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Government of Canada / Gouvernement du Canada
Canadian Food Inspection Agency / Agence canadienne d'inspection des aliments

Nepean, Ontario
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97-068N
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Dr. F. Moulin

Your file / Votre référence
Our file / Notre référence

March 26, 1999

MEMORANDUM TO: U.S. Enquiry Point

SUBJECT: **WTO notification - G/SPS/N/USA/144 dated February 3, 1999**

The following are our comments on this subject. The comments were made in cooperation with Health Canada.

The Canadian position has not changed. We still do not believe that end product testing is the best means to ensure consumer protection against E. Coli O157:H7 because of its the low prevalence.

We have also some concerns/questions on the new approach:

1. What is the rational for expanding the current policy to "non-intact" products? Is there an indication that these products were linked to human illnesses? Further, we believe that most of the products being considered for this policy are not likely to be eaten undercooked.

2. We find that the proposed approach is confusing and could be very difficult to implement. We believe that the end use should be the criteria to categorize products of concern, i.e., any beef, being intact or non-intact cut, used to manufacture ground beef found contaminated with E. Coli O157:H7 should be subject to compliance action. Under the Canadian approach action would be taken against ground beef derived from any product contaminated with E. Coli O157:H7. Moreover, we propose that the appropriate compliance action be determined based on the level of risk which is assessed using the level of generic E. coli in the contaminated product. Attached for information is the detailed Canadian policy.

Thank you for the opportunity to provide our comments.

Dr. F. Moulin
Acting Director
Food of Animal Origin Division

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GUIDELINES FOR RAW GROUND BEEF PRODUCTS FOUND POSITIVE FOR *ESCHERICHIA COLI* O157:H7

Guideline no. 10
Issued by Food Directorate
Health Protection Branch
Health Canada
December 8, 1998

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SCOPE

For a variety of reasons some ground beef processors/packers test for the presence of *Escherichia coli* O157:H7 in raw product. Neither the Food and Drugs Act nor the Meat Inspection Act (Meat Hygiene Manual) require testing for this pathogen. Health Canada does not recommend routine testing for this organism as a public health measure as its prevalence is too low for testing to be effective. None-the-less, when *Escherichia coli* O157:H7 is detected, appropriate public health measures need to be taken. Guidance is provided to the Canadian Food Inspection Agency (CFIA) and other interested stakeholders regarding appropriate public health measures in the situation where a lot of ground beef is implicated due to a positive test for *E.coli* O157:H7 for ground meat, carcasses or trimmings, or a ground beef equipment surface. Health Canada has initiated the development of a Policy on Raw Foods of Animal Origin which will consider this issue. However, we recognize that we may need to take action in the short-term and these guidelines represent our current position.

INTRODUCTION

Ground beef is a raw food of animal origin (RFAO) which forms a significant portion of the diet of Canadians. Consumers expect meat products to be safe for consumption when handled and cooked properly. However, like any other raw food, ground beef may be contaminated during production, processing, storage and marketing with biological agents which may be hazardous to human health. Ground beef products occasionally pose a high risk to the consumer due to their potential for carrying disease causing bacteria which could survive an inadequate cooking process or be spread if the meat was mishandled during transportation, storage or preparation. *Escherichia coli* O157:H7 is one of the bacteria that has been identified as the cause of several major foodborne outbreaks involving ground beef. Ground beef products, unlike whole muscle cuts, may have bacterial contamination through to the middle of the product thus requiring a thorough cooking to inactivate all the bacteria in each pattie or portion of product.

E.coli O157:H7 is the most commonly isolated serotype of all the enterohemorrhagic E.coli, sometimes referred to as EHEC organisms. All EHEC strains produce a potent verotoxin (a cytotoxin active on Vero cells) and infection with an EHEC organism can result in haemorrhagic colitis (bloody diarrhea) and haemolytic uraemic syndrome (HUS). An infectious dose could be as low as 10 cells. HUS is a life threatening complication of haemorrhagic colitis for about 10% of the cases. Approximately half the HUS patients require kidney dialysis and their illness may last from several days to many months or

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years with a mortality rate of 3-5%. Children under 10, the elderly and immuno-compromised patients are at greatest risk to diseases caused by EHEC.

Cattle faecal material is believed to be the primary source for EHEC organisms although they have been found in birds as well as pigs and deer. Studies in Canada have found the extent of *E.coli* O157:H7 contamination in cattle to vary from <0.3% to 1.5% (Cassin 1996). Faecal material may be spread to carcasses during hide removal or evisceration and this contamination may be spread to other carcasses by equipment and personnel during fabrication. Ground beef is most often contaminated when ground beef is produced from contaminated trimmings or by contact with contaminated equipment surfaces. Fresh meat is an ideal medium to support the growth of faecal pathogens, however, strict temperature control during production and distribution can be an important barrier to minimize their growth. Thorough and effective sanitation of all food contact surfaces is necessary to limit the spread of contamination from one day's production to the next.

