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Report to Rep. Toby Moffett; by Paul G. Dembling, Acting Comptroller General.

Issue Area: Food (1700); Consumer and Worker Protection: Safety of Food Additives (905).
Contact: Human Resources Div.
Budget Function: Health: Prevention and Control of Health Problems (553).
Organization Concerned: Food and Drug Administration.
Congressional Relevance: Rep. Toby Moffett.
Authority: Food, Drug, and Cosmetic Act, as amended; Food Additives Amendment of 1958 (21 U.S.C. 348). 21 C.F.R. 170.3(e). 21 C.F.R. 170.22.

Acrylonitrile is a volatile, clear liquid, which can be formed into more complex compounds known as polymers that are used to make various plastic articles. Beverage bottles made of acrylonitrile copolymers are lightweight, do not cause injury if broken, and are, therefore, desirable to consumers. A characteristic of such bottles, however, is that after polymerization, a small amount of "residual" acrylonitrile that has not combined with other monomers remains in the plastic and may become part of the substance in the bottle. Some acrylonitrile copolymers also depolymerize to some extent, allowing additional acrylonitrile to migrate to the food. Findings/Conclusions: In January 1977, Food and Drug Administration (FDA) officials decided that the use of acrylonitrile in making plastic bottles for carbonated beverages and beer should be banned and that all other acrylonitrile uses should be restricted to a maximum permissible migration level of 0.05 ppm. On March 7, 1977, Monsanto Company filed a motion in the U.S. court of appeals requesting a review of FDA's suspension of its regulation authorizing the use of acrylonitrile in bottles intended to hold soft drinks. In its motion, Monsanto Company maintained that FDA had not followed the procedures required by section 409 of the Federal Food, Drug, and Cosmetic Act in suspending the regulation. The primary issue of this motion was whether FDA could remove a previously lawful product from the market without notice and opportunity for affected parties to contest the action. The court ordered that FDA's suspension of the regulation be lifted until May 18, 1977, and that FDA hold the required public hearing promptly. The outcome was that acrylonitrile copolymers used to fabricate beverage containers were judged to be food additives and were not safe for use in food. FDA terminated all regulations that permit acrylonitrile in beverage containers. (SW)

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REPORT OF THE COMPTROLLER GENERAL OF THE UNITED STATES

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Food Additive, Acrylonitrile, Banned In Beverage Containers

Acrylonitrile has been used for about 30 years to make various plastic food containers. Recent studies show that, when used in beverage containers, this substance migrates to the packaged beverage, contaminating it.

Based on these studies and on the results of a public hearing concerning these issues, on September 23, 1977, the Food and Drug Administration published a final order terminating all regulations that permit acrylonitrile in beverage containers.

HRD-78-9

NOVEMBER 2, 1977

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

The Honorable Toby Moffett
House of Representatives

Dear Mr. Moffett:

In your letter of March 15, 1977, you requested our observations on the Food and Drug Administration's (FDA's) March 11, 1977, decision to stay its food additive regulations that had permitted acrylonitrile to be used in making beverage containers. You indicated that FDA's only scientific data on which to base such a decision was the preliminary report of a 2-year study which was only half completed.

We interviewed FDA officials; reviewed legislation, regulations, and practices relating to FDA's regulation of food additives; examined FDA's records relating to the regulatory status of acrylonitrile; and reviewed testimony presented at a public hearing on acrylonitrile used to make beverage containers.

As agreed with your office, we are sending copies of this report to the Secretary of Health, Education, and Welfare and the FDA Commissioner. Unless you publicly announce its contents earlier, we will not distribute this report further until 7 days from the date of the report.

REGULATION OF FOOD ADDITIVES

The Federal Food, Drug, and Cosmetic Act, as amended by the Food Additives Amendment of 1958, requires FDA to establish regulations prescribing the conditions under which a food additive may be safely used (21 U.S.C. 348). The act defines "food additive" as any substance that becomes or may reasonably be expected to become a component of food, either directly or indirectly, or which may otherwise affect the characteristics of the food. The effective date of a regulation may be stayed if a hearing is sought by any person adversely affected by such a regulation.

