Industry Problems in Developing Intentional Food Additives

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FOOD additive problems affect many diverse areas of American industry. Some companies, like the chemical manufacturer and flavor compounder, may prepare substances intended for deliberate addition to food. Others, like the package fabricator, the machinery manufacturer, the pesticide formulator and the petroleum refiner, may be more concerned with substances which unavoidably get into food. The food processor and feed manufacturer are users of food additives.

Many companies with related interests have approached food additive problems through their trade associations; it has been estimated that at the present time there are between 50 and 100 different trade associations to whom food additive developments are of concern. It is obvious, therefore, with such a range of interests, that there is no over-all industry attitude or position of food additive matters. I shall provide you with one viewpoint on a few food additive problems, a viewpoint likely to be shared by many in industry, but certainly not by all. It must be considered a personal viewpoint and not necessarily one shared by my company or by the chemical industry.

I shall use the term food additive in the sense defined by the Food Protection Committee of the National Research Council, namely "A substance or a mixture of substances, other than a basic foodstuff, which is present in food as a result of any aspect of production, processing, storage or packaging." I must define this term because the legal definition of food additive, under the Food Additives Amendment of 1958, is a much more restricted designation from which most additives in everyday use are excluded because they are generally recognized as safe.

It is convenient to divide food additives into two classes. When they are introduced to preserve or to improve the quality of the product, they are known as intentional additives, because they are purposely added to serve a specific need. In contrast, other food additives are known as incidental additives. They include substances like pesticides, which are required for the production of crops and which may remain in small quantities in the food. Because my experience has been with intentional additives, I will limit my remarks largely to problems with this type of product.

INTENTIONAL ADDITIVES

Since intentional additives are introduced into food for specific purposes, they may be classified in terms of what they do. Possibly the most extensive and authoritative list of intentional food additives is that compiled by the Food Protection Committee of the National Research Council. It is entitled, "The Use of Chemical Additives in Food Processes." This booklet was first published in 1956 and is currently being brought up to date through revision.

An important group of intentional additives are the nutrients, the vitamins, minerals and amino acids which may be added to certain staple foods to restore nutrients lost in processing and to otherwise eliminate general dietary deficiencies. Iodized salt, vitamin D fortified milk, enriched cereals and grains, and vitamin A fortified margarine are illustrations of usage of intentional additives which are

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Presented at a Symposium on Additives and Residues in Human Foods at the University of Missouri School of Medicine, Columbia, Missouri, on April 27, 1960.

not only endorsed by leading nutritionists but in many states are required by law.

For those who must or who prefer to minimize sugar consumption in their diets, a variety of foods are commercially available containing saccharin or cyclamate, non-nutritive sweetener additives. Food colors and flavors are two classes of additives whose uses are obvious. Incidentally, in terms of numbers of different compounds, flavor chemicals exceed all other intentional additives combined. Artificial food flavors are generally mixtures of many different compounds, carefully selected and blended. Such blends are, however, still simpler than natural flavors. For example, natural orange and grape flavors have each been shown to consist of at least several dozen different compounds.

Emulsifiers, surface active agents, sequestering agents, maturing agents, buffers, acids and alkalis are other classes of intentional additives of particular importance to the food processor. They permit him to compensate for natural variations in his raw materials such as hardness of water, acidity of cream and baking properties of flour, and enable him to produce foods which are consistent in appearance and which remain physically stable.

Much of the food we purchase today is preserved from deterioration by some sort of physical treatment, such as cooking, canning, bottling, pasteurizing, refrigerating, freezing or dehydration. In some cases, intentional additives are used for similar purposes. Antioxidants, for example, prevent rancidity in fatty foods. Antimycotics prevent molding of bread, citrus fruits and cheese. Vitamin C is used to prevent darkening and flavor changes in freshly cut and frozen fruit and in peeled potatoes. Antibiotics can extend the shelf life of refrigerated poultry and fish.

The foregoing are just a few examples of what we mean by intentional food additives. Keep in mind that these are substances deliberately added to foods for specific purposes, to improve nutritional quality, attractiveness, uniformity, keeping quality, ease of preparation and cost. Intentional food additives must benefit the consumer in either a direct or indirect way. Otherwise, there is no justification for their use.

