STATEMENT OF

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

to the

NATIONAL ACADEMY OF SCIENCES - INSTITUTE OF MEDICINE

COMMITTEE FOR A STUDY ON SACCHARIN AND FOOD SAFETY POLICY

September 7, 1978

My name is Jerome H. Heckman of the Washington, D.C. law firm of Keller and Heckman. I am General Counsel of The Society of the Plastics Industry, Inc. (hereinafter SPI or The Society) and am presenting this statement on its behalf. By way of background, The Society has over 1,400 member companies and is the major national trade association of the plastics industry, its membership being responsible for an estimated 75% of the total dollar volume of sales of plastics in this country. Primarily through its Food, Drug and Cosmetic Packaging Materials Committee, SPI has been the spokesman for the plastics industry in cautioning against over-regulation of food packaging materials. To a large extent, Comments filed by SPI in Food and Drug Administration (FDA) rule making proceedings over the years have been further elaborations upon the basic theme of SPI's testimony at the Congressional Hearings[1/] which led to passage of the Food Additives Amendment of 1958.

1/ "Hearings Before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 85th Congress, on Bills to Amend the Federal Food, Drug and Cosmetic Act with Respect to Chemical Additives in Food," published by the United States Government Printing Office in 1958. The hearings in question were held on July 15, 16, 17, 18, 19, 22, 23, 24; August 6, 7, 1957; and April 15, 1958. Hereinafter, reference to the hearing record is made by referring to it simply as "Food Additives Hearings, page _____."

Since we have now been given to understand that this Committee will review the case history of acrylonitrile as an indirect food additive as part of its review of food safety policy, a word about my personal background may be useful. Since enactment of the Food Additives Amendment of 1958, I have advised many clients on matters involving food additives, particularly so-called indirect additives, which are defined as substances such as components of food packages or processing machinery that "may reasonably be expected to become components of food." One such client is Monsanto Company which wrote off $35.6 million as a result of the Commissioner of Food and Drugs' decision to revoke the Food Additive Regulations permitting the use of acrylonitrile/styrene (AN/S) copolymers for use as beverage containers after an initial determination (in error, we believe) that acrylonitrile from such bottles may reasonably be expected to become a component of food. The Petitioners for the four Food Additive Regulations affected by the Commissioner's Order in the acrylonitrile case are all members of SPI. In one capacity or another, I was involved in all aspects of the rule making proceedings, litigation and negotiations that preceded the Commissioner's ban on AN/S copolymer beverage containers and the subsequent court appeal which is now pending.

The Society submits to this Committee that the regulation of trace migrants from food packaging materials, particularly as such regulation is now affected by § 409(c)(3) of the Federal Food, Drug and Cosmetic Act (Act), has become the most anomalous and obsolete aspect of current food safety policy. By applying novel theories of statutory construction, FDA has turned its responsibility

for assuring the safety of food packaging materials into carte blanche authority to selectively and arbitrarily ban any or all food packaging.[2/] The Society believes that the regulatory burdens associated with FDA's selective approach to packaging are not justified by the level of risk associated with food packaging materials; are inconsistent with the regulation of these materials in other countries; and stifle the development of needed new, innovative food packaging. This statement will propose two statutory changes for this Committee's consideration that we believe are necessary to return perspective and consistency to the regulation of food packaging materials.

I. FOOD ADDITIVE DEFINITION

The first statutory change that we urge this Committee to recommend is amendment of the definition of the term "food additive" so that a presumptive level of toxicological insignificance for components of packaging materials will be officially sanctioned. A review of the background which led to the current definition and FDA's various attempts to regulate packaging materials under this definition should make apparent why such a statutory change is essential.

