## **Control of Pesticides on Food**

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Pesticides are today considered essential for the production of an adequate, high quality food supply. But pesticides are poisons, and some of them, if not used

properly, may leave harmful residues in or on food. In fulfilling its responsibility to protect the public from the addition to food of poisonous or deleterious substances, the Food and Drug Administration is therefore concerned with pesticides. Its objective is to limit pesticide residues to amounts that will be completely safe for consumption. It is concerned primarily with the possibility of chronic poisoning, rather than of acute poisoning, since the quantities of residues are ordinarily minute.

In accomplishing this objective, the Food and Drug Administration establishes tolerances for pesticide residues; that is, it sets the amount that may remain legally on crops shipped in interstate commerce. Establishment of a tolerance means that the pesticide can be employed usefully in agriculture, that residues within the tolerance are safe, that when the pesticide is used properly it will leave residues that are within the prescribed limit, and that crops shipped in interstate commerce shall not bear residues exceeding the prescribed limit. FDA may exempt a pesticide from the requirement of a tolerance if it finds that the pesticide will not leave poisonous residues.

Mr. Rankin is assistant to the Commissioner of Food and Drugs in charge of the pesticide chemicals program. He has been with the Food and Drug Administration since 1939. The first regulations listing formal tolerances for pesticides were issued in March 1955. These tolerances were set under a public hearing procedure that required the Department of Health, Education, and Welfare to determine not only what level of residue is safe, but also that the pesticide is necessary in the production or handling of crops. This procedure was not particularly satisfactory to anyone. It was cumbersome and it required a health agency to make agricultural decisions.

Today, tolerances are established under a Federal law enacted in 1954, the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act, also known as the Miller amendment. This law provides new, more convenient procedures for determining how much poisonous agricultural spray or dust may remain safely on crops. It recognizes that sprays and dusts are necessary to insure a continuing supply of high quality foods, and it is designed to permit the effective use of these materials without hazard to the consumer. It assigns agricultural functions to the Department of Agriculture and health functions to the Department of Health, Education, and Welfare. It does not, however, make any change in the basic requirement that foods in interstate commerce shall be free of dangerous quantities of pesticide residues, which is a part of the Federal Food, Drug, and Cosmetic Act.

The new law provides that, within its jurisdiction, a raw agricultural commodity shall not be marketed if it bears a residue of a pesticide chemical, except under one of the following conditions:

1. The pesticide chemical is generally recognized by experts as safe. 2. The Government has established a safe tolerance for the residues of the pesticide chemical, and the residues remaining on the food are within this tolerance.

3. The Government has exempted the pesticide chemical from the requirement of a tolerance.

(For practical purposes a raw agricultural commodity is a crop as it is harvested, and a pesticide chemical is a substance that will destroy or control pests such as insects and weeds. More exact definitions are given in the law itself.)

## How the Law Works

There are three principal steps leading to the establishment of a tolerance under the new law:

1. A manufacturer of a pesticide (or any other interested party) submits a petition to the Food and Drug Administration requesting the establishment of a tolerance, a copy of which he sends to the Department of Agriculture requesting certification that the pesticide is useful for the purpose for which a tolerance is sought. In the petition, he must supply information about how he proposes to use the pesticide, the quantity of residues that will remain on the foods, and the toxicity of the residues when they are consumed throughout the life of test animals, such as rats or dogs.

2. Department of Agriculture scientists determine whether the pesticide is useful in agriculture when employed as proposed by the petitioner. If they find that it is, the Department transmits to the Food and Drug Administration a certificate of usefulness and also its estimate of the residues that are likely to remain on the foods.

3. Food and Drug Administration scientists study the experimental data given in the petition and all other available information, including that from the Department of Agriculture. On the basis of this study, FDA establishes a tolerance that meets both the requirements of safety and the needs of agriculture. The tolerance is set forth in a regulation published by the Commissioner of Food and Drugs. Residues within this amount may legally remain in or on the crops to which the tolerance applies. The same procedure is followed in exempting a chemical from the requirement of a tolerance.

Thus far, formal tolerances or exemptions have been established for almost 100 pesticide chemicals. When the Miller amendment becomes fully effective on July 22, 1956, all pesticides will fall in one of four classes:

Safe chemicals. These may be used without a tolerance or an exemption, because they are not considered poisonous as used on crops. Sulfur, lime, and lime sulfur are in this group.

Chemicals exempted from the requirement of a tolerance. These are considered poisonous, but they are exempted for use on growing crops because excessive or harmful residues will not occur when they are so used. Many copper compounds and pyrethrins are among the materials in this group. (As yet, no pesticide has been exempted for postharvest use.)

Chemicals with a zero tolerance or its equivalent. Some of these, such as mercury- and selenium-containing compounds, are so toxic that no residue whatsoever should remain on food as it is marketed. Others in this group have not been studied enough to show whether they deserve a higher tolerance. Still others, such as tetraethylpyrophosphate, can be employed usefully in agriculture without leaving residues at harvest time. Any pesticide not specifically included in another group has the equivalent of a zero tolerance.

A zero tolerance does not mean that the chemical is barred from use in agriculture; it means that it must be used in such manner that no residue will remain when the crop is shipped.

Chemicals with tolerances higher than zero. Tolerances higher than zero have been set for numerous chemicals which are safe if the residues are kept within a certain limit but which are not safe for uncontrolled use. The tolerance for a chemical applies only to specific crops. The fact that a tolerance is in effect for one crop does not mean that residues of the same chemical may remain on another crop.

According to the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, all "economic poisons" must be registered with the Department of Agriculture before they are shipped in interstate commerce. The directions for use on labels of pesticides thus registered should yield crops with residues within the tolerances set by FDA. Growers, therefore, have one simple rule to follow: They should use pesticides according to the label directions—on the crops specified, in the amounts specified, and at the times specified.

