

NRC Report Unfavorable to Poly Emulsifiers

Statement of the Food Protection Committee says that polyoxyethylene stearate is not proved completely safe for food use

A REPORT on the polyoxyethylene stearate emulsifiers for food use has been issued by the Food Protection Committee of the National Research Council. The NRC committee found that the safety of the emulsifying bread softeners has not yet been conclusively proved and therefore it does not recommend the acceptance of the agents for use in food.

The status of the emulsifying bread softeners has been unresolved since the Food and Drug Administration issued its tentative bread order in 1950, when these products were omitted from the prospective standards. Subsequently, when the FDA standards went into effect the manufacturers withdrew their products from the market. Both the Food and Drug and the chemical manufacturers have awaited the report of the NRC committee which has been active in presenting methods and standards for the evaluation of the safety of chemical additives proposed for food.

The NRC Food Protection Committee was set up at the request of the food and chemical industries. Evaluation of evidence on polyoxyethylene stearate was, however, undertaken at the request of FDA.

FDA originally questioned the use of the synthetic softeners in bread in its tentative bread standards which were proposed in August 1950. At that time the FDA presented proposals for the ingredients which should or could be present in white bread to be sold in interstate commerce. (For discussion of standards of identity of foods see *Ag and Food*, July 22, page 640). At the time of the original standards for bread the FDA observed that the addition of the synthetic emulsifying agents to bread was misleading in that the softening agents when added to the bread caused it to remain soft for a longer length of time. Bread with the synthetic softeners was interpreted to be misleading to the consumer as to its age. The FDA also challenged that the safety of the oxyethylenes remains unproved.

Following the publication of the tenta-

tive standards for bread the chemical manufacturers and some bakers protested the exclusion of the stearates from the tentative standards and a prolonged debate ensued.

Final standards of identity for bread were published by the FDA in May 1952. These standards excluded the chemical standards of the polyoxyethylene mono-stearate type from the list of permitted ingredients. The mono- and diglycerides, softeners derived from natural products, were permitted on the grounds that they improved the action of the bread shortening without deceiving the consumer. The polyoxyethylene stearates were specifically banned on the grounds that they were deceptive and had not been adequately tested for their safety as bread ingredients.

Oscar Ewing, then Federal Security Administrator, ruled that the safety of the oxyethylenes had not been finally established and that the scientific investigations of their suitability were incomplete. He said at that time that if the polyoxyethylene stearates should be proved definitely safe the standards hearings would be reopened. In effect, FDA then challenged the chemical manufacturers to prove that the additives would be safe for use in foods.

Following the publication of the final standards, Atlas Powder Co., one of the principal manufacturers of oxyethylenes, filed a petition in a U. S. Court of Appeals. The petition requested a review of the bread standards and also asked the court for a stay order on the effective date of the bread standards.

The court granted a stay which postponed the effective date of the bread standards order relating to the softeners. However, the court refused to reopen the bread standards question.

Similar appeals were filed by Glyco Products Co. and Research Products Co. who were the other principal suppliers of the oxyethylene emulsifiers. In all these cases the U. S. Appeals court

refused to reopen the bread standards hearings. When the enforcement stays granted by the court expired on May 8, 1953, FDA announced that it would enforce the bread standards and seize bread which contained the polyoxyethylene stearate emulsifiers.

Since that time the chemical manufacturers have not sold their emulsifiers for use but have gone ahead with toxicological testing programs to get evidence on the relative safety of the materials. The NRC report is a compilation of test projects completed up to January of this year, which have been conducted by the industries involved, FDA, and other groups.

In this report, NRC observes that: "The introduction of a new additive which does not positively contribute to the nutritional quality of a food presents a situation demanding particularly conservative judgment. The use of such an additive in a variety of basic foods which are unavoidably consumed by all groups within the population in both health and disease, requires that sufficient evidence be obtained to provide a positive demonstration of harmlessness."

The NRC report indicates that although there is no evidence that the oxyethylenes are in any way harmful to humans when fed in normal amounts, but holds, nevertheless, that it is still not established that they are harmless. Under the FDA regulations it will be necessary to prove beyond reasonable doubt that they could do no harm.

Atlas says it has invested more than a quarter of a million dollars in research grants to study the safety of the chemical emulsifiers as food additives. Many of the research projects being conducted by independent research groups are not yet completed. Some of these reports, which Atlas considers to be important to the problem, will be completed in the next few months. Meanwhile NRC says it will reopen the polyoxyethylene stearate question only if new research evidence indicates a clear need for reconsideration of the data. They say that the decision was reached with the unanimous consent of the Food and Nutrition Board.