Member of MCA's chemicals in foods committee makes statements on food additives legislation

MODIFICATION OF THE PRESENT Food and Drug Law to cope with the problems presented by the deliberate addition of chemicals to foods has been a topic of discussion since the end of World War II.

It seems agreed by all interested parties that the present Food and Drug Law needs modification. There is a question of how the law should be modified.

The Food and Drug Administration has pointed out two weaknesses in the present law. First the law requires no advance information to the Government of an intent to distribute or use a new chemical additive, with the possible consequence that an unsafe or inadequately tested chemical might be used for a considerable period of time prior to detection by the Government. Secondly, detection may only be the starting point, for the FDA must demonstrate the additive to be poisonous or deleterious for food use.

It appears that there is general agreement in both food and chemical industries that the present law is deficient in these respects.

Both industry and government appear to have had difficulty with the blanket prohibition against the use of "poisonous and deleterious" substances in foods. The problem here is that this part of the present law fails to recognize the basic principle of selective toxicity; for virtually every substance consumed by man has a toxic limit and it is somewhat illogical to bar the use of a highly beneficial substance simply because it may, at some level of intake, have a potentially harmful effect.

The O'Hara Bill (H.R. 9166), introduced during the 83rd Congress, attempted to cover all three of these points by providing that the manufacturer of a new additive file an application with FDA for permission to use the new substance and, at the same time, submit test data and other information. This bill also attempted to cope with blanket prohibition against "poisonous and deleterious" substances by providing for use of a new additive if it could be proved safe "for its intended use." The O'Hara bill would permit the use of a new chemical additive only in accordance with regulations promulgated by FDA. This is often referred to as the "Licensing System," and it is at this point that the basic questions appear.

Conservative elements in both the food and chemical industries say that evaluation of experimental data and appraisal of potential harm are a subjective process involving personal opinion. Therefore, they say it is not wise to grant such extensive "yes" or "no" authority to the FDA.

While agreeable to mandatory pretesting and advance submission of test data, conservative elements insist that the FDA should continue to exercise its traditional policing function.

Some modification appears inevitable, and the MCA as a representative of the chemical industry seems to favor adjustment.

Fred Bartenstein, Jr., counsel for Merck & Co. and a prominent member of the Chemicals in Foods Committee of the Manufacturing Chemists' Association, recently made a statement on food legislation before the American Bar Association's Food, Drug, and Cosmetic Law Division. Mr. Bartenstein's expanded statement is thought by many industry people to be a well considered approach to the whole problem. It is reprinted in full below.

MCA Statement

MCA says its members are in favor of any modernization of the present law which will provide maximum safeguards to public health and at the same time will not interfere with the scientific advances needed to improve and extend our food supply. "We believe," says MCA, "that the food industry and government officials concerned with this question have the same objectives. However, there are differences within all three groups as to details of the legal approach. Our objective is to work with the food industry and the Government toward the best regulation of law from the standpoint of public interest. We think Mr. Bartenstein's article represents a reasonable middleground approach."

Mr. Bartenstein's article follows.

