Notice of the opportunity for a hearing was specifically given to Schering, Peter Hand Foundation, and Central Soya's McMillan Feed, but FDA also said any manufacturer or distributor of an identical, related or similar product may submit data and/or request a hearing.

"If review of the data submitted by an applicant or any other interested person warrants the conclusion that there exists substantial evidence demonstrating the safety of the product(s) for the labeling claims involved, the Commissioner will rescind this notice of opportunity for a hearing," FDA said.

Dienestrol diacetate is cleared under a Food Additive Order (§121.266) for use in chicken and turkey feed to promote the distribution of fat for tenderness and bloom. It has a 48-hour withdrawal period, and a New Animal Drug regulation (§135g.46) provides that no residues are permitted in the uncooked edible tissues of chickens and turkeys under the mouse uterine weight method prescribed in the regulation.

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TOLERANCE SET FOR PESTICIDE RESIDUE IN DRIED CITRUS PULP

A Food Additive Order was issued Jan. 29 to set a tolerance for residues 0,0-dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate of 2.5 p.p.m. in dried citrus pulp, as a result of application of the insecticide to growing citrus fruit.

The new §121.1247 resulted from a Petition filed by Chemagro (See FOOD CHEMICAL NEWS, March 27, Page 35). The firm had originally requested a tolerance of 25 p.p.m., but later amended the Petition to reduce the request to 2.5 p.p.m. On the same day, the Environmental Protection Agency established a tolerance of 0.1 p.p.m. for negligible residues of the insecticide in or on citrus fruit.

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FEED PRODUCERS "SURPRISED" BY NEW FDA PCB TOLERANCES

The feed manufacturing industry was unpleasantly surprised by reductions in proposed "tolerances" for polychlorinated biphenyls by the Food and Drug Administration, comments arriving at the agency note.

The American Feed Manufacturers Association (AFMA) noted that FDA's first proposed interim tolerances had been 5 p.p.m. in animal feed components and 0.5 p.p.m. in "complete and finished animal feed" (See FOOD CHEMICAL NEWS, March 13, Page 36). However, in the final issuance in late December of an Environmental Impact Statement on PCBs, the agency forecast the temporary tolerances it expects to set for the industrial compound, changing the components tolerances to 2 p.p.m. and the temporary tolerance for complete and finished animal feeds to 0.2 p.p.m.

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AFMA said its discussions with Bureau of Veterinary Medicine personnel indicated "a sound basis" for the previous levels and the association thus did not comment on the proposal. However, AFMA had noted a "terminology error" in the earlier proposal and had expected it to be corrected by the time of the final impact statement, AFMA stated, explaining:

> "A finished feed can be a complete type feed, a concentrate type feed or a premix type feed. ...We request that complete and finished feed be changed to 'mixed animal feeds (on a complete feed basis)'."

Calling the new levels "unrealistic," AFMA said surveillance is not geared to levels of 2 and 0.2 p.p.m. and that these levels "may be too low to accurately reflect background levels."

The Association also objected to the method of FDA's publication, noting that the Environmental Impact Statement had not been formally published, and stating that simply making the document available at the agency's Parklawn building "simply cannot reach as many parties as the Federal Register, which is monitored for such information." AFMA asked for publication of a new proposal in the Federal Register.

Central Soya told FDA that a feed concentrate to be mixed 1:1:3 with grains should have a tolerance of 0.8 p.p.m., and said "industry could not assure that finished feeds would always be within the 0.2 p.p.m. tolerance."

Beacon Feeds, supporting the AFMA position, said it is "impossible to realize the possible effect of the new proposed levels of 2 p.p.m. and 0.2 p.p.m." The company elaborated:

> "With the current feed situation involving tremendously tight protein supplies at relatively high prices, further pressure of unrealistic tolerance levels would force up the prices of animal products used for human food, or could result in a reduced supply of human food."

Nutrena Feeds Division, which said it "shares the concern" of AFMA, also called for a rewriting of the proposal in "terms generally used and recognized" by the industry.

Other temporary tolerances forecast by FDA in the Impact Statement were: (1) Milk and dairy products, 2.5 p.p.m. on a fat basis (no change); (2) poultry, 5 p.p.m. on a fat basis (no change); (3) eggs, 0.5 p.p.m. (no change); (4) fish and shellfish, edible portions, 5 p.p.m. (no change); (5) infant and junior foods, 0.2 p.p.m. (changed from 0.1 p.p.m.), and (6) paper food-packaging material, 10 p.p.m. (changed from 5 p.p.m.).

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