03-025IF
03-025IF-636
Philip M. Seng

May 7, 2004

FSIS Docket Clerk, Docket #01-033DF,
Room 102, Cotton Annex, 300 12th and C Street, SW
Washington, DC 20250-3700

The U.S. Meat Export Federation (USMEF) appreciates the opportunity to provide comments to FSIS in regards to the Emergency Final Rules (Docket numbers: 03-025IF, 03-048N, 01-033IF, and 03-038IF) which have been enacted in response to the discovery of one Canadian origin dairy cow in Washington State, USA which was diagnosed and confirmed to have Bovine Spongiform Encephalopathy. The USMEF is a non-profit trade association working to create new opportunities and develop existing international markets for U.S. beef, pork, lamb and veal. The USMEF has eight distinct sectors, representing the entire U.S. red meat production, processing and distribution system. Allied industries, which provide critical inputs to the red meat industry, are also active on the USMEF Board of Directors. Over 90 percent of U.S. red meat exports are from red meat companies represented by USMEF. USMEF provides market intelligence for international markets and addresses concerns or problems faced by its membership in these international markets. USMEF commends the Food Safety Inspection Service along with other agencies of the United States Department of Agriculture (USDA) for their rapid response to this issue and for the means by which the investigation was conducted along with the efficient methods by which information and results of the investigation were conveyed. While we commend FSIS for the speed at which the final rules were implemented under emergency conditions, we have several questions and comments surrounding several of the details of the rules.

Our comments and questions are located in the following pages and in the additional attachment accompanying this document. We apologize for sending an attachment to these comments; however, due to the detailed photographs which are included in the comments and the shear size of the file, we have no choice but to send the attachment in Adobe Acrobat format. Thank you for your attention to our concerns.

Sincerely

Philip M. Seng
President/CEO
U.S. Meat Export Federation

9 CFR Parts 309, 310, 311, 318, and 319
Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

The definition for Specified Risk Materials (SRM) is consistent with the Canadian definition and it is stated on this page that this was a purposeful decision. We question the reasons behind patterning the United States definition of Specified Risk Materials following the conclusive results that the origin of the index animal was in fact Alberta, Canada. This would indicate that the United States is still without an indigenous case of BSE while Canada could now claim two indigenous cases. It would appear that the response and the definition of the SRM material within the United States should be based on the most current peer reviewed science. It is USMEF's understanding that countries which wish to export beef and beef products to the United States must also comply with this new rule. How will FSIS provide assurances that products imported by the United States were produced in compliance with the new regulations? Will there be surveillance, auditing, or monitoring to ensure compliance?

Has a date been determined when FSIS will publish compliance guidelines for use by small and very small establishments?

As written, there will be two ways which be allowed for use in determination of animal age; one through the use of documentation and the other through the use of dentition of each individual animal. It is also stated that because the National Animal Identification System for the U.S. is not yet complete there is not a uniform standard of documentation which FSIS can rely on to verify the age of cattle slaughtered. There are certain establishments within the U.S. which have company-specific animal identification systems in place. Will FSIS accept private systems of animal identification and private certification of animal age at the time of slaughter or must certification be supplied by an entity within USDA such as the Agriculture Marketing Service?

What is the basis for the FSIS calculation for the estimate of burden to be placed on establishments? We also ask if estimates for burden have been calculated for small and very small establishments.

We request that FSIS review pertinent research regarding the distal ileum of the small intestine and we request that FSIS allow for the separation of the distal ileum from the remaining portion of the small intestine (jejunum and duodenum) and that the remaining portion of the small intestine be allowed for processing and human consumption.

The definition for Specified Risk Materials (SRM) is consistent with the Canadian definition and it is stated on this page that this was a purposeful decision. We question the reasons behind patterning the United States definition of Specified Risk Materials following the conclusive results that the origin of the index animal was in fact Alberta, Canada. This would indicate that the United States is still without an indigenous case of

BSE while Canada could now claim two indigenous cases. It would appear that the response and the definition of the SRM material within the United States should be based on the most current peer reviewed science.

