

Institute for Risk Assessment Sciences

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Removal of Specified Risk Material from the bovine intestinal tract and mesentery under slaughterhouse conditions, for animals originating from Member States or third countries with a controlled or undetermined BSE risk.

PREFACE

In accordance with Annex V, Regulation (EC) No 999/2001 and Commission Regulation (EU) No 2015/728, this report is drafted to elucidate the removal of Specified Risk Material (SRM) from the bovine intestinal tract and mesentery of animals originating from a BSE controlled or undetermined risk country, under slaughterhouse conditions.

This report, combined with a comprehensive instruction film on SRM removal, is intended for both (veterinary) competent authorities and slaughterhouse staff. Where possible the information will be presented in such a way to allow for direct use in practical conditions.

The content of the report and instruction film are drafted with the utmost care for correct interpretation and generic interpretation of scenes presented.

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INTRODUCTION

This report and related instruction films address the removal of Specified Risk Material (SRM) from the bovine intestinal tract and mesentery under slaughterhouse conditions, for animals originating in Member States or third countries with a controlled or undetermined BSE risk. To this effect, the embryonic origins of the different anatomical structures, which are included in the bovine intestinal tract (IT) and mesentery, are taken into account to provide clear guidance and accurate descriptions.

Subsequent sections in this report will provide hands-on information on the correct identification and removal of SRM. In addition, detailed descriptions and background information are provided to give the necessary context as to why or how certain sections of the IT and mesentery are to be removed and destroyed as SRM or can be kept for human consumption or Category 3 use.

1. BSE PATHOGENESIS AND RELEVANCE TO SRM

Pathogenesis studies serve as the basis for the definition of SRM¹ and already in 1997 a SRM ban was implemented^{2,3}. The assessment of the exclusion of certain SRM at a particular age limit is based on available data of ongoing experimental pathogenesis and dose/incubation period studies and on knowledge of the epidemiology of BSE with respect to age at infection and age at detection by clinical and active surveillance. On the basis of pathogenesis studies results it can be assumed that in the Central Nervous System the likely detectable infectivity appears at about ³/₄ of the incubation time. Based on the earliest clinical manifestations seen in pathogenesis studies and assuming that the last quarter of the incubation period would be positive for infectivity, the earliest infectivity would have to be assumed at 26 months.

SRM such as brain, spinal cord and intestine of animals of certain species/ages, are defined in Regulation (EC) No 999/2001 as amended, and are considered as the animal tissues potentially containing the highest level of Transmissible Spongiform Encephalopathy (TSE) infectivity in an animal infected with BSE, thus requiring complete removal from the food and feed chain. On the basis of BSE pathogenesis studies and scientific opinions, there is clear evidence that SRM removal is the most important human health protective measure against BSE. SRM removal eliminates at least 97% to 99,7% of BSE-infective tissues from an infected animal. Excluding SRM from the food and feed chain considerably reduces the exposure of the consumers to the possible BSE agent present.

In chapter 6 of the 2014 EFSA opinion⁴ the BSE infectivity distribution and accumulation in bovine intestine and mesentery is described in great detail, taking into account the most relevant scientific papers available on this subject.

These sources indicate that in the ileum:

- the BSE agent accumulates from the first months post exposure and persists till clinical onset;
- abnormal PrP associated with BSE infection mainly accumulates:
 - in the lymphoid follicles of the ileocecal plate and to a lesser extent in the myenteric and mucosal plexus during the first half of the incubation period;
 - in both the ileocecal plate and myenteric and mucosal plexus during the second half of the incubation period.

However, since bioassays performed on distal ileum used homogenates from the whole organ as inoculum, the infectious titre obtained encompasses the infectivity associated with both lymphoid and nervous structures.

¹ Scientific Steering Committee, Scientific Opinion adopted on 9 December 1997. Listing of Specified Risk Materials.

² Commission Decision 97/534/EC, on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies.

³ Commission Decision 2000/418/EC, regulating the use of material presenting risks as regards transmissible spongiform encephalopathies and amending Decision 94/474/EC.

⁴ EFSA Panel on Biological Hazards, 2014. Scientific Opinion on BSE risk in bovine intestines and mesentery. EFSA Journal 12(2), 3554 (LINK).

In the jejunum, these sources indicate that:

- the BSE agent can be detected as early as 4 months post-challenge and persists until clinical onset;
- the BSE agent is probably mainly associated with lymphoid follicles;
- the BSE infectivity remains limited.

No specific data are currently available with regards to BSE agent presence/ infectivity/level in the duodenum.

As for the caecum and colon it was indicated that no data was available concerning:

- the possible accumulation of the BSE agent in lymphoid follicles in the colon;
- the moment of the incubation period from which the colon can accumulate BSE agent;
- the range of infectious titre in the colon of BSE infected cattle.

The subsequent quantitative assessment provided for by the 2014 EFSA opinion came to the following conclusions concerning infectivity:

- In a BSE infected bovine, the relative distribution of the infectivity in the different portions of the intestines and in the mesenteric tissues varies with the age of the animal, reflecting the stage of incubation of the disease;
- In a BSE infected healthy slaughtered bovine:
 - up to 36 months of age, the infectivity in intestine and mesentery is mainly (on average more than 90%) associated with the ileocecal plate (distal part of jejunum plus ileum) and the caecum;
 - o over 36 and under 60 months of age, there is a substantial inter-individual variability in the relative contribution of intestinal and mesenteric structures to the total infectivity;
 - from 60 months of age, the infectivity in intestine and mesentery is mainly (on average more than 90%) associated with the mesenteric nerves and the Celiac and Mesenteric Ganglion Complex;
 - duodenum, colon and mesenteric lymph nodes contribute less than 0.1% to the total infectivity in an infected animal regardless of the age at slaughter.
- The total infectivity that is associated with the intestines and the mesentery varies with the age of the infected animal. On average, it peaks at about 15 BoID₅₀ (Bovine oral Infectious Dose 50%) in animals younger than 18 months before progressively declining to 8-9 BoID₅₀ (in animals between 24 and 48 months of age) and dropping to 0.7 BoID₅₀ in animals older than 60 months.

