International Association of Fish and Wildlife Agencies

Representing Fish and Wildlife Agencies since 1902

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 03D-0186

To Whom It May Concern:

The purpose of this letter is to provide the comments of the International Association of Fish and Wildlife Agencies (IAFWA) in reference to Food and Drug Administration draft guidance for industry "Use of Material from Deer and Elk in Animal Feed" (Docket No. 03D-0186). The Association includes in its membership all 50 State fish and wildlife agencies, which have constitutional and/or statutory authority and responsibility for the conservation of fish and wildlife within their borders

The IAFWA commends the FDA's previous bovine spongiform encephalopathy (BSE) regulation prohibiting ruminant animal material from being used in ruminant feed (21 CFR 589.2000) in order to prevent a BSE outbreak in the USA. Furthermore, IAFWA recognizes the current Draft Guidance also is intended to prevent a transmissible spongiform encephalopathy (TSE) outbreak. However, IAFWA is concerned about FDA's current thinking regarding chronic wasting disease (CWD), as reflected in the Draft Guidance, and already has witnessed unintended consequences of this approach. The Draft Guidance, as currently written, hinders animal health and wildlife management agency efforts to identify new areas where CWD occurs and it simultaneously increases, rather than decreases, the likelihood of CWD-positive carcasses entering the non-ruminant animal food chain.

The IAFWA believes the Draft Guidance reflects an overreaction on the part of FDA, and it sends a message to the public and animal food industries that simply cannot be supported with good science. The FDA apparently has failed to recognize that CWD is not BSE. The latter is known to be a food-borne disease and consumption of material containing BSE-contaminated tissues is the only known natural mode of transmission of BSE. By contrast, CWD is known to be transmitted laterally from affected deer and elk to susceptible deer and elk; there is no evidence CWD is a food-borne disease transmissible to non-ruminant animals. There are other important differences between CWD and BSE; however, the difference between BSE and CWD in the mode of transmission is of the greatest relevance to FDA's current thinking regarding CWD.

The IAFWA's primary concern about the Draft Guidance, in addition to the inaccurate message it projects, is with Section III in which the FDA recommends that any feed or feed ingredients containing material from a CWD-positive animal be recalled or otherwise removed from the marketplace. Basically, a recall is triggered if a deer/elk from an area not considered at high risk for CWD tests positive and material from this animal has entered the non-ruminant animal food chain via a rendering operation. Section III hinders our ability to find new areas where CWD occurs because it promotes avoidance of CWD testing, thereby increasing the chances for CWD to go undetected and for positive animals to enter the animal feed system.

Experience has demonstrated that current CWD surveillance techniques can detect the disease in a new area (non-endemic zone) while at a relatively low prevalence but that higher prevalence of CWD is discovered when detection is delayed. Early detection offers greater opportunities to eliminate the disease; and early detection depends on cooperation of hunters, meat processors, taxidermists and renderers. This cooperation was severely impacted by the FDA-CVM's Update of November 12, 2002: During 2002 hunting seasons, IAFWA member states collected approximately 147,000 deer and elk heads or associated tissues for CWD surveillance. However, in some states wildlife managers and cooperating hunters were turned away because meat processors and/or renderers would not accept deer and elk that were to be tested for CWD. As currently written, the Draft Guidance will perpetuate this highly undesirable situation.

In a new CWD area, only a very small amount of CWD-positive material from one or very few animals is likely to enter the non-ruminant food supply. The FDA's recommendation for recall of a small amount of material is unnecessary in view of the facts that CWD is not BSE, CWD is not known to be a food-borne disease, and rendering is known to reduce infectivity of TSE prions.

If adopted as written, the Draft Guidance will result in fewer deer and elk being tested for CWD than otherwise would be available. This conceivably could result in delayed discovery, or failure to discover, a new CWD area. The same deer and elk, whether CWD exposed or not, will go into the non-ruminant animal food chain, they simply will not be tested. Thus, the FDA Draft Guidance will result in more CWD-positive material, not less, being used for non-ruminant food and will be counterproductive to National efforts to detect and control CWD.

In summary, we request that FDA reconsider Section III of the Draft Guidance. Thank you for the opportunity to comment.

Sincerely,

Brent Manning
President

CC: State Fish and Wildlife Directors
Dr. John Fischer
Dr. Tom Thorne