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February 19, 1968

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To the Members of the SPI Food Packaging Materials Committee

Re: National Conference on Indirect Food Additives

Gentlemen:

As a convenient way of providing those of you who were not in attendance at the above-referenced Conference with something of a report on developments, we have obtained permission to reproduce, and are herewith enclosing Pages 3 through 15 of this week's issue of Food Chemical News. The Editor of the publication, Mr. Louis Rothschild, has indicated to us that he expects to give the sessions some further coverage in his next issue but the enclosed should serve to provide you with an indication of the thrust of the sessions, at least for the time being.

According to other information we have received, copies of the verbatim transcript of the Conference will be available from the reporting company by Tuesday of this week. Those of you who wish to do so may obtain copies of the transcript by writing to the reporting company at the following address:

Ace - Federal Reporters, Inc.
415 Second Street, N. E.
Washington, D. C. 20002

Incidentally, the cost for the transcript will be 17¢ per page and we understand that the total charges should be somewhere between $40 and $60. Many of you might find it most worthwhile to have all of the material since, if nothing else, it could prove helpful to you

in explaining various characteristics of the food additive regulatory scheme to your own associates, as well as to customers.

As far as follow-up work is concerned, during the next week I will be with George Ingle at the SPI Board of Directors meeting where we believe we shall have some opportunity to review the entire situation, and consider ways in which the momentum for reform so clearly evident during the Conference may perhaps be maintained. At the same time, we shall be discussing plans for our next SPI Food Packaging Materials Committee meeting so I am sure that I will be in touch with you again in these connections fairly soon. Meanwhile, we think it is fair to say that there is already some impetus for the Food and Drug Administration to take affirmative action, at least to the extent of responding to an inter-industry letter forwarded to Dr. Goddard on February 9, 1968. For your further information in this connection, a copy of this important letter is also enclosed herewith.

Cordially yours,

Jerome H. Stockman

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FOOD CHEMICAL NEWS

Editors: Louis Rothschild, Jr.; Raymond Galant
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February 19, 1968

FDA AGREES TO CONSIDER FRAWLEY PROPOSAL ON INDIRECT ADDITIVES WITH OBVIOUS RELUCTANCE; "MIDDLE GROUND" SUGGESTED AT MEETING

Spokesmen for the Food and Drug Administration sharply challenged a proposal by Hercules' Dr. John P. Frawley to exempt most packaging materials from food additive administrative procedures at last week's indirect additives conference held by the agency in Washington (See FOOD CHEMICAL NEWS, Jan. 22, Page 21; Feb. 5, Page 16; and Feb. 5, Page 18).

Frawley has formally proposed that indirect additives - - except for heavy metals and pesticides - - be excluded from the Petitioning requirement if they are used at 0.2% or less of a formulation in accordance with good manufacturing practice. There has been a great deal of interest in his proposal.

FDA statements at the Feb. 13-14 meeting were the first formal response to the Frawley proposal. Dr. W H. Summerson, director of FDA's Bureau of Science, said he would not "dispute directly" with Frawley, but said his paper was a "justification" of FDA's policy. Actually, it was difficult to interpret the Summerson presentation as other than a rejection of the Frawley proposal.

However, FDA-ers seemed to modify their stance during the meeting and they made it clear at the end that the Frawley proposal will receive consideration. There were even suggestions on both the part of industry and FDA of seeking a "middle ground" position between that of the agency and that represented by Frawley's proposal.

FDA-ers Speak of Changes, but Resist Industry Proposals

Despite promises by FDA-ers, including Commissioner Goddard, that the conference was directed towards changes in the handling of indirect additives, Summerson and L. L. Ramsey, Assistant Bureau of Science Director for Regulatory Programs, seemed reluctant to grant that either of two major industry proposals had any merit.

There was industrial unanimity on either the Frawley proposal or some variation of it, and on the desirability of forming an FDA-Industry Advisory Committee to work on the overall problems of indirect additives. Regarding the committee, Summerson again appeared reluctant to consider such a step, but ultimately gave qualified approval to the recommendation (See following story).