Substances used in accordance with approvals given by the Department of Agriculture and FDA before the enactment of the 1958 Food Additives Amendment are not subject to such regulations. These approvals, generally known as prior-sanctioned approvals, were based on safety requirements less formal and restrictive than those provided by the 1958 amendment.

FDA's food additive regulations (21 C.F.R. 170.3(e)) state that a material used to produce containers and packages is considered a food additive if it may reasonably be expected to become a component, or to directly or indirectly affect the characteristics of food packed in the container. Packaging material that migrates to the food is an indirect food additive.

The Food Additives Amendment of 1958 and FDA regulations require that a petitioner requesting the approval of an indirect food additive demonstrate the safety of the additive with appropriate data showing the amount of the substance that is expected to migrate to food and the results of toxicological studies. The amendment also requires FDA to consider the probable consumption of the additive when determining the safety of the proposed use of a food additive.

According to an FDA Division of Toxicology official, the number and type of toxicological tests the agency requires for a safety evaluation of an indirect additive depend on the amount of the chemical that is expected to migrate to the food. He said that FDA requires only acute toxicity data to insure that a substance is not a highly toxic chemical when anticipated migration is "virtually nil" (generally less than 0.05 parts per million (ppm)), provided that the substance is not a heavy metal or a pesticide and there is no reason to suspect carcinogenicity or teratogenicity. More extensive toxicological test data is required when migration of a substance is anticipated to be "negligible" (more than 0.05 ppm but less than about 1.0 ppm).

WHAT IS ACRYLONITRILE?

Acrylonitrile is a volatile, clear liquid. Because of its relatively low molecular weight, it is classified as a monomer, which, when joined with certain other monomers through a process known as polymerization, can form more complex compounds known as polymers that are used to make various plastic articles.

Acrylonitrile copolymers, a class of polymers, have been used for about 30 years in various food containers, such as margarine tubs, vegetable oil bottles, and pipes for handling food products. Copolymers with high concentrations of acrylonitrile have excellent barrier (pressure-holding) characteristics. Since such copolymers have low permeability to gases, they are suitable for carbonated beverage bottles that must retain gas for extended periods.

Beverage bottles made of acrylonitrile copolymers are lightweight, do not cause injury if broken, and are therefore desirable to consumers. A characteristic of such bottles, however, is that after polymerization, a small amount of "residual" acrylonitrile that has not combined with other monomers remains in the plastic and may become part of the substance in the bottle. Some acrylonitrile copolymers also depolymerize to some extent, allowing additional acrylonitrile to migrate to the food.

BASIS FOR INITIAL SAFETY DETERMINATION

FDA's initial prior-sanctioned approvals of acrylonitrile's use in food-contact articles were based on analytical data indicating that there was no significant migration of acrylonitrile to food under the conditions of its intended use. These approvals included uses for oleomargarine wraps and equipment and containers used in food processing.

Pursuant to the 1958 Food Additives Amendment the approval process for food additives requires the submission of a petition proposing the issuance of a regulation that would prescribe the conditions under which an additive may be safely used. Since 1958 FDA has issued 20 food additive regulations approving various additional acrylonitrile uses in food-contact articles. These approvals were based on data submitted with petitions which showed no significant migration of acrylonitrile to the packaged food. The first regulation allowing the use of acrylonitrile in plastic beverage bottles was issued to Vistron Corporation on June 11, 1970.

SAFETY LATER QUESTIONED

Extraction studies submitted by the E. I. duPont de Nemours Company with its June 14, 1973, petition to FDA requesting approval for use of its acrylonitrile bottle to package soft drinks showed that acrylonitrile migrated from bottles to food when stored at elevated temperatures for

extended periods. Extraction studies can measure, through analytical methods, the amount of a substance that has migrated to a food. Based on the new evidence and the fact that improved procedures for detecting and measuring acrylonitrile had been developed, FDA began a complete review of all safety data available on this substance.

