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Division of Dockets Management
Food and Drug Administration
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Re: Docket No. 2004N-0081; Use of Materials Derived from Cattle in Human Food and Cosmetics

Devro Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA) interim final rule banning "prohibited cattle materials" from human food and cosmetics. 69 Fed. Reg. 42256 (July 14, 2004).

Devro Inc. is the U.S. division of Devro Ltd., a United Kingdom based manufacturing company. Devro is the world's leading producer of collagen sausage casings. Besides our U.S. operation based in South Carolina, we also have the following production sites located around the world:

United Kingdom-	2 factories
Czech Republic-	3 factories
Australia-	1 factory

Our South Carolina based operation is the largest single factory in the group and supplies over 40% of the collagen casings used in the U.S. While the details of the processes employed at our various locations are slightly different, in all cases we use the same basic raw material, bovine skin collagen. In the case of our U.S. operations, this skin collagen is obtained as a by-product of the leather industry. Our partner leather tanneries obtain all their hides from slaughterhouses subject to continuous inspection by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS).

Devro strongly supports FDA's efforts to eliminate any potential risk to the U.S. food supply from bovine spongiform encephalopathy (BSE). However, we believe that our product, collagen casings, poses unique issues that may not have been taken into account by FDA in drafting the interim final rule banning "prohibited cattle materials" from human food and cosmetics. We urge FDA to make clear that collagen made from cattle hides that have passed ante-mortem inspection by USDA is not a "prohibited cattle material."

1. Background Information

Collagen casings are made exclusively from collagen obtained from hides and skins.¹ No other animal derived materials are involved in the manufacture or processing of collagen casings. At the present time, there are only two companies manufacturing collagen casing in the United States. Both these companies share similar processes and use the same raw materials and suppliers.

The process begins with removal of the cattle hide at a federally inspected establishment. All of the collagen used by Devro to make collagen casings comes from the hides of cattle slaughtered at federally inspected establishments after passing ante-mortem inspection and being designated as fit for human consumption. Almost immediately after slaughter, the hide is removed from the animal and separated from the rest of the carcass. The hide is sent down a chute into a “raceway” or similar collection system to be cooled to maintain leather and collagen quality.

Removal of the hide occurs before removal of the head, brain, vertebral column, spinal cord, and other specified risk materials (SRMs). Therefore, the hide does not come into contact with, and cannot be contaminated by, SRMs.² Removal of the hide occurs before post-mortem inspection of the carcass.³ Once the hide is removed from the carcass, the association between a particular hide and a particular carcass is lost. The vast majority of cattle hides are taken from carcasses that subsequently pass post-mortem inspection.

The hide is then shipped to a tannery where it is washed again to remove any loose material. Next, the hide undergoes hair removal, removal of any remaining meat or fat, and splitting longitudinally to separate the outer layer, which is used in leather production, from the interior or corium layer, which is used to make collagen products. See attached diagram of a hide cross-section to see the part of the hide used by our industry. The collagen layer then goes into a clean room where some preliminary

¹ While bone and certain other tissues also contain collagen, skin collagen is stronger than bone collagen and therefore a far superior starting material for casings. We are not aware of any manufacturer of collagen casings in the world that uses bone collagen. Most collagen casings are made from bovine skin collagen, although some casings are made from porcine skin collagen.

² The only possible exposure of the hide to SRMs would result from brain splatter during stunning, which occurs prior to slaughter and hide removal. However, FSIS will condemn heads of cattle 30 months or older unless the establishment can ensure that stunning does not result in brain leakage. FSIS Notice 4-04 (Jan. 14, 2004). Even if an establishment cannot ensure this, any brain material adhering to the hide would be minimal and would be present only on the outer layer of the hide. Such brain matter likely would be removed from the hide in the raceway water or during subsequent washing and de-hairing of the hide at the tannery. In addition, since any brain matter would only be present on the outer layer of the hide, and that outer layer is stripped away and used for leather production, it would not contaminate the corium, the inner layer of the hide that is used in the production of collagen casing. Finally, any brain matter likely would be present only the faceplate, which is removed from the rest of the hide before the corium is stripped away.

³ Post-mortem inspection, which involves inspection of the internal organs, would be impossible without prior removal of the hide.

processing occurs before being shipped to Devro's plant. At Devro's plant, the collagen is exposed to high pH during the manufacturing process, which would reduce BSE infectivity in the unlikely event it were present.⁴

Collagen casings are used in a wide variety of food products including sausage and breakfast links, bratwurst, Snack sticks, hor d'oeuvre size hotdogs (cocktail sausage), kosher hotdogs, and some high-end hams.

2. FDA's Interim Final Rule

Under the interim final rule, human food and cosmetic products may not be manufactured from, processed with, or otherwise contain "prohibited cattle materials." The term "prohibited cattle materials" includes any material from cattle that have not been inspected and passed. 69 Fed. Reg. at 42273 (21 C.F.R. § 189.5(a)(1)). The term "inspected and passed" is defined to mean that the "product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated." 69 Fed. Reg. at 42273 (21 C.F.R. § 189.5(a)(2)). In the preamble to the interim final rule, FDA states that the definition of "inspected and passed" is consistent with the USDA definition at 9 C.F.R. § 301.2.