Industry representatives at the meeting, generally, were aware that the conference had been inspired by pressure from a House Small Business subcommittee. The calling of the meeting enabled FDA to tell the subcommittee that it was "doing something" with regard to indirect additives. This circumstance, plus the apparent resistance of the FDA-ers to the industry suggestions, left many industry representatives extremely skeptical at the end of the day and a half meeting.

The possibility of a "middle ground" solution to the "significant" migration problem was raised after Ramsey, in his paper, said:

> "Before beginning the extractability studies for a minor component of a food contact surface, one is well advised to make a computation of the amount which might be added to food if it all migrated. If such computation showed that no more than 0.01 p.p.m. of the substance could possibly be added to the food, the extracts usually need not be tested for such substance. The acceptability of the sensitivity level achieved in any analysis to show the likely level of migration depends upon the toxicity of the substance. It has never been the intention of FDA to require, and we do not now require, the industry to pursue an analytical showing of the level of migration any lower than considerations of safety demand. Thus, the sensitivity of an analytical method deemed satisfactory for showing the level of possible migration into food may range all the way from 1 or 2 p.p.b. to several p.p.m."

Summerson explained that, "If the amount expected in any food is equivalent of 0.01 p.p.m. or less, we consider it 'virtual lack of migration' and request only an LD_{50} on the chemical." He said if the amount ranges between 0.01 p.p.m. and 3 p.p.m. the agency requests 90-day toxicity studies on two species of animals. For extractives over 3 p.p.m., Summerson said, the agency requests long-term feeding studies. He pointed out that there have been some exceptions to these rules.

Under questioning, Summerson said there is a "soundness of certain portions of Dr. Frawley's thesis," conceding that there is some "unjustifiable expense" for testing. Asked whether FDA will provide a "documented commentary" on the Frawley proposal, Summerson replied: "Undoubtedly."

Noting Frawley's position and current FDA policy, Summerson said, "Somewhere in between will be a position that both Dr. Frawley and FDA can live with."

Frawley noted that FDA "is willing to accept 0.01 p.p.m." without toxicological work, noting that he has proposed a level of 0.1 p.p.m. without studies. It is "just a matter of degree," he commented. Noting that FDA, at low levels, requires just an LD_{50}, he said this "doesn't tell you a thing." Frawley urged FDA and industry to find a "middle ground."

Saying that Frawley's proposal will be seriously considered, Summerson - - who denied that testing over the past 10 years has represented a waste of time and money - - said he would like to be able to permit the avoidance of some toxicological work. "This is what we're trying to shoot for," he added.

Fred J. Delmore, director of FDA's Bureau of Voluntary Compliance, said he does not feel that FDA and industry views "are too far apart." Jerome H. Heckman, representing the Society of the Plastics Industry, said a "middle ground" approach seems "a good place to start."

Frawley Proposal Praised for "Soundness," Hit as "Sheer Nonsense"

Despite Summerson's concession that there is "soundness" in part of Frawley's proposal, the FDA-er said much of what Frawley proposed for a "single cut-off place" is "sheer nonsense."

Summerson's paper, which dealt almost solely with the Frawley proposal, said, in part:

> "Unless premarketing clearance is practiced, the only method of detecting harmful effects is retrospective with respect to exposure to the suspected agent. The latent or 'incubation' period from the time a chemical agent is first applied to the human being until the time that cancer occurs is often 10 years or more. This means that one may have to wait a number of years before results of an exposure may even be detected. It is obvious, therefore, that after the 10 year period, with changing food habits, additives and packaging, it is well nigh impossible to isolate an additive as the original causative agent of a cancer. Thus, if we are to give the consumer the protection he expects and demands, we must require premarket testing.
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> "This seems obvious when we describe it this way, but even today we have offered to us a statement to the effect that the proponent feels no food additive clearance is necessary because he has no knowledge of any bad effects from his product.
>
> " x x x unless a relatively acute poison is involved an effect is not likely to be routinely traced to a causative agent in food or packaging."

