Basic operating regulations under Miller Bill to be issued in November

Members of the panel discussion on how to operate under the Miller pesticide residue amendment at the NACA meeting were: J. A. Noone, NACA technical advisor; J. T. Coyne, of the Pesticide Regulation Branch of USDA; Lea Hitchner, executive secretary of NACA and panel moderator; William W. Goodrich, FDA assistant general counsel; and John D. Conner, NAC counsel.

SPRING LAKE, N. J.—The general procedure to be followed for pesticide tolerances was outlined in a panel discussion at the recent meeting of the National Agricultural Chemicals Association. William W. Goodrich, assistant general counsel for the Food and Drug Administration, told the association that the basic operating regulations to implement the new amendment to the Food and Drug Act will be issued some time in November. These regulations will be concerned with definitions of a raw agricultural commodity and how tolerances will be fixed and the relative safety of different pesticidal chemicals will be established. The administrative procedure for filing petitions must be worked out. The procedure for appointment and functioning of the ad hoc committee from the NRC also must be established.

Mr. Goodrich said a draft of the proposed regulations will be forwarded to the NACA for discussion before it is formally adopted.

Other participants in the panel discussion are shown above.

The Miller Bill makes two fundamental changes in the previous almost inoperable procedure for the establishment of pesticide residue tolerances. The law outlines a separation of operational responsibility between the USDA and the FDA. The Department of Agriculture is responsible for deciding on the agricultural usefulness of the pesticide while the FDA is responsible for decisions regarding the safety of the chemical if used.

The Secretary of Health, Education, and Welfare is expected to issue a series of proposed tolerances for most of the insecticides now in use. These tolerances will be quantitative statements of the amounts of a chemical in parts per million which the FDA believes can be present on raw agricultural commodities without harm resulting to consumers. As initially published these tolerances will be in the form of proposed limits and interested parties will have an opportunity to present their views to the FDA.

The new amendment also outlines the general procedure for establishing residue tolerances for insecticides which are not now in general use or for which the FDA does not have sufficient data to arrive at a decision. Under the new amendment no pesticide residue can remain on a food crop unless a tolerance has been established by the Department of Health, Education, and Welfare.

Manufacturers of pesticide chemicals for which no tolerance has been established must initiate action on the part of the FDA by a formal petition. This petition must be filed with the FDA requesting that a residue tolerance be established. In the petition the manufacturer specifies the tolerance desired and includes basic scientific data which indicates the tolerance is reasonable. The data must include reports on toxicity studies and residues determined on food crops following application of the chemical. In addition to the residue and toxicity data the manufacturer must include a statement of the proposed use of the chemical and scientific data indicating that it is effective for control of a specific pest, or pests, on specific crops.

The Plant Pest Control Branch of the USDA will be responsible for determining the usefulness and probable residue levels resulting on the basis of data supplied by the manufacturer. Plant Pest Control is the same branch of the USDA that industry people have been dealing with for registration and labeling o pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act.

The USDA has a maximum of 60 days to complete its evaluation of the experimental data contained in the industry petition. If the USDA finds that experimental data warrant approval, the petition will be forwarded to the FDA with a statement that the chemical is useful for the control of certain pests on certain crops when applied at certain application levels. The USDA will also inform FDA of the residue levels likely to result following use of the chemical as proposed.

FDA Action

The FDA has 90 days to process the data after it has been received from USDA. The FDA proceedings will be based on informal hearings between scientific representatives of the manufacturer and the FDA. As a result of these discussions an informed scientific opinion will be developed by the FDA on safe tolerances for specific crops. If the tolerance which is established as a result of these discussions is greater than the level of residue which USDA people have said is likely to result from use of the chemical as a pesticide, then it seems that the pesticide will be approved.

If FDA announces a tolerance which is unsatisfactory, the manufacturer can file objections, request a formal hearing, and the question can be referred to a court for judicial review. In the judicial review the recommendations and findings of the FDA scientists and the advisory committee of the National Academy of Sciences will be entered as legal evidence. The Miller legislation was designed specifically to eliminate the cumbersome procedure of establishing tolerances by formal hearings and it is not anticipated that industry will usually resort to this operation.

During the discussions between the FDA and industry representatives either group can call on an ad hoc committee of the National Academy of Science to study the data and render an opinion.

The final tolerance is set by the Secretary of Health, Education, and Welfare but it is anticipated that considerable weight will be given to the opinion expressed by this advisory group.