EPA, he said, needs to do a better job before acting under Section 24(c) and is likely to be asking for more hazard evaluation data. EPA is also considering changes that would allow States to deal with cancelled or suspended products, Smith said.

The AAPCO members, while charging EPA with not always listening to them, stressed the value of SFFIAC continuing as the only real mechanism available to State pestici officials to give EPA their views.

FDA TOLERANCE PROPOSALS FOR PCBs HIT BY EDF; APPARENT POLICY SHIFTS NOTED

The Food & Drug Administration's April 1 proposals regarding temporary tolerances for polychlorinated biphenyls (PCBs) in food and feed are "disappointing and inadequate," according to the Environmental Defense Fund (EDF). The Fund's toxic substances spokesman, Dr. Joseph Highland, said FDA "could have done better if it had allowed health considerations to play a role equal to economic considerations."

Of particular concern to Highland was FDA's decision not to propose zero, or "least detectable" tolerances for fish, shellfish and poultry products. Highland also hit FDA for failing to make a commitment to eventually set zero tolerances. EDF wants zero tolerances for PCBs.

The proposal's publication has prompted remarks by Environmental Protection Agency officials that FDA has abondaned its policy on "most sensitive species."

Also, EPA officials say, the PCB tolerance proposals have "rekindled" claims that the Department of Health, Education and Welfare (HEW) "shirked its responsibility" by failing to state the dangers of breastfeeding "as clearly as the benefits are stated." EPA officials criticized HEW for failing to sponsor research into "subtle effects" of PCBs and other chemicals in human breastmilk and pointed to the FDA proposal as one which will refocus attention on the chemicals-in-breastmilk problem (See Jan. 19, Page 10), as well as on an upcoming EPA proposal on PCBs (See Jan. 26, Page 9).

Highland, who serves on the National Cancer Institute's Clearinghouse on Environmental Carcinogens, said the following statement made by FDA in its April 1 proposal "has absolutely no basis in fact:

> "The relatively high levels of commercial PCBs required to produce the carcinogenic response suggest the probability that liver damage may be required before the onset of carcinogenesis."

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"Any suggestion that the results observed are due to the feeding of 'high doses' of PCBs and therefore are of questionable significance is scientifically incorrect and untenable," Highland said. He added that "such reasoning goes completely contrary to that used by FDA in its recent action to ban the use of saccharin as a food additive." In addition, Highland said, the study which FDA was referring to was interpreted by EPA and independent scientists as "clearly demonstrating the carcinogenicity of PCBs" and served as part of the basis for EPA rules banning

PCB discharges from capacitor and transformer manufacturing plants (See Feb. 9, Page 2).

EPA sources said FDA statements such as "persons whose consumption of PCBs... is substantial... have not exhibited any adverse health effects" beg the question as to whether effects may go undetected.

On the subject of species sensitivity, both Highland and EPA sources said experimental data on infant monkeys weaned by PCB-contaminated mothers was not properly taken into account by FDA, which argued that monkeys may be more sensitive to PCBs than are humans. FDA also argued that the monkeys were exposed to PCBs which are less chlorinated than those to which humans and human infants are exposed and thus the adverse effects manifested by the monkeys could not automatically be expected to appear in humans. The lower chlorinated PCBs are metabolically more active and more acutely toxic than the variety to which humans are exposed, FDA said.

In the monkey tests using the less chlorinated PCB, University of Wisconsin researcher James Allen showed that infant monkeys nursing from mothers who had been fed 2.5 part per million PCB daily exhibited hair loss, skin discoloration, slow growth, behavioral disorders and learning disabilities.

Another shortcoming in Allen's data, FDA's proposal stated, is that the experimental PCBs used by Allen were contaminated by "unknown quantities of at least five different chlorinated dibenzofurans," whereas humans and human infants are likely to get little or no dibenzofuran from contaminated foods or human breastmilk. Dibenzofuran contamination was also a problem in carcinogenicity data cited by EDF as a reason for going to zero tolerances, FDA said.

FDA Distrust of Monkey Data May Endanger Human Infants, Highland, EPA Staff Say

In response to these FDA contentions, Highland and two EPA officials who asked not to be identified said it is highly unusual for FDA to discount animal data because the test species may be too sensitive. They also said that FDA, particularly in its proposal for fish, ignored the possibility that PCBs may adversely affect the human immune system (See Jan. 26, Page 13). Dr. John Moore of HEW's National Institute for Environmental Health Sciences (NIEHS) said it is "fairly well established that PCBs do suppress immune systems."

Highland pointed out that human infants nursed by American women with average PCB contamination (1.8 p.p.m. in breastmilk) receive about one-seventh of the dose which produced overt toxic, behavioral and learning defects in monkeys.

