Industrial Chemicals

Res. Admin.,- MRL

Dr. E. P. Aikman

Industrial Chemicals

Research - MRL

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SPI FOOD PACKAGING MATERIALS COMMITTEE
CONFERENCE WITH FDA PERSONNEL ON
FOOD ADDITIVE REGULATIONS
WASHINGTON, D.C., DECEMBER 13, 1966

1. A special meeting of the SPI Food Packaging Materials Committee was arranged with representatives of the Food and Drug Administration to discuss present status of Food Additive Regulations. FDA was represented by Mr. Lessel L. Ramsey, Deputy Director, Bureau of Scientific Standards and Evaluation, and Dr. Joseph McLoughlin, a scientist of long experience in the Bureau. Industry questions were sent to Mr. Ramsey in advance of the meeting and discussion was confined to these questions or those very closely related because of limited time.

2. As summary of the most important points in the attached list of questions and answers three statements may be made. FDA concedes that much could be done to consolidate and clarify present regulations but their personnel is inadequate, priority for this is low and they hope that industry will offer leadership in this direction. Present day regulations are not to be interpreted in any broader sense than specifically stated, e.g., an adjuvant or coating regulated for resin X may not be used for resin Y without petition and regulation for such use. Finally, toxicological and analytical data submitted to FDA are considered in the public domain after a regulation covering the additive has issued.

3. In the opinion of the writer, Mr. Ramsey and Dr.McLoughlin gave as straightforward answers to questions as possible under the circumstances. FDA is not likely to relinquish any authority it thinks granted by the Act but would welcome means and procedures to provide broader generalizations in the regulations without sacrifice of public safety.

Original Signed
W. A. Knapp

WAK:dmk
Attachment

W. A. Knapp
Consultant - Toxicol gy

ASI 00000137

cc: Mr. J. C. F doruk, Attn. Mr. C. B. Miller
Mr. J. L. Damon
Mr. K. W. Dieckmann,Circ.A.Steinberg,J.Kusmick,C.Thomson

Industrial Chemicals Division
Allied Chemical Corporation

Answers to Questions at FDA Conference of SPI Plastics Packaging Sub-Committee December 13, 1966

(1) With respect to the "no-migration" concept in the Food Additives Amendment, FDA takes the position that if you test for migration you are conceding that the material may reasonably be expected to become a component of food and is therefore a food additive. This attitude is not popular but remains the official position of FDA. FDA will still issue letters conceding that a material "may not reasonably be expected to become a component of food" but the probability of migration must be quite remote. Mr. Ramsey cited the conclusion of the special committee of the National Research Council wherein it was stated that registration of a pesticide on a no-residue basis was scientifically untenable. By the same reasoning, the degree of migration of a food additive should be known and, if necessary, limits placed on migration. FDA feels that unless a substance is GRAS there must be regulation controlling limit of addition and method of determining additive. Where use of additive is self-limiting (e.g., food acids) limits are frequently omitted. Catalysts in polymeric materials are mostly not listed in regulations because FDA has been assured by industry that residues are virtually non-existent and do not migrate.

(2) With respect to printing inks on packaging materials, FDA takes attitude that they are not additives if there is a functional barrier between it and food. What constitutes a functional barrier is poorly defined and remains the responsibility of the producer. In this connection, Dr. McLoughlin reminded that the polyolefins occasionally do permit migration and do not always constitute a functional barrier. It may be presumed here as in first question that if you test for migration and find some you have a food additive. Dr. McLoughlin also cited a case where migration was detected via off-taste in food.

(3) With respect to the Frawley hypothesis presented at the American Chemical Society Meeting in September 1966 ("any component of an article contacting food which is present in the article or its coating at a level not exceeding 0.2% by weight is generally recognized as saf , provided it is not a heavy metal or a pesticide"), FDA has some objections. They point out that 0.2% of a material in one coating may not be the equivalent of the same amount of the material in another, i.e., there may be no correlation between composition and migration. Dr. McLoughlin conceded that it might be possible to grant GRAS status to minor constituents under known conditions of use, provided migration data are available. From the total discussion to this point, the writer gained the impression that FDA wanted migration data whether or not the migrant constituted any risk to public health. They felt that they must in some manner build up a total picture of additives in the American diet from all sources.

