JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR.
ROBERT E. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY, JR.
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBECK
CHRISTINE A. MEAGHER

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 457-1100
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER
202/457-1132

May 2, 1977

RECEIVED MAY 13 1977

Mr. Ralph L. Harding, Jr.
The Society of the Plastics
Industry, Inc.
355 Lexington Avenue
New York, New York 10017

Dear Ralph:

In the event that you have not received the direct communication, enclosed is a letter from the Federal Trade Commission regarding the cellular plastics combustibility case. By means of that letter, the FTC has acknowledged that SPI's Compliance Report has been accepted as satisfactory and that SPI is in compliance with the November 4, 1974 Consent Order in Docket C-2596.

We suggest that a copy of this letter be retained in the appropriate file at the SPI offices, while we will be retaining the letter here.

Cordially yours,

Peter

Enclosure

cc: Mr. Thomas J. McGrath
Mr. John R. Lawrence

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BOROHESANI, JR.
ROBERT B. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY, JR.
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBECK
CHRISTINE A. MEAGHER

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 457-1100
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER

(202) 457-1110

April 1, 1977

TO: SPI-Food, Drug and Cosmetics Packaging Materials Committee
SPI-Public Affairs Committee
SPI-PAC Plastic Beverage Container Group
SPI-PAC-VCM/PVC Producers Group and
SPI-PAC Acrylonitrile Safety Group

Re: Petition To Initiate Rule Making Proceedings: Amendment to Definition of Food Additives, Section 170.3(e) of the Food Additive Regulations

Letter Highlights

On March 30, 1977, a Petition to amend the definition of "food additive," was filed on behalf of SPI's Food, Drug and Cosmetics Packaging Materials Committee, with the Food and Drug Administration. A copy is enclosed.

Ladies and Gentlemen:

Following up on our March 24, 1977 letter concerning the above referenced matter, this is to advise you that we have now filed a Petition on behalf of SPI's Food, Drug and Cosmetic Packaging Materials Committee with the Food and Drug Administration to amend the regulatory definition of "food additive." A copy of the Petition as it was submitted to FDA on March 30, is enclosed. The more than 500 pages of attachments are not included due to their bulk.

As you will note, the proposed amendment seeks to define when a substance "may reasonably be expected to become a component of food," i.e., when it is a "food additive," in objective terms which would make 50 ppb a toxicologically insignificant amount for most materials. Where highly toxic

substances such as heavy metals or known carcinogens are involved, the amendment would establish a "no migration" level of toxicological insignificance in accordance with a risk no greater than 1×10^{-6} in a lifetime as determined by the so called "Mantel-Bryan" statistical procedures.

It is, in our view, critically important to the entire future of the food packaging industries that an objective standard of this type be established by FDA. As we see it, the regulatory crises which have recently arisen vis a vis polyvinyl chloride and acrylonitrile food packaging materials have been largely the result of FDA's inconsistent interpretations of the meaning of the term "food additive." Establishment of an objective scientific standard along the lines we are now advocating could go a long way towards putting FDA's decision making process on a less "fluid" basis.

If, after reviewing the Proposal, you agree that an objective standard of this type should be established for determining "food additive" status, you may want to advise FDA of your company or personal views. The Agency and trade press do review the mail received on food and drug issues closely and are affected by widespread support for a position.

We will, of course, let you know as soon as FDA takes further action with respect to this Petition. In the meantime, should you have any questions or comments concerning any aspect of this matter, please do not hesitate to contact us.

Cordially yours,

George W. Strickman

Enclosure

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMROV
JOSEPH E. HADLEY, JR.
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBECK
CHRISTINE A. MEAGHER

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 457-1100
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER

Hearing Clerk
Food and Drug Administration
Department of Health, Education and Welfare
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

Re: Petition to Initiate Rule Making Proceeding

Dear Sir:

The Society of the Plastics Industry, Inc. (SPI), by its attorneys and acting through its Food, Drug and Cosmetics Packaging Materials Committee,[1/] hereby submits this Petition pursuant to Section 4 of the Administrative Procedures

1/ SPI is a Corporation organized under the Not-For-Profit Corporation Law of the State of New York. It is composed of approximately 1100 member companies and individuals who supply raw materials; process or manufacture plastics or plastics products; engineer or construct molds or similar accessory equipment for the plastics industry; and engage in the manufacture of machinery used to make plastics products or materials of all types. SPI 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. The Food and Drug Administration is quite familiar with the constitution and activities of the Society as a result of our many filings and participation in other proceedings of direct consequence to plastics producers. Copies of SPI membership directories, organization charts, and the like have been supplied to FDA in connection with some of these filings. Any further background information desired can be supplied immediately upon request by the Food and Drug Administration.

Act of 1946 (5 U.S.C. §553), Section 409 of the Federal Food, Drug and Cosmetic (FD&C) Act of 1938, as amended (21 U.S.C. §348), and Sections 10.25 and 10.30 of the Administrative Practices and Procedures Regulations (21 C.F.R. §§10.25 and 10.30),to request the Commissioner of Food and Drugs to amend Section 170.3(e) of the Food Additive Regulations(21 C.F.R. §170.3(e)).