FDA found that available toxicity data on acrylonitrile consisted primarily of two series of long-term feeding studies. One series, entitled "The Pharmacology and Toxicity of Acrylonitrile and Acrylon" (by P. E. Tullar, George Washington University, Nov. 1, 194), does not, according to FDA, meet current standards for the toxicological testing of substances such as food additives. An FDA Division of Toxicology official said that, at best, a tentative "no-adverse-effect" level for acrylonitrile could be established from this study at 38 ppm.

The other series of studies available at that time was made by Svirbely and Floyd of the U.S. Public Health Service at the Taft Sanitary Engineering Center in Cincinnati in the late 1950s. The series consisted of 2-year feeding studies in rats and dogs and a 3-generation rat reproduction study. A final report on this series was never prepared, and according to FDA, the available data provided only limited information that was inadequate to establish a no-adverse-effect level for acrylonitrile.

Based on the results of its review, FDA concluded that the safety of acrylonitrile was questionable, that the level of acceptable migration should be limited, and that additional information and studies were needed on (1) analytical methods concerning migration and (2) toxicity.

FDA regulations (21 C.F.R. 180.1) state that substances with a history of use in food for human consumption or in food-contact surfaces may at any time have their safety or functionality brought into question by new information that in itself is inconclusive. An interim food additive regulation for the use of any such substance may be issued

> "* * * when new information raises a substantial question about the safety or functionality of the substance but there is a reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time

> while the question raised is being resolved by further study."

On November 4, 1974, FDA published in the Federal Register a proposed interim food additive regulation for acrylonitrile intended for use in food-contact articles. This regulation proposed, for an interim period, a limit of 0.3 ppm as the maximum amount of acrylonitrile allowed to migrate to food and required that toxicological studies be conducted to determine the safety of low levels of acrylonitrile ingestion.

The 0.3-ppm migration limitation was established by applying a 100 to 1 safety factor to a tentative no-adverse-effect level of 38 ppm, which was based on the 1947 P. E. Tullar study. FDA regulations (21 C.F.R. 170.22) provide that

> "* * * a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals."

On June 19, 1975, the Manufacturing Chemists Association submitted, for FDA review, protocols for a series of studies designed to provide the toxicity data called for by the proposed interim regulation. On July 18, 1975, FDA informed the association that the protocols, with some technical modifications, were acceptable. The association contracted with the Dow Chemical Company to make the studies. The studies were sponsored by the following manufacturers or major users of acrylonitrile: American Cyanamid Company, Borg-Warner Chemicals, Dow Chemical Company, E. I. duPont de Nemours and Company, Monsanto Company, Standard Oil Company (Ohio), Tennessee Eastman Company, and Uniroyal, Incorporated.

After publishing its proposed interim regulation on acrylonitrile, FDA issued regulations permitting duPont, Borg-Warner, Monsanto, and Dow to use acrylonitrile to make plastic bottles.

ISSUANCE OF FINAL INTERIM REGULATION

On June 14, 1976, FDA issued in final form the interim food additive regulation on the use of acrylonitrile in food-contact articles. The regulation established the maximum permissible level of acrylonitrile migration at 0.3 ppm

pending the results of the ongoing toxicity studies. Thirty days were allowed for comments on and objections to the regulation.

Four manufacturers and one industry association submitted comments to FDA on the interim regulation. These comments included questions about

--the appropriateness of a 120 degree Fahrenheit temperature requirement for migration studies,

--the technical inconsistency of the volume-to-surface ratio requirements for migration measurement,

--the possibility of extending the 30-day comment period to allow time to obtain FDA's migration test methodology and evaluate the regulation's impact on the product being manufactured, and

--the lack of prior knowledge about the existence of the proposed regulation.