Never-the-less, ground beef does occasionally become contaminated with EHEC organisms. In 1993, undercooked hamburger was found to be responsible for an outbreak of illnesses due to *E.coli* O157:H7 in the Western USA which involved more than 500 individuals, four of whom died. It is estimated that 75% of all haemorrhagic colitis and haemolytic uraemic syndrome (HUS) cases in Canada are attributed to infection with *E.coli* O157:H7. Improperly cooked ground beef has been the most frequently identified risk factor for haemorrhagic colitis (Health Canada, March 1995). Therefore the risk of exposure to EHEC organisms in ground meat is considered significant since Canadians consume a relatively large amount of ground beef largely as hamburgers. Public attention has continued to focus on the presence of pathogenic *E.coli* in ground meat due to recent recalls of ground beef in the USA and Canada.

RELEVANT FACTORS

It must be noted that all RFAO may contain human disease causing pathogens such as *Salmonella, E.coli O157:H7, Campylobacter* and *Listeria monocytogenes*. EHEC organisms like *E.coli* O157:H7 are quite hardy and in some cases may be able to survive some sanitation and decontamination processes such as acid sprays and dips. Some procedures such as steam pasteurization can reduce contamination substantially but treated products are still subject to recontamination. Although sanitation and decontamination procedures are being constantly improved it is not considered possible or practical at this time to eliminate every pathogen, including *E.coli* O157:H7, from RFAO.

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A food safety system established in Canada should be based on International *Codex Alimentarius* General Principles of Food Hygiene. This involves the implementation of hazard analysis and critical control point systems (HACCP) or a farm gate-to-consumer plate approach to enhance food safety.

The gate-to-plate approach includes implementation of good farming practices (GFP) at the producer level and good manufacturing practices (GMP) at the processing level, using the principles of the HACCP system. These are all key elements in the risk management of RFAO and should be implemented by the beef industry to minimize *E.coli* O157:H7 in ground beef. In addition, the gate-to-plate approach recognizes that consumers must be informed about the appropriate ways to handle and prepare RFAO. Consumer education is therefore an integral part of the risk management system.

As stated earlier, Health Canada, with the CFIA and others, is developing a Policy on RFAO to reduce the risk of exposure to pathogens in RFAO. This policy will include the gate-to-plate approach. Recommendations on microbiological testing to assess the adequacy of sanitation practices and effectiveness of practices to minimize faecal contamination will be considered in the policy development.

Concern over the presence of *E.coli* O157:H7 in raw ground beef products has resulted in several initiatives from the food industry and regulatory agencies. For example, government agencies have encouraged the industry to create effective HACCP plans. Health Canada has proposed new GMP regulations and CFIA has developed a voluntary Food Safety Enhancement Program (FSEP). Some processors have implemented steam pasteurization of carcasses to further reduce pathogens. Others are considering a pasteurization treatment of all trimmings. Many processors are keeping better records on incoming and outgoing raw material in order to trace product if a recall becomes necessary. In addition, many slaughter houses are pressuring cattle producers to meet more stringent farming practices. Other interventions such as irradiation are being considered. All of these efforts should lead to improved slaughter, grinding, and processing operations which should lower the health risks for the consumer.

THE PURPOSE OF MICROBIOLOGICAL TESTING

Microbiological testing of raw material and in line samples may be useful in determining whether a process is under control. However, microorganisms such as *E.coli* O157:H7 or *Salmonella* may not be good candidates for verifying process control because they are not uniformly distributed, their numbers are usually to low for quantitative recovery and rapid

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and inexpensive methods for their recovery are not readily available. None-the-less, many ground beef processors/packers are testing for the presence of *E.coli* O157:H7. They do this to meet certain purchase specifications in contractual agreements or to meet export requirements, for example ground beef that is being shipped to the USA. When *E.coli* O157:H7 is found in ground beef appropriate public health measures need to be taken to ensure the hazard is controlled. Due to difficulties in defining a lot or limiting the lot size at the processing level a considerable amount of ground beef product may be implicated by a positive finding. On the other hand testing programs for *E.coli* O157:H7 that are in use in the industry do little to assure the safety of the finished product. For example, if the prevalence of *E.coli* O157:H7 was 1% in a combo of ground meat that was to be used to make a lot of hamburgers, then 300 hamburgers from that lot would have to be analysed to be 95% confident that *E.coli* O157:H7 was absent (Schilling).