Summerson said that unless a component is "generally recognized as safe" or has a prior sanction, "it seems reasonable to expect that research must be done to establish whether or not any component of the packaging material will get into the food." He added, "If the answer to the question is 'yes,' then the research should show how much may get in and whether this amount is safe for the people who may eat the food." He continued:

> "Certainly if there is no reasonable expectation of migration or if the amount of migration is 'insignificant' there is no need for animal feeding data. On the other hand, does the toxicity data to date indicate that there is need for toxicity testing on the food packaging chemicals which do migrate? Can we assume that any component of a food container that does not exceed a certain amount, say 0.2%, will always give an insignificant amount (less than 0.1 p.p.m.) in the total diet and therefore be safe? If we eliminate the pesticides, heavy metals, and carcinogens . . ., this generalization has considerable appeal and some reliability on the basis of 'published' toxicity data.
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> "This generalization does not take into consideration whole meals in packaged materials, the use of an ingredient in more than one class of packaging material, and the additive effect of similar ingredients. Nor does it account for the food faddists or other individuals with unusual food preferences who choose such unbalanced diets which would contain a disproportionate amount of a migrating compound from packaging material. Add to these the probability that thick containers, such as plastic bottles, contribute far more to the food than plastic coating of a few mils thickness of the same substance."

Summerson said that, "Long-term feeding studies as reported in the literature may not be representative of the total scientific knowledge on all possible and useful food packaging chemicals."

The FDA-er said that some plasticizers extract in fatty foods at 100 p.p.m. or more in the total diet. Those in common use have low toxicity, he said, but FDA has had requests for use of triorthocresyl phosphate and others could also be toxic. He noted that tight restrictions are placed on certain monomers, such as acrylamide. "Certainly they are used at safe levels," Summerson said, "but without any regulation, would this be true?"

He said there is increasing concern about sensitizing chemicals, giving as examples toluene diisocyanate and certain epoxy curing agents. "We have objected to the use of these compounds even at levels below 0.2% of the formulation," Summerson added. He also said it has been necessary to restrict monomer content and low molecular weight functions for alkylphenolethylene oxide condensate type emulsifiers. Summerson concluded:

> ". . . with the ever increasing use of food packaging, more and more segments of our population are exposed to greater amounts of packaging chemicals. Some, including babies, may have their entire diet exposed to food packaging chemicals. Therefore, I believe . . . that industry and FDA must know the relative safety of each migrant."

Asked whether there is any evidence of migration of packaging components greater than those presented by Frawley, Summerson said he does not know. Frawley said there is, but that most substances do not. Asked whether there have been any two-year feeding studies that did not gibe with Frawley's, Summerson said there are "plenty" of them, but not necessarily on known packaging components. Frawley said he concluded that except for pesticides and heavy metals, no packaging materials are toxic at 40 p.p.m. or less. FDA's Dr. Joseph McLaughlin, Jr., disagreed, pointing to acrylonitrile.

Summerson said that Frawley's sources "bias the data," since highly-toxic substances are not found in two-year studies, because the animals do not survive for two years. He said some proposed additives never get to the two-year testing stage. Frawley responded that because of a possible bias in the data, he added an additional safety factor of ten.

FDA cannot set a "floor" simply because no problem has become apparent, Summerson added.

Ramsey asked the industry representatives to put themselves in the place of FDA-ers, asking: " . . . how would you exercise control? Would you take your own advice and say we have gone much too far?"

He noted that the "world climate of toxicological opinion is extremely conservative," saying that there is concern about "microinsults."

Dr. Norton Nelson, of the New York University Medical Center, agreed that "some simplification is required," but warned against "over-simplification." He said "any single set of concentration limits" are not likely to be found. Nelson said a cut-off point might work well for well-understood classes of materials, but might not be adequate for others. He said he does not see how FDA could "permit itself to become restricted" from dealing with new compounds "in a rational way."

Frawley noted the scientific support his proposal has received, particularly in comments to FDA on its proposed food additive procedural regulations. Noting that he made his proposal about 18 months ago, Frawley said, " . . . I have yet to hear of a single commercial chemical which might be used in food packaging which would be an exception."