Intentional Food Additives Legislation

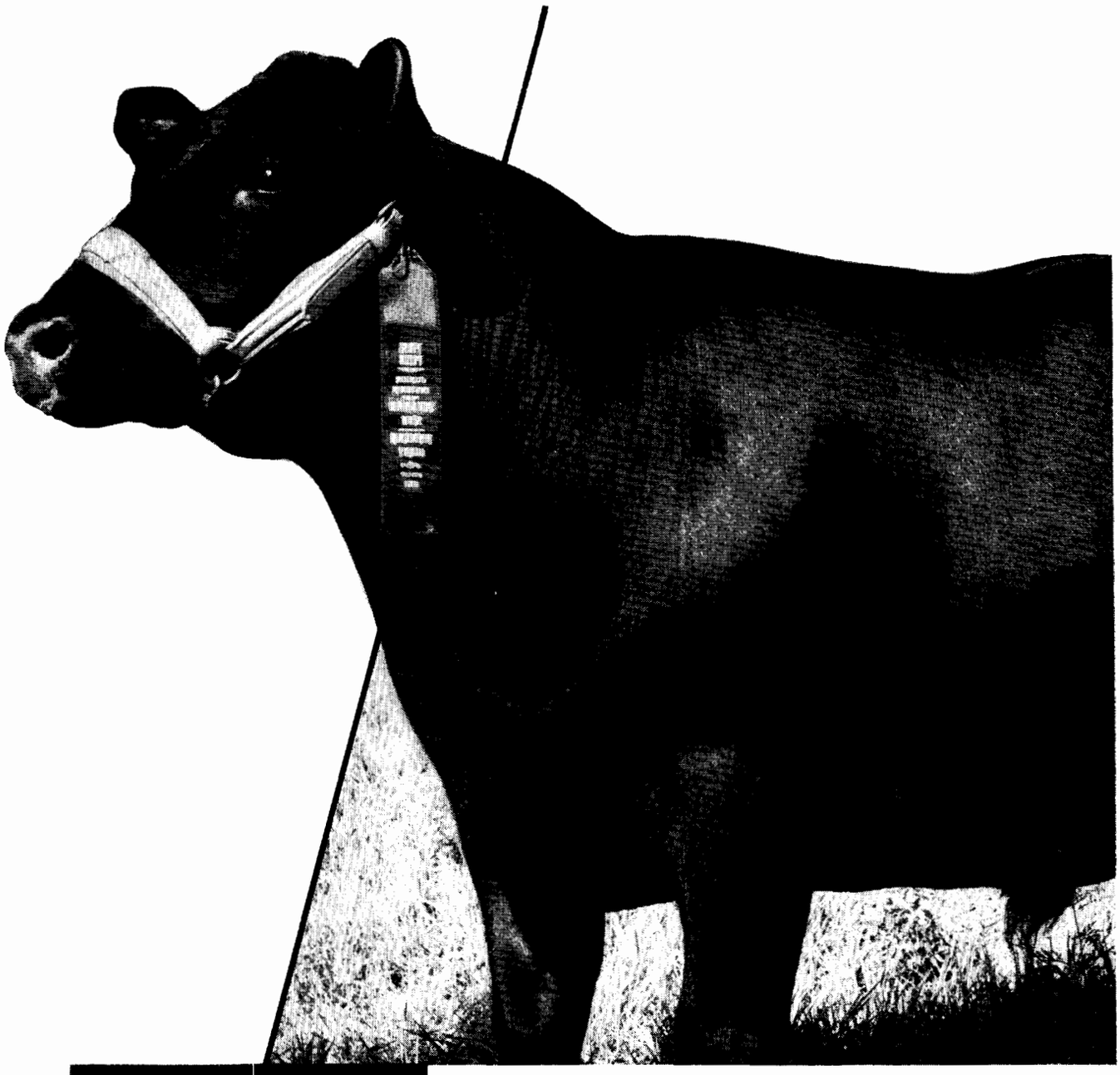
"It has been my privilege for several years to work closely with various members of the chemical industry on the problem of new legislation affecting intentional food additives. That work has brought me into touch with members of the food industry who are equally interested in the subject.

"It is my impression that a majority of food-additive producers, sometimes referred to as 'the chemical industry,' feel that changes should be made in existing laws affecting the use of new additives. The reason for this feeling is not surprising. The portion of the 'chemical industry' concerned with the food-additive question is in reality a part of the food industry itself. For the most part, it is fully sensitive to the delicate character of food production and to the high degree of public responsibility that goes with it. This is true, if for no other reason, because of its close contact with food customers. The food-additives industry knows the immediate and ultimate values of putting safety first and of seeing to it that our laws are fully strong enough to protect the public health.

"It has been asked recently why makers of food additives have not taken a firmer position for or against specific legislation. The answer is that they have wanted to work with the rest of the food industry in arriving at a solution. Production of foods in which additives are contained is generally a joint project between suppliers and buyers of the additives. Safety and wholesomeness of food are determined not only by the character of the ingredients but by the quantity and manner in which they are used. Any new law that goes to the heart of safety must take into account both of these factors. It is for this reason that the majority of those who produce additives have come to consider it essential that the two parts of the industry try to arrive at a joint solution. Efforts for several years have been directed toward attaining that solution.

"Actually, a great deal of progress has been made in bringing various viewpoints together. It appears that food-additive makers agree with most of the basic principles publicly asserted by some of the food groups. They agree with the premise that every new ingredient proposed for use in food should be adequately pretested for safety before use. They agree with the principle that no man should be his own referee on the issues of safety and adequacy of safety testing. But they urge that he continue to bear full responsibility for his own compliance with law and that the refereeing be by traditional policing and court actions. There seems to be general agreement that all testing data on a substance should be supplied to the government ahead of its use in foods.