In figures 1 and 2 taken from the 2014 EFSA opinion, the estimated mean infectivity by intestine and mesentery tissue type and of processed products by age at slaughter are summarized.

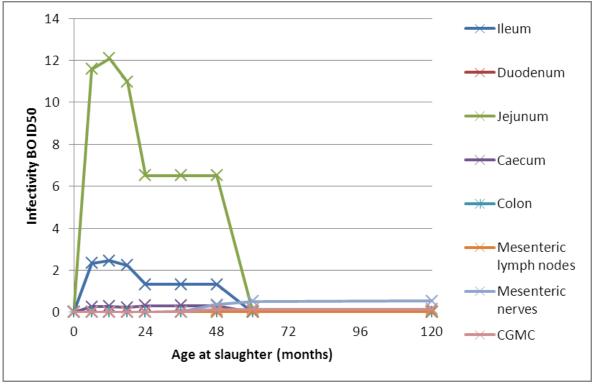


Figure 1, summary graph of estimated mean infectivity by intestine and mesentery tissue type (Bol D_{50} per infected animal) by age at slaughter

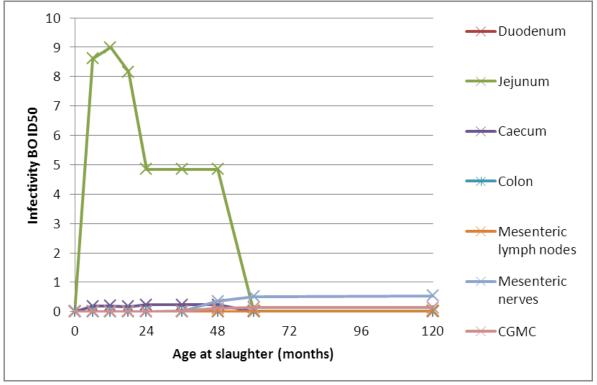


Figure 2, summary graph of estimated mean infectivity of processed products (BoID₅₀ per infected animal) by age at slaughter

Together, these infectivity data clarify which tissues are to be removed as SRM from animals originating from countries with a BSE controlled or undetermined risk in order to reduce the potential BSE risk sufficiently. The EFSA BIOHAZ Panel finally concluded in its 2014 opinion that "whatever the scenario, the removal of the last 4 metres of the small intestine and of the caecum from the food and feed chain would result on average in more than a 90% reduction of the total infectivity associated with intestine and mesentery in BSE infected cattle up to 36 months of age."

Based on these conclusions, Annex V, Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) No 2015/728 using the following arguments:

- "According to the EFSA Opinion, in BSE infected bovine animals: (i) up to 36 months of age, more than 90% of the BSE infectivity is associated with the last 4 metres of small intestine and the caecum; (ii) between 36 and 60 months of age, there is a substantial inter- individual variability in the relative contribution of intestinal and mesenteric structures to the total infectivity; (iii) from 60 months of age, more than 90% of the BSE infectivity is associated with the mesenteric nerves and the celiac and mesenteric ganglion complex; (iv) the duodenum, the colon and the mesenteric lymph nodes contribute less than 0,1% to the total infectivity in an infected animal regardless of the age at slaughter. The EFSA Opinion also states that the total infectivity associated with those tissues varies with the age of the infected animal, with a peak in animals younger 18 months before a progressive drop in animals older than 60 months."
- "The EFSA Scientific Opinion on the revision of the quantitative risk assessment (ORA) of the BSE risk posed by processed animal proteins (PAPs)⁵ published in 2011 states that 90% of the total infectivity amount in a BSE clinical case is associated with central and peripheral nervous system tissues, with about 10% associated with the distal ileum. The residual infectivity in the parts of the intestines other than the last four meters of the small intestine and the caecum can be considered as negligible. The complete elimination of risk is not a realistic objective for any risk management decision."

Annex V now stipulates that from animals originating from countries with a BSE controlled or undetermined risk, the following SRM needs to be removed:

- The skull excluding the mandible and including the brain and eyes, and the spinal cord of bovine animals aged over 12 months;
- The vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia of bovine animals aged over 30 months; and
- The tonsils, the last four meters of the small intestine, the caecum and the mesentery of bovine animals of all ages.

⁵ EFSA Panel on Biological Hazards, 2011. Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAPs). EFSA Journal 9(1), 1947 (LINK).

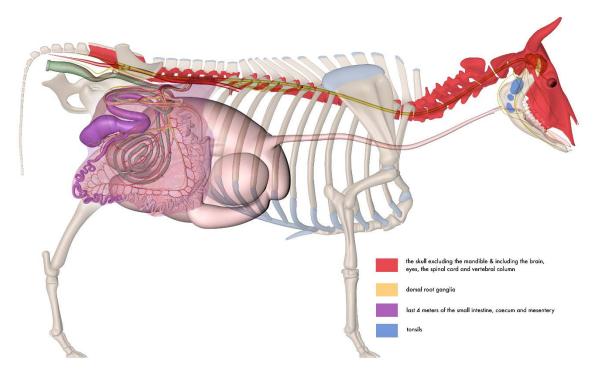


Figure 3, bovine SRM in an animal with a controlled or undetermined BSE risk status, according to Annex V, Regulation (EC) No 999/2001

In annex II a detailed description is given on the embryonic origins of the bovine mesentery in relation to SRM. This section provides the backgrounds needed to understand the anatomical reference points used in the various videos and written instructions.

