PCB Article

the intake of sodium in dietary management." The agency said, "This promulgatory separation is being made to avoid delays that may be encountered in acting on the balance of this matter."

In FDA's proposals, the two sections were §125.7 and §125.8, but FDA last week stuck with the §125.8 and §125.9 section numbers in order to make them compatible with the current regulations. The numbers presumably will be changed to §125.7 and §125.8 when the rest of §125 is finalized.

The only change made in the section on hypoallergenic foods was the extension of the requirements to make them applicable to a product "offered as food suitable as a substitute for another food having allergenic property." Both the old regulation and the new one cover products "for special dietary use by reason of the decrease or absence of any allergenic property."

As did the old regulation, the new requires that labeling bear: (1) the common or usual name and the quantity or proportion of each ingredient (including spices, flavoring and coloring); (b) a qualification of the name of the food or the name of each ingredient to reveal the plant or animal that is the source of the food or ingredient, if the food or ingredients consist in whole or in part of plant or animal matter and the name does not clearly reveal the specific plant or animal that is the source; and (c) a statement of the nature and effect of any treatment or processing, if the changed allergenic property results from the treatment or processing.

The only change in the section on foods for regulating the intake of sodium provides that the number of mg. of sodium is to be declared on the label as the nearest multiple of 5 mg. as determined by appropriate analysis, except that if the food contains not more than 10 mg. of sodium in 100 grams of the food and not more than 10 mg. in a specified serving, the label "shall bear a statement to that effect."

Both the old and new regulations provided that the label must bear a statement of the number of mg. of sodium in 100 grams of the food and a statement of the number of mg. of sodium in a specified serving. The regulation covers food represented for special dietary use "by reason of its use as a means of regulating the intake of sodium or salt (sodium chloride) . . . "

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EDF CALLS PROPOSED PCB TOLERANCES "INADEQUATE"

The Environmental Defense Fund said last week that the temporary tolerances proposed by the Food and Drug Administration for polychlorinated biphenyls are "completely inadequate to protect human health and welfare."

Noting that the levels proposed for temporary tolerances are higher than PCB levels found in a majority of food samples, even in the publicized instances of contamination of eggs and milk "at which the Commissioner expresses himself 'concerned,'" EDF "strongly urged" the FDA to revise the proposed temporary tolerances downward by a factor of 5-10.

The Fund noted that the lowest no-effect level established in experimental animals is 0.1 mg/kg/day, in Japanese Quail, using American-made Aroclor, and the lowest dose which caused overt symptoms in the "Yusho" incident in Japan was about 200 mg/kg/day.

The letter suggested that a provisional Acceptable Daily Intake for man be set at "no higher than" 1 mg/kg/day, saying that this offers a safety factor of no more than 10, which is "even lower if the possibility is considered of additive or synergistic toxicity with other fat-soluble chemicals found in the same foods, such as DDT, dieldrin, lindane and hexachlorobenzene." EDF said:

> "At the proposed tolerance levels, consumption of 800 ml. of milk (3.5% fat), 140 grams of eggs, or 14 grams of fish per day by an adult would each account for this proposed ADI. Thus these proposed tolerance levels, even supposing that they could be strictly enforced, would not protect the adult population from potentially hazardous levels of PCBs. Those who consume milk, eggs, poultry and/or fish by preference are especially at risk."

Suggesting tolerance levels "of no more than 0.2 p.p.m. in milk fat, 0.04 p.p.m. in chickens, 0.1 p.p.m. in egg yolk, 0.1 p.p.m. in pork, 0.6 p.p m. in fatty fish . . . and 0.2 p.p.m. in fish with less than 4% fat," EDF stated that these tolerance levels could be achieved and enforced immediately, "except in the case of fish, where mean levels are already higher than this in many species . . ."

