

QUESTIONS FOR DISCUSSION BY THE
FOOD AND DRUG ADMINISTRATION PANEL

Prepared For

Special Meeting of The Society of
the Plastics Industry's Food
Packaging Materials Committee

Shoreham Hotel, Washington, D.C.
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The following questions were prepared on the basis of suggestions made by the members of the Food Packaging Materials Committee of The Society of the Plastics Industry. It is anticipated that this list of questions, which is being supplied to the Food and Drug Administration in advance, will provide the basis for all discussions at the Special Meeting of the Food Packaging Materials Committee to be held on December 14, 1966.

All members of the Committee who plan to be in attendance at the December 14 sessions should familiarize themselves with the questions posed so that, if subsidiary extemporaneous questions are posed at the meeting, they will be raised in connection with discussion of the most appropriate question set forth below. It is to be understood that the Chairman of the Food Packaging Materials Committee may have to limit the asking of additional extemporaneous questions in light of time considerations.

Question No. 1

As the Food and Drug Administration is well aware, one of the most vexing problems faced by almost every packaging material supplier or producer relates to the so-called "no migration" or "no extraction" concept. Under the law, it is recognized that substances which "may not reasonably be expected to become components of food" are not really "food additives". However, there are many situations which, from a practical point of view, demand obtaining Food and Drug Administration confirmation of "non-additive" status to satisfy the packaging industries' customers.

At one time, this need could be met rather simply by corresponding with the Food and Drug Administration, supplying such extraction or other data as might appear appropriate, and then eliciting an FDA opinion as to whether a substance, in a given intended use, would or would not be considered a food additive under the "may not reasonably be expected to become a component of food" criterion.

Since about 1961, generally speaking, we understand that the policy of the Food and Drug Administration has been to refuse to give so-called "no migration", "non-additive" letters which might be used to assure customers of satisfactory status. This has, in a number of cases, led to petitions and regulations governing what would really appear to be "non-additives" within the meaning of the law.

With this background in mind:

- a. In what situations may so-called "no migration", "non-additive" letters still be obtained upon the filing of a proper request and any necessary associated data?
- b. Is the Food and Drug Administration giving any new thought to this over-all problem and, if so, have there been any changes in the so-called "no migration" policy, or are any to be anticipated in the near future? How may we best keep abreast of shifts in FDA thinking along these or related lines?

Question No. 2

In the past we have been advised that the Food and Drug Administration does not consider components of printing inks food additives in the absence of any indication that the inks are likely to leach from the outer surface of a wrapping material to foods. Under what conditions may it be assumed now that the Food and Drug Administration position remains the same as to printing inks and components thereof?

Question No. 3

At the recent American Chemical Society Symposium on Safety Evaluation of Coatings and Plastics for Food Packaging, Dr. Frawley concluded that "any coating material at a level not exceeding 0.2% by weight is generally recognized as safe, provided it is not a heavy metal or pesticide." What is FDA's thinking on this matter? Does FDA plan to pursue this approach at all in dealing with minor indirect additives, or are other approaches under consideration to alleviate the problems and confusion with respect to these minor food packaging components?

Question No. 4

On many occasions it seems likely that scientific personnel in the Food and Drug Administration's Divisions of Food Standards and Additives and Toxicological Evaluation might well have questions, or desire minor clarification, as regards data submitted in a food additive petition. When this occurs, are the scientific personnel in these Divisions free to communicate directly with petitioners concerning any such questions? May the petitioner feel free to communicate with personnel in the Divisions to determine whether or not such questions exist, and to obtain definitive and authoritative first-hand reactions to the data submitted in a petition?

Question No. 5

The following questions relate to the status of a food packaging material component when there is in existence some form of approval for use of the substance as a direct food additive. It is recognized that a variety of situations can be presented when this set of basic circumstances is involved.

- a. Is it safe to assume that, if a substance is listed as "GRAS" in Section 121.101 of the Food Additive Regulations, applicable to intentional food additives, it may be used as a packaging or processing material component without the necessity for any additional regulations? In answering this question, assume that the use as a possible indirect additive will not result in any addition of the substance to foods greater than would be permitted in direct additive use.

b. If a material is covered by a conventional direct food additive regulation (without narrow limitations), may it be assumed that it can be used as a packaging material component without the necessity for additional regulations.

c. Suppose a direct additive regulation exists (again without narrow limitations), based upon a petition by one company. Suppose another company subsequently submits a petition for an indirect additive regulation for the same chemical, complete except for the omission of toxicological data, but incorporating by reference, sight unseen, the toxicological data on which the direct additive regulation is based.

Will FDA grant the petition and promulgate the proposed indirect additive regulation?

Question No. 6

The following questions are asked with reference to the possibility of eliminating extraction studies in certain special "indirect additive" situations:

a. Suppose a company submits a petition for an indirect additive regulation proposing use of a component for specific packaging applications and, in so doing, reasonably estimates the portion of the diet that may be packaged in material employing the component. Suppose further that the data in the petition or otherwise available shows that, under the intended conditions of use, even if all of the additive were to migrate, the level of addition of the regulated substance to food would be safe. Is there any need to undertake migration studies or file extraction data in such circumstances?

b. Assume that a company wishes to have a substance added to an existing regulation such as the one governing can enamels. In filing the petition, the company submits toxicological data showing that as much as 50 ppm of the substance would be safe should this amount migrate to food from a can enamel formulation. Is it necessary for the petitioner to submit extraction data

in addition to the toxicological studies if he is willing to have his substance regulated under the 50 ppm maximum extraction criterion already established in the can enamel regulation for all other components?

