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Dictated November 13, 1967

To the Members of the SPI Food Packaging Materials Committee

Re: Food and Drug Administration Proposed Food Additives Procedural Regulations (32 Fed. Reg. 152, p. 11443

Gentlemen:

Enclosed herewith, for your general information, is (1) a copy of an acknowledgment letter we have received from Mr. Alan T. Spiher of the Food and Drug Administration relative to the SPI Comments filed on November 6, and (2) reproductions of Pages 13 through 24 of this week's issue of Food Chemical News. We obtained permission from Mr. Rothschild of Food Chemical News to send you the latter material as a means of giving you a general idea regarding most of the important Comments filed by other parties relative to the rule making.

We hope you will find this information of considerable interest. You may be assured that we shall be keeping in close touch with this situation as it develops and shall inform you whenever there is something of significance to report.

Cordially yours,

Jerome H. Heckman

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

November 8, 1967

Mr. Jerome H. Heckman
Keller and Heckman
1712 - N - Street, N. W.
Washington, D. C. 20036

Dear Mr. Heckman:

We have your Brief of November 6, 1967, addressed to the Hearing Clerk, commenting upon the proposed revision to the food additive procedural regulations published in the FEDERAL REGISTER of August 8, 1967 (32 F. R. 11443).

We appreciate your comments and will consider them along with others received in preparing a recommendation for final action in this matter.

Sincerely yours,

Alan T. Spiher, Jr.
Petitions Control Branch
Bureau of Science

The U.S. delegates to the Codex Committee meeting were FDA's Dr. O. Garth Fitzhugh and Agriculture Department's Dr. K. C. Walker. USDA's G. E. Hilbert was an observer and advisers to the U.S. delegates were Hercules' Dr. John P. Frawley, Shell's Dr. R. F. Glasser, and Dow's G. E. Lynn.

COMPLETE REVISION OF INDIRECT ADDITIVES SYSTEM URGED

As expected, the proposed revision by the Food and Drug Administration of its procedural food additive regulations has led to a challenge of the agency's whole system of handling clearances for indirect food additives, especially those that do not migrate to food (See FOOD CHEMICAL NEWS, Aug. 14, Page 3).

In a 69-page brief, the Society of the Plastics Industry urged that the procedural regulation proposals be held in abeyance while immediate action be taken to institute a new system of clearances for indirect additives. SPI asked that either a legislative hearing or an advisory committee "be instituted immediately."

The Society urged either a "public legislative type hearing before the Commissioner" or "an Industry-Government Advisory Committee . . . to study the administration of the Food Additives Amendment . . . as it relates to 'incidental additives,' and report back to the Commissioner with detailed findings and recommendations as promptly as possible . . ."

SPI said that "due process calls for nothing less than a full investigation of the root problems in Petition handling," urging a "reevaluation of basic substantive principles in light of the statutory mandate, with a view towards adopting a more sensible interpretation of what is reasonably expected to become a component of food . . ." Needs listed by SPI included:

> "(1) A much clearer definition of what needs to be regulated; (2) A sensible means for obtaining FDA concurrence on an informal basis that some materials simply do not require a formal regulation; (3) An understanding and taking into account of the commercial facts of life which make it impossible for manufacturers of components, as distinguished from finished packages or machines, to submit data which only the food processor or final package formulator could possibly have; and (4) A new regulatory scheme including but not limited to reasonable procedural regulations, which takes into account in some rational way the difference between regulations looking towards the coverage of components, and regulations covering end packaging or processing equipment products."

"In addition to conducting a basic reevaluation of the entire incidental additives regulatory plan," SPI said, "the FDA should promulgate regulations and adopt new procedures aimed at making its policies more effective and more widely understandable."

SPI added its endorsement to a proposal by Hercules' Dr. John P. Frawley, which would exempt from the administrative procedures all indirect additives - - except heavy metals and pesticides - - used at 0.2% or less in accordance with good manufacturing practice (See FOOD CHEMICAL NEWS, Oct. 30, Page 3). SPI said the Frawley proposal "can be adopted within the scope of FDA's broad rulemaking."