Only the Natural Resources Defense Council filed an objection questioning the safety of acrylonitrile in food-contact applications. It cited several reasons for questioning the safety of acrylonitrile.

--The 1947 P. E. Tullar study, which concluded that acrylonitrile causes cancer.

--The fact that acrylonitrile, also known as vinyl cyanide, is chemically related to vinyl chloride, a known carcinogen.

--An epidemiology study of Japanese acrylonitrile workers which found a correlation between exposure to the substance and impairment of liver function.

Based on the lack of sufficient data supporting the safety of acrylonitrile, the council on July 13, 1976, requested that a stay be granted of any food additive regulation under which acrylonitrile might reasonably be expected to migrate to a food product. The council requested that the stay remain in effect pending a hearing and a decision on its objection.

STUDY RESULTS

Studies done in response to the need for additional information on acrylonitrile include toxicity studies identified in the interim food additive regulation and migration studies designed to measure very small amounts of the substance in food.

Toxicity studies

On December 9, 1975, the Manufacturing Chemists Association submitted to FDA results of two toxicity studies by Dow Chemical. In the first study, rats were fed acrylonitrile at levels of 0, 35, 85, 210, and 500 ppm in their drinking water for 90 days.

The study report stated that:

> "Results of this study indicate that male and female rats may ingest water containing at least 85 ppm of acrylonitrile for a period of 90 days without a deleterious effect on any of the parameters evaluated."

The report noted that decreased body weight gains were observed in male rats in the top dose level and in female rats in the two top dose levels. It further reported that small but significant increases in liver to body weight ratios were observed in male and female rats on water containing 500 and 210 ppm acrylonitrile.

During the second study, purebred beagle dogs were fed acrylonitrile at levels of 0, 100, 200, and 300 ppm (eight dogs per level) in their drinking water for 6 months.

The study report concluded that:

> "Ingestion of AN [acrylonitrile] in the drinking water by male and female dogs at 200 and 300 ppm for a period of 6 months was associated with toxicological manifestations primarily and secondarily related to AN.
>
> "Ingestion of AN in the drinking water at 100 ppm for 6 months resulted in no toxicological manifestations in male or female dogs."

The FDA toxicologist who evaluated the study, however, stated in a February 1977 memorandum to the Director of FDA's Division of Food and Color Additives that:

> "With the normal criteria of toxicity data evaluations, the no-effect level appears to be lower than 100 ppm (8-10 mg/kgm [milligrams per kilogram]). The effect at this level was a slight lag in growth, and microscopic changes in the esophagus, with increased thickening of the epithelium of the tongue."

He said that at the two higher dose levels, effects such as growth lags, increased mortality, and reduced liver function were noted.

On April 19, 1976 the Manufacturing Chemists Association submitted to FDA the results of a study conducted by Younger Laboratories on the joint toxic action between acrylonitrile and potassium cyanide. This study in which male and female rats were orally given mixtures of acrylonitrile and potassium cyanide showed no evidence of synergistic effect on acute toxicity.

On October 13, 1976, the association submitted results from mutagenicity studies made in three different laboratories. Only one laboratory reported evidence of mutagenic effects from one of several tests that it conducted.

In November 1976 the association submitted to FDA a report entitled "Teratologic Evaluation of Acrylonitrile Monomer Given to Rats by Gavage." The study, conducted by Dow Chemical, was designed to evaluate the effects of acrylonitrile on embryonal and fetal development. In the study pregnant rats were given, on days 6 through 15 of gestation, either 0, 10, 25, or 65 mg of acrylonitrile per kilogram of body weight by gavage (oral administration of a substance directly to the stomach through a feeding tube). At the 65-mg feeding level, effects such as maternal toxicity, increased numbers of fetal malformations, decreased fetal weight, and minor skeletal variants occurred. At the 25-mg feeding level, maternal toxicity and malformations also occurred, but with less frequency. The report stated that at the 10-mg (approximately 100-ppm) feeding level, there was no evidence of toxicity to either the mother or her developing embryo or fetus.