## **Enforcement Procedures**

The Food and Drug Administration enforces the Federal law with regard to pesticide residues on foods as follows:

Before the growing season, it studies new developments with regard to pesticides and new recommendations in spray schedules issued by the State agricultural authorities. During the growing season, FDA inspectors keep in touch with State authorities and growers to determine what sprays and dusts are used and how. The inspectors may pick up a few samples from farms, shipping points, or produce markets for laboratory examination to determine the accuracy of earlier tentative conclusions about the quantity of the residues remaining.

When the inspectors visit a growing area, they go openly. They cooperate with the State and local agricultural authorities, and they make every effort to be helpful. Unfortunately, the FDA laboratory facilities are extremely limited and cannot make tests for pesticide residues for all those who would like to have such tests made. However, if any of the samples collected from farms show high residues, the appropriate State authorities are immediately alerted so that steps may be taken to reduce the residues before the crop is shipped. Two examples of such preventive measures and their effectiveness may be cited.

In the fall of 1955, FDA learned that some growers in Texas were planning to use a chlorinated hydrocarbon pesticide on cabbage approximately 2 weeks before harvest. Past experience had indicated that application of this chemical that close to harvest would yield toxic residues. FDA notified its nearest field office, the United States Department of Agriculture, and the manufacturer of the pesticide chemical. The Department of Agriculture telephoned State agricultural officials, and they, in turn, warned the county agents. The manufacturer notified insecticide formulators in the area and asked them to help prevent misuse of the material. An FDA inspector went immediately to the area and warned the growers at a meeting and by television and radio. As a result, the chemical was not used as planned, and the cabbage crop, when harvested, was safe for shipment.

In another case, some growers sprayed their lettuce with a pesticide the residues of which are not permitted on this crop. The rate of application recommended by the State was doubled, and harvesting was started too soon after spraying. FDA found that there were high residues of the chemical on the lettuce as harvested. It notified the State authorities immediately, and the State authorities directed the growers to trim the lettuce severely at harvest to remove the outer leaves containing the poison. One grower shipped two carloads of lettuce without trimming it, and they were seized by the FDA.

FDA would much rather prevent violations than seize crops. Seizure action is reserved for extreme cases. Ordinarily, preventive measures are adequate to insure the shipment of satisfactory produce.

In commenting on seizures, George P. Larrick, Commissioner of Food and Drugs, said: "Growers do not have excessive spray residues on their crops when they observe proper precautions in using agricultural sprays and dusts, but misuse of such chemicals can leave poisonous residues that make a crop illegal in interstate commerce."

State and local health departments will continue to receive reports of injury and illness attributed to pesticide residues in food. In many instances investigation will show that pesticides are not at fault.

However, there may be occasions when misuse of a pesticide will leave dangerous residues on food. In these instances the health department can be of great value to agriculturalists and to the Food and Drug Administration by determining, among other things, what pesticide was employed, when it was applied to the crop, what rate of application was used (generally in pounds of actual pesticide per acre of crop), what stickers, spreaders, or adjuvants were employed with the chemical, when the crop was harvested, and what methods were employed to reduce the residue, such as washing or brushing or discarding of outside leaves of such crops as cabbage and lettuce. This type of information will help those responsible for recommending spray schedules to determine whether present label directions on pesticides are in need of revision.

An example of the type of misuse that may cause difficulty occurred last year in southern California: To control aphids, a grower sprayed a field of mustard greens with nicotine sulfate solution a few hours before harvest. The nicotine sulfate was old and the grower assumed that it was weak. He prepared a spray twice as strong as recommended. Then, because the aphid infestation was heavy, he applied it at four times the recommended rate per acre. The mustard greens were harvested less than 24 hours after spraying and marketed immediately. State and local health authorities embargoed outstanding lots of the greens when they began causing illness. Samples of the greens contained 70 to 90 parts per million of nicotine.

FDA appreciates reports of this type of misuse. They will help determine how well established tolerances are being met in actual practice. Reports may be sent to the nearest FDA district office or to headquarters in Washington, D. C.

## **Research in Cancer Chemotherapy**

Under contract with the Public Health Service, five laboratories are engaged in large-scale screening of chemical compounds in the search for drugs useful in treating cancer. It is expected that they will test approximately 2,000 compounds by July 1, 1956.

The laboratories, which began work early this spring, are: Microbiological Associates, Bethesda, Md.; Wisconsin Alumni Research Foundation, Madison, Wis.; Southern Research Institute, Birmingham, Ala.; Hazleton Laboratories, Falls Church, Va.; and Stanford Research Institute, Menlo Park, Calif. The Cancer Chemotherapy National Service Center of the Public Health Service National Cancer Institute has the responsibility for supervising the contracts.

Each compound will be tested against three different kinds of mouse tumors implanted into various strains of mice bred for cancer susceptibility, under procedures for animal screening established by a panel of the Cancer Chemotherapy National Committee. This committee, representing the leading organizations and Government agencies in the field of cancer research, was established in May 1955 to sponsor a national voluntary program of cooperative research and development in cancer chemotherapy.

At present, surgery and radiation are the only means of achieving cancer cures, but some forms of cancer, such as acute leukemia, are not amenable to these treatments. Other forms may be diagnosed only after they have spread throughout the body, too late to be benefited by either surgery or radiation. In such cases, chemical treatment appears to offer the greatest hope. Compounds now in use have been successful in prolonging the useful life of patients suffering from cancer of the breast or prostate or cancer of the blood-forming tissues, but these compounds are not curative.