

S Foods Inc.

1-22-13 Naruohama, Nishinomiya,
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July 27, 2004

Docket No. 2004N-0081
RIN-0910-AF47
Division of Dockets Management,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Dear Sirs,

S Foods Inc., established in 1967, is a Japanese meat processor listed on the First Section of the Tokyo Stock Exchange, specializing mainly in imported beef with approximately US\$ 500 million of our annual turnover. We have focused on American beef and variety meat for many years, and especially our product, "kotetchan," which is made from the boiled beef small intestine with the distal ileum removed, has been widely sold throughout Japan for more than 20 years.

We submitted our comment regarding the FSIS interim final rule on February 18, 2004. As the new FDA's interim final rule was issued on July 14, we are writing our comment to the FDA on your prohibition of certain cattle materials.

We strongly ask that the small intestine with the distal ileum removed should not be designated as a prohibited cattle material. The small intestine with the distal ileum removed is free from BSE infection and the small intestine can be easily and effectively removed from the distal ileum.

The FDA is prohibiting the use of the entire small intestine in FDA-regulated food and cosmetics as a prohibited cattle material because: (1) It is difficult to distinguish one end of the small intestine from the other once the organ has been removed from the animal, (2) there is no international agreement on how much of the small intestine should be removed to ensure that the distal ileum is separated from the upper part of the intestine, and (3) there is no way for a manufacturer or processor to document that the distal ileum was adequately removed since there is no international consensus on the issue. FSIS also requires "that establishments remove the entire small intestine" "to ensure that the distal ileum is completely removed from the carcass" in its interim final rule of Docket No. 03-025IF.

Some U.S. major packers had already resolved the above issues and had been producing and exporting the small intestine with the distal ileum removed to Japan under established procedures until December 24, 2003. Indeed, organizations representing beef producers and processors in the U.S. and Canada including AMI, CCA, CMC and NCBA declared that "the distal ileum is only a small part of the small intestine and can be scientifically defined and removed" in their letter to USDA and AAFC on April 7,

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2004.

The distal ileum adherent to the cecum is the lower half of the ileum that is the posterior portion of the small intestine, and has 12 to 18 inches in length. The small intestine is cut at 80 inches back from the junction of the cecum in the processing plant. It enables the plant to remove whole part of the ileum and a portion of the jejunum. A product with this procedure has been approved by USDA as "the boiled beef small intestine with the distal ileum removed." In Japan as well, the small intestine is approved as safe food by the Ministry of Health, Labour and Welfare with the procedure cutting the small intestine at 2 meters (approximately 80 inches) back from the junction of the cecum. In addition, the removed distal ileum is incinerated here in Japan. Please confer "Definition of the Beef Distal Ileum (written by U.S. MEF)" attached as for the detailed definition and the removal procedure of the distal ileum.

These procedures demonstrate the safety of the small intestine production as follows:

(1) Cutting 80 inches of posterior portion of the small intestine including the distal ileum attached to the cecum would provide the small intestine completely without the possible risk material. (2) The cutting point to remove the distal ileum that is SRM has been established in Japan. USDA has approved the same criteria in production of the small intestine for export to Japan when the first BSE case was found in Canada. At least, bilateral agreement between Japan and the U.S.A. had been made regarding the specification of the small intestine. In addition to the above procedures: (3) Incorporating these procedures into HACCP guidelines or being verified by the administrator would ensure the appropriate process.

We would like to emphasize that the beef small intestine with the distal ileum removed is human food, providing us with precious source of protein which is essential for our human population. Although FSIS has not yet announced the final decision on its proposed rule, we sincerely ask you would consider our above mentioned trade achievement to exclude the small intestine with the distal ileum removed from prohibited risk materials.

Respectfully,

A handwritten signature in black ink, appearing to read 'Hayao Morishima', is written over a horizontal line.

Hayao Morishima
President & CEO
S Foods Inc.

Enc.

April 7, 2004

The Honorable Ann M. Veneman
Secretary, Department of Agriculture
14th and Independence, SW
Washington, DC 20250

The Honorable Robert Speller
Minister of Agriculture & Agri-Food
930 Carling Avenue
Ottawa, Ontario
K1A 0C5

Dear Secretary Veneman and Minister Speller:

The undersigned organizations, representing the beef producers and processors in the U.S. and Canada, are writing to request the harmonization of the food safety regulations enforced by your respective organizations. Although significant progress has been made in the last three months toward this goal, there remain areas in need of further attention.

