



CENTER FOR
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HEALTH

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

Dear Sir or Madam:

This references the agency's draft guidance for industry: "Use of Material from Deer and Elk in Animal Feed," published in the Federal Register on May 16, 2003. It finalizes the official response following the informal definition of policies outlined for and previously discussed with the rendering industry at or around the period of November 4-11, 2002.

While the latest defined policies and agency's current thinking appear superficially benign, the Center for Bio-security, Food Safety & Public Health (CBFSPH) feels an obligation to address concerns with aspects of the guidance, with special reference to chronic wasting disease (CWD) and analogous inferences of implied risk.

CBFSPH accepts the non-binding and enforceable limits of the guidance document as recommendations only. It also recognizes that the constraints of use of material as feed ingredients in all animal feed are restricted to cervids (deer and elk) that are positive for CWD or are considered high risk.

The suggestion that "the potential risks from CWD to humans or non-cervid animals such as poultry and swine are not well understood," borders, however, on stretching the limits of precaution beyond the realms of reason, and a definite exaggerated concept of risk based on the existing epidemiology of this disease.

The uncertainties of a complex disease, while distinctly challenging, should not provide an agency the option to exceed the established and traditionally accepted boundaries of reasonable and accountable guidelines. This will put the agency in the untenable position to defend a policy (ies) as good without being able to specify what it is good for. There are many aspects of disease control that are not well understood, and that will likely never change, but that should not necessarily foster guidelines without logical and justifying grounds.

While CBFSPH is very committed to support the promotion of bio-security, from its broadest concepts, to produce safe feed/food in the protection of animal and public health, the Center feels that proposed guidelines/policies that are "inflated" from even a suggested perspective,

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like the poorly understood linkage of CWD to human health alluded to, including the expressed concern about the use of feed ingredients from rendering raw material of CWD affected cervids in all animal species e.g. reference swine and poultry. This takes the feed ingredient use issue out of context to the known accepted risks, and disenfranchises an industry, to a degree, in the process.

The impact of the guidance document will be limited by geography, and the likelihood that the rendering companies involved may modify their practices to conform to the agency's current thinking. But, on principle, that does not make the proposed policy right. It also sends the wrong message in the management and communication of risk to consumers and the public at large, by basically perpetuating doubts that greatly magnify the known risks.

The Center, however, does not plan to delve into a lengthy debate with the agency's feed/food safety objectives in the protection of animal and human health. Nor does it necessarily disagree in totality with some of the agency's major concepts of preventive controls. But, the Center knows that the agency's professional staff of experts is fully aware of the published peer-reviewed literature on the transmissibility theories of CWD, and there are no inferences to humans, swine, or poultry to heighten concern that will affirm the thinking in the guidance document. That is the unfortunate aspect of the topic.

CBFSPH continues, nonetheless, to support CVM's goals for feed ingredient safety, and USDA's Animal and Plant Health Inspection Service (APHIS) for eradication of both CWD and scrapie. Additionally, CBFSPH recommends to CVM/FDA to re-examine its hazard analysis and critical control points (HACCP) initiative that could go a long way in assuring product safety and consumer confidence. The implementation of HACCP, together with the existing feed rule that adequately addresses this subject, could preclude the need for an agency current thinking update or guidance document.

In spite of some differences in philosophy that may emerge on policy issues, CBFSPH commends the agency for responding to the complex challenges associated with the control of the transmissible spongiform encephalopathies (TSEs), and commits to work and cooperate with CVM in the arena of feed/food safety and the continuous protection of animal and human health.

Sincerely,



Don A. Franco