

~~Let from~~ - Vinyl Chloride
Res. Project

FOOD CHEMICAL NEWS

It was suggested by FDA "that anyone who has significant safety information on a prior-sanctioned ingredient submit such evidence to the FDA now, or as it becomes available to them, or as they request affirmation of the safety of the prior-sanctioned ingredients." The agency said that publication of a proposal to place limitations on use of a prior-sanctioned ingredient "will, in any event, provide for submission of such information."

FDA rejected arguments in the comments that "prior-sanctioned food ingredients are exempt from safety evaluation under the adulteration provisions of the Act," saying they can be "poisonous and deleterious adulterants of food." The agency said that §701(a) gives "sufficient legal authority" to permit the prior sanction regulations for both direct and indirect food ingredients, including any finding that they are adulterants.

Discussing the all-inclusive nature of Subpart E, FDA said that regulation of "food additives," determinations of "general recognition of safety," or "prior sanctions" should all be "a matter of public record." Subpart E will contain a complete list of prior sanctions both for direct and indirect food ingredients.

Conceding that "not all known prior sanctions are presently listed in this subpart," FDA said, "This will be remedied by publication of the prior sanction status of those ingredients supplied in response to the FDA's request for information on prior sanctions...and as requests for affirmation of the safety of prior-sanctioned ingredients are acted upon."

FDA previously "revoked" all letters affirming the prior sanction status of substances -- while not revoking the prior sanction status itself -- and asked that firms and associations holding such letters inform the agency.

"PRIOR SANCTION" REGULATION PROPOSED FOR PVC

The Food and Drug Administration on May 17 proposed a "prior sanction" regulation affirming the prior approval of polyvinyl chloride resin for general food packaging use, but banning its use in packaging alcoholic beverages.

The PVC prior sanction proposal followed by two days FDA's finalization of its §121.2000 regulation to provide for a complete listing of "prior sanctions" for both direct and indirect food ingredients, with limitations where necessary (See preceding story).

The proposed §121.2009, on which comments may be made until July 16, is the form taken by FDA's expected proposal to ban use of PVC for packaging alcoholic beverages (See FOOD CHEMICAL NEWS, May 14, Page 3). Actually, the Treasury Department's Bureau of Alcohol, Tobacco and Firearms followed FDA's recommendations by banning PVC liquor bottles effective May 11 (See FOOD CHEMICAL NEWS, May 14, Page 2).

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"Lehman List" Prior Sanction Formalized

In addition to imposing the ban on PVC liquor and wine bottles, the proposed §121.2009 would formalize the old "Lehman List" prior sanction for PVC food packaging. The "Lehman List" was a 1956 paper by former FDA Director of Pharmacology Dr. Arnold J. Lehman, and the Society of the Plastics Industry has urged that the new prior sanction regulations include the prior sanctions from that article.

§121.2009 would provide that polyvinyl chloride resins consist of basic resins produced by the polymerization of vinyl chloride, and that the resins have a maximum volatility of not over 3% when heated for one hour at 105° C., and an inherent viscosity of not less than 0.35 when determined by ASTM Method D 1243-66. FDA commented that this is the material that has had a prior sanction "for use as a component of film for food wraps or as a can enamel."

The proposed regulation provides that "polyvinyl chloride resins meeting the criteria... may be used as a component of food packaging material, other than packaging material for use in contact with alcoholic foods."

FDA said "it is clear" that Lehman's acceptance of "the resins was based on their lack of migration when tested for solubility in the listed solvent systems," and "did not refer to polyvinyl chloride bottles and did not name an alcoholic medium as a test system."

Noting reports that vinyl chloride monomer migrates to alcoholic beverages after one year of storage, FDA said that "vinyl chloride monomer as such is a poisonous and deleterious substance." The agency wrote that it "knows of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods." Limitations of "prior sanctioned" ingredients is based by FDA on the §402 food adulteration section of the law.

CEQ Recommended Against Use of PVC for Liquor Bottles

The Council on Environmental Quality recommended against granting permission for use of PVC containers for packaging alcoholic beverages several weeks before FDA took the same stance. CEQ's opposition, however, was based on fear that Treasury's approval of PVC containers for liquor use would mushroom into demands for similar types of plastic packaging for other beverages and uses.

