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VCM

VCM-PVC MANAGEMENT SUMMARY

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SPECIAL "UPDATE" BULLETIN

FDA MAY BE RETHINKING CURRENT POLICY

ON MIGRATION FROM FOOD PACKAGING MATERIALS

Several important developments have occurred in recent months which indicate that the Food and Drug Administration (FDA) may take a less rigid position in future rulings in resolving the current controversy over migration of residual vinyl chloride monomer (RVCM) from food packaging.

Some developments were directly concerned with vinyl chloride. Others, which related to several different materials, could set a pattern for the settlement of the RVCM issue.

As more and more data become available regarding the minimal risk of vinyl chloride migrating from food packaging, it is entirely possible the FDA will reverse its previously expressed position and decide that migration from all presently used polyvinyl chloride is trivial and not worthy of regulatory attention.

This special "Update" bulletin explains how this issue arose and summarizes a number of major developments in an attempt to put this complex issue into perspective.

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Background On The Issue

The migration issue first came to light in 1973, prior to the discovery of a link between VCM exposure and angiosarcoma, when a manufacturer of distilled alcoholic beverages reported to the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) the presence of vinyl chloride in vodka and gin packed in experimental PVC bottles. The BATF banned the further use of experimental PVC bottles with alcoholic beverages. At the same time, the FDA published a proposed regulation which would ban the use of polyvinyl chloride from all alcoholic foods but would reaffirm the "prior sanctions" for all other uses. In addition, the FDA began to study the question of vinyl chloride migration from food packaging.

In July 1975 the Health Research Group, a Ralph Nader affiliate, petitioned FDA to ban completely all PVC food packaging materials. That September, the FDA responded by: (1) withdrawing its "prior sanctions" for all rigid and semi-rigid PVC products; (2) proposing a ban on the use of rigid and semi-rigid PVC products, including bottles, blister packs, boxes and pipe, except for water pipe; (3) permitting the continued use of water pipe under an interim food additive regulation until further proof of "no migration" is obtained. The FDA further stated that it had reason to believe there was no migration from plasticized PVC film, can and cap liners, coatings, gaskets or flexible tubing and, therefore, proposed to affirm the prior sanctions for their continued use.

In December 1975, The Society of the Plastics Industry (SPI) submitted its comments on the proposed FDA regulation stating that the manufacturing processes for PVC had been dramatically improved and that there was no risk to the public from the use of PVC food packaging materials. In its submission, SPI pointed out that in using the FDA test method it found that all new PVC packages contained essentially no detectable vinyl chloride monomer. SPI also urged the FDA to adopt a substitute ruling which requires that rigorous test methods be used to assure no reasonable expectation of VCM migration.

Residual VCM Greatly Reduced

In April 1977, at the request of the FDA's Bureau of Foods, SPI submitted data showing that the polyvinyl chloride industry had reduced the residual vinyl chloride monomer in rigid and semi-rigid products from levels of approximately 500 parts per million (500ppm) to levels well below five one hundredths parts per million (.05ppm). The SPI also provided a rationale explaining why no vinyl chloride can reasonably be expected to migrate from such rigid and semi-rigid PVC food-contact products.

Also in April 1977, the SPI petitioned the FDA to amend the regulatory definition of "food additive." The SPI petition proposed that any substance which poses no special toxicological problems and which cannot be detected migrating to food with an analytical procedure sensitive to 50 parts per billion (50ppb) would, by definition, not be considered to be a food additive.

Acrylonitrile Enters The Arena

In February 1977, FDA moved to ban beverage containers made from acrylonitrile (AN). At that time, FDA staff members indicated the Agency would not finalize its ruling on PVC migration until the AN cases had been decided.

In August 1977, an FDA Administrative Law Judge ruled against the use of acrylonitrile (AN) to fabricate beverage containers. That fall, in a letter to the Ethyl Corporation, FDA Commissioner Donald Kennedy said the final rule on the use of polyvinyl chloride food packaging materials "will necessarily reflect many of the judgments and conclusions of the law reached in the related final decision on the status of acrylonitrile." Once again, the FDA indicated that the vinyl chloride decision was to be tied to the fate of acrylonitrile.

On September 17 the FDA issued a final order banning the use of AN for beverage bottles. One month later, as the first step in appealing the FDA's acrylonitrile (AN) beverage container decision, SPI filed a "Petition for Review" in the United States Court of Appeals in Washington. Similar petitions were submitted by several companies and other companies indicated they would file amicus curiae briefs. In response to further petitions by SPI and companies, the time to file "Petitioners Briefs" has been extended to June 20, 1978.

Recent Developments

A development in January 1978 revealed that the FDA may be taking a less conservative position on risk assessment in the future than it had in the past. In releasing a report on the assessment of the risk of liver cancer from aflatoxin contamination of corn and peanut products, the FDA showed it had drastically departed from the methodology the industry used for vinyl chloride (VC) and acrylonitrile (AN) risk assessments. In the case of VC and AN the risk extrapolation was handled very conservatively using the Mantel-Bryan "worst case" interpretation in a manner to yield a 99 percent confidence factor for the result. No such conservative treatment of the toxicological data was applied for aflatoxin before performing the Mantel-Bryan statistical extrapolation.