"This proposal has received overwhelming support from my profession," the toxicologist said, explaining that "24 other toxicologists from universities and industries have supported this proposal in writing to the FDA" and "almost as many others have privately supported it." Stressing his finding that 0.1 p.p.m. should be the cut-off point for toxicological significance, Frawley said, "I believe the body of scientific fact and opinion justifies immediate adoption of this concept by FDA."

"Several lawyers have advised me that this support from the scientific community of and by itself confirms that these uses are generally recognized as

safe . . . and that no action on the part of the FDA is necessary," Frawley said, adding, "I will not enter into a legal debate on this premise, but I think the evidence is clear that uses at or below this level of 0.2% offer no significant hazard to health . . ."

Frawley's original proposal was based on the premise that migration at 0.2% or below will contribute migrants at the pharmacologically insignificant level of 0.1 p.p.m. or less. He expanded the proposal last week to add that "major components which can be shown by suitable migration studies to contribute no more than 0.1 p.p.m. to the diet should be considered nonmigratory." He explained:

> "One additional guideline is needed to help prevent the continued waste of effort and that is a level of migration for components used at levels above 0.2% which also can be considered safe without toxicological studies. We frequently refer to this type of component as 'nonmigratory.' It is a logical extension of my previous proposal that we adopt the same level of 0.1 p.p.m. as a level of no significant migration. If a use of a major component can be confirmed by suitable analytical studies to contribute no more than 0.1 p.p.m., it should also be considered safe."

Frawley said that his 0.2% dividing line "is unduly restrictive for most uses of packaging components," explaining that "many materials used at higher levels in less permeable substrates than paper will contribute less than 0.1 p.p.m." He said a "more limited study" of migration to food conducted with a radioactive plasticizer used at 28% in polyvinyl chloride film suggested that "a 0.6% level of an additive in plastics will contribute no more than 0.1 p.p.m. to the diet." Frawley added, "The data are insufficient for me to propose the adoption of this dividing line for plastics, but they clearly confirm that paper and rosin size are a suitable choice as the extreme example of migration to food." He suggested that, "Perhaps some carefully directed research will permit establishing other dividing lines in the future."

The Hercules scientist based his proposal on two-year chronic toxicity tests on 245 different substances, which he said constituted 90% of all such studies. For all but pesticides and heavy metals, he said, "every compound was without toxic effect in experimental animals when fed for a lifetime at a dietary concentration of 40 p.p.m." Applying a 100-fold safety margin, Frawley found that every compound which has been studied is safe for man at a total dietary concentration of 1 p.p.m." Because of possible bias in the cross-section of studies, Frawley proposed "that we protect ourselves by adding another factor of ten and adopt 0.1 p.p.m. as a level of toxicological insignificance for all materials other than pesticides and heavy metals."

". . . a compound which would be toxic to man at 0.1 p.p.m. would have revealed its extremely high toxicity in . . . (industrial) exposures and it would have been rejected as incompatible for the food packaging industry," Frawley said. He added that carcinogens are automatically barred under the Food Additive Law.

Frawley said he studied paper coated with rosin size for extraction, and that the studies demonstrated "that at a level of 1.0% the maximum dietary contribution will be 0.5 p.p.m., and at a level of use of 0.2% an insignificant amount of not more than 0.1 p.p.m. will be contributed to the diet."

Heckman urged that an FDA-industry advisory committee consider the questions: "Is there any possibility that 'regulatory' as distinguished from more absolute, analytical techniques could be prescribed to set a practical standard for what packaging material components must be regulated in the present sense? Can this at least be done for broad categories of substances, leaving the others for more concentrated scientific and regulatory attention?"

Stein, Hall's Max Goldfrank, representing the Adhesives Manufacturers Association, endorsed the Frawley proposal and said, "If this doctrine is sound for food-contact materials, as I believe it is, then it is even more valid for adhesives components where there is substantially no chance of migration."