2. BOVINE ANATOMY RELEVANT FOR THE REMOVAL OF SRM

This chapter provides a short overview of the bovine anatomy which is relevant for the removal of SRM. Illustrations are presented to elucidate the anatomical structure and position of the gastro-intestinal tract (GIT) in the cow, the orientation of the GIT towards the three main suspension points and certain reference points or anatomical features for the intestinal SRM.

A more detailed background on the anatomical origins of the GIT is described in Annex II.

2.1 Anatomical description

The gastro-intestinal tract is vertically positioned in the abdominal cavity, with the intestines between the rumen and the abdominal wall on the right side of the animal.

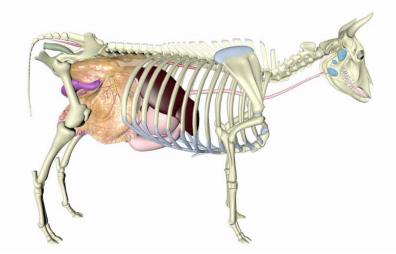


Figure 4, position bovine intestinal tract

Zooming in on the intestinal tract, the liver (1) becomes clearly visible on the front rightside of the rumen, with the gall bladder protruding just below.

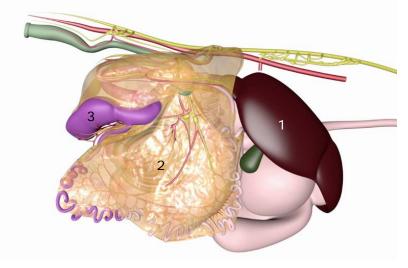


Figure 5, overview position bovine intestinal tract

The intestinal tract is covered by the omentum majus (2) and the caecum, as part of the SRM (3) becomes visible at the rear of the entire GIT.

When the stomach complex, liver and omentum majus are removed, the remaining intestinal tract can be viewed in its original position.

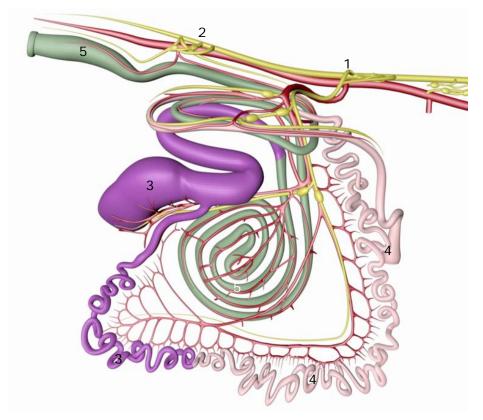


Figure 6, bovine intestinal tract, original position with suspension points (1,2), SRM (3) and duodenum-jejunum (4) and colon (5)

The main suspension point of the intestinal tract is located around the A. mesenterica cranialis (1), directly above the intestinal tract. All major blood vessels, nerves and lymphatic ducts from the mesentery converge at this point. The caecum and last four meters of the small intestines (3) can be identified as SRM, whereas the duodenum-jejunum (4) and spiral shaped colon (5) are considered safe for further use.

Towards the end of the colon a second suspension point is visible, located around the A. mesenterica caudalis (2). Any tissue directly linked to this point is also considered safe for further use (as explained in more detail in Annex II).

2.2 Anatomical reference points

Based on the descriptions provided, the following practical reference points can be given for the removal of the intestinal SRM:

- Ileum and distal jejunum (combined total length 4 meters): ileocecal orifice is the end-point of the ileum, proximal ending is 4 meters away, hand measured; The ileum can be identified by ligament remnants on both sides (plica ileocecalis and mesoileum), the jejunum has these only on one side: mesojejunum;
- Caecum: blind-ending, with the plica ileocecalis on one side. Distal end is at far end of the ansa proximalis coli;

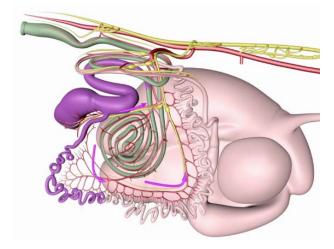
- Mesentery: remaining tissue, including different ligaments, neural and lymphatic tissue, blood vessels and fatty tissue, after removal of colon ascendens and transversus. The entire mesentery is considered SRM, excluding any further processing.

3. ORAL INFECTION ROUTE OF BSE PRIONS

Although an initial uptake of BSE prions is already possible via the tonsils in the oral cavity, the main route of infection is further down the gastro-intestinal tract.

BSE contaminated feed passes through the different stomach compartments and enters the duodenum. The main uptake of the BSE prions is done via the Peyer's patches (ileocecal plate), which are located in the ileum and caecum, surrounding the ileocecal orifice.

The BSE prions now migrate over time (Figure 5, arrows) via the lymphatic and neural structures in the mesentery to the neural ganglions close to the A. mesenterica cranialis and then via the spinal cord to the brain.



