TENNESSEE EASTMAN COMPANY
DIVISION OF EASTMAN KODAK COMPANY
KINGSPORT TENNESSEE 37662

Telephone 615-246 2111

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Mr. James R. Carnes
Secretary-Treasurer
Manufacturing Chemists' Association, Inc.
1825 Connecticut Avenue
Washington, D. C. 20009

Jerome H. Heckman, Esq.
Counsel for the Society of the Plastics Industry
Keller and Heckman
1712 N Street, N.W.
Washington, D. C. 20036

Proposed Food Additives Procedural
Regulations, 32 F.R. 152, p. 11443

Gentlemen:

Following are our comments on these proposed regulations. They are sent to you jointly, although we assume MCA is primarily interested in direct food additives and SPI in indirect food additives, to avoid the necessity for separate letters.

These comments have been prepared in haste in order to comply with the request of the SPI's Food Packaging Materials Committee that they be mailed to Mr. Heckman by October 7. They are intended to let the committees that will be drafting comments on the proposed regulations know the points that we are so far concerned about and to give such comments on them as have so far occurred to us. They are not intended to be exhaustive.

1. Section 121.50 Content and form of food additive petitions.

Paragraph (a). The requirement that any published information used in support of the petition shall be submitted in reprint form is too general. Petitions may cite textbooks and other works for which reprints are not available, but that are or should be readily available to FDA. It seems to us that the requirement of submission of reprints should be limited to published information that is not readily available in technical libraries to which FDA may reasonably be expected to have access; and that if reprints of any kind of cited publication

are not available, it should be enough to require the petitioner to quote extracts sufficient to support the petitioner's position.

Paragraph (c). It may seem small to object to the requirement that "the text" of petitions be submitted on 8 x 10½-inch stationery. Certainly this is not a point anyone would like to take to court, but we think the inconvenience involved in the proposed requirement should be brought to the attention of the Administration.

We do not know what the Administration means by "text". If the word applies to supporting data, such as extraction and toxicology studies that may be performed for the petitioner by other parties, it means that not only the petitioner but the sources of such data must maintain and use a stock of stationery that is government-size. If it applies to other exhibits, it means the photographic reduction of those exceeding the 8 x 10½-inch dimensions, which could be expensive.

If "text" means only the petitioners' summaries, indexes, and comments on the supporting data, the inconvenience of two supplies of stationery falls on the petitioner alone.

However, there appears to be no purpose in creating this inconvenience in whatever degree. We know of no other government agency that has such a requirement, and it would appear unlikely the Administration's file cabinets cannot accommodate files designed for predominantly 8½ x 11-inch documents.

We suggest that this part of the proposal would be reasonable if it provided that, where possible, petitions and supporting data be submitted on stationery not exceeding 8½ x 11 inches or in such form as to be easily bound with stationery of such size.

Paragraph (d). It is, of course, with Section 121.50 (d) that members of MCA and SPI are most concerned. Certainly the SPI committee should make as strong an argument as possible that where the safety of a packaging material results from "virtual lack of migration" there should be a procedure for official recognition that the packaging material is not within the statutory definition of "food additive". So far we have seen no better approach in support of this point than the brilliant Frawley paper, "Toxicological Evaluation of Migratory Food Additives." We understand that Dr. Frawley has done more

work in this field since the presentation of this paper in September of 1966 to the American Chemical Society. We think SPI should certainly take advantage of the arguments presented by Dr. Frawley for the establishment of a quantitative level of the components of a packaging material below which there need be no concern about migration, provided the components are not heavy metals or pesticides or barred under the Delaney Clause.

Further, with respect to Section 121.50 (e):-

Under II A 1 a i, the provision for citation of compendia that recognize the name of the additive as the common or usual name "unless the name is being proposed as the common or usual name," seems nonsensical. If "unless" is changed to "if", the requirement makes sense.

The same comment applies to the provision on nomenclature of indirect additives, II A 2 a i.