The hazard analysis and critical control point (HACCP) system is being recognized as the method of choice for achieving process control and a more effective means than end product sampling programs. A HACCP plan is based on a risk assessment in which all potential hazards are identified. The steps in the process where these hazards should be monitored or controlled are identified. The plan also specifies what target (organism, compound or object) should be monitored and what degree of variation is considered within acceptable limits and what is considered unacceptable variation. The plan specifies the type of corrective action and when it should be taken. Every HACCP system needs to be validated and verified to determine its effectiveness. This would include microbiological testing to ensure that the interventions used are effective, not only for the target organism but are also suitable for controlling other pathogens that could be present.

As noted above processors/packers/retailers may test for the presence of *E.coli* O157:H7. When microbiological testing is done, Health Canada recommends that levels of generic *E.coli* also be assessed as a direct indicator of faecal contamination. Enteric pathogens such as *E.coli* O157:H7 and *Salmonella* are present sporadically and this makes routine monitoring for their presence impractical. In addition, methods for the quantitative recovery of these pathogens are lacking. However, in situations where the level of generic *E.coli* is increased, the risk of these pathogens being present is also considered to be increased. Therefore, Health Canada is proposing that the level of generic *E.coli* be used as indicative of the extent of faecal contamination and hence an indicator of increased potential risk posed to the consumer by a lot of ground beef that has been found positive for *E.coli* O157:H7. We recognize that a linear relationship between specific pathogens, e.g. *E.coli* O157:H7, and levels of generic *E.coli* has not been demonstrated. Never-the-less, for the

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purposes of this guideline we are suggesting that the type of recall action taken on lots of ground beef that have tested positive for *E.coli* O157:H7 can be based on the level of generic *E.coli* measured in a representative portion of the lot of ground beef. It is important to note that all lots which have tested positive for *E.coli* O157:H7 will be subject to product action, but the extent of that action will be determined by the level of generic *E.coli*.

DEFINITION OF A LOT

For the purpose of this policy a production lot of ground beef will be defined as all ground beef produced at one establishment from one clean-up and sanitation to the next clean-up and sanitation. However, permission to subdivide a lot may be given if a manufacturing establishment is operating under a HACCP plan (recognized and audited by CFIA). An assessment will be made by CFIA based on a review or audit of the HACCP plan in place at the plant to ensure that all critical control points are under control as per microbiological test results. Every unit of a subdivided lot must be identifiable, and the processor must provide analytical (microbiological) results appropriate to each of the sub-lots. For example, the levels of generic *E.coli* should not exceed 100 cfu/g from five sample units representing product manufactured at the beginning, middle and end of the lot or sub-lot.

GUIDANCE

All lots of ground beef could potentially be contaminated with *E.coli* O157:H7. However, when a lot of raw ground beef, whether imported or domestic is confirmed positive for *E.coli* O157:H7, an assessment must be made by the manufacturer and CFIA to determine the potential for the consumer to be exposed to an unacceptably high level of *E.coli* O157:H7 i.e. a level at which the consumer might not be able to prevent cross-contamination and/or organism survival through handling and cooking practices normally used in the home. This is also necessary when trimmings or carcasses have tested positive for *E.coli* O157:H7 if they were subsequently used to manufacture ground beef. An equipment surface in direct contact with ground beef that tests positive for *E.coli* O157:H7 may also implicate a lot of ground beef. As indicated above, levels of generic *E.coli* as well as information about the extent of distribution will be used to determine whether a positive finding of *E.coli* O157:H7 could pose an increased risk to the consumer. All positive findings should be reported to CFIA to assist in determining the level of risk for the consumer and to ensure that appropriate risk management steps have been taken.

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Levels for generic *E.coli* which would be considered acceptable (m value) or unacceptable (M value) based on a three class sampling plan are normally established by comprehensive national baseline studies. In the absence of extensive data regarding the levels of generic *E.coli* in ground beef products at the processor level, Health Canada has assessed the information available from research studies and reviewed the guidance for levels of *E.coli* in other food products and proposes the following guidelines.

Ground Beef

The most aggressive risk management response is considered appropriate when a lot of ground beef, positive for *E.coli* O157:H7, has been distributed to the consumer level and the level of generic *E.coli* is either unknown or exceeds 100 cfu/g. In these situations a recall to the consumer level is recommended. The risks are considered high that consumers may not be able to handle or prepare these products safely.

