> of the two strains is significant at the P=:034 level. Fewer tumors were observed in the female mice treated with Red No. 2. Thus, combining both sexes there is no statistically significant increase in total tumors with Red No. 2..."

Discussing the Russian study, Gaylor said none of 50 control non-inbred rats showed tumors while 13 of 50 animals administered chemically pure amaranth at 2% in the diet had malignant tumors.

Calling this "highly statistically significant," Gaylor added, "The significance level cannot be discounted by assuming that the occurrence of no tumors in the control group is unusual."

He noted another test with no tumors in 50 control Wistar rats and an FDA study in which only one tumor in 89 control Sprague-Dawley rats was observed, although the mortality in the latter study was high.

"The primary question is whether or not the amaranth tested would qualify as FD&C Red No. 2," Gaylor said.

FDA ANNOUNCES FOUR ISSUES FOR PCB PUBLIC HEARING

The Food and Drug Administration on March 12 announced there will be a public hearing on objections to the agency's §406 "poisonous and deleterious substance" tolerance of 10 p.p.m. for polychlorinated biphenyls in food-packaging paper and paperboard (See FOOD CHEMICAL NEWS, Feb. 17, Page 2).

The hearing, requested by paperboard manufacturers and associations, will be conducted by an Administrative Law Judge yet to be selected. The Civil Service Commission has authorized FDA to hire a full-time Administrative Law Judge.

Notices of appearances for the hearing must be submitted to FDA by April 11, but no date for the hearing has been selected. Noting that direct testimony must be in written form, FDA indicated that the Administrative Law Judge would have great discretion in allowing or denying cross-examination. The agency said:

> "Witnesses whose written direct testimony has been submitted for the hearing record shall be subject to oral cross-examination by any party upon a showing to and determination by the Administrative Law Judge for each such witness that such cross-examination is necessary to adduce relevant testimony required for a full and true disclosure of evidentiary facts. A nonparty participant may be permitted to conduct such cross-examination upon a showing and determination, in addition to a finding by the Administrative Law Judge that his or her interest cannot otherwise be adequately protected."

Again, FDA stayed the §406 tolerance, but at the same time said it "will enforce the PCB level of 10 p.p.m....by seizing, as adulterated food..., any paper food-packaging material shipped in interstate commerce containing PCBs in excess of that level."

FDA framed the issues for the public hearing, as follows:

"(a) Whether or not, based on available medical and scientific evidence and on the recognition of experts qualified by scientific training and experience to evaluate the toxic effects of PCBs, there is a sufficient long term human toxicity hazard from dietary intake of PCBs for the Commissioner...to find necessary for the protection of public health the promulgation of a tolerance of 10 p.p.m. for these substances in paper food-packaging materials...

"(b) Whether or not, in promulgating the tolerance level of 10 p.p.m. for PCBs in paper food-packaging material..., the Commissioner...properly and adequately took into account the extent to which PCBs cannot be avoided in the production of paper food-packaging material from recycled paperboard.

"(c) Whether or not, in establishing ... an exemption from the tolerance of 10 p.p.m. for PCBs in paper food-packaging material for such material separated from the food therein by a functional barrier which is impermeable to migration of PCBs, the Commissioner ... adequately took into account the effect of an exemption providing for such a barrier on the production of paper food-packaging material from recycled paperboard, including a consideration of the availability of barriers which are not impermeable but which prevent or reduce such migration of PCBs to varying degrees.

"(d) Whether or not, based on available scientific data, the Commissioner ... properly concluded, as a basis for promulgating the tolerance of 10 p.p.m. for PCBs in paper food-packaging material ..., that paper food-packaging material is a demonstrated source of PCBs contained in the food packaged therein."

Six objectors said there is no long term hazard posed by current dietary intake of PCBs, noting data from FDA's total diet studies and various publications.

"Since the Commissioner promulgated the PCB tolerance for paper food-packaging material on the basis of his conclusion, inter alia, that existing toxicological and exposure data on PCBs establish the possibility of chronic toxicity necessitating the reduction of the levels of PCBs in foods as soon as possible, he concludes that the facts cited in support of this objection raise a genuine and material issue of fact warranting a hearing ...," FDA said.

Noting the references, the objectors had said that the average dietary intake of PCBs is no more than 4.2 micrograms per day for an adult, and that this is so far below FDA's acceptable safe level of 175 micrograms per day as to render the intake toxicologically insignificant.

FDA also concluded that in view of its "obligation ... to balance the level of the PCB tolerance against the extent to which PCBs cannot be avoided in paper food-packaging material manufactured from recycled paperboard, the facts cited in support of this objection raise further genuine and material issues of fact ..."

