Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Targeted Survey Investigating Bacteria of Concern in Green Onions

RDIMS # 3643173

Canada

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Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system in order to better protect Canadians from unsafe food and ultimately reduce the occurrence of foodborne illness.

Green onions have been reported to be responsible for several outbreaks of foodborne illness in North America. The Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO) has ranked green onions in the second highest priority group of concern in terms of microbiological hazards among fresh fruits and vegetables. Often eaten raw, green onions are subject to extensive handling during and after harvest where pathogens of concern can be introduced at any step in the production. *Salmonella*, *Shigella* and *Escherichia coli* (*E.coli*) O157 have been identified as the primary bacterial pathogens of concern in green onions.

Considering these factors and their relevance to Canadians, green onions have been selected as one of the priority commodity groups of fresh fruits and vegetables for enhanced surveillance under the FSAP. Over the course of this four-year baseline study (2010/11 to 2013/14), approximately 4,500 green onion samples will be collected from retail locations and tested for the presence of various pathogens of concern. The main objectives of this targeted survey (2010/11) were to generate baseline surveillance data on bacterial pathogens *Salmonella*, *Shigella* and *E. coli* O157, and on generic *E.coli* (an indicator of fecal contamination) for green onions available in the Canadian market. In total, 591 samples of green onions (imported and domestic, conventional and organically grown) were collected and tested.

The results of the 2010/11 survey indicate that bacterial pathogens and generic *E. coli* were not detected in the majority (99.7%) of the green onion samples. A very small fraction (0.2%) of the green onion samples was found to be contaminated with *Salmonella*. One product recall resulted from the findings of the food safety investigation. In addition, one sample was found to have elevated, yet marginally acceptable, levels of generic *E. coli*. These results suggest that most green onions in the Canadian market sampled during this survey were produced under Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs).

The CFIA regulates and provides oversight to the industry, works with provinces and territories, and promotes safe handling of foods throughout the food production chain. However, it is important to note that the food industry and retail sectors in Canada are ultimately responsible for the food they produce and sell, while individual consumers are responsible for the safe handling of the food they have in their possession. Moreover,

general advice for the consumer on the safe handling of foods is widely available. The CFIA will continue its surveillance activities and inform stakeholders of its findings.

1 Introduction

1.1 Food Safety Action Plan

In 2007, the Canadian government launched a five-year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP) (1), aims to modernize and strengthen Canada's safety system for food, health and consumer products. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The Canadian Food Inspection Agency's (CFIA's) Food Safety Action Plan (FSAP) (2) is one element of the government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility of occurrence of these risks, improve import and domestic food controls, and identify food importers and manufacturers.

Within the FSAP, there are 12 main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess and prioritize potential food safety hazards through risk mapping, information gathering and analysis of foods in the Canadian marketplace. Targeted surveys are one tool used to test for the presence and level of particular hazards in specific foods.

1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the potential occurrence of hazards in food commodities. The microbiological targeted surveys aim to establish baseline data on priority and/or emerging microbiological hazards in targeted commodities, primarily fresh fruits and vegetables and imported food ingredients. A statistically significant number of samples will be collected over several years to allow for seasonal and/or production variations. This work differs from regular CFIA microbiological monitoring activities, which test samples of a broad range of commodities for multiple hazards and are aimed to determine the compliance of defined lots with established microbial standards or guidelines for regulatory purposes.

To identify food-hazard combinations of greatest potential health risk for the targeted surveys, the CFIA uses a combination of scientific literature, documented outbreaks of foodborne illness, and/or information gathered from the Food Safety Science Committee (FSSC), a group of Canadian federal, provincial and territorial subject matter experts in the area of food safety (3).

This targeted survey (2010/11) represents part of the collection of over 4,500 green onion samples over four years (2010/11 – 2013/14), which was designed to gather baseline

information on the occurrence of microbial pathogens of concern, as well as the presence and levels of generic *E.coli*, in green onions available to Canadians at retail.

