

FOOD CHEMICAL NEWS

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PROPOSED FOOD ADDITIVE PROCESSING REQUIREMENTS HIT

The requirements for food additive processing data in the Food and Drug Administration's procedural regulation proposals were hit in comments submitted to FDA last week (See FOOD CHEMICAL NEWS, Aug. 14, Page 3).

Criticizing the requirements for such data for irradiation, the Army's Natick Laboratories said the "detailed engineering data pertaining to the radiation source and dosimetry" would "pertain to only one particular source, usually of a research facility" and that "the data would not be applicable to other sources, especially those of a manufacturing facility."

Irradco, Inc. and Isotopes, Inc., also hit the requirement for the "large amount of detail," noting the requirements for data on the type of encapsulation used, the geometry of radiation mechanism, the speed of movement by the radiating head, the number of curies in the source used, the total time of exposure, the nature of the dosimeter, the frequency of dosimetry, dosimeters and phantoms to be used, Atomic Energy Commission licenses, and labeling. The firms recommended that:

"(1) The procedure clearly distinguish between specific information required concerning facilities in which the research was done and future facilities in which production might occur; and

"(2) The data required for approval of a specific radiation processed food be confined to the radiation process conditions (source isotope, dose, permitted dose range, etc.) rather than configuration and hardware details which would be highly restrictive to commercial feasibility. Demonstration that a particular facility can produce a specific food within the conditions approved by the FDA should be independent of the original Petition."

Noting the proposed data requirements, the companies said, "It is not clear whether the Petition requests this information primarily to evaluate the research conditions under which the supporting data supplied in the Petition were obtained, or requests this information for the specific facility in which the food covered by the Petition will be processed." If the latter is true, Irradco wrote, "it would appear that a new Petition would be required for each food item for each separate facility in which such a food could lawfully be processed."

The firm said "such a procedure would be self-defeating," since "investment in a food irradiation plant cannot normally be undertaken until the intended food has been approved; consequently the Petition for the food, when submitted, cannot specify the details of all plants in which such a food might be processed."

Lilly's Elanco wrote that the requirements for details of the manufacturing process represents a "misconception of the relationship of the manufacturing process to the food additive regulation finally adopted." The company continued:

"A given additive may be manufactured by different processes without any effect on its safety or effectiveness. Once a food additive regulation is adopted, it is non-exclusive and others may manufacture the additive by a totally different process. The Petitioner should be as free as others to vary the manufacturing process by new innovations as long as the safety and effectiveness of the end product is not affected. . . . if, as a Petitioner, we would be restricted to the process in the Petition, then others should also be so restricted."

The Rubber Manufacturers Association said the proposed requirements are "simply not applicable to the vast majority of molded rubber products that become a component of food processing equipment." RMA said the proposed procedures "would have the effect of forcing all but a few rubber companies with large research laboratories out of the food handling business."

As an example, the Association noted there are 207 manufacturers of O-rings, which are commonly-used sealing devices. RMA said:

" . . . the manufacturer has no control over end use and is not able to determine what part of his production might be employed as food contact surfaces. While it is true that the basic polymer will probably be the same, the filler, plasticizers, stabilizers, accelerators, and antioxidants can vary widely. This could require the publication of as many as 207 separate regulations, assuming that all O-ring manufacturers' product at some time or other is in contact with food."

More Protection of Confidential Data Urged

Elanco Products urged more emphasis on protection of confidentiality of data, saying that the provision on "master files" should "be made explicit . . . that no information in such a file would be released for any purpose without the consent of the person submitting it." The firm said, "This should include the situation where such disclosure is to be published in the regulation and the applicant chooses to withdraw his application prior to publication."

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RMA also said that "if it is deemed necessary" to publish trade secrets in Food Additive Orders, "the Petitioner should be given the opportunity before publication to decide whether he wishes to have it published or whether he wishes to withdraw the Petition."

Elanco said, "The exclusion of the toxicological data from confidential treatment is unacceptable," explaining that "the development of such data involves a substantial expense for the applicant who would not customarily publish it." The company said publication of such data would violate the Administrative Procedures Act.

The rubber manufacturers' group also said the master file provision does not appear to contain "adequate assurances that confidential information and trade secrets will be safeguarded . . ." RMA asked for a greater "degree of protection and confidentiality . . ."

The Association proposed that "there should be a system under which one could submit information entitled to protection as a trade secret that would be kept confidential and would not be revealed in any situation with the exception of enforcement action."

RMA hit the proposed requirement for an estimation of migration of a food additive to food "based on total diet (daily) of the consumer," saying this is "almost impossible to make without exhaustive tests." The group added that "feeding tests . . . in our opinion are meaningless in considering the effect of indirect food additives."

Elanco also said that estimation of amount of a feed additive in the total daily diet would present problems, explaining that a Petitioner "would have no way of determining the total intake of the additive from other sources." The firm said a requirement that Petitions state "the maximum safe level in the diet of the consumer" is "impractical." "There is no way to determine the maximum safe level, even though a great deal of information might be developed on the no-effect level," Elanco said.

