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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

RE: Docket No. 2004N-0081

This submission is in response to a request for public comment on the interim final rule concerning *Use of Materials Derived From Cattle in Human Food and Cosmetics; and Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle; Final Rule and Proposed Rule (Federal Register Vol. 69, No. 134, Wednesday, July 14, 2004, pp. 42256-42285)* on behalf of the North American Natural Casing Association (NANCA), a trade association that represents the majority of natural casing producers and brokers in North America, and the International Natural Sausage Casing Association (INSCA), a trade association representing most major companies in the world producing and trading natural casings, as well as all country and regional associations. Our members produce, buy, sell, and distribute casings worldwide. The US industry processes the casings saved by slaughterhouses in the United States in addition to importing and exporting significant amounts of casings to meet domestic and global demand.

Natural casings, which are derived primarily from the intestines of hogs, sheep, and beef cattle, are used in a wide variety of high quality sausage products that constitute a significant industry in North America and throughout the world. Of the three primary types of natural casing, only beef casings are affected by this interim final rule.

Beef Casings: The three most commonly used types of natural beef casing are beef rounds, beef middles, and beef bung caps. Beef rounds are derived from the small intestine of cattle, beef middles from the large intestine, and beef bung caps from the caecum, which connects the large and small intestines.

Beef rounds are used in a wide assortment of quality sausage products, including numerous varieties of ring bologna, knockwurst, blood sausage, and ring liver sausage, as well as specialty sausages such as mettwurst, kishka, and holsteiner. In addition, the majority of halal sausages are made using beef casings (smaller diameter halal sausages generally are made using lamb casings). Processors can substitute collagen casings for some types of sausage made from natural beef rounds, but this generally results in a lower quality product with a decreased market value.

Beef middles and beef bung caps also are used in a wide range of quality sausage products. Sausages made from beef middles include bologna, dry and semi-dry cervelats, dry and

cooked salami, and veal sausage. Sausages made from beef bung caps include veal sausage, large bologna, and cooked salami.

The United States imports most beef intestines for use as natural casings from South American countries such as Brazil, Argentina, and Uruguay, which currently are not included on the US BSE risk list. Brazil, Argentina, Uruguay, and other South American countries also are classified as BSE free by the European Union, which has elaborate risk analysis programs in effect to determine BSE risk. Prior to the diagnosis of a BSE-infected animal in Canada, the United States also had imported beef casings from Canada. Currently, only limited amounts of beef intestines from animals slaughtered in the United States are saved for use as natural casings. However, there has been a demand for the US product in several countries, primarily in Europe, where the US product currently is not allowed to be imported, and the growth potential for this product would be significant if trade restrictions not based on science were removed. Greater amounts of beef small intestines are saved for an edible product exported primarily to Asia (Japan and Korea) and Mexico (as *tripas*). This is an important value-added product for cattlemen and meat packers, and these exports consequently are important to our industry overall.

The manufacture of sausages from natural beef casings generates tens of millions of dollars in sales every year for the North American casing industry and employs significant numbers of people. The industry is committed to preserving this valuable market, while at the same time providing the public with the safest product possible.

In the notice published on July 14, 2004, specifically at letter F on pg. 42259, FDA requested information as follows: "[w]hether processors may be able to effectively remove just the distal ileum."

This submission responds only to that question. Responses to this and other questions were also submitted previously to FSIS on September 3, 2004, and to FDA on August 13, 2004, in response to requests for comments from FSIS and FDA on related issues.

A. Producers in the United States, Canada, and Major Exporting Countries Already Have a Policy of Effectively Removing the Distal Ileum at the Time of Slaughter.

The casing industry does not consider the distal ileum to be usable as a casing, and to our knowledge, no portion of the distal ileum is saved for use as a casing. The industry already has adopted the practice of removing and disposing of the distal ileum from all cattle at the time of slaughter. Thus, although not recommended by the OIE guidelines, a decision to impose a higher standard, a uniform rule requiring the removal of the distal ileum from all cattle, regardless of the BSE risk classification of the region of origin, could easily be complied with by BSE free and low risk countries which have sent this product to the US. In particular, major exporters of beef casings to the United States, such as Brazil, Argentina, Paraguay and Uruguay, already are able to certify the removal of the distal ileum upon request, using achievable and verifiable standards, and Australia has a regulation that requires the removal of the distal ileum from countries with a low incidence of BSE. It is clear that the removal of the distal ileum is not a new concept and that standards for its removal could be approved quickly.

