

Livestock Identification — The FDA-CVM's Perspective

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The responsibility at the federal level for the food safety regulation is implantable animal identification products at the Food and Drug Administration (FDA). Within FDA, the Center for Veterinary Medicine (CVM) is the public health organization that enables the marketing of effective animal drugs, food additives, feed ingredients, and animal devices that are safe to animals, humans, and the environment. Implantable electronic animal identification products are regulated under the Federal Food, Drug, and Cosmetic Act. The regulation of these products also falls under USDA/FSIS to make certain, during slaughter, that the product does not enter human food. It also looks to the FCC for the regulating the radio frequency used in the transmitter.

The CVM decision that these ID products are food additives has been public since September 1990. Since then, CVM has seen some activity on the part of the manufacturers of these products to obtain approval. However, there has not been great progress to date. More is needed.

There is a second public health provision that can be used to regulate these products. It is the animal device section. This provision is applicable if the identification product is removed from the animal at slaughter, disposed of in a landfill, and does not become incorporated into either the human food or animal feed derived from the carcasses. We think of these products for the most part as food additives because we believe it unlikely that the products will all be removed at slaughter. In January 1991, the FAP requirements were outlined in a presentation to the Annual Meeting of the National Cattleman's Association. These are the full FAP requirements. Since then, we have learned a little about the chemical composition of some of the implantable ID products. We know that some contain lead and cadmium. Of these elements, the amount of lead present is of greatest concern. There are many other elements present as well. However, the health implications of lead and cadmium are the more significant.

While the lead present would be a health concern if it were to be found in human food, in my view, we are not concerned about the animal health effects of this lead if it were to be present in meat and bone meal as consumed by food-producing animals. This analysis is based on the generally known metabolism characteristics of lead.

Our position could change if new information were to come to our attention. At this moment, the current information is the basis for our position that, the unapproved food additive status and their use in animals does not justify the assignment of enforcement resources to stop the use of these products.

It seems that the principle remaining regulatory hurdle for manufacturers of these products is to assure that the product does not become a component of human food. These issues seem to amount to:

- a) a universal reader and
- b) use of a universal reader at each slaughter facility

I look forward to the discussions over the next two days. I am hopeful that substantial progress can be achieved. We support efforts to have animals uniquely identified. It would be very helpful in proper drug investigations and tracking animals to determine the cause of an illegal residue.