codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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DISCUSSION PAPER ON GUIDELINES FOR THE APPLICATION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE TO THE RISK BASED CONTROL OF ENTEROHEMORRHAGIC *ESCHERICHIA COLI* IN GROUND BEEF AND FERMENTED SAUSAGES

Prepared by the United States, with the assistance of Australia, Austria, Canada, China, France, Germany, Japan, Netherlands, and the European Union

BACKGROUND

At the 36th Session of the Codex Committee on Food Hygiene, the Delegation of the United States introduced the *Discussion Paper on the Risk Profile for Enterohemorrhagic* Escherichia coli *(EHEC) Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork.* The Delegation of the United States informed the Committee that to proceed with this work clear guidance was needed as to the format of the risk management document to be developed and the specific food commodity to be considered. Based on the risk profile the Delegation of the United States proposed that future work focus on ground beef. The similarity, at least with respect to the ingredients, of fermented sausage to ground beef was noted and the drafting group was requested to also consider this commodity. The Committee noted that the risk profile was a good starting point to begin risk management work on EHEC but observed that several gaps still needed to be addressed. They welcomed the global approach taken in the risk profile discussion paper and highlighted the importance of primary production in the development of risk management guidance. The Committee noted that no risk assessment had yet been undertaken for this pathogen, and concluded that such an evaluation would be beneficial to the development of risk management guidance. The Committee requested that the FAO/WHO JEMRA undertake such work. However, the Committee also concluded that sufficient information were available to initiate work on the guidance document.

The Committee agreed that a drafting group led by the United States, with the assistance of Austria, Australia, Canada, China, EC, France, Germany, Japan, the Netherlands, New Zealand and Sweden would initiate the development of guidance in the format of the *Recommended International Code of Practice: General Principles of Food Hygiene*. It also agreed to change the title to "Discussion Paper on Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of Enterohemorrhagic *Escherichia coli* in Ground Beef and Fermented Sausages" (see Appendix I).

The Committee further agreed that the Working Group would develop for transmittal to FAO/WHO JEMRA specific questions and related scientific advice that should be provided in order to advance the development of the risk management guidance being developed by the Committee (see Appendix II). The purpose of this Appendix II is to outline the risk assessment questions, contributing factors, and potential interventions that the CCFH would like the JEMRA to assess.

The Committee is invited to consider documents and take decisions on the above matters.

APPENDIX I

DISCUSSION PAPER ON GUIDELINES FOR THE APPLICATION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE TO THE RISK BASED CONTROL OF ENTEROHEMORRHAGIC *ESCHERICHIA COLI* IN GROUND BEEF AND FERMENTED SAUSAGES

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INTRODUCTION

Enterohemorrhagic *Escherichia coli* (EHEC) was first identified as a human pathogen in 1982 when strains of a previously uncommon serotype, O157:H7[1], were implicated in two outbreaks of hemorrhagic colitis in the United States (1).(2) Since then, outbreaks of EHEC O157:H7 infection have occurred throughout many regions of the world, (3) as have outbreaks of infections from non-O157 serotypes of *E. coli*, including O26:H11, O111:H8, O103:H2, O113:H21, and O104:H21 (4,5). In the U.S., Mead et al. (6) have estimated the incidence of non-O157 EHEC is between 20 and 50% that of *E. coli* O157:H7 infection. [We request additional incidence data.]

Human response from EHEC ingestion ranges from asymptomatic infection to death, with the incubation period ranging from one to eight days. Illness typically begins with abdominal cramps and non-bloody diarrhea that can progress to bloody diarrhea within two to three days (7). Usually 70% or more of symptomatic patients will develop bloody diarrhea (8). Infection with EHEC may lead to further complications, most notably hemolytic uremic syndrome (HUS), the most common cause of acute renal failure in young children.

Incidence of EHEC infection varies by age group, with the highest incidence of reported cases occurring in children. Mead et al. (6) estimated 73,480 cases of *E. coli* O157:H7 infection occur annually in the U.S., of which 62,456 (85%) are a result of foodborne exposure. The incidence of *E. coli* O157 infection in the U.S. has decreased from an average of 2.3 cases per 100,000 persons during 1996-1998 to 1.1 cases per 100,000 persons in 2003 (9). [We request additional incidence data.]

EHEC have been isolated from various domestic animals and wildlife, including sheep, swine, goats, and deer (5). Cattle, however, are considered the main reservoir of EHEC. Accordingly, data based on outbreaks and sporadic infections indicate consumption of beef, including ground beef and processed beef products, is the most important source of foodborne EHEC infection. Beef was cited as the source of 46% of the foodborne outbreaks with a known vehicle of transmission in the U.S. during the years 1993 to 1999. Of the 21 beef-associated outbreaks that occurred in the U.S. during 1998-1999, ground beef was identified as the vehicle in 19 (90%). Other forms of beef have also been implicated in outbreaks of EHEC infection.

An in-depth review of infection from foodborne EHEC, including E. coli O157:H7, may be found in the accompanying annex.

SECTION I – OBJECTIVES

The primary objective in developing these guidelines is to provide practical guidance on control measures that can be employed to reduce EHEC infections associated with the consumption of ground beef and fermented sausages.

SECTION II - SCOPE

2.1 SCOPE

This code of practices focuses on measures throughout the food chain to reduce the hazards associated with EHEC in ground beef and fermented sausages containing ground beef.

[1] Throughout this document specific mention is made of *E. coli* O157:H7, which, because of its implication in the first recognized outbreak of EHEC infection, and subsequently, several other major outbreaks, coupled with its unique physiology (in terms of EHEC) thus facilitating selective enrichment of the pathogen, is the EHEC most frequently referred to and described. In most if not all instances concerning the control measures described here, *E. coli* O157:H7 may be considered synonymous with EHEC.

2.2 USE

The guidelines described here are intended to provide advice to governments for reducing/eliminating EHEC in ground beef and fermented sausages. The guidelines focus on control measures that are specific for EHEC or that require particular attention. The provisions of this document are supplemental to and should be used in conjunction with, the *Recommended International Code of Practice-General Principles of Food Hygiene,* CAC/RCP 1- 1969, Rev. 3, 1997. While intended for governments, the information provided should also prove useful to industry and other interested parties.

2.3 DEFINITIONS

Definitions of the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* and the *Proposed Draft Guidelines for the Validation of Control Measures* are used here.

For the purposes of this Code, the following expression has the meaning stated:

Entrerohemorrhagic *Escherichia coli* (EHEC). A subset of Shiga toxin-producing *E. coli*, including *E. coli* O157:H7, which typically cause bloody diarrhea (hemorrhagic colitis) and may lead to the hemolytic uremic syndrome. Only those strains which cause hemorrhagic colitis are considered to be EHEC.

SECTION III - PRIMARY PRODUCTION

EHEC, particularly *E. coli* O157:H7, is ubiquitous in dairy and beef cattle (11) and epidemiologic studies have found that cattle manure is the primary source of most human *E. coli* O157:H7 infections. [Please provide additional information on primary sources of EHEC in other areas.]

3.1 ENVIRONMENTAL HYGIENE

Water is a conduit by which EHEC may enter production units. Water trough design is particularly important. Measures should be taken to prevent cattle from standing in or defecating in water troughs. In addition, saliva in the mouth of cattle has been demonstrated to contain *E. coli* O157:H7. Thus, use of control measures specific to EHEC (e.g. antimicrobials, probiotics) should be considered as part of the control system, though the potential public health impact of antimicrobials as a control measure should be considered.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

3.3 HANDLING, STORAGE AND TRANSPORT

Where possible, calves should be housed separately from adult cattle as this practice shows evidence of reducing prevalence through the shedding of EHEC in calves. Calf susceptibility to infection from EHEC is elevated by stresses associated with weaning, transport, and relocation.

Stress and long periods of transport increase fecal shedding of EHEC. Thus, efforts to limit stress of cattle prior to and during transport should be used to reduce EHEC shedding on arrival at the feedlot.

Washing and sanitizing of trailers after each load of animals should be done to curtail EHEC spread between animals by contaminated trailers and/or bedding (12).

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Where possible, care should be taken to reduce the potential for contamination with fecal material. Illness from EHEC infection have occurred as a consequence of handling livestock or being in close proximity to grazing areas known to have been used by cattle.

Visitors should be discouraged from handling livestock or entering areas known to have been used by cattle.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

At slaughter, control of entry and contamination caused by EHEC at slaughter is based on sanitation procedures, control of cross-contamination, and inspection for visual fecal contamination. Various methods may be used during slaughter processing to reduce EHEC levels. Meat may become contaminated with EHEC when beef carcasses come into contact with contaminated hides and feces during slaughter (13).

4.1 Location

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

4.2 Premises and Rooms

Premises and rooms should be designed to limit cross-contamination by building personnel. For example, employees working in processing operations should not travel through slaughter operations.

Holding pens, ramps, unloading chutes, curbs, and runways should be constructed so to be readily and thoroughly cleaned to prevent EHEC contamination. They should be in good repair, resistant to wear, properly curbed, and well drained, with liquid wastes delivered into the plant waste system. Holding pens should be located outside of or effectively separated from the slaughtering department by full-height partitions of impervious material to avoid dust, odor, and contamination of the slaughtering area. Livestock pen capacity should be sufficient to prevent overcrowding in order to reduce the possibility of unsanitary conditions, including the possibility of transfer of fecal material from one animal to the next.

