Progress in Implementing The Miller Amendment

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Preventive enforcement will ordinarily be adequate to ensure the shipment of satisfactory produce

FEW INDIVIDUALS in the United States escape exposure to a wide variety of chemical compounds used for the control of pests which threaten the food supply. With the phenomenal increase in production and use of pesticides during recent years, it became apparent that a new procedure was necessary for determining what levels of residue of these necessary pesticide chemicals can be tolerated safely in or on crops.

The old method under the Federal Food, Drug, and Cosmetic Act was the public hearing procedure. This required the Department of Health, Education, and Welfare to determine before setting a tolerance that the pesticide is necessary in the production or handling of crops and then what level of residue is safe. This cumbersome procedure required a health agency to make agricultural decisions and was not particularly satisfactory to anyone.

So new legislation, sponsored by Congressman A. L. Miller and others, was enacted into law in July 1954. It is referred to commonly as the Pesticide Chemicals Amendment to the Federal Food, Drug, and Cosmetic Act.

It sets up more convenient procedures than were available before. It recognizes that sprays and dusts are necessary to ensure a continuing supply of high quality foods in this country and is designed to permit the effective use of these materials without hazard to the consumer. It assigns agricultural functions to the Secretary of Agriculture and health functions to the Secretary of Health, Education, and Welfare. (These functions have been delegated by the two Secretaries to constituent organizations within their Departments.)

The new law provides that a raw agricultural commodity[1] shall not be marketed within its jurisdiction if it bears a residue of a pesticide chemical,[2] unless:

> The pesticide chemical generally is recognized by experts as safe; or
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> Upon completion of an adequate amount of scientific evidence the Government has established a safe tolerance for residues of the chemical or has exempted it from the requirement of a tolerance;
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> If a tolerance has been established the residues remaining on the food are within the safe tolerance level.

To secure a tolerance under the new law, a manufacturer of a pesticide (or some other person) submits a request or petition to the Food and Drug Administration. He supplies information about the quantity of residue that remains on specified crops and about the toxicity of the residues when they are consumed over the life span of test animals such as rats or dogs. (Chart I lists the information required

[1] "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.

[2] "Pesticide chemical" means any substance which alone, in chemical combination, or in formulation with one or more other substances is an economic poison within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, and which is used in the production, storage, or transportation of raw agricultural commodities.

in the petition). He also asks the Department of Agriculture to certify that the pesticide chemical is useful in agriculture.

When the Secretary of Agriculture certifies that the chemical is useful, and when Food and Drug scientists have determined from the available evidence what residue of the pesticide will be without hazard to man, the Commissioner of Food and Drugs publishes a regulation which states the tolerance or amount of the pesticide residues that may remain legally in or on specified crops. The tolerance may be set at zero. To secure an exemption from the requirement of a tolerance, the petitioner follows the same procedure but requests an exemption rather than a tolerance.

The law specifies in detail the administrative procedures to be followed in establishing tolerances and time limits within which the job must be done. Chart II outlines briefly the course followed in establishing a tolerance or exemption where there is agreement between the petitioner and the Government about the proper action to be taken. Chart III lists appeals available to the petitioner if he does not agree with the Government's action.

FDA is working with agriculture and industry to reduce the amount of research required to show what residues remain after use of a pesticide. Several agencies have studied the wisdom of establishing tolerances for groups of related crops on the basis of fewer analytical determinations than would be required if each commodity in the group were considered alone. Some crops have been grouped tentatively, and the proposed groupings are under study now. Chart IV shows some proposed groupings.

Under the amendment all pesticides fall in one of five classes:

Safe chemicals. These may be used without a tolerance or exemption. Table I lists the chemicals recognized as safe.

Chemicals exempted from the requirement of a tolerance. These may be used on growing crops without the establishment of a tolerance. They have been exempted because excessive or harmful residues will not occur when they are applied to growing crops. There are no exemptions for chemicals for postharvest use. Table II lists the pesticide chemicals that are exempt from the requirement of a tolerance.

Chemicals with a zero tolerance or the 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 have not been studied enough to show whether they deserve a higher tolerance; any pesticide chemical not specifically listed in another group has the equivalent of a zero tolerance. Table III shows chemicals in this group. 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. For example, TEPP has a zero tolerance but it is so volatile that it can be used near harvest without leaving any residues on the harvested crop.

Chemicals with tolerances higher than zero. Table IV lists the chemicals with tolerances higher than zero. The tolerances apply only to specific crops; the numerical value of each tolerance and the crops to which it applies are given in the regulation setting the tolerance.