Citing figures which suggest that the median level of PCBs in human milk in the U.S. is in the range of 20-60 p.p.b., the Fund said this level appears to be hazardous to breast-fed babies. "Assuming that a breast-fed baby consumes 160 g/kg/day, these levels correspond to 3-10 mg/kg/day, 3-10 times larger than the maximum figure suggested" for an ADI, EDF said.

In addition to revising the proposed temporary tolerances downward, EDF also strongly urged FDA "to issue warnings to pregnant women who intend to breast-feed their babies to restrict their intake of fish to species that have been thoroughly monitored by FDA and found to be uniformly within the tolerances suggested above."

"Unless these two measures are taken, the proposed rules will be totally inadequate to protect the public health, even on the basis of the present incomplete knowledge of the long-range health hazards of PCBs and their breakdown products," EDF stated.

Further, the Fund noted that PCBs made in France, Germany, and Japan are probably considerably more toxic than American-made PCBs due to the presence of highly toxic impurities or breakdown products and, "accordingly," urged "FDA to set lower tolerance levels for imported foods (especially imported cheese and fish) than for domestic foods, at least until further investigation is made of this hazard."

In another comment filed last week, the Virginia Institute of Marine Sciences said that FDA personnel have "indicated that substances not listed may be taken to have a zero tolerance level" of PCBs. Noting that shellfish were omitted from the list, the Institute said: "Shellfish are efficient concentrators of many pollutants and hence have been analyzed for polychlorinated biphenyls. While no Virginia samples have exceeded 5 p.p.m. PCB's (proposed tolerance for fish), most samples contained a measurable quantity. For this reason a zero tolerance level for shellfish would certainly be harmful to the industry, unreasonable and unfounded."

VIMS asked that shellfish either be included under fish at 5 p.p.m. PCB's, or be specifically excluded from the proposal.

As expected, on May 18 FDA extended the time for comment on the proposal for 60 days (See FOOD CHEMICAL NEWS, May 15, Page 42). Container Corp. of America had asked such an extension in its preliminary comments filed last week, and further asked that the period be extended "until appropriate sampling and testing procedures and compliance standards have been proposed by the FDA and we have been afforded a reasonable opportunity to consider and comment" on these.

Clevepak Corp. and Reynolds Aluminum had asked that the time for comment be extended 4 months and 120 days, respectively. Noting the lack of a testing procedure for non-paper packaging materials, the questions of effectiveness of "barriers" and insufficient data on the presence of PCB's in packaging materials other than paper, Reynolds stated:

> "The trade and professional associations serving the food and packaging industries are providing communications and coordinating activities between their member companies in order to provide the most effective reduction of PCB's possible from our food supply. This activity will continue during any delay granted in the implementation of the proposed regulation."

Diamond National Corp. requested that the section on food packaging materials be withheld "until industry studies on reliability and reproducibility of test results and studies relating to transfer from packaging materials to foods are completed and evaluated," as did the John Strange Paperboard Division of Menasha Corp.

Saying that present testing for PCB is "extremely complex and lengthy," Strange said the procedures have shown "erratic results and discrepancies in reproducibility of data . . . (and) water was shown to contain large amounts of PCBs."

The only "quick answer," according to the firm, "is to eliminate all paper from food-grade packaging which could result in 1,000,000 tons of consumer waste paper removed from recycling and increase the solid waste disposal program."

The Can Manufacturers Institute said it agreed that FDA "should take all reasonable steps to limit the amount of PCB contamination in the nation's food supply," but was concerned "about the unreasonableness of certain portions" of the proposal.

Saying the "intent" was to apply temporary tolerances to paper food-packaging materials, CMI noted that the regulation "carries the all inclusive term 'food-packaging material.'" It is "unreasonable to expect PCB's in corrugated shipping cartons to become a component of the contained canned food," the Institute said, asking that the regulation be changed to refer specifically to "paper food-packaging materials," with a further notation: "where it is reasonable to expect the contained PCB to become a component of the packaged food."