Water troughs or devices with suitable overflows should be located over or adjacent to pen floor drains, and designed to limit the opportunity for contamination with fecal material.

4.3 Equipment

Equipment should be thoroughly cleaned and sanitarily maintained throughout slaughter operations in order to reduce the potential for cross-contamination with faecal material or material from the gastrointestinal tract.

4.4 Facilities

Facilities should be designed so that air-flow proceeds from clean to less clean areas rather than vice-versa in order to reduce the potential for cross-contamination.

SECTION V - CONTROL OF OPERATION

[TEXT WILL BE ADDED ON CONTROL OF OPERATIONS FOR FERMENTED SAUSAGE.]

5.1 CONTROL OF FOOD HAZARDS

OBJECTIVE:

Slaughter and processing operations should be controlled to reduce the frequency and level of contamination by *E. coli* O157:H7 in beef, and to minimize the growth of *E. coli* O157:H7 in beef during subsequent distribution, marketing, and home use.

Rationale:

- The introduction of *E. coli* O157:H7 into the slaughter environment has resulted from inadequate prevention of transferring fecal and ingesta material from the hide and the gastrointestinal tract of cattle onto beef carcasses.
- *E. coli* O157:H7 contamination likely is present at low frequency and at a low level.
- The sporadic nature of contamination decreases the likelihood of finding the pathogen, and no indicator or index organisms are identified to accurately predict or verify the presence of this pathogen.
- The large and irregular surface of the carcass makes it difficult to sample and find contamination with *E. coli* O157:H7. Sampling manufacturing trimmings and the finished ground beef product presents a greater likelihood of finding the pathogen than does sampling the carcass.
- The process of fabricating beef carcasses into small pieces of muscle tissue whereby the contaminated exterior surfaces of muscle tissue are mixed and reduced into smaller pieces for forming into ground beef and sausages causes these products to become contaminated.

Slaughter:

Sanitary dressing procedures are some of the most important steps for controlling EHEC contamination. These procedures, together with HACCP, provide a successful framework for the control of EHEC and other pathogenic organisms.

E. coli O157:H7 is an enteric pathogen. Thus, procedures to prevent fecal contamination are the primary control measures. Innovative mitigations, such as trimming, hot water and acid washes, and steam vacuuming, should be used to reduce/eliminate faecal contamination of carcasses at slaughter. Such mitigations should be validated and verified by each establishment to demonstrate that sanitary dressing procedures are consistently performed and that the frequency of faecal contamination is reduced to low as possible.

The "dry landing" area where the stunned animals exit from the knocking box should be kept clean and dry of all blood between each animal in order to avoid the build-up of an unsanitary condition.

Hides and hooves should be decontaminated by washing and, when practical, dehairing should be performed before dehiding in order to reduce carriage of microorganisms from hides and hooves to the carcass during dehiding. Washing of hides and hooves should allow sufficient drip time to prevent drip water from becoming a vehicle for contamination during the skinning operation.

When cattle are slaughtered by the "on-the-rail" method, the "rodding" of the esophagus (weasand) should occur before head removal in order to effectively separate the muscle tissue from the esophagus. The esophagus should be effectively closed to prevent the escape of rumen contents. The weasand meat, which typically is used in the manufacture of ground beef, has been identified as a source of *E. coli* O157:H7 in manufacturing trimmings. When cattle are slaughtered by the "bed" method, the rodding of the esophagus may be deferred until the animal is positioned on the bed.

When head skinning begins, carcasses should be separated or positioned to avoid contamination of heads or other skinned areas of the neck, and should be removed as soon as possible after skinning to further reduce EHEC contamination exposure. The head and cheek meat, which typically are used in the manufacture of ground beef, have been identified as sources of *E. coli* O157:H7 in manufacturing trimmings. Heads should be removed so to avoid soiling them with rumen contents of which this ingesta may contain EHEC organisms. This can usually be accomplished by tying the esophagus and then pulling the head sharply to the side as the gullet is cut. Removal of rumen content contamination is extremely difficult because of its finely comminuted character. The individual assigned as the head skinner should clean and disinfect the knife as frequently as necessary, especially if contaminated, but at least once at the beginning of the process for each animal. Horns, all pieces of hide, and eardrums should be removed from each head prior to washing. The equipment used for holding heads for trimming and dehorning should be cleaned between each head. Heads should be washed in compartments or areas that control the splash of wastewater to prevent contamination of other heads or adjacent carcasses. The oral and both nasal cavities should be thoroughly flushed before washing the outer surfaces of each head. Lighting in the head wash cabinet or compartment should be sufficient (e.g., no less than 50-foot candles at the level of the head) in order to properly examine the heads for defects, including fecal or ingesta material.

Front and hind feet of cattle should be removed before incisions are made in the carcass. In removing the front feet, care should be taken to expose as little as possible the tissues of the foreshank and leave a "tie" of the hide completely covering the shank as far down as possible toward the carpal articulation where the cut is made to remove the foot.

Except for the original incisions for sticking and starting the skinning operations at the poll and shanks, incision into the skin should be made with the knife blade directed toward the hair side of the skin to prevent contaminating the flesh with cut hair. As the skinning operation proceeds, care should be taken so that the outside surface of the hide is continually reflected away and preferably downward from the carcass. Each area should be skinned back far enough to permit the hide to stay in a rolled-back position before the skinner proceeds to another skinning location. On-the-rail dressing operations start with the hind shanks and proceed downward while in bed dressing, skinning operations begin at the midline and shanks and proceed downward. With on-the-rail layouts, the lower skinning should not begin until the carcass has passed the points of common contact, such as hindquarter skinning platforms. Also, in this type of operation the foreshanks may be left on until the brisket and foreshanks are partially skinned. This helps to avoid shank contamination. When using mechanical hide pullers, the tremendous energy exerted during the final removal of the hide can generate aerosols. Air flow at this step in the slaughter operation should direct any aerosols created away from the carcasses being skinned to prevent contamination of the carcasses.

In all types of cattle dressing procedures, the dropping of the bung should be a final part of the rumping operation. The perineal skin should be reflected laterally over the anus, leaving the external sphincter muscle intact in order to ensure that fecal material is not released. The incision into the pelvic cavity to "ring" the bung should be made by a person with clean hands and a clean knife. Prior to evisceration, the rectum and neck of the bladder should be secured to prevent urine and fecal leakage. A plastic bag may be used for this purpose.

The tail should be skinned out without contamination to tail or carcass. Because the tail and switch may be highly contaminated with urine and manure, attention should be given to frequent hand and tool washing at this point. This is particularly important when the same person performs other tasks involving carcass contact.

Knife-trimming, washing, steam vacuuming, and spot cleaning systems can be used to remove viscera contamination. Pre-evisceration carcass washing using anti-microbial sprays may also be applied at this step.

Removal of the viscera from the carcass is a critical phase of the dressing operation. Care should be taken to avoid cutting or breaking the paunch and intestines. If carcass tissues from visceral contents become contaminated, they should be removed by trimming with a knife or cleaver, and antimicrobial application should be considered as a supplemental part of the control system.

Chilling Carcasses:

Measures to control the holding temperature of the carcass after the final wash or after any control step designed to reduce pathogenic organisms on carcasses should be in place. All carcasses should begin chilling within 1 hour from bleed-out. Refrigeration controls should be defined, established and recorded so that carcasses reach a temperature of 40 °F or less within 24 hours.

To prevent cross contamination and to allow efficient air circulation, cooler storage rails should be placed at least two feet from refrigeration equipment, walls, columns, and other fixed parts. Also, traffic or header rails during transport should be at least 3 feet from the walls. Sides of beef should be placed in the chiller so that there is no contact between them to allow efficient air circulation and to prevent cross-contamination between carcasses. Condensation should be prevented or minimized.

Application of an organic acid antimicrobial treatment on chilled carcass surfaces should be considered to supplement carcass decontamination intervention strategies initiated during pre-chill slaughter operations.

Fabrication of Carcasses:

Sorting procedures for segregating been manufacturing trimmings into those for use in raw ground beef versus fermented sausage and other ready-to-eat products are some of the most important steps for reducing the potential for human exposure to EHEC contamination. Typically, steaks, roasts, and processed products including sausage are either adequately processed or cooked by food establishment operators or by the consumer to result in a safe product. However, raw ground beef requires additional control measures throughout the production process, from the farm to the table, because consumers prefer such product to be undercooked for purposes of quality. Consequently, additional care should be taken to ensure that contamination with EHEC organisms is as low as feasible, particularly on beef manufacturing trimmings for use in raw ground beef production.

Beef manufacturing trimmings for use in raw ground beef may be additionally treated with antimicrobials for reducing the level of *E. coli* O157:H7 beyond those used at slaughter.

In order to effectively ensure that EHEC contamination is as low as feasible, beef manufacturing trimmings should be sampled and tested in a manner to find low levels of contamination and to divert potentially positive material to ready-to-eat product (e.g., fermented sausage) rather than to use as raw ground beef. Such mitigations and sampling procedures should be validated and verified by each establishment to demonstrate that the mitigations are consistently performed and that the frequency of contamination is reduced to low as possible (NOTE: An annex should be developed to provide appropriate guidance on the design of a sampling and testing program for EHEC in manufacturing trimmings).

Temperature of the carcass fabrication room should be maintained at 50 °F or lower and product should be handled as quickly as possible. Limiting the temperature of the room and the time product is exposed to the environment will facilitate minimization of the growth of EHEC organisms.

Measures should be implemented to prevent cross contamination from traffic and from people in the carcass fabrication room.