Comments regarding the removal of the distal ileum of the small intestine are attached in a separate document. Due to the detailed photographs which accompany the attached file, the shear size of the file makes it necessary to condense the information into an Adobe Acrobat format.

9 CFR Parts 301, 318, and 320
Meat Produced by Advanced Meat/Bone Separation Machinery and meat Recover (AMR) Systems

This rule states that AMR product may not contain any brain, trigeminal ganglia, spinal cord, or dorsal root ganglia. Is the detection limit or "allowable" level of SRM material the same as published in previous regulations? Will the measurement of these substances be strictly under the jurisdiction of USDA or will individual entities have the ability to test and certify that products meet the requirements of this final rule?

It is our understanding that the brain, spinal cord, trigeminal ganglia, and dorsal root ganglia are not Specified Risk Materials if they originate from animals under the age of 30 months. If they are not SRM products, it is our understanding that their presence in AMR product would represent a "misbranding" or a labeling issue and not a food safety concern and thus they would be handling accordingly. Why does AMR product produced from materials derived from animals less than 30 months of age need to be part of a HACCP plan if this represents a misbranding issue and not a food safety concern?

As vertebral column is defined as a Specified Risk Material only from animals over the age of 30 months, USMEF feels that beef stock, beef extracts, and other beef products derived from bones, should be able to include the vertebral column from animals under the age of 30 months. This product should not be required to be identified as having the potential to contain CNS tissues. Vertebral column bones derived from animals under the age of 30 months is not considered a Specified Risk Material and thus poses extremely minimal risk to humans.

We also request clarification as to the meaning of the statement made which reads: "FSIS will ensure that materials that could present a significant risk to human health, but whose infectivity status cannot be readily ascertained are excluded from the human food supply".

What is the basis for the FSIS calculation of the estimate of burden? Was a calculation of the estimate of burden conducted for small and very small establishments?

9 CFR Part 313
Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter

As it is stated in this document, FSIS is not aware of any United States slaughter establishment utilizing air injection stunning equipment. As this is the case, what is the purpose of implementing a rule which prohibits the use of such equipment? It would appear that this rule would be unnecessary and that it would be perhaps detrimental to consumer confidence in the safety of US beef production systems.

FSIS indicated having knowledge that air-injection stunning devices are available and allowable in countries that may export beef products to the United States. How will FSIS assure compliance to this regulation in foreign countries?

FSIS indicates that Australian law does not ban the use of air-injection stunning methods. Will FSIS restrict the importation of Australian beef products if the Australian law continues to be inconsistent with U.S. regulations regarding air-injection stunning?

USMEF concurs with FSIS in their decision to reject the option of a performance standard. A performance standard and testing for CNS emboli would be costly and unwieldy to both industry and government enforcement officials.

Bovine Spongiform Encephalopathy Surveillance Program

As stated in the document, FSIS will not apply the mark of inspection to products until the results of the APHIS BSE testing was known by FSIS and the establishment. As it is now known that the carcasses of tested animals will be "held" until results of BSE testing are known, does this apply to all products from the tested animals? Must all offal, viscera, hide, etc. be held along with the carcass of the tested animal until results of the APHIS test are known? May items which are destined for inedible rendering be allowed to pass through to inedible rendering prior to the receiving of the results of the BSE test as these products will be excluded from the human and ruminant food chain?

Preliminary Analysis of Interim Final Rules and An Interpretive rule to Prevent the BSE Agent From Entering the U.S. Food Supply

Page 21: Table 1. Annual estimates of average SRM amounts affected by the SRM Interim final rule.

USMEF requests the origin or basis for the USDA estimate of 11 pounds yielded per animal of small intestine (including the distal ileum). USMEF estimates of this weight have been greater than 12 pounds. A one pound increase would increase the volume by 14.5 million pounds.

Page 23: SRMs excluded from the human food supply.