The Manufacturing Chemists Association also endorsed the Frawley proposal, urging "that the administrative policy be established and regulatory provision be made for rapid or automatic acceptance of food additives which are present in packaging material in small quantity." The Frawley proposal was also endorsed last week by the American Paper Institute, University of Miami's Dr. M. L. Keplinger, and Medical College of Virginia's Dr. A. M. Ambrose.

In addition to asking adoption of the Frawley proposal, SPI also asked provision for FDA advisory opinions on whether or not an incidental additive needs clearance. SPI urged new regulations or interpretations to "make it clear that any party may submit data about a substance intended to be used in a food package, or in food processing equipment, and may thereby obtain a direct and unequivocal response from FDA indicating whether or not it believes such a substance in the intended use described would constitute a food additive or not . . ."

Noting FDA fears that responses to such inquiries might be used for promotional purposes, SPI said that if FDA deems it necessary it can make it clear "that it is a violation of federal law to advertise that a product is 'FDA approved,' when, in fact, FDA does not approve products but merely advises on their status in light of applicable regulations."

FDA Urged to Make Public Advisory Opinions

Along with the advisory opinions practice, SPI urged that FDA adopt a procedure similar to that used by the Federal Trade Commission, "whereby the general public can be advised of advisory opinions or similar pronouncements which have a continuing and significant effect." FTC issues news releases disclosing such advisory opinions, but not identifying the parties who ask the interpretations.

SPI said, "Whatever formal process is used, such opinions or policy statements should be issued in a way that will permit ready reference and a degree of regulatory permanence."

The Society noted that in the first two years of administering the Food Additive Law, FDA did issue to firms, when requested, letters saying that since a substance showed no migration into food, it did not require clearance. In 1961, FDA stopped issuing these letters, presumably because of fears that such letters were being used in sales promotion. Early in 1962, FDA adopted the policy that "if there was enough reason to run extraction studies" on an indirect additive, the substance is automatically considered a "food additive," whether or not the extraction studies actually showed migration to food (See FOOD CHEMICAL NEWS, Jan. 22, 1962, Page 8).

Under this FDA position, SPI said, "anything in a food contact surface is a food additive . . . unless a producer evidences the ultimate in irresponsibility by refusing to test for possible migration." Noting that the 1962 policy switch was announced in speeches by FDA-ers, with no opportunity for comment by industry, SPI said: "No rulemaking proceeding was announced or instituted. No hearing was held. No public health or safety basis was even alleged to justify the institution of a new policy which has led to the filing of an immense number of Food Additive Petitions . . ."

The SPI brief, written by Washington Attorney Jerome H. Heckman, noted that regulation of indirect additives "has proven the most complex and the most time consuming activity" under the Food Additive Law. The Society said that "average processing time for handling indirect additive Petitions probably averages more than a year, whereas Petitions relating to direct additives are almost always handled to completion . . . within the 180-day statutory deadline." SPI continued:

> "We believe that the reason for the way in which the situation has developed to an almost hopeless state lies in the failure of the FDA to adhere to sound regulatory precepts with special emphasis on its obligation to carve out and distinguish in a practical way between those areas requiring close regulatory control, and those where excessive regulation serves no useful purpose."

SPI, charging that many Food Additive Orders "serve only to mislead the uninformed," gave the following examples of alleged defects under the current system:

"A great many of the regulations imply that the materials listed therein are the only ones suitable for the intended application, even where all or almost all of the ingredients in the regulation have been included on a 'no-migration anticipated' assumption. These 'laundry list' regulations imply that anything not included may not be safely used and practical experience proves that marketing unlisted products is impossible even with the strongest evidence that they may not be expected to become food components.

" x x x Many of the regulations contain extraction limitations which are in no way intended to be indicative of what is expected to become a component of food. These limitations are not 'tolerances' in the accepted sense, but, rather, are only intended to identify the substance being regulated so as to characterize it with a set of specifications. . . . the regulations should make it entirely clear that the specification approach was being used. Since the regulations . . . do not so indicate, however, foreign governments, as well as industry personnel here, have misunderstood the regulations as prescribing a sort of limit on the degree to which a packaging material will be allowed to 'contaminate' foods.