1.3 Codes of Practice, Acts, and Regulations

International food safety standards, codes of practice, and guidelines relating to food, food production and food safety are developed under the joint FAO/WHO Codex Alimentarius Commission. Producers of fresh fruits and vegetables are encouraged to follow these international codes of practice. Of relevance for this survey are the *Code of Hygienic Practices for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) (4) and the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969) (5). These codes address GAPs and GMPs which, when applied, control and reduce the potential for contamination with microbial, chemical, and physical hazards at all stages of production of fresh fruits and vegetables, from primary production to packaging.

Fresh fruits and vegetables available in the Canadian market must comply with the *Food and Drugs Act* (FDA) (6) and the *Food and Drug Regulations* (FDR) (7), which prescribe certain restrictions on the production, importation, sale, composition and content of foods and food products. Section 4(1)a of the FDA prohibits the sale of food contaminated with foodborne pathogens, while sections 4(1)e and 7 prohibit the sale of unsafe food and food produced under unsanitary conditions.

Fresh fruits and vegetables that are imported or domestically produced and marketed inter-provincially must also comply with safety requirements of the *Fresh Fruit and Vegetable Regulations* (8) under the *Canada Agricultural Products Act* (9). These regulations are intended to ensure that fresh fruits and vegetables sold to consumers are safe, wholesome and properly graded, packaged and labelled.

The *Fresh Fruit and Vegetable Regulations,* and the food-related sections of the FDA and FDR are enforced by the CFIA.

FSAP targeted surveys are primarily conducted for surveillance and not for regulatory compliance purposes. However, results indicating a potential risk to public health for any samples tested under this survey will trigger food safety investigations, including activities such as follow-up sampling, inspections of facilities, and consultations with Health Canada for health risk assessments. Depending on the findings, a recall of the affected product may be warranted.

2 Survey on Green Onions

2.1 Rationale

Green onions have been reported to be responsible for several outbreaks of foodborne illness in North America. From 1994 to 2010, there were seven documented outbreaks associated with green onions contaminated with microbial pathogens (Appendix B). Some of these outbreaks were associated with the bacterial pathogens *Shigella* and *E. coli* O157. Surveys of fresh produce conducted in 1999 and 2000/2001 by the United States Food and Drug Administration (US FDA) (10, 11) have also identified the presence of *Shigella* or *Salmonella* in 3.1% of domestic and 1.7 % of imported scallions/green onion samples tested, suggesting that green onions were generally more likely to be contaminated than many other vegetables.

Green onions are grown at ground level and, as such, can be easily contaminated in the field by the use of improperly composted manure, wildlife feces or untreated irrigation water. The unique structure of green onions, with their moist hollow tubular leaves, offers ideal growth conditions and protection from washing for microbial pathogens. In addition, green onions require extensive handling during harvesting and packaging and can, therefore, be contaminated by infected handlers. During processing, the use of contaminated water for rinsing, cooling and icing also represents a potential source of pathogen introduction. Even though pathogens associated with green onions can be destroyed with cooking, their presence creates a potential risk for foodborne illness as green onions are often consumed raw.

Green onions were classified in the second highest priority group of concern in terms of microbiological hazards among fresh fruits and vegetables during a joint FAO/WHO Expert Meeting in 2007 (12). This was based on multiple factors, such as historical outbreaks and potential for contamination by pathogens.

Based on the above information and the Food Safety Science Committee's recommendations (3), green onions have been selected for enhanced surveillance under FSAP. The overall objective of this surveillance is to gather baseline information on the occurrence of pathogens of concern (pathogenic bacteria, viruses and parasites) and indicators of fecal contamination in green onions available to Canadians at retail.

This targeted survey (2010/11) is part of the information collection, with a focus on investigating the presence and distribution of bacterial pathogens (*Shigella*, *E. coli* O157:H7/NM, and *Salmonella*) and the presence, distribution and levels of generic *E. coli* (an indicator of fecal contamination) in imported and domestic, conventional and organically grown green onions.