Under II A 2 b iii, we are sure the SPI committee will be particularly concerned with the provision calling for description of manufacturing processes, raw materials, and adjuvants. While we may have no uncompromising objection to disclosure in confidence of such information to the Administration in the case of new types of food-contact surfaces, as a new polyolefin or polyester, we certainly do not want to have to supply this information with respect to packaging materials that are already covered by regulations just because some new component is being added for which, alone, clearance is being sought. It is not clear under the wording of the proposal that petitioners in such instances would not be required to provide detailed information about the basic resin. The existence of a prior regulation should be specified as adequate reason for omitting information about substances covered by that regulation.

Further, we no doubt share the feeling of the whole of industry that we do not want to be required in any case to submit more of this kind of information to FDA than we have to. We would like to see this subparagraph's opening words be "Manufacturing process, including for food contact surfaces, to the extent reasonably required to demonstrate safety, . . ."

Subparagraph II B 1, Direct Additives (32 F.R. 11445) is of great concern to all manufacturers of direct food additives. It requires data "obtained by adequate methodology" showing the fate of the additive "in the food."

The requirement grows, of course, out of Section 409 (b) (2) (D) of the statute which provides that a food additive petition "shall . . . contain . . .

> (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use . . ." (underlining ours.)

The present regulation, Section 121.51, requires such a description of "practicable methods" in the language of the statute.

On their faces, there seems little difference between the present and proposed requirements as to substances formed in or on food from at least one standpoint: compliance with either, in some and perhaps many instances, is impossible. The way out appears to be in convincing FDA (if it needs convincing) that the statutory phrase "shall . . . contain" is directory rather than mandatory, and that therefore the statute does not demand literal compliance but compliance only to the extent reasonably possible in each particular instance, consistent with public safety.

The proposed requirement is both indefinite and unreasonable. Thus:

a. What does "the food" mean? Does it mean, for example, the food component into which the additive is directly introduced, as the oil to which an antioxidant is added to inhibit rancidity, or does it mean all the foods of which such a food component may ultimately become a part, as bakery products and potato chips and the other foods that may be prepared using oils protected by antioxidants? If the proposal means the former, it should say so; if it means the latter, its scope is too broad for hope of compliance.

   Pursuing this example of the indefiniteness of the proposed requirement further, consider the problems involved in submitting for clearance a direct food additive that may be suited for initial addition to many foods, as distinguished from being one suited for initial addition to a food component such as an oil that in turn becomes a component of many foods. See our comments under b, next below.

The proposed requirement, unlike the present Section 121.51, does not say whether it applies to food in all phases of preparation, as raw, processed, and finished. With each such stage in the life of the food, the possibilities of reaction and reaction products will vary, and within each stage still more possibilities of different reactions and reaction products may develop depending upon the time during which the food is stored in that stage. The proposed requirement makes no effort to define the scope of the data required with respect to subject matter or time.

b. A method for determining the fate of an additive in a food may or may not exist in a particular case. Development of such a method in a particular instance may be beyond present scientific ability. If it can be developed, the cost may be prohibitive. If the additive is a multipurpose one, such investigations as are scientifically possible may, if required, involve such numbers of foods and such numbers of kinds of analytical procedures as to delay the marketing of the additive for years. Yet the nature of the additive or the quantity proposed for use, or both, may be such as to leave no reasonable doubt in the minds of qualified scientists that, whatever its fate in all foods, the additive will produce no hazard to public safety. In such circumstances it would be unreasonable to require development of such a method before clearance of the additive.

Developments in the history of foods, such as the fairly recent discovery of possible harmful effects of agents used to bleach flour, and the published conclusions of reputable scientists such as those comprising the National Research Council, clearly indicate that the Administration should have the right in a proper case to require convincing evidence that a food additive will not result in toxic reaction or conversion products in the foods in which it may be expected to be found. We do not think industry can argue against the fact that the Administration, subject to possible appeal to the courts, must have the authority to decide what is a proper case for the presentation of detailed analytical data. Our only hope would appear to be to persuade the Administration that, to be enforceable and to avoid the blocking of progress in food science, the proposed requirement must be reasonable in its wording and in its enforcement, and that therefore the wording of the proposed requirement should (perhaps) be somewhat as follows:

> In the case of a direct food additive, the petition shall present evidence based on sound scientific opinion that the additive, because of its chemical or physical nature or the quantity present, or other reasons, may not be reasonably expected to produce reaction or conversion products in the food that would be hazardous to the health of the consumer of the finished food. The petitioner may be required to support such evidence by the submission of analytical or other data, including tests on animals, based on adequate methodology.