"We have always worked closely with FDA officials," said Rex D. Davis, ATF Director, "and abided by their decisions on substances which may be present in alcoholic beverages." He continued:

"Even though the toxicity of distilled spirits in plastic containers has not been definitely established, our concern for consumer safety has dictated our immediate action."

The experimental period for PVC use for alcoholic beverages had been originally scheduled to end on June 30.

Davis pointed out that ATF recently released an Environmental Impact Statement (See FOOD CHEMICAL NEWS, April 30, Page 32) that indicated that PVC bottles could be used as containers for distilled spirits. He said this was based on the impact to the environment rather than to the chemical stability of the container which was the responsibility of FDA officials.

He said he had instructed "our laboratory personnel to continue to work closely with them (FDA) on this matter."

CEQ's comments, filed by Chairman Russell E. Train, evaluated comments of other agencies and the public, which he claimed were essentially negative and "lead us to conclude that it would be unwise to move ahead with the proposal at this time." He explained:

"The Environmental Impact Statement and the supportive analyses, while thorough in their evaluation of the effects of a shift to PVC for liquor bottles, do not take into account the full significance that a Federal 'stamp of approval' for this limited application would have on future decisions by others to use plastics for packaging.

"What is clear from the supporting documentation is that this approval would be seen as an important precedent upon which could be built future, more widespread applications of plastics."

Train said, for example, FDA already has proposals before it which would clear plastics for packaging soft drinks and malt beverages.

"There is little doubt that a Treasury approval of PVC for liquor bottles would be an influential factor on this and similar future decisions," Train wrote, adding:

"This points to the need to carefully evaluate the environmental impact of PVC in liquor bottles. On balance, we see minor detrimental effects from the limited application proposed, but potential major impacts from subsequent expansions of their use into other areas, a circumstance that might be encouraged by the proposed Treasury action."

He said CEQ's concerns are the potential for damage to incinerators from overall increases in the PVC content of solid waste; the potential of hydrochloric acid damage from fires in locales where significant amounts of PVC bottles are on hand; and the more ready separation and recyclability of glass.

"Until we understand more about the effects of PVC on the full range of our solid waste problems, and until we are sure Federal approval of PVC uses will not encourage

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an undesirable increase in other applications," Train declared, "it would seem to make more sense from an environmental viewpoint to continue the use of glass containers for liquor."

IMPURITIES IN TESTED SACCHARIN PROMPT TIME EXTENSION

The Food and Drug Administration is expected to extend the time limit on its interim Food Additive Order for saccharin, in part because of a question involving impurities in those saccharins that have been used in tests where tumors have been reported.

Summaries of all the test results so far were presented May 17 to the National Academy of Sciences subcommittee on nonnutritive sweeteners, which met in Philadelphia. FDA has granted NAS a contract to review test results and come up with a finding on whether or not saccharin is a carcinogen.

The subcommittee is headed by Thomas Jefferson University's Dr. Julius M. Coon, and its other members are: University of Wisconsin's Dr. R. K. Boutwell, University of Kansas' Dr. John Doull, Maine MD Dr. David W. Fassett, New York State Agricultural Experiment Station's Dr. Willard B. Robinson, and Massachusetts Institute of Technology's Dr. Gerald N. Wogan.

Order Expected to be Extended Until Final NAS Report

The interim Order expires June 30. Rather than extend it to a specific date, FDA is expected to continue interim clearance until the NAS subcommittee has made its final report and the agency has acted upon it.

Word of the impurities started circulating in industry circles last week. Some industry spokesmen believe the impurities are the key to the saccharin problem, noting that the process which led to the impurities is no longer used. A few industry representatives privately express doubt that the level of the impurities could be large enough to be significant.

Sodium saccharin used in feeding studies by the Wisconsin Alumni Research Foundation and by FDA was produced by the Remsen-Fahlberg process. It is understood that the impurities may include o-toluene sulfonamide, and ortho and para sulfonylbenzoic acid, and may be carcinogenic.

The WARF studies showed bladder tumors when the saccharin was fed at 7.5%. FDA's three-generation reproduction study showed bladder tumors in three test animals fed 7.5% saccharin. However, it is understood that saccharin produced by the Remsen-Fahlberg process was also used in studies at the German Cancer Center at Heidelberg, the Rijks Institute in The Netherlands, Osaka University in Japan, the Canadian Food and Drug Directorate, and the National Cancer Institute.

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