Lots of ground beef which are positive for *E.coli* O157:H7 but contain levels of generic *E.coli* less than or equal to 100 cfu/g are still considered to represent sufficient risk to require that they be recalled, but the level of generic *E.coli* indicates that the product was handled and produced under acceptable GMP, therefore a recall to the retail level is considered appropriate.

Fresh ground meats are of particular concern because they have a short shelf-life and are often already in distribution to the consumers before microbiological results become available. Table I provides a summary of the action to be taken when a lot of ground beef is found positive for *E.coli* O157:H7.

The above-mentioned level for generic *E.coli* is attainable on a routine basis, based on an assessment of a number of large scale patty manufacturing plants, when following good sanitation and handling practices. Even better results may be achieved by patty plants and grinders that enforce incoming quality control standards on all raw ingredients (e.g. microbiological and maximum temperature). Each manufacturer should regularly verify the sanitation process using appropriate microbiological markers. A recall to the consumer level can be avoided if all the raw ground beef implicated by the tested material is restricted from direct sale to the consumer pending the results of analysis. Appendix I provides a sampling plan and methods for determining the levels of generic *E.coli*. At least five sample units should be examined from the positive lot using either a quantitative Health Protection Branch (HPB) method or another method considered equivalent as outlined in Appendix 1.

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Carcasses or Trimmings

If carcasses or trimmings are tested and found positive for *E.coli* O157:H7, any ground beef derived from these carcasses or trimmings are also considered to be positive for *E.coli* O157:H7. Table II outlines the action to be taken on ground beef manufactured from carcasses or trimmings that tested positive.

Equipment Surfaces in Contact with Ground Beef

If an equipment surface in direct contact with ground meat, such as grinders, hoppers, augers, is found positive for *E.coli* O157:H7, product action on the implicated ground beef is also required. Table II outlines the action recommended on the implicated ground beef.

Disposition of Implicated Product

Due to increased risk (elevated levels and tampering), all implicated raw ground beef product recalled from the consumer level should be rendered or destroyed in a fashion that does not cause further contamination of the environment. Other implicated raw product, including trimmings, recalled from the retail level should also be rendered or destroyed if it is not further processed at a registered establishment to destroy this pathogen. The implicated products may be reprocessed at the registered establishment provided it has been held under the CFIA's supervision at all times and every portion of the product receives a heat process sufficient to ensure microbiologically safety (e.g. ground beef patties must reach an internal temperature of 70°C).

Follow-up After a Positive *E.coli* O157:H7 Finding

In addition to monitoring the effectiveness of any recall, follow-up action is necessary to assess whether the positive result is an isolated occurrence and to ensure that appropriate action has been taken to correct the problem. In the case of any positive, GMP/HACCP review should be undertaken. The type of additional follow-up action is dependent on which raw materials have been found positive. The processor/packer, in co-operation with the CFIA, should determine what action, if any, is appropriate for other product produced under the same conditions as the positive lot. Any additional product identified as implicated through this follow-up should be disposed of as indicated above.

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Follow-up when Raw Ground Beef or Ground Beef Product is Positive
In most cases the implicated lot can be limited to one day's production based on an effective clean-up and sanitation process. Implicated product may be further limited if an establishment can justify subdividing a lot based on the HACCP plan and sufficient microbiological testing as described previously under the definition of a lot. The levels of generic *E.coli* in samples from the subdivided lot as well as any additional sampling for *E.coli* 0157:H7 may be used to help determine the nature and extent of product action required. For example, when the level of generic *E.coli* is consistently ≤ 100 cfu/g in all subdivided lots, product action may be limited to the subdivided lot from which the positive was recovered provided any additional tests for the presence of *E.coli* 0157:H7 is also negative. However, if the level of generic *E.coli* was to exceeded 100 cfu/g for any the other subdivided lots of that days production, the lot should be considered from clean-up to clean-up i.e. the lot can not be subdivided. Due to the potential for spread, the recovery of *E.coli* 0157:H7 is considered to impact all raw product produced after the positive finding on the same day of production but may not impact raw product produced before the positive was detected.

Follow-up when a Combo(s) is Positive
The potential for spread to other combos produced under the same conditions will be evaluated based on microbiological results for the combo produced immediately before and/or after the positive combo. If the levels of generic *E.coli* in either of these combos is >100 cfu/g the potential for spread will be considered high and all the combos produced that day under the same conditions as the positive combo will be implicated. If generic *E.coli* results for the implicated combos are not available they should be sampled for *E.coli* O157:H7 and generic *E.coli*. If these combos have been used to manufacture ground beef these products should be handled the same way as products from a positive combo. If results from other combos indicate the potential for spread is high, (isolation of another *E.coli* 0157:H7 positive or generic *E.coli* count >100 cfu/g) additional recall action is considered necessary. Trace backs to the producer/processor should be undertaken to determine the source of the problem and to ensure that steps have been taken to correct the problem. Consideration may be given to trace outs depending on an assessment of the potential for spread.