Dow Chemical sought clarification of the kinds of food packaging materials to be covered and also whether all food packaging materials included "are to be governed by the same limits of PCB content."

Asking that an "accurate and commonly accepted" methodology be provided for determining PCB content in various food-packaging materials, Dow enclosed a proposed analytical method for plastics, employing gas chromotography and mass spectrometry, with a sensitivity of 0.1 p.p.m. and positive identification of the PCB component.

Dow also asked clarification of what "is intended by the term" PCB, noting the complexity of the isomer content and the "inherent error in calculating one or two isomers in terms of an Aroclor containing possibly 50-60 isomers."

Questioning the classification of tolerances as temporary, Dow wondered "whether it is realistic to hope for the total elimination of PCB's in food and food packaging materials in the foreseeable future."

Mead Corp. said PCBs are classified as "being of moderate acute toxicity; about 1/50th of that of DDT," and that Aroclor 1242 (the PCB found in paper and paperboard), is less toxic than PCB's of greater chlorine content, such as Aroclor 1254. Calling the present proposal for food-packaging materials "unworkable," Mead suggested an alternative approach:

> "I. Set guidelines for tolerances of PCB's in foods. These have been established for some foods, and relatively few others would need to be established to cover the 15 types included in the FDA Market Basket survey.
>
> "II. Using the guidelines established in I, determine permissible levels in packaging materials by use of a formula based on (a) package to food weight ratio, (b) the presence (or absence) of an effective PCB barrier, and (c) extent of migration anticipated."

Mead noted that "this proposed approach provides for consideration of the foods such as infant and junior foods where lower tolerance of PCB in the food has been established and also takes into account the varying needs arising from differences in package size (or package to food weight ratio) as, for example, portion packs compared to institutional packs."

Container Corp. of America also suggested that the regulation should be based on amount of PCBs found in food, adding that "regulation of food is sufficient to effectively control any potentially harmful PCBs in packaging materials."

Container Corp. hit the lack of "an acceptable procedure for determining probability of compliance," asking, "Would the proposed regulation be violated if nine out of ten samples contained 4 p.p.m. of PCB in each while one out of ten samples contained 7 p.p.m. of PCB?"

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MORE SOPHISTICATED QUALITY CONTROL REQUIREMENTS PREDICTED

Regulatory agencies "will require a far more sophisticated level of quality control" of the food industry in the future, it was predicted by Dr. E. M. Foster, of the Food Research Institute, in a speech before the Chicago Section of the Institute of Food Technology recently.

"I would not be surprised if the day comes when new products can be marketed only after the processor provides evidence of a thorough safety analysis, with built-in safeguards in the event of mishandling," Foster said, adding: "I know one company with $300 million annual sales that bought its first microscope last year. I anticipate that company and others like it will soon have sophisticated laboratory facilities if they are to continue to operate in the food business."

After reviewing some problems that may face the food industry, Foster stressed the need for ambitious scientific work "necessary to assure a safe and wholesome food supply," commenting that he does not know who will do this work nor "who is going to pay for it."

Traditional feeding tests with laboratory animals "are not enough," Foster said adding that, "Even long term practical experience with the entire human population is discounted on the grounds that we might be even healthier than we are if we had not been eating such and such."

He predicted that it will become more difficult to satisfy "everybody about the safety of food additives," explaining, "It's going to take the usual toxicologic studies plus more work on metabolism in the animal plus evidence that the material is not carcinogenic, mutagenic, or teratogenic,. There may be even more requirements in special cases." Regarding the question of who will do the necessary food safety work and who will pay for it, Foster said:

> "The Food and Drug Administration and the U.S. Department of Agriculture are certainly not prepared to take on the job; they have their own day-to-day problems. The people I know at the National Institutes of Health seem to feel that food problems are a bit beneath their concern; go see someone else they say. Few questions in food safety are 'basic' enough for the National Science Foundation, and