In that regard, an issue warranting further discussion and change involves identifying the distal ileum as a specified risk material (SRM) and the scope of that requirement. The Canadian Food Inspection Agency (CFIA) regulation lists the distal ileum of all cattle as a SRM, yet CFIA policy requires removing the entire small intestine. The interim final rule published by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture, also established that the distal ileum is a SRM, with the regulation requiring removal of the entire small intestine. Although the net effect of the two organization's approaches is effectively the same, one is implemented through a regulation, while the other is implemented as a policy directive

We agree that the distal ileum should be classified as a SRM. However, the regulatory and policy requirements in place in the U.S. and Canada requiring removal of the entire small intestine to ensure that the distal ileum is removed is unwarranted and not based on science. The distal ileum is only a small part of the small intestine and can be scientifically defined and removed. The remaining portion of the small intestine is a highly useful and valuable product that is safe. Protocols exist that have been implemented to accomplish the goal of food safety and those protocols could be adopted in both countries.

We, and other interested parties, have or will be providing more details to both governments regarding protocols that could be adopted. We urge both governments to work together to evaluate this situation and change this requirement to allow a portion of the small intestine to continue to be used.

Sincerely,

American Meat Institute
Canadian Cattlemen's Association
Canadian Meat Council
National Cattlemen's Beef Association

Cc:

Mr. Richard Fadden, President, CFIA
Mr. Paul Haddow, Executive Director of International Affairs, CFIA
Mr. Robert Carberry, Vice-President, Programs, CFIA
Dr. Brian Evans, Executive Director, Animal Products Directorate, CFIA
Dr. Merv Baker, Director, Food of Animal Origin Division, CFIA
Dr. J.B. Penn, Under Secretary of Farm and Foreign Agricultural Services, USDA
Dr. Elsa Murano, Under Secretary for Food Safety, USDA
Mr. Bill Hawks, Under Secretary for Marketing and Regulatory Programs, USDA
Dr. Barbara Masters, Acting Administrator, Food Safety and Inspection Service, USDA
Dr. Peter Fernandez, Acting Administrator, Animal and Plant Health Inspection Service, USDA
Dr. Ron DeHaven, Deputy Administrator, Veterinary Services, APHIS, USDA

Definition of the Beef Distal Ileum

Beef small intestine is a valuable export commodity to U.S. red meat exporters. Exports of beef small intestine are estimated to be valued at over \$9.0 million in 2003 to Japan alone and thus it should be considered a priority to maintain this market while maintaining the integrity of both the domestic and international food supplies.

It is well documented that the infective agent of Bovine Spongiform Encephalopathy (BSE), the prion, can be found in certain tissues of the distal gastrointestinal tract (Wells et. al., 1994) The agent has been documented to have been found in certain lymph-reticular system tissues called the Peyer's patches, which are concentrated in the distal ileum of the small intestine (Wells et. al., 1994). Current research indicates that the infective agent is not found in other gastro-intestinal tissues other than the distal ileum (Wells et al., 1998). Specifically, research has shown that the infective agent is not present in the duodenum and the jejunum portions of the small intestine even when the agent is found in the ileum (Terry et al., 2003). Additionally, the infective agent for BSE has only been found in the distal ileum of cattle which were inoculated with the BSE infective agent; due to the increased amount of infective agent the animals were exposed to; the agent has not been reported to have been found in animals which have succumbed to the disease naturally (Wells et al., 1998; Terry et al., 2003).

Thus, the research and science have pointed to the distal ileum of the small intestine as being a risk material for the BSE infective agent, albeit a small risk. The science and research also support that the distal ileum contains the only tissues in the gastro-intestinal tract which contain the infective BSE agent. Therefore, the remaining portion of the small intestine should be allowed to remain as an accepted, edible product for human consumption. The following is a description of a method which would be suitable for use as a guideline for the removal and separation of the distal ileum from the remaining edible portion of the gastro-intestinal tract of bovine animals.

General Description

The beef small intestine that is processed for export to international market is comprised of the small intestine beginning at the stomach, including the duodenum, and the jejunum anterior to a point commonly referred to as the "flange". (Figure 1.)

The ileum of a beef animal will, on average, be 15 to 24 inches in length (dependent on age and size of animal). The ileum is very distinguishable as it is a very straight portion of the intestine (Figure 3.). The anterior portion begins where the cranial mesenteric artery ends and the ileum terminates at the cecum and colon. (Weaver, 1986; Habel, 1975; Schummer, 1979; Van Metre, 2003). (Figure 2. and Figure 3.)

