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June 6, 1977

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TO: All Members of SPI-PAC-AN Safety Group

Re: Proposed Rulemaking, Acrylonitrile
Copolymers Intended for Use in Contact
With Food; 42 Fed. Reg. 13562-13565;
Docket No. 77N-0078

Gentlemen:

Following up on our June 1, 1977 meeting, we are enclosing a draft copy of the comments which will be submitted, on behalf of the Society of the Plastics Industry, Inc., to the Food and Drug Administration with respect to the above referenced Rulemaking proceeding on acrylonitrile. Please review these comments and advise us of any additional changes you feel should be made.

Since these comments must be finalized and filed with FDA by June 9, we have sent this draft to you by messenger service. To allow us sufficient time to incorporate whatever suggestions you may have in the comments before they are submitted to FDA, we will need to hear from you by the end of the day on June 8. Accordingly, any revisions you may have should be telephoned in to me as soon as you have an opportunity to review this latest draft.

We look forward to hearing from you shortly with regard to this matter.

Cordially yours,

Peter Thomas Smith

Enclosure

SPI-07904

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

Re: Acrylonitrile Copolymers Intended
for Use in Contact With Food; Notice
of Proposed Rule Making; 42 Fed. Reg.
13562-13565; Docket No. 77N-0078.

Dear Miss Peterson:

Responsive to the above-referenced Food and Drug
Administration Notice of Proposed Rule Making published
on March 11, 1977, the Society of the Plastics Industry,
Inc. (SPI)^{1/}, by its attorneys, and acting through its Food,

^{1/}SPI is a Corporation organized under the Not-For-Profit Corporation Law of the State of New York. It is composed of approximately 1200 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.

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Drug and Cosmetic Packaging Materials Committee and its Acrylonitrile Safety Group, hereby respectfully submits its views with regard to the proposed amendments to Parts 180 and 181 of the Food Additive Regulations. More specifically, these Comments are directed toward the proposed amendment of Section 180.22 (formerly Section 121.4010) and Section 181.32 (formerly Section 121.2010) which deal, respectively, with acrylonitrile copolymers generally and prior sanctioned acrylonitrile copolymers.

It has always been the basic position of the Society that plastic packaging materials intended for use in contact with food should be manufactured and used in a manner which will assure protection of the public health and safety. To this end, SPI has worked closely in the past with FDA to develop reasonable regulations for plastic food packaging materials.

Although the Food and Drug Administration is to be commended for responding favorably to some of the SPI objections to the current Interim Regulation and current Prior Sanction Affirmation, it is our view that the amendments in the Instant Proposal on AN represent a considerable degree of regulatory "overkill." The Proposed Regulations are far more burdensome than is necessary to protect the public health.

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For example, in proposed sub-paragraph (b) (1) of Section 180.22 the migration limitation on AN monomer would be reduced from 0.3 parts per million (ppm) to 0.05 ppm. Evidence in the FDA files indicates that there is no likelihood that even as much as 1% of the present diet (in fact, the figure is closer to 0.02%) will be packaged in AN based copolymers. When this actual food contact is considered with the recent toxicological information on AN, the proposal provides a "safety" factor of 150,000! The Proposal has also failed to take into account the fact that many AN copolymers are primarily used for the packaging of refrigerated foods with a very limited shelf life. These facts notwithstanding, the Society is confident that the industry will make every effort to comply with what may well be an unnecessarily severe limitation.

Of more significant concern, is the need for the modification of the testing procedures set forth in the proposed AN Regulations and the clarification of several of the terms used.

I

Extraction Test Temperatures, Sections 180.22 and 181.32
(formerly Sections 121.4010 and 121.2010)

Under the terms of proposed Sections 181.22(a) (1) and (2) and 181.32(b) (1) and (2), extraction testing for single use items would be required to be conducted at a

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temperature of 120°F, unless a higher temperature exposure may occur^{2/}, regardless of the fact that the actual intended conditions of use may be well below room temperature. This is inconsistent with the present Guidelines for testing which FDA has established and unnecessarily severe in light of the proposed extraction limitation of 0.05 ppm and actual uses of AN as a food contact plastic.

To the best of our knowledge, FDA's practices have uniformly required that food packaging materials be "extracted to equilibrium" at a time and temperature which provides a reasonable exaggeration of the intended conditions of use. (Guidelines at 9). This procedure assures that any substance extracted would represent the maximum that might appear in food.