The US Meat Export Federation has developed a detailed anatomical description of the beef small intestine that could be used to develop a model of certification for the removal and

disposal of the distal ileum. [See **Attachment 1**, Photographs and definition of the bovine ileum] The ileum, which varies in average length from 15 to 24 inches depending on the age and size of the animal, is recognizable as the very straight portion of the intestine, with the proximal half beginning where the cranial mesenteric artery ends and the distal half terminating at the caecum. The portions of the beef small intestine used for casing, the duodenum and the proximal portion of jejunum, terminate at a point known as the "flange." Removal at the flange would include the entire ileum and the distal portion of the jejunum, which would measure a total of 36 to 72 inches in length depending on the age and size of the animal. This description was developed with full scientific oversight and has widespread support in the industry. This model easily could be adopted to certify the removal of the distal ileum from beef casings imported into the United States from BSE minimal risk regions.

This definition provides the basis for two readily verifiable standard operating procedures for the certified removal of the distal ileum. The first procedure begins with the removal of the small intestine from the abomasum. Then the small intestine is separated from the caecum at the ileocaecal orifice, and the ileum is separated from the jejunum at the flange. The resulting segment containing the ileum would measure 36 to 72 inches in length depending on the age and size of the animal. In an alternative procedure, following the removal of the small intestine from the abomasum, the small intestine remains attached to the caecum. Then separation is made at a point 36 to 80 inches from the caecum, leaving behind the remaining edible portions of the small intestine. Leaving the ileum attached to the caecum at this initial stage provides an easily verifiable point of reference for on-line inspectors. Finally, the 36 to 80 inch portion containing the ileum is separated from the caecum at the ileocaecal orifice, leaving the caecum and the large intestine for edible use.

Furthermore, Food Safety and Inspection Service (FSIS) already has approved a standard operating procedure, based on a procedure developed by a major exporter in the US industry, to certify the removal of the distal ileum from the remaining portions of the small intestine for beef casings intended for export. Prior to the diagnosis of a BSE-infected animal in the United States in December 2003, the Government of Japan, which requires the removal of the distal ileum from all beef casings, accepted the importation of beef casings from the United States on the basis of the US government-certified removal of the distal ileum. In particular, the procedure approved by FSIS requires the removal of at least 80 inches of the small intestine, as measured from the junction of the ileum and the caecum, in order to certify removal of the distal ileum.

NANCA and INSCA have prepared a CD that demonstrates the distinctive appearance of the bovine ileum. [See **Attachment 2**,] The entire ileum is embedded in the ruffle fat and therefore, as a practice, is discarded with the fat. For the purpose of the CD, we have removed the ileum from the ruffle fat – a process that can be accomplished only by hand with scissors – to show its distinctively straight shape and irregular surface, which makes it clearly distinguishable from the portion of the small intestine saved for use as edible beef rounds. The distinct shape of the ileum means that an inspector easily could verify that the distal ileum has been removed. As demonstrated by these pictures, the ileum is not useable as a casing and is never saved for such purpose, due in large part to the fact that the ileum has no curve and an irregular thick surface. Finally, in order to save this part animal as a distinct product, it would have to be removed from the ruffle fat using a time consuming and expensive process.

Due to the fact that the US government and the meat industry have available more than one acceptable standard to certify the removal of the distal ileum from the remaining portions of

the small intestine, we see no need to require the removal and disposal of the entire small intestine.

We respectfully request that FDA consider this science-based information when making its final rules. We believe that taking this information into account in the final rule will allow the North American casing and sausage industry to continue to provide a valuable product to the public, while ensuring the highest level of safety for the food supply in the United States.

Please contact us if we can provide further information or assistance in connection with issues involving the safety of natural casings.

Sincerely,

Shirley A. Coffield
Executive Secretary and Legal Counsel
North American Natural Casing Association