In enacting the Food Additives Amendment of 1958, and understandably concentrating on concepts that would be effective to regulate substances intentionally added to foods, Congress paid virtually no attention to the fact that a

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2/ Examples of selective and arbitrary exercise of FDA authority are numerous. While the Food Additives Amendment of 1958 requires that nitrites now be banned, creative FDA staffers, reluctant to order such a step, are now claiming complete discretion as to when such a ban takes effect. Food Chemical News, Vol. 20, p. 50, August 21, 1978. Maintaining that diffusion can be a basis for food additive status for components of packaging materials is another example of creative regulation being used to overcome a lack of delegated aurhority. See text accompanying footnote 12.

substance deliberately added to food presents altogether different potential problems than substances which may unintentionally become trace components as a result of inevitable migration from packaging materials. As a result, for all practical purposes it saddled FDA with a regulatory scheme which has evolved into a legislative straight jacket that does not even fit the patient's basic physique.3/ In point of fact, this is not as surprising as one might think. The record in the Congressional Hearings does show that, in the company of a very few others, the plastics industry warned that "Laws written . . . with food in mind should not be indelicately applied to packaging components . . ." and that adoption of a measure of the type ultimately enacted "would undoubtedly require an immense increase in the FDA budget," as well as other serious and unwarranted dislocations.4/ Our pleas were largely ignored, or at best put down as relative to a nonexistent or insignificant problem. The subject was considered so inconsequential by the proponents of the 1958 law that very little discussion of it appears in the record. Indeed, to the extent that the matter was discussed by a member of the House Subcommittee, the clear impression was left that industry should rely on the fact that FDA could be counted upon, in some vague sense, to continue being reasonable in its handling of packaging materials problems.5/

3/ Appearing on NBC's Meet the Press on June 25, 1978, Commissioner of Food and Drugs, Donald Kennedy stated:

> "eventually we may need to contemplate some adjustments in those laws [Federal Food, Drug and Cosmetic Act], as our analytical sensitivity improves to the point where we find ourselves banning substances, packaging materials, say, on the grounds that a very, very few molecules find their way into the food supply."

4/ Food Additives Hearings, pp. 117, 131, 150-51, 472 and 494-95.

5/ Food Additives Hearings, p. 488.

How wrong were we? In light of what has happened, it is clear that we grossly understated our fears and Congress misread the potential for mischief. Of the 248 pages in Parts 172-178 of the Code of Federal Regulations (1977) concerning food additives, over two-thirds are devoted to Indirect Additives Regulations. It can be assumed with certainty that at least a similar proportion of FDA's Food Additives Petition budget is also devoted to this nonexistent public health "problem." Many of these Indirect Additive Regulations concern substances that have never been proven to be present in food, or are present in such trivial amounts that they present no possible risk of any sort.

The relevant statutory language now states that: " 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component . . . of any food" (Section 201(s) of the Act). The relevant FDA regulations in this regard state that: "A material used in the production of containers and packages is subject to the definition [of a food additive] if it may reasonably be expected to become a component . . . of food packed in the container." and "If there is no migration of a packaging component from the package to food, it does not become a component of the food and thus is not a food additive." 21 C.F.R. § 170.3(e) (1977).

The legislative history of the Food Additives Amendment of 1958, as well as the policies enunciated by FDA in papers given by its offical spokesmen over the years, including recent addresses and letters, all compel the conclusion that a food packaging material, or a component thereof, is not supposed to be subject to all of the burdensome pre-clearance requirements of the law where scientific studies reveal no reasonable expectation of migration to foods with adequately sensitive test methods.

In light of the assurances that FDA would continue to be reasonable in determining when a substance was reasonably expected to become a component of food and the fact that the state-of-the-art was such that analytical chemists were generally unable to detect concentrations of substances at less than several parts per million (ppm), the law may not have been totally unreasonable or unworkable when enacted; in overview, the acrylonitrile case you plan to study, among others, proves that it has now become so. In 1958, if a substance were found to migrate into food-simulating solvents in tests designed to exaggerate actual intended conditions of use, then the level that could reasonably be expected to be present in food would be in the range of several ppm. At such a level, it was reasonable to regulate these substances as food additives subject to all the pre-clearance machinery required for a direct additive.

Initially, FDA administered its authority to regulate packaging materials in a reasonable manner. FDA advised packaging manufacturers that if extraction studies indicated no migration, then the packaging material was not a food additive.[6/] Often, packaging manufacturers would submit the results of extraction

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6/ Food Packaging Under the Food Additives Amendment—What Needs to be Done, pp. 2, 3. Paper presented by Mr. Checchi (then Assistant to Deputy Commissioner Harvey) at 14th Annual Paper and Plastics Conference, Chicago, Illinois, September 22, 1959.

