Swift & Company

August 6, 2004

Docket No. 2004N-0264
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

SUBJECT:

In response to the FDA advance notice of proposed rulemaking on possible changes to its feed regulation (21 C.F.R. 589.2000) and other additional measure being considered to mitigate the risk of bovine spongiform encephalopathy (BSE) 69 Fed Reg. 42288 (July 14, 2004).

OVERVIEW

The initial ban on ruminant-to-ruminant cattle feed that was put in place in 1997 – seven years BEFORE the discovery of the first and only case of BSE in the United States – is one key step in a comprehensive series of preventive steps that are effectively preventing the spread of BSE in the United States' domestic cattle supply. To further expand regulations for SRM removal from the feed chain would not be based in science, is not economically feasible and is not needed. Additionally, it would create an environmental problem that local municipalities aren't prepared to handle.

USDA's response to BSE in the United States: In January, after the first case of BSE was discovered in the United States (Washington State), SRMs were banned from the food chain by the USDA. This was a yet another precautionary measure to protect humans from animal materials that, while extremely unlikely to contain any BSE-related prions, are the only portions of the animal found to contain them. While this decision was not science-based, it was done both out of an abundance of caution and to help maintain consumer confidence.

Minimal risk from SRMs in younger cattle: When looking at the cattle population and the risk associated with this population, it is scientifically accepted that animals under 30 months of age pose a minimal risk for BSE. All these animals – which account for nearly 90% of all cattle processed in the U.S. – were born after the 1997 feed ban. Similarly, in tests conducted in Europe in 2002 on 1.6 million cattle under 30 months of age, not a single animal tested positive for BSE. So one has to ask why the SRMs of this group

would be excluded from animal feed. If the SRM removal effort is designed to mitigate risk, it should concentrate on where the risk is: the animals that die on farms and never make it to the anti mortem inspection process. Beef processing plants already have yet another food safety firewall in place: USDA/FSIS personnel at each of our plants who are trained to inspect these animals and look for signs of BSE or nervous disorder before they enter the food chain.

The need to clearly define the Distil Ileum: The FDA lists the entire small intestine from all animals as one of the proposed banned SRMs. This differs from the list issued by UDSA, which only bans the Distal Ileum from human consumption. Due to the lack of a common definition of the Distal Ileum, FSIS has classified the entire small intestine as an SRM. The vast majority of the scientific community agrees the Distal Ileum is the only portion of the small intestine that should be classified as an SRM (a definition of the Distil Ileum is attached). The balance of the small intestine is a safe food for human consumption.

Environmental concerns: Swift & Company operates beef plants in the states of Idaho, Utah, Colorado, Nebraska and Texas. If the proposed SRM ban is implemented, we will have an additional 10,000 to 20,000 tons of SRM-classified materials per year that must be sent to landfills. To further complicate the issue, the states of Nebraska and Utah already are limited on landfill space and will not accept these raw "internal organs." Even with an additional rendering or cooking step, environmental issues remain. Some of the materials from the Nebraska and Utah plants would still need to be shipped to out-of-state landfills, creating significant cost and logistical challenges.

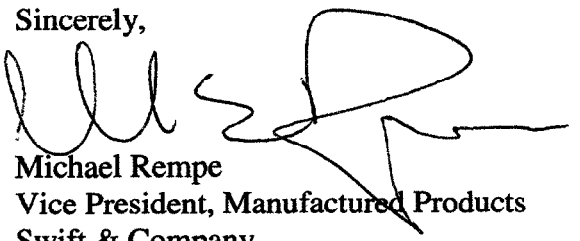
The cost of an expanded SRM list: Not only is the expanded list of SRMs not scientifically supported, but it would have a negative financial impact on the agriculture community. For example:

- The Distal Ileum accounts for 4 pounds per head. The proposal to include the entire small intestine as an SRM increases that to 16 pounds per head.
    - As an industry, that equals roughly 576 million pounds of product to be land filled, or 40 filled trucks going to landfills every business day.
    - The cost to the industry for this disposal is estimated to exceed $25 million per year
- Among older cattle (over 30 months of age), the SRMs would total 106 pounds per head.
    - As an industry, that equals an additional 530 million pounds of product per year, or 35 filled trucks to landfills each business day
    - The cost to the industry for these older cattle alone is another $25 million per year.
- The total cost of SRM disposal for both groups if cattle is estimated at more than $50 million for the industry. This diminished value of the livestock will be translated into a combination of lower prices paid to cattle producers/ranchers and higher beef prices for consumers.