1 P.P.M. Migration to Food or Solvents Suggested as Cut-off Point

Mobil Chemical's E. W. Erhardt and Continental Can's Dr. Robert Henry, representing the Can Manufacturers Institute, recommended that the cut-off point for toxicological insignificance be 1 p.p.m. migrants in food or food-simulating solvent. Erhardt said this would be of the same "order of magnitude" as Frawley's proposed cut-off point of 0.1 p.p.m. in the total diet.

Henry said, "The hundreds of extractability studies that have been performed in the past 15 years have established the level of potential migration that has proven to be without hazard," adding that, "Before 1960 extractives of 1 p.p.m. or less in accepted food-simulating solvents were considered by the FDA as satisfactory evidence of safety in virtually all instances." He said that "none of the substances so cleared has presented any health problems."

He urged that substances, except heavy metals, used in can manufacture which migrate 1 p.p.m. or less in solvents be considered "generally recognized as safe." Henry also recommended that there should be a mechanism within FDA "whereby a letter of concurrence with our conclusions can be obtained for those customers who demand 'something from FDA.'"

Market Basket Surveys of Residues Urged

Monsanto's George W. Ingle, representing the Society of the Plastics Industry, said "what is needed is . . . to add the explicit phrase 'of toxicological significance' to the statutory definition of food additive." Such legislation, he said, would "provide the conceptual basis for determining the requirements for Petitioning and regulating these chemical compounds and uses within limits for which it can be agreed that there is no toxicological significance."

Saying there is a need to reliably correlate extraction figures with levels actually in the diet, Ingle urged that FDA's market basket surveys of pesticide residues be expanded "to include carefully selected indirect additives in estab-

lished uses." He said other "simplifying improvements" could go forward, and that the market basket analysis "should be considered as a continuing long-term monitoring . . ." From the resulting "representative levels," Ingle said, "order-of-magnitude categories could be established for many other additives, if initial results justified."

Ingle said that levels of migrants actually found in the total diet could be compared "with those concentrations found to have detectable effects in . . . animal feeding studies," and that "this comparison would indicate where these human dietary levels lie on the scale of toxicological significance." He suggested that this work be handled by a government-industry-university panel.

Noting Frawley's data on insignificant levels for paper containers, Ingle said the approach he suggested could extend to other substrates. The data, he said "would develop validated perspective as to which are toxicologically unimportant sources of food additives" and "should end present confusion between chemical compounds actually added to the food packaging material, and the specified chemical compound, frequently an impurity or derivative, which alone may migrate to food."

Ingle concluded that, " . . . we could adopt the Frawley proposal and other logical extensions of it to intelligently omit broad uses of chemical compounds in packaging and other food contact material from the requirement for regulation."

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FDA-INDUSTRY INDIRECT ADDITIVES ADVISORY COMMITTEE URGED

Formation of a Food and Drug Administration-industry advisory committee to tackle the problems of indirect additives was urged by virtually all industry speakers at last week's FDA-sponsored conference on indirect additives in Washington and in an industry letter to FDA Commissioner Goddard.

The suggestions for an advisory committee met the same kind of reluctance from FDA spokesmen at the meeting that greeted proposals to exempt some packaging materials from Petition requirements (See preceding story). Eventually, agency spokesmen said they would both consider the proposal for exemptions for some indirect additives and that they will relay the advisory committee recommendation to the Commissioner's Office.

With interest in indirect additives being shown by a House Small Business subcommittee, it appears that FDA may have to at least make the gesture of forming an agency-industry committee to demonstrate good faith.

After initially expressing great doubt about an advisory committee, because of conflict-of-interest considerations, Dr. William H. Summerson, director of FDA's Bureau of Science, agreed to support the advisory committee recommendation "to the extent it is feasible . . ." He said he had intended to express no objection to the formation of such a committee, but was only questioning implementation of it. Summerson said he will ask Goddard to consider the proposal.

Summerson's qualified approval of the advisory committee idea came shortly after Jerome H. Heckman, general counsel for the Society of the Plastics Industry, accused FDA of "negativism." ". . . the only thing we have to fear is FDA's fear," Heckman commented.