Intentional food additives and adulterants are sometimes confused. The purpose of an adulterant in this connection is deception, to make a food look better than it really is, to disguise deterioration or decomposition, to substitute for a valuable ingredient, to cheapen. The function of an adulterant is almost precisely the opposite of an intentional food additive, this is, deceiving or degrading as compared to improving. Adulterants have no place in our food supply and we have long had laws prohibiting their use.

Intentional food additives are absolutely essential to our life today. Without them, our diet would be nutritionally inadequate, restricted, monotonous and expensive. Without them, familiar foods like bread, processed fruit, soft drinks, cheese, margarine, canned vegetables, ham, sausage, candy and ice cream would be eliminated from our meals. We would be left with a few fruits, vegetables and meats to be eaten without benefit of sugar, salt, butter or spices.

On the basis of our past experience, it seems obvious that our use of intentional food additives in the future will increase.

The United States today has the most nutritious and wholesome food supply in its history and in the world. In the future, it seems likely that we will continue the same conservative approach to the use of nutritional adjuncts that we have followed in the past. However, with our increasing knowledge of nutritional requirements and deficiency diseases, some modification in vitamin content, protein composition, and particularly the fat composition of our diet, may be desirable through food selection and food fortification practices.

Important reductions in food spoilage losses have been achieved through the use of pesticides, refrigeration, freezing, rapid transportation and chemical preservatives. Much still remains to be accomplished, for food spoilage is still a multibillion dollar challenge and a luxury that we cannot continue indefinitely to afford with our expanding population.

Convenience foods, unknown a generation ago, are now readily available to take the drudgery and uncertainty out of home cooking.

Additives made some of these developments practical, and promise exciting possibilities for the future.

Another development of great importance to the consumer is in food quality. The wormy apple, the stale cracker, the rancid peanut have almost disappeared from the scene. The tough steak may be the next to go. Intentional food additives have made, and will continue to make, important contributions to the availability of foods of consistently high quality in your future.

These are just a few of the areas in which food additives will perform functions of increasing importance in the years ahead. I have not attempted to speculate on possibilities which have no basis in commercial reality today, but it must be obvious that much effort is being devoted to exploring entirely new fields of application for additives to food. Certainly, if there is one thing which we in industry do not lack, it is in ideas of ways in which our foods can be improved in quality, in availability and in cost, through the proper use of food additives.

THE FOOD ADDITIVES AMENDMENT

The Federal Food Drug and Cosmetic Act was amended in 1958 through the enactment of the Food Additives Amendment. This amendment is a major piece of legislation which provides extensive controls over the use of intentional and incidental food additives.

The legislation was enacted with two purposes in mind according to the Committee on Interstate and Foreign Commerce of the House of Representatives: (1) to protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels.

These are noble objectives. They are supported by industry. Specific legislation to accomplish these objectives was advocated by industry groups for several years prior to enactment of the present law. To the extent that the Food Additives Amendment continues to fulfill these objectives, I am sure it will continue to be regarded by industry as a good law.

Enactment of the Food Additives Amendment has created a number of problems for industry because of its scope and its newness. It has raised questions concerning the status of hundreds of substances commonly used in or on our foods for years. It has involved the products of suppliers with no background of experience in dealing with food regulations and with the Food and Drug Administration. It has threatened formulators with exposure of their trade secrets.

Under such conditions, it is hardly surprising that there has been much misunderstanding on the part of many companies concerning the Food Additives Amendment and its interpretation. Even with companies considered to be experienced in dealing with food law, there has been widespread frustration because of regulatory delays.

Although these are all problems which time must solve, I do not wish to minimize their importance to industry. The Food and Drug Administration has done a tremendous job in the time available to them in administering the Food Additives Amendment, but there is serious concern as to whether there is enough time before March 6, 1961, when present temporary extensions expire, to permit both the Food and Drug Administration and industry to deal properly in deciding the status of hundreds of existing food additives. An amendment to the law to permit further extensions for food additives when there is no danger to public health has been widely advocated by industry spokesmen as a means of avoiding a potentially chaotic situation.