For certain foods, particularly those in the meat and dairy categories, where the packaged food is chilled, then shipped and stored under refrigerated conditions, "extraction to equilibrium" at 120°F is unreasonably excessive. In the past, FDA has recommended that these materials be "extracted to equilibrium" at the appropriately exaggerated

^{2/} If the packaging material is intended for use at elevated temperatures such as may be involved when food is hot filled or heat treated in the container (pasteurized or sterilized), the material must be extracted for a time and temperature which reflect the highest intended temperature of contact followed by extraction to equilibrium at 120°F if the food is to be shipped and stored under ambient conditions.

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temperature of 70°F. With the proposed reduction in permitted AN extraction levels and the minor dietary contact, there is no reason to contradict the established Guidelines by requiring a temperature of 120°F. Copies of correspondence in which FDA has advised that extraction at 70°F is appropriate for refrigerated uses are attached.

We would, therefore, urge that Sections 180.22(a)(1) and (2) and Sections 181.32(b)(1) and (2) be amended by eliminating the specific temperature requirement and replacing it with a requirement that the extraction temperature be appropriate to the expected conditions of use.

We would also note that proposed Section 181.32(b)(2) concerning repeated use articles provides that the extraction limitation be determined from "...equilibrium extraction levels...as related to food volumes contacted during initial batch usage." 42 Fed. Reg. 13564. We believe this is an editorial oversight. It is apparent that what was intended was testing at times and temperatures representative of the intended conditions of first batch use. Accordingly, we would recommend that proposed Section 181.32(b)(2) be amended to state "...extraction levels...at times and temperatures representative of the intended conditions of use as related to the food volumes contacted during initial batch usage".

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II

Extraction to Equilibrium, Sections 181.22 and 181.32
(formerly Sections 121.4010 and 121.2010)

In light of some recent FDA statements, it is also our view that the phrase "extraction to equilibrium" in proposed Sections 180.22 and 181.32 needs to be clearly defined. In the past, "extraction to equilibrium" in migration testing with aqueous solvents or foods^{3/} has meant that if the results of extraction studies at 72 hours, 96 hours and 120 hours are essentially constant, (or at additional successive 24-hour samples until the results are constant), the measured result is deemed to represent the maximum quantity that would be extracted from the packaging material under long term storage conditions. In the event that the three successive samples show the substance to be non-detectable, this too was deemed to represent "extraction to equilibrium" with "no migration" at the limit of analytical sensitivity.

Recently, however, in connection with its "Stay of Regulations" directed at acrylonitrile copolymer beverage containers (42 Fed. Reg. 13546-13548), the Food and Drug Administration indicated it may be abandoning the foregoing

^{3/}When heptane is used, the first measurement is made after 6 hours of exposure, the subsequent samples being taken at 4-hour intervals until three successive determinations are constant.

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interpretation. During the course of a conference between FDA personnel and representatives of a company that manufactured AN copolymer beverage containers, an Administration official stated that regardless of how long or at what temperature the samples had been exposed, a finding of "non-detectable" could not be interpreted to mean that a material had been extracted to equilibrium. Rather, he stated that samples should be exposed and tested at whatever temperatures and times (however unrealistic) might be necessary to produce some measurable migrating species. This was apparently without regard to the distortion of the package or the demonstrated limited shelf life of the food. Only when some extracted material could be found would the required successive determinations be conducted to demonstrate "extraction to equilibrium."

The problem is even further compounded because the preamble to the instant Proposal states that FDA's Indirect Additives Laboratory is developing analytical methodology which may be "...capable of detecting AN at levels at least as low as 0.04 ppm," but "...is working to refine the confirmatory procedure at 0.05 ppm and below." 42 Fed. Reg. 13563. If the procedure can be validated only at 0.05 ppm and if extraction must be continued until some AN is "forced" to appear in the test solvents, no copolymer can comply

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with the proposed AN Regulations. Any AN sample which is tested and appears to comply, i.e., one that shows the substance to be non-detected with the appropriately sensitive method, cannot be deemed to have been extracted to equilibrium. If exposure times and temperatures are sufficiently exaggerated and extended so that some AN will be "forced" to appear, the material will likely exceed the proposed limitations.