2.2 Targeted Micro-organisms

2.2.1 Bacterial Pathogens (*Salmonella*, *E. coli* O157 and *Shigella*)

Bacterial pathogens *Salmonella* and *E. coli* O157, are found naturally in the intestines of animals, such as poultry and cattle respectively (13). Most outbreaks associated with these bacterial pathogens are linked to the consumption of contaminated food of animal origin (e.g., chicken, raw milk and beef). However, in the last decade, fresh fruits and vegetables have emerged as significant sources of these bacterial pathogens related illnesses (14). Fruits and vegetables can typically become contaminated with *Salmonella* and *E. coli* O157 in the field, by improperly composted manure, contaminated water, and/or wildlife feces (15).

Humans are the only host of *Shigella*. Food contaminated by infected food handlers and water contaminated with human feces are the most common causes of shigellosis. Shigellosis illnesses have been known to be associated with consumption of contaminated fruits, vegetables, shellfish, and chicken (13).

2.2.2 Generic *E. coli* - an Indicator of Fecal Contamination

Typically, *E. coli* bacteria that inhabit the large intestines of humans and animals are harmless. Due to their regular presence in the stools of humans and animals, the occurrence of *E. coli* in foods indicates direct or indirect contamination with fecal matter (16). The presence of generic *E. coli* in foods can also indicate potential contamination with pathogenic enteric micro-organisms, such as *Salmonella* or *E. coli* O157 that also live in the intestines of infectious humans and animals. It is important to note that the presence of generic *E. coli* in food only implies the increased risk of contamination with pathogenic micro-organisms but does not conclusively indicate that these pathogens are present. High levels of generic *E. coli* in fresh produce sold at retail are an indication that contamination has occurred at some point between production and the time of sale.

2.3 Sample Collection

All samples were collected from national retail chains and local/regional grocery stores as well as other conventional retail and natural food stores and farmers' markets located in various cities across Canada. The number of samples collected in various regions across Canada was based on the relative proportion of the population in the respective regions. Domestic samples were collected during the summer months (June-September). Imported samples were collected primarily in the fall, winter, and spring months. Samples that were labelled as organic at retail were identified as "organic" in this survey. Other samples were identified as "conventional".

For this survey, a sample consisted of a single sample unit (e.g., individual consumer-size bundle(s) from a single lot) with a total weight of at least 200 g. Collected samples were required to be shipped under conditions that limited the growth of micro-organisms during transit. Samples were declared "unfit" for analysis if there were issues regarding the conditions in which the sample was handled or shipped.

2.4 Sample Distribution

Table 1. Distribution of Green Onion Samples

(Percentages of total number of samples are shown in brackets)

Product Origin	Production Practice		Total
	Conventional	Organic	
Imported	181 (30.6%)	144 (24.4%)	**325 (55.0%)**
Domestic	199 (33.7%)	67 (11.3%)	**266 (45.0%)**
Total	**380 (64.3%)**	**211 (35.7%)**	**591 (100%)**

The vast majority of the conventional imported samples originated from Mexico (260/325, 80.0%), and the USA (56/325, 17.2%). Two samples came from Chile, and one each from China, Guatemala, and Thailand. Four samples collected in the winter were from unidentified foreign countries.

Of the imported organic samples, 88.2% (127/144) originated from Mexico. Of the 17 remaining imported organic samples, 16 (11.1%) were from the USA and 1 (0.7%) from Chile.

2.5 Method Details

The samples were analyzed using the analytical methods published in Health Canada's *Compendium of Analytical Methods for the Microbiological Analysis of Foods* (17) (Appendix C). These methods are the same that are used for regulatory testing by the CFIA and are fully validated for the analysis of fresh fruits and vegetables.

For the detection of *Salmonella*, *E.coli* O157/NM and *Shigella*, a two-step procedure was employed. Samples were first screened by PCR-based methods. Presumptive positive results were confirmed by isolation, purification and identification procedures. Enumeration of generic *E. coli* was accomplished by the most probable number (MPN) or direct plating procedure.