Follow-up when a Carcass(es) is Positive
If both sides of a carcass which has tested positive for *E.coli* O157:H7 have been excluded from any further processing, i.e no material from these carcasses has entered the food chain, no additional sampling is considered necessary. Such isolation should result in a

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review of GMP/HACCP to address any areas of concern. Contaminated carcasses should be disposed of as indicated above under implicated product.

Imported product which tests positive will be handled in the same way as domestic product. CFIA will follow-up on imported products by notifying the appropriate inspection agency in the exporting country. Incoming lots may be tested when considered necessary. Testing could include sampling for specific pathogens of concern, e.g. *E.coli* O157:H7, but could also be based on an assessment of the levels of other appropriate indicator organisms.

Note: In consideration of liability or trade implications, a processing establishment is free to take more aggressive recall action than recommended here on raw ground beef product sold to the consumer.

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GLOSSARY

Trimmings — Portions of the exterior surfaces of a beef carcass removed during the dressing process. Trimmings are primarily used to produce ground beef. Trim is rated on its fat/beef ratio.

Combos — One large plastic lined cardboard box or plastic container mounted on a pallet which can hold approximately 950 kg or 2000 lbs of trimmings.

Positive Combo — A combo or trimmings that has been tested and found positive for *E.coli* O157:H7.

Lot — All ground beef produced at the same establishment under the same conditions from one clean-up and sanitation to the next clean-up and sanitation.

Subdivided Lot — Under certain condition a lot may be subdivided based on a recognized HACCP plan. Every unit of product in a subdivided lot must be identifiable (date/lot coded), and the processor must provide sufficient analytical (microbiological) results to assess the safety of the subdivided lot. (e.g. The level of generic *E.coli* is $\leq$100 cfu/g)

Implicated Lot — All ground beef derived from raw ingredient that tested positive for *E.coli* O157:H7. This could include trimmings or carcasses used to make ground beef or a lot of ground beef in contact with an equipment contact surface that has tested positive.

Microbiological Safety — Although the memo refers to 70°C for hamburger patties a higher temperature or a hold time may be necessary to ensure that sufficient lethality has been applied depending on the heating and cooling process and the size of the product.

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Appendix I:

1. Procedure for the analysis of ground beef for determining the levels of generic *E.coli*

The level of generic *E.coli*, should be determined by examining 5 randomly selected sample units of ground beef from the positive lot or from ground beef derived from trimmings or carcasses that have tested positive for *E.coli* O157:H7. If an equipment surface in direct contact with ground beef has tested positive 5 randomly selected sample units of ground beef should be examined from each implicated lot. Sample units should represent product produced at the beginning, middle and end of the lot. Sample units should not weigh less than 25 g and should not be composited. Samples must be analysed in a laboratory accredited by the CFIA using a HPB quantitative method such as MFHPB-19, MFHPB-26, MFHPB-27 or MFHPB-34. Other methods will be considered equivalent to the HPB methods if they are validated by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method. They must show agreement within the 95% upper and lower confidence limits for the appropriate MPN index.

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Table 1

Recommended action when ground beef is tested for *E.coli* O157:H7

Product	*E.coli* O157:H7	Level of Generic *E.coli* in Ground Beef	Recommended Product Action	Follow-up
Ground Beef	Detected	Not done	Recall to consumer level	GMP/HACCP review
	Detected	>100 cfu/g in any of five sample units per lot	Recall to consumer level	GMP/HACCP review
	Detected	≤100 cfu/g in five sample units per lot	Recall to retail level	GMP/HACCP review
	Not detected	>100 cfu/g in any of five sample units per lot	No action	GMP/HACCP review
	Not detected	≤100 cfu/g in five sample units per lot	No action	Not required

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Table II

Recommended action for ground beef derived from trimmings, beef carcasses or an equipment surface in direct contact with ground beef which has been found positive for *E.coli* O157:H7

Product	Level of Generic *E.coli* in Derived Ground Beef	Recommended Product Action	Follow-up
Ground Beef derived from trimmings, carcasses or an equipment surface that tested positive for *E.coli* O157:H7	>100 cfu/g in one or more of five random samples of ground beef derived from positive product	Recall to consumer level	GMP/HACCP review
	≤100 cfu/g in five random samples of ground beef derived from positive product	Recall to retail level	GMP/HACCP review