An industry spokesman from the floor reflected the feeling that industry had been allowed to come to the meeting and let off steam, but that the decisions "had been made" by FDA in advance.

At the end of the first day of the meeting, Summerson asked industry to think over the proposal for an advisory committee, asking, "How can it work out?" He expressed concern about "conflict of interest" because the committee would be made up of both the regulators and the regulated.

The next morning, conceding the existence of an 1962 Executive Order signed by President Kennedy and authorizing advisory committees, Summerson stressed that the Executive Order had emphasized freedom from conflict of interest. He said he was involved with the use of advisory committees when he was at the Army's Edgewood Arsenal, and that advisory committees there were never effective because of "conflict of interest."

Summerson said that FDA does use advisory groups, but he said they may deal only with technical points, since policy decisions must be made by the agency. Industry spokesmen agreed that all decisions would have to be made by FDA's front office.

However, the FDA-er said the concept of an industry-government group advising what regulation of indirect additives should be like is "untenable." "We couldn't get away with it if we wanted to," he commented. Summerson also expressed the opinion that if there were such a committee - - limited to "technical points" - - conflict of interest considerations would dictate that if a problem in the plastics industry, for example, were discussed, the representative of that industry would have to leave the room during the discussion and could not read the minutes.

Summerson's suggestion that any such committee should have representatives of consumers on it, as well as government and industry representatives, was readily accepted by industry spokesmen at the conference.

The FDA scientist added that "it depends upon the emotional climate at the time" whether an advisory committee could be formed and how successful it would be.

Heckman said that an advisory committee is clearly authorized by the Executive Order, with FDA appointing a chairman, organizing the committee, and setting up safeguards. He said this has been done by the Federal Communications Commission. Heckman added that conflict of interest is a matter for lawyers to discuss. B. F. Goodrich's William C. Becker, representing the Rubber Manufacturers Association, said there is no question of conflict of interest since industry and FDA have a "common . . . interest in the consumer."

Humble Oil and Refining's Dr. George W. Fiero, representing the American Petroleum Institute, noted that the War Production Board during World War II, of which he was a member, found industry advisory committee meetings "very valuable." Sun Oil's Dr. W. Wayne Stewart, also representing API, said the Health, Education and Welfare Department's air pollution control group has an industry advisory committee, stressing it is not a "liaison committee." Stewart said, "There are and can be formed advisory groups to regulatory agencies," adding that these can be used for development of "criteria" but not for "standards."

New York University's Dr. Norton Nelson expressed the view that there would be no conflict of interest, since differing interests should be represented.

Fred J. Delmore, director of FDA's Bureau of Voluntary Compliance, said he could not "authorize an advisory committee," but that BVC can offer a procedure for setting up an "industry liaison committee." He said there is precedent for this. If industry should set up a liaison committee, Delmore said, BVC would "welcome it." He requested any such committee to tell him what areas are to be discussed, and said he will then set up meetings. Delmore noted that an industry liaison committee has developed specific "good manufacturing practice" guidelines for a portion of the food industry and that these may eventually become regulations (See story, Page 24).

The letter sent to Goddard, which noted the existence of Executive Order 11007, said the indirect additive conference "cannot take the place of a round table discussion between your scientists and administrators and their industry counterparts." The letter, signed by American Paper Institute President Edwin A. Locke, Jr., was on behalf of the Adhesives Manufacturers Association, American Paper Institute, American Petroleum Institute, Can Manufacturers Association, Rubber Manufacturers Association, Soap & Detergents Association, and Society of the Plastics Industry.

Heckman stated the case for an advisory committee at the conference, in part as follows:

> ". . . the presently used regulatory approaches are so inconsistent, so complex, and so virtually incomprehensible to most of those in the regulated industry that anything short of an in-depth reevaluation of the entire situation under circumstances which allow for careful analysis, and the development of detailed, comprehensive recommendations, cannot bring about the type of reform so urgently needed.
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> ". . . unless this Conference is viewed as nothing more than an organizational meeting, or an exercise in problem identification, it could lead to superficial treatment of the subject matter which might do more harm than good."

