Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2009-2010 Targeted Surveys

Targeted Surveys of Bacterial Pathogens and Generic *E. coli* in Tomatoes in the Canadian Market

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Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and strengthen Canada's food safety system in order to better protect Canadians from unsafe food and ultimately reduce the burden of foodborne illness. The funds allocated under the FSAP allowed for the implementation of an enhanced surveillance program with an objective of collecting information on the priority hazards in various food products by conducting targeted surveys over a five-year period from 2008/09 to 2012/13. In the area of microbiological hazards in food, the targeted surveys focused on foodborne pathogens of concern in fresh produce and imported food ingredients.

In the last decade, fresh fruits and vegetables have been increasingly reported in association with foodborne illness, with tomatoes being the second most frequent vehicle in the produce associated outbreaks. Although these outbreaks have been mainly reported in the U.S., the microbiological quality of tomatoes in Canada remains of concern, as the supply sources are similar in both countries. For many years in Canada and the U.S. imported tomatoes have made up a large portion of the tomato consumption. Field-grown tomato production is seasonal in Canada and in many regions of the U.S., which in the fall, winter and spring is complemented by imports predominantly from Mexico. U.S.-grown tomatoes constitute about 25 percent of Canadian tomato imports.

Outbreaks associated with tomatoes have been predominantly linked to *Salmonellae,* followed by Norovirus and Hepatitis A virus. In the U.S., a single outbreak each of shigellosis and campylobacteriosis have been associated with contaminated tomatoes. In the past decade there has been a rapid increase in the market share for tomatoes grown using organic practices. The use of composted animal manure and plant debris in the production of organic produce has raised concerns about an increased likelihood of contamination with enteric pathogens, especially *E. coli* O157:H7. In contrast to pathogenic strains of *E. coli*, there are many strains of this bacterium that are harmless. These harmless strains inhabit the large intestine of humans and animals and are shed into the environment in feces. If pathogenic organisms are also present, they are shed alongside the harmless generic *E. coli*. Therefore, *E. coli* is considered to be the best available indicator for fecal contamination in produce, and its levels are used to assess the adherence to good agricultural/farming practices. Ultimately high numbers of *E. coli* in tomatoes may point to an inadequate agricultural/farming practises and/or lack of cleanliness and proper sanitary conditions during production, packaging, and/or storage.

Considering all these factors, tomatoes have been selected for enhanced surveillance under FSAP with an overall objective to gather baseline information on the occurrence of bacterial pathogens and indicator bacteria (*E. coli*) in tomatoes available to Canadians at retail. This targeted survey was designed to gather information on the presence and distribution of some bacterial pathogens of concern:

i) *Salmonella* spp. and *Shigella* spp. in tomatoes,

ii) *E. coli* O157:H7 and *E. coli* O157:NM in organic tomatoes, and
iii) The presence, distribution, and levels of indicator bacteria, generic *E. coli*, in tomatoes.

In this survey a total of 1414 retail samples of fresh tomato were analysed, including imported (701 samples) and domestically produced (713 samples), conventional (1211 samples) and organically grown tomatoes (203 samples). These samples were analysed for bacterial pathogens of concern (*Salmonellae and Shigellae*) and indicator bacteria (*E. coli*). In addition, all samples of organic tomatoes, both imported (101 samples) and domestic (102 samples) and a comparable number of conventional domestic tomatoes (103 samples) were tested for the presence of *E. coli* O157:H7 and *E. coli* O157:NM. In none of the samples analysed the bacterial pathogens and generic *E. coli* were detected, which suggests Good Agricultural Practices and sanitary conditions during packaging, transportation and storage.

Up-to-date results of various tomato-monitoring programs show similar results to those obtained under this survey. These findings combined with the epidemiological evidence linking foodborne illness to the consumption of tomatoes, suggest that the contamination of tomatoes with pathogens is sporadic. The sample size employed in this survey (1414 samples) allows us to conclude that the prevalence of these pathogens in retail tomatoes during this study was below 0.2%. To obtain a better estimate of the "true" prevalence of pathogens in tomatoes, a greater number of samples would be required.