The distal portion of the ileum can be generically defined as the portion, or half, of the ileum which is adherent to the cecum; thus estimated at one to one and one-half feet in length (Habel, 1975; Van Metre, 2003). The proximal portion of the ileum being defined as the portion, or half, of the ileum which is adherent to the jejunum; thus estimated at one to one and one-half feet in length (Habel, 1975; Van Metre, 2003).

The flange is located in the distal jejunum; estimated at one and one-half to two feet from the end of the cranial mesenteric artery and the anterior ileum (dependent on size of animal). Removal at this point would include the entire ileum and a portion of the jejunum (Weaver, 1986; Van Metre, 2003). (Figure 1.)

The portion of the intestine removed would include the entirety of the ileum, thus including the distal ileum, along with a short portion of the distal jejunum; the removed items would equal approximately three to six feet in length (36 to 72 inches; dependent on age and size of animal). (Figure 2. and Figure 3.)

Processing Procedures

1. The small intestine is removed from the abomasum.
2. Separate the small intestine from the cecum at the ileocecal orifice. Separate the ileum from the jejunum at a point commonly referred to as the flange. The entire portion being three to six feet in length (36 to 72 inches; dependent on age and size of animal). Separation would be monitored by FSIS personnel prior to transfer of products to inedible rendering (ileum) and for processing (remaining jejunum and duodenum of small intestine).
3. Flush out and clean the remaining portion of the small intestine

Alternative removal:

1. Remove small intestine from abomasum
2. Leaving small intestine attached to the cecum, measure a 36 to 80 inch section back through the entire ileum and into the jejunum, and make separation at that point.

* Leaving distal ileum attached to the cecum provides an easy point of reference for on-line verification by USDA or CFIA.

* Precedent - 80 Inches is an ultraconservative severance, for which precedent exists with prior precedent (i.e. Japan product specs prior to DEC23).

Verification (options)

1. Plant management will monitor procedure according to approved HACCP guidelines to verify proper procedures.
 - a. Removal of the ileum would be designated as a critical control point and

this process would be directly verified by FSIS personnel. The process

would be completed on the evisceration table in sight of FSIS personnel.

2. Plant management will monitor the procedure according to pre-requisite programs.

This procedure would be verified by FSIS.

3. FSIS would oversee the process and verify that the procedure was correctly completed. However, the procedure would take place in a location which was not within site of FSIS personnel.

Note: The figures shown and referred to were taken from an approximately 1500 pound Holstein cow. Thus, it should be noted that the measurements shown would be, on average, larger than most animals slaughtered in the United States.

References

Habel, R.E., 1975; *The Anatomy of the Domestic Animals: ruminant digestive system*. Ed. 5, Philadelphia: WB Saunders Co. p. 904

Schummer A., Nickel R., Sack W.O., 1979; *The Viscera of Domestic Animals*. Ed. 2, New York: Springer-Verlag, p. 169

Terry, L. A., Marsh, S., Ryder, S. J., Hawkins, S. A. C., Wells, G. A. H., Spencer, Y. I., 2003; Detection of disease-specific PrP in the distal ileum of cattle exposed orally to the agent of bovine spongiform encephalopathy. *The Veterinary Record*: 152, pages 387-392

Weaver A.D., 1986; *Bovine Surgery and Lameness*. London: Blackwell Scientific Publications, p. 68

Wells, G.A.H, Dawson, M., Hawkins, S. A. C., Green, R. B., Dexter, I., Francis, M. E., Simmons, M. M., Austin, A. R., Horigan, M. W., 1994; Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. *The Veterinary Record*: 135, pages 40-41

Wells, G. A. H., Hawkins, S. A. C., Green, R. B., Austin, A. R., Dexter, I., Spencer, Y. I., Chaplin, M. J., Stack, M. J., Dawson, M., 1998; Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. *The Veterinary Record*: 142, pages 103-106

Van Metre D. C., 2003; DVM, DACVIM; Assistant Professor, Food Animal Medicine and Surgery, Colorado State University. Personal Telephone Interview. July 14, 2003.