If pathogens were detected, the isolates were further characterised by pulsed field gel electrophoresis (PFGE), i.e., DNA typing, at the CFIA's PFGE Centre. Serotyping for *Salmonella* spp. was performed at the *Salmonella* Typing Laboratory, Laboratory for Foodborne Zoonoses, Public Health Agency of Canada (PHAC), in Guelph, Ontario.

2.6 Assessment Guidelines

The assessment criteria used in this survey (Tables 2 and 3) are based on the principles of the *Health Products and Food Branch Standards and Guidelines for Microbiological Safety of Foods* (17) and associated methods published in Health Canada's *Compendium of Analytical Method* (18).

Table 2. Assessment Guidelines for Pathogenic Bacteria in Green Onions

Bacterial Analysis* (Method Identification Number)	**Assessment Criteria**	
	Satisfactory	**Unsatisfactory**
***E. coli* O157:H7/NM** (MFLP-30, Supplement 1 & 2, and MFLP-80)	Absent in 25 g	Present in 25 g
Salmonella* spp.* (MFLP-29 modified and MFHPB-20)	Absent in 25 g	Present in 25 g
Shigella* spp.* (MFLP-26 and MFLP-25)	Absent in 25 g	Present in 25 g

* *Compendium of Analytical Methods* (18).

**No criteria have been established by Health Canada at this time for these bacterial pathogens in fresh fruits and vegetables. However, in the absence of a specified criteria, presence in foods is considered to be a violation of FDA Section 4(1)a and is therefore assessed by the CFIA as unsatisfactory.

Table 3. Assessment Guidelines for Generic *E. coli* in Green Onions

Bacterial Analysis* (Method Identification Number)	**Assessment Criteria**		
	Satisfactory	**Investigative**	**Unsatisfactory**
Generic *E. coli* (MFHPB-19 and MFHPB-27)**	≤ 100	$100 < x \leq 1{,}000$	$> 1{,}000$

* *Compendium of Analytical Methods* (18).

** Concentration unit depends on method used. For MFHPB-19 method: MPN/g, for MFHPB-27 method: CFU/g.

Unsatisfactory sample assessments were subject to follow-up actions, such as directed follow-up sampling, inspection of establishment, health risk assessment, and/or product action (e.g., product recall).

Samples assessed as investigative in this survey required some follow-up activity. This could include, for example, further sampling (to verify the levels of generic *E. coli* in the samples in question) or data gathering for program design purposes.

2.7 Survey Limitations

Samples tested during this survey were collected at retail locations across Canada, as opposed to monitoring samples that are picked up at distribution points and warehouses. As such, products sampled at retail could be mixed and originate from different shipments and/or suppliers. Though this represents what the Canadian consumer experiences, this imposes certain limitations with respect to the traceability of the products and the identification of the source of contamination in the case of positive results.

Results obtained for a targeted survey sample are from the analysis of a single sample unit. This sampling and testing strategy precludes the extrapolation of the laboratory result to the whole production lot as it is not statistically representative. This imposes certain limitations in the interpretation of the results in the absence of additional information.

Potential reasons for contamination cannot be elucidated based on a single sampling point (e.g., sampling at retail only). Therefore, it is not possible to determine if a breakdown of GAPs has occurred (e.g. contamination while the crop was on the field or during harvest), if a breakdown of GMPs has occurred (as the food is washed, packaged and sent to market) or if cross-contamination occurred during transportation, storage, or at the store where the sample was picked up.

Finally, given the seasonality, as well as the varying channels of commerce, the source of the products can change dramatically from one season to the next. As such, there is an insufficient number of samples in this survey to carry out a detailed analysis of the results based on a country of origin. In cases of positive results, unsatisfactory rates between countries are not considered to be statistically comparable.

3 Results

Of the 591 green onion samples analysed, a total of 589 samples (99.7%) were assessed as satisfactory (Table 4). *E. coli* O157 (H7 & NM) and *Shigella* spp. were not detected in any of the green onions sampled in this survey.