1 Introduction

1.1 Food Safety Action Plan

The Food Safety Action Plan (FSAP) (1), which is part of the Government of Canada's broader initiative, the Food and Consumer Safety Action Plan (FCSAP) (2), aims to modernize and strengthen Canada's food safety system.

The Canadian Food Inspection Agency has been given the reponsibility to lead the FSAP in the area of enhanced surveillance of foods. The CFIA works on the FSAP initiative with various stakeholders including other federal departments (e.g. Health Canada, the Public Health Agency of Canada and Agriculture and Agri-Food Canada), provincial, and territorial partners.

As part of the FSAP enhanced surveillance initiative, targeted surveys have been designed and implemented for various foods and associated hazards. The targeted surveys will provide information to allow the CFIA to address specific questions regarding the levels and presence of various microbiological and chemical hazards in targeted foods in the Canadian market.

1.2 Targeted Surveys

FSAP targeted surveys are designed to: (i) focus on priority and/or emerging food hazard issues, (ii) address areas not covered by regular CFIA monitoring activities, and/or (iii) to enhance existing CFIA sampling activities. The development of the FSAP targeted surveys were based on the information gathered from the *Food Safety Science Committee Summary Report 2008* (3), along with prioritization activities carried out under the FSAP.

1.3 Codes of Practice, Acts and Regulations

At the international level, food safety standards are developed under the joint FAO/WHO Food Standards Programme. Producers of fresh fruits (including tomatoes) and vegetables are encouraged to follow the internationally accepted standards and codes of practice developed by the Codex Alimentarius Committe, which provide guidance for the safe production of food at international level. The *Code of Hygienic Practices for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) (4) and *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) (5) were developed by the Codex Alimentarius Committee on Food Hygiene under the joint FAO/WHO Food Standards Programme. These codes address Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) which, when applied, control and reduce the potential of contamination with microbial, chemical, and physical hazards at all stages of production of fresh fruits and vegetables, from primary production to packaging. They outline basic requirements pertaining to environmental hygiene, hygienic production (related to the

requirements for water, manure, biological control of soil, packing, facility and personal hygiene), handling, storage, transportation and sanitation.

In Canada, food safety is governed through legislation. Fresh fruits (including tomatoes) and vegetables must comply with Sections 4 and 7 of the *Food and Drugs Act* (FDA) and the *Food and Drug Regulations* (FDR), which prescribe certain restrictions on the production, importation, sale, composition and content of foods and food products. By virtue of the Section 4a of FDA the sale of food contaminated with foodborne pathogens is prohibited, while Sections 4e and 7 prohibit the sale of unsafe food and food produced under unsanitary conditions.

Prohibited sales of food (*Food and Drugs Act*)

4. (1) No person shall sell an article of food that:

a) has in or on it any poisonous or harmful substance;
b) is unfit for human consumption;
c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
d) is adulterated; or
e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Unsanitary manufacture, etc., of food (*Food and Drugs Act*)

7. No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

Section A.01.040 of the FDR (below) describes prohibitions on the importations of unsafe food.

Importations (*Food and Drug Regulations*)

A.01.040. Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.

Fresh fruits (including tomatoes) and vegetables sold in Canada must also comply with safety requirements of the *Fresh Fruit and Vegetable Regulations* (FFVR) under the *Canada Agricultural Products Act.* The FFVR is intended to ensure that fresh fruits and vegetables sold to consumers are safe, wholesome, properly graded, packaged and labelled. Both the FFVR and the FDR are enforced by the CFIA.

Fresh fruits and vegetables sold in Canada must comply with the FDA and Regulations. Although the FSAP surveys are not conducted for regulatory purpose, the foodborne

pathogens and/or excessive levels of generic *E. coli*, if detected in any sample tested under this survey, would trigger food safety investigations, including activities such as follow-up sampling, inspections of facilities, and health risk [a] assessment. Depending on the findings, a recall [b] of the affected products may be recommended and/or implemented.