Cross-contamination from airflow in the carcass fabrication room should be prevented.

Carcasses for hot boning (deboned before chilling) should be transported to the boning areas directly from the slaughter department. The boning room environmental temperature should remain at 50 °F (10 °C) or lower, and boning should not be delayed.

Grinding:

Some establishments producing raw ground beef product don't slaughter cattle or fabricate carcasses but purchase boneless manufacturing trimmings. Such establishments can control for the presence of EHEC organisms by limitations placed on the suppliers of source materials. These establishments may use purchase specifications to ensure receipt of source materials that have undergone interventions that eliminate or reduce *E. coli* O157:H7 to an undetectable level. The establishment with purchase specifications should ask for documentation from the suppliers accompanying the product showing that the purchase specifications are being met. The receiving establishment should verify that the purchase specifications are being met. A grinding establishment that has a purchase specification program and is receiving source materials for grinding from an establishment that is utilizing a validated pathogen reduction intervention on beef carcasses and routinely verifying the intervention through *E. coli* O157:H7 testing should receive documentation from the supplier stating that a validated intervention is being used, and that the intervention is operating effectively as shown by negative tests for the pathogen during verification testing.

For raw ground beef, irradiation is one of the most effective treatments for eliminating *E. coli* O157:H7. Other antimicrobial treatments are not as effective for raw ground beef due to the high level of antimicrobial needed to treat the increased surface area of ground product compared to manufacturing trimmings and steaks and roasts, resulting in enhanced labeling considerations. For fermented sausages, an adequate lethality can be delivered by heat or other treatments to assure at least a 5-log inactivation or an equivalent process when used in combination with HACCP and a Good Manufacturing Practice for fermented sausage.

For general guidelines on the use of systems such as HACCP, see *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

5.2 Key Aspects of Hygiene Control Systems

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

5.3 Incoming Material Requirements

Slaughter facilities should identify and obtain cattle from farms or feedlots known to use production systems and controls demonstrated to reduce carriage of EHEC by cattle.

Incoming animals should be visually inspected to ensure minimal mud and faecal contamination.

Also see *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

5.4 Packaging

Finished product storage areas should not exceed 40 °F.

Also see *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

5.5 Water

For guidelines regarding use of potable water in food handling and processing, see *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

5.6 MANAGEMENT AND SUPERVISION

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

5.7 DOCUMENTATION AND RECORDS

Timely and accurate recordkeeping is essential at slaughtering facilities. Sound and detailed records facilitate trace-back and trace-forward investigations should there arise a public health risk associated with the establishments product. Establishments should strive to record (i) farm sources and practices associated with their cattle, (ii) control and intervention methods used during slaughter operations, and (iii) product disposition.

Slaughter and processing operations should develop a lotting system to code and track beef, from incoming raw material source to finished product.

5.8 RECALL PROCEDURES

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 MAINTENANCE AND CLEANING

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

6.2 CLEANING PROGRAMMES

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

6.3 PEST CONTROL SYSTEMS

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

6.4 WASTE MANAGEMENT

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

6.5 MONITORING EFFECTIVENESS

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

7.1 HEALTH STATUS

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

7.2 ILLNESS AND INJURIES

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

7.3 PERSONAL CLEANLINESS

Particular attention should be paid to the cleanliness of the hands and clothing of employees assigned to handling the carcasses during hide opening and removal, feet and head removal, and evisceration. Touching the hide and then touching the carcass without cleaning and sanitizing the hands or protective clothing could serve as a source of contamination.

Also see *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

7.4 PERSONAL BEHAVIOUR

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

7.5 VISITORS

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

SECTION VIII - TRANSPORTATION

8.1 GENERAL

Storage room and transportation vehicle temperature should be maintained at 40 °F or lower, as should the average internal meat temperature. All temperatures should be frequently monitored.

Opportunity for contamination from airflow, traffic and from people, and other environmental sources should be minimized.

8.2 REQUIREMENTS

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

8.3 USE AND MAINTENANCE

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

Slaughter and processing operations should develop a lotting system to code and track beef, from incoming raw material source to finished product.

9.2 PRODUCT INFORMATION

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

9.3 LABELLING

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

9.4 CONSUMER EDUCATION

Food preparation practices and consumer behavior affect the probability of contracting an EHEC infection. Aggressive efforts should be made to discourage consumption of products made from raw minced beef, such as “tartare” steak and beef “americaine.” Use of a food thermometer should be encouraged in order to accurately determine whether the cooked beef is safe. Color of cooked ground beef should not be used as an indicator of doneness.

Consumer education efforts should stress awareness of and precautions against cross-contamination between raw meat products and either cooked foods or raw vegetables and fruit.

SECTION X - TRAINING

10.1 Awareness and Responsibilities

Use of Good Agricultural Practices, Good Manufacturing Practices, Quality Assurance programs, and HACCP measures should be strictly adhered to reduce prevalence and levels of EHEC in ground beef and fermented sausages. Workers throughout the food production continuum, including farmers, manufacturers, and retailers should continue to educate themselves and their employees on how to implement and correctly use these measures.

Also see *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

10.2 Training Programmes

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

10.3 Instruction and Supervision

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

10.4 Refresher Training

See *Recommended International Code of Practice – General Principles of Food Hygiene* (10).

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ANNEX: Revised Risk Profile for Enterohemorrhagic *Escherichia coli* in Ground Beef and Fermented Sausages

Prepared by the United States, with the assistance of Australia, Austria, Canada, China, France, Germany, Japan, Netherlands, and the European Union

Background

At the 36th Session of the Codex Committee on Food Hygiene, the Delegation of the United States introduced the *Discussion Paper on the Risk Profile for Enterohemorrhagic* Escherichia coli *(EHEC) Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork* (Agenda Item 10b)22. The Delegation of the United States informed the Committee that in order to proceed with this work clear guidance was needed as to the format of the risk management document to be developed and the specific food commodity to be considered. Based on the risk profile the Delegation of the United States proposed that future work focus on ground beef. The similarity, at least with respect to the ingredients, of fermented sausage to ground beef was noted and the drafting group was requested to also consider this commodity. The representative of the World Health Organization noted that the biggest outbreak of food borne illness caused by EHEC was linked to sprouts and cautioned the Committee against limiting its work to one commodity only.

The Committee noted that the risk profile was a good starting point to begin risk management work on EHEC but observed that several gaps still needed to be addressed. They welcomed the global approach taken in the risk profile discussion paper and highlighted the importance of primary production in the development of risk management guidance. The Committee noted that no risk assessment had been undertaken for EHEC and suggested this could be the next step.

The Committee agreed that the drafting group led by the United States, with the assistance of Austria, Australia, Canada, China, EC, France, Germany, Japan, the Netherlands, New Zealand and Sweden would progress with the development of this paper in the format of the *Recommended International Code of Practice: General Principles of Food Hygiene* together with an annex. The Committee agreed that the Working Group would take a systematic approach to reviewing the available information and, according to the type of risk management document to be developed, identify very specific questions for any necessary risk assessment work or specific scientific advice. It also agreed to change the title to "Discussion Paper on Guidelines for the Application of the General Principles of Food Hygiene to the Risk Based Control of Enterohemorrhagic *Escherichia coli* in Ground Beef and Fermented Sausages."

Scope

This risk profile follows the general format of the *Recommended International Code of Practice: General Principles of Food Hygiene.* As such, it focuses on EHEC throughout the food chain, from primary production to the final consumer. The paper focuses on EHEC in ground beef and fermented sausage, though other commodities are included for contextual purposes. The paper includes an overview international guidance documents and codes of practice likely to mitigate the occurrence of EHEC infection in humans together with risk management activities for consideration by Codex Committee on Food Hygiene.

Pathogen of Concern

Enterohemorrhagic *Escherichia coli* (EHEC).

Commodities of Concern

The commodities of concern for this risk profile are ground beef and fermented sausage, as recommended by the Committee at its 36th Session.

Epidemiology of EHEC Infection

E. coli strains pathogenic for humans are characterized as enteropathogenic *E. coli* (EPEC), enterotoxigenic *E. coli* (ETEC), enteroinvasive *E. coli* (EIEC), diffusely-adherent *E. coli* (DAEC), enteroaggregative *E. coli* (EaggEC), and enterohemorrhagic *E. coli* (EHEC). The EHEC group comprises a subset of Shiga toxin-producing *E. coli* (STEC), which includes strains of *E. coli* that cause bloody diarrhoea and which produce either Shiga toxin 1 (Stx1), Shiga toxin 2 (Stx2), or both. Some EHEC strains also contain genes that encode for the ability to attach to and damage intestinal tract cells, causing what is commonly referred to as attaching-and-effacing lesions. For a detailed review of the pathogenesis of EHEC and other STEC, see Paton and Paton (1) and Nataro and Kaper (2).

EHEC were first identified as human pathogens in 1982 when strains of a previously uncommon serotype, O157:H7, were implicated in two outbreaks of hemorrhagic colitis (bloody diarrhoea) in the United States (3,4) Since then, outbreaks of EHEC O157:H7 infection have occurred throughout many regions of the world, (5) as have outbreaks of infection from non-O157 serotypes of *E. coli*, including O26:H11, O111:H8, O103:H2, O113:H21, and O104:H21 (6,7). In the U.S., Mead et al. (8) have estimated the incidence of non-O157 EHEC is between 20 and 50% that of *E. coli* O157:H7 infection.

