

# FPC: Nearing Approval?

by Barbara J. Culliton

While the undernourished children of the world wait for a reprieve from hunger, U.S. scientists wait for the Food and Drug Administration to give the green light to an edible fish protein concentrate that may help. Scientists are extracting from fish a high protein food additive intended to bring nutrition to a starving world.

Meanwhile, FDA is waiting for the product's developers and supporters to come up with a product that meets its standards for purity and safety. FDA's reasoning is, "If it's not good enough for U.S. citizens under U.S. law, how can we offer it to the world?"

And for years now, it hasn't been good enough.

There are signs that the waiting game may be coming to an end, but no one can be absolutely sure. The hitch to FDA approval, and the "only major obstacle" now, according to an FDA spokesman, is that the concentrate developed by the Interior Department's Bureau of Commercial Fisheries contains too much fluoride; enough to cause mottling of the teeth if a child were to consume large quantities of the protein additive over a long period of time. Mottling occurs as a result of too much fluoride intake at the time teeth are calcifying.

A committee of the National Academy of Sciences has reviewed fish pro-

tein concentrate and declared it safe and wholesome for human consumption.

Among the scientific and political supporters of the high-protein additive, there is feeling that FDA is quibbling, that the possibility of mottling is outweighed by the nutritional benefits that are so sorely needed. But FDA has consistently considered anything that changes the natural body composition toxic, even if the change is only a cosmetic one, and it wants the fluoride to go.

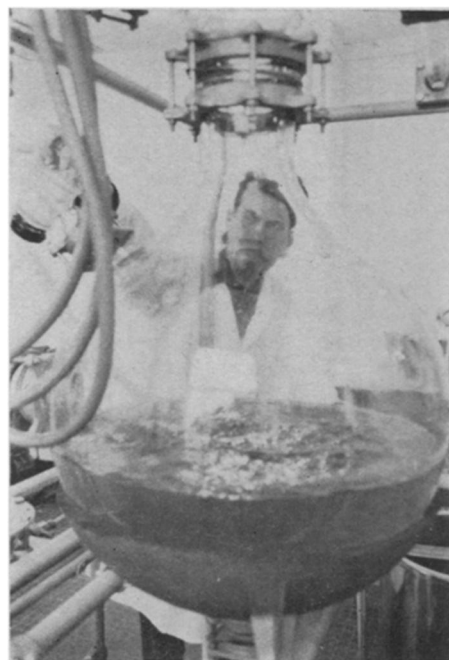
Two petitions are currently on file: one from the Department of Interior's Bureau of Commercial Fisheries and one from the VioBin Corp. of Monticello, Ill. Both use whole red hake to make their product, but they use different processing methods. Commercial Fisheries' system yields a concentrate that contains 200 parts per million fluoride, while VioBin's new method, described in an interview by Ezra Levin, president, cuts the fluoride content to 35 ppm by extracting the bone from the fish before processing. The advantage of Interior's additive, however, is that grinding up the whole fish (head, tails, viscera and all) is supposed to be less expensive.

In Commercial Fisheries process, fresh, whole fish are kept frozen from the moment they are caught until they are ground up and dehydrated. The powdered fish are cleaned (defatted and deodorized), with an isopropyl alcohol solution and dried in a vacuum drum dryer.

At one time FDA rejected the product because the residue of isopropyl alcohol was too great, but since then the process has been refined sufficiently to remove it. Other grounds on which FDA has rejected fish protein concentrate in the four years it has been coming up for review are that its lead content was too high (a problem that has been remedied) and, earlier, that the product violated "filth" standards and would be "unaesthetic to American housewives."

The Levin process uses isopropyl alcohol at the end, but first removes fat and water in an intermediate step using ethylene dichloride.

Researchers working for Commercial Fisheries have recently completed clinical tests on human subjects fed fish protein concentrate to determine how much of the 200 ppm fluoride the body holds. The results aren't in yet. But since the fluoride is in a very insoluble form, they believe most of it passes out of the body as waste.



The Washington Post

The Extraction Still

If Commercial Fisheries can demonstrate that a very low percentage of the fluoride actually enters the human system, then the amount of fluoride in the product is irrelevant, the FDA spokesman agreed, and the review committee will act accordingly.

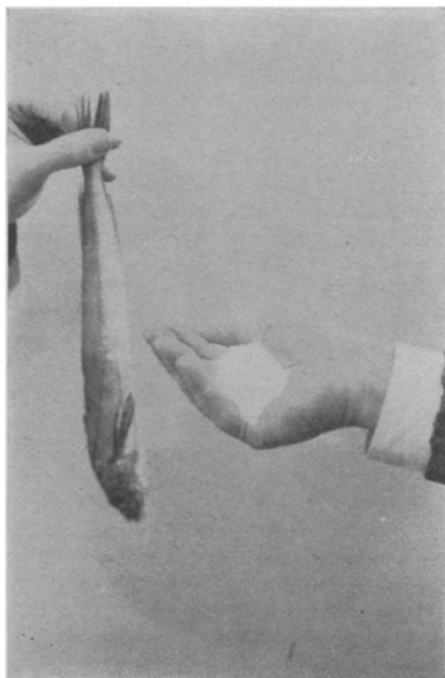
Once all the new evidence is in, FDA will probably act very quickly, the spokesman said. President Johnson and FDA Commissioner James L. Goddard are interested in getting the program moving and production started as soon as possible.

Interior estimates that the concentrate can be made commercially, at a profit, for 25 cents a pound.

Mr. Levin says that VioBin is ready and able to produce fish concentrate in any quantity within six months, and at a cost of about 20 cents a pound.

VioBin is already manufacturing it in limited quantities and selling it abroad for experimental purposes. One can legally export any commodity if it complies with the laws of the country that receives it. Mr. Levin cited Indonesia as one place where the food additive has gotten a warm welcome; Peru is another.

Commercial Fisheries is not ready to go into production on such short notice, but legislation signed by President Johnson last month authorizes construction of a \$1 million pilot plant and leasing of a second plant. The legislation also authorizes studies to be made abroad to find simple, effective applications for the high protein concentrate.



The Washington Post

The fish makes the flour