" x x x The regulations now include a vast number of prior-sanction, 'GRAS,' and otherwise exempt materials. . . . since 1960, the FDA has steadfastly refused to add to its prior sanction or GRAS listings, but has also refused to concur in 'non-additive' status on the basis of reasonable extraction criteria. . . , and has, instead, in effect insisted that anyone who requires an indication of some sort of FDA agreement about compliance with the law to sell his products obtain it by going through the tortuous Petition-regulation process.

" x x x The way in which the handling of Petitions has developed, with an increasingly unreasonable insistence on the most sophisticated type of scientific data to justify the issuance of a food additive regulation has, without question, led many small businessmen, and even larger ones, to forego any attempt to market perfectly safe products in the food packaging and food processing equipment areas."

Regarding the FDA proposals to revise the food additive procedural regulations (See following story), SPI said the proposals present "something of an enigma," since they "(1) presuppose the correctness of a number of underlying policies - - largely unwritten or at least uncodified - - which we deem questionable at best; (2) ignore the need for a number of substantive guidelines of far greater urgency than the need for paper size specification, and the like; and (3) look toward the imposition of ever increasing burdens on industry without any due regard for the relevance of such requirements to the public interest, much less that of industry or sound regulatory policy."

SPI expressed "sincere disappointment" in the FDA proposal because of "its basic superficiality and the fact that it in no sense bespeaks the agency's awareness of and responsiveness to the many indications it has received in the past year or two about the need for responsible and thorough reevaluation of the 'incidental additives' problem."

The FDA proposal "will continue to be wholly untimely until there is a careful reappraisal of some of the essential policies which now have such great and unfortunate impact on the food packaging material industries," SPI continued, saying: " . . . more detailed regulations to prescribe mandatory data and formalities for food additives should be delayed until the Administration has met the greater need in this field, i.e. that of adopting long overdue substantive regulations covering such matters as FDA's concept of its jurisdiction over packaging materials under the Food Additives Amendment . . ."

While the "status quo prevails," the brief said, "the Food Additive Regulations covering incidental additives can only become more and more meaningless, as th listings and divergence of regulatory criteria become increasingly profuse." SPI asked that the FDA proposal "be set aside or withdrawn until such time as the complete reevaluation called for has been undertaken."

The SPI comments were endorsed last week by Dow Chemical.

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FOOD ADDITIVE PROCEDURAL PROPOSALS' LACK OF CONFIDENTIALITY HIT

As the deadline arrived for comments on the Food and Drug Administration's proposed revision of the food additive procedural regulations (See FOOD CHEMICAL NEWS, Aug. 14, Page 3), a large number of industry groups and firms expressed concern over the lack of protection for "trade secrets" provided in the proposals (See FOOD CHEMICAL NEWS, Sept. 11, Page 2; Sept. 18, Page 12; Oct. 2, Page 10; Oct. 9, Page 14; Oct. 16, Page 3; and Nov. 6, Page 20).

Noting that the proposals would not consider analytical methodology and toxicological data as confidential, Upjohn wrote that, "As a plain fact, such information is a trade secret," and "in the absence of a compelling public need, publication of such data is clearly illegal."

The National Agricultural Chemicals Association said that "if a summary of the toxicological data submitted by a Petitioner is to be made available to others, the summary should be prepared jointly by FDA and the Petitioner or at least declared acceptable by the Petitioner."

Procter & Gamble said there is no reason to disclose methodology and toxicology to other persons than regulatory officials, saying, "If it is intended to permit qualified scientists outside the FDA to participate in the decision-making process with respect to the safety or control of food additives, we feel that the FDA is not fulfilling its responsibility." The firm said, "The responsibility for making a decision on the adequacy of safety data was given by the Congress to the Commissioner of the FDA - - and not to the scientific community at large."

The company said that if the information not to be held confidential "were to be made available to the public at large, Petitioners would undoubtedly experience greater difficulty in obtaining approval for new additives," and if it were to be made available "only to certain qualified individuals who have the need or right to know, we have difficulty understanding how the FDA would determine the need or right of the individual to know." P&G concluded:

> "If the purpose of the proposal is to permit the FDA to obtain the assistance of special scientific consultants in making decisions with respect to some food additives, we suggest that the FDA simply request permission from the Petitioners involved to disclose the information to the individuals from whom assistance is sought."