> "Once the extraction studies are completed, you will find yourself confronted with one of two possibilities. There may be no expected migration of any substance to food. If so, you're home free. The packaging material you have tested is not subject to the Amendment, except in the unlikely event that it otherwise affects the characteristics of the food contained in it." (Emphasis supplied.)

studies to FDA and obtain formal concurrence from the Agency that the packaging material was not a food additive. In fact, in the case of some Food Additive Petitions filed for packaging materials, FDA rejected the Petitions on the basis that extraction studies indicated no migration with methods sensitive to 1 ppm and, hence, the packaging material was not reasonably expected to become a component of food and not a food additive.[7/]

FDA's age of reason in interpreting the term food additive as applied to packaging materials began to erode within two brief years. In 1960, for reasons unrelated to public health and safety, the Agency abruptly announced abandonment of its practice of formally concurring in non-additive status where extraction studies indicated an absence of migration. FDA's response to industry arguments that FDA had an obligation under its procedural regulations to provide industry with sound and clear-cut advice as to the Food Additive Amendment status of products upon request sounded like something Alice might have heard in Wonderland. The Agency's attorneys contrived a rationale that went something like this: "If a company goes to the trouble of conducting extraction studies, it must believe that some or all of its product 'may reasonably be expected to become a component of food' and, hence, the product and/or its components are legally 'food

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7/ "Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 86th Congress, on Bills H.R. 7624 and S. 2197," published by the United States Government Printing Office in 1960 at 104-05. The Hearings in question were held on January 26, 27, 29, February 10, 11, March 11, April 5, 6 and May 9, 1960.

additives'! "[8/] Under this theory, it is clear that there really could be no such thing as a meaningful exemption from the law for non-migrants since, as a practical matter, no responsible manufacturer would conclude that a food-contact substance is not a food additive without performing some type of extraction analysis or studies.

While we now assume FDA no longer formally embraces the tautology of then Deputy Commissioner Harvey's theorem, the philosophical outlook it evidenced is far from dead. Despite repeated requests by industry, FDA has never firmly quantified the meaning of "may reasonably be expected" nor has it established workable procedures for how one goes about concluding that a substance may not reasonably be expected to become a component of food. As the sensitivity of analytical methods for detecting trace migrants from packaging materials improves, the burden of FDA's policy of vagueness has been and will continue to be grossly magnified.

8/ The FDA legal theory was first explained in a documented form in an address given by the then Deputy Commissioner of the FDA, John L. Harvey, at Rutgers University on January 18, 1962. In pertinent part, Commissioner Harvey's explanation was as follows:

> "We came to the conclusion that we had opened Pandora's box and had better find a way to close it before the situation got completely out of hand. We therefore reevaluated our position after consultation with our legal counsel and came to the conclusion that basically, if there was enough reason to run extraction studies on packaging or equipment materials, why shouldn't it be concluded that it would be reasonable to expect that the substances involved would, in fact, become a part of the food? Since the law refers to 'reasonably to be expected' we then began to advise those who asked that we were not in a position to give them a letter which would absolve their product from any responsibility from under the Food Additives Amendment but instead suggested that they file petitions. That is the present status of this item." (Emphasis supplied.) Harvey, Food Additives and Regulations, 17 Food Drug Cosm. L.J. 275 (1962).

More recently,[9/] FDA scientists have advised packaging materials manufacturers that a material will not be considered a food additive if no detectable extraction is observed with a validated analytical method when the material is tested "to equilibrium" in accordance with the Agency's Guidelines. These official Guidelines[10/] were supposed to provide an idea of the absolute maximum amount of a packaging substance that might migrate to foods under the intended conditions of use. Thus, FDA requires and specifies that the testing be under exaggerated time, temperature and exposure conditions. On occasion, FDA has even reviewed a manufacturer's data indicating no migration based on extraction conditions and simulated actual conditions of use, and issued letters concurring in non-additive status. Such letters are not issued routinely, however, and often require submission of the same extensive amount of data as would be required for issuance of a Food Additive Regulation.