A. Action Requested.

More specifically, the Petitioner requests the Commissioner to amend that Section by adding the following:

* * * *

(e)... "In the absence of special circumstances which warrant a contrary conclusion due to confirmed and reliable scientific evidence that a substance in a food contact surface presents significant risk of irreversible harm to human health, a substance will be deemed not "reasonably...expected to result, directly or indirectly, in its becoming a component...of any food," if it is found to be undetectable in the food simulating solvents recommended in the current FDA "Guidelines for Chemistry and Technology Requirements of Indirect Food Additives Petitions" when the solvents are examined using validated analytical methods sensitive

to at least 50 ppb. In the case of a heavy metal, an economic poison, a material synthesized or prepared for use because of its biological activity, a substance known to be a carcinogen, and any other case where confirmed and reliable scientific evidence indicates that a potential significant risk of irreversible harm exists, it will only be concluded that the substance may not reasonably be expected to become a component of food if the substance can not be detected in the food simulating solvents, after an exposure that reasonably simulates intended conditions of use, by the application of a validated analytical procedure sufficiently sensitive to assure a risk no greater than 1×10^{-6} in a lifetime. The degree of risk will be determined by the use of the Mantel-Bryan procedure set forth in Mantel, M. and Bryan, W., Safety Testing of Carcinogenic Agents, 27(2) Journal of the National Cancer Institute 455-470 (1961), and modified in Mantel, M., et al., Improved Mantel-Bryan Procedures for Safety Testing of Carcinogens, 35 Cancer Research 865-872 (1975).

B. Statements of Grounds.

The proposal we are advancing in this Petition is simply that the Food and Drug Administration amend its existing regulations so that they can be applied on a sound scientific and regulatory basis to each case as it arises, thereby obviating the need to handle questions with little real public health or safety significance in varying ways because of sometimes emotionally charged circumstances. The adoption of the proposed rule change could also do a great deal to reduce or eliminate the amount of staff time and energy which the Food and Drug Administration now commits to handling the voluminous filings which pre-empt and, we believe most authorities would agree, preclude the devotion of proper attention to areas of genuine public concern.

It is respectfully submitted that the orderly dedication of scarce government and non-government resources requires prompt publication of this rulemaking proposal since it looks toward the sensible delimitation of the excessive paperwork and many other problems which have resulted from the uncertain and inconsistent interpretation of the phrase "may reasonably be expected to result, directly or indirectly, in [a substance] becoming a component...of any food...." FD&C Act §201(s); 21 U.S.C. §321(s). If the publication of a regulation responsive to this Petition so requires, it is suggested that the Commissioner exercise his discretion to order a public hearing of the type authorized and described

in Sections 10.50(b) and 16.1, et seq. of the Admimistrative Practices and Procedures Regulations (21 C.F.R. §§10.50(b) and 16.1, et seq.) immediately.

Since 1960, it has become increasingly apparent that the vagaries in the Food and Drug Administration's interpretations of the statutory phrase "may reasonably be expected to...[become] a component...of any food..."[2/] have given rise to such critical uncertainty about "incidental additive" status that this factor alone has had a chilling, stultifying effect on ordinary commerce which could never have been foreseen or intended by Congress. Continuing developments--especially the refinement of analytical methodology to a stage far beyond that which was known or conceived when the Food Additives Amendment of 1958 was enacted--have turned uncertainty into near economic disaster in recent cases. This is partly a result of the simplistic treatment of scientific information which has all too often been reported without perspective. Such problems inevitably result when scientific complexity reaches the stage where it becomes impractical for the public to understand the true significance under actual life conditions of toxicological reports on materials used for such applications as food packaging.

The consternation caused by the vagueness of the statutory and regulatory language is not new. Attached hereto

---

2/ The legislative history and the plain meaning of this phrase indicate that it was indended to exclude a great many, if not most food packaging materials from regulatory coverage.

are copies of the following papers and documents which should serve as a reasonable sampling of how persistent concern over the problems arising from what has come to be called the "no-migration" concept have been since at least 1960:

(1) Heckman, J. The Packaging Industry and the Food Additives Amendments of 1958--It's Time for a Change in the Law, Food and Drug L. Journal 648 (December, 1966);

(2) Comments of SPI to FDA, "Proposed Food Additive Procedural Regulations," November 6, 1967.

(3) Frawley, J., Scientific Evidence and Common Use as a Basis for Food-Packaging Regulations, 5 Food and Cosmetics Toxicology 293 (1967);

(4) U.S. Department HEW, National Conference on Indirect Food Additives, February 13, 1968 (Transcript);

(5) Ramsey, L., The Food Additive Problem of Plastics Used in Food Packaging, November 4, 1969;

(6) Comments of SPI to FDA, "Proposal Regarding Regulations of Prior Sanctioned Food Ingredients," September 22, 1972;

(7) Blank, C., The Delaney Clause: Technical Naivete and Scientific Advocacy in the Formulation of Public Health Policies, Calif. L. Rev. 1084 (1974); and

(8) Comments of SPI to FDA, Docket No. 75-N-0190, "Vinyl Chloride Polymers in Contact with Food," December 19, 1975.