CONCLUSION

The existing SRM regulations and BSE firewalls make it scientifically unnecessary and fiscally and environmentally imprudent to further expand the list of SRMs that are banned from the feed chain. Unnecessarily expanding the definition of SRMs will hurt both the U.S. beef industry as well as the American consumer.

Sincerely,



Michael Rempe
Vice President, Manufactured Products
Swift & Company

Attach. – Distil Ileum data

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 $3.5 million every year 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 and 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

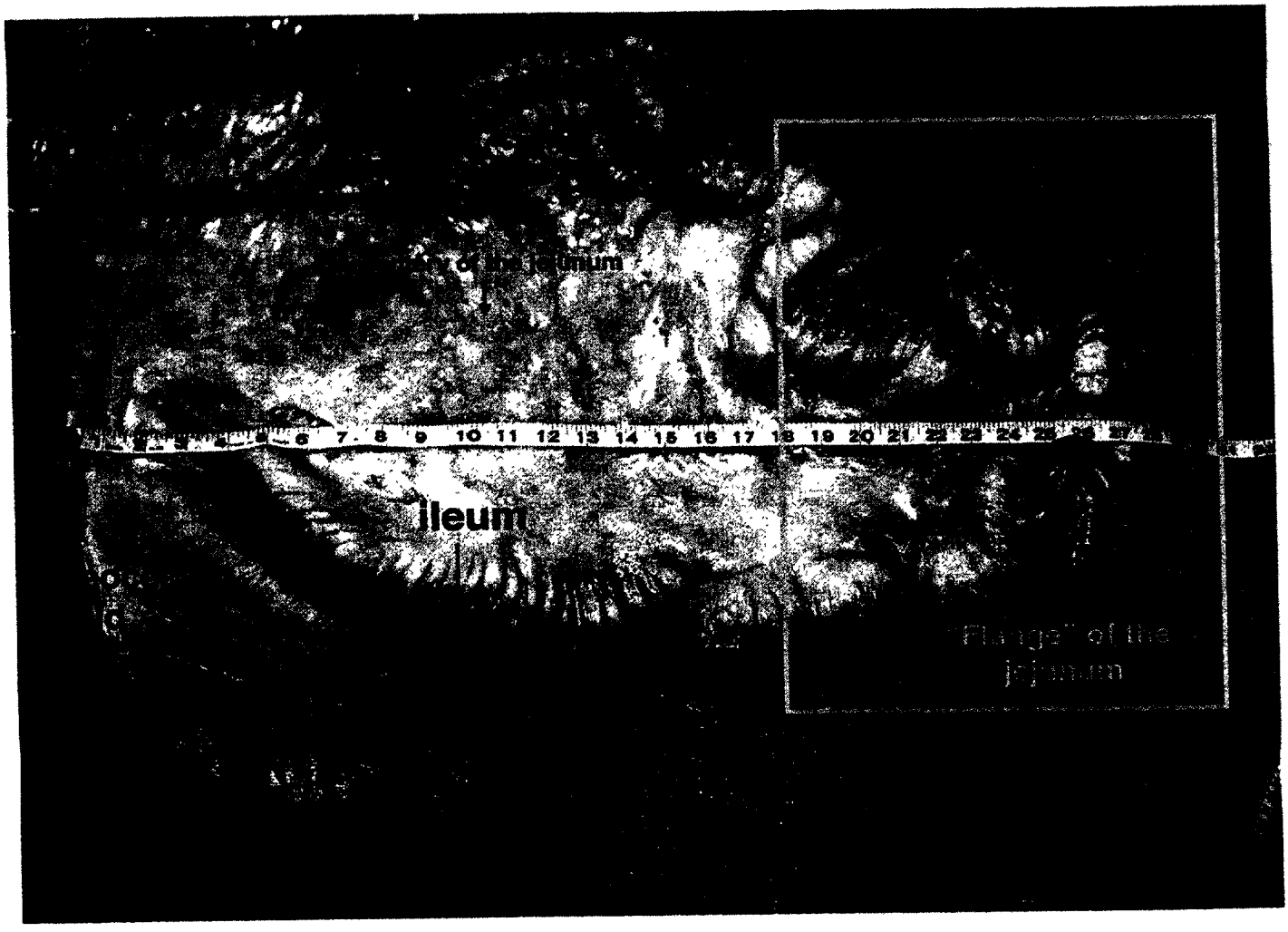


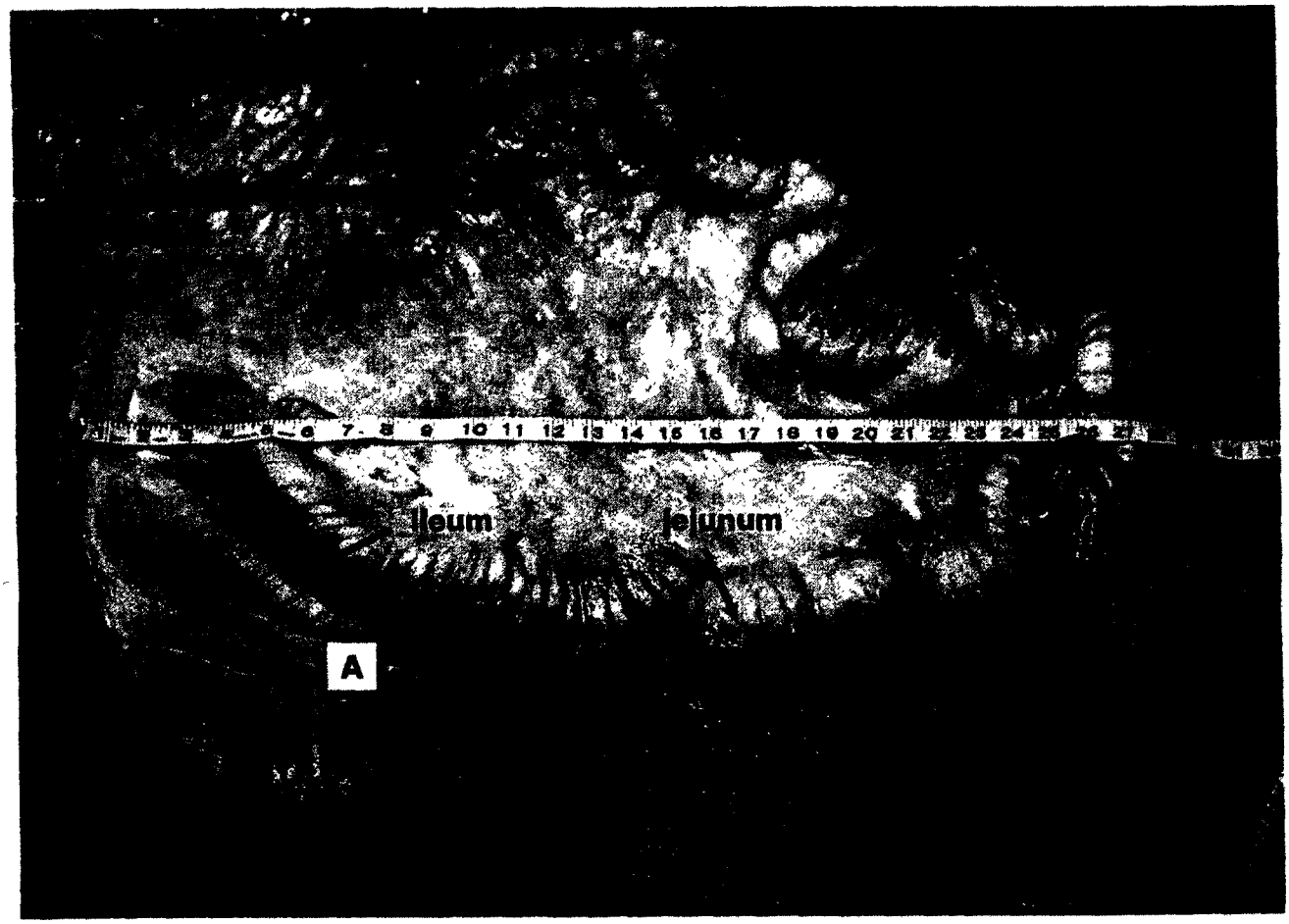
Figure 2.

