



L-tryptophan: what made this GM food supplement kill 37 people and disable 1500?

The effects of L-tryptophan

It is regularly stated by the biotechnology companies and US Government that GMOs have caused no negative health effects in America. However, as well as the reported allergic reactions to GM StarLink maize (which accidentally contaminated the US food supply) one GMO that was intentionally sold for consumption has had very serious effects. The genetically engineered amino acid L-tryptophan was marketed in the US in 1989 as a food supplement by the company Showa Denko K.K. Tragically, within a few months of being sold the supplement had caused the deaths of 37 Americans and the permanent disability of at least 1,500 others. (Source: House of Representatives 1991. *FDA's Regulation of the Dietary Supplement L-Tryptophan.*)

It was later shown that L-tryptophan contained unusual and highly toxic contaminants. None of the conventionally produced tryptophan previously sold had been toxic. Although it was never established if the toxicity resulted from the genetic engineering process, US Government officials state that they have not ruled out a link. Some experts think the problem resulted from changes in the manufacturing process. Tryptophan is produced by micro-organisms as a by-product and absorbed in gel, from which it is extracted. At the same time as the GM version was introduced, there had been changes to the filtration process which were meant to clean the product. However, other scientists believe that the toxic effects must be attributed to an unexpected side effect of the genetic engineering procedure. The genetic modification of the micro-organisms had not only greatly increased the activity of the gene producing tryptophan but also caused a higher production of a toxic by-product. Perhaps, while adequate cleaning could have avoided the problem, genetic engineering had still caused a new or higher risk than conventionally produced tryptophan.

A definitive answer on the cause of the toxic effects was never reached because all relevant evidence in Showa Denko's laboratory was destroyed before it could be examined.

Response of the FDA and US Government

The only concrete action the US Food and Drug Administration took was to remove *all* tryptophan supplements from the market, even though no conventionally produced tryptophan had previously been known to cause the illness.

On July 18, 1991, Douglas Archer, the Deputy Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), was invited to testify before the House of Representatives regarding the agency's actions in response to the L-Tryptophan tragedy. In Dr Archer's prepared remarks he did not once mention that the

toxic batches had been produced through genetic engineering or make any other mention of genetic engineering.

On September 27, 1991, Dr. James Maryanski, Co-ordinator of the FDA's CFSAN Biotechnology Working Group, met with representatives of the Government Accounting Office and was questioned about L-Tryptophan and the potential that genetic engineering was the cause of the illness (termed EMS). According to Dr. Maryanski's memo of the meeting: "We do not yet know the cause of EMS *nor can we rule out the engineering of the organism*". [emphasis added]. (FDA Administrative Record at 22,923.)

In a meeting in May 2003, Dr Laura Tarantino, Deputy Director of Office of Pre-market Approval at CFSAN, told a Soil Association representative that the FDA did not know if the toxic effects were due to the genetic engineering, but the FDA did not consider that this meant pre-market approval needs to be introduced for GM foods in the US as the economic consequences of safety failures is an adequate discipline (the company which produced L-tryptophan is no longer producing the product). Currently there is no legal requirement for the approval of GM foods in the US, only an understanding that the companies should submit assessments of the safety of GM food products for the consideration of the FDA.

To date, despite the L-tryptophan tragedy, the biotechnology companies and the US government continues to state that no GM food has caused any human health problems in the US and that company risk assessment methods are adequate. This important subject is often trivialised. For instance, in September 1999, David Aaron, U.S. deputy secretary of commerce, declared, "Not a rash, not a sneeze, not a cough, not a watery eye has been developed from this (GM foods)." (Reported by Reuters, 9.16.99)

Source

1. "Why FDA policy on genetically engineered foods violates sound science and US law", Statement of Steven M. Druker J.D., Executive Director, Alliance for Bio-integrity. Delivered at the FDA public meeting, Washington D.C., 30 November 1999. Panel on Scientific, Safety, and Regulatory Issues. www.biointegrity.org
2. Dr Laura Tarantino, Deputy Director of Office of Pre-market Approval at the FDA Center for Food Safety and Applied Nutrition (CFSAN), personal communication, May 2003

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