Noting a proposal that any method or process entitled to protection as a trade secret will not be revealed unless it is necessary to do so in a regulation or in a hearing, P&G proposed a requirement "that the Commissioner secure the prior agreement of the Petitioner to reveal matters that are normally regarded to be trade secrets, if, in the judgment of the Commissioner, this is the only way a meaningful regulation can be promulgated."

The Manufacturing Chemists Association suggested, in such cases, that if revelation of a trade secret is deemed necessary in a regulation, the Petitioner be given an opportunity to either approve of the regulation or "in the alternative" to "withdraw his Petition . . ."

MCA urged that lack of confidentiality be limited to analytical methods "which do not reveal confidential processing information and the general summary of the toxicological basis on which a food additive regulation is based," retaining confidentiality and trade secret protection for "detailed descriptions of toxicological studies and the raw data of such studies . . ."

Merck wrote that, "We have no objection to the release of the analytical methods employed in determining the tolerances or residues of a food additive in food, since this information is necessary for subsequent users to determine that their products meet the tolerances specified in the regulation and thus contributes to the protection of the consumer." However, the firm did object "to release of the toxicological basis on which a food additive regulation is promulgated."

The Animal Health Institute hit the proposal that methodology and toxicology not be considered confidential, saying, "It is for the courts to determine, by applying traditional concepts of law, what may or may not be a trade secret."

Parke, Davis questioned "how the alteration of the confidential treatment of information will aid in improving the quality, organization, and scientific review of Food Additive Petitions." "We would strenuously object to the public disclosure of any information which would form the basis for the approval of a Food Additive Petition, or an antibiotic or New Drug Application, and through which a manufacturer could avoid toxicological studies and the compilation of safety data."

The company asked FDA to clarify the meaning of a "summary of toxicological data." Noting that the new NDA Form 356-V, referred to in the proposals, is not yet available, Parke, Davis said "we have no way of knowing if a suitable means is provided for separating New Drug data from Food Additive data," adding that "confidential NDA data should not be placed in the food additive files." The company said non-confidentiality should be limited to "the analytical method or methods proposed by the Petitioner for regulatory control and the summary of toxicological data . . ."

Geigy wrote that all toxicological submissions should be considered confidential, saying, "a great burden is imposed in dividing submissions into confidential and unrestricted components." The Society for the Plastics Industry urged that non-confidentiality should be limited to "analytical methods relied upon for enforcement of regulations" and "Petitioner's conclusion as to" the toxicological basis for the Order.

Requirements for Processing Details Criticized

There were many complaints about the amount of data required in the proposals regarding manufacturing processes. Upjohn commented that "to limit the initial Petitioner to a particular method of manufacture is unfair . . ." NACA also said the requirements "exceed the statutory authority," explaining that Congress "intended that the Secretary should have the right to request information on manufacturing processes whenever there was some special need for such information."

NACA said "it was not intended that the Secretary could or would require manufacturing process information as part of every Petition," asking that the information be required only "upon a determination by the Secretary that there is need for that information in a specific instance."

The Association also said submission of specifications on raw materials would "serve very little purpose in most situations." NACA said "a chemical meeting the specification for the food additive should be acceptable, irrespective of the manufacturing process by which it was made," adding that such specifications should be requested only in specific instances where there is a specific need.

MCA urged that the processing data requirement be amended to require only a "brief description of manufacturing process(es) and a listing of raw materials and their specifications." The Association said "detailed processing information would serve no real purpose," adding that "once a Petition is approved and a food additive regulation is published any manufacturer may produce the additive using any manufacturing process known, so long as the food additive meets the product specification established in the applicable regulations and the manufacturer adheres to good manufacturing practices."

The letter from MCA said that processing information "should be required only in special situations and not as a matter of routine," and that "the description of specific analytical techniques" to check raw materials specifications "could be provided to FDA but certainly they should not be required as a routine matter."

Atlas Chemical Industries said the requirement for data on processing, specifications, reproducibility, and stability "are objectionable in that they do not exclude this type of data where this data is unnecessary," urging that the data be required only "when the chemical identity and composition is not known." Merck urged deletion of the requirements for detailed processing data, and AIII said that a requirement for revealing manufacturing methods in minute detail has no relationship to safety since subsequent producers do not have to provide this information.