USMEF is not in favor of any of the alternatives presented by FSIS. USMEF feels that Alternative 3 would be the most favorable, however, USMEF feels that a procedure should be available which would allow for the removal of only the distal ileum. Please see our comments on page three along with the accompanying attached document. This would allow the salvage of the remainder of the small intestine.

Page 25 - Use of 'Trepas' and price

In *Table 4. Average net revenue loses due to exclusion of SRMs under the Interim Final Rule*, small intestine is classified as Casings and Trepas. Trepas are an export product for Mexico, and since edible intestines are also exported to Japan and some other markets, we request clarification on the quantity and analysis for the Trepas classification. Does this only include product destined for Mexico, or does the analysis for Trepas include small intestine destined for other markets also?

Also, the price per pound for Trepas is listed at $0.37 cents. USMEF's analysis shows Trepas priced at approximately $0.55 cents per pound in December 2003. We request verification of Trepas values prior to the BSE discovery.

Page 26: Table 5. Comparison of Average Change in Potential Human Exposure and cost of Regulatory Alternatives.

USMEF would like to make the point that the removal of the small intestine does not make a significant impact in the reduction in human exposure; however, the removal of the small intestine has a substantial impact on the cost. USMEF feels that a procedure should be available which would allow for the removal of only the distal ileum. Please see our comments on page three along with the accompanying attached document. This would allow the salvage of the remainder of the small intestine.

Page 31 Salvage Value of Non-ambulatory Disabled Cattle

In *Table 6 - Cost of prohibiting use of non-ambulatory disabled cattle from human food use*, Salvage value is shown to be zero. Under the proposed rule, these animals would be eligible for inedible rendering. USMEF requests clarification on why the proposed analysis does not consider the rendering value of these animals.

Page 33: HACCP plan development, record keeping and certification.

While USDA has estimated the costs associated with development of the programs to implement the interim final rules, USMEF feels that there are many additional costs incurred by U.S. companies which have not been included. USMEF feels that additional labor, employees, and training costs should be included in this analysis and these costs impact the U.S. industry.

Page 36 Cost impacts of SRM interim final rule

In *Table 8 - Summary: Cost impacts of the SRM interim final rule*, the estimated costs of SRM ban and regulations averages $37.1 million. A recent study conducted by *Cattle-Fax* estimates costs related to SRM removal to be approximately $100 million. There is a considerable disparity between these numbers. USMEF requests a more comprehensive analysis comparing the two estimates which would include input from industry resources.

Page 43: Domestic Economic Impacts

The impact of BSE on changing U.S. beef production levels may be insignificant due to the supply situation prior to the discovery. The U.S. cowherd is currently in the eighth year of contraction which drove prices to record levels prior to the BSE discovery. Although the discovery of BSE has impacted prices negatively, they remain well above previous year prices at levels typically needed to spur heifer retention and eventually, production increases.

U.S. Meat Export Federation estimates the negative price impact on live cattle due to the BSE discovery at $10.25 per hundredweight (cwt). This scenario is calculated by estimating impact of additional weekly pounds of beef supplied domestically rather than exported and adding to it the lost premiums paid for variety meats internationally. The calculations are shown below:

Loss of premiums paid for variety meats:

Combined Price Impact Including Supply Effects:

Although USMEF is optimistic regarding the current BSE bans, the 2004 estimated annual flow used in the previous table assumes that current bans will continue through 2004. This is done to estimate annual losses from the bans currently in place.

The combined calculations in the previous tables show a decrease in live cattle prices by approximately $10 per hundredweight due to the discovery of BSE.

Page 58 Restoration of Beef Export Markets

The text states, "About 40 countries have banned beef from the United States." We have determined that approximately 64 countries initially banned U.S. beef products and that currently 15 of these markets have reopened to some degree. We request an update of this statistic in the text.

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 were 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 bovine 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 bovine 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 bovine 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 bovine 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 bovine 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.
3. Separate the 36 to 80 inch section from the cecum (leaving the cecum and large intestine for edible use) and dispose of the 36 to 80 inch portion containing the distal ileum.