"Some of the food people have proposed that the Food and Drug Administration



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should finally be permitted to say 'yes' or 'no' to the use of an ingredient before it is put to use, based on its views of adequacy of testing and its views of relative safety in the light of usefulness. Other food people feel that FDA has adequate powers under existing law. Still others have pointed out that existing law has a disadvantage in being interpretable to forbid an additive that has a safe use.

"There is a middle-of-the-road approach shared, I believe, by the majority of food-additive producers and by a substantial number of food-industry representatives. This approach is prompted by the belief that the Federal Food, Drug, and Cosmetic Act is and should remain basically a policing measure. Practically all the mandates of the Act—and most of them involve similar issues of public health and safety—are enforced as policing measures. The industry is given the rules and is expected to abide by them. Failure to obey the rules results in policing action by FDA. Before further extension of the licensing type of control—such as that on food colors, new drugs, insulin and antibiotics—a bona-fide effort should be made to strengthen existing rules, remove defects and furnish new enforcement weapons. The following rather specific additions to the federal food and drug Act comprise that middle-of-the-road approach, given a great deal of thought by industry representatives. If these changes were adopted, they would result in a significant strengthening of the statute:

(1) Add a new provision to the Federal Food, Drug, and Cosmetic Act that no new ingredient intended for food use should be shipped in interstate commerce or used in foods unless the shipper or user submits to FDA his full data on safety.

(2) Add a provision that the Administration have a reasonable time in which to review this data.

(3) Amend the law to provide that it is a violation to ship an ingredient (or a food containing it) which is unsafe in the manner used or intended to be used, or which has been inadequately tested for safety for food use.

(4) To resolve initial differences between FDA and the supplier or user of the ingredient, add a provision for informal conferences and, possibly, for advisory scientific bodies to be available to either government or industry."

Additions to Act Would Prevent Use of Unsafe Ingredients

"The resulting law would not allow an untested or unsafe ingredient to be used before FDA discovers its existence or while the Administration tries to get evidence to prove it is unsafe. Prior notice and time for evaluation of submitted data is a prerequisite to shipment or use. If the Food and Drug Administration is of the opinion that the ingredient should not be used, it can move, before such ingredient reaches the market by the traditional procedure of injunction. If that agency is right in its position, what it needs to succeed in the courts is immediately at hand: evidence showing lack of safety or showing inadequacy of testing.

"The proposed changes would leave the supplier free to ship the ingredient or the user to use it at the end of the prescribed periods, whether or not there has been final agreement with FDA unless, of course, the Administration takes the matter to court, as noted above. This procedure has the advantage of not giving to FDA the power of vetoing the ingredient and, therefore, of not having to shoulder any of the supplier's or user's primary responsibility.

"I believe that in the great majority of cases, as now, agreement would be reached between the supplier or user and the government. In cases where there would be disagreement, the courts would decide the issues in the first instance, with the enforcing agency bearing the burden of showing lack of safety or inadequacy of testing, not an unfair burden with all the evidence that would be necessary for the determination at hand."

"The Administration's practical operating power under such an amended statute would be perhaps as great as its legal one. There would be few instances in which a supplier would be bold enough to go ahead with sales of a proposed ingredient if FDA were dissatisfied with the submitted evidence. Of interest to food companies, anyone wanting to may determine from the Administration directly whether a notification has been filed on any proposed ingredient and whether the official attitude is favorable or unfavorable.

"This increase of FDA police powers seems to me to be justified in the interest of public-health protection. It would better accord with scientific realities than the present law. It has the virtue of protecting the industries against arbitrary, timid or nonscientific decision, and it does avoid further travel down the trail of government licensing control over the food drug and cosmetic industries. This, of course, is a policing measure, and requires active enforcement. It is axiomatic that the Administration should have the people and the facilities and, therefore, funds to enforce it thoroughly.

"These changes which, as I have said, have the close attention of representatives of the food industry, particularly of the food-additive producers, may yet be the genesis of an industry-wide bill."

(Bartenstein's statement reprinted by permission from Food, Drug, Cosmetic Law Journal, *October, 1954)*