The Army suggested that the requirement for an estimate of the amount of an additive in the daily diet "be amended to distinguish between chemical type additives and ionizing radiation, inasmuch as radiation is not a cumulative additive and there is no residual additive to be measured in the total daily diet of the consumer."

Elanco asked that the definition of "radiation" covered by the regulations - - which "includes radiation of any wavelength" - - be narrowed, saying the proposed definition would cover exposure to heat, light, and radiation from many other environmental sources.

Noting the requirement for analytical methodology, the Army commented:

"It is not clear whether this . . . pertains to the methodology followed in the collection of evidence for inclusion in a Petition or whether it is intended to apply to methods for

enforcement of a regulation. It is suggested that the paragraphs pertaining to methods clearly distinguish between radiation processing and other types of additives. The reason for this is that at the present time there is no known method for determining if a particular food product on a grocer's shelf has been intentionally subjected to radiation. The only manner in which this can be determined is to monitor the processing of the product."

Irradco and Isotopes also said that "there is no method of analytically determining the type, energy, or dose of radiation (considered as a food additive) to which a food has been subjected." The companies said the requirement should be amended "to clarify how it is to be applied to the case of radiation, taking into account the absence of any available analytical methods."

Elanco noted the reference regarding "new drugs" which also are "food additives" to the proposed New Drug Application Form FD 356V, noting it does not yet exist. Saying this precludes comment on this section, the company asked "that the proposed regulations be stayed until the form has been published."

Saying that the present regulations provide that when a substance is both a "new drug" and a "food additive," submission of an NDA is construed also as a Food Additive Petition, Elanco commented: "Unless similar language is included in the proposed regulations, it appears that the NDA will no longer be considered as a Petition for a food additive in such situations and that a separate Petition will have to be filed . . ."

Noting a requirement in a section pertaining to "new drugs" which are "food additives" for a "practical chemical assay," Elanco said this "is not in the best interest of the regulatory agencies, the industry, or the consuming public." The limitation, the firm explained, would rule out microbiological, biological, "and other highly sensitive and reliable assay methods and inhibit progress in the analytical sciences." Elanco said the Food Additive Law requires only a "practicable" method, and noted that some existing Food Additive Orders for feed additives specify a biological assay method.

Inclusion of Veterinary Drugs May Be Temporary Measure

FDA-ers concede that inclusion of veterinary drugs and feed additives in the food additive procedural regulation proposals is a stop-gap effort to avoid development at this time of a separate set of regulations for these products. Formulation of separate regulations at this stage, they say, would be undesirable in view of possible enactment by Congress of the Animal Health Institute's bill to centralize all veterinary drug clearances (See FOOD CHEMICAL NEWS, Oct. 9, Page 3). Separate procedures would be developed after passage of such a bill.

The Army endorsed the proposed creation of food additive master files. However, the Natick Laboratories hit as unclear a proposed requirement for data on the "nutritive composition of irradiated foods." The Army suggested that this be changed to cover "vitamin composition for which requirements have been established." The Army also requested clarification of the requirement "for data on food ordinarily stored for a period of time . . ."

The Natick letter questioned the meaning of the phrase "no effect level" with "respect to irradiated foods . . ." and hit the requirement for "complete raw data in each Petition" as "very burdensome." The Army said, "The creation of a master file as contemplated would obviate the necessity for this data."

Elanco said the proposed regulations are ambiguous as to the relationship between the Food Additive Law (§ 409) and the Pesticide Law (§ 408), asking clarification. The company hit the requirement for reprints of supporting scientific papers, saying that reprints "are often unavailable and photostatic copies should be sufficient for review of the Petition." Elanco also criticized the requirement that Petitions be on 8 x 10 1/2-inch pages.

RMA noted that under the proposals, if a Petition cannot be filed, FDA will return to the Petitioner two of the three submitted copies. The Association asked that all three copies be returned.

Irradco said it has a contract from AEC to design, build and operate the first commercial plant for irradiation sterilized foods, and that Isotopes is under contract to Irradco for designing, construction, and operation. Irradco said it will file supplementary comments on the proposed regulations within 15 days.

Elanco said that, "The proposed regulation does not present a well-organized Petition," adding that the proposed form "requires the duplication of information throughout the Petition." RMA commented that FDA's proposal "could have the effect of freezing the state of the art of rubber technology to its present level."

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NO CHANGE DETECTED IN PESTICIDE RESIDUE PATTERN IN 3 YEARS

Results of the Food and Drug Administration's market basket sample of pesticide residues for fiscal year 1967 showed no significant changes in the levels, frequency, and types from those in the past, according to data made available to FOOD CHEMICAL NEWS.

The largest number of residues continue to be found in the fatty products of animal origin. DDT continues to be the chlorinated residue most frequently found, and degradation products of DDT the next most frequently encountered, followed by dieldrin, lindane, and BHC. Malathion continues as the most frequently encountered organophosphate.