

From Catherine W. Carnevale, interviewed by Suzanne Junod and Robert Tucker, 10 February 2009:

We talked about aflatoxins before, regarding my job in BVM. When I was in the Office of Regulatory Affairs, we dealt with aflatoxins too. Aflatoxins fall into that unavoidable-contaminant category. And in ORA, because I was not kind of strictured by just dealing with animal-feed type issues like I dealt within the Bureau of Veterinary Medicine, suddenly I was dealing directly with human foods as well as animal feeds.

Aflatoxins are a toxin that are produced by *Aspergillus flavus*. *Aspergillus flavus* is a mold, so it grows where most molds would grow, in hot and moist conditions.

Aflatoxin is considered a mycotoxin, which means a mold toxin, and there are many thousands of mold toxins that are toxic to humans and other animals. *Aspergillus flavus* is found in America's favorite crop, which is corn. Corn is grown all over the U.S., but we think of it mainly in the South, I think, and certainly that's where aflatoxins are primarily found in corn. They're primarily found where there's an early summer, moist conditions.

Just like what occurred with the heptachlor situation, there was a reason for aflatoxin levels increasing in the mid-'80s. There was a change in the way corn was grown. Corn used to be grown with rows about three feet apart. Farmers decided that they could have increased agricultural efficiency and the equipment could still get down the fields if they'd grow it two and a half feet apart. And what that did was to give more of a foliage umbrella to trap the humidity. These higher moisture levels could cause more mold on the ears of corn, and the production of aflatoxin. Aflatoxins didn't really occur in the sweet corn that we eat, like corn on the cob. The mold was mainly in the hard corn that is used for animal feed.

So, you'd get the aspergillus growing in the corn kernels and then southern state weather conditions perfect for the toxin production. You didn't need very much of the toxin. The nature of aflatoxin is that a very small amount of it is enough to cause some pretty evil effects. It's toxic to the liver, so it's a hepatotoxin. It can cause cancer over time. And it is toxic to animals, as well.

We were having a number of bad crop years in the early to mid-'80s. The FDA's action level for aflatoxins was 20 parts per billion in corn. The level in milk was 0.5, I think, parts per billion in milk. There were a fair number of studies that were coming out that showed that ruminant animals could handle, because they could detoxify the aflatoxin in one of their four stomachs. So the question was, can we safely feed aflatoxin-contaminated corn to ruminant animals? Can we take this bad corn that has been tested and found to have higher levels of, perhaps, 100 parts per billion or 400 parts per billion, and feed it to dairy cows or feedlot animals or sheep or goats? Thus, in bad aflatoxin years we could make use of this corn and not just have to throw it away, which was increasingly causing enormous economic impact on the corn farmers in the South.

So we ran the science and found that, yes, in fact, these animals could consume higher levels of aflatoxins without adverse health consequences, residues in edible tissues, or levels above the level of concern in milk.

So we decided to grant exemptions to states, when there was a bad year and the states were willing to take the responsibility to channel corn with higher levels to the appropriate animals. The agency scientists and certainly I felt that it could be done safely. It required that states and FDA manage the corn supply, the entire corn supply in the Southern states.

In any case, we had meetings with states, we had meetings with the industry, we

had meetings with everybody. We tried to see if this fix was workable because we were finding out about contamination levels late in the season. How long can the corn stay in the elevators? Normally, there's a quick turnover. And we had to produce *Federal Register* documents that were announcing the exemption early enough to allow time for states to apply and be granted the exemption and get their program started. So, although this was a logistical nightmare, we had gone through a similar situation almost in a Chinese fire-drill way a couple of years previously where millions of bushels of corn had had to be dumped. We did not want that to happen again if there was a way to avoid it. And so we went out with a *Federal Register* document and changed the action levels for aflatoxins in feed that would be fed to specific types of animals based on the science we had. And the document was as tight as we could make it science-wise. The science behind these levels is still solid.

We explained the legal basis for the policy in terms of aflatoxin being an unavoidable contaminant, that is, it could not be avoided by good manufacturing practice. We were changing our action levels to provide for the safe use of this feed. And I think it was a good thing. The work that we did back then is valid today.