

FDA Received Earlier Allegations

In June 1993, FDA received allegations from a carrageenan manufacturer that the same PNG manufacturer identified in the 1994 allegations was using an illegal pesticide to decontaminate PNG; the decontamination resulted in ECH residue. The allegations stated the manufacturer was using an illegal pesticide, EtO, but did not indicate that use of EtO caused public health concerns.

According to FDA officials, FDA receives many "trade complaints," i.e., complaints from one manufacturer alleging that another manufacturer has not complied with FDA regulations. FDA's standard procedure in handling trade complaints that do not involve immediate public health implications is to refer the case to the relevant district office for follow-up. In this case, FDA did not have any reason to believe the trade complaint had public health implications. Due to reorganization and office moves within FDA, these allegations were inadvertently not referred to a district office.

In August 1993, the PNG manufacturer accused of using EtO submitted a written statement to FDA stating that it had used EtO to process PNG. The manufacturer agreed to stop using EtO to manufacture PNG sold in the United States. Under standard FDA procedures for handling illegal actions, FDA would issue a warning letter to the company in violation. If the company acknowledged that it would cease the violative actions, then FDA would allow time for the company to comply with the regulations and would follow up to ensure that the company was no longer in violation. In this case, FDA did not issue a warning letter.

As previously discussed, in February 1994 FDA received further allegations that this manufacturer had continued to use EtO to decontaminate PNG. At this time, FDA sent a letter to the manufacturer stating that EtO is not approved in the United States for manufacturing carrageenan and acknowledging the manufacturer's claim to cease U.S. distribution of PNG processed with EtO. FDA, in conjunction with the PNG importer, is taking steps to ensure that the adulterated PNG is removed from the U.S. market.

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