On January 14, 1977, the association submitted to FDA a 13-month interim report on a 2-year rat feeding study being made by Dow Chemical. The study, scheduled for completion about November 1977, involves feeding rats acrylonitrile in their drinking water at concentrations of 0, 35, 100, and 300 ppm. With respect to feedings at the 100- and 300-ppm levels, the interim report stated that:

> "It is concluded that administration of AN under the condition of this study has significantly lowered body weight, produced pathologic changes in the gastric epithelium, increased the incidence of masses of the ear duct and produced proliferative lesions in the central nervous system of rats. The significance of the higher incidence of subcutaneous masses in the mammary region of the rats is less clear, and its resolution will have to await further progress in the study."

On April 11, 1977, the Manufacturing Chemists Association provided FDA with updated information on the interim findings of Dow's 2-year rat feeding study. According to the association, the study investigator had found tumors of the central nervous system in two rats on the 35-ppm feeding level of the same type found earlier in rats on the 100- and 300-ppm feeding levels.

The association also notified FDA that another 2-year study in which rats were being exposed to 0, 20, or 80 ppm acrylonitrile by inhalation showed the following interim results.

--Three rats in the highest dose group (80 ppm) developed tumors of the central nervous system comparable to those reported in the 2-year ingestion study.

--An increased incidence of ear canal tumors and mammary region masses was detected at the 80-ppm level.

--An apparent increase in the subcutaneous masses of the mammary region was detected in the rats in the 20-ppm group.

--No ear canal or central nervous system tumors were found in the 20-ppm group.

According to an FDA Division of Toxicology official, although an inhalation study is not directly relevant to ingestion toxicity, the findings of tumors similar to those in the feeding study and tumors other than of the lung or respiratory tract indicate the systemic nature of the apparent carcinogenic effect of acrylonitrile after absorption.

By letter dated May 23, 1977, the E. I. duPont Company provided FDA with preliminary results of an ongoing epidemiology study of workers exposed to acrylonitrile in a textile fibers plant. The preliminary findings revealed a possible relationship between exposure of in-plant workers to acrylonitrile and cancer. A higher-than-expected incidence of various types of cancer was found among the 470 males surveyed. These men began working in the polymerization area of the plant between 1950 and 1955 and are either still actively employed by or retired from the company. Medical data analyzed through December 31, 1975, showed that 16 cancer cases among this group were found, compared with an expected company rate of 5.8 and a national rate of 6.9. The cases include six lung cancers (1.5 expected) and three colon cancers (0.5 expected). All cases of cancer occurred in the group having initial exposure during startup of the plant in 1950 through 1952.

Migration/extraction studies

In 1975 FDA began to develop methodologies for measuring acrylonitrile migration. The team leader responsible for FDA's efforts stated in written testimony for a public hearing (see pp. 16 and 17) that FDA had developed and confirmed an extraction test method capable of measuring acrylonitrile at levels of 0.04 ppm. He said that FDA's method is based on one submitted by duPont which uses gas liquid chromatography.

The team leader said that two migration studies on acrylonitrile bottles have been made with FDA's method. On August 6, 1976, FDA began a migration study using two test groups of acrylonitrile bottles--four 32-ounce bottles from Monsanto and four 16-ounce bottles from Borg-Warner--which, according to FDA's analysis, contained 9 to 10 ppm and 25 ppm residual acrylonitrile, respectively.

Two of the bottles from each company were filled with the food simulant 3 percent acetic acid and two with food simulant 8 percent ethanol, and each was heated to 120 degrees Fahrenheit. Food simulants are often used in place of food

products during migration tests in order to simplify detection and measurement by eliminating many of the unknown substances that might be present in food. Acetic acid is generally accepted as a substitute for carbonated beverages and ethanol as a substitute for alcoholic beverages.

Test samples were withdrawn from the bottles over a period of about 5 months. The following table presents the average concentrations of acrylonitrile found on January 12, 1977, in samples drawn from the bottles during the test period.