Also in January 1978, in a letter to FDA Commissioner Donald Kennedy, Tenneco Chemical Company urged that a further final comment period be offered prior to the adoption of the final order on vinyl chloride polymers in contact with food. Tenneco pointed out that in 1975, when the order was proposed, the company had submitted data from laboratory analyses. This data showed rigid and semi-rigid Tenneco PVC sheet then in production contained no detectable residual vinyl chloride monomer when tested by a technique developed by the FDA that had a lower level of detection of approximately 350 parts per billion (350ppb).

Tenneco said that it had learned that FDA scientists have developed new techniques for determining RVCM in food-contact materials that have claimed lower limit detections of one-to-two parts per billions (1-2ppb). As these new techniques may have been applied to Tenneco rigid and semi-rigid products, the company said, it wanted the opportunity to submit additional data. Furthermore, Tenneco said its own analytical chemists evaluated the new FDA techniques and their evaluation was that there were significant problems with the new FDA techniques that make them unsatisfactory for determining RVCM in PVC film.

"Circumstances Changed Significantly," Says FDA

In response to the Tenneco letter, William F. Randolph, FDA Acting Associate Commissioner for Compliance, said the FDA was "aware that the circumstances have changed significantly since our proposal was issued on September 1, 1975" and "that the public will be given an additional opportunity to submit data and comments." The precise nature and timing of "that opportunity" have not yet been decided, he said.

In mid-February 1978, Ethyl Corporation presented preliminary data to FDA technical personnel which showed that residual vinyl chloride monomer (RVCM) can be stripped from PVC to a level of approximately two parts per billion (2ppb) and that this may well be the lowest level to which RVCM can be reduced. FDA scientists agreed that if these data are confirmed and supplemented by studies with bottles, the diffusion model for predicting migration (used for AN) would not be applicable to these low levels of RVCM. Thus, the principles of the AN beverage container decision would not be relevant to PVC containers.

Maltoni Data Fails To Show AN Carcinogenic

In the early spring of 1978, the final report of ingestion and inhalation tests of acrylonitrile (AN) on rats by Prof. C. Maltoni of the Institute of Oncology and Tumor Centre of Bologna, Italy, became available. In brief, the tests failed to show whether or not AN is carcinogenic. "At present, our data do not make definitive evaluations possible," the researchers said, and proposed further investigations.

In addition to his studies of acrylonitrile, Prof. Maltoni also has been conducting ingestion and inhalation studies of vinyl chloride on rats. His final report on these studies has not yet been made available but is expected shortly.

Using the FDA risk assessment for aflatoxin as a model, and all available data on VC and AN, a staff scientist at Keller and Heckman, legal counsel to SPI, recently calculated the risk associated with these two residual monomers in food packaging. Although his calculations should be considered only illustrative and not conclusive because he lacked complete data, his findings do give a rough indication of the risk involved.

Cancer Risk: One In One Hundred Million

When applying the Mantel-Bryan "worst case" assumptions to vinyl chloride, the scientist calculated that if a man's entire diet was contained in PVC packaging a safe total dietary exposure to man would be 5.2-10.4 parts per billion (5.2-10.4ppb). Since it is assumed that PVC could not package more than 10 percent of the diet, an actual migration level of ten times the safe exposure level could be set as a "tolerance." This tolerance (not more than 5.2-10.4ppb migrating to food) assumes that the risk of cancer could not exceed one in one hundred million. Therefore, a finding of "non-detectable" with an analytical method sensitive to two parts per billion (2ppb) should assure virtually absolute safety.

In a similar calculation for AN, assuming that 5 mg/kg administered three times a week is a "no effect level," and that no more than 50 percent of the carbonated beverage consumption were packaged in AN copolymer containers, the scientists calculated a tolerance of 31 parts per billion (31ppb) would be virtually absolute safety. Therefore, the present analytical sensitivity of 10 parts per billion (10ppb) is sufficient to reduce any risk from AN to below any meaningful level.

Summary

Much has happened since the controversy over the migration of residual vinyl chloride monomer (RVCM) from food packaging arose in 1973. Newer, more sensitive equipment and more advanced techniques have been developed which permit the measurement of RVCM migration in parts per billion instead of parts per million.

In the last few years PVC manufacturing processes have been dramatically improved. One major company reported that it had stripped RVCM to as low as two parts per billion (2ppb) which, it said, may be the lowest level to which RVCM can be reduced.

The Food and Drug Administration (FDA) appears to be having second thoughts about regulations for RVCM. Although originally FDA indicated that its ruling on vinyl chloride would follow "the judgments and conclusions of law in its decision on acrylonitrile," recently the Agency admitted that circumstances had "changed significantly" since its proposal on vinyl chloride. Consequently, the FDA said, the public will be given additional opportunity to submit data and comments on the vinyl chloride proposed regulation.

In its report on risk assessment in regard to liver cancer from aflatoxin contamination, the FDA took a less conservative position in its methodology than the industry took for vinyl chloride. Using the more conservative procedure for aflatoxin as a model, a scientist calculated that the risk of cancer from migration of RVCM would be far less than one in one hundred million.

Rarely is it sensible to try to second guess what action a government agency, such as the FDA, will take on an issue as complex as the vinyl chloride migration issue. However, recent developments certainly seem to indicate a possible future resolution of the migration problem which would include the continued use of polyvinyl chloride in food packaging.

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