Failing the obtaining of such a general rewording of the proposed subparagraph, it seems to us that an acceptable change might be amendment of the introductory sentence as follows:

> "In the case of direct additives, unless adequate reasons for omission are advanced, data obtained by adequate methodology . . ."

Subparagraph II B 2, Indirect Additives, is of comparable importance to manufacturers of food packaging materials.

Continuing the line of comment made with respect to II B 1, above, it should be noted that the third sentence of this subparagraph includes the phrase "and its conversion products." Must data also be presented with respect to the fate in food of additives migrating from packaging materials? Perhaps not, under the provisions of the fourth sentence, which call only for migration data on the food itself or "extraction data using" simulated food solvents; but if so, arguments against the provision have been suggested above and are the more cogent because, generally, additives enter food from packaging materials only at a very low level.

Turning to other aspects of Subparagraph II B 2, this would, of course, be an appropriate point in the regulation for a reasonable interpretation of the phrase "may reasonably be expected to result" in the first sentence. Dr. Frawley's rule might be included here. Whether or not successful,

SPI should make the strongest argument possible that where migration of a component from a packaging material cannot be shown by the best current analytical procedures, the petitioner is entitled to a ruling that the component is not a food additive.

The provisions of the first and second sentences of the subparagraph, calling for description of "the conditions of use in detail with respect to the individual foods or classes of food contacted" and for the inclusion in this information of such things as "temperature and period of contact and the ratio of weight of food to contact surface area" are unrealistic and unreasonable unless the requiring of this information is qualified by some wording requiring only the petitioner's reasonable estimate of these conditions.

A reason that these provisions are unreasonable is that as a rule petitioners for clearance of packaging materials are marketers of raw materials only and are removed from the actual packaging and storage operations in nearly every instance by a number of steps and in some instances by many steps. The best they can do is give their reasonable anticipation of uses, storage conditions, and package sizes.

Subparagraph II C 4 a, Technical effect, direct additives. In view of the provisions of Section 409 (b) (2) (C) and 409 (c) (4) (B) of the statute, this subparagraph seems unobjectionable.

Subparagraph II C 4 b, Technical effect, indirect additives. The legislative history of the Food Additives Amendment states (3 U.S. Code Congressional and Administrative News, 85th Congress Second Session 1958, page 5306):

> "The phrase 'physical or other technical effect' refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food." (Underlining ours.)

This statement is consistent with the understanding between SPI and FDA at the time of enactment of the Amendment. Therefore, the requirement of data demonstrating the technical effect of an indirect additive on a food-contact article such as a packaging material is without the intended scope and purpose of the Act. FDA's sole basis for inquiry in this

regard is to determine the anticipated level of migration of the additive from the food-contact article to the food, the proposed level of usage, and whether at those levels the additive is safe.

No more is required or should be required under the statute, because in this respect, the statute is self-policing. No manufacturer of a food-contact article is going to propose addition of a component that has no effect on the article itself. Economics forbids.

The second sentence of the subparagraph should be deleted.

Paragraph (f). It seems to us that the provision that trade secrets will not be revealed unless it is necessary to do so in a regulation should be amended to give any petitioner for such a regulation the right to withdraw his petition and his data after notice of the proposed revelation.

2. Section 121.51, Processing of Food additive petitions. Under paragraph (c) of this proposed section, FDA may consider a petition withdrawn without prejudice and publish a notice to this effect if the petitioner delays in providing requested information or samples. The right to take this unilateral course depends on whether the information or sample has been requested "a reasonable time in advance of the 180 days after filing." It seems to us that this provision should be amended to give the petitioner thirty days notice of the proposed "withdrawal", with opportunity to supply the requested material or agree on an extension of time to do so.

Yours very truly,

EASTMAN CHEMICAL PRODUCTS, INC.

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Assistant Secretary