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

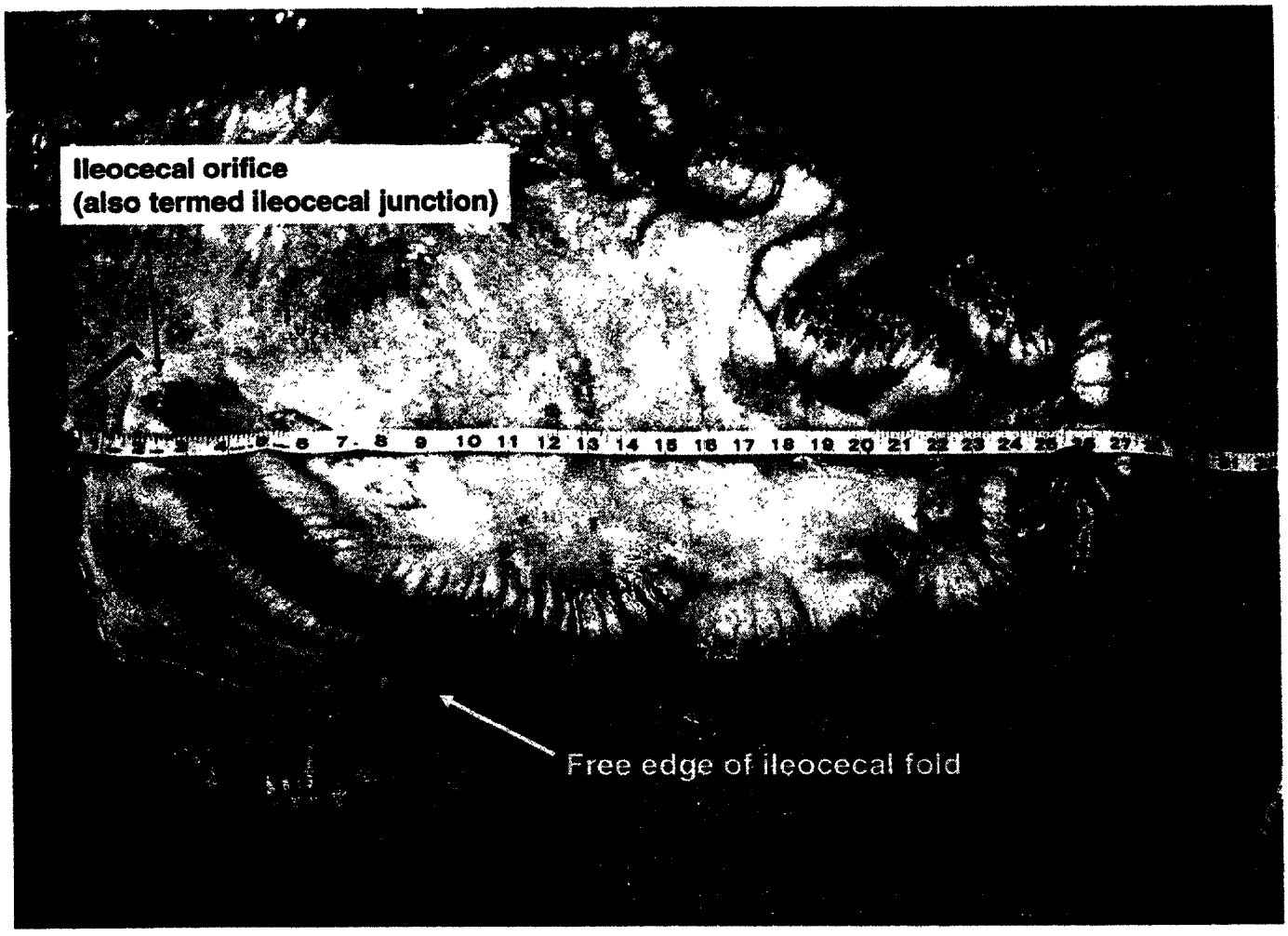
Figure 3.

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.

U.S. Meat Export Federation