1.4 Potential Microbiological Hazards in Tomatoes

In recent years, Canadian consumption of fresh tomatoes has remained relatively stable (in the range of 6.76 to 7.43 kg/person/year from 1981 to 2009), while the varieties of tomatoes available on the market has changed significantly (6; 7). Over this time the production of field tomatoes has decreased, the production of greenhouse tomatoes has increased (7), and organically grown tomatoes have taken an increasing share of the Canadian market (8).

Production practices and growing conditions can affect the microbial status of tomatoes. Tomatoes grown in open fields are exposed to more potential sources of contamination, such as wild animals and contaminated water than those grown in greenhouses (7). Further, organically grown tomatoes can face a different level of microbial exposure through animal and human manure, which is a widely used organic fertilizer. Although, proper composting of manure will inactivate pathogens, they can survive for extended periods in improperly composted manure and can subsequently contaminate fresh vegetables grown in soil amended with that manure. For this reason, the use of manure has led to concerns about the potential contamination of the vegetables with human pathogens such as *E. coli* O157:H7, *Salmonella* spp. and *Shigella* spp. The methods of manure application and the time between the application and harvesting may influence the associated risk of pathogen transfer from manure-amended soil to vegetables. Studies suggest that there are likely no differences between organic and conventional produce in microbial safety if GAP are followed in organic manure applications (9; 10).

Tomatoes may become contaminated with pathogens if handled improperly during primary production, harvesting, post-harvest handling, processing and/or distribution and subsequently can cause foodborne illness. According to the U.S. Centers for Diseases Control and Prevention, five commodity groups made up 76% of produce associated foodborne disease[c] outbreaks[d] between 1998 and 2006, with 17% outbreak linked to tomatoes, which became the second most frequent vehicle of the produce associated outbreaks (11).

1.4.1 Pathogenic *Escherichia coli*

A small number of *E. coli* strains are capable of causing human disease. Based on the disease syndromes and characteristics, there are five recognized classes of pathogenic *E. coli* that cause gastroenteritis in humans: enteroaggregative, enterotoxigenic, enteropathogenic, enteroinvasive, and enterohemorrhagic (EHEC) (12; 13). The EHEC class includes verotoxin-producing *E. coli* (VTEC) that can produce Shiga-like toxin that cause severe diarrhea. The EHEC include the most important serotype *E. coli* O157 and more than 100 other non-O157 strains, such as O26, O45, and O103 (13). Of the numerous

serotypes of EHEC that are known to produce these toxins, *E. coli* O157:H7 and *E. coli* O157:NM (non-motile) are most frequently implicated in human diseases (14). *E. coli* O157 bacteria are found naturally in the intestines of ruminant animals, such as cattle, sheep and deer, as well as certain other animals, such as rabbits and pigs.

Transmission of *E. coli* O157:H7/NM can occur via the consumption of contaminated food or water, as well as by person-to-person transmission. While ground beef is still the most common food source of transmission, fresh fruits and vegetables have emerged in the last two decades as a significant source of *E. coli* O157 related illness. Raw fruits and vegetables can be contaminated with *E. coli* O157 in the field by improperly composted manure, contaminated water, wildlife, or poor hygienic practices of the farm workers.

In Canada, VTEC infections reported to the Notifiable Disease Reporting System have declined from 1804 cases in 2000 to 1130 cases in 2004. Most of the infections were caused by *E. coli* O157 serotype (15). In the U.S., a total of 2348 laboratory confirmed *E. coli* O157 infection cases and 224 non-O157 cases reported to Centers of Disease Control and Prevention in 2005 (16).

1.4.2 *Salmonella* spp.

Salmonella is a genus of Gram-negative, rod-shaped bacteria that normally live in the intestines of animals such as poultry, swine, wild birds, domestic pets, and reptiles. There are over 2500 serotypes of *Salmonella* spp. and virtually all are capable of causing human disease, known as salmonellosis.

Transmission of *Salmonella* often occurs through the ingestion of contaminated food of animal origin (i.e. meat, poultry, eggs and milk), as *Salmonella* is found naturally in the intestines of warm-blooded animals. *Salmonella* spp. can be excreted in animal faeces and remain viable in the field for a relatively long period of time. Therefore, produce grown in fields can be contaminated by improperly composted manure. Infected humans are another potential source of *Salmonella*. An infected person remains infectious throughout the duration of the illness and continues to excrete the bacteria for some time after symptoms have stopped. Illnesses of salmonellosis have been associated with consumption of fruits and vegetables (e.g. tomatoes, cantaloupes and sprouts), spices, sesame products, and nuts (e.g. peanut products and almonds).