SPI said that "even assuming such proprietary information regarding manufacturing processes is afforded the utmost confidentiality, requiring it is unnecessary and beyond the intent of the law," urging a requirement only for "a general description of the manufacturing process, including any relevant production controls employed to assure a reproducible product."

R quirements For Average and Maximum Amounts in Diet Hit

MCA hit requirements for giving average and maximum amounts of the additive in the daily diet, saying that these requirements are applicable only to direct additives. The Association said that indirect additives "do not lend themselves to meaningful estimates of either the average or the maximum levels that might be expected in the total daily diet." Because of FDA's 100-to-1 safety ratio, MCA said, there is no need for the requirements, adding:

> "In addition to the deletion of the requirement of an estimated quantity of daily consumption of an indirect additive, we urge that as to dir ct additives, a P titioner n ed only estimate the average quantity of the direct food additive to be expected in the total daily diet of the consumer. It should be realized that

an estimate of the average quantity will be a somewhat arbitrary figure, but an estimate of the maximum anticipated consumption will be even less meaningful."

Atlas Chemical Industries and AHI also urged that the requirement for an estimate of a maximum quantity of an additive in the daily diet be deleted, retaining the requirement for an average consumption figure. SPI said that "as regards incidental additives, even a finished package fabricator would be hard pressed to make any sort of guess as to how widely his package might be employed and for which foods, unless he is asking for exceptionally limited coverage for the use of his product." The Sooiety said, "The failure to distinguish between the different types of suppliers of products, and their consequent limitations in providing data, is a fatal defect in the conception of" the proposed requirement for a maximum quantity figure.

SPI noted it has challenged in the past FDA's requirement for data showing minimum level of an additive to accomplish the intended physical or technical effect. The Society urged FDA to clarify the proposal to require the minimum level necessary for the intended effect only where "(1) a true 'tolerance' is required for the substance in question to assure safety; (2) migration to foods is a function of additive concentration in a food contact surface; and (3) a minimization of the amount of the additive used in a food contact surface is necessary to stay within the in-foods tolerances prescribed." P&G also urged that data on the amount necessary to achieve the intended effect should be "required only in those cases where it is necessary to establish a tolerance for the use of the additive to assure its safety."

A number of letters hit the requirement that the Petitioner must identify the scientists who perform research noted in the Petition, other than the Petitioner himself. NACA said a Petitioner should not have to routinely give names and professional qualifications of all the scientists who participated in research. MCA wrote that the Petitioner should have to identify only the personnel who were "responsible for assuring accuracy and reliability" of the research.

Parke, Davis said it considers confidential "the list of investigators we have contracts with to conduct studies." Geigy said FDA's proposed requirement is "tantamount to setting up unauthorized standards for investigators and is unncessary." SPI suggested that the name of an outside laboratory could be given, without identifying the individual scientists.

A number of letters hit FDA's proposed requirement that Petitions be submitted on pages 8 x 10 1/2 inches, saying that only the Federal Government uses this size page, whereas the standard size in industry is 8 1/2 x 11 inches. The page size requirement was hit by Upjohn, NACA, P&G, MCA, Merck, AHI, Parke, Davis, Geigy, and SPI. The latter suggested an alternate provision that, "Data submitted or reproduced . . . shall be included in the Petition in such a way as to facilitate filing with all possible recognition and consideration for the fact that standard size files are employed by the FDA."

There were many objections to the proposal that reprints of scientific papers referred to in Petitions be included, with the objectors urging that photocopies be equally acceptable. This point was made by NACA, P&G, AHI, Parke, Davis, SPI, and MCA. The latter urged a provision that "in the event that the published material is readily available to FDA, references can be made to the publications in lieu of furnishing reprints or photocopies." SPI suggested that reprints or photocopies should not be necessary if the paper is in "recognized scientific or technical manuals (such as ASTM Standards publications)."

A number of letters hit the proposal that precludes reference to material in a food additive "master file" if it was submitted to FDA more than ten years prior to a current submission. The 10-year rule was hit by Upjohn, P&G, MCA, AHI, Parke, Davis, and SPI.