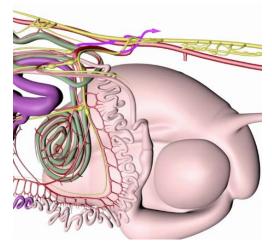
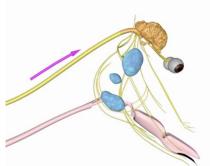


Figure 7, BSE prion uptake in the bovine intestinal tract and migration to the brain

As the Peyer's Patches are not uniformly distributed between individual animals and the intestinal surface covered by the Peyer's Patches vary with age, the decision is clear why the entire caecum, ileum, distal section of the jejunum (together 4 meter) and mesentery are designated as SRM.



4. BOVINE SLAUGHTER LINE – ANIMAL ID AND TRACEABILITY

Each animal presented for slaughter has a distinct BSE risk status based on its country of origin and moment of slaughter. To determine whether the animal has a negligible, controlled or undetermined BSE risk status, the Decision Tree as explained in Annex III is applicable.

To ensure that the correct BSE risk status is applied throughout the entire slaughter line and the corresponding SRM removed, the correct identification and traceability of the carcass must be ensured.

When the animal is stunned and suspended for bleeding, the information linked to the animal's identifying yellow ear tag determines which SRM is to be removed from the carcass.

The unique ID number of the animal, located on the ear tag, is transferred by an operator onto a set of stickers, which are placed on the animal.

After dehiding the ear tag stays with the cow hide for identification purposes while the carcass remains properly identified by the stickers.

The closed carcass is presented for evisceration (Picture 1). After opening the abdominal cavity, spreaders are placed to allow good access to the cavity. The spleen is removed first and the ligaments which suspend the GIT are severed with great care to avoid unwanted punctures of the GIT and subsequent faecal contamination of the cavity and organs.



Picture 1, evisceration of the carcass

Using gravity, the GIT now falls from the carcass into a transport tray which remain linked until the Post Mortem (PM) decision is made by the supervising competent authority. Next to the PM decision, the BSE risk status of the carcass is taken into account and the GIT is clearly marked for either complete processing (BSE negligible risk status) or partial processing and SRM removal (BSE controlled or undetermined risk status).

After the PM decision the GIT can now be formally separated from the carcass and is transported to the gut room for further processing. Upon arrival in the gut room the markings on the GIT will indicate if the entire GIT can be processed or whether certain SRM needs to be removed.

The stomach complex is separated from the intestinal tract and the omentum majus is cut from the stomach surface.

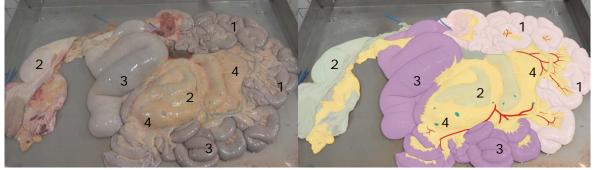
The intestinal tract is now ready for transfer to a designated area for further processing. Given the line speed and focus on correct handling during the slaughtering process, a best practice will be to slaughter cows per batch, based on the BSE risk status of the animals, instead of mixing cows with different BSE risk statuses.

5. REMOVAL OF THE LAST 4 METERS OF SMALL INTESTINES AS SRM

This chapter describes the step-by-step procedure done by the gut room operator to remove the last 4 meters of the small intestines.

The presented description of the oral infection route of BSE prions in chapter 3 clarifies why these last four meters are regarded as SRM and therefore designated for removal and destruction.

Picture 2 shows the intact bovine intestinal tract, together with an illustrated version. The duodenum and jejunum (1) and colon (2) can be identified; as SRM, the last four meters of the small intestines (ileum and distal part jejunum), caecum (3) and surrounding the spiral shaped colon, the mesentery (4) can be identified.



Picture 2, intact bovine intestinal tract

The main suspension points of the intestinal tract (Picture 3), surrounding the A. mesenterica cranialis (1) and caudalis (2) can be clearly identified.

The last four meters of small intestines, including the ileum can be removed by cutting the small intestines from the mesentery starting at the stomach end and working towards the caecum.



Picture 3, suspension points intestinal tract

- The intestinal tract is positioned over the edge of the table, to allow good visibility of the area where the intestine is cut from the mesentery. Using a sharp knife, the cut is made as close as possible to the surface of the intestine. The separated small

intestines are placed in a suitable container next to the table. Care is taken not to cut into the intestine itself or spill the separated small intestines on the floor;

- When approaching the end of the jejunum and start of the ileum, the entire tract is repositioned to present a good view of the ileum, caecum and ileocecal fold. Any content of the ileum is manually removed to reduce faecal contamination of the mesentery when the ileum is finally cut from the caecum;
- Incisions are carefully made in the fatty tissue to avoid unwanted punctures of the ileum. The ileum is then manually separated from the mesenteric fat;
- The ileum is picked up while it is still attached to the caecum and cut further from the mesentery towards the edge of the ileocecal fold (Picture 4, (1)). As a final step, the remaining length of small intestines still attached to the mesentery is now completely cut from the mesentery;



Picture 4, separation of the ileum from mesentery

- With the ileum still attached to the caecum, a minimum length of four meters is hand-measured from the small intestines (Picture 5). A first cut is made, separating the usable small intestines which can now be transported elsewhere for further processing into beef rounds;
- A second cut is made close to the ileocecal orifice, producing the four meter section of small intestines which needs to be destroyed as Category 1 specified risk material.



Picture 5, hand-measuring four meters of small intestines

6. REMOVAL OF THE COLON AND CAECUM FROM THE MESENTERY

This chapter describes the step-by-step procedure done by the gut room operator to remove the colon and caecum from the mesentery.