Disease Characteristics

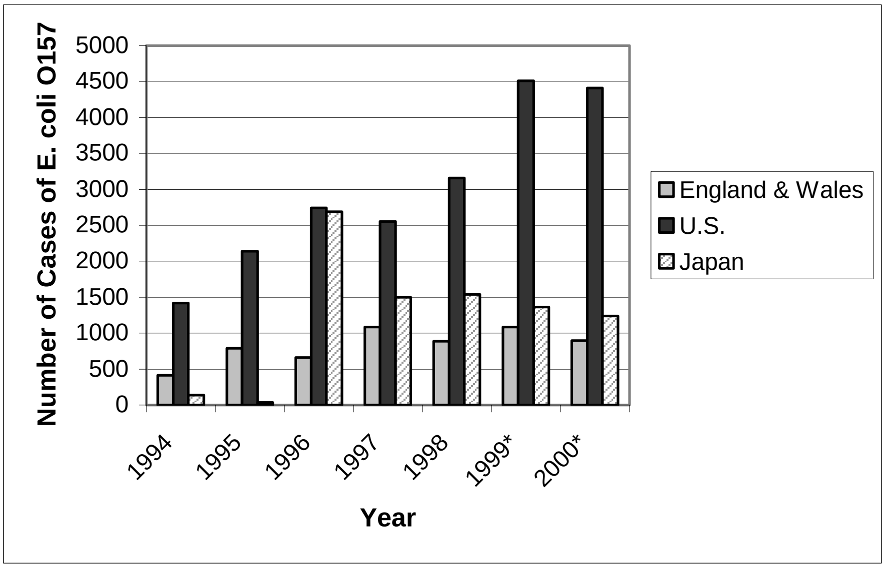
Human response from EHEC ingestion ranges from asymptomatic infection to death, with the incubation period ranging from one to eight days. Asymptomatic shedding of EHEC occurs (9), but the proportion of exposed individuals who shed EHEC but do not develop symptoms is unknown. Illness typically begins with abdominal cramps and non-bloody diarrhoea that can progress to bloody diarrhoea within two to three days (10). Usually 70% or more of symptomatic patients will develop bloody diarrhoea (11). More severe manifestations of EHEC infection include hemorrhagic colitis (HC), hemolytic uremic syndrome (HUS), and occasionally, thrombotic thrombocytopenic purpura (TTP).

Symptoms of HC include severe abdominal cramps followed by grossly bloody diarrhoea and edema, erosion, or haemorrhage of the mucosal lining of the colon; complications include upper-gastrointestinal bleeding and stroke (12). Approximately 30 to 45% of patients are hospitalized (11,13). Of the 631 cases ascertained by the U.S. Centers for Disease Control and Prevention (CDC) in 1999, 39% were hospitalized (14). HUS, meanwhile, is the most common cause of acute renal failure in young children, yet it also has long-term complications. Siegler et al. (15) found that HUS causes chronic renal sequelae, usually mild, in 51% of survivors (48% of all cases) however, Elliot et al. (16) have observed significantly lower renal failure statistics in Australia. Neurological complications occur in about 25% of HUS patients (10). Generally, neurological symptoms are mild, but serious complications, such as seizure, stroke and coma, can occur (12). Similar to treatment for EHEC infection, only symptomatic treatment for neurological complications is available, making this manifestation of HUS especially dangerous and an important cause of death in HUS patients. Other complications of HUS include pancreatitis, diabetes mellitus and pleural and pericardial effusions (10). In a nationwide study of HUS patients, 46 (55%) of 83 patients required either peritoneal dialysis or haemodialysis during the acute phase of their illness (17). Siegler et al. (15) found that severe kidney or neurological impairments (end stage renal disease or stroke) occurred in 9 (5.7%) of *E. coli* 157:H7 HUS cases over a 20-year period in Utah. Various studies have suggested the mortality rate associated with HUS is between 3 and 7% (15,17-19).

Incidence of Infection

The incidence of EHEC infection varies by age group, with the highest incidence of reported cases occurring in children. However, the elderly are also at increased risk for EHEC infection. Using surveillance data, and accounting for the factors that contribute to underreporting, Mead et al. (8) estimated 73,480 cases of *E. coli* O157:H7 infection occur annually in the U.S. of which 62,456 (85%) are a result of foodborne exposure. During 1994-2000, the number of reported cases of *E. coli* O157:H7 in the U.S. increased more than two-fold from 1,420 (0.8/100,000 people) in 1994 to 4,410 (approximately 1.6/100,000 people) in 2000 (20). Cases in the U.S. are reported by passive surveillance through the National Notifiable Diseases Surveillance System (NNDSS).[2] This is a passive surveillance system in which health care providers report notifiable disease cases to local or state health departments. Other national or regional surveillance systems include 1) Enter-net[3] which includes a catchment area of 15 European Union (EU) member states as well as Switzerland and Norway, 2) The Communicable Disease Network Australia – National Notifiable Surveillance System,[4] 3) Japan's Statistics on Communicable Diseases in Japan (former Ministry of Health and Welfare) and the National Epidemiological Surveillance of Infectious Diseases (NESID) which are reported in Infectious Agents Surveillance Reports[5] and 4) the EU's Zoonoses Reporting System.[6] In addition to these surveillance systems, the EU, Japan and U.S. have each developed a pulsed-field gel electrophoresis (PFGE) database to assist in epidemiological investigations of disease from this and other bacteria. The increase in reported cases of *E. coli* O157:H7 over time is probably due to a combination of factors, including 1) improvement in the effectiveness of the surveillance system over time, 2) increased awareness of *E. coli* O157:H7 infection among health care providers and the public leading to improved detection and reporting, 3) enhanced ability to detect disease through better diagnostic tests (see text box), and 4) a true increase in the incidence of disease. Figure 1 illustrates the rising incidence of *E. coli* O157:H7 infection in three different regions of the world.

Figure 1. Number of reported cases of *E. coli* O157:H7 infection, U.S. (1994-2000),[a] England and Wales (1994-2000),[b] and Japan (1996-2000).[c]



a) CDC, NNDSS; Cases include suspect and confirmed human isolations.
b) PHLS Laboratory of Enteric Pathogens; Cases include only isolates, obtained from stool samples, that are submitted to PHLS from laboratories in England and Wales. They are confirmed, serotyped, phage typed and VT typed at PHLS.
c) Ministry of Health and Welfare, National Epidemiological Surveillance of Infectious Diseases; Cases are restricted to those with stool samples that have been culture confirmed and include all O157 serotypes.

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[2] http://www.cste.org/nndss/reportingrequirements.htm
[3] http://www.phls.org.uk/topics_az/ecoli/data.htm
[4] http://www.health.gov.au/pubhlth/cdi/nndss/year054.htm
[5] http://idsc.nih.go.jp/iasr/22/256/tpc256.html; http://idsc.nih.go.jp/index.html; Note that in the former system, known as the Ministry of Health and Welfare, communicable diseases in Japan were reported in "Statistics on Communicable Diseases in Japan" and, during a transitional period, in the "Annual Report on National Epidemiological Surveillance of Infectious Diseases". The new system, known as the National Epidemiological Surveillance of Infectious Diseases (NESID), publishes "Infectious Agents Surveillance Reports" monthly describing pathogen isolates and related information and "Infectious Disease Surveillance Data" annually describing notified human cases (IDSD is currently only available by CD-ROM format).
[6] EU Council Directive 92/117/EEC; http://europa.eu.int/eur-lex/en/com/pdf/2001/en_501PC0452_01.pdf

In 1996, the Emerging Infection Program Foodborne Diseases Active Surveillance Network (FoodNet) began a program of active surveillance of clinical laboratories for specific foodborne diseases, including *E. coli* O157:H7. Five states in the U.S. participated initially (Minnesota, Oregon, and selected counties of California, Connecticut and Georgia) (21). As of 2000, the areas under active surveillance included 8 states representing 29.5 million persons (10.8% of the 1999 U.S. population). The number of cases of *E. coli* O157:H7 infection reported annually to FoodNet ranged from 388 in 1996 to 631 in 2000 (14,21). Because the population under surveillance has increased, it is more appropriate to compare the number of reported cases per 100,000 persons in a population.

Data on the prevalence of symptomatic *E. coli* O157:H7 infection prior to the inception of FoodNet are scarce and include studies which estimate between two and 10 cases for every 100,000 persons (22,23). The higher estimates obtained in some of these studies is likely a consequence of the active method for data collection and may provide a more accurate estimate of the incidence of *E. coli* O157:H7 infection thereby suggesting that state-wide passive surveillance programs are hindered by underreporting.

Disease Progression

The percent of *E. coli* O157:H7 infections which progress to HUS varies between sporadic cases and those associated with outbreaks. Between 3 to 7% of sporadic, and 20% or more of outbreak associated cases of *E. coli* O157:H7 infection will progress to HUS (10). The proportion of patients who develop HUS following *E. coli* O157:H7 infection is influenced by a variety of factors including age, bloody diarrhoea, fever, elevated leukocyte count, and toxin type (24). Wong et al. (25) found that 10 (14.1%) of 71 children with *E. coli* O157:H7 infection developed HUS. Similarly, the severity of HUS illness may differ between sporadic cases and those associated with outbreaks; outbreaks often resulted in a shorter diarrhoeal prodrome, a higher rate of bloody diarrhoea and severe hemorrhagic colitis (16).