Chemicals for which the new law is not fully effective. The date the amendment becomes fully effective may be extended until July 22, 1956, where necessary. A number of ex-

FDA's Enforcement Procedures

Education

Advise all concerned with use of pesticides of tolerances and how they may be met

FDA personnel study the problems of agriculture

Investigation

Determine spray practices

Collect field samples of crops

Examine field samples

Preventive Enforcement

Where possibility of high residues is discovered try to achieve correction:

Through government agencies—advise appropriate workers in USDA and states

Through trade associations

With help of pesticide manufacturer or distributors

Through publicity—notices in newspapers, and on radio and TV

Other Enforcement

Where other efforts are not successful, formal legal actions may be taken in the Federal Courts

To Conform with Miller Amendment

Use sprays and dusts as directed on the pesticide label:

1. **On the crops specified;**
2. **In the amounts specified;**
3. **At the times specified.**

Chart I. Information Required in Pesticide Petition

- The name, chemical identity, and composition of the chemical;
- The amount, frequency, and time of application of the pesticide chemical;
- Full reports of investigations made with respect to the safety of the pesticide chemical;
- The results of tests on the amount of residue remaining, including a description of the analytical methods used;
- Practicable methods for removing residue which exceeds any proposed tolerance;
- Proposed tolerances for the pesticide chemical if tolerances are proposed.
- Reasonable grounds in support of the petition. (Ordinarily a showing that the requested tolerance is safe, and that it will be met when the the proposed directions for use of the pesticide are followed will constitute reasonable grounds.)

tensions have been granted. An extension permits a pesticide chemical to be used under conditions that were acceptable before the Pesticide Chemicals Amendment became law. It does not permit indiscriminate use of the material. On July 22, 1956, all pesticide chemicals will fall in one of the first four classes.

There are about 95 pesticide chemicals whose status under the amendment should be established before July 22, 1956. Eighty-three of these have definite status today with regard to one or more uses. That is, they are safe, exempt from a tolerance, or have a specific tolerance which is zero in some cases. Most of the remaining chemicals will have tolerances or exemptions established by July 22.

When a tolerance is established by the Federal Government this means that residues up to the tolerance level are safe; this has been established by adequate experimental studies on animals. It means that the pesticide can be employed usefully in agriculture; this has been established by the certificate of usefulness furnished FDA by the Department of Agriculture. It means that when the pesticide is used properly it will leave residues that are within the permitted level; FDA will not establish a tolerance unless there is evidence that it can be met. And it means that crops should bear no more than the tolerance level of residue. Thus, the formal tolerances now being established assure everyone concerned with the production and marketing of raw agricultural commodities that pesticides with tolerances or exemptions can be used on crops effectively without rendering them contraband. And the formal tolerances assure the consumer that pesticide residues permitted on crops are without any hazard to the public health.

Chart II. Steps in Securing Pesticide Tolerance

(Possible appeals are listed in Chart III)

- Manufacturer or other interested person submits petition to USDA and FDA.
- Within 15 days FDA files petition (If it is not acceptable for filing, FDA advises petitioner of specific reasons it may not be filed; in such case, petitioner may supplement the petition or ask in writing that it be filed as originally submitted.)
- Within 30 days after filing, USDA certifies usefulness or declines to certify. (USDA may extend the time for an additional 30 days if it needs to.)
- Ninety days after USDA certificate of usefulness arrives, FDA establishes tolerance or grants exemption.

Some people assume that the Pesticide Chemicals Amendment will render crops in interstate commerce more likely to be seized by the Federal Government. This is not correct. The new law does not change the basic requirement that foods in interstate commerce shall be free of dangerous quantities of spray residues. This requirement has been a part of the basic statute since 1938. What the new law does is establish a more convenient method of determining what residue is safe and announcing this tolerance level publicly.

The Commissioner of Food and Drugs publishes regulations establishing tolerances or exemptions in the *Federal Register*. Additionally FDA prepares in nonlegal form a summary of the tolerances and exemptions; it was issued in the spring of 1955 and is kept current by amendments as new regulations are published. The Department of Agriculture mails copies of the summary to agriculturalists; the National Agricultural Chemicals Association mails copies to pesticide manufacturers; and FDA sends copies to food and drug and other health officials.

What Is the Grower's Position?

But it doesn't help the grower to know the tolerance values in parts per million. He does not have laboratory facilities for determining what residues are on his crops. What is his position? How is he to determine that he is meeting the requirements of the Federal law?