FDA usually applies a safety factor of 100 to a "no-effect level," but "in their brilliance in this case," Highland said, FDA is not allowing a safety factor of even 10 with respect to overt effects and is not even considering long-term, less observable effects.

EPA sources say HEW has been remiss in not advising against breastfeeding beyond two months, since most of the psychological and immunological benefits of breastfeeding, they say, are realized within that time. To buttress their argument, they point to the presence of contaminants other than PCBs in human breastmilk.

Highland also asserted that humans, like Allen's monkeys, could be exposed to lower chlorinated PCBs. He added that FDA had no proof that Allen's monkey infants ingested dibenzofurans. Similarly, he said FDA had no proof that humans do not ingest dibenzofurans when they consume PCB-contaminated food. Finally, he suggested that even if dibenzofurans were present in the milk which the infant monkeys received, it is impossible to say whether the observed effects were caused by the dibenzofurans or the PCBs themselves. The same statement applies to carcinogenicity tests on PCBs which FDA is downplaying, Highland said, because of "tiny amounts" of dibenzofurans.

Most of the Proposals Do Go to "Lowest Detectable" Residues

Under the FDA proposal, FDA would reduce temporary tolerances for PCB residues in the following commodities:

-- Milk would be dropped to 1.5 p.p.m. (from 2.5 p.p.m.) on a fat basis.

-- Manufactured dairy products would be reduced to 1.5 p.p.m. (from 2.5 p.p.m.) on a fat basis.

-- Poultry would be lowered to 3 p.p.m. (from 5 p.p.m.) on a fat basis.

-- Eggs would be dropped to 0.3 p.p.m. (from 0.5 p.p.m.).

-- Fish and shellfish -- edible portions, which exclude head, scales, viscera, and inedible fones -- would be reduced to 2 p.p.m. (from 5 p.p.m.).

Unchanged will be the 0.2 p.p.m. tolerance for finished feeds for food-producing animals; the 2 p.p.m. level for animal feed components and in concentrates, premixes and supplements; the 0.2 p.p.m. for infant and junior foods; and the 10 p.p.m. temporary tolerance in paper food-packaging materials used for human food and animal feeds.

No proposal was made for red meat containing PCBs.

All the FDA proposals except for fish-shellfish, poultry and food packaging would set tolerances at the lowest level of detectability.

As justification for its decision on poultry, FDA said that since the occurrance of PCB residues in poultry feed is low, the likelihood of residues in poultry reaching 3 p.p.m. is "very small." The proposal also stated that if analytical methodology to enforce feed residues below 0.2 p.p.m. becomes available, FDA may lower the poultry tolerance. For the time being however, FDA found that it would be "inconsistant to set tolerances on the two products at levels such that the use of one

product that complies with the applicable tolerance (feed) causes the second product (poultry) to be illegal."

On fish, FDA said it could not propose a 1 p.p.m. tolerance because "a tolerance at 1 p.p.m. for fish sold in interstate commerce would have a substantially adverse impact on this country's commercial freshwater fishing industry and, to a lesser extent, the commercial marketing of saltwater species. The Commissioner estimates that the loss to fresh and marine fisheries as a result of enforcing this legal limit would be a maximum total landed value of $18 million or $127 million after processing ... The Commissioner points out that because most commercial fishing is done by fairly small operators who may specialize in one or two species, the elimination of any species, even though it may account for only a fraction of the total catch, could be disastrous for them."

FDA concluded that a 2 p.p.m. tolerance "will provide adequate protection for all but those population groups that consume above average amounts of freshwater fish from contaminated waters."

The agency said the new tolerance "would eliminate a relatively minor percentage of marine fish and less than 25% of freshwater fish from commercial markets."

Although a higher tolerance "would be more economically desirable," the agency said, such a tolerance would "add to the risk for the so-called average consumer and those population groups who regularly consume freshwater fish." FDA concluded that the compromise 2 p.p.m. tolerance represents "a proper balance" between safety and economic considerations.

FDA said "no systematic adverse health effects could be demonstrated" among Michigan sportsfishermen who had consumed an average of 46.5 milligrams PCBs per year, as opposed to the yearly average of 16.8 milligrams which would be consumed by most Americans if all fishes in their diet contained 2 p.p.m. PCBs.

Because of a lack of demonstrable adverse health effects in this test group, FDA said it could not agree with EDF's contention that FDA's temporary tolerances are insufficient to protect public health. FDA noted that the Delaney anti-cancer clause in the Food, Drug & Cosmetic Act "does not apply to an environmental contaminant, such as PCBs, that is unavoidably present in food." FDA continued:

> "A tolerance that would totally prohibit such a substance in the food, when that substance cannot be avoided, would be inappropriate in the absence of a grave danger to health, for it would make all foods *containing* the substance unlawful per se."

The proposals are open for public comment for 60 days.