The presented description of the oral infection route of BSE prions in chapter 3 clarifies why the caecum and mesentery are regarded as SRM and therefore designated for removal and destruction.

Picture 6 shows the bovine intestinal tract after removal of the small intestines, together with an illustrated version. The colon (1) can be identified; as SRM, the caecum (2) and surrounding the spiral shaped colon, the mesentery (3) can be identified.



Picture 6, colon and caecum embedded in mesentery

In order to prevent faecal contamination of the remaining intestinal tract and mesentery, the caecum can only be separated from the colon as SRM after the two have been cut from the mesentery.

- The intestinal tract is positioned on the table with the caecum on the left. The colon is now manually torn from the mesentery, leaving as little as possible fatty tissue and suspensory ligaments attached to the colon. Any content of the colon is manually replaced to reduce the chance of burst and possible faecal contamination;
- When the entire colon is manually separated, the caecum is now carefully cut from the mesentery;
- In picture 7, presenting the colon (1) and caecum (2), the end of the ansa proximalis coli (3) is clearly visible, which marks the starting point of the colon;



Picture 7, marking the caecum as SRM

- Taking into account the distance between the ileocecal orifice (right blue tie-wrap) and start of the colon (left blue tie-wrap) a sufficiently large safety section is included to include the entire ileocecal plate formed by the Peyer's patches;

- The colon can now be cut from the caecum and can be transported elsewhere for further processing into beef middles;
- The remaining caecum and mesentery are now clearly identified and available to be destroyed as Category 1 specified risk material;
- The manual technique shown in the film can be considered a best practice as it will reduce the risk of unwanted puncture of the intestinal wall and subsequent faecal contamination. However, any other technique should also be allowed if a similar end result is possible.

7. ANALYSIS OF SRM PRESENCE AS HIGH RISK HAZARD

In order to prevent as a high-risk hazard the potential presence of SRM remaining after the processing of the bovine intestinal tract into beef casings, a hazard analysis is warranted to determine whether a Critical Control Point is applicable or whether the hazard can be averted as part of the prerequisite programme for the production of beef casings.

The following steps may be relevant:

- Step 1 Hazard analysis: presence of SRM is considered as a hazard with a high risk. Only applicable to those animals originating in a country with a BSE controlled or undetermined risk status;
- Step 2 Identification of CCP: the CCP is able to ensure that no SRM is present after processing of the bovine intestinal tract into beef casings;
- Step 3 Critical limits: zero tolerance on presence of SRM in bovine natural casings;
- Step 4 Monitoring: as SRM presence in beef casings is considered a high risk, either a continuous monitoring procedure should be applied or a suitable percentage of the batches of casings produced should be determined and monitored to ensure the CCP is under control. The actual monitoring procedures at production level will need to be developed by the slaughterhouse itself taking into account all specific details applicable to its own situation;
- Step 5 Corrective measures: in case SRM is found to be present in a certain batch of produced beef casings, the entire batch is disposed of as SRM;
- Step 6 Records keeping: all information should be recorded concerning production of beef casings, percentage (100% or less) of casings checked (based on Step 4) and possible corrective measures taken (Step 5);
- Step 7 Verification procedures: The establishment's dedicated HACCP team should regularly evaluate if all steps taken meet the required objective, being the absence of SRM in processed beef casings. In addition, the establishment's HACCP plan should be annually audited by the competent authorities including an evaluation of results of production and monitoring procedures. However, the actual frequency of evaluations and audits should be determined as part of the overall applied monitoring procedures.

From a practical viewpoint the following comments can be made:

- Given the large varieties in weight and size of the bovine intestinal tract, due to age, sex, species difference and moment of slaughter, it is unlikely that a proper automated control system can be developed. Therefore, a batch-wise approach should be proposed, based on manual or visual controls. In addition, it should be taken into account that the possibility exists that the GIT is condemned as part of the PM decision. Therefore not all available GIT will be processed;
- Based on the daily slaughtering schedule for a particular plant, it is advisable to slaughter those animals with a BSE negligible risk status first, as no SRM restrictions are applicable.

Therefore, if as a prerequisite only animals with a BSE negligible risk status are slaughtered, the subsequent hazard analysis is completed and no SRM risk is applicable.

When slaughtering these animals is finished, animals with a BSE controlled or undetermined risk status can be processed. This would then include a clear marking on the GIT, which can be made at the point in the slaughter line where the final PM decision is made by the competent veterinary inspector.

Here, the GIT will either pass with SRM removal applicable or the GIT is condemned based on the inspector's decision;

- As the daily number of cattle with a BSE controlled or undetermined risk status is known and the number of condemned GITs is known at the end of the daily slaughtering process, the total number of SRM can be calculated. Per cow, one section of 4 meters of small intestines, one caecum and one mesentery should be accounted for.

This number should correspond with the number of sets of beef rounds (produced from the small intestines) and beef middles (produced from the large intestines) produced per animal;

- Per day / per shift an overview should be presented including the number of cattle slaughtered, GITs condemned by PM decision, number of sets of beef rounds and middles produced, number of SRM removed and any corrective actions taken due to nonconformities found during that particular production period.

Final remark

From an economical perspective it is highly unlikely that apart from the small intestines, the colon is harvested for the production of beef middles from animals originating in a country with a BSE controlled or undetermined risk, as too much time is needed to remove it properly from the mesentery (as described in chapter 6).

