Fact or Fiction?

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Regulatory Alchemy

Use of common sense to try to understand some regulations can be a very frustrating experience. Pressure by environmental groups and the public, questionable science by regulating agencies, and inconsistent enforcement by various regulators helps create this confusion. Yes, I'm aware you already know this, but here's how one issue not related to our industry was handled.

Influence of Pressure

This example shows the influence of pressure by environmental groups and the public. It involves a decision made over 20 years ago by the Food and Drug Administration (FDA) involving three different substances—aflatoxin B1, saccharin, and 2-4 DAA (used in hair dyes). Each of these had been shown to cause cancer in animals, while aflatoxin B1 had been shown to also cause cancer in people. The annual number of persons who were predicted to die prematurely as a result of exposure to these substances were: 1,600 from aflatoxin, 500 from saccharin, and three from 2-4 DAA.[1] From this information, one doesn't have to be a rocket scientist to note that aflatoxin is considerably more dangerous than the other substances, with 2-4 DAA hardly being in the same ball park as the other two. Guess how it all played out?

Public and environmentalist pressure was inversely proportional to the number of persons who would be affected. The outcry was against 2-4 DAA. Regulators struggled with these issues and as Richard Wilson and Edmund Crouch report: "The FDA could not act on the last of these [2-4 DAA] (and still be intellectually honest) without acting on the first two. FDA declined to lower the 'action level' for aflatoxin in peanut butter by calling it a 'natural' additive."[1]

Background

Before discussing how the issue with saccharin was solved, here's some background. It all started with a Canadian study wherein rats on a diet containing large doses of saccharin developed bladder cancer. How large a dose? The saccharin made up five percent of their diet. It was the equivalent of a person drinking 800 cans of diet soda in a day.[2]

The FDA handled saccharin by sending their risk analysis to Congress, who with remarkable expediency made an exception.[1] This was done, in part, by using cigarettes as a role model. David Faigman quotes Senator Richard Schweiker (Pennsylvania): "Many Americans fail to see why saccharin should be singled out for such drastic action. Cigarettes, known to endanger human health in many ways, are allowed to be sold freely and openly. Anyone may choose to smoke or not to smoke; all that is required is that he be warned of the hazards." So, Congress passed a law that prohibited the FDA from banning saccharin and required the following label to be affixed to all products containing saccharin: "Use of this product may be hazardous to your health. This product contains saccharin, which has been determined to cause cancer in laboratory animals."[2]

Comparing saccharin with aflatoxin, here's what Joseph Rodricks reports: "Saccharin is the least potent carcinogen ever detected in an animal study; that is, the dose required to produce a given lifetime incidence of tumors is greater than that of any other known animal carcinogen. Near the other extreme of the potency scale is our old friend, the mold-produced compound aflatoxin. A dose about one-ten millionth that required by saccharin was needed to increase the incidence of tumors in experimental animals."[3]

Here's the story on hair dyes. The FDA had announced in early 1978 that all dyes containing the questionable chemicals would carry a warning label stating that it was an animal carcinogen. Hair dye manufacturers were quick to reformulate their products to eliminate the dyes used in rodent tests before the warning label could go in effect. However, as Adam Lieberman points out: "This was not enough for some consumer activists, who accused hair-care companies of using substitute chemicals that were as hazardous as the substances removed. The cosmetics companies objected to the methodology of the original tests, noting that the rodents drank the

dye—obviously not the method of human exposure. Furthermore, the doses used on the laboratory rodents were the equivalent of a woman drinking 25 bottles of hair dye every day for her entire life."[4]

Lieberman also adds: "Most recently, Brigham and Women's Hospital conducted a study involving more than 99,000 women that was specifically designed to determine whether a link existed between cancer and hair dyes. That study showed no greater risk of blood or lymph cancers among users of dyes. The National Cancer Institute is currently on record as concluding that, while further research is needed in this area, 'no recommendation to change hair dye use can be made at this time.' Today, anywhere from 20 to 60 percent of Americans are estimated to use some type of hair coloring; most of it contains coal-tar dyes."[4]

More on Aflatoxin

Some final words on aflatoxin. As Elizabeth Whelan reports, "Commercial peanut products sold in this country can have no more than five parts per billion-traces that can and often do remain in spite of cooking, processing or home-roasting peanuts. Be assured that this level does not threaten human health."[5] She uses this example "to make the point that something natural like peanut butter can have toxins—toxins that consumers normally ignore in their quest to eliminate 'unnatural' products from their diet." As Thomas DeGregori adds: "What is natural is routinely not questioned or considered a cause of any of our dietary or health problems."[6]

Some Final Words

Let's assume that you believe in re-incarnation and in your next life you will come back as a chemical. Make sure that you return as a 'natural' chemical rather than as a 'synthetic.' Don't worry about your toxicity to animals and humans. If you wisely choose the 'natural' category you can be zillions of times more toxic to humans but you'll be left alone. By contrast, if you make the mistake of returning as a 'synthetic' you run the risk of big trouble. Someone might show that if a rat consumed the equivalent of a human drinking 800 cans of soda containing your chemical it might get cancer. Or if you return as a 'synthetic' hair dye researchers might show that if a woman drank the equivalent 25 bottles of hair dye containing your synthetic every day for her entire life, she might get cancer. We all know that women don't drink hair dye, but if you are dumb enough to return as a synthetic, you will be treated as a 'chemical *non grata*.' This is what I call "regulation alchemy." ***P&SF***

References

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3. Joseph V. Rodricks, *Calculated Risks*, (Cambridge University press, 1995), 161.
4. Adam J. Lieberman, "Hair Dyes, 1977", in *Facts Versus Fears: A Review of the 20 Greatest Unfounded Health Scares of Recent Times,* 2nd Edition, (New York, American Council on Science and Health, September 1997), 13.
5. Elizabeth M. Whelan and Fredrick J. Stare, *Panic in the Pantry*, (New York, Prometheus Books, 1992), 72.
6. Thomas R. DeGregori, *Bountiful Harvest*, (Washington, DC, Cato Institute, 2002), 71.