Salmonellosis is one of the most common foodborne illnesses world-wide. The incidence[e] of salmonellosis varies depending on geographic, demographic, socioeconomic and environmental factors. There were approximately 6,000 cases of *Salmonella* infections reported in Canada each year during 2000-2004, according to current available data from the National Notifiable Disease Databases-Summary (15). It is believed that the actual number of infections is much higher due to under reporting (15). In the United States, an estimated 1.4 million cases occur annually. Of these, approximately 40,000 are laboratory confirmed cases reported to the CDC, the estimated annual cost is approximately US $3 billion (17-19).

1.4.3 *Shigella* spp.

Shigella is a genus of the Enterobacteriaceae family. Shigella are Gram-negative, non-motile, non-spore forming, rod-shaped bacteria that are very closely related to *E. coli*. There are four groups or species of *Shigella*: *S. dysenteriae*, *S. flexneri*, *S. boydii*, and *S. sonnei*. *Shigella dysenteriae* are considered the most virulent and can produce a potent cytotoxin[f] known as shigatoxin. *Shigella sonnei* and *S. flexneri* account for a majority of the cases of shigellosis in Canada (15) and the United States (20).

Shigellosis rarely occurs in animals and is principally a human disease. Infection is spread through the faecal-oral route. Food contaminated by infectious food handlers and water contaminated with human faeces are the most common causes of shigellosis.

World-wide, shigellosis remains a common infectious disease. The annual number of shigellosis illnesses and deaths in Asia was estimated to be 91 million and 414,000, respectively (21). In Canada, *Shigella* infections reported to the Notifiable Diseases Reporting System (NDRS) were 1156 cases/year in 2000 and 720 cases/year in 2004 (15). The reported cases declined overall between 2000-2004, with the exception of a spike in 2002 (1355 cases/year). The elevated cases that year related to a foodborne outbreak of *S. sonnei* in Ontario traced back to contaminated pasta salad (15). In the US, a total of 10,336 laboratory confirmed *Shigella* cases were reported to the CDC in 2006, that translates to an average national incidence of 3.5 per 100,000 population (20).

1.4.4. Generic *E. coli* as an Indicator Organism

Typically, *E. coli* bacteria that inhabit the large intestine of all humans and animals comprise the harmless saprophytic strains. Due to their regular presence in stools of human and animals, the occurrence of *E. coli* in foods indicates the direct or indirect pollution of fecal origin. Hence, the generic *E. coli* count in tomatoes (as in other ready-to-eat food) exceeding the tolerances suggests that Good Agricultural/Manufacturing practices have not been followed and consequently, indicates inadequate general cleanliness and sanitary conditions during production, packaging, and storage. The presence of *E. coli* in foods also suggests the potential for contamination with pathogenic enteric organisms, e.g., *Salmonella* and/or *Shigella*. Yet, the presence of generic *E. coli* in food only implies the increased risk of contamination with enteric pathogens but it cannot be considered as evidence that these organisms are present.

1.5 Foodborne Disease Outbreaks Associated with Tomatoes

There have been 29 reported foodborne disease outbreaks worldwide related with the consumption of contaminated tomatoes during 1990 – 2009 (Appendix C). These outbreaks have been associated with bacteria (72.4%) and viruses (27.6%) (Table 1.1).

Table 1.1 Pathogens Associated with Tomatoes Linked Outbreaks (1990 - 2009)

Type of Pathogen		**Outbreaks**	
		(n)	**(%)**
Bacteria	*Salmonella* spp.	19	
	Shigella spp.	1	
	Campylobacter	1	
	Subtotal	***21***	***72.4***
Viruses	Hepatitis A	3	
	Norovirus	5	
	Subtotal	***8***	***27.6***
Total		**29**	**100**

** Appendix C provides a full list of foodborne disease outbreaks linked with tomatoes.*

S.: Salmonella

As can be seen, the majority of outbreaks were caused by *Salmonella* spp. (19 out of 21 outbreaks) follow by viruses, Hepatitis A and Norovirus. It has to be noted that the frequency of gastrointestinal illnesses reported may be underestimated.