Although this has represented an enlightened approach compared to the 1962 exercise in semantical circumlocution, it has not been without substantial defects; worse, as of now we have no way of knowing whether this policy is viable. Why? Because just last year, to carry out its bent on banning acrylonitrile copolymers used to fabricate beverage containers, FDA stated that it would not agree to a "no migration" position unless testing had been conducted for so long a

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9/ A series of correspondence with FDA in 1970 confirming that extraction studies were an appropriate basis for concluding that non-migratory components of packaging materials are not food additives is presented as Attachment 1.

10/ FDA Guidelines for Chemistry and Technology--Requirements of Indirect Additive Petitions (March 1976).

time and at such a high temperature--no matter how unrelated to intended conditions of use--that some migration under some condition is shown. FDA advised one of the packaging manufacturers in that case that until detectable migration of a suspected carcinogen is found, one cannot say that the extraction work has been conducted "to equilibrium" and it cannot conclude, therefore, that there is no reasonable expectation of migration. Although rhetoric may have changed since 1962, the reasoning used indicates that all of us remain Alices in Wonderland.

Today, substances may be detected routinely at contentrations in the range of a few ppb and in some instances in ppt. Clearly, levels this low were not contemplated to be considered components of food to which the onerous pre-clearance requirements for intentional food additives would normally apply. Indeed, even at a level of presumed migration of one ppm, no substance suitable for use as a component of food packaging materials has ever been known to cause injury to humans or animals.[11/]

The fact that something may be subjected to very exaggerated food-simulating solvent testing, and that exquisite analytical techniques can be applied to show the presence of the substance in the solvents at any level, sometimes well below 0.05 ppm, is now considered by FDA as conclusive evidence that the substance can reasonably be expected to migrate, i.e., that it is a food additive. The time-consuming and expensive pre-clearance requirements applicable to food additives are then brought into full force and effect. Beleagured consumers are

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11/ Frawley, J. P., A Reasoned Approach to Regulation Based on Toxicologic Considerations," 23 Food Drug Cosm. L.J. 260 (1968).

forced to bear still another regulatory cost but no offsetting benefit to public health has been achieved. As the art of analytical chemistry continues to improve, either more time and money will be spent preparing and processing Food Additive Petitions which request clearances for inconsequential amounts of substances, or all innovation will cease.

It is not hard to see that FDA has converted the product of those whose genius results in increasing analytical sensitivity into a disaster that hastens the day when any food packaging material could be banned according to the subjective inclinations of a Commissioner of FDA or Secretary of Health, Education and Welfare (HEW). The most desirable materials to use for food-contact applications are obviously those from which substances cannot reasonably be expected to migrate. Yet, in the face of FDA's harsh and ever-changing concept of "reasonably to be expected," few manufacturers will invest the time and capital to develop and manufacture materials whose superior properties make it impossible to conduct an extraction "to equilibrium." Furthermore, increases in the sensitivity of analytical methods might eventually be able to detect migration. If the substance found to migrate happens to cause cancer in animals when fed at huge doses, comparatively speaking, then the packaging material (food additive) must be banned.

The latest step in FDA's ever increasing regulation of an ever decreasing packaging component "threat" is its decision banning the use of acrylonitrile copolymers for beverage containers.[12/] Prior to this decision, it was generally believed that the sine qua non of food additive status was detectable migration to

12/ 42 Fed. Reg. 48528 (1977).

food-simulating solvents under the intended conditions of use. Having failed to establish this essential prerequisite for food additive status, FDA strained the original intent of Congress beyond all belief and hypothecated the presence of acrylonitrile monomer in food-simulating solvents on the basis of theoretical diffusion of monomer that could be detected in the bottle wall. In its opinion, this hypothecation was sufficient to establish food additive status.