Between 1997 and 1999 at FoodNet sites located within the U.S., the overall incidence of HUS among children younger than 15 years of age was 0.7 per 100,000; this was similar to the frequency observed in other nations such as Austria (0.65 per 100,000) and Australia (0.64 per 100,000) (16). For children younger than 5, the incidence was 1.4 and 1.35 per 100,000 in the U.S. and Australia respectively (14). In a nationwide study of 83 patients with HUS in the U.S., 46 (55.4%) were younger than 5 years old and an additional 27 (32.5%) were 5 to 17 years old (17). In 1999, 35.3% of reported HUS cases in the U.S. occurred in 1- to 10-year-olds, 17.6% of cases occurred in 10- to 20-year-olds, and 14.1% of cases occurred in persons older than 60 (14). A national study of post-diarrhoeal HUS in the U.S. estimated that $\leq$ 20% of HUS cases were due to non-O157 EHEC; however, the authors qualified that estimate, commenting that it was difficult to determine the proportion of EHEC-associated HUS due to non-O157 EHEC (17). In Australia, between July 1994 and June 1998, only 8% of the EHEC associated cases of HUS were the result of *E. coli* O157 infection (16). This suggests that while illness from HUS is similar on different continents, the predominant EHEC serotype responsible may vary.

Occasionally, patients with EHEC infection develop thrombotic thrombocytopenic purpura (TTP), a condition similar to HUS but one which is more likely to occur in adults and with more prominent neurological findings and less renal involvement than HUS. In a study by Banatvala et al. (2001), of 73 children and 10 adults that met the case definition of HUS, 8 (11.0%) children and 8 (80.0%) adults also met the case definition for TTP; none of the 8 children, but 2 (25%) of the adults, died. That said, it should also be noted that there are causes of TTP other than the association with EHEC, and that prior to the 1980s, gastrointestinal infections were not strongly implicated in the pathogenesis of TTP. Indeed, some evidence suggests that when associated with EHEC infection, TTP is probably the same disorder as HUS (10).

While the incidence of HUS is similar on different continents, the EHEC serotypes responsible for the syndrome may vary. Serotype O157:H7 however, remains as the prototypic EHEC strain and responsible for the majority of EHEC infections, as well as the leading cause of HUS worldwide. A number of national and regional disease surveillance systems record *E. coli* O157:H7 infections. Recently, the U.S. CDC has also included all Shiga toxin-producing *E. coli* on their surveillance list. A critical part of that effort is detection and improved diagnostic tests, such as polymerase chain reaction (PCR) assays for Shiga toxin genes has augmented our ability to detect EHEC in environmental samples, foods and water. Such assays offer quicker turn-around time and improved sensitivity, however, it is important to bear in mind that the implementation of new diagnostic tests may give rise to other complications (e.g., inability to compare incidence data generated by culture-based versus PCR-methods). Also, the financial costs of equipment, reagents and personnel training required to implement newer diagnostic technologies may render them impractical for developing countries.

Survival of EHEC in Food

Temperature, pH, salt, and water activity influence the survival and growth of EHEC in food (7). Studies on the thermal sensitivity of *E. coli* O157:H7 in ground beef indicate the pathogen has no unusual resistance to heat and that heating ground beef sufficiently to kill typical strains of *Salmonella* will also kill *E. coli* O157:H7. The optimal temperature for growth of *E. coli* O157:H7 is approximately 37^{o}C (98.6^{o}F), and the organism will not grow at temperatures below 8°C to 10°C (46^{o}F to 50^{o}F) or above 44^{o}C to 45^{o}C (26,27). *E. coli* O157:H7 survives freezing, with some decline in the concentration of *E. coli* O157:H7 (28).

E. coli O157:H7 has been reported to be more acid-resistant than other *E. coli*. Acid resistance may thus enhance the survival of EHEC in mildly acidic foods and may thus explain their ability to survive passage through the stomach. However, the extent of acid-resistance varies among EHEC strains and is influenced by growth phase and other environmental factors. Once induced, acid resistance is maintained for long periods of time during cold storage, and stationary-phase *E. coli* O157:H7 are more resistant than growing cells to acid (7). The presence of other environmental stresses, such as temperature or water activity stress will raise the minimum pH for growth (26). *E. coli* O157:H7 survives in such foods as dry salami, apple cider, and mayonnaise, which were previously considered too acidic to support the survival of foodborne pathogens. *E. coli* O157:H7 can also survive for extended periods under conditions of reduced water activity while refrigerated; however, it does not tolerate high salt conditions (26).

Vehicles of Infection

Food vehicles implicated most frequently in outbreak of EHEC infection have been raw or undercooked foods of bovine origin, especially undercooked hamburgers and unpasteurised milk, though an increasing number of outbreaks have been associated with the consumption of raw or minimally processed fruits and vegetables (Table 1).

Table 1. Examples of documented food- and waterborne outbreaks of infection from Enterohemorrhagic *Escherichia coli* (EHEC), worldwide, 1982-2002.[a]

YEAR (MONTH)	SEROTYPE	LOCATION	SETTING	VEHICLE	NO. CASES (DEATHS)	REFERENCE
1982 (FEBRUARY)	O157:H7	OREGON, U.S.	COMMUNITY	GROUND BEEF	26	(3)
1982 (MAY)	O157:H7	MICHIGAN, U.S.	COMMUNITY	GROUND BEEF	21	(3)
1984 (SEPTEMBER)	O157:H7	NEBRASKA, U.S.	NURSING HOME	GROUND BEEF	34 (4)	(29)
1985	O157:H7	CANADA	NURSING HOME	SANDWICHES	73 (17)	(30)
1987 (JUNE)	O157:H7	UTAH, U.S.	INSTITUTIONS FOR MENTALL	GROUND BEEF/PERSON-TO-	51	(31)

Year (Month)	Serotype	Location	Setting	Vehicle	No. Cases (Deaths)	Reference
			y retarded persons	person		
1988 (October)	O157:H7	Minnesota, U.S.	School	Precooked ground beef	54	(32)
1989 (December)	O157:H7	Missouri, U.S.	Community	Water	243 (4)	(33)
1990 (July)	O157:H7	North Dakota, U.S.	Community	Roast Beef	65	(34)
1990 (September – November)	O157:H7	Saitama, Japan	Nursery	Drinking water	42 (2)	(35-37)
1991 (November)	O157:H7	Massachusetts, U.S	Community	Apple cider	23	(38)
1992 (?)	O119:?	France	Community	Goat cheese	>4	(39)
1993 (January)	O157:H7	California, Idaho, Nevada, and Washington, U.S.	Restaurant	Ground beef	732 (4)	(7,11,40)
1993 (July)	O157:H7	Washington, U.S.	Church picnic	Pea salad	16	(7)
1993 (August)	O157:H7	Oregon, U.S.	Restaurant	Cantaloupe	27	(7)
1994 (February)	O104:H21	Montana, U.S.	Community	Milk	18	(41)
1994 (May)	O157:H7	Edinburgh, Scotland	Community	Milk	71 (1)	(42)[B] (43)
1994 (November)	O157:H7	Washington and California, U.S.	Home	Salami	19	(44)
1995	O157:H7[C]	Fife, Scotland	Community	Drinking water	633[C]	(36,45)
1995 (February)	O111:NM	Adelaide, Australia	Community	Semidry sausage	>200	(46)

Year (Month)	Serotype	Location	Setting	Vehicle	No. Cases (Deaths)	Reference
1995 (October)	O157:H7	Kansas, U.S.	Wedding	Fruit salad/punch	21	(7)
1995 (November)	O157:H7	Oregon, U.S.	Home	Venison jerky	11	(47)
1995 (July)	O157:H7	Montana, U.S.	Community	Lettuce	74	(48)
1995 (September)	O157:H7	Maine, U.S.	Camp	Lettuce	37	(7)
1995 (December) – 1996 (March)	O157:H-	Bavaria, Germany	Throughout Bavaria[D]	Commercial mortadella and teewurst?	28 (3)	(49)
1996	O118:H2	Komatsu, Japan	School	Luncheon (salad?)	126	(50,51)
1996 (July)	O157:H7	Osaka, Japan	Community	White radish sprouts	7,966 (3)	(50)
1996 (October)	O157:H7	California, Washington, and Colorado, U.S., and British Columbia, Canada	Community	Apple juice	71 (1)	(52)
1996 (November)	O157:H7	Central Scotland	Community	Cooked meat	<501 (21)	(53,53)
1997 (May)	O157:H-	Scotland	Hospital	Cream cakes	12	(54)
1997 (July)	O157:H7	Michigan, U.S.	Community	Alfalfa sprouts	60	(7)
1997 (July/August)	O26:H11	Southeastern Japan	Day care center	Prepared foods, vegetables?	32	(55)
1997 (November)	O157:H7	Wisconsin, U.S.	Church banquet	Meatballs, coleslaw	13	(7)