A list of bacterial enteric pathogens identified in the tomatoes-associated outbreaks is provided in Table 1.2

Table 1.2 Bacterial Pathogens Associated with Tomatoes Linked Outbreaks*

Time	Bacterial Pathogen	Contamination Source	Outbreak Location	Confirmed Cases
2008	*S.* Saintpaul	Pre-harvest	USA/17 states	1442
2007	*S.* (unknown)	Not identified	Minnesota	22
	S. Newport	Pre-harvest	Multistate	65
	S. Newport	Pre-harvest	New York	10
	S. Typhimurium	Not identified	Minnesota	23
2006	*S.* Norfolk	Pre-harvest and packing	USA/multistate	106
	S. Norport	Pre-harvest and packing	Multistate	459
	S. Berta	Unknown	Multistate	16
2005	*S.* Braenderup	Not identified	USA/multistate	84
2004	*S.* Javiana	Not identified	Canada/USA	7
	S. Braenderup	Food preparation	Multistate	137
	Multiple *S.* serotypes	Unknown	Multistate	429
2003	*S.* Virchow	Not identified	California	11
2002	*S.* Newport	Pond water used for irrigation	USA/multistate	510
	S. Javiana	Not identified	Florida	159
2000	*S.* Thompson	Not identified	USA	43
1999	*S.* Baildon	Farm or packing	USA	86
1993	*S.* Montevideo	Packing shed	USA multistate	100
1990	*S.* Javiana	Packing shed	USA multistate	176
2001	*Shigella flexneri* 2a	Infectious food handler	New York,	886
2004	*Campylobacter*	Unknown	USA/Ohio	13

** Appendix C provides a full list of foodborne disease outbreaks linked with tomatoes.*

S.: Salmonella

Epidemiological investigations of these outbreaks found that the majority of the implicated tomatoes were contaminated with *Salmonella* in various ways in the field prior to harvest (Table 1.2). Suspected risk factors included growing fields exposed to wild animals, irrigation water exposed to animal faeces, and fertilizers from improperly composted animal manure (22). Once contaminated, *Salmonella* can persist for extended periods of

time in the soil (23). In addition, studies suggest that *Salmonella* can internalize and survive within the inner tissue of tomatoes as tomato fruits develop prior to harvest (24;25).

Contamination may also occur in the tomato processing plants after harvest. Due to hydrostatic pressure, *Salmonella* can infiltrate whole tomatoes when they are submerged in a dump tank used to chill the produce. This occurs when the tomato temperature (e.g. 25°C) is higher than the water temperature (e.g. 10°C) (26). *Salmonella* that have infiltrated into the tomatoes cannot be removed by normal washing practices (27).

Studies also suggest that several serotypes of *Salmonella* can survive the acidic conditions of tomatoes (pH 4.1 - 4.4) during storage at refrigeration temperatures, and can grow rapidly when storage temperatures increase above that of refrigeration (e.g. 20°C and 30°C) (26;28).

Shigella and *Campylobacter* were also associated with tomato linked outbreaks in the last two decades (Table 1.2). Tomatoes were identified as an unusual transmission vehicle for a large scale shigellosis outbreak. The investigation found that tomatoes served in restaurants were contaminated by an infectious shigellosis food handler in a tomato processing plant (29). While, a single *Campylobacteriosis* outbreak with several infected cases was linked to tomatoes served in the restaurant (Table 1.2).

1.6 Objective of the Targeted Survey

This survey was designed to gather information in the Canadian retail market on the presence and distribution of some bacterial pathogens of concern:

i) *Salmonella* spp. and *Shigella* spp. in tomatoes;

ii) *E. coli* O157:H7 and *E. coli* O157:NM in organic tomatoes; and

iii) The presence, distribution, and levels of indicator bacteria, generic *E. coli,* in tomatoes.

