Government Problems in Dealing with Additives and Residues in Food

PAUL DAY, PH.D.*

ABOUT a year and a half ago, after it had been publicly announced that I had been appointed to a newly-created position with the Food and Drug Administration, I received a number of letters and comments from friends and acquaintances. One man—a former university professor of pharmacology who had recently been operating a drug research and testing laboratory—wrote: "So you are going with my old enemy, the Food and Drug Administration. Congratulations and condolences." Another friend—a member of a family with unusual and somewhat unorthodox views on drugs and health—said: "I wish you success. It is about time that the Food and Drug Administration did something about protecting the public."

These two comments represent extreme views about the enforcement activities of the Food and Drug Administration. One group seems to believe that it is an unreasonable ogre waiting for a chance to jump on and destroy legitimate industry; the other, that it is a complacent bureaucracy which does nothing to protect consumers from dangerous substances in foods and drugs but is, in fact, a tool of big business. Because these extreme and contradictory views are held by small groups of people it may be concluded that the Food and Drug Administration is probably taking a sane, reasonable course—protecting the public against dangerous substances in foods, drugs, and cosmetics without unduly harassing proper agricultural and industrial activities. When an agency is criticized by both extremes it is possible that it is doing its job well. This may, in fact, explain why the Food and Drug Administration is the neglected stepchild of the federal government in the opinion of some people. We are not radical enough to gain the support of the rabid food faddists, but too insistent upon a reasonable observance of the law to have the wholehearted support of some segments of the regulated industries.

The policies and viewpoints of the Department of Health, Education and Welfare and of the Food and Drug Administration are contained in the mandate of laws as passed by the Congress. To be sure, at times the Department of Health, Education and Welfare and the Food and Drug Administration may have some influence on the nature of the bills submitted to the Congress and adopted by it, but in the final analysis Food and Drug Administration must be guided by federal law as written by the Congress and as interpreted by the courts. We can take only such actions as are specifically authorized; to fail to enforce the law as effectively as possible would be a neglect of duty.

In discussing a subject of this kind there is a temptation for an official of the Food and Drug Administration to stick closely to the wording of laws and regulations. This avoids the possibility that he will be misunderstood by a person concerned with the strictly legal aspects of the matter. But the legal phraseology would not be very meaningful to you, whose training has been in science rather than in law. Consequently I shall attempt to explain, in common English words, the meaning of the laws and regulations as currently

From the Food and Drug Administration, U. S. Department of Health, Education and Welfare, Washington, D. C.

* Scientific Director.

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interpreted by the courts and by the Food and Drug Administration.

The forerunner of the present Food, Drug and Cosmetic Law was passed more than fifty years ago, but during that half-century numerous changes have been made in the law. These have been required because of changes in agricultural practices, food technology and dietary habits of the American people. When the first general food law was passed by the Congress in 1906, food technology was in its infancy. Most of the food going into the home was in the raw, unprocessed form. Prepackaged foods were relatively unknown; cheese was cut from the "wheel," flour was weighed out of a sack or barrel and sold in bulk. Processed fruits and vegetables in cans were common, but the home preserving of fruit in glass jars was likewise common. Condensed and evaporated milk were common articles of commerce but dried milk powder was unheard of. Market milk was often dipped out of a bulk container into the customer's own pail. Much of the food of the average family was either produced on its own farm or backyard garden or was obtained locally from nearby farms.

At that time there was no great concern about spray residues of pesticides on food. Agricultural poisons to control pesticides were almost exclusively inorganic compounds such as copper, arsenic, lead, and fluorine or natural poisons such as nicotine and rotenone.

But poisons *were* being used in food. Dr. Harvey W. Wiley, the father of the first pure food law, was a zealous campaigner against preservatives in food. He organized his "poison squad"—volunteers who became human guinea pigs to test the chemical preservatives of that day. Among the substances being used were formaldehyde, boric acid and benzoic acid. Dr. Wiley was thus concerned about the problem we are discussing today—chemicals in food.

Dr. Mahoney (see page 277), used the term "food additive" to include any foreign chemical which finds its way into food, whether intentionally added to produce a flavor or color, or to produce a physical effect; or whether it becomes a residue in food from pesticide treatment of the crop. In the legal sense, as defined by the Food Additive Amendment of 1958, the term "food additive" has a much more restricted meaning. It does not include pesticides on raw agricultural products, coal-tar colors, substances generally recognized as safe and substances permitted by prior sanctions. This difference in usage of the term can lead to confusion. They can be distinguished in writing by using capital letters to designate the legal term "Food Additive," and using lower-case letters for the more general term. In the spoken word, however, there is no easy means of indicating capital letters. It might be well for me to outline the various types of additives, residues, and contaminants in foods from the *legal* standpoint.