He recommended "that there be a government-industry cooperative effort employing working committee techniques to analyze as many of the problems as can be identified, and to develop carefully considered recommended solutions for these problems on a joint basis, rather than through ex parte presentations of the type being made here."

FDA-ERS DENY CHANGE IN POLICY ON NO-EXTRACTIVE ADDITIVES

Food and Drug Administration representatives at last week's conference on indirect additives in Washington denied that there had been any change in policy towards indirect food additives for which tests show no extraction.

The agency has held since 1960 that if a manufacturer runs extraction tests on a packaging material and concludes the substance is not a "food additive" the firm may take no further action unless it desires FDA concurrence. When data showing the lack of extraction is presented to FDA, the agency holds that a Food Additive Petition must be filed on the theory that the running of extraction tests presupposes the possibility of migration into food.

An FDA staff paper sent to the House Small Business Regulatory subcommittee last month indicated that this policy had been changed (See FOOD CHEMICAL NEWS, Jan. 22, Page 21). The agency wrote: "Where FDA's review of the proferred extraction studies confirms a lack of potential migration, no regulation is necessary."

FDA-ers indicated to FOOD CHEMICAL NEWS that the staff paper did in fact confirm a policy change which had taken place about a year and a half before, and that in some cases where the agency had confirmed lack of migration no Petitions were required (See FOOD CHEMICAL NEWS, Feb. 5, Page 16).

However, FDA spokesmen at the conference last week said that there has been no change in the policy, although they conceded that in some cases no Petition is required.

It is apparent that there is a grey area here, and the number of substances allowed to be marketed without clearance under a Food Additive Order has varied over the years. FDA-ers told FOOD CHEMICAL NEWS that it is a matter of "interpretation" rather than a matter of "policy." It is believed that the "interpretation" changed, at least for a while, and that FDA did give concurrence to no-migration findings in at least a few cases.

Policy May Be Reappraised by FDA

However, the policy of not giving such concurrence in most cases is still in effect. FDA-ers indicated that this policy might be reappraised as a result of last week's conference.

When asked whether there was a change in policy, L. L. Ramsey, Assistant Director of FDA's Bureau of Science for Regulatory Programs, said that if there was a policy change "I am not aware of it." "I don't know of any policy change," he added. He said that a manufacturer has the responsibility of deciding whether a substance is a "food additive" "on his own."

Asked whether FDA would confirm a finding of no extractives, as it did in 1959 and 1960, Ramsey pointed out that since 1960 the policy has been not to send a letter of concurrence. The agency has stated, he explained, that if concurrence was needed, it would have to be via a Food Additive Order.

Ramsey conceded that there have been exceptions. He pointed out that it was decided not to require clearance for catalysts, unless a firm desired clearance and filed a Petition. He also said that in some cases, where the potential for migration is "nil," FDA has said a substance is not a "food additive" without migration studies.

Dr. William H. Summerson, director of the Bureau of Science, added that "food manufacturers can decide for themselves that a substance is not a food additive because of its lack of migration to food." However, he said that "industry has taken the position that they need FDA's concurrence and usually presents the extraction data with a formal request for an opinion or a regulation." Summerson said that "usually this request requires concomitant toxicity data to show safety."

The FDA scientist said, "Eventually requests for regulations through the Petition method became the approach of industry for every substance which had even a remote possibility of migrating into food."

Advisory Opinions Urged

Jerome H. Heckman, general counsel for the Society of the Plastics Industry, asked that an advisory committee (See preceding story) consider the questions: "Is it not possible to enunciate better, more selective ground-rules on when Petitions are really required, and what they should contain, by use of codified FDA rulings in specific cases, and/or the issuance of Advisory Opinions which would help build a coherent, understandable, and carefully rationalized body of law in these areas?"

