encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. In the Federal Register of September 7, 2005 (70 FR 53063), we amended the interim final rule to make changes, including providing that the small intestine of cattle, formerly prohibited cattle material, could be used in human food and cosmetics if the distal ileum was removed by a specified procedure or one that the establishment could demonstrate is equally effective in ensuring complete removal of the distal ileum. Since 2005, peer-reviewed studies have been published showing the presence of infectivity in the proximal ileum, jejunum, ileocolic junction, and colon of cattle with BSE. Therefore, we are reopening the comment period for the interim final rule to give interested parties an opportunity to comment on the new studies concerning infectivity in parts of the small intestine other than the distal ileum.

DATES: Submit either electronic or written comments by May 3, 2013.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You may also submit comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 14, 2004 (69 FR 42256), FDA published an interim final rule entitled “Use of Materials Derived From Cattle in Human Food and Cosmetics.” The interim final rule prohibited the use of certain cattle material to address the potential risk of BSE in human food and cosmetics. The interim final rule designated the small intestine as prohibited cattle material and prohibited its use in human food or cosmetics. In the Federal Register of September 7, 2005 (70 FR 53063), we amended the interim final rule to allow the use of the small intestine if the distal ileum is removed by a procedure that removes at least 80 inches of uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

On January 12, 2004, the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), issued an interim final rule to designate materials that could potentially contain BSE infectivity as specified risk materials (SRMs) and prohibit their use for human food (see “Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle”; 69 FR 1862; January 12, 2004). FSIS’s interim final rule designated the distal ileum as an SRM but required that the entire small intestine be removed and disposed of as inedible to ensure the effective removal of the distal ileum. On September 7, 2005, FSIS, like FDA, amended its interim final rule to permit the use of the entire small intestine for human food if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the ceco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment demonstrates is effective in ensuring complete removal of the distal ileum.

When the FDA and FSIS amendments to the interim final rules were published in 2005, BSE infectivity had been demonstrated in lymphoid tissue of the distal ileum. In naturally occurring cases, sparse immunostaining had also been observed in the myenteric plexus of the distal ileum indicating the presence of PrPSc—a TSE-specific protein (Ref. 1). Because the myenteric plexus extends throughout the small intestine, both FDA and FSIS considered that it was possible that infectivity might also exist in the myenteric plexus of the jejunum or the duodenum. We stated in our 2005 amendment to our interim final rule that if we became aware of data indicating that other portions of the small intestine harbored BSE infectivity, we would take action appropriate to the public health risk. FSIS stated in its 2005 amendment to its interim final rule that while it believed that the primary tissues of concern for spreading the BSE agent had been identified, FSIS would use the results of future studies on BSE to further refine its policies with regard to BSE (70 FR 53043 at 53047; September 7, 2005). In 2007, FSIS issued a final rule to make permanent the interim measures implemented in 2004 and amended in 2005 (72 FR 38700; July 13, 2007).

Since we amended our interim final rule in 2005 and FSIS issued its final rule in 2007, peer-reviewed studies have been published showing the presence of some infectivity in the proximal ileum,
II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.


Leslie Kux,
Assistant Commissioner for Policy.