Six objectors said that the tolerance would unnecessarily harm the nation's recycling effort, adding that the impact on recycling "will neither be minimized nor negated by an exemption solely for barriers impermeable to PCB migration as provided by the order in that cans and bottles, the only barriers currently established as impermeable to PCB migration, are packaged in corrugated containers, 99% of which ... are made from virgin stock rather than from recycled paperboard."

FDA said the objectors also asserted that the barrier standard of impermeability is "unreasonable" because "every barrier commonly used with recycled packaging material is permeable to gas and to some PCB migration ..." The firms and associations proposed that polyvinylidene-coated paper and glassine, which may significantly reduce PCB migration, be included within the barrier exemption.

Noting objections regarding the relationship between the level of PCBs in paper material and that in packaged food, FDA said that since its "basis for promulgating ... a tolerance for PCBs in paper food-packaging materials is (the) ... determination that paper food packaging is a demonstrated source of PCB contamination of packaged foods, ... the facts cited by this objection raised a further genuine and material issue of fact warranting a hearing ..."

The objectors in this instance said, according to FDA, "(1) that much of the PCB content of packaged food is recognized by FDA as attributable to sources other than paper food-packaging material, and (2) that the survey by the FDA of the problem of PCBs in paper food-packaging material ... showing 67% of paper packaging samples to contain PCBs and 19% of the food samples in the survey to contain PCBs are insufficient data to establish that the PCBs in food come from packaging."

There were many other grounds for a hearing proposed by the objectors, and they were rejected by FDA.

Noting objections based on FDA's legal authority, FDA concluded that "this objection presents no ground which warrants a public hearing ... in that it raises a purely legal issue, not a genuine and material issue of fact that could be decided upon adduction of evidence at a hearing."

The objectors, as they have done in comments on FDA's §406 proposals (See story, Page 13), said paper food-packaging material is not a "food" within the meaning of the Act, so a §406 tolerance may not be established. Noting court decisions, including the ones on migrants from pottery, FDA said, "PCBs in paper food-packaging which migrate to the food packaged therein and are subject to ingestion by consumers as part of the packaged food ... become a component of the food."

Objectors said that FDA had omitted consideration of certain factors in establishing the tolerance. FDA responded that "since the respondents advancing these objections have presented no data on these factors or on variance of PCB content of paperboard and amount and time of vapor phase emission, and have not alleged that any such data exist, the Commissioner concludes that the objections raise no genuine and material issue of fact requiring a hearing." The agency added:

> "As a matter of law, under §406 ..., the Commissioner in promulgating a tolerance for an unavoidable poisonous or

> deleterious substance added to food is not required to consider factors for which there is no existing data in establishing a particular tolerance level; rather, under this section, he is required to establish a level based on existing data to the extent he finds necessary to protect the public health. In the absence of data on the factors above, the Commissioner concludes that the PCB tolerance was properly established under the act on the basis of existing toxicological and migration data."

If data on these factors become available, FDA added, "they will be considered if they warrant a reassessment of the PCB tolerance level."

Also rejected as a ground for a hearing were objections that some paperboard plants will be unable to fully comply with the tolerance because they lack analytical and monitoring capabilities. FDA concluded "that neither of these objections creates a factual hearing issue." It added: "As a matter of law, a tolerance...is applicable on an industry-wide basis in that §406 contains no provisions for exemptions from the tolerance for particular segments or plants of the affected industry."

FDA turned down objections which suggested regulatory alternatives, including PCB tolerances for packaged foods rather than for the packaging materials. The agency said:

> "If the criteria of a regulatory section of the act are fulfilled with respect to substances added to food..., it is within the discretionary authority of the Commissioner to choose to regulate such substances under that section to advance the purpose of the act to protect the public health, even if the substances could be regulated differently under §406 or other sections of the statute... The Commissioner therefore concludes that proposed regulatory alternatives to his promulgation of the PCB tolerance for paper food-packaging material do not raise a genuine and material issue of fact requiring a hearing."

Noting an objection to the Sept. 4, 1973, effective date of the tolerance, FDA said since the effective date was stayed, "this objection is moot."

Noting an objection that the tolerance conflicts with recycling policy stated in the National Environmental Policy Act, FDA said it had "properly evaluated the impact of the PCB tolerance within the context of NEPA," and that the alleged conflict "does not raise any genuine and material issue of fact requiring a hearing... but is an issue which is solely for review by a federal district court..."

●

NET CONTENTS EXEMPTION FOR WRAPPED CANDIES PROPOSED

The Food and Drug Administration March 13 published the proposal by the National Confectioners Association which would exempt from net quantity of contents labeling requirements individually wrapped pieces of confectionery of not more than 2 ounces (See FOOD CHEMICAL NEWS, Oct. 28, Page 24).