PESTICIDES

Pesticide residues on raw agricultural products are controlled under terms of the Pesticide Act of 1954, the so-called Miller Amendment to the Food, Drug and Cosmetic Act. A manufacturer who wishes to introduce a new insect-killer or other agricultural poison which may become a contaminant in food, registers the substance with the Department of Agriculture. If that Department, upon examining the information submitted, sees the likelihood of the substance appearing as a residue or contaminant in food, the matter is referred to the Food and Drug Administration. The manufacturer may petition the Food and Drug Administration for a residue tolerance for the substance on raw agricultural products. If the Department of Health, Education and Welfare, that is, the Food and Drug Administration, finds that the substance is harmless to man and animals, its use may be permitted without a tolerance being imposed. If it is toxic to man or animals and if the data submitted by the manufacturer show that its use will result in small, but safe, levels of residue, the Secretary of Health, Education and Welfare is authorized to issue a regulation establishing tolerances on designated food and feed products. It is then the responsibility of the Food and Drug Administration to see that these tolerances are not exceeded.

Before a pesticide manufacturer submits a request to the Department of Agriculture for

a registration of his label he has the substance tested under actual farm usage. Such experiments may be carried out on the manufacturer's own experimental farm. Or, as many of you know since you have participated in such studies, the tests are often carried out by state agricultural experiment stations in cooperation with the manufacturer. Such testing will show the necessary level of use to obtain the desired result and will reveal the desired time and frequency of application. This information, together with analytical methods and the results of toxicological tests, is submitted in his petition to the Food and Drug Administration for a tolerance. The Food and Drug Administration must be convinced that the proposed tolerance level is safe before issuing a regulation permitting use of the substance.

Illegal residues of pesticides on food or feed crops may result if the label instructions as to dosage and method of application are disregarded or ignored. This means that persons who use agricultural chemicals must be able to read, must understand what they read, and must be willing and intelligent enough to follow the instructions. There was a time in certain areas of the world when the production of food crops was deligated to illiterate peons. Even in early American years many farmers lacked formal education. But those days are gone forever. Many agricultural chemicals are too potent to be placed in the hands of persons who cannot read and therefore cannot follow the label instructions.

Even intelligent and educated persons have occasional lapses when they fail to understand the real significance of instructions. To be followed, instructions must be in terms which the person can understand. Furthermore, instructions for use of agricultural chemicals should be placed on labels where they can be readily seen. A colleague recently showed me a label which he had cut from a 100 pound sack of poultry feed. The feed contained a drug which had possibilities for harm if the instructions for use were not carefully followed. But the warnings were printed on the *back* of the label, and the label had been stitched to the burlap bag longitudinally and down the middle. The warning instructions could not be read until the label was removed.

FOOD COLORS

Synthetic so-called coal tar colors are not covered by the Food Additive Amendment of 1958 but are still controlled by the provisions of the 1938 Food, Drug and Cosmetic Law. When the 1938 law was passed by the Congress it was believed that the coal-tar colors in use were completely harmless. The law provided, therefore, that certified colors shall be ". . .harmless and suitable for use." Later it was found that some of those colors were not, in fact, harmless when fed to laboratory animals in relatively large amounts. Under the provisions of the law, therefore, the Food and Drug Administration was required to remove such colors from the certifiable list. The 1938 law does not provide for setting tolerances for colors which are harmful in large amounts but which would be safe under conditions of use. There are now bills before Congress which, when passed, will permit the Food and Drug Administration to set tolerances for colors which are toxic in large amounts but which would be harmless in the amounts used.*

PROVISIONS OF THE FOOD ADDITIVE AMENDMENT

The Food Additive Amendment of 1938 to the Food, Drug and Cosmetic Law classifies several types of contaminants or residues in foods. They are (1) substances generally regarded as safe; (2) substances with prior sanction for use; and (3) food additives. As I indicated earlier, coal tar colors and pesticides on raw agricultural products are excluded from the provisions of the law. The term "Food Additive" is defined, legally, in a very special sense.

Substances Generally Recognized as Safe

The Amendment excludes from its provisions a substance which is generally recognized as safe ". . .among experts qualified by scientific training and experience to evaluate its safety." The law does not state how many experts must recognize a substance to be safe,

* The Color Additive Amendments became Public Law 86–618 on July 12, 1960.

or whether a majority of such experts must so recognize it, or whether *all* such experts must accept its safety. Suppose that a substance falls into such a highly specialized group of compounds that only five persons in the United States have any detailed and intimate knowledge about it; if all five of these men believe it to be safe, is this general recognition of safety? Or, suppose that 100 experts are questioned about a specific substance; ninety-nine of them express the opinion that it is safe, but one who has some special information unavailable to the other ninety-nine states that the substance is unsafe. These are some of the kinds of problems faced by the Food and Drug Administration in the evaluation of substances "generally recognized as safe." Nevertheless, after some lost time, several hundred substances have been classified in this group and lists of them published in the Federal Register.