Year (Month)	Serotype	Location	Setting	Vehicle	No. Cases (Deaths)	Reference
1998 (May/June)	O157:H7	New Hampshire, Massachusetts, Maine, and Rhode Island, U.S.	Community	Ground beef	22 (1)	(20)
1998 (June)	O157:H7	Wisconsin, U.S.	Community	Cheese curds	63	(56)
1998 (June)	O157:H7	Wyoming, U.S.	Community	Water	114	(57)
1998 (July)	O157:H7	North Carolina, U.S.	Restaurant	Cole slaw	142	(7)
1998 (July)	O157:H7	California, U.S.	Prison	Milk	28	(7)
1999 (March)	O157 PT^{E}21/28	North Cumbria, Great Britain	Community	Milk	114	(58)
1999 (May, June, July)	O157:?	Applecross, Scotland	Campsite	Drinking water	6	(59)
1999 (June)	O157 PT^{E}2	North Wales	Farm festival	Ice cream, cotton candy	24	(60)
1999 (July)	O111:H8	Texas, U.S.	Cheerleading camp	Lunch, ice, corn, dinner roll	55	(61)
1999 (August)	O157:H7	New York, U.S.	Fair	Well water	900 (2)	(62)
1999 (September)	O157:?	Göteberg, Sweeden	Hospital staff party	Lettuce	11	(63)
1999 (September)	O157:H7	Illinois, U.S.	Pig roast	Steer	323	(64)
1999 (October)	O157:H7	Ohio, U.S.	Community	Ground beef	8 (1)	(64)
1999 (November)	O157:H7	California,	Restaurant	Beef tacos	13	(65)

Year (Month)	Serotype	Location	Setting	Vehicle	No. Cases (Deaths)	Reference
		Nevada, and Arizona, U.S.				
2000 (March and April)	O26:H11	Mecklenburg-West Pomerania, Lower Saxony, Hesse, Germany	Day care center	Beef ("Seemerolle")?	11	(66)
2000 (May)	O157:H7[F]	Walkerton, Ontario	Community	Drinking water	2,300[E] (7)	(36,67-69)
2000 (June)	O157:H7	Texas, U.S.	Prison	Gravy	45	(70)
2000 (July)	O157:H7	Wisconsin, U.S.	Restaurant	Watermelon, sirloin tips	736 (1)	(70)
2000 (October)	O157:H7	California, U.S.	Community	Red grapes	14	(70)
2001 (July)	O157:H7	Illinois, U.S.	Private home	Ground beef	19 (0)	(71)
2001 (November)	O157:H7	North Carolina, U.S.	School	Butter/ milk[G]	202	(71)
2001 (November)	O157:H-	Eastern Slovakia	Extended family	Milk	9	(72,73)
2001 (November/ Dec-ember)	O157 PT[E]21/ 28	Lancashire, Great Britain	Butcher's shop	Cooked meats	30	(74)
2002 (June/July)	O157:H7	Colorado, California, Iowa, Michigan, South Dakota, Washington, and Wyoming, U.S.	Community	Ground beef	28	(45)

[a]Adapted from Schroeder and Meng (75).

[b]Roberts and Upton (43) provided fascinating and detailed insight into the costs associated with this milkborne outbreak of *E. coli* O157:H7 infection. General medical practice costs per case of *E. coli*

O157:H7 infection were estimated at £135 (ca. US$205 in May 1994). Average costs associated with hospitalization were estimated at £8,417 (ca. $12,766). When projected over thirty years to account for persons likely to experience long-term renal damage, the total costs associated with the outbreak were estimated at an eye-opening £11.9m (ca. $18,048,730) or £168,032 (ca. $254,854) per case.

[c]Outbreak defined based on hospital admission record review for children admitted with the hemolytic uremic syndrome (HUS) to the four paediatric haemodialysis centres in Bavaria from 1990 to March 1996.

[d]In addition to *E. coli* O157:H7, *Campylobacter* spp. were implicated in the Fife waterborne outbreak. Infection with *Campylobacter* and *E. coli* O157:H7 was culture-confirmed in eight and six persons, respectively. Two of the persons with confirmed *E. coli* O157:H7 infection developed the hemolytic uremic syndrome (HUS) (36,76).

[e]PT, phage type.

[f]In addition to *E. coli* O157:H7, *Campylobacter jejuni* and *C. coli* were implicated in the Walkerton waterborne outbreak. Although it is not possible to apportion the precise number of the ca. 2,300 outbreak cases due to each of these pathogens, insight may be gleaned from the following observations: of the 675 cases for which a stool sample was obtained, 163 (24%) were positive for *E. coli* O157, 97 (14%) were positive for *C. jejuni*, and 7 (1%) were positive for *C. coli*; of the seven persons who died as a result of the outbreak, five developed the hemolytic uremic syndrome (HUS); and stool cultures from the five HUS cases showed that three were infected with *E. coli* O157:H7, two with *C. jejuni* (36,68,77).

[g]The source of this outbreak was traced to a "tasting" event held in the school gym. The food was brought to the school and prepared by a local community member. As a result of these and other findings from the outbreak investigation, the North Carolina Department of Environment and Natural Resources recommended that, in general, schools not allow persons to bring in foods from non-commercial sources. Specifically, they recommended against allowing the following foods to be brought from home: ground beef and ground beef-containing products, venison, and unpasteurized milk and/or juices (78,79).

Multiple case-control studies have indicated ground beef as a predominant risk factor for EHEC infection (Table 2). Dry fermented meats have also been implicated in reported outbreaks of EHEC infection (80). Cooked and fermented sausages have also been implicated in outbreaks of EHEC infection (49).

Table 2. Case-control studies implicating ground beef as a vehicle of infection with Enterohemorrhagic *Escherichia coli* (EHEC).

Study Type	Findings	Reference
Case-control, sporadic illness	Consumption of ground beef with "pink center" had 34% population attributable risk.	(81)
Case-control, sporadic illness	45% of ill persons consumed ground beef with "pink center" in the preceding week while only 33% of controls did the same.	(82)
Case-control, sporadic illness	Ground beef with "pink center" was a statistically significant risk factor while consumption of just ground beef was not.	(83)
Prospective study	Rare ground beef was consumed more often by ill persons than healthy persons.	(23)
Case-control, sporadic illness	Consumption of undercooked ground beef had an attributable risk factor of 17%.	(13)

Ground beef was identified as the transmission source in seven of 13 (53.9%) outbreaks that occurred between 1982 and 1993 in the U.S. (24). Beef was cited as the source of 46% of the foodborne outbreaks with a known vehicle of transmission in the U.S. during the years 1993 to 1999. Of the 21 beef-associated outbreaks that occurred during 1998-1999, ground beef was identified as the vehicle in 19 (90%). Five (26%) of the 19 ground beef/hamburger-associated outbreaks occurred in multiple states. Two outbreaks in 1999 were attributed to roast beef and one of these was a result of environmental contamination from manure in a pasture where a picnic was held.

Other products of bovine origin that have been implicated in a number of outbreaks of EHEC infection include raw and improperly pasteurised cow's milk, as was demonstrated by an *E. coli* O104:H21 outbreak from contaminated milk (84). Milkborne outbreaks mostly have been associated with the consumption of raw milk or milk products from local farms. Raw milk is often contaminated with enteric organisms during its collection and may result in a direct risk for consumers choosing to drink raw milk. It should be emphasized, however, that effective pasteurisation eliminates pathogens from milk, including EHEC.

Fruits and vegetables contaminated with EHEC have accounted for a growing number of recognized outbreaks. As a whole, leafy green vegetables were cited as the source of 26% of foodborne outbreaks with a known vehicle of transmission in the U.S. during the years 1998 to 1999. Contamination of vegetables may occur in several ways, including use of manure or water contaminated with fecal matter as fertilizer (85-87) and through handling by workers with poor health and hygiene. The fact that fresh produce is minimally processed and consumed raw increases the likelihood of EHEC infection. Use of good management practices (GMPs), such as those aimed at ensuring water quality, worker health and hygiene, pest control, and proper sanitation, provides the cornerstone for minimizing food safety hazards from EHEC in fresh vegetables and fruits (88).

Other important risk factors for contracting EHEC infection are exposure to farm animals or the farm environment, eating at a table service restaurant, using immune suppressive medication (for adults only), and obtaining beef through a private slaughter arrangement (83). However, current data based on outbreaks and sporadic infections indicate consumption of ground beef remains the single most important source of foodborne EHEC infection. Leafy green vegetables are the second most significant cause of human foodborne illness cases of EHEC as they are subject to contamination and they are eaten raw.

Having reviewed various aspects of EHEC infection, this document now summarizes data available EHEC from the farm-to-table continuum, beginning with primary production and ending with consumption. Key data gaps are indicated; filling these gaps would greatly strengthen any risk assessment undertaken for human illness from EHEC in ground beef and fermented sausage.

PRIMARY PRODUCTION

EHEC have been isolated from the faeces or gastrointestinal tracts of cattle, sheep, horses, pigs, turkeys, dogs, and a variety of wild animal species (7,89-93); consequently, foods associated either directly or indirectly with animals (meat or dairy products) or foods subject to contamination by animal waste products (for instance, via manure fertilizers) are frequently implicated as vehicles of transmission for human illness. Epidemiological studies have found that cattle manure is the primary source of most human *E. coli* O157:H7 infections. In fact, *E. coli* O157:H7 has been described as ubiquitous in dairy and beef cattle and is present at least occasionally on most farms or feedlots (94,95). Factors contributing to the presence of *E. coli* O157:H7 in cattle include its ability to survive for at least 4 months in water trough sediments (94); and its presence in animal feeds (95).