Photographs and definition of the bovine ileum
David C. Van Metre, DVM, Diplomate, ACVIM
January 13, 2004

Figure 1. Relevant Anatomy & Terminology

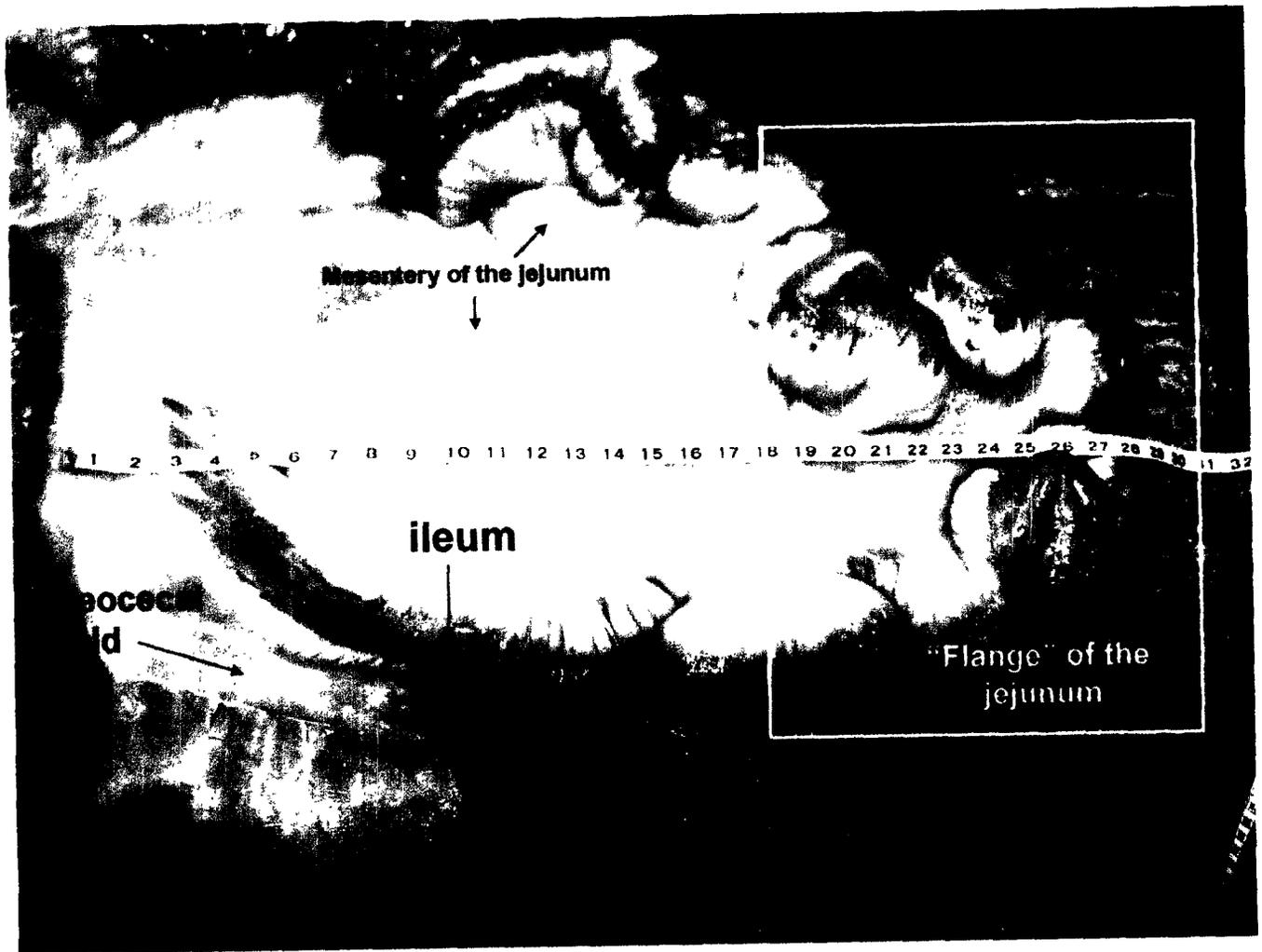


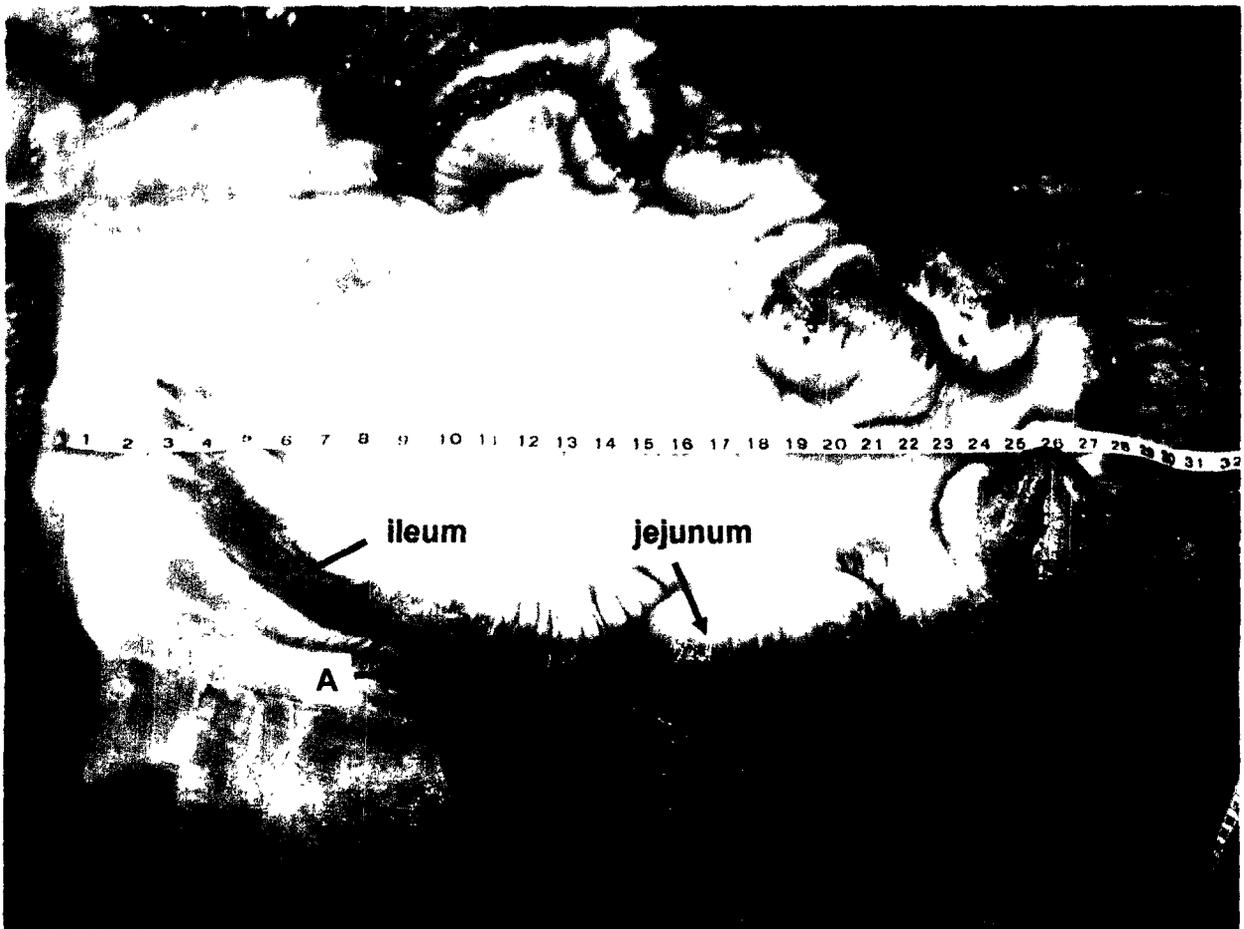
Figure 2.

Published definitions of the bovine ileum

1. From Weaver AD, Bovine Surgery and Lameness. London: Blackwell Scientific Publications, 1986, p. 68:

The junction of the jejunum and ileum is the point where the cranial mesenteric artery ends, and the cranial limit of the ileocaecal fold.

The cranial limit of the ileocecal fold is labeled as point "A" in the picture below. This is this author's definition of the junction between the jejunum (intestine to the right) and the ileum (intestine to the left)



