



August 13, 2004

Division of Dockets Management  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Docket No. 2004N-0257. Proposed Rule: Record keeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle**

Dear Sir or Madam:

This letter responds to the Food and Drug Administration's (FDA or the agency) July 14, 2004, request for public comment regarding the above-referenced proposed rule. The American Meat Institute (AMI) is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. Our member companies account for more than 90 percent of U.S. output of these products.

AMI and its members agree that establishing and maintaining records sufficient to demonstrate that a food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials is a record keeping necessity in today's environment of concern over control of bovine products that potentially could harbor infectious prions. As discussed below, a strict application of the regulations promulgated and enforced by the Food Safety and Inspection Service (FSIS) and the Animal and Plant Health Inspection Service (APHIS) should result in minimal record keeping duties for FDA-regulated facilities.

FSIS and APHIS have strict regulatory requirements regarding the health, age and ambulatory condition of bovines slaughtered, separation of specified risk materials (SRMs), and disposition of bovine products disallowed for human food or animal feed. All of these activities must be documented, and the records maintained, by slaughter establishments, and those establishments that manage bovine products and by-products.

AMI proposes that, if the bovine products entering an FDA-regulated facility come from a FSIS-inspected establishment, a purchasing specification (signed annually) defining the requirements for exclusion of prohibited cattle materials as defined in the interim final rule, "Use of Materials Derived From Cattle in Human Food and Cosmetics," would be adequate and meet the intention of the proposed record keeping rule. Thus, the proposed rule on record keeping goes too far in its suggestion that "a signed and dated affirmation (with contact information) by the slaughter establishment" is required for each "particular shipment." This redundancy is unnecessary if purchasing specifications detail the requirements and an annual review of the specification is undertaken between the supplier and customers for the bovine products. Where products change hands on multiple occasions, e.g., through an importer, there may be a need to have more frequent record checks, or to have records transferred with each lot of imported bovine products.

AMI agrees with that electronic record keeping is adequate and that a two-year trace back capability is needed, unless the shelf life of the manufactured product is for a lesser duration, in which case the maintenance requirement should correspond to the shorter shelf life.

The American Meat Institute appreciates the opportunity to submit these comments. If you have any questions regarding the information provided in these comments or anything else regarding this issue, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Dopp", with a long horizontal flourish extending to the right.

Mark Dopp  
Senior Vice President, Regulatory  
Affairs and General Counsel

cc: Patrick Boyle  
Mike Brown  
Jim Hodges  
Lynn Kosty  
Janet Riley  
Skip Seward