B. F. Goodrich's William C. Becker, representing the Rubber Manufacturers Association, said, "I recognize the difficulty that the FDA has in rendering advisory opinions, but I would suggest that it is terribly difficult for industry seeking to abide by the law to be told that it must make its own decision as to the law's applicability in very difficult areas with the risk of seizure or prosecution if that decision is incorrect."

Monsanto's George W. Ingle, representing the Society for the Plastics Industry, expressed concern "with FDA's interpretation that the act of testing for extraction is, in itself, proof that migration of an indirect additive was reasonably expected." He called "this interpretation . . . totally unwarranted," asking that "quantitatively sound policy . . . be established."

Stein, Hall's Max Goldfrank, representing the Adhesives Manufacturers Association, recalled that during hearings on the Food Additive Law, Rep. Dingell (D-Mich.) asked, ". . . would it be possible to obtain a statement from FDA upon presentation of adequate facts to justify a conclusion that an adhesive is or is not a food additive, without going through the procedure . . . for filing a Petition and getting it acted upon?" Goldfrank said that former FDA Deputy Commissioner John L. Harvey wrote in response: "It is our view that under the revised bill we would have authority to give advice of this type and it would be our intent to do so." Goldfrank commented that, "So far as I know, to this day FDA has consistently refused to use this authority."

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COMMERCE PUTS HEAT ON INDUSTRY TO STANDARDIZE PACKAGE SIZES

The Department of Commerce has begun to put the heat on industry to develop voluntary standards of package sizes, and has bypassed the traditional route through Washington's trade associations to high level company executives directly.

A half dozen meetings had been held with company presidents and board chairmen in Washington, New York, and Chicago by last week, and others have been scheduled.

Malcolm Jensen, who is director of Commerce's Office of Weights and Measures and also manager of Engineering Standards, was heading up a whirlwind of activity aimed at getting industry cooperation with the Department's National Bureau of Standards.

Commerce has been given responsibility under the Fair Packaging and Labeling Act to determine whether the number of containers in which any given commodity is packaged has proliferated to the extent that consumers cannot make effective comparisons and value judgments.

Commerce issued regulations on how it would determine "undue proliferation," but has made no such citations, as they are called (See FOOD CHEMICAL NEWS, July 31, Page 18).

A proposed revision of its product standardization rules has been sharply criticized by industry (See FOOD CHEMICAL NEWS, Nov. 20, Page 8).

Commerce Release Cites Progress in Instant Coffee, Salad Oils

However, a press release issued Feb. 16 by Acting Secretary Howard J. Samuels claimed credit for actions by two groups of food producers who he said "are voluntarily reducing the number of containers in which their products are packaged for retail sale."

Some 50 other groups are in various stages of study in the Department, he continued, "aimed at similar reductions."

NLM

American Paper Institute

Office of the president

260 MADISON AVENUE, NEW YORK, N. Y. 10016 (212) 889-6200

(7)

February 9, 1968

Dr. James L. Goddard, Commissioner
Food and Drug Administration
Department of Health, Education,
and Welfare
200 C Street, S.W.
Washington, D.C. 20204

Dear Dr. Goddard:

The industry groups named below welcome your review of the approach to "indirect food additives" (packaging materials, machinery lubricants, etc.) under the Federal Food, Drug and Cosmetic Act and the Conference which you have called for February 13 and 14 at which they and others will have an opportunity to express views. They have requested and authorized me to write you in their behalf.

They believe you will agree that however valuable the Conference will be, it cannot take the place of round table discussion between your scientists and administrators and their industry counterparts.

These organizations, which we believe represent the industries filing most of the indirect additives petitions, respectfully suggest that soon after the conclusion of the Conference an "Industry-Government Advisory Committee" be

created along the lines envisaged by Executive Order Number 11007 and in accordance with that Order. Such a committee would report its findings and recommendations to you.

Sincerely,

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Edwin A. Locke, Jr.

In behalf of:

Adhesive Mfrs. Ass'n. of America
American Paper Institute, Inc.
American Petroleum Institute
Can Manufacturers Institute
Rubber Manufacturers Association
Soap & Detergent Association
Society of the Plastics Industry