The disasterous implications of the diffusion principle as a basis for determining food additive status, particularly when coupled with the Delaney Clause, should be readily apparent to this Committee. In the real world, there is no such thing as 100% purity or absolute freedom from contamination. The acrylonitrile monomer in the wall of an acrylonitrile copolymer beverage container is an unwanted, nonfunctional contaminant. Until relatively recently, little attention was paid to these trace residues in packaging materials since the amounts that could get into food were so low (often undetectable) that both industry and FDA were unconcerned. As soon as industry developed evidence to indicate that some monomers used for plastics packaging might conceivably become subject to the Delaney Clause because of the absolutism of its mandate, the plastics industry undertook highly successful efforts to eliminate, to the extent possible, the amount of unreacted monomer in packaging materials.[13/]

13/ In response to FDA's proposal to ban food-contact applications of rigid and semirigid PVC, SPI submitted extensive Comments which, inter alia, documented the drastic reductions in monomer level that were achieved between 1973 and 1975. As noted below, these reductions are still continuing. A copy of the SPI Comments in that rule making is attached as Attachment 2.

It may or may not be possible to completely eliminate all residual monomers or reduce them to a point where it can be proven that migration becomes virtually impossible, thereby rebutting the presumption of diffusion established in the acrylonitrile case.[14/] Until such evidence can be fully developed, however, all packaging materials, not just plastics, are in jeopardy. If a single carcinogenic molecule exists in a glass bottle, tin can or paperboard container, such a molecule can be presumed to migrate and thereby trigger a ban of the packaging material as a carcinogenic food additive.

Under FDA's current interpretation of the "may reasonably be expected" language, its resources will be diverted away from truly significant health risks as improving analytical techniques detect increasing numbers of "contaminating substances" in packaging materials.

Our proposal to amend the definition of a food additive to specifically recognize the concept of toxicological insignificance would restore a sense of perspective to FDA's regulation of food additives and do away with the wasteful squandering of scarce tax dollars on a regulatory program that not only serves no legitimate public health purpose but also impedes the development of new, innovative and energy efficient packaging materials. While the term toxicological insignificance is hard to define from an objective standpoint, the concept is very basic. There can hardly be disagreement with the old axiom that "too much of

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14/ Ethyl Corporation, working closely with scientists in the Bureau of Foods, has developed data which indicate that at a concentration of 1-2 ppb, residual vinyl chloride in PVC is apparently bound to active sites in the polymer matrix and does not migrate to food-simulating solvents. Other companies are pursuing similar research with residual acrylonitrile; the status of one manufacturer's research is documented in the statement submitted to this Committee by Monsanto Company.

anything is harmful"; likewise the wisdom of "everything in moderation" is easily appreciated. Toxicological insignificance--if you take a small enough amount, nothing is harmful--is no more than a different formulation of the same idea.

Based on levels for toxicological insignificance adopted by FDA in a draft of a proposed rule making;[15/] recommendations of the Food Protection Committee of the Food and Nutrition Board of the National Research Council published in "Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals and Food"; and the seminal article on the concept by J. P. Frawley,[16/] we are proposing that 50 ppb be recognized as a presumptive level of toxicological insignificance for components of packaging materials. In order to provide a means for dealing with those few substances known to be toxicologically significant at levels of 50 ppb and below, we propose that the Commissioner of FDA be permitted to establish a level of toxicological insignificance less than 50 ppb. It is not contemplated under our proposal that the level of toxicological insignificance for any substance could be zero; rather the Commissioner of Food and Drugs would be required, using all available evidence, to establish a finite level of contamination

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15/ This draft was forwarded to the chief executive officers of all the major packaging materials associations by a letter dated May 6, 1969, from Mr. L. L. Ramsey, Assistant Director for Regulatory Programs, in FDA's Bureau of Science. Copies of this letter and a later paper given by Mr. Ramsey to explain his proposal are presented as Attachment 3.