Therefore, there will be no need to remove the SRM in separate sections as described in chapters 5 and 6. A final cut can be made at 4 meters proximal to the ileocecal orifice, leaving the ileum and distal jejunum attached to the caecum. The small intestines are now available for beef round production, while the remainder of the intestinal tract, together with the mesentery is destroyed as Category 1 material.



Picture 8, final cut, leaving 4 meters of intestines attached to the caecum as SRM

8. FREQUENTLY ASKED QUESTIONS (FAQs)

In the preparation of this project and final report different FAQs were asked. These are listed below and the responses provided either directly answer the questions or refer to a specific section of this report.

- Q1: How to remove the mesentery while the colon is not to be removed as SRM?
- A1: After separation of the entire small intestine and caecum from the mesentery, the colon is removed. What remains are the various suspensory ligaments and embedded tissues which are regarded to be the remaining mesentery. This is then destroyed as SRM. Chapters 4 and 5 and related films describe this in great detail.
- Q2: Is the mesocolon also part of the mesentery or just the part attached to the duodenum, jejunum and ileum (which means a different cutting technique)?
- A2: The mesocolon ascendens and transversus, together with the mesoduodenum, mesojejunum mesoileum (including the plica ileocecalis) form the mesentery (see also annex II). They are not separated further and are all considered SRM.
- Q3: Is the omentum SRM?
- A3: The omentum is not considered SRM, as its embryonic origin is different than the mesentery. It can therefore be used for further processing (see also annex II).
- Q4: How can the content (manure) of the intestinal tract be separated without complaints?
- A4: Removing the manure from the intestinal tract which is eligible for human consumption is done after the SRM is removed. During the production steps described in this report and video, great care is taken to prevent any unwanted faecal contamination. Several manure removing techniques are known varying from manual removal to mechanical. Therefore, as the manure removal has no effect on the SRM removal it is not considered in this report and films.
- Q5: What requirements have to be in force for machines which are used for the before mentioned activities and how can operators prove that these machines are fit for these activities?
- A5: The removal of SRM is done manually. Any mechanical requirements have no relevance to the SRM removal and is therefore not considered in the films.
- Q6: How can it be assured that these SRMs are not mixed with the rest of the intestines, and end in the food chain?
- A6: Per chapter or film on the removal of SRM, specific attention is paid to the identification of these tissues after removal. Chapter 7 subsequently provides practical suggestions on the control and supervision of SRM removal and

destruction, preventing unwanted mixing with product fit for human consumption.

- Q7: How can the GIT be properly marked to indicate NO SRM or SRM Removal in the gut room, based on the BSE risk status of the corresponding animal, after the PM decision is made and which person should do this?
- A7: For the purpose of marking the GIT, a specifically designed ID label or colour dye (suitable for use in a food producing environment) can be used. A logical option would be that the person deciding on whether the vertebral column in the corresponding carcass is deemed SRM also decides on how the animal's GIT should be marked, either as SRM, fit for human consumption, Cat 3 or Cat 2.
- Q8: How much time (estimate) will it take to cut the small intestines from the mesentery and separate the usable section (duodenum-jejunum) from the last four meters (SRM)?
- A8: An experienced operator could do this in less than 2 minutes. However, this varies per person and location and a proper indication can only be made if sufficient experience is gathered by the operator.
- Q9: How much time (estimate) will it take to remove the colon & caecum from the mesentery and separate the usable colon from the caecum (SRM)?
- A9: An experienced operator could do this in 3 to 5 minutes. As it is very labour intensive and should be done with great care to prevent the colon to burst and avoid faecal contamination, it is likely that in Europe this kind of procedure is not done in day-to-day practice as it would not be economically feasible. However, as the procedure is allowed in accordance with current EU legislation, the procedure is included in this report. If it is not done in practice, the entire mesentery AND caecum AND attached colon are deemed SRM.
- Q10: Can the average weight of the entire IT or the separated mesentery as SRM be given as a point of reference for complete removal of all SRM?
- A10: Due to the extensive individual variation (based on animal's age, sex, breed, purpose) between animals, an accurate average weight cannot be indicated. This is clearly illustrated by the information included in the 2014 EFSA opinion (paragraph 9.2, rendering fat from mesentery)⁶, with weights varying between 1.6 kg for a <7 months old calf up to 9-15 kg for a heavy bull.

⁶ EFSA Panel on Biological Hazards, 2014. Scientific Opinion on BSE risk in bovine intestines and mesentery. EFSA Journal 12(2), 3554 (LINK).

ANNEX I Product name and anatomical reference

Bovine origin	
Bung cap (EU)	Casings prepared from the most distal part of the blind gut (caecum) of cattle
Bung end (EU)	Casings prepared from the proximal part of the blind gut (caecum) of cattle, connected to the large intestines
Beef middles	Casings prepared from the proximal part of the large intestines of cattle, starting at the blind gut
Beef rounds	Casings prepared from the duodenum and jejunum of cattle

ANNEX II The bovine mesentery in relation to SRM

The mesentery is the general name for the suspensory ligament of the intestinal tract and get its topographical meaning if added which part of the intestinal tract it suspends (duodenum, jejunum etc.). There are no sharp delineations between the respective intestinal parts. The supply from the arteries is quite clear and relatively straightforward. To understand the relationship between the different parts of the mesentery, its fusion and thus blood, lymph and nerve supply, we have to go back to its ontogeny.