While not clear, this might be interpreted to mean that "prohibited cattle materials" include any material from cattle that has not passed both ante-mortem inspection *and* post-mortem inspection by FSIS.

3. Materials, such as bovine skin collagen, derived from cattle hides that have passed ante-mortem inspection should not be considered "prohibited cattle materials."

Devro requests that FDA clarify that materials derived from cattle hides that have passed ante-mortem inspection are not "prohibited cattle materials." This could be accomplished by amending the definition of "inspected and passed" in the interim final rule to add the following sentence at the end: "In the case of cattle hides, 'inspected and passed' means that the hides come from cattle that have been inspected and passed ante-mortem inspection."

As discussed above, cattle hides are removed before post-mortem inspection. There is no post-mortem inspection of the hide, and there is no need for such inspection. Post-mortem inspection of the carcass is unrelated to the safety of the hide.

⁴ European Commission, *Opinion and Report on Safety with Respect to TSE Risks of Collagen Prepared from Ruminant Hides*, adopted by the Scientific Steering Committee at its meeting of 10-11 May 2001, p. 2 ("The production of collagen from hides and skins involves always an alkali step – using lime, or a lime sodium sulphide solution or a diluted sodium hydroxide solution – which can be assumed to have some TSE infectivity inactivation capacity should TSE agent be present by contamination of the hides"). U.S. collagen production also uses an alkali step.

There is simply no reason why a hide taken from an animal that has passed ante-mortem inspection, but not post-mortem inspection, should be considered “prohibited cattle material.”

a. The reasons given by FDA for prohibiting materials from cattle that have not been inspected and passed only pertain to ante-mortem inspection, not post-mortem inspection.

In the preamble to the interim final rule, FDA offers several reasons for prohibiting from use in human food and cosmetics materials from cattle that have not been inspected and passed. These reasons only justify banning materials from cattle that have not passed ante-mortem inspection. None of the reasons offered by FDA apply to post-mortem inspection.

FDA states that cattle that have not been inspected and passed “are likely to have died on the farm or en route to slaughter” or to have been slaughtered at a rendering facility, and therefore may have “a neurological disorder associated with a higher risk of BSE.” 69 Fed. Reg. at 42259. None of these risks is present in an animal that has passed ante-mortem inspection.

While ante-mortem inspection is intended to protect against BSE by condemning non-ambulatory disabled cattle and cattle that exhibit central nervous system (CNS) disorders, post-mortem inspection cannot detect BSE or animals at higher risk of BSE. Post-mortem inspection can detect SRMs in meat and other edible tissues, but this has no bearing on the safety of the hide that has already been removed from the carcass. Nor would post-mortem inspection of the hide itself serve any purpose, since the risk of SRM contamination of the hide is so remote.

We note that the *Terrestrial Animal Health Code* of the Office International des Epizooties (OIE) makes no mention of post-mortem inspection as a safeguard against BSE. It does, however, recognize the importance of ante-mortem inspection, recommending trade in meat and meat products only if derived from cattle that have passed ante-mortem inspection.⁵

b. Bovine skin collagen is recognized internationally to be free of BSE infectivity, even if sourced from a clinically infected animal.

Cattle hides and collagen made from cattle hides are internationally recognized to be free of BSE infectivity. The OIE recommends no BSE-related restrictions on trade in collagen from hides and skins, regardless of the BSE status of the country of origin.⁶

⁵ OIE, *Terrestrial Animal Health Code 2004*, Articles 2.3.13.14 through 2.3.13.16.

⁶ 69 Fed. Reg. 42288, 42295 (July 14, 2004). According to the OIE, “[w]hen authorizing import or transit of the following commodities, Veterinary Administrations should not require any BSE related conditions, regardless of the BSE status of the cattle population of the exporting country or zone: d. gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head)....” OIE,

This means that the OIE believes that, even if a hide were taken from a BSE-infected animal, collagen made from that hide would pose no risk to humans. In fact, the OIE appears to consider collagen obtained exclusively from hides and skins to be equivalent in terms of BSE risk to protein-free tallow, which FDA has specifically excluded from the definition of “prohibited cattle materials.”⁷

The United States and Canada appear to share the same view of the safety of cattle hides. Although the U.S. imposed restrictions on importation of ruminant products from Canada after discovery of a BSE-positive cow in Canada in May 2003, the U.S. continues to allow free trade in ruminant hides and ruminant hide derived products.⁸ Similarly, Canada imposed trade restrictions on ruminant products from the United States following discovery of a BSE-positive animal in Washington in December 2003, but exempts hides, wool, skins and their derivatives from these restrictions.⁹

The European Commission’s Scientific Steering Committee concluded that collagen and gelatin made from cattle hides are safe for use in human food and cosmetics, provided the hides are sourced from cattle that have passed ante-mortem inspection and the risk of SRM contamination is minimal.¹⁰ According to the committee’s report, cattle hides “are not considered to be part of the group of tissues that potentially represent a risk with regard to TSEs.”¹¹

c. If cattle hides are “prohibited cattle materials” because they have not passed post-mortem inspection, then a number of food products with long histories of safe use would be banned from human food and cosmetics.