2. Sample Collection and Analytical Methods

2.1 Sample Collection

Fresh tomatoes were sampled for microbiological testing according to the "Guidelines for the national wide surveys in bacteriology of fresh fruits & vegetables and imported peanut/products conducted under Food and Consumer Safety Action Plan – Fiscal year 2009/2010."

Fresh whole tomatoes, both field and greenhouse grown, were collected. Sample collection was categorized according to the growth conditions (conventional and organic) and country of origin (imported and domestic). In accordance to the objective of FSAP targeted surveys, sampling was carried out solely at retail outlets, purchasing products in a way that mimics the consumer's behaviour. While this sampling protocol is consistent with the objectives of the FSAP surveys, it imposes some challenges with respect to the products' identification and traceability, particularly for the products displayed and sampled from bulk.

All samples were collected from the main stream grocery supermarkets, other conventional retail and Natural Food Stores located across Canada. A "sample" represented a single sample unit, i.e., tomatoes selected randomly from bulk or individual consumer size packages with a total weight of no less than 200 g. When sampled from bulk, the tomatoes were collected in a manner that avoids any cross-contamination during sampling. This sampling protocol should be taken into consideration for the purpose of food safety investigations, health risk and compliance assessments in case of positive results for pathogens and/or indicator bacteria.

As per CFIA procedures, samples were shipped by courier to CFIA's laboratories using sufficient ice packs and insulated packing material to ensure that they were between 0 - 7°C upon receipt, and if not, the sample was declared as unfit for the analysis and rejected.

2.2 Analytical Methods

All samples were analysed using analytical methods published in the *Compendium of Analytical Methods* for the Microbiological Analysis of Foods (Table 2.1) (30).

The enumeration of generic *E. coli* (*E. coli* count) was accomplished by most probable number (MPN) or direct plating procedures. For detection of *Salmonella*, *Shigella,* *E. coli* O157:H7 and *E. coli* O157:NM, the two-step procedure was employed. Samples were first screened by PCR-based methods and any positive result, if obtained, would require confirmation by the isolation, purification and identification procedures. The test sample consisted of an analytical unit of 25 g for the detection of pathogens and of 10 or 11 g for *E. coli* count.

Table 2.1 Analytical Methods Used for Microbial Analysis

Bacteria	Method *	Brief Description
Generic *E. coli*	MFHPB-19	Enumeration method by MPN ** procedure
	MFHPB-27	Enumeration method by direct plating
***E. coli* O157:H7/NM**	MFLP-30 & supplement 2	PCR-based screening method
	MFLP-80	Isolation and confirmation method
***Salmonella* spp.**	MFLP-29	PCR-based screening method
	MFHPB-20	Isolation and confirmation method
***Shigella* spp.**	MFLP-26	PCR-based screening method
	MFLP-25	Isolation and confirmation method

* *Compendium of Analytical Methods (30).*

** MPN: Most Probable Number

2.3 Assessment Guidelines

The samples were assessed as "satisfactory", "unsatisfactory" or "investigative" using the criteria provided in Table 2.2.

Table 2.2 Assessment Guidelines

Micro-organism and Method of Analysis*	Assessment		
	Satisfactory	**Investigative**	**Unsatisfactory**
Generic *E. coli* (MFHPB-19 & 27)**	≤ 20 /g	20 < x ≤ 1000 /g	> 1000 /g
E. coli O157:H7/NM (MFLP-30, MFLP-80 & Supplement 2)	Absent in 25g	n/a	Present in 25 g
Salmonella spp. (MFLP-29 & MFHPB-20)	Absent in 25g	n/a	Present in 25 g
Shigella spp. (MFLP-26 & MFLP-25).	Absent in 25g	n/a	Present in 25 g

* *Compendium of Analytical Methods (30).*

** Concentration unit for MFHPB-19 method: MPN/g (Most Probable Number/gram), for MFHPB-27 method: CFU/g (Colony Forming Unit/gram).