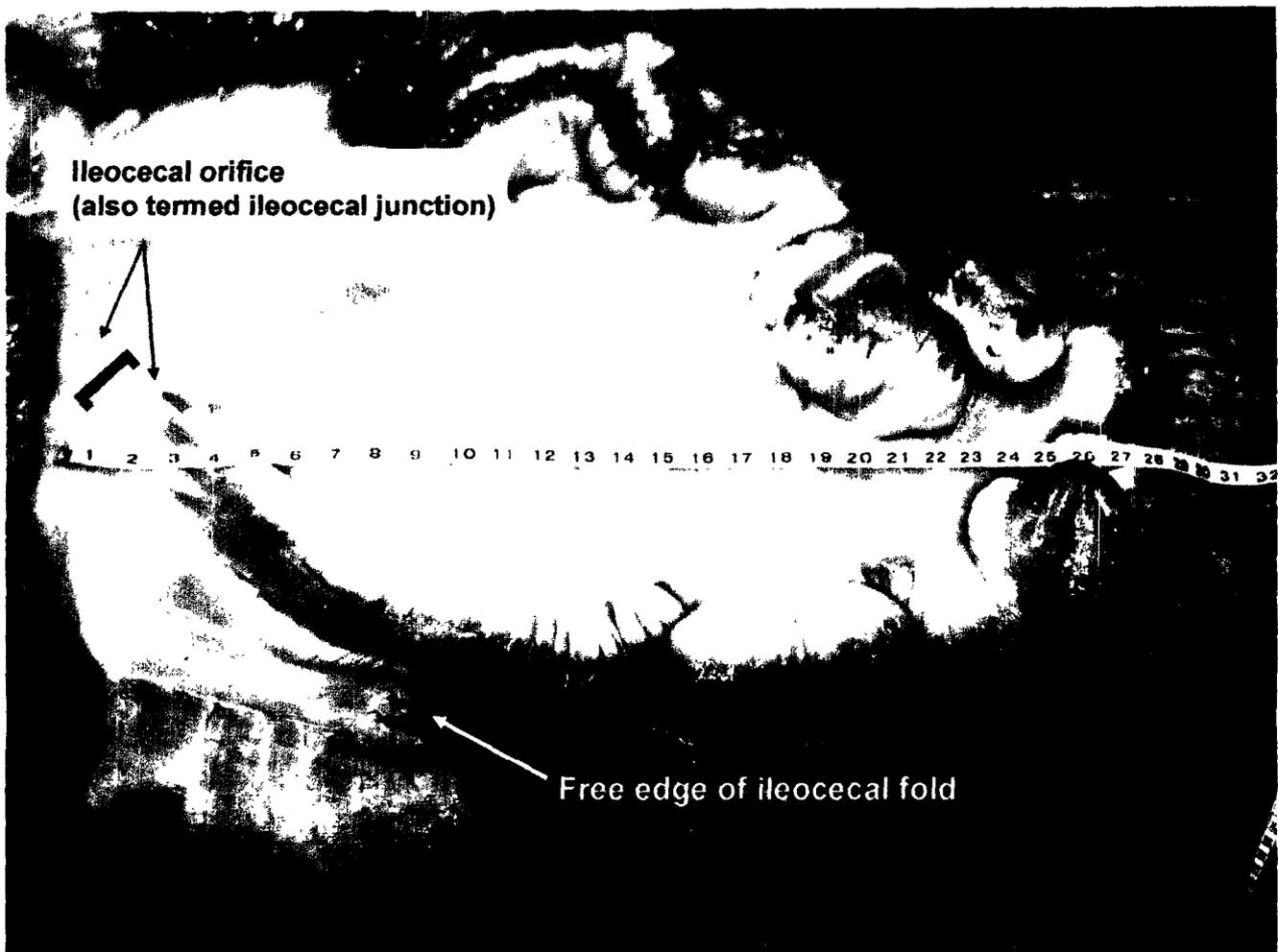
Photographs and definition of the bovine ileum

Figure 3.

Published definitions of the bovine ileum

2. From Habel RE. Ruminant digestive system. In: Getty R, ed., The Anatomy of the Domestic Animals. Ed. 5, Philadelphia: WB Saunders Co., 1975, p. 904:

The ileum is defined as the terminal part of the small intestine, from the free edge of the ileocecal fold to the ileocecal orifice. Its cranial [distal]part is adherent to the cecum and colon [brackets mine.]



By this definition, the ileum would be contained within the brackets as shown in the photograph below:

3. From Schummer A, Nickel R, and Sack WO, The Viscera of Domestic Animals. Ed 2, New York: Springer-Verlag, 1979, p. 169:

The ileum is the straight, terminal part of the small intestine, passing cranially ventral to the cecum, to which it is connected by the ileocecal fold.

Thus, these definitions indicate that the ileum can be defined as that part of the small intestine attached to the cecum via the ileocecal fold. This is essentially the same segment of intestine as defined in the image above.