The broadness of FDA's proposed definition of "irradiation" was hit by AHI, Merck, and Upjohn.

Petitioner Opportunity to Review Order Urged

MCA and P&G proposed that a Petitioner should have the right to review a Food Additive Order before its publication in the Federal Register, if the Order differs from the clearance proposed in the Petition. P&G suggested that if the Order deviates from the proposal made in the Petition the Petitioner should be given ten days to consider the changes.

P&G hit the proposed requirement for data on representative "production" batches of the additive, saying that "it is frequently impossible to use production equipment for the manufacture of test batches of new additives," and that pilot plant equipment is normally used. The firm asked deletion of the term "production" preceding "batches," as did MCA. SPI asked that as an alternative to "production" batch data, a Petitioner be allowed to submit data on "available developmental or experimental samples . . ."

P&G and MCA hit the requirement for data on no-effect levels in "several species of test animals," asking that the words "several species" be deleted.

There were a number of objections to a requirement that data for veterinary drug products which are also "food additives" include a "practical chemical assay method." Upjohn, MCA, Merck, and AHI hit the requirement as ruling out physical and microbiological methods. FDA was urged to omit the word "chemical."

Noting references in the FDA proposal to a new NDA form 365V, Upjohn noted it is not currently available, and urged that the procedural regulations should either drop mention of the NDA form or be withdrawn until 365V is available.

Upjohn urged that instead of providing for simultaneous approval of NDAs and Food Additive Petitions, the "responsibility for approval of Food Additive Petitions and veterinary NDAs should be placed in on area of FDA so that Peti-

tions can effectively be considered simultaneously." The company recommended that the food additive procedural regulations should exempt "substances for which an NDA is also being filed."

Merck and AHI said that under current procedures an NDA or antibiotic proposal is also construed as a Food Additive Petition, but that the proposal is unclear on this point. The letter asked addition of a provision that an NDA will also be construed as a Food Additive Petition and that the food additive aspects of the NDA shall be processed simultaneously.

MCA raised a question on the notices of filings of Petitions for feed additives, as follows:

> "In the past, the agency has noticed human food additive proposals in the Federal Register on a broad general basis. . . . On the other hand, with respect to animal feed additive Petitions, the agency has set forth the proposal in great detail. It is suggested that human food additive proposals and animal food additive proposals should be treated equally, and both should be published in the Federal Register in general terms. Publication of the details of a proposal (prior to approval) is an invitation for purchasers to use the food additive (particularly in animal feeds) for a use which has been proposed but is not yet the subject of a regulation."

Upjohn said that FDA's definition of "food additive" is too "vague," adding that, "Because of FDA's failure to clarify the statutory definition by regulation, administrative practices have resulted in Food Additive Petitions being required for many substances clearly not falling within the statutory definition." The company said that if substances "may not reasonably be expected to become a component of food, the regulations should clarify the statutory definition by making it clear that Food Additive Petitions are not required for such substances."

Merck wrote that the proposals indicate that a drug is a "food additive" when it is added to feed, but a non-drug substance is a "food additive" when added to either feed or drinking water. "There does not appear to be any clear reason for this different treatment," the company said.

ACI hit the effects of the proposed regulation on indirect additives, noting that some Food Additive Orders define only basic substrates, some define basic substrates and list adjuvants, and some list classes of adjuvants that may be used on approved food contact surfaces. The proposed requirements, the firms said are "confusing and inapt in that they tend to treat the adjuvants for food contact surfaces in terms of the food contact surfaces." For example, Atlas said, a requirement for data from product batches of food contact surfaces would not be applicable to adjuvants.

Merck asked that the regulations be limited regarding indirect additives to substances in food-contact surfaces "the intended use of which results or may reasonably be expected to result in its becoming a component or otherwise affecting the characteristics of any food."

SPI - - which asked a complete reappraisal of the handling of incidental additives (See preceding story) - - said the definition of "indirect additive" in the proposed regulations "would not only include what the statute contemplates, i.e., those substances reasonably expected to become components of food, but also materials 'incidentally' present in a final package, regardless of whether such component might be expected to become a component of food."