It will be noted by anyone reviewing the transcripts of the National Conference on Indirect Food Additives, Mr. Lessel Ramsey's paper of November 4, 1969, and the papers presented by the undersigned on various occasions, that an objective and dispassionate resolution of this problem has been needed for at least fifteen years.

We respectfully submit that this need has now become urgent in light of the current regulatory confusion which could cast unnecessary doubt on the safety of all food packaging materials. The pending "crises" on polyvinyl chloride and acrylonitrile are nothing more than precursors of what is to come if more specific and determinative ground-rules are not laid down. It seems clear that the underlying causative factors for the present instability can best be dealt with in a general rule-making proceeding where scientific facts and legal concepts can be objectively examined, without passion.

The Food and Drug Administration has long advised manufacturers of packaging materials to conduct extraction tests to determine whether a component of a packaging material is a food additive and make their own decision as to whether a substance should be considered a "food additive." Without a workable and generally understandable definition of the phrase "may reasonably be expected to...[become] a component...of any food," however, a manufacturer can not presently draw

that conclusion with certainty, regardless of what the most sophisticated extraction tests may show. Simple justice, as well as the orderly administration of the Food, Drug and Cosmetic Act, demand that the Food and Drug Administration clarify the meaning of its present regulatory language so all may become aware of the standard of performance required for food contact articles, and can assure themselves, their customers and the public of compliance with applicable FDA regulations.

The proposed amendment embodies, in operative terms, the concept set forth in Section 170.3(i) of the Food Additive Regulations (21 C.F.R. §170.3(i)), i.e. that FDA can conclude there is no significant risk of harm where the probable consumption of a substance, its cumulative effect in the diet, and the application of appropriate safety factors so indicate. The proposal would allow the use of a substance in a packaging material with no regulatory concern when its intended use provides an equally appropriate basis for determining that a component of food packaging materials will not be present in food at a concentration so low that safety is assured as a matter of common sense.

The concept advanced here is designed to take care of routine cases as well as those that might seemingly involve "extremely toxic substances." The former would be handled by the 50 ppb detection criterion, and the latter by application of the Mantel-Bryan criterion for analytical sensitivity which the Food and Drug Administration has already embraced

as reasonable for biologically active substances[3/] whose potential for harm is orders of magnitude greater than that for packaging materials.

Without modern packaging materials, it is estimated that the food supply available to the world--many parts of which already face the specter of starvation--would be reduced by 25% or more. In light of that fact, it is, in our view, clear that any risk-benefit comparison must necessarily weigh heavily in favor of lifting the air of uncertainty among packaging materials suppliers, food packagers and consumers that has been created by present Food and Drug Administration policies.

C. Environmental Impacts.

With regard to environmental impacts, it is respectfully submitted that there will be no significant environmental impact as a consequence of the approval of the proposed amendment.

The instant Proposal requests only a clarifying amendment to the regulatory definition of "food additives" in Section 170.3(e) of the Food Additive Regulations (21 C.F.R. §170.3(e)). This is essentially a procedural matter relating to the statutory phrase "may reasonably be expected to result in a [substance] becoming...a component of food...." FD&C Act §201(s); 21

3/ On February 22, 1977, the Food and Drug Administration established Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals, 42 Fed. Reg. 1042 (Feb. 22, 1977). In doing so, the Administration authorized the use of the "Mantel-Bryan" method of statistical extrapolation to define operationally the no-residue standard in Section 409(c)(3)(4) of the FD&C Act. 21 U.S.C. §348(c)(3)(A).

U.S.C. §321(s). The clarification requested will not increase or decrease the consumption of raw materials or energy and will not result in the introduction of new or additional substances to the solid waste, air or water streams. As such, there will be no adverse environmental effects, either primary or secondary, reversible or irreversible, short-term or long-term, and no other parties should object to the proposal on environmental grounds.

The only alternative to the proposed action would be to allow the present confusion to continue. This would have the same result environmentally, but an otherwise undesirable impact on the food packaging industry and the Food and Drug Administration.

It is further noted that Section 25.1(c) of the Environmental Impact Considerations Regulations indicates that an environmental impact statement "will not be required for amendments to existing regulations...unless the change is substantial." 21 C.F.R. §25.1(c). The additional language requested in this Petition does not change the Food and Drug Administration's statutory obligations in any way. It simply attempts to delineate the presently undefined method for determining when a substance is a "food additive," and to remove the uncertainty and confusion which now exist. Thus, under the terms of Section 25.1(c), an environmental impact statement is not required.

THE FOREGOING CONSIDERED, it is respectfully urged that the amendment to the rules set forth above be proposed forthwith and, if necessary, that a hearing on the matter be ordered immediately. This would allow the rule change to be effectuated without delay.

The undersigned certifies that, to the best of his knowledge and belief, this Petition includes all data, information, and views on which the Petition relies, and that any representative data and information which may be unfavorable to the Petition is of such broad and common knowledge that it need not be specifically included here.

Respectfully submitted,

Jerome H. Heckman

Peter Thomas Smith

Attorneys for Petitioner

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

(202) 457-1100