Clearly, the ground work has been laid for a classic "Catch-22." We would recommend that the term "extraction to equilibrium" be defined as indicated above in the first paragraph of this section.

III

Extraction as a Measure of Container Size,
Sections 180.22 and 181.32
(formerly 121.4010 and 121.2010)

With further respect to the proposed method of extraction testing, Sections 180.22 and 181.32 of the Proposal would require that AN concentrations be expressed in parts per million of the actual container contents. This proposed simplification of the present Interim Regulation is a desirable step to accommodate the Comments and Objections previously submitted by SPI in connection with the earlier rulemaking procedures on this matter.

Contrary to the essence of SPI's Objections, however, the Proposal still relates the extraction limitation to the contents of an actual container instead of relating

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it to resin or compound characteristics. As a result, it is not feasible for an AN resin or compound supplier to assure that his material will comply with the proposed requirements because he cannot know what size or shape container the food packager will employ.

This is not a new or unique problem. FDA has long dealt with this situation reasonably and consistently in its March 1976 "Guidelines for Chemistry and Technology Requirements of Indirect Food Additive Petitions." The Guidelines indicate at page 19 that "Generally, 10 grams of food is considered to be in contact with each square inch of surface." Reliance upon such a fixed relationship of volume of food to surface of container has made it possible in the past for FDA and the manufacturer to test a material and determine whether it complies with the required extraction limitation without regard to actual ultimate container size and shape.

It should also be noted that this standard ratio (approximately equivalent to an ordinary one pint container) is a reasonable basis for estimating total dietary exposure to a food additive. While it is true that the ratio of surface to volume would generally increase when a smaller container was used leading to a possible increase in concentration of the additive in the food, the smaller container inherently limits the quantity of food eaten and

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thus limits the total dietary intake. Similarly, the total dietary exposure of someone consuming large quantities of food in large containers is limited because the lower surface-to-volume ratio for larger containers reduces the possible maximum concentration of the additive in the food, thereby also limiting the total dietary intake.

Therefore, we recommend that the extraction limitation in the final AN Regulation be expressed as a concentration in the food-simulating solvent (or food) based on the assumption that 10 grams or cubic centimeters of food contact each square inch of interior package surface. This would make the AN Regulations consistent with other Food Additive Regulations as well as FDA's Guidelines and provide a feasible and enforceable requirement.

IV

Calculating AN Extraction for Repeated Use Articles, Section 180.22(c) (formerly 121.4010(c))

Some clarification is also needed with respect to proposed Section 180.22(c) relating to repeated use articles. The text as proposed states, "Where acrylonitrile copolymers represent only a minor component of a polymer system, calculations based on 100 percent migration of the acrylonitrile component may be substituted...." 42 Fed. Reg. 13565. We believe this is intended to mean 100 percent migration of any residual acrylonitrile monomer component, but the Proposal can readily

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be interpreted to mean that the calculation is to be based on the content of polymerized AN. This latter alternative clearly could not have been intended, so we request appropriate clarification.

It is suggested that the proposed language might be amended by substituting the words "residual acrylonitrile monomer" in sub-paragraph(c). The final Regulation would then read "...based on 100 percent migration of the residual acrylonitrile monomer...."

V

Additional Teratology Testing, Section 180.22
(formerly Section 121.4010)

Finally it is noted that proposed Section 180.22(e) would require that additional teratological testing be undertaken on AN. Since AN has already been demonstrated to be a teratogen with a specific threshold level for rats, many orders of magnitude above any possible dietary exposure, there is, in our view, no purpose to be served by a second test. Should another teratology test be conducted with a second species, AN would either be shown to be non-teratogenic for that animal or its teratogenic effect would be confirmed. If the second test does not confirm the rat study, FDA will prudently, undoubtedly deal with AN as a teratogen; if the second test confirms the first, nothing new will have been learned. Neither of these results, it seems to us, will

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change scientific knowledge to any extent commensurate with the cost. Accordingly, we would suggest that the proposed requirement of further teratogenic testing be deleted from the final Regulation.

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The foregoing premises considered, The Society of the Plastics Industry, Inc., recommends that the AN Regulations in question be amended as proposed after changes are made in keeping with the above comments.

Respectfully submitted,

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General Counsel for The
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