The Society hit the proposed requirement for use data for indirect additives, saying that a Petitioner could not foresee all uses. SPI suggested the following provision:

"If transfer to food results or may be reasonably expected to result from the use of a food additive in processing, in packaging material, or in food processing equipment, the Petitioner shall describe the categories of use by listing the generic food categories, i.e., fruits, vegetables, meats, etc. to be packaged, as well as temperature limitations (e.g., maximum temperature at which package may be filled, stored, or cooled, and when a Petition is submitted by the manufacturer of the food contact surface, area and mil. thickness, including weight) of the film or other container such as a bottle or coating exposed to food in the minimum size package.

"The Petitioner shall furnish an estimate of the maximum as well as the average quantity of the food additive, and, where appropriate, its conversion products to be expected in the generic categories of foods for which coverage is sought. This estimate shall be based on experimental migration data using the food itself or on extraction data using solvents that simulate various types of food. These data will reflect the most severe conditions, as well as the more usual conditions of the proposed usage. The food or the extracts are to be analyzed by methods of adequate sensitivity and reliability for th food additive components of the food-contact surface. Details of the analytical procedure must be furnished including sufficient data to verify the claimed sensitivity and reliability of the methods."

SPI hit the requirement for data bearing on the molecular weight distribution in basic resins, saying, "For many materials there is no established method for determining molecular weight distribution and the realtively few techniques that have been developed for this purpose are not only complex but present difficulty as far as providing reproducible data is concerned."

The Society proposed instead that, "For polymeric substances, include the average molecular weight and the molecular weight distribution in the basic resin, where possible; otherwise submit data concerning other properties which provide indications of the nature and degree of resin extractibility with suitable explanations and the methodology used to make relative determinations."

MCA also asked deletion of the requirement for molecular weight distribution of polymeric substances, saying the methods are "generally complex and difficult t repr duc ."

In its letter to FDA, Upjohn hit a proposed requirement fixing the exact wording of the letter of transmittal of the Petition, asking that other pertinent information be permitted. The company objected to a provision that the Commissioner may request additional information in a Petition, saying that under law, "If the Commissioner feels that the Petition is lacking certain information . . . , he is to publish an Order denying the Petition and specifying the reasons."

Upjohn said the 90 and 180-day time limits for FDA consideration of Petitions "have been and are being ignored by FDA" urging the provision of "some administrative procedure . . . (to) provide relief for the Petitioners against undue delays."

P&G objected to a proposed requirement that a Petitioner demonstrate the fate of a food additive in foods, recommending "that Petitioners be asked to predict the fate of the additive in the food based upon what is known about the chemistry of the additive and the chemistry of the food system or systems in which it will be used." The company said many additives are cleared for a wide range of foods "and it would be an insurmountable. . . task to demonstrate their fate under the conceivable conditions of use." P&G added that "the identification of the additive and the results of the biological studies demonstrating the safety of the additive under the conditions of intended use would seem to preclude the need for this proposal."

A requirement that notices of filing of Petitions include the name and address of the Petitioner was also hit by P&G as "an unnecessary and premature disclosure of manufacturer's interest in a new product development."

MCA urged that a food additive "master file" be also applicable to proposals involving foods, drugs, colors, and pesticides. The Association hit the provision that if required samples are not submitted within 180 days of the filing of the P tition it is deemed withdrawn, suggesting that FDA requests for additional data or samples be made within 45 days of filing, or at the most 90 days. MCA said, "The Petitioner should not be penalized by withdrawal of Petition when, in fact, notice in advance of 180 days is not adequate to fill request."

Merck urged that the proposals exempt from the food additive regulations any pesticide chemical added to a feed if it is "generally recognized as safe and effective when used for such purpose."

The comments by MCA, which requested a public hearing on the proposed procedural regulations, were endorsed last week by Dow Chemical and by Atlas Chemical Industries.

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HOUSE VOTES UNANIMOUS APPROVAL TO AHI BILL

The House last week voted 317-to-0 to send the Animal Health Institute's legislation (HR 3639) to the Senate, as expected (See FOOD CHEMICAL NEWS, Nov. 6, Page 2).