* Leaving distal ileum attached to the cecum initially provides an easy point of reference for on-line verification of the length of the inedible portion 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

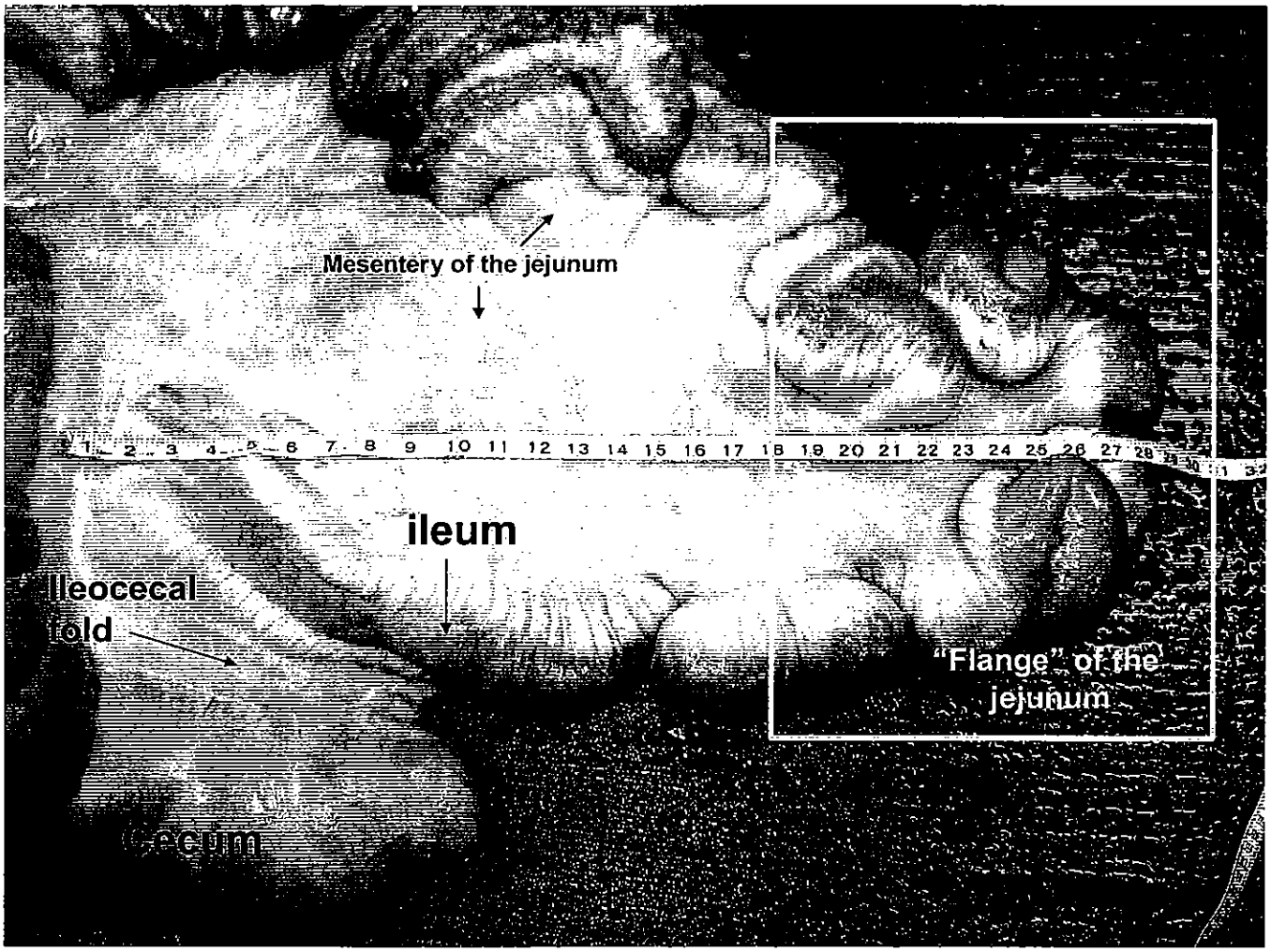


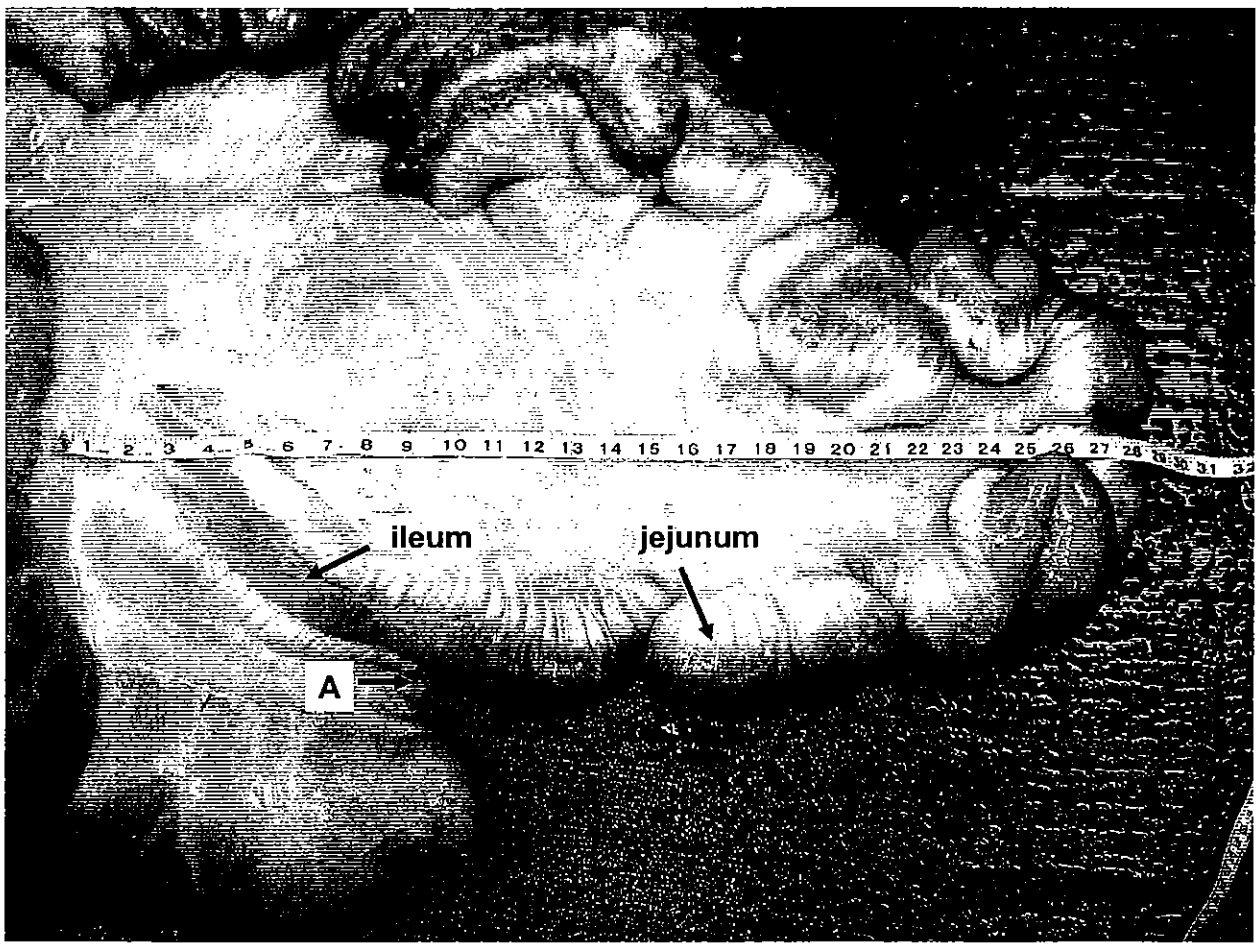
Figure 2.