If the definition of “prohibited cattle materials” is interpreted to include all materials that have not passed both ante-mortem and post-mortem inspection, then cattle hides and any materials derived from cattle hides would be prohibited from human food and cosmetics. This would have a tremendous impact on entire industries, including collagen casings and gelatin. This would effectively prohibit the use of collagen and gelatin made from cattle hides in human food and cosmetic products. It would provide no public health benefit, because post-mortem inspection of the carcass has no bearing on the safety of the hide taken from that carcass.

Terrestrial Animal Health Code 2004, Article 2.3.13.1. As noted above, the collagen used by Devro is taken from hides from which the faceplate (i.e., the hide from the head) has already been removed.

⁷ See OIE, *Terrestrial Animal Health Code 2004, Article 2.3.13.1.*

| ⁸ 68 Fed. Reg. 31939 (May 29, 2003).

⁹ Canadian Food Inspection Agency, *Update to Import Restrictions – United States.*

¹⁰ European Commission, *Opinion and Report with Respect to TSE Risks of Collagen Produced from Ruminant Hides*; EC, *Updated Opinion on the Safety with Regard to TSE Risks of Gelatine Derived from Ruminant Bones or Hides from Cattle, Sheep or Goats*, adopted by the Scientific Steering Committee at its meeting of 28-29 June 2001.

¹¹ EC, *Opinion and Report with Respect to TSE Risks of Collagen Produced from Ruminant Hides*, p. 4.

Banning bovine skin collagen would have a devastating effect on Devro as well as the more than 50 U.S. establishments that use our collagen casings in their products. Many of these plants only manufacture products that use collagen casing, and so would likely be forced to go out of business. Products like sausages and Snack sticks that cannot be made without collagen casing might become unavailable.

4. FDA has seriously underestimated the economic impact of the interim final rule.

In its regulatory impact analysis, FDA appears to have omitted entire industries that would be subject to the interim final rule. FDA's analysis seems only to consider the industries that are end-users of cattle materials and to overlook industries that produce intermediate products. As a result, it includes no mention of the rule's impact on manufacturers of collagen casing, gelatin, and other intermediate products.

In the case of the collagen casing business, the impact of this ruling would be devastating. The total loss in U.S. sales for Devro would be in the range of approximately \$30,000,000.00 per year. We estimate that we have less than 45 percent of the U.S. market for collagen casing, so the total loss in revenue to all producers would be significantly more than \$50,000,000.00 annually. In combination with our only U.S. competitor (Nitta Inc.), we estimate that we provide over 70 percent of all the collagen casings used domestically. The direct impact on Devro would be to cause our South Carolina plant to be closed with the loss of over 350 well paid manufacturing jobs. In addition, we feel a similar number of jobs would be lost at our U.S. competitor in New Jersey.

The impact on our customer base would be even more financially damaging as in most cases there would be no alternative to collagen casings, films and doughs to supply these U.S. based operations. There are no non-U.S. manufactures that have either the hide supply or the spare manufacturing capacity to fill the void in the market that would be left by an adverse interpretation of this interim ruling. In addition, there are no substitute technologies that would allow these operations to produce similar products without collagen casing. Because our customers take our product and fill it with expensive meat products like beef sticks and breakfast links, the retail value of the products produced with our casings as well as those of our U.S. and foreign competitors is actually much larger than the cost of the collagen. The estimated retail value of products sold in collagen casings/films is as follows:

<u>Product Type</u>	<u>Retail Value</u>
Fresh Breakfast links-	\$672,000,000.00
Processed Sausage-	\$230,000,000.00
Snack Sticks	\$1,006,000,000.00
Cocktail Sausage	\$291,000,000.00

Total Value: \$2,199,000,000.00

In our present delicate economic environment, the loss of over \$2 billion dollars in commerce would lead to the loss of literally thousands of jobs and the closure of scores of manufacturing plants. This is totally unnecessary as there is no risk associated with bovine hide collagen products as presently manufactured.

We hope that FDA will correct this oversight in the final rule.

* * * * *

In conclusion, Devro urges FDA to clarify that collagen is not a “prohibited cattle material,” provided it is made exclusively from the hides of cattle that have passed ante-mortem inspection.

We appreciate this opportunity to share our views with the agency.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "George Hayes", with a long horizontal flourish extending to the right.

George Hayes
Regulatory Affairs Manager

Attachment

cc: Office of Information and Regulatory Affairs
Office of Management and Budget
ATTN: Ms. Fumie Yokota, Desk Officer for FDA

Attachment 1: Bovine hide cross section showing the area used by all collagen casing and film manufacturers