Our year and a half of experience under the Food Additives Amendment has served to reveal many other problems which time can only aggravate if corrective steps are not taken. Some of these problems are of particular concern to the scientist because they seem to represent instances in which the ability to act and to regulate on the basis of right scientific judgment has been sacrificed to administrative convenience and political emotion.

The prime example of this is, of course, the

so-called Delaney clause which prohibits approval for use in food of any substance found to induce cancer when ingested by man or animal. This is the clause which has helped bring to a practical standstill progress in animal feed additives and has already caused two leading pharmaceutical companies to curtail severely their research programs in this area.

Various arguments have been raised against the Delaney clause. These are in essence based on the fact that experienced judgment as to whether a hazard exists in the use of an additive has been replaced by an arbitrary requirement permitting no interpretation. I should like to emphasize that in the widespread opposition expressed to the Delaney clause, there has at no time been any suggestion that harmful carcinogens be permitted in the human diet. Although many believe the Delaney clause should be dropped entirely, a simple qualification by specifying that to be prohibited from use the additive must be found to induce cancer when ingested by man or animal "in amounts and under conditions reasonably related to the intended use" would remove most industry objections.

Another vexation to the scientist is defining the practical equivalent of zero. You may be aware that a food packaging component is not a food additive if it does not migrate into the food. Certain pesticides are approved on the basis that there is no residue in the edible part of the food. A drug for animal use may be approved on the basis that it leaves no residue in edible tissue. All these applications pose the question of how one can demonstrate that a substance is not present. It is, of course, quite possible for the analytical chemist to develop methods capable of detecting one part of additive in one million parts of food and by such a procedure he may show that no detectable quantity of additive is present. By more refined techniques he might show no detectable additive in 10 million parts, in 100 million parts, or even a billion parts of food. The law gives the analyst no guidance as to the practical equivalent of zero that it will accept.

Conversely, if there is an effective food additive regulation involving a zero residue specification developed on the basis of an analytical method sensitive to one part in a million, will this approval hold in the event of the development of a more sensitive procedure which might show, for example, a detectable residue of one part in 100 million? It is probably fair to say that at the present time, anyone operating under a zero tolerance requirement is vulnerable to progress in analytical chemistry.

In order to resolve problems of this sort, we badly need principles, based either on scientific testing or on experience, which will guide both industry and the regulatory agencies in establishing limits for additive residues sufficiently small to be negligible insofar as safety is concerned. This will in turn enable the analyst to determine the sensitivity of the methods he must develop in order to detect whether a biologically significant residue of an additive is present in a food.

Other areas in the Food Additives Amendment could be cited in which there is an apparent conflict between scientific judgment and the regulation or in which such a conflict could develop if the regulation were interpreted very narrowly. It would seem highly desirable to both government and industry to resolve such situations and in this connection the Food Protection Committee is playing an important role.

THE FOOD PROTECTION COMMITTEE

The Food Protection Committee operates under the Food and Nutrition Board of the National Research Council, National Academy of Sciences. It was formed about ten years ago as an advisory group, its primary purpose being to provide critical evaluation of information concerning the use of chemical additives in foods for the Council and encouragement of the food industry and as a guidance for public agencies.

The Food Protection Committee membership is drawn entirely from universities. However, through its panels, the Committee maintains effective liaison with governmental agencies, trade and scientific associations, and interested industries.

During the almost ten years of its existence, the Food Protection Committee has issued several authoritative reports on food additive problems including one on "Insignificant Levels of Chemical Additives in Food," another on "Principles and Procedures for Evaluating the Safety of Food Additives," and a third on "Problems in the Evaluation of Carcinogenic Hazard from the Use of Food Additives." In preparing these reports, the Food Protection Committee has had available to it the experience and advice of the most outstanding and knowledgable scientists in this country.

The regulations of the Food Additives Amendment provide that in matters of the adequacy of the methods employed to demonstrate safety for the proposed use, the Food and Drug Administration will be guided by the current publications of the Food Protection Committee.

Many of us in industry believe that a more thorough acceptance of the broad principles expressed in the reports of the Food Protection Committee in the regulation and enforcement of the Food Additives Amendment would do much to resolve many of the conflicts that described herein.