Many risk factors thought to influence EHEC prevalence and their levels in cattle apply to whole herds rather than to individual cattle. Therefore, mitigation strategies typically target herd-level risk factors for EHEC control. The roles that water, including effluent used to irrigate animal feed and crops, age of the animals receiving feed, and the feed itself play in colonizing herds may prove to be critical to on farm management strategies and should be considered in developing mitigation strategies for reducing EHEC on farm (95-97). Herds of feedlot cattle (steers and heifers) are more likely to have colonized animals than breeding herds (cows and bulls). Additionally, when a feedlot herd is positive for EHEC it is likely to have significantly more colonized animals than breeding cattle herds (98). Limited evidence suggests dairy and cow-calf herds are similar with respect to *E. coli* O157:H7 (99). There is also evidence to suggest increased seasonal incidence of *E. coli* O157:H7 in cattle in the warmer months, which correlates to an increased incidence of EHEC infection and HUS in human populations during this time (10,100,101).

Zhao and colleagues have previously shown that probiotics may be an effective means by which to reduce EHEC on farm (102,103). Recently, Brashears and colleagues (104) observed a decrease in fecal shedding of EHEC, and subsequently, hide contamination, following administration of *Lactobacillus*-based feed to cattle; and Schamberger and colleagues (105) showed that addition of colicin-producing *E. coli* to cattle feed reduced fecal shedding of EHEC O157:H7.

Whether specific correlations can be made between specific feed management regimes and EHEC carriage in cattle and other food animals is an open question. There is, however, some evidence to suggest that practices such as brief periods of hay feeding are effective in reducing the number of cattle shedding E. coli O157:H7 thereby suggesting feeding regimes may be useful mitigation strategies to reduce EHEC on farm (106).

A risk assessment for human illness from EHEC in ground beef and fermented sausage should address the following questions related to on farm practices:

- What is the effect of probiotics and bacteriophage and of specific feeding regimens on fecal shedding of EHEC by cattle?
- What is the effect of specific manure composting regimens on the prevalence/levels of EHEC in ground beef and fermented sausage?

TRANSPORTATION, SLAUGHTER, AND PROCESSING

Calf susceptibility to infection from EHEC in the environment, such as holding facilities or feedlot pens, and stunning box floors (107), is elevated by stresses associated with weaning, transport, and relocation. Bach and colleagues have recently shown that lack of preconditioning and long periods of transport increase fecal shedding of EHEC, thus arguing that preconditioning may serve to reduce EHEC shedding by range calves on arrival at the feedlot (82). EHEC levels in transport trailers may also be significantly reduced by washing and sanitizing trailers after each load of animals; doing so would be expected to curtail EHEC spread between animals by contaminated trailers and/or bedding (82,108).

Meat may become contaminated with EHEC when beef carcasses come into contact with contaminated hides and faeces during slaughter (109). Thus, a determination of the quantitative association between the incoming status of cattle and the outgoing status of harvested meat is critical in an exposure assessment. This quantitative correlation between pre-harvest and post-harvest contamination may best be predicted using fecal *E. coli* O157:H7 prevalence data (109).

Grinding meat may introduce EHEC into the interior of the meat, and thus, when ground beef is not heated to an appropriate internal temperature (e.g., >68°C)[7] or when it is cooked unevenly, EHEC may survive. Moreover, in most countries, many thousands of pounds of meat trim from multiple carcasses are ground together thereby allowing a small number of carcasses with EHEC to contaminate a large supply of ground beef. Contaminated beef may also transfer EHEC to meat grinding equipment, which may later contaminate other lots of raw meat. Ground-beef products, therefore, pose a greater hazard than do intact cuts of meat.

[7] Recommendations ranging between 68.3 and 71°C have been made.

A risk assessment for human illness from EHEC in ground beef and fermented sausage should address the following questions related to transportation, slaughter, and processing:

- What is the effect of specific measures to minimize contamination of carcasses at slaughter on the prevalence/levels of EHEC in ground beef and fermented sausage?
- What is the effect of measures to prevent contamination of carcasses at slaughter on the prevalence/levels of EHEC in manufacturing trim, steaks and roasts, ground beef, and fermented sausages?
- What is the effect of varying processing parameters e.g., pH or acidification, time and temperature of fermentation/drying, etc. on sausage and other ready-to-eat commodities?
- What is the effect of specific measures such as temperature control and antimicrobial sprays to prevent or control growth of EHEC in ground beef/fermented sausage during transit and storage?

CONSUMER BEHAVIOR

Food preparation practices and consumer behaviour affect the probability of contracting an EHEC infection. Specifically, undercooked beef (in particular ground or minced products) has been correlated to risk of infection (see above). Interestingly, though cooking beef products to an internal temperature of ≥68 ˚C has been shown to be an adequate precaution against EHEC infection, consumers continue to choose undercooked or raw beef products.[8] In certain countries, for example, consumption of products made from raw minced beef, such as "tartare" steak and beef "americaine," is common. Awareness of and precautions against cross-contamination between raw meat products and either cooked foods or raw vegetables would likely reduce the likelihood of infection.[9] Consumer behaviour that can limit illness from vegetables contaminated at the farm is likely limited to thoroughly cleaning produce, in particular those commodities destined to be consumed raw. It should be noted, however, in the case of sprouted seeds and some fruits and vegetables which have been shown to internalize EHEC (87), washing may not be a sufficient intervention.

A variety of foods may become contaminated with EHEC through cross-contamination with beef or other meats and contaminated kitchen surfaces during food preparation. For instance, mayonnaise and mayonnaise-based dressings and sauces were identified as the most likely foods to have been contaminated in a recent series of outbreaks of *E. coli* O157:H7 infection in the U.S. (110). Nevertheless, relatively little information exist on the effect of cross-contamination on pathogen transport.

A risk assessment for human illness from EHEC in ground beef and fermented sausage should address the following questions related to consumer behaviour/awareness:

- What is the effect of reducing consumer exposure to contaminated ground beef and fermented sausage on illnesses from EHEC?
- What is the effect of measures designed to minimize contamination of food products (e.g., Recommended Codes of Practice, Risk Management Guidelines, Certification Programs, etc.) on illnesses from EHEC in ground beef and sausage?

SUMMARY OF RISK MANAGEMENT QUESTIONS

Any potential risk assessment for human illness from EHEC in ground beef and fermented sausage should seek to address the following questions:

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[8] http://www.fsis.usda.gov/oa/news/1998/colorpr.htm

[9] http://www.fsis.usda.gov/oa/pubs/keep_apart.htm

On farm practices

- What is the effect of probiotics and bacteriophage and of specific feeding regimens on fecal shedding of EHEC by cattle?
- What is the effect of specific manure composting regimens on the prevalence/levels of EHEC in ground beef and fermented sausage?

Transportation, slaughter, and processing

- What is the effect of specific measures to minimize contamination of carcasses at slaughter on the prevalence/levels of EHEC in ground beef and fermented sausage?
- What is the effect of measures to prevent contamination of carcasses at slaughter on the prevalence/levels of EHEC in manufacturing trim, steaks and roasts, ground beef, and fermented sausages?
- What is the effect of varying processing parameters e.g., pH or acidification, time and temperature of fermentation/drying, etc. on sausage and other ready-to-eat commodities?
- What is the effect of specific measures such as temperature control and antimicrobial sprays to prevent or control growth of EHEC in ground beef/fermented sausage during transit and storage?

Consumer Behavior/Awareness

- What is the effect of reducing consumer exposure to contaminated ground beef and fermented sausage on illnesses from EHEC?
- What is the effect of measures designed to minimize contamination of food products (e.g., Recommended Codes of Practice, Risk Management Guidelines, Certification Programs, etc.) on illnesses from EHEC in ground beef and sausage?

DATA GAPS

Based on review of available information, largely as summarized above, the following data gaps have been identified. Filling these gaps is needed to strengthen any risk assessment undertaken for human illness from EHEC in ground beef and fermented sausage.

On farm

- The effect of employing probiotic bacterial flora in cattle on reduction of EHEC.
- The effect of various feeding regimens on reduction of EHEC.
- The effect of different composting protocols of reduction of EHEC
- The effect of proper and effective water treatment and application during processing on reduction of EHEC
- The effect of hygienic measures at the farm (such as cleaning and disinfection of premises between lots) on reduction of EHEC

During Slaughter, Processing, and Transport

- Data on cross-contamination of EHEC between carcasses during carcass splitting.
- Industry and consumer practices for various methods of manufacturing ground beef and fermented sausage.
- Time-temperature data (quantitative) for chillers in slaughter establishments.

- Marketing data on the proportion of beef ground at slaughter versus at retail.
- Information on processing and mitigation strategies to reduce the number of EHEC in ground beef and fermented sausage.

Consumer Behaviour/Awareness

- Information describing the critical contamination levels of meat products that may lead to cross contamination of uncooked produce.
- Information on the maximum density of EHEC in ground beef and raw vegetable servings as related to matrix effects, competitive microflora, and environmental conditions (e.g., pH, water activity).
- Predictive microbiological data on the increase and decrease in the number of EHEC in ground beef and fermented sausage under various storage and preparation conditions along with frequencies of occurrence of these storage and preparation conditions.
- Data on retail and consumer storage, cooking, and consumption (frequency and serving size) patterns by type of ground beef meal (e.g., grilled hamburger in July and baked meat loaf in October).

Other

- Information describing the human health impact of EHEC in less developed nations.
- Commodities likely to be associated with EHEC foodborne illness in less developed nations.
- Data regarding the exposure dose of EHEC likely to cause illness in susceptible populations.
- Frequency and severity of illness among children ages 0 to 5 from EHEC, particularly among those that become ill from consuming ground beef, fermented sausage, and raw produce.
- Descriptive epidemiologic information about sporadic cases of EHEC infection, including the month of disease onset, age, sex, hospitalizations, summary of clinical manifestations (including severe disease manifestations), and food vehicles involved (if known).
- Additional case-control studies of sporadic EHEC cases to calculate etiologic fraction attributable to ground beef.

