THE IMPORTANCE OF FOOD ADDITIVES AND GOVERNMENT REGULATION OF THEM

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In the discussion below the definition of food additives which has been developed by the Food Protection Committee, a part of the Food and Nutrition Board of the National Academy of Sciences is used. This definition states that a food additive is a substance or a mixture of substances, other than a basic foodstuff, which is present in a food as a result of any aspect of production, processing, storage, or packaging. The term does not include chance contaminants.

The food additive activity of the Manufacturing Chemists' Association began in 1950 with the formation of our Food Additives Committee. This Committee is composed of toxicologists, chemists, doctors, labeling experts and lawyers. Since 1950 this Committee has worked diligently to aid the Federal Government in the development of the Food Additives Law and in the effective administration of the law. These efforts culminated in passage of the Food Additives Amendment of 1958. The law had the strong support of our Association which represents 193 chemical companies in the United States and Canada. The United States segment represents over 90% of the productive capacity of the chemical industry.

Some preliminary comments concerning food additives are in order at this point. As all of you are aware all components of foods are chemicals. The great bulk of foods is comprised of chemicals classified as carbohydrates, fats, proteins, minerals and water. In addition to the natural chemical composition of foodstuffs, chemicals may be incorporated, either directly or indirectly, during the growing, storage, or processing of foods. Such chemicals may be either intentional additives or incidental additives.

Intentional food additives serve one or more of these purposes: improve nutritional value, enhance quality or consumer acceptability, improve the keep-
ing quality, make the food more readily available or facilitate its preparation. These intentional food additives may be classified as follows:

1. Acids, Alkalies, Buffers, Neutralizing Agents
2. Bleaching and Maturing Agents, Bread Improvers
3. Emulsifying, Maturing, and Thickening Agents
4. Flavoring Materials
5. Food Colors
6. Nutrient Supplements
7. Preservatives, Antioxidants
8. Miscellaneous Intentional Additives

All of these classes of food additives are described quite fully in the Food Protection Committee's publication 887 entitled, The Use of Chemicals in Food Production, Processing, Storage, and Distribution.

Such chemicals are absolutely necessary in our food distribution pattern of today. One hundred years ago, commercial food processing was largely limited to salting, smoking, fermenting, and drying of a few products. Today there is available to everyone, a steady supply of fresh foods and vegetables and processed products that retain practically all of the nutritive quality and flavor of the fresh product. It has been said, and I wholeheartedly agree with the statement, that there is not the remotest possibility of producing our present food requirements without the help of chemicals. Many times we hear of organically grown products. However, the proponents of such a method of agriculture fail to make it clear that if such a system were to be adopted the price of most foods would increase two times, three times or more, as compared to present prices. As a matter of fact, certain foods would be impossible to grow or prepare for market without the use of chemicals.

I do not believe that I need to comment on the fact that our population and that of the world is increasing at a very rapid rate with the result that we will need ever increasing amounts of food to feed such an expanding population. The time may very well come when we will no longer have a surplus of food such as this country is blessed with today.

It is regrettable that in this field of food additives, there is very little public understanding of the valuable role which food additives play in making available the nutritious foods we enjoy today. I believe that one of our major troubles has been that the public in general considers that the addition of any chemical to a food is the addition of a substance which may in some way, harm the individual eating the food. However, as you know, this is not so. Certainly the public is quite familiar with salt, a very common seasoning agent. Even this widely accepted chemical could be toxic if ingested in large amounts.

Our Association firmly believes that qualified experts in the food field have a duty to educate the public to the great benefits which chemicals confer upon our society. Your association can be very helpful in this endeavor.

What we are doing in the way of a concrete educational program on food additives may be of interest. Our Association has engaged a firm of experts in this field to develop the program. The objectives of it are:

1. To provide key "food professionals" with accurate, documental information on the story of food additives.
2. To create an awareness and appreciation of the fact that our food supply continues to be better and safer, thanks to modern food technology.
3. To give, among other factors, a better understanding of the role of food additives in:
   a. Protecting food, improving its keeping qualities and increasing safety.
   b. Improving the flavor, nutrient value, and texture of food.
   c. Helping to make possible the many convenience foods.

We hope by this program to reach the following groups: teachers and supervisors of high school home economics, college foods teachers and administrators, public health specialists, and interested physicians, home demonstration agents and extension specialists, food editors; radio and television broadcasters on food topics, nutritionists and dietitians and home economists in business.

One of the first steps undertaken has been the preparation of a basic food additives booklet, entitled, Food Additives: What They Are/How They Are Used. Copies of this booklet are available from our Association upon request. If you would like one, please fill out the form which you will find at the back of the room, and return it to us. This booklet covers many aspects of food additives presenting technical information in popular, readable language.

Leading food scientists from education, government and industry served as advisors in the development of the manuscript to insure both scientific accuracy and usefulness. We have distributed some 85,000 copies of this booklet to date. The response has been excellent and we believe that the booklet is filling a sorely felt need for information of this type.

In addition to the basic reference booklet there are available a number of users guides addressed to various groups informing them how to make use of the basic food additives booklet. It is also planned to prepare filmstrips on the subject of food additives to aid individuals who address groups con-
concerning this subject. Such filmstrips will tell the story of food through the ages concentrating on the achievements since the turn of the century.

A review of government regulation of food additives goes back many years. In 1906, Congress passed the Pure Food and Drug Act, the purpose of which was to prevent and penalize unsanitary practices in food handling and adulteration of food with worthless substances. Then in 1938, Congress broadened consumer protection by passing the Food, Drug & Cosmetic Act.

Later a system of informal conferences grew up between FDA and industry resulting in the issuance of sanctions for the use of certain food additives. This was, however, in the face of the implication in the law that poisonous and deleterious substances were not to be used in any amount. The Food and Drug Administration however, by about 1953, began to emphasize and enforce this poisonous per se doctrine.