Although the primary gut develops as one endodermal tube, three main parts can be distinguished. The forgut extends from the pharynx to the cranial part of the duodenum until the level where the liver and pancreas buds develop. One of its main characteristics is the presence of a ventral suspensory ligament, which is hardly recognizable in the esophagus but still prominent as the lesser omentum in the stomach area. In the dorsal mesentery a cavity develops that is divided into the infracardiac space in the thorax and the bursa omentalis in the abdomen by the development of the diaphragm.

The broncho-esophageal artery, a direct branch of the aorta in the thorax, and the celiac trunk, the first artery to arise caudal to the diaphragm in the abdomen are responsible for the blood supply of the foregut. The venous return in the thorax is through the azygos veins, and in the abdomen through veins that drain into the hepatic portal vein. The foregut is innervated parasymphatically by the vagus nerve. The sympathetic nerve supply originates in the thorax from the stellate ganglion and in the abdomen from the celiac ganglion located on the celiac trunk.

The midgut comprises the intestines caudal to the foregut and the first one-third of the transverse colon. During the embryological development it forms a loop suspended by a dorsal mesentery consisting of a cranial descending and a caudal ascending limb. The caudal part of the foregut is positioned more or less horizontally; the first part of the descending limb becomes the part of the duodenum caudal to the liver and pancreas buds. The jejunum is formed from the remainder of the descending limb develops into the cecum, the ascending colon, as well as the first part of the transverse colon. The presumptive ascending colon is arranged in a spiral coil and the mesocolon fuses with the mesojejunum. Hence, the ascending colon becomes localized centrally in the same mesentery that carries the jejunum in its periphery.

The midgut is supplied by the cranial mesenteric artery (right vitelline artery), which forms the basis of the root of the mesentery. In the duodenum an anastomosis occurs between the cranial arteria pancreatico-duodenale from the truncus celiacus and the caudal arteria pancreatico-duodenale which is an indirect branch of the arteria mesenterica cranialis.

The suspensory ligament (mesentery) can thus be divided into a mesoduodenum, mesojejunum, mesoileum, including the plica ileocecalis, mesocolon ascendens, and transversus. The venous return is again via the hepatic venous portal vein.

In recent studies the extrinsic innervation to the ileum of cattle was elucidated using retrograde axonal transport of HRP (horse radish peroxidase): the distal ileum was supplied by sympathetic postganglionic neurons from both the celiac and cranial mesenteric ganglia and some spinal sensory neurons in the dorsal root ganglia. The vagal motor and sensory supply could hardly be detected.

The major splanchnic nerve branches off at the 6th, 7th or 8th thoracic ganglion and receives fibres from the more caudal spinal ganglia except from the last 2 to 3. It passes the diaphragm between the diaphragmatic crurae and ends in the celiac ganglion. Two

to three smaller nerves from the first two lumbal ganglia, the minor splanchnic nerves communicate with the major nerve, terminate at the celiac and renal plexus. In the abdomen mostly 6 paravertebral ganglia are present, whose branches terminate at the plexus celiacus and mesenterica cranialis.

The small celiac and large cranial mesenteric ganglia are connected to each other and their contralateral counterparts by large, cell-rich fibres.

The celiac ganglion is connected by fibres with the:

- Plexus gastricus and n. vagus,
- Plexus ruminalis sinister and dexter,
- Plexus hepaticus,
- Plexus lienalis,
- Plexus pancreaticus,
- Ganglia phrenica.

The ganglion mesenterica cranialis is in connection with the:

- Plexus celiacus,
- Plexus renalis and suprarenalis,
- Nn splanchnici minors and lumbales,
- Plexus uretericus,
- Plexus mesenterica caudalis.

The more horizontally positioned hindgut develops into the remaining portion of the transverse colon, descending colon and the rectum, excluding the anal canal. This part of the intestines is supplied by the caudal mesenteric artery and is innervated by the caudal mesenteric ganglion and the nn. pelvini.

In conclusion, based on the vascular distribution the parts of the original midgut can rather easily be distinguished. A slight overlap occurs in the duodenum just caudal to the inlet of the gall duct, by means of an anastomosis between the cranial and caudal pancreatico-duodenal arteries. This is also the case in the transverse colon between the arteria colica media from the cranial mesenteric artery and the left and right colic artery from the caudal mesenteric artery.

The autonomic nerve supply to the midgut is mainly supplied by the cranial mesenteric ganglion/plexus, but crosstalk with the celiac and renal ganglia exists.

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- Anatomie comparée des mammifères domestiques, tome 3 Splanchnologie I by Barone R., fourth edition, Editions Vigot.
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ANNEX III Decision trees application correct SRM list

The purpose of this annex is to clarify the wording "*animals whose origin is in Member States with a negligible BSE risk*" in Commission Regulation (EU) No 2015/1162 of 15 July 2015 amending Annex V to Regulation (EC) No 999/2001 as regards removal of Specified Risk Material (SRM) for bovine animals originating from Member States with negligible BSE.

From the 5th August 2015, the date of entry into force of Commission Regulation (EU) No 2015/1162, the EU TSE Regulation provides for two lists of SRM for bovine animals: a "full SRM list" applicable for bovine animals originating from Member States or third countries with a controlled or undetermined BSE risk and a "reduced SRM list" applicable for bovine animals originating from Member States with negligible BSE risk. These two lists are summarised below.