One point is of special interest in connection with safety: the Amendment states (Sec. 201 (t)): "The term 'safe,' as used in paragraph (s) of this section and in section 409, has reference to the health of *man or animal*" (emphasis supplied).

"Food Additives"

Food Additives, in the legal technical sense, are substances added to or which become components of food which are *not:* pesticides on raw agricultural products, coal tar colors, substances with prior sanction under the "grandfather clause" of the law or substances generally recognized as safe. It is evident that to be classified legally as a Food Additive it is either not entirely safe, or it has not been adequately tested or in use long enough that its safety is recognized by scientists qualified to evaluate such safety. The Amendment gives the Secretary authority to exempt from the tolerance provisions of the law, substances which he deems to be safe on the basis of information supplied in a Petition. Or, if a substance to be used in food processing, manufacture, packaging or storage will not yield residues in the finished food products, it may likewise be exempt from the provisions of the law.

For all other additives, approval for use must be obtained through Petition to the Secretary of Health, Education and Welfare. Such a petition must include information on the chemical nature of the material, mode of manufacture, toxicological data on safety, practicable method of analysis for the additive and a statement of intended conditions of use. If the Secretary finds that the use of the additive will be safe, will not lead to deception or misbranding, and will effect its intended use without exceeding necessary safe tolerances, he may issue an order permitting its use.

Food Additives have sometimes been classified as (1) incidental, and (2) intentional. The *incidental* additives include such substances as traces of packaging material which migrate into the food, lubricants from processing or packaging machinery, and metals or other components of processing machinery which are dissolved or abraded into the food during manufacture.

The *intentional* additives are those which are added purposefully to confer some physical, chemical or other effect upon the food. They may include enzymes, antioxidants, emulsifiers, antifoaming agents, dough conditioners, mold-inhibitors, flavors and a score of others.

COMMENTS

These general considerations may seem either confusing, or redundant, depending upon the extent of your background information. The public is well aware of a number of controversial problems facing the enforcement program of the Food and Drug Administration under the Food Additive Amendment. You have all heard of the aminotriazole-cranberry situation under the Pesticide Act, the diethylstilbestrol-poultry controversy, and the general problem of the policy of carcinogenic substances. The dairy industry is worried about antibiotics and pesticides in milk and dairy products.

Regarding the last mentioned subject, the Food and Drug Administration has been concerned about pesticides and antibiotics in milk for several years. Surveys of market milk were made in 1955, 1956 and again in 1958. Between the 1956 and the 1958 sampling pro-

grams, an intense educational campaign was instituted in cooperation with other governmental and nongovernmental agencies. That educational campaign sharply reduced the number of samples containing these contaminants, but did not reduce them to zero. The Food and Drug Administration therefore announced its intention to sample milks and milk products in its enforcement program, and, if any were found illegal, to take regulatory action. News media have carried the information recently that shipments of evaporated milk produced in California have been seized because of illegal contamination with chlorinated hydrocarbon pesticides.

The problem of antibiotics in fluid milk poses two problems, one of economics, the other of health. Antibiotics in milk going to cheese manufacturers interfere with the action of bacterial starter cultures. This is a serious economic problem. On the health side, many people are sensitive to traces of penicillin, and may suffer severe illness or even death from a small trace of the drug. There is no justification for antibiotics getting into milk; the milk producer can control this by discarding milk from cows given penicillin for treatment of mastitis by following the directions for use; that is, by discarding the milk for seventy-two hours after treatment. Milk from an infected udder is not fit for use whether it contains an antibiotic or not, so there are two reasons for destroying such milk. Penicillin used in the treatment of other bovine diseases, such as that given by parenteral injection, can be kept out of market milk by discarding the milk for an appropriate length of time. The Food and Drug administration has recently proposed appropriate label warnings for antibiotic preparations given intramuscularly or intravenously.

The matter of keeping pesticides out of milk and dairy products is not quite as simple as it is for penicillin, since milk producers often buy feed for their stock. However, the producer can control this by purchasing feed only from reliable sources, known to supply pesticide-free stocks. The producer may also wish to insist upon a guarantee that the feed or forage he purchases does not contain any non-permitted pesticide residues.

No one in government wishes to stifle the proper use of chemicals in food production and processing. None of us wants to go back to the days of moldy bread, wormy apples, expensive steak and tough poultry. Yet that is what would happen if the use of agricultural chemicals were unduly restricted. We all have a stake in this—farmers, industry, consumers, the government—for we are all consumers. In government our concern is that *potentially* dangerous substances are properly used.