Question No. 7

Prior to the early days of the Food Additive Amendment, in designing extraction studies and evaluating the results thereof, the volume-to-surface ratio most often employed was 2 to 1, or 2 ml. solvent per sq. in. of area. In promulgating Section 121.2514 of the Regulations -- the so-called "can enamel" regulation -- the Food and Drug Administration moved to the somewhat more realistic approach of using a 10 to 1 volume-to-surface ratio and clearer specifications as to varying intended conditions of use. Recently, there appears to have arisen some confusion as to which of the ratios, or what other ratios, should be applied. For example, there appears to be some FDA thinking in the direction of a return to the 2 to 1 ratio.

- a. What are the reasons for the changes in FDA thinking in this area if, indeed, the thinking has changed?
- b. Where the nature of the intended use of a given indirect additive can be fairly accurately defined by a petitioner, will the Food and Drug Administration consider evaluation of the petition by reference to actual volume-to-surface ratios anticipated, disregarding the 2 to 1 or 10 to 1 "rules of thumb"?

Question No. 8

A company is manufacturing a paperboard container for use in contact with aqueous and fatty foods. All the ingredients are cleared under Section 121.2526, with all but one minor ingredient included in paragraph (a) where no extraction test is required. However, with the one ingredient listed in paragraph (b), the extraction test must be run. It is, and net corrected extractives of 0.6 mg./sq. in. (i.e. 0.1 mg./sq. in. over the regulatory limit) are found. What does the company do?

Question No. 9

Several regulations in Subpart F refer to "basic polymers" or "base polymer". What is meant by these terms?

Question No. 10

In many of the food additive regulations it is provided that a regulated substance may be used with, or made with other adjuvant substances including "substances permitted for such use by applicable regulations". In trying to determine when a collateral regulation is "applicable" so that the substances cleared under it may be used with other materials without requiring further regulations, what is FDA's position on the following situations:

- a. Suppose one wishes to use one of the adjuvants listed in the acrylics regulation, Section 121.2591, in a polyolefin formulation. Under what circumstances would this be appropriate without recourse to the filing of a new petition?
- b. Suppose a polymer is "prior sanctioned" or "GRAS", or is regulated under a provision such as that for nylon resins (Section 121.2502), where no adjuvants are listed. Is it permissible to use with such a resin selected adjuvants listed under such regulations as the one for "resinous and polymeric coatings for polyolefin film" (Section 121.2569)? In other words, may it be assumed that the listings of resinous and polymeric coatings for polyolefin film is, in a practical sense, "applicable" so that the materials listed in that regulation can be employed in conjunction with other resins?
- c. If the response to these questions is that, in both cases, the use of an "adjuvant" listed as satisfactory for use with one polymer may not be used with others under the "applicable regulation" doctrine, what is the rationale for not permitting such cross-referencing, and how may petitioners be guided in deciding whether or not a regulation is truly "applicable" or not?

Question No. 11

What prevents FDA from developing more of the functional type regulations (e.g., 121.2541 - Emulsifiers and/or surface active agents) with broader applications, whereby approval of a substance for a functional use covers packaging materials generally?

Question No. 12

Subpart F of the food additive regulations has become a large catalog of food packaging and equipment components used in broad and specific applications. Does FDA have any plans to revise Subpart F by simplifying, consolidating, clarifying, deleting, or making the regulations more uniform? If so, how and when will this be accomplished?

Question No. 13

Experiences have varied as to arranging for discussion and review by FDA of analytical and toxicological results prior to the filing of a petition. What does FDA now recommend to the potential petitioner to make such meetings most meaningful? How can such preliminary work be undertaken effectively to obviate the possibility of a later demand by FDA that a petition be "withdrawn without prejudice" due to a need for additional studies or data never previously requested?

Question No. 14

In a paper delivered at a recent American Chemical Society Symposium, an FDA spokesman stated that a petitioner for a food additive regulation must provide "proof that the additive has a bona fide function in relation to the Amendment", and that there must be "adequate proof that the additive is safe and effective under a given set of conditions." What is the legal basis for the Food and Drug Administration's apparent requirement for proof of efficacy of an incidental food additive? Please explain what interest the Food and Drug Administration might have as to whether or not a component of a food packaging material performs its intended function in a package, assuming, of course, that the additive is not intended to migrate to foods.

Question No. 15

Are FD&C certified colors permitted as components of food contact articles provided they do not color the food with which they are in contact in any way that is "visible to the naked eye"?

Question No. 16

Generally speaking, it has been the custom in the plastics and other industries to use inorganic pigments on a "no migration" basis. More specifically, industry has generally taken the position that unless an inorganic pigment used in a plastic has measurable extraction in amounts greater than 10 ppb, it may be considered a "non-additive" requiring no formal regulatory coverage. Is this a sound position for industry to take where inorganic pigments are concerned?

Does FDA presently have in mind, or have under active study, any criteria for the use of pigments or dyes in packaging materials? Any other comments on the general question of pigments and dyes in packaging applications would be welcomed.