Solvent	Acrylonitrile found	
	Monsanto bottles	Borg-Warner bottles
3 percent acetic acid	0.062 ppm	0.112 ppm
8 percent ethanol	.078 ppm	.126 ppm

An FDA project manager involved in regulating acrylonitrile told us that the Borg-Warner bottles used in this test were early prototype bottles, not those made from copolymers that complied with the final Borg-Warner regulation.

According to the team leader, the second FDA study used empty and filled Monsanto bottles obtained from the Coca Cola Bottling Company of New York on August 9, 1976. In one portion of the study, two empty bottles, whose walls were found to contain approximately 7 to 8 ppm of residual acrylonitrile, were filled on February 14, 1977, with 3 percent acetic acid and stored at 120 degrees Fahrenheit. After various periods of time, samples of the acid were withdrawn and tested. The average amount of acrylonitrile found in the acid samples is indicated below.

Date	Elapsed time	Average amount of acrylonitrile (estimated) (note a)
2/24/77	10 days	0.005 ppm
3/ 1/77	14 days	.005 ppm
3/15/77	28 days	.005 ppm
4/12/77	56 days	.018 ppm
5/10/77	84 days	.022 ppm

a/These values are estimated because the gas liquid chromotography method is not capable of accurately quantifying concentrations of acrylonitrile less than 0.04 ppm.

In another phase of the study, four of the bottles filled with Coca Cola were maintained at room temperature from the time of collection until January 1977. FDA extraction studies showed concentrations of acrylonitrile in the Coca Cola ranging from 0.013 to 0.029 ppm.

The FDA laboratory confirmed these findings with mass spectrometric and polarographic techniques. Both techniques confirmed the levels of acrylonitrile found in the Coca Cola using the gas liquid chromotography method. The laboratory team leader believed that FDA's studies unequivocally establish that acrylonitrile beverage containers can reasonably be expected to become, and in fact do become, a component of the beverage packaged in them.

DECISION TO BAN USE OF ACRYLONITRILE

An FDA project manager involved in regulating acrylonitrile told us that, on the basis of the positive findings of the teratogenic study (see p. 8), FDA officials decided in November 1976 to revise the interim regulation for acrylonitrile regarding its use in making plastic bottles for carbonated beverages and beer by reducing its permissible migration level from 0.3 ppm to 0.05 ppm. This level approximated the lowest attainable level of measurable detection. A draft revision to the interim regulation dated November 1976 was prepared.

After receiving the interim report on Dow's 2-year chronic-feeding study in January 1977, FDA officials decided that the use of acrylonitrile in making plastic bottles for carbonated beverages and beer should be banned and that all other acrylonitrile uses should be restricted to a maximum permissible migration level of 0.05 ppm. According to FDA's Office of General Counsel, this decision was based not only on the findings of the teratology and chronic-feeding studies but also in combination with (1) data developed by FDA extraction studies indicating that migration of acrylonitrile occurs in beverage containers containing the substance, (2) indications that the containers being manufactured might not meet the proposed 0.05-ppm limit on acrylonitrile migration, and (3) the possibility of much greater consumer exposure to acrylonitrile from carbonated beverage containers than from other food-contact uses.

On February 15, 1977, FDA published its environmental impact statement in the Federal Register which included an

announcement of the agency's intentions to (1) suspend the use of acrylonitrile in making plastic bottles for carbonated beverages and beer and (2) reduce the allowable amount of acrylonitrile migration from 0.3 ppm to 0.05 ppm for all other food-contact articles.

