LEGISLATION AND REGULATIONS

Bar Group Discusses O'Hara Food Bill

CHICAGO.-The O'Hara Bill (H.R. 9166) on food additives died a natural death with the adjournment of the 83rd Congress. Developed by leaders of the milling, dairy, meat, and baking industries, the bill nevertheless ran into opposition from certain segments of the food industry. According to Charles Wesley Dunn, food law authority, it is practically essential for manufacturers to get together a new food legislation before January 1. Dunn is chairman of the division of food, drug, and cosmetic law of the American Bar Association. At the ABA's annual meeting here August 16-20 the division assembled a panel of the leading supporters and opponents of the O'Hara Bill to discuss a food chemical additive amendment to the 1938 Federal Food, Drug, and Cosmetic Act.

Roy C. Newton, of Swift & Co. who played an important part in the O'Hara Bill's development, says the food industries believe that they should continue to improve their food products from the standpoint of nutritive value, wholesomeness, palatability, and convenience. But in so doing public health and welfare should continue to be the first considera-Newton's group believes that every substance not represented by long usage in human diet should be subject to question as a food ingredient and should be thoroughly tested by animal experimentation. The law should also require similar testing of a new product before it is put on the market. The FDA should examine the test results in both cases and should make the final decision on the acceptability of the product.

Under the present law the FDA can withhold an unstandardized food from the market only if it can prove that it contains a substance injurious to the human body. (An "unstandardized" product is one for which the FDA has not promulgated standards governing optional ingredients. The majority of foods are not standardized in this sense.)

Newton said that he has not taken a position for or against the O'Hara Bill because he does not have the legal experience to judge its particular wording, but if the bill will put into effect the principles above, he thinks it should be supported.

Against. Probably the most outspoken opponent of the O'Hara Bill is Fredus N. Peters of Quaker Oats. He says that the bill transfers responsibility

for the safety of food "from the manufacturer, where it belongs, to one individual who has to pass on every new food additive." He envisages a bottleneck which would greatly reduce the rate of introduction of new additives. He believes that by forcing the manufacturer to go to a government official for decision, research will be severely hampered.

The O'Hara Bill calls for the Secretary of Health, Education, and Welfare to pass on the functional value of the proposed additive for its intended use. "Since when is a chemical's toxicity affected by its functional value?" Peters asked. He believes that it is dangerous to give the Secretary such power.

Peters also took exception to many other points in the bill, among them, requiring listing chemical composition of additives and method of manufacture. Also brought up was the point that prior approval by the FDA, or even long use by humans, does not always ensure the safety of an additive. New data have often brought to light harmful effects of an approved product. Newton agreed that prior approval does not guarantee safety, but that someone other than the manufacturer should be the referee who decides whether a product is harmful or not.

Modify. The objectives sought by the O'Hara Bill are basically sound, provided some important changes are included, Erwin P. Snyder, general counsel for Kraft Foods, told the division. The 1938 Food and Drug Act is not only inadequate from the FDA's standpoint, but also is not adequate from point of view of the chemical and food manufacturer. Under this law all substances are classified on either toxic or nontoxic without regard to quantity. Thus, to prove a case, it is held sufficient for the Government to show merely that an ingredient is poisonous or deleterious, that is, it has a potentiality for harm, and that it exists in some quantity, however minute, in the food. This is unjust because a substance has toxic properties only in relation to the quantity in which it is present in the food. True, provisions are included for establishing tolerances, but their language is such as to make their use almost impossible. Snyder would modify the act so that a substance not injurious to health "when used in the quantities and manner intended" might be added to a food product.

Snyder suggests that the "functional value intended use" phrase opposed by Peters be changed so that the Secretary may consider the possibility of danger to public health as compared with potential economic and other benefits likely to result in an additive's adoption. If an ingredient demonstrates no measurable hazard, then mere convenience or desire should be sufficient ground to sanction its use. On the other hand, if the health hazard is great, a showing of the necessity of using the material would be required.

Time Limit. To eliminate the possibility of a continuing failure of the Secretary to act on an application for new additives, a provision should be incorporated to provide that unless an application is denied within a reasonable time, such as six months, the application should be deemed granted.

Snyder called for a number of other changes, including the deletion of the requirement for giving the chemical composition of a proposed additive. This may be unknown and so it should be necessary only to give pertinent chemical information.

It is obvious that there are considerable differences of opinion within the food industry regarding new food additives legislation. The chemical industry, represented by the Manufacturing Chemists Association, has not yet become involved to any great extent in the controversy although MCA is keeping a close watch on developments. In all probability the food and chemical manufacturers will get together, under the leadership of Mr. Dunn, and back a new bill in the next Congress.

A Scientific Viewpoint. Paul Logue, Monsanto, summed up four major reasons for incorporating various additives in foods as follows: to produce desirable changes in the food product; to prevent undesirable changes; to prevent spoilage; to compensate for deficiencies which may exist in the food.

Dr. Logue believes that we are coming more and more to the concept that the standards for foods are not established by nature but rather by man's nutritional requirements. He believes that in the future there may be an increase in the tendency to fortify naturally occurring foods with other nutritional substances as in the example of milk fortified with vitamin D.

Dr. Logue also said "the use of chemicals in foods is not new; their use is not capricious; they serve a definite and beneficial purpose; and as new needs arise, new chemicals will be found to serve them.