In answering the questions, it will be wise to review recent developments in pesticide regulation. In 1947 the Federal Insecticide, Fungicide, and Rodenticide Act became law. It requires economic poisons, a term that includes pesticides, to be registered by the Department of Agriculture before they are shipped interstate. Before registering a pesticide USDA determines that it is effective for the control of pests, and that the label has adequate directions for use and adequate warnings to protect the user while he is applying the poison. But USDA went a step further. It asked FDA to consider the toxicity and residue data submitted with a new chemical and to state whether the proposed directions for use would be apt to leave hazardous residues that would make a crop illegal under the Federal food laws. FDA was glad to cooperate. For several years now it has commented on new pesticides upon request. If there were evidence that proposed directions would leave particularly harmful residues, or if there were not enough information to permit a sound opinion, FDA recommended that the pesticides not be registered for use on food crops.

The formal tolerances now being established are for the most part the same as the old informal tolerances that served as a basis for these recommendations to the Department of Agriculture.

So the grower has a clear guide. He should use pesticides according to the directions appearing on an approved label—on the crops specified, in the amounts specified and at the times specified. If he follows these precautions, his crop should bear residues that are within established tolerances and he should have no concern about shipping it from one State to another.

In addition to placing information about tolerances in the hands of those

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who need it, Federal Food and Drug Inspectors are studying the problems involved in application of agricultural sprays and dusts. They are studying state spray schedules in advance of the growing season to keep abreast of new developments with regard to pesticides or new recommendations by the states. During the growing season, inspectors in growing areas keep in touch with state authorities and growers to determine what sprays and dusts are being used and how. The inspectors may pick up a few samples from farms or from shipping points for examination in the laboratory. These examinations are a check on earlier observations made during the growing season about the likelihood of high spray residues.

Then during the shipping season, the inspectors collect samples at shipping points and at destination for further examination for spray residues. When Inspectors go into a growing area to make investigations, they go openly, they will cooperate with state and local agricultural authorities, they make every effort to be helpful in connection with inspectional activities.

Unfortunately, FDA's laboratory facilities are extremely limited. FDA cannot test samples for spray residues for all who would like to have such tests made on their crops; however, if samples that it collects to confirm inspectional observations show high residues before a crop has been placed in interstate commerce, it will get in touch with the appropriate State authorities immediately so that steps may be taken to reduce the residues prior to shipment.

There have been a couple of examples recently of the type of preventive enforcement being undertaken in this field. In the latter part of November 1955 FDA learned that some growers were planning to use a chlorinated hydrocarbon pesticide on cabbage approximately two weeks before harvest. Past experience indicated that application of the chemical that close to harvest would yield toxic residues. FDA notified its nearest field office, the USDA, and the manufacturer of the pesticide chemical. The Department of Agriculture telephoned state authorities and they warned county agents. The manufacturer notified insecticide formulators in the area and asked them to help prevent misuse of the material. A Food and Drug Inspector went immediately to the area and warned farmers at a growers meeting and by television and radio. These efforts prevented misuse of the insecticide and the cabbage crop, when harvested, was safe for shipment.

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

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

Table I. Safe Pesticide Chemicals[a]

Lime
Lime sulfur
Sodium carbonate
Sodium and potassium analoges of lime sulfur
Sulfur

[a] As of Feb. 10, 1956.

Table III. Pesticide Chemicals with Zero Tolerances

(or the equivalent)[a]

Aramite (on alfalfa and soybeans, whole plant)
Calcium cyanide
Dinitro-*o*-*sec*-butyl phenol
Dinitro-*o*-cresol
Hexaethyl tetraphosphate
Hydrocyanic acid
Mercury-containing compounds
Selenium and selenium compounds
Tetraethyl pyrophosphate
And all pesticides not listed in other tables

[a] As of Feb. 10, 1956.

Table II. Pesticide Chemicals Exempt from Requirement of a Tolerance[a]

Allethrin (on certain crops only)
Bordeaux mixture
Copper acetate
Copper carbonate (basic)
Copper-lime mixtures
Copper oxychloride
Copper silicate
Copper sulfate (basic)
Copper-zinc chromate
Cube root
Cuprous oxide
Derris root
N - Octylbicyclo - (2,2,1) - 5 - heptene - 2,3-dicarboximide
Petroleum Oils
Piperonyl butoxide
Piperonyl cyclonene
N-Propyl isome
Pyrethrins
Pyrethrum
Rotenone
Ryania
Sabadilla

[a] When applied in accordance with good agricultural practices, as of Feb. 10, 1956.

What a Tolerance Means

(A tolerance is the amount of pesticide residue that is permitted by Federal regulation to remain in or on a crop.)

The residue must not exceed the tolerance

A residue within the tolerance level is safe

The pesticide is useful in agriculture

The pesticide can be used so that a safe residue remains