Table 4: Summary of the Results for Green Onion Samples Analyzed for *E. coli* O157:H7/NM, *Salmonella* spp., *Shigella* spp. and Generic *E. coli*

(Percentage of total number of samples are shown in brackets)

Product Origin	Production Practice	Number of Samples	Assessment		
			Satisfactory	Investigative	Unsatisfactory
Imported	Conventional	181	181	0	0
	Organic	144	144	0	0
Domestic	Conventional	199	198	0	1
	Organic	67	66	1	0
Total		**591**	**589 (99.7%)**	**1 (0.2%)**	**1 (0.2%)**

One sample (0.2%) of domestic conventional green onions from Ontario was found to be unsatisfactory due to the presence of *Salmonella.* Serotype *S.* Oranienburg (Antigens 6,7:m, t:-) was identified from this sample.

One sample (0.2%) of domestic organic green onions was found to have an elevated level of generic *E. coli* (260 CFU/g). The sample was assessed as investigative since the *E. coli* counts were elevated, but below the unsatisfactory threshold of 1000 CFU/g. Further evaluation of this sample did not result in any immediate follow-up activities.

4 Discussion and Conclusion

From this survey (2010/11), it was determined that 99.7% of the samples were negative for the bacterial pathogens tested and had acceptable levels of generic *E. coli*. Bacterial pathogens *E. coli* O157:H7/NM and *Shigella* spp. were not detected in any of the 591 green onion samples tested. However, one domestic sample was found to be unsatisfactory due to the presence of *Salmonella*. Another domestic sample was assessed as investigative due to elevated, yet marginally acceptable, levels of generic *E. coli*.

A food safety investigation was initiated by the CFIA to follow up on the positive *Salmonella* sample, which resulted in one product recall. Over the same period, an outbreak of salmonellosis was occurring in Ontario. Contaminated green onions were suspected of being the source of the illnesses since the serotype and PFGE pattern from the sample isolate were identical to those obtained from the affected individuals. However, epidemiological trace-back activities by the Ontario Ministry of Health and Long-Term Care could not conclusively link the green onions to the source of the outbreak.

Surveys conducted by the US FDA on bacterial pathogens in fresh produce in 1999 and 2000/2001 identified that 1.7% of imported and 3.7% of domestic green onions sampled were contaminated with either *Shigella* or *Salmonella* (10, 11). More recent studies from other jurisdictions on Ontario and Alberta grown produce (19,20), and testing from the USDA Microbiological Data Program on fresh produce sold in the USA (21) have shown results similar to the ones obtained in CFIA's survey with regards to bacterial contamination in green onions, with levels ranging from 0 to 0.8%.

The overall finding of this survey suggests that the vast majority of green onions in the Canadian market are produced and handled under acceptable GAPs and GMPs. However, contamination of green onions with *Salmonella* can occur, which represents a food safety risk. As well, elevated *E. coli* levels can occur. While generic *E. coli* do not lead to illness, their presence is used by the CFIA as an indicator that unwanted micro-organisms may potentially be introduced during the production, processing, and marketing of these commodities.

While the food industry and retail sectors in Canada are ultimately responsible for the food they produce and sell, and individual consumers are responsible for the safe handling of the food they have in their possession, the CFIA regulates the industry, provides oversight and promotes safe handling of foods throughout the food production chain. Surveillance activities will continue and the CFIA will inform stakeholders of its findings.

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Appendix A: List of Acronyms and Abbreviations