Thus far, some of the typical immediate problems resulting from passage of the Food Additives Amendment have been discussed. Let us consider now what is happening to our long range research programs from which new food additives for 1965 and 1970 should be coming.

PROBLEMS OF INDUSTRY

Justifying the effort to develop a new food additive is at best difficult. Here are some of the problems.

(1) We must find an effective additive, sometimes a very difficult undertaking, always an uncertain one. In an additive development our company undertook a few years ago, more than 3,000 compounds were prepared and tested in one application before we found one that met our needs for effectiveness.

(2) The additive must be economical and acceptable for food use in terms of color, flavor, taste, physical properties, ease of use, etc., a further limiting factor.

(3) The additive must be safe. It is a fairly simple matter to detect gross toxicity and eliminate a highly toxic product from a testing program at an early stage. Less obvious toxicity takes longer to spot. The possibility that an effective additive may be toxic further decreases chances of successful research; occasionally much time and effort is invested in a product before it becomes obvious that it is unacceptable.

The difficulties and expense of food additive research, the severe requirements for an acceptable product, and the long time required to clear a product for commercial use all require that we restrict our objectives to markets of considerable size. Some companies have indicated that a market of one million dollars per year was the minimum they could consider in justifying a research program. Although the value of the food produced in this country is very large, it should be kept in mind that intentional food additives are often used at extremely low concentrations. Research on certain types of intentional food additives such as new flavors and new food colors is likely to be greatly reduced for such reasons.

Enactment of the Food Additives Amendment can be expected to make the field of food additive research distinctly less attractive to industry for several reasons.

(1) The amendment has introduced a major new requirement, that for a suitable analytical method for determining the additive in food, which will increase the cost of the development appreciably.

(2) The requirement that a food additive petition be filed and approved will probably delay the marketing of a new food additive for at least an additional six months.

(3) The announcement, by publication in the Federal Register, that a company has petitioned for approval of a new food additive can be expected to precede the approval of the petition by at least five months. This is ample time for competition to develop a manufacturing process, erect a production unit and be ready to market the additive as soon as the approved regulation issues. Unlike the approval procedure for new drugs, which is

sometimes cited as a parallel regulation, the Food Additives Amendment deliberately discloses the development of the company that has discovered the additive, borne the expense of developing analytical and safety information, and prepared the petition. The Food Additives Amendment goes far in destroying the traditional privilege given to enterprising companies under our American system of being able to proceed in confidence with a new development and to achieve a competitive advantage by being first on the market.

(4) Finally, it should be emphasized that a company which believes it has performed a thorough and competent job in preparing a Food Additive Petition and in supplying the volumes of data required, has a rather poor chance for regulatory approval. In a recent address by the Deputy Commissioner of the Food and Drug Administration, it was indicated that as of mid-March 1960, petitions withdrawn because of incomplete information outnumbered those approved by 50 to 10. Such experience can only further decrease the attractiveness of food additives as a field for research.

These are but a few of the problems facing industry under the Food Additives Amendment. They not merely affect companies and products brought under the jurisdiction of the Food and Drug Administration for the first time but also those of whom it used to be said that the Food Additives Amendment would simply formalize the procedure they had been following voluntarily for years. They are problems affecting those who would work for a better and more abundant food supply for tomorrow.

On the basis of our past experience, it seems obvious that an increased usage of intentional food additives will be needed in the future not only to meet the food requirements of our expanding population but also to enable us to continue to enjoy the freedom of an economy in which today the efforts of only 13 per cent of our people need to be devoted to food production. One of our great sources of strength lies in the effort we can direct toward pursuits other than those concerned with producing our food and maintaining our existence. It would be a tragedy if, by our decisions today, we deny this source of strength to the America of tomorrow.

The public must be assured that its food supply and its permitted food additives are safe. The public must also be assured of its rights to the benefits resulting from the proper use of food additives not only today, but also in the future. How to reconcile these objectives without compromise is a challenge to scientists in industry, in the university and in government. Certainly, a better understanding, appreciation and respect for our mutual problems is an essential first step for I cannot concede that there should be any basic conflict in our philosophies.