The assessment criteria are based on the *Health Products and Food Branch Standards and Guidelines for Microbiological Safety of Foods* (*Interpretive Summary*) (31) and associated methods published in the HC's *Compendium of Analytical Methods* that were employed in this survey (30). These methods are used for regulatory testing by the CFIA and are fully validated for the analysis of fresh fruit and vegetable samples, including tomatoes. Thus, the presence or absence of *Salmonella*, *Shigella*, *E. coli* O157:H7 or *E. coli* O157:NM was determined in a 25 g sample unit drawn from a sample submitted for analysis and a positive result (presence in 25 g) was assessed as "unsatisfactory", while a negative result, i.e., absence in 25 g, was assessed as "satisfactory".

A "satisfactory" assessment for the generic *E. coli* indicates that the organisms were either not detected by enumeration, or found at the very low levels (i.e. ≤20 CFU/g). *E. coli* counts in the range 20 – 1000 CFU/g would be assessed as "investigative". An "investigative" result requires some form of follow-up activities, e.g. further sampling to verify the levels of generic *E. coli* in the tomatoes in question. Result indicating *E. coli* level > 1000 CFU/g was assessed as "unsatisfactory".

An "unsatisfactory" sample assessment, if obtained, would trigger a follow-up action, including food safety investigation, directed follow-up sampling, inspections of establishments, health risk assessments, and/or product action (e.g. product recall).

2.4 Data Analysis and Reporting

Sample information and analytical results were recorded in a Record of Analysis (ROA) of the CFIA's Laboratory Sample Tracking System (LSTS) and reported using Cognos 8 Query Studio data reporting system. The positive results, if obtained, were to be immediately forwarded to the Food Safety Division, Office of Food Safety and Recalls and Fresh Fruits and Vegetables Commodity Program.

2.5 Statistical Consideration

The expected prevalence of pathogens in the population surveyed (d) was determined by using the following formula (32):

$$n = -\ln (1-p) / d/100$$

where n = number of sample units that were sampled and tested, p = probability or confidence level set at 95 % and d =expected prevalence of pathogens.

2.6 Limitations

The collection of samples at retail which was employed in this study offered the benefit of being close to the point of consumption and therefore, reflects well the consumer's exposure to the microbiological hazards of concern. However, it imposed certain limitations with respect to the traceability of products in case of positive results, since the samples were collected from bulk or from the units pre-packaged at packers or at the retail level. Further, in this study, a single sample unit (n = 1) was collected from a partial lot displayed at the retail while, typically, the lot acceptance criteria and subsequently a decision pertaining to a lot compliance with respect to microbiological standards are based on the laboratory results obtained for five sample units randomly drawn from the whole production lot. In case of positive results, these factors would have to be taken into consideration during the food safety investigations, health risk and compliance assessments.

3. Results

3.1 Overview of Samples Collected

As per the survey design, roughly the same numbers of imported and domestic tomato samples were collected (702 imported, 721 domestic). Within each of these two categories, conventionally and organically grown products were sampled at a ratio of 6 to 1, which approximately mirrored the market share and, consequently, the consumers' exposure to conventional versus organic tomatoes (Table 3.1a).

Table 3.1a. Number of Samples Collected - Imported vs. Domestic

Origin	**Growth Conditions**	**Samples (n)**	**Subtotal (%)**	**Total (%)**
Imported	Conventional	601	85.6	*49.3*
	Organic	101	14.4	
	Sub-total	*702*	*100*	
Domestic	Conventional	619	85.9	*50.7*
	Organic	102	14.1	
	Subtotal	*721*	*100*	
Total		**1423**		**100**

As shown in Table 3.1b, within the conventional and organic tomato groups, the sample distribution between imported and domestic tomatoes was kept even.

Table 3.1b. Number of Samples Collected - Conventional vs. Organic

Growth Conditions	Origin	Samples (n)	Subtotal (%)	Total (%)
Conventional	Imported	601	49.3	***85.7***
	Domestic	619	50.7	
	Subtotal	***1220***	***100***	
Organic	Imported	101	49.8	***14.3***
	Domestic	102	50.2	
	Subtotal	***203***	***100***	
Total		**1423**		**100**

3.1.1 Sample Distribution by Province

The number of samples collected in various geographical regions was based on the relative proportion of the population in respective regions, but also on other operational requirements such as the availability of products or the distance between the site of sampling and the testing laboratory. Therefore, the provincial distribution of samples remained relatively consistent among the types of products collected (i.e. imported, domestic, conventional, organic), Figures 3.1 and 3.2.