(4) With respect to contacting FDA scientists, Mr. Ramsey could see no objection to contacting before petition was submitted or after review and letter from FDA outlining any additional data needed. In all cases he thought it best to contact Mr. McFarland or one of his administrative staff and not the scientist directly. From his point of view,any opinion from an individual scientist is not the opinion of the FDA institution.

(5) GRAS materials may usually be used as a packaging or processing material component without further regulation, but not always. FDA representatives reminded that GRAS materials in §121.101 are frequently listed as to use or amount used. The use of direct additives as components of packaging materials is similarly subject to the same limitations. Concerning petitions for extension of uses of a food additive by a company not supplying toxicological data for original listing, FDA expounded a new doctrine, namely, that toxicological data is not proprietary information and not confidential information after a regulation has issued, i.e., information is then in the public domain. To date, toxicological data has

usually been made available to new petitioners for extended uses of an old product because they are usually customers of the producer and source of information is positively located in FDA files. However, FDA will not search their files for such information unless the FDA scientist has recollection that information available is adverse. We were told that this policy will extend to analytical procedures and to manufacturing procedures where such disclosure is necessary to insure safety of the food. If the petitioner discloses information which he feels to be highly confidential, he should so identify in the petition. If FDA feels that confidentiality with respect to such information is not in the public interest, they will notify petitioner who may reconsider disclosur .

(6) With respect to need for extraction studies, FDA wants to know degree of migration of food additive whether or not the food additive has been demonstrated to be safe at much higher levels. A second petitioner may request regulation for another use of the same or very similar additive and toxicologists want to know all sources of the material, i.e., total body burden. It was also mentioned that drugs and cosmetics may be sources of the same materials added to foods. In short, FDA wants migration data on every indirect additive and believe they have the power to demand it. Ultimately, this will lead to reasonably accurate data on daily intake.

(7) With respect to ratio of volume of package to surface area there is nothing magic about the 2-ml/in^2 or 10-ml/in^2 ratios. Some recent regulations use the 2:1 ratio because of geometry of the Maturi cell. What FDA wants to know is good estimate of total intake of additive; if consumption is from package of different ratio this may be used. It is extremely doubtful that change in calculated intake via change in ratio will be judged adequate reason for acceptance or rejection of a regulation.

(8) If the minor ingredient is not included in par.(a) of §121.2526 , extraction tests must be run, i.e., regulati n means what it says. If one wishes to get the minor ingredient listed in par. (a) of this regulation they may

submit petition to justify. Dr. McLoughlin pointed out that many substances in par. (a) are limited as to purpose and extent of use.

(9) To Dr. McLoughlin a basic polymer is the product of polymerization of one or more monomers and may contain such adjuvants as are necessary to the polymerization (i.e., catalyst, etc.). It does not include plasticizers and other adjuvants added in formulation of the basic polymer with other materials. It was suggested that industry might wish to offer a definition of basic polymer.

(10) A substance listed as a permissible adjuvent in one regulation may not be used in another regulation, i.e., a given regulation is not to be interpreted in any broader sense than is stated. FDA realizes, for example, that some coatings permitted on one substrate may be equally suitable on others but this is not always the case.

(11) In response to this question, FDA pointed out that they prefer the functional type regulation and that they start d this type on their own initiative. Industry, of course, has petitioned for additions to these regulations but they did not initiate the type. Such regulations would probably require industry committees to assemble lists of functional additives to be covered by the regulation.

(12) There is a great deal that can be done in the way of codification of present regulations but FDA does not have the personnel to do this immediately and there are many more pressing problems. It was hinted that this is a task industry might care to undertake. It was stated that the industry knows more about polymers and packaging than FDA does and that suggestions from industry would be welcomed. This looks like a good spot for an industry committee to make a thorough study and then offer a complete re-codification of Subpart F covering packaging materials.

(13) FDA will make no guarantees that conferences either prior to or during consideration of a petition represent the official institutional opinion. They are glad to give advice during such conferences but one or two individuals cannot make the total decision for FDA.

(14) FDA spokesmen think that some reasonable demonstration of efficacy can be demanded. Legislative history indicates that Congress had in mind additives with some useful purpose and that mere addition without utility would not be in the public interest.

(15) The answer is yes - certified food colors are permitted in food contact articles. With respect to inorganic pigments (CdS, CdSe, Hg, compounds, etc.,) FDA is concerned about any increase in present background levels. The 10 ppb figure may not apply to highly toxic metals.

(16) Answered by (15) above.