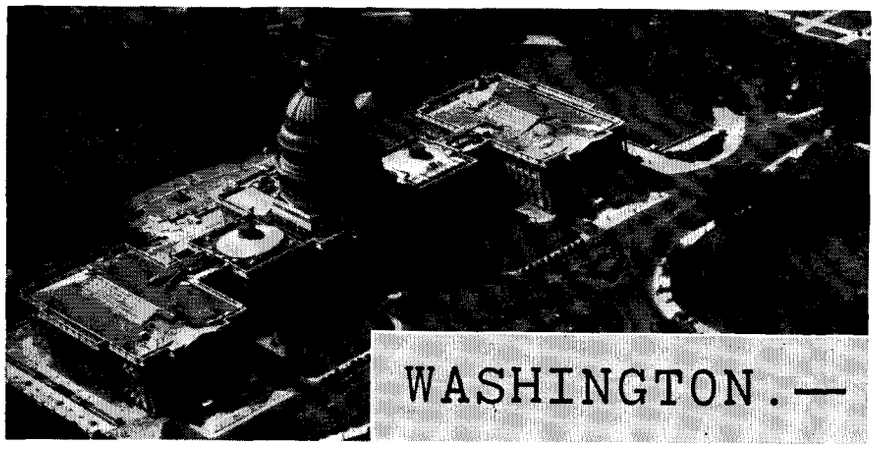

New philosophy in administration of food and drug laws involved in Miller pesticide bill

CONGRESSIONAL APPROVAL of the Miller bill on pesticides may well initiate a new philosophy with respect to the food and drug laws. Whether such a change would be desirable appears to depend on the interests of the party involved.

The major indications of the possible new approach were developed at a recent hearing on the Miller bill, officially entitled the "Pesticides-Residue Amendment to the Federal Food, Drug, and Cosmetic Act" (see news story, page 594). There was general agreement among all witnesses as to the desirability of the general objectives of the bill. These are to protect the consumer without discouraging the research and development of pesticides needed by the farmers to produce the essential foods and fibers. From this point on, however, several differences of opinion arise.

Issues to Be Resolved

The principal issues involved relate to the philosophy of keeping harmful materials out of foods to the maximum extent possible, the procedures for establishing tolerances, and the line of demarcation between the authority of quasi-judicial agencies like the Food and Drug Administration and the authority of the courts.

These issues were brought into the discussion by Charles W. Crawford, Commissioner of the Food and Drug Administration, and William W. Goodrich, counsel for FDA.

The Food and Drug Act prohibits the interstate transportation of food which contains an added poisonous or deleterious ingredient unless it is required in production or cannot be avoided in good manufacturing practice. Where such an ingredient is required, as in the case of pesticides, residue tolerances are established to protect the public.

The Miller bill, Mr. Crawford stated, reverses this policy in one respect. It would require the Secretary of the Department of Health, Education, and Welfare to establish a tolerance for a pesticide which the Secretary of Agriculture determined was useful.

Another difference of opinion relates to the establishment of residue tolerances. Supporters of the Miller bill said that the FDA has had authority for 15 years to establish tolerances for pesticidal residues, and yet has established only one. In 1950, FDA held hearings for 10 months to collect evidence on which to establish residue tolerances for 100 basic chemical pesticides used on 75–80 different fruits or vegetables.

Tolerances have not yet been announced for any of the chemicals, and according to Mr. Crawford, final regulations will probably not be ready until the next growing season. Proponents state that such prolonged delays are bad for all concerned. The new bill, they state, would overcome this deficiency.

Another related issue arises from the fact that the Secretary of Health, Education, and Welfare, who issues the tolerances, is the final authority for all practical purposes. Proponents of the new bill feel that there should be judicial appeal to the secretary's tolerance rulings as provided in the Miller bill.

The Miller bill would accomplish this by a *de novo* proceeding. Legal witnesses FDA counsel Goodrich; Harold M. Stephens, chief judge of the U. S. Circuit Court of Appeals, District of Columbia; and James M. Morris, judge in the U. S. District Court, District of Columbia, discussed this question in considerable detail before the Congressional committee.

A *de novo* proceeding, they said, means that a person who did not agree with a ruling of the FDA administrator could request a trial in the U. S. District Court for the District of Columbia. Under *de novo* proceedings, the court does not limit itself to its usual functions, which are to determine questions of legality or clarity of statutes, or legality or arbitrariness of actions of administrative officers. The court instead is called on to start from the beginning and hold a new trial. The decision of the district court can then be appealed to the U. S. Circuit Court of Appeals for the District of Columbia.

The legal witnesses all said that such a procedure constituted a novel departure from present law. These witnesses added that what the bill actually did was to place in the hands of the courts such nonjudicial responsibilities as regulation-making. These are rightfully the functions of Congress or executive agencies acting in accordance with Congress' instructions. Making petitioners come to Washington for trials, the witnesses felt, was unfair. They should be allowed to seek action in courts in areas where they reside or have their business.

The judges feel that Congress should eliminate the proposed judicial appeal procedures of the Miller bill and rely upon legal appeal procedures which exist in the food and drug act. Judge Stephens suggested that Congress might specify that hearings before administrative or quasi-judicial officers be of the "due process" type.

De novo proceedings, Mr. Goodrich said, would result in administrative agencies being no more than agencies to collect and transmit evidence and information to the courts. In this event, he said, it would be simpler to place the whole matter in the courts and omit the government agencies completely.

Zero Tolerance Concept

If tolerances must be established for every pesticide which the Secretary of Agriculture certifies as being useful, the Secretary of Health, Education, and Welfare would face many serious problems. Rodenticides and fungicides are included under the heading of pesticides in the Miller bill. A rat poison, like compound 1080, is so lethal that FDA would not allow any amount of it in food and so would establish no tolerance. Under the Miller bill, Mr. Crawford said, a tolerance would have to be established for it because it is useful.

One suggestion has been made that zero tolerances be established in such cases. This is a contradiction in terms, Mr. Crawford said, as complete exclusion is not a tolerance.

These points outlined above are indicative of the complex problems involved in enacting legislation which protects the consumer and yet is not unduly restrictive for the producer or user. Until the committee has had time to study the testimony, it is not possible to predict how it may resolve the different views.