At that time the Coca Cola Company was test marketing its product packaged in acrylonitrile bottles manufactured by Monsanto Company. On February 14 and 16 and March 3, 1977, Monsanto met with FDA officials and presented data in an attempt to convince FDA to withdraw its intended ban on the use of such bottles. Monsanto's primary points were that (1) the migration test procedures which require storing the bottles at 120 degrees Fahrenheit until no further migration occurs were unreasonable since sealed soft drink bottles deform at that temperature and the contents are ruined, (2) in lieu of a ban, a standard should be set allowing no acrylonitrile migration to soft drinks when the bottles are stored for 30 days at 120 degrees Fahrenheit (equivalent to 2 years of storage at room temperature) and tested with a proposed test method sensitive to 0.01 ppm, and (3) the safety data submitted to date plus the metabolic studies in progress would enable FDA to limit acrylonitrile consumption by setting a migration standard for acrylonitrile bottles.

After evaluating Monsanto's data, FDA officials still believed that the safety of acrylonitrile was sufficiently questionable to warrant banning its use in plastic bottles for carbonated beverages and beer. FDA advised Monsanto that (1) migration testing at 120 degrees represents only a slight exaggeration of possible storage and transportation temperatures and would cover all eventualities in the storage and shipments of the final product, (2) it could not guarantee that 120 degrees for 30 days represents the point at which all potential migration of acrylonitrile has occurred, nor could it determine, with available data, that consuming large volumes of a beverage containing up to 0.01 ppm acrylonitrile was safe, and (3) it could not set a no-effect level for acrylonitrile from the available data and the metabolic studies need to be completed before conclusions on such a level could be drawn.

On March 11, 1977, FDA published two notices in the Federal Register. One notice proposed several amendments to the interim food additive regulation for acrylonitrile, including (1) the reduction of the maximum permissible amount of the substance allowed to migrate from packaging

material other than beverage containers from 0.3 ppm to 0.05 ppm, (2) the deletion of duplicative requirements for submission of migration data on repeated-use articles, (3) a requirement for higher test temperatures, if needed, to simulate actual use conditions, and (4) a requirement for additional teratogenic tests in a species other than rats.

The other notice suspended the food additive regulations that permitted acrylonitrile to be used to make beverage containers. The notice stated that the regulations were being suspended pending full review of the objections and request for hearing filed by the National Resources Defense Council on July 13, 1976. (See p. 6.) The notice also said the Commissioner anticipated that, when the Dow Chemical chronic-feeding study was completed or possibly sooner, it would be appropriate to convene an evidentiary hearing to resolve the factual issues raised in the Council's objections.

FDA'S ACTION STAYED

On March 7, 1977, Monsanto Company filed a motion in the U.S. court of appeals requesting a review of FDA's suspension of its regulation authorizing the use of acrylonitrile in bottles intended to hold soft drinks. On March 11, the court sustained Monsanto's motion pending its review of the merits and ordered that oral arguments be presented on March 16. The court granted the Natural Resources Defense Council permission to present oral arguments.

In its motion Monsanto maintained that FDA had not followed the procedures required by section 409 of the Federal Food, Drug, and Cosmetic Act in suspending the regulation. Monsanto said that the regulation issued to it permitting the use of acrylonitrile in beverage bottles could not be suspended without prior notice and a hearing. According to Monsanto the primary issue was whether FDA could remove a previously lawful product from the market without notice and opportunity for affected parties to contest the reasonableness, necessity, or legality of the action.

In an affidavit submitted with its motion to review FDA's suspension of the regulation, Monsanto's group vice-president stated that the most sensitive validated test methods available showed that no migration occurred in Monsanto bottles under the intended conditions of use. He said that if Monsanto's motion were not granted, the company would suffer irreparable harm in at least the following ways.

--It would be unable to sell existing inventories of about 15 million bottles valued at more than $2 million.

--It would be unable to resume operations at some plants and facilities, and hundreds of jobs would be permanently lost.

--A large part of its capital investment in the facilities producing the bottles, exceeding $60 million, would be lost.

--It would lose potential sales of more than $30 million in 1977 and projected sales of more than $100 million annually by 1980.