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

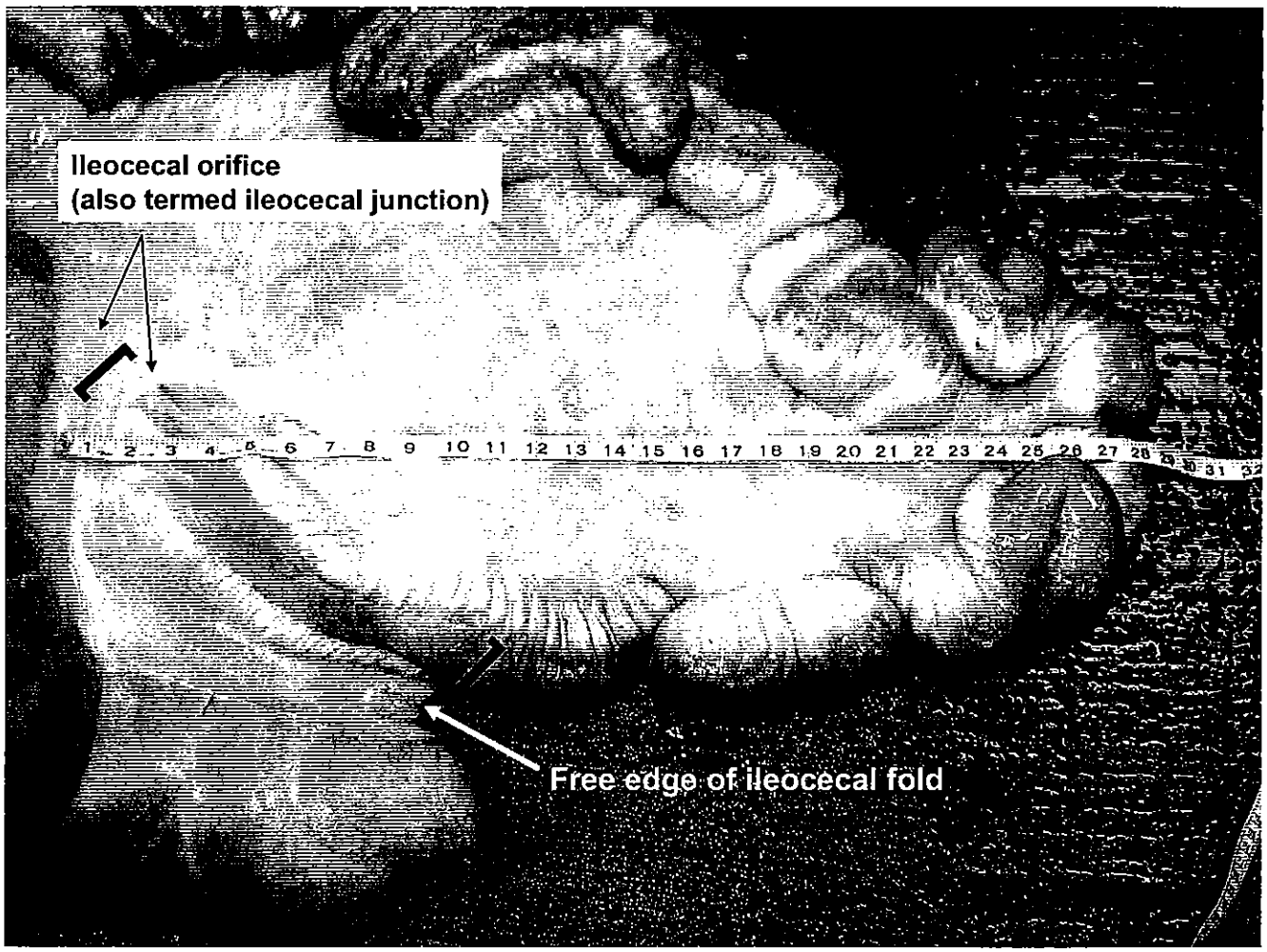
Figure 3.

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.