Summary of EU SRM lists after the entry into force of Commission Regulation (EU) No 2015/1162:

1. Animals whose origin is in Member States or third countries with controlled or undetermined BSE risk 2. Animals whose origin is in Member States with negligible BSE risk

BOVINES	"full SRM list"	"reduced SRM list"
Skull, excluding the mandible and including the brain and the eyes, of bovine animals over 12 months	SRM	SRM
Spinal cord of bovine animals over 12 months	SRM	SRM
Tonsils of bovine animals of all ages	SRM	Food and feed*
Last 4 meters of the small intestine of bovine animals of all ages	SRM	Food and feed*
Vertebral column, excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of bovine animals over 30 months	SRM	Food and feed*
Mesentery, including mesenteric fat, mesenteric ganglion complex and mesenteric nerves, of bovine animals of all ages	SRM	Food and feed*
Caecum of bovine animals of all ages	SRM	Food and feed*

*Without prejudice to feed ban and food safety rules

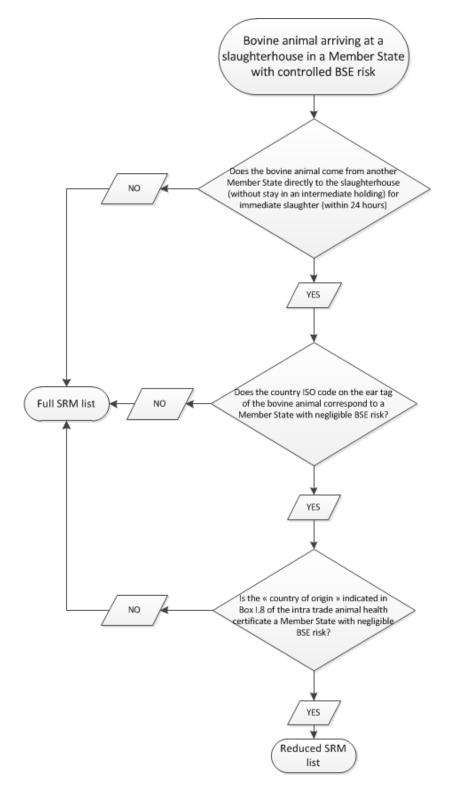
In order to ensure a harmonised approach in the EU, the decision trees below are intended to serve as guidance to decide on the list of SRM (full list or reduced list) to be applied at slaughterhouse level.

The reference for the BSE status of Member States is the latest version of Commission Decision 2007/453/EC, at the date of slaughtering the animal (see <u>MAP</u>).

In Member States with negligible BSE risk, the reduced SRM list is applied, except when the ISO code on the ear tag of the bovine animal corresponds to a Member State with a controlled BSE risk (or third country with a BSE controlled or undetermined risk). This can be summarised as follows:

Bovine animal arriving at a
slaughterhouse in a Member State
with negligible BSE risk
*
Does the country ISO code on the ear tag
✓ of the bovine animal correspond to a YES /→ (Full SRM list)
Member State with controlled BSE risk?
Y.
NO /
V
Reduced SRM list
Reduced Shiw list

In Member States with controlled BSE risk, the full list is applied except when the bovine animal is directly introduced from a Member State with negligible BSE risk, for immediate slaughter (within 24 hours), and where the ear tag and the intra-Union trade animal health certificate both refer to a Member State with negligible BSE risk. This can be summarised as follows:



ANNEX IV Applicable EU legislation

Updated April 2016

Introduction

An overview of the different EU legislation applicable to the removal of SRM from the bovine intestinal tract and mesentery is in the table below.

- Each reference is linked to the actual document in English on the EUR-Lex website (<u>http://eur-lex.europa.eu/en/index.htm</u>);
- If the document is required in a different language go to the <u>search engine on the</u> <u>EUR-Lex website</u>, choose natural number or consolidated text (consleg) and enter the year and number of the document. The language of the search result can be changed in the header of the page;
- Where possible the "Consolidated Text" version (consleg) will be used, as this text will be the original Directive / Regulation or Decision with the latest amendment included in the document.

Please note that the EUR-Lex website should always be checked first for the most recent consolidated version, as these may change without inclusion in this report.

Applicable EU legislation					
Reference + link	Subject	Specific text on SRM, keywords or comment			
Regulation (EC) No 999/2001 (consolidated version)	laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies	Annex V: 1. Definition of specified risk material The following tissues shall be designated as specified risk material if they come from animals whose origin is in a Member State or third country or of one of their region with a controlled or undetermined BSE risk:			
<u>Commission Regulation</u> (EC) No 2015/728	amending the definition of specified risk material set out in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies	 (a) as regards bovine animals: (i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months; (ii) the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and (iii) the tonsils, <u>the last four meters of the small intestine, the caecum and the mesentery</u> of animals of all ages. (b) as regards ovine and caprine animals (i) the skull including the brain and eyes, the tonsils and the spinal cord of animals aged over 12 months 			
Commission Regulation (EC) No 2015/1162	amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies	 or which have a permanent incisor erupted through the gum, and (ii) the spleen and ileum of animals of all ages. 2. Specific requirements for Member States with negligible risk status <u>Tissues listed in point 1.(a)(i) and 1.(b)</u>, which are derived from animals whose origin is in Member States with a negligible BSE risk, shall be considered as specified risk material. 			
Commission Decision 2007/453/EC (consolidated version)	establishing the BSE status of Member states or third countries or regions thereof according to their BSE risk	Contains a list of all countries with a BSE negligible risk status and BSE controlled risk status. Per list a specific decision tree is applicable for the removal of SRM at slaughterhouse level (Annex III). Website European Commission: TSE/BSE – impact on trade (LINK) Please check the following map (LINK) with the BSE status of the EU Member States → Here you can find the reference to the latest amendment of Commission Decision 2007/453/EC.			