16/ See n. 11, supra.

for which there is reasonable certainty that the level is toxicologically insignificant. In the case of carcinogens, such levels would be determined by risk assessment techniques where a predetermined "acceptable risk," i.e., 1 in a million, had been established as an acceptable criterion of insignificance.17/

The specific amendment to § 201(s) of the Federal Food, Drug and Cosmetic Act that would accomplish the above-defined objectives would be the addition of a 6th exemption from the definition of a food additive. The added exemption to § 201(s) would read as follows:

> "; or, (6) any substance used as a component of food-contact articles provided it is not reasonably expected to contribute more than 0.05 parts per million to the contacted food as determined by analysis of the food after storage under intended use conditions, or by appropriate extraction studies which properly simulate intended conditions of use (in terms of time, temperature and type of food contacted), or by calculation assuming 100 percent migration: Provided, That the

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17/ Professor Wilson of Harvard has suggested that risks lower than 10^{-5} (1 in one hundred thousand) should not be regulated based on his multilinear approach to risk assessment. By comparison, FDA has endorsed a risk level of 10^{-6} as socially acceptable in its regulations (currently suspended by a court order on procedural grounds) establishing Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals which utilize the slightly less conservative risk extrapolation procedure of Mantel and Bryan. 21 C.F.R. § 500.800 (1977).

Secretary may by regulation establish a lower limit for a substance where a determination is made that such action is required to protect the public health."[18/]

II. THE RISK ASSESSMENT APPROACH TO CARCINOGENS

Should this Committee embrace the concept of toxicological insignificance, as we are urging, its application in the case of carcinogens might require a bit of fine tuning of the Delaney Clause to eliminate any potential conflict between that Clause and the amended definition of food additive recommended above. Actually, if the above recited amendment to § 201(s) were reasonably applied, there would be no necessity to amend the Delaney Clause for food packaging since the Clause only applies to food additives. Unfortunately, if experience has taught anything in this field it is that one cannot predict what will seem reasonable to an ever-changing cast of Food and Drug Administration policy makers faced with an unforeseeable variety of political circumstances; thus, the minor changes to the Delaney Clause that we are suggesting here are but a logical extension of the concept of toxicological insignificance.

No human endeavor is without some risk; the willingness to take reasonable and prudent risks is close to the essence of human nature. Regardless of the number of tests conducted on any substance, whether natural or synthetic, its presence in the environment always presents some chance of harm. It is a fundamental fact of life that risk can never be completely avoided; rather, it must constantly be weighed against benefit or compared to the risk of reasonable alternatives to determine whether the risk can and should be prudently accepted.

18/ Bills providing for such an amendment were introduced in the 95th Congress by Representatives Ashley and Sisk as H.R. 6979 and 9602, respectively. Congressman Ashley's comments upon introducing H.R. 6979 are provided as Attachment 4.

A commonplace example of a cancer risk so trivial it is readily accepted without second thoughts may help to illustrate this principle. Everyone is well aware that radiation is a cause of cancer. It is also well-known that television sets are a source of radiation and, hence, watching television theoretically increases one's risk of cancer. Shielding greatly attenuates this radiation, but it cannot reduce the dose to zero. Nonetheless, the resulting risk is so negligible that it need not be considered in deciding to buy a television or watch a program. In other words, the level of risk is so low as to be without any decisional significance.

Advances in analytical chemistry have made it possible to detect the presence of substances in food or, more often, food-simulating solvents, at levels which are orders of magnitude below that at which any significant risk of harm exists. Furthermore, continuing research has shown that a large number of substances, both natural and synthetic, may be capable of causing cancer in animals when consumed in gross amounts. Some such substances are essential nutrients at much lower levels. Thus, we submit that simple common sense should be enough to indicate that an absolute ban on any food additive found to cause cancer in animals can no longer be tolerated. When the risk of cancer from the use of a food additive is insignificant compared to the good it will do, or when compared to the risk from known carcinogens and other toxicants that naturally occur in the diet, it makes no sense to forego the benefits to be gained by controlled use of the additive.

The Saccharin Study and Labeling Act and the existence of this Committee reflect the growing awareness in Congress that despite the political appeal of legislating a "no risk" approach to cancer, such extremist "populism" is now

untenable. As usual, a popular idea taken to an extreme has inevitably led to a politically unpopular result, e.g., the saccharin debacle. Food safety policy for carcinogens is much too important to be treated as a political football; it is time to adopt a rational policy towards cancer and to acknowledge that the risk of cancer from certain products may be so slight that it can comfortably be ignored.