This was the background which led to the eventual passage of the Food Additives Amendment of 1958 with the strong support of the food and chemical industries. However, at the last minute the controversial Delaney Cancer Clause was added to the law without any hearings having been held on the clause.

The Food Additives Amendment applies to substances which result, or may reasonably be expected to result, directly or indirectly, in becoming components of food, unless the substances are "generally recognized by qualified experts as safe for their intended use," or have prior approval or sanction. Thus, it covers (a) direct additives such as flavorings, vitamins, and minerals added to improve nutrient values, sweeteners, preservatives, emulsifiers, stabilizers and thickeners, acids, alkalies, buffers, neutralizing and bleaching agents, and (b) indirect additives such as those that may migrate from packaging, in coatings of citrus fruit, from adhesives in packaging, or inks and plasticizers.

Our Association has published a Manual entitled, *How to Proceed Under the Food Additives Amendment*. In this Manual there are a number of questions posed which will aid in a determination of whether a product is subject to the Food Additives Amendment. The booklet then goes on to specify how to proceed if a regulation is desired and also gives information concerning the filing of a petition proposing a regulation for a food additive, as well as information concerning objections, hearings and appeals.

The Food Additives Amendment is certainly a major step forward in progressive legislation since it recognizes that there is a safe and unsafe level of intake of any substance.

The Food Additives Amendment placed an enormous additional burden upon the Food and Drug Administration. The Food Additives Amendment of 1958 covered not only intentional additives, but also incidental additives. Incidental additives are those which find their way into food by migration. Thus, minute amounts of certain substances may migrate to the food from, for example, a packaging material. After the passage of the Food Additives Amendment, it was realized that in many cases there was absolutely no information concerning what did migrate from packaging materials and there were few analytical methods available to ascertain such migrants and their amounts. The Food and Drug Administration now has adopted the policy that in place of attempting to write individual regulations say for 100 substances in paper which may conceivably migrate to food, one regulation should be developed specifying the ranges in composition, performance requirements, and conditions of use which will insure that the paper is safe for its intended use.

Many of you have read about the controversy which raged, concerning Ex-Secretary Flemming's action on cranberries at Thanksgiving time in 1959. Secretary Flemming's action was taken as a result of information that some cranberries had been contaminated with aminotriazole, a suspected carcinogen. This contamination resulted from the failure by farmers to follow the directions for use placed on the label by the manufacturer.

The following year a Color Additive Law was considered by Congress and extensive hearings were held by the House Committee on Interstate and Foreign Commerce. After considerable discussion, the Delaney Cancer Clause was also inserted in the new Color Law.

Under the Delaney Cancer Clause now appearing in both the Food Additives Amendment and the Color Additives Amendments it is forbidden to use any substance in any amount whenever it is "found to induce cancer when ingested by man or animal, or if it is found by the Secretary (of Health, Education and Welfare) after tests which are appropriate for the evaluation of the safety of additives for use in food to induce cancer in man or animal."

An eminent toxicologist has made the statement that at the present time there is no way of experimentally determining whether there is a safe level for a particular carcinogen. He also states, however, that there is sufficient experience and actual human use of natural and synthetic carcinogens to define rather well a safe intake for many specific substances. Thus, in this phase of food additive control, many people in the scientific community believe that the "rule of reason" should be used,
They cite, among other references, the Kistiakowsky Report of the Panel on Food Additives. This report was prepared at the direction of President Eisenhower after the cranberry incident. The report, I believe, presents the proposition - that the “rule of reason” should apply in the determination of safety of additives, including carcinogens or suspected carcinogens.

With your permission, I would like to quote a portion of the Kistiakowsky Report concerned with the “Problem of the Relation of Dose to Consequence in Man”:

“. . . For a number of carcinogens that have been studied, however, there is evidence for the existence of a level of ingestion at which no carcinogenesis occurs during the life of the animals when tested in limited numbers. Also, dose-response curves for certain potent carcinogens in animals have been worked out from which can be reliably predicted the probability of an individual, in a given sized population, developing a tumor from a given dose of carcinogen. Such curves lead to the conclusion that dietary levels of carcinogenic agents exist at which the probability of cancer induction in animals is near zero.

“The conclusion derived from animal studies has relevance to certain common components of the diet of man. In foodstuffs, as they occur in nature, one finds traces of chemicals which in larger amounts are generally accepted as carcinogenic, such as certain inorganic arsenic compounds, radium and selenium. It can be shown by methods of analysis now available that ordinary table salt derived from rock salt contains trace amounts of radium and that foodstuffs containing iron salts are contaminated by minute quantities of arsenic. Although it cannot be stated absolutely that these traces of carcinogenic materials have never induced cancer in any human, the available evidence has not directed suspicion to these trace amounts as significant to the over-all cancer morbidity.

“There is additional evidence which indicates that a dose-response relation for carcinogens exists in man . . .

“From the experience obtained in animal experiments and study of humans who have been exposed to carcinogens in the course of their work such as cited above, the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available.”

You will note that this quotation ends with the comment that it will be necessary to weigh scientific evidence as it becomes available. This is really the nub of the problem today. There is not at hand the necessary scientific evidence to support or refute the basic position of the Delaney Cancer Clause. There is a great need for a sharper definition of what is a carcinogen. Also the entire subject of carcinogenesis needs more quantitative and analytical evaluation by scientists.

It is hoped that eventually an agreement may be reached for a projected program of study of this important problem of carcinogenesis. Such a program might be jointly undertaken by industry, government and academic institutions. It is only with a joint approach of this kind that the vexing problem of carcinogenesis may be eventually solved.