SUMMARY/RECOMMENDATION

The Committee should encourage the implementation of practices that can be used to prevent or minimize 1) the colonization of cattle with EHEC, 2) the contamination of ground beef with faeces 3) the contamination of water with bovine faeces and 4) the contamination of food crops with bovine faeces. It is possible that the benefits achievable through downstream interventions are less important than those obtained via interventions at the farm, due in large part to the multiple infection pathways (and commodities) that can be minimized through effective manure management on the farm. A risk assessment may be useful in evaluating risk management options within the context of a farm-to-table continuum so that their relative importance can be definitively established.

Any risk assessment undertaken to evaluate potential mitigation scenarios for human illness from EHEC should provide estimates of the risk of illness, hospitalization, and death from EHEC in those countries for which sufficient data are available. In so doing, illness should be explicitly defined by CCFH as a specified endpoint. It should seek to answer, to the extent possible, the risk management questions outlined above. Presently, there is sufficient cause for concern and available information and data to warrant a risk assessment for EHEC in ground beef and fermented sausage. Filling the data gaps outlined above would serve only to strengthen any future risk assessment for human illness from EHEC.

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APPENDIX II

DRAFT REQUEST FOR SCIENTIFIC ADVICE AND A RISK ASSESSMENT NEEDED TO SUPPORT THE DEVELOPMENT OF A DRAFT RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR THE CONTROL OF ENTEROHEMORRHAGIC *ESCHERICHIA COLI* IN GROUND BEEF AND FERMENTED SAUSAGES

Background

At the 36th Session, the Delegation of the United States introduced the Discussion Paper on the Risk Profile for Enterohemorrhagic *Escherichia coli* (EHEC) Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork (Agenda Item 10b). Based on the risk profile the Delegation of the United States proposed that future work focus on ground beef. The similarity, at least with respect to the ingredients, of fermented sausage to ground beef was noted and the drafting group was requested to also consider this commodity.

After reviewing the risk profile, the Committee concluded that the next step was to use the risk profile to initiate work on the development of a "*Draft Code on Hygiene for the Control of Enterohemorrhagic* Escherichia coli *in Ground Beef and Fermented Sausages*." The purpose of this document is to provide practical guidance to governments, industry, and other interested parties on approaches to reducing the risk of these products serving as the vehicle for EHEC, thus reducing the public health impact of this pathogenic microorganism. The Committee agreed the draft code of hygienic practice would be developed by a drafting group led by the United States, with the assistance of Austria, Australia, Canada, China, EC, France, Germany, Japan, the Netherlands, New Zealand and Sweden. In accordance with its general approach to risk management, the Committee charged the working group to consider the problem from "farm to fork."

In requesting the development of the draft code of hygienic practice, the Committee observed that no international risk assessment was currently available and concluded that the availability of a targeted risk assessment would be beneficial for the development of the draft international code of hygienic practice. Accordingly, the CCFH requested that the FAO/WHO (through JEMRA) undertake a product/pathogen pathway risk assessment directed at determining the factors that influence the risk of hemorrhagic colitis (HC) and related sequelae (e.g., hemolytic uremic syndrome (HUS)) associated with the consumption of these products. The overall purpose of the risk assessment is to identify the factors that contribute to the risk of disease as a result of practices and control measures undertaken at production, manufacturing, distribution, marketing, and home use. The information generated is intended to allow the drafting group of the draft code of hygienic practice to recommend procedures and practices on the basis of their effectiveness in controlling the risk associated with these products.

The purpose of this Appendix II is to outline the risk assessment questions, contributing factors, and potential interventions that the CCFH would like the JEMRA to assess. Again, the purpose of these questions is to provide the drafting group with information related to the impact that different steps in the farm-to-table continuum have on the consumers' risk of EHEC infections associated with these products. The information needed is listed below in conjunction with the four phases of a risk assessment: hazard identification, hazard characterization, exposure assessment, and risk characterization. After completion of the initial iteration of model, the Committee requests that JEMRA communicate with the working group to arrange to conduct appropriate "what-if scenarios" that will benefit the working group in its deliberations.

To the greatest extent practical, the Committee requests that the risk assessment be conducted in a quantitative manner. Multiple biological end points (e.g., diarrhea, bloody diarrhea, HUS, death) should be considered so that severity can be estimated. The Committee additionally requests that the JEMRA include quantitative estimates of the uncertainty and variability associated with the risk estimates and an interpretation of the significance of the uncertainty and variability in relation to the development of practical guidance by the working group.

Information Needed (Risk Assessment Questions)

Hazard Identification

What is the proportion of EHEC infections that are attributable to ground beef and fermented sausages?

Does the risk of EHEC infections associated with these products vary from country to country and can these differences be attributed to differences in production, manufacture, distribution, marketing, or consumer use of these products?

Are there sources of EHEC other than the live animal that result in the contamination of ground beef or fermented sausages with the pathogen?

Hazard Characterization

What is the impact of chronic diseases, immune status, antacid consumption, and other host factors on the susceptibility of different subpopulations or age groups to EHEC infections?

What are the contributing factors that influence the rate of chronic sequelae associated with EHEC infections associated with these products?

Do food matrix effects (e.g., induction of acid resistance during fermentation) increase the virulence of EHEC isolates (i.e., decrease the infectious dose)?

Exposure Assessment

On-Farm:

What is the relative contribution of different sources of EHEC on-farm to the likelihood and extent of harbourage of EHEC in a herd?

What factors influence the within-herd prevalence of EHEC within the intestinal tract of bovine species?

Are there differences in the incidence and prevalence of EHEC in different classes of cattle (e.g., beef, dairy, bulls)?

What is the effect of different on-farm intervention (e.g., biosecurity programs, control of vermin, competitive exclusion, immunization) on the incidence and prevalence of EHEC in herds? Does this reduction in likelihood of contamination result in a reduction in risk of EHEC infections to the consumer?

At Slaughter:

Does the means and extent of transport to the slaughter facility influence the likelihood that a carcass will be contaminated with EHEC after slaughter?

Is the likelihood that a carcass will become contaminated during slaughter influenced by geographical location or season?

Is the likelihood that a carcass will become contaminated during slaughter influenced by the “weather” or the cleanliness of the animal at the time of slaughter?

What are the factors that contribute to the extent of EHEC contamination on carcasses after slaughter and the spread of EHEC among carcasses?

What is the effect of specific control measures to minimize contamination of carcasses at slaughter on the prevalence/levels of EHEC in ground beef, beef trimmings, and fermented sausage? Does this reduction in likelihood of contamination of the carcass result in a reduction in risk of EHEC infections to the consumer?

Processing/Ground Beef:

What are the factors that contribute to the prevalence of EHEC in ground beef?

What are the effects of different interventions on the prevalence of EHEC in ground beef? Do the reductions in the likelihood and extent of contamination at this point result in a reduction in the risk of EHEC infections to the consumer?

What is the likelihood that microbiological testing programs will identify contaminated lots so that those lots can be diverted from going into commerce?

What is the potential impact of microbiological testing programs on the reduction of the risk of contaminated lots of ground beef?

Processing/Fermented Sausage:

What is the likely extent of growth that will occur during the initial manufacture of fermented sausage before the product no longer supports the growth of EHEC?

What is the extent of inactivation of EHEC likely to occur during the manufacture and maturation/drying of fermented sausages?

Do the methods/formulations for manufacturing and maturing fermented sausages differ among countries or regions and is there a relationship between methods/formulations of manufacturing and the incidence of EHEC infections?

What reduction in the frequency and extent of EHEC contamination of fermented sausages is likely to occur, and does this reduction in exposure levels equate to an equivalent reduction in the risk of EHEC infections in consumers?

Distribution and Marketing:

What is the impact of handling and storage practices during distribution and marketing on the frequency and extent of EHEC contamination in ground beef?

Are there differences in the risk associated with ground beef produced in central facilities versus that produced in retail establishments?

What is the likelihood that contaminated ground beef or fermented sausage products would be a source for cross-contamination during retail operations?

Consumer Handling:

What is the effect of storage and handling in the home on the frequency and extent of EHEC contamination of ground beef and fermented sausage?

What is the likelihood that contaminated ground beef or fermented sausage products would be a source for cross-contamination within the home?

What is the impact of cooking on the risk that ground beef consumption will result in EHEC infections in consumers? What is the relationship between extent of cooking and reduction of risk?

Do the methods of preparation of ground beef differ in different countries or regions and is there a relationship between method of preparation and incidence of EHEC infections?

What is the frequency of consumption of these products by the population and what is the ranges of serving sizes consumed on those occasions.

Risk Estimates

What is the risk "per serving" for EHEC infections associated with ground beef and fermented sausages for different countries or regions?

What is the risk "per annum" for EHEC infections associated with ground beef and fermented sausages for different countries or regions?

What are the key factors that seem to be responsible for differences in "per serving" and "per annum" risks associated with different countries or regions?

What are the key factors that seem to be responsible for differences in "per serving" and "per annum risks" associated with different subpopulations within and between countries or regions?

Time Frame

The results of the risk assessment and expert consultation would be most effective if completed within the next 18 months. This should include periodic reports to the CCFH and consultations with the working group that is developing the international code of hygienic practice. As mentioned above, once the initial model has been developed, the risk assessment team should met with the working group to discuss potential "what-if scenarios" that would be useful to the working group.