An effective food safety policy for carcinogens must be based on sound scientific principles that are as applicable to artificial sweeteners as they are to preservatives in processed meats; aflatoxin contamination of peanuts, corn and milk; and trace migration of unavoidable contaminants of food packaging materials. In our opinion, risk assessment is the appropriate discipline for dealing with all types of food safety decisions. Accordingly, this Committee should recommend legislation clearly establishing authority for FDA to deal with the reality of carcinogens in food by applying risk assessment techniques to set tolerances at levels where the risk of cancer is insignificant.

In the case of food packaging materials, the level of potential migration of unavoidable contaminants is miniscule; the calculated risk associated therewith, while finite, is so trivial that regulatory control is clearly unnecessary. The polyvinyl chloride (PVC) and AN/S copolymer cases are two examples of the kind of over-regulation that can result when only a zero risk seems politically acceptable. Both of these polymers can be utilized to satisy desirable food packaging requirements. Without PVC film, self-service meat counters in supermarkets would not be possible; not as widely known, PVC and its copolymers are essential components of currently used cap liners and sealing gaskets for glass containers and

coatings for the interior of metal cans. AN/S copolymers are suitable for holding carbonated beverages and provide significant environmental advantages over alternative beverage containers because of their extremely light weight which conserves energy during transportation and of their decreased potential for causing injury due to breakage. Because of FDA's zero risk approach to food packaging materials, AN/S copolymers have been banned for beverage container applications; if the principles leading to that ban were applied to PVC, a return to brown paper meat wrap and serious disruption of other packaging systems would follow.

Can such drastic actions be justified on the basis of undue risk? Clearly not. While both the vinyl chloride monomer used to make PVC and the acrylonitrile monomer used in making AN/S copolymers have been implicated as carcinogens in some species under some conditions, it is important to note that neither substance is intentionally added to food or to food packaging, nor is there any evidence that the amounts of these substances that might find their way into the diet from packaging materials would be harmful. The level of risk associated with these miniscule amounts of contaminants can be conservatively estimated by risk assessment techniques.

Professor Richard Wilson of Harvard University, a well-known authority on risk assessment, testified at the FDA hearing on AN/S copolymer beverage containers that using the extremely conservative linear method for extrapolating the cancer incidence observed in laboratory animals to humans, the individual risk of early fatality from consuming beverages in an AN/S copolymer beverage container was no higher than 1 in 290 million (3.5×10^{-9}) per year.[19/] Also testifying at this

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19/ Testimony of Professor Richard Wilson, FDA Docket No. 76N-0070, Exhibit M-90, p. 32. A copy of this testimony is provided as Attachment 5.

FDA hearing, Allan W. Dickinson, a Fellow In Statistics at Monsanto Company, applied the familiar Mantel-Bryan risk extrapolation model to the interim data of the chronic rat study and projected an annual cancer risk to humans of less than one in a trillion (1×10^{-12}/per year).[20/] At the time these beverage containers were banned, manufacturers were developing better stripping methods to further eliminate residual acrylonitrile monomer that would have reduced even further the maximum theoretical risk presented.

Risk assessment analyses have also been conducted relevant to vinyl chloride monomer. One of the most conservative of these assessments is presented in Drinking Water and Health, published by the National Academy of Sciences in 1977. At page 785, the lifetime human risk from vinyl chloride in drinking water is presented as $3.0 \times 10^{-7}Q$, where Q is the concentration in parts per billion (ppb) of vinyl chloride in drinking water which is assumed to be consumed at a rate of 1 liter/day. Since the risk extrapolation technique used for this formula is linear in dose, the formula may easily be adapted to estimate the risk associated with any given concentration of vinyl chloride in an average 1.5 kg diet. Currently, levels of residual vinyl chloride monomer in PVC film (density 1.2 g/cc) are about 1 ppb. By making some assumptions as to the amount of vinyl chloride free to migrate (10%), the amount of the diet packaged in PVC film (10%), the volume-to-surface ratio for food packaging (10 ml/in^2) and the thickness of PVC film (0.002 in), one can estimate a conservative maximum for dietary concentration of vinyl chloride from PVC film of approximately 0.04 parts per trillion (ppt). The corresponding lifetime human risk, applying the conservative NAS formula, is only 1.8×10^{-11}.