CFIA: Canadian Food Inspection Agency

CDC: Centres for Disease Control and Prevention

CFU: colony forming unit

CFU/g: colony forming units per gram

E. coli: *Escherichia coli*

FAO: Food and Agriculture Organization of the United Nations

FDA: *Food and Drugs Act*

FDR: *Food and Drug Regulations*

FCSAP: Food and Consumer Safety Action Plan

FSAP: Food Safety Action Plan

FSSC: Food Safety Science Committee

GAPs: Good Agricultural Practices

GMPs: Good Manufacturing Practices

HPB/MFHPB: Health Protection Branch/ Microbiology Food Health Protection Branch

MFLP: Microbiology Food Laboratory Procedures

HC: Health Canada

MPN: Most Probable Number

NM: non-motile

PCR: Polymerase Chain Reaction

PFGE: Pulsed Field Gel Electrophoresis

PHAC: Public Health Agency of Canada

spp.: species

USDA: United States Department of Agriculture

US FDA: United States Food and Drug Administration

WHO: World Health Organization

g: gram

Appendix B: Global Foodborne Disease Outbreaks Associated With Green Onions Contaminated with Microbial Pathogens (1994 - 2010)*

Year	Micro-organisms	Vehicle	Country	Cases	Source
1994	*Shigella flexineri*	Onion, green	USA, Multi-state	97	Outbreak alert database, Center for Science in the Public Interest
1996	Hepatitis A Virus	Onion, green	USA	60	CDC line list 1996 (Information provided by Judy D. Greig, Laboratory for Foodborne Zoonoses , PHAC)
1997	*Cryptosporidium parvum* (Protozoan parasite)	Onion, green (suspected)	USA	54	US FDA: Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh-cut Produce, Chapter IV (Information provided by Judy D. Greig, Laboratory for Foodborne Zoonoses, PHAC).
1998	Hepatitis A Virus	Onion, green	USA	43	J Infect Dis 2001 18398):1273-6 (Information provided by Judy D. Greig, Laboratory for Foodborne Zoonoses, PHAC).
2000	Hepatitis A Virus	Onion, green / scallions	USA, Multi-state	32	Outbreak alert database, Center for Science in the Public Interest
2003	Hepatitis A Virus	Onion, green	USA	742	MMWR November 28, 2003. 52(47);1155-1157 (Information provided by Judy D. Greig, Laboratory for Foodborne Zoonoses , PHAC).
2006	*Escherichia coli* O157:H7	Onion, green / scallions (suspected)	USA	300	CDC (Information provided by Judy D. Greig, Laboratory for Foodborne Zoonoses , PHAC).

* The data presented were collected from several sources of information, such as peer-reviewed journals, newspapers, press releases, health units, national laboratory and government websites.

Appendix C: Analytical Methods Used for Microbial Analysis

Bacterial Analysis	**Method Identification Number (Date Issued)***	**Title of Method**
***Shigella* spp**	MFLP-26 (February 2006)	Detection of *Shigella* spp. In Foods by the Polymerase Chain Reaction (PCR)
	MFLP-25 (March 2006)	Isolation and Identification of *Shigell*a spp. From Foods
***E. coli* O157:H7/NM**	MFLP-30 (May 2003, Supplement 1 May 2005 & Supplement 2 November 2006)	The Dupont Qualicon Bax® System Method for the Detection of E. Coli O157:H7 in Raw Beef and Fruit Juice
	MFLP-80 (March 2008)	Isolation of *E. coli* O157:H7 or NM in Foods
***Salmonella* spp.**	MFLP-29** (July 2007, modified)	The Qualicon Bax® System Method for the Detection of Salmonella in a Variety of Food and Environmental Samples
	MFHPB-20 (March 2009)	Methods for the Isolation and Identification of *Salmonella* from Foods and Environmental Samples
Generic *E. coli*	MFHPB-19 (April 2002)	Enumeration of Coliforms, Faecal Coliforms and of *E. coli* in Foods
	MFHPB-27 (September 1997)	Enumeration of *Escherichia coli* in Foods by the Direct Plating (DP) Method

* Published *in the Compendium of Analytical Methods* (22)

** MFLP-29 was performed as written with the following modification: Secondary enrichment was performed as outlined for cantaloupes, i.e., transferred from buffered peptone broth as specified to RVS and TBG broths (Rappaport-Vassiliadis Soya Peptone broth and Tetrathionate Brilliant Green broth) and incubated for 24 ± 2 h at 42.5°C. After incubation 2 ml from each of RVS and TBG are combined to one sample and proceed with step 7.3.1.4 of the method.