FDA argued that it had followed the administrative procedures outlined in section 409 of the act, which was its basis for the suspension. FDA said that its authority to suspend the regulation was derived from that regulation's dependence on the results of ongoing efforts to establish safe conditions for use of acrylonitrile, as outlined in its interim regulation. FDA also argued that (1) Monsanto was given the opportunity, through FDA's advance notice of its intentions in the environmental impact statement, to present data and arguments to the agency before the suspension was issued and (2) more importantly, Monsanto would have further opportunity at an evidentiary hearing to challenge FDA's judgment about the lack of safety of acrylonitrile in beverage bottles. FDA said that Monsanto's argument that a hearing should precede rather than follow the suspension is more appropriately directed at the Congress because section 409(e) provides that food additive regulations are effective at the time of publication in the Federal Register but may thereafter be stayed if objections are filed and a hearing is sought. FDA noted that the Congress has not provided for delaying regulations or for an automatic suspension upon receipt of objections.

FDA said that, although it did not dispute Monsanto's assertion that the administrative suspension would result in loss of sales for Monsanto and "economic dislocation" of those workers laid off, it did not believe these injuries amounted to "irreparable injury." FDA said that Monsanto's claim was mitigated by the fact that it had been on notice since February 1975, when the regulation for its product was issued, and in fact since November 1974, when the proposed

interim regulation for acrylonitrile notified all interested parties that the safety of the substance was an open question and that its use could be affected at any time by FDA action. According to FDA, the very real questions about the safety of the bottle could not allow Monsanto to assert its economic losses as a basis for continuing to expose the public to a potential health hazard.

The court determined that for FDA to order a suspension of regulations based on objections filed 8 months earlier by the National Resources Defense Council constituted "arbitrary and capricious administrative action" and that the requirement of section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act that a hearing be held "as promptly as possible," compelled FDA to process objections more expeditiously than it had in this case.

On March 18, 1977, the court ordered that FDA's suspension of the regulation issued for Monsanto's product be lifted until May 18 and that FDA hold the required public hearing promptly and issue final findings and conclusions by that date. On April 11, 1977, all parties involved in the case requested a 120-day extension, which the court granted, thus setting a new date of September 19 for issuance of final findings and conclusions.

The hearing process required by the court has been completed. Five parties participated: FDA, Monsanto Company, Borg-Warner Corporation, Vistron Corporation, and the Natural Resources Defense Council. The major issues addressed during the hearing, which was conducted by an administrative law judge, were (1) whether or not acrylonitrile is a food additive as defined by law and (2) whether or not the safety of acrylonitrile used to fabricate beverage containers has been shown.

Cross-examination of witnesses took place from June 20 through 27, 1977, and briefs were submitted to the administrative law judge for a decision. On August 4 the judge rendered an initial decision that acrylonitrile does migrate to food, thus making it subject to regulation under the act, and that it has not been shown to be safe for use in food.

The FDA Commissioner reviewed the initial decision along with exceptions filed by the manufacturers. The Commissioner's final decision, effective September 19, 1977,

affirmed the initial decision of the administrative law judge by finding "* * * that acrylonitrile copolymers used to fabricate beverage containers are food additives and that they have not been shown to be safe." The Commissioner's decision concluded the hearing process required by the court of appeals, and an official of FDA's Office of General Counsel said that a copy of the decision was filed with the court on September 20.

On September 23 FDA published in the Federal Register, to be effective 90 days from that date, a final order terminating all regulations which permit the use of acrylonitrile in making beverage containers.

An official of FDA's Office of General Counsel said that interested parties can now file objections to the decision with the court, which could review the basis for FDA's decision. He added that 6 months or more may be required to complete a court of appeals review of the decision. At that time the parties would be required to accept the court's decision or appeal the case to the U.S. Supreme Court.

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As requested by your office, we have not obtained the Department of Health, Education, and Welfare's written comments on the matters in this report. However, we have discussed these matters with FDA officials and have considered their comments.

Sincerely yours,

Paul G. Dembling

ACTING Comptroller General
of the United States