20/ Testimony of Allan W. Dickinson, FDA Docket No. 76N-0070, Exhibit M-88, p. 3. A copy of this testimony is provided as Attachment 6.

The degree of these risks from food packaging are so small that they are difficult to comprehend. Risks on the order of 1×10^{-10} are equivalent to a potential for one excess cancer for every 10 billion persons. Since the population of the United States is only 220 million persons, the risk corresponds roughly to a potential for a little over one excess cancer in the country each century! Certainly, such a risk level does not merit decisional significance in any reasonable regulatory system.

Even without PVC or AN/S copolymer food packaging, everyone faces a 1 in 1 (100%) chance of dying. The odds of getting cancer are 1 in 4 (25%), while the odds of dying from cancer are 1 in 5.6 (18%). There can be no doubt that cancer prevention and cure deserve high priority. However, cancer is not a single disease. Lifestyle factors such as tobacco, alcohol and poor eating habits represent a significant portion of human cancer risk[21/] while other portions of human cancer risk can be attributed to natural, unavoidable sources, such as background radiation (1 in 76,000/yr).[22/] As shown above, migration of residual monomers from food packaging contribute no more than 0.00000001% (one hundred millionth of one percent) to the total 25% risk of cancer.

FDA has applied risk assessment to unavoidable contaminant situations, e.g., aflatoxin contamination of peanuts,[23/] where no absolute prohibition of carcinogens exists; furthermore, FDA has recognized that carcinogenic risks in food may be so low as to be insignificant.

21/ Wynder and Gori, Contribution to the Environment to Cancer Incidence: An Epidemiologic Exercise, 58 J. Natl. Cancer Inst. 525 (1977).

22/ Testimony of Professor Richard Wilson, supra at 32.

23/ Assessment of Estimated Risk Resulting from Aflatoxin in Consumer Peanut Products and Other Food Commodities, Bureau of Foods, Food and Drug Administration, January 19, 1978.

The FDA tolerance for aflatoxin contamination of peanuts is currently 20 ppb; the FDA risk assessment cited above attempts to justify a proposed reduction of this tolerance to 15 ppb and to discount the need for a reduction below 15 ppb. The reduction in risk calculated for a reduction of the tolerance from 15 ppb to 5 ppb is 1 in 200,000 (0.5 per 100,000). This reduction is termed "no significant gain in the protection of the public health."[24/]

It seems to us that it is a misappropriation of Agency resources to require it to regulate indirect food additives presenting risks much lower than 1 in 100,000 while dismissing as insignificant other much larger risks that exist in the food supply. It is time to give FDA rational guidelines for dealing with the cancer risk associated with food additives.

We propose that guidelines permitting FDA to weigh the benefits as well as the risks associated with human use of a food additive shown to cause cancer in animals are necessary and should specifically require the Agency to consider the following points before deciding to permit or deny the use of any additive:

(1) biostatistical methods for evaluation or risks and the results of their application;

(2) availability of alternative substances and the common knowledge that dietary exposure to a single additive will be lessened by the clearance of as many safe alternative substances as possible;

(3) the relevance of testing done with animals to human experience or metabolism;

24/ Id., p. 20.

(4) available epidemiological information; and

(5) any other factors which the Commissioner may prescribe in suitable regulations to be relevant.

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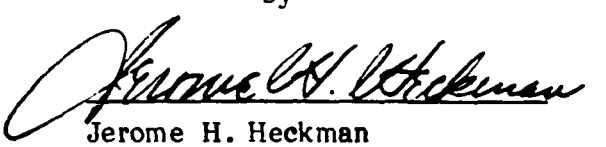
In this statement we have attempted to highlight food safety policy problems that impact uniquely on packaging materials. As noted, Congress had relatively little impetus to deal carefully with these problems when enacting the Food Additives Amendment of 1958. In light of what has come about scientifically, and in the regulatory sphere, we urge this Committee to recommend that Congress evaluate the current situation, and revise the basic law now applicable to indirect additives.

Respectfully submitted,

The Society of the Plastics Industry, Inc.

by



Jerome H. Heckman
General Counsel

Counsel:

Keller and Heckman
1150 17th Street, N.W.
Washington, D.C. 20036

(202) 457-1110

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