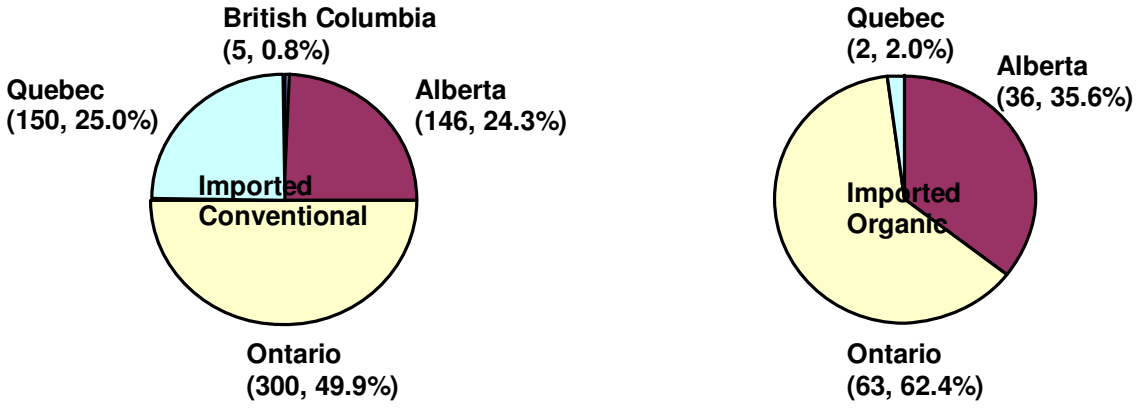

Figure 3.1 Imported Tomato Sample Distribution by Province (n, %)

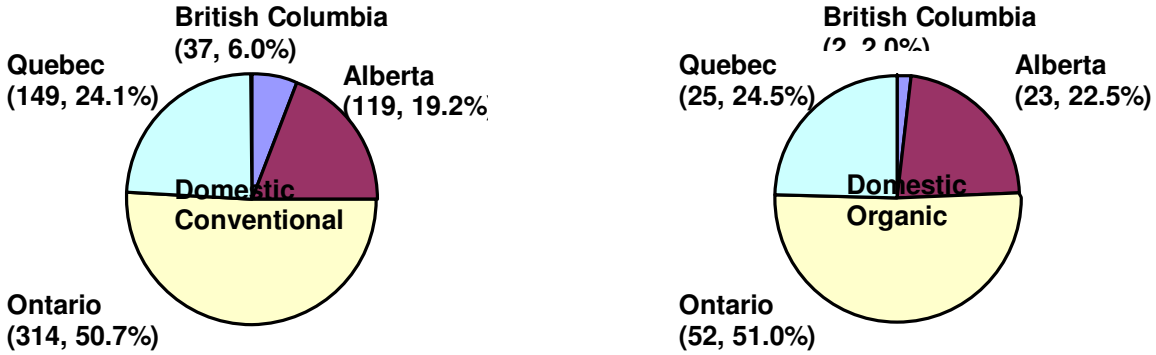

Figure 3.2 Domestic Tomato Sample Distribution by Province (n, %)

3.1.2 Imported Tomatoes - Sample Distribution by Country of Origin

A total of 702 imported tomato samples, 601 conventional and 101 organic, were collected. Most of the imported conventional tomato samples were from Mexico and the U.S., with the remaining samples were imported from other countries, as outlined in Table 3.2.

Table 3.2 Imported Tomatoes – Samples Distribution by Country of Origin

Country of Origin	Conventional		Organic		Total	
	(n)	(%)	(n)	(%)	(n)	(%)
Mexico	440	73.2	73	72.3	513	73.1
USA	135	22.5	9	8.9	144	20.5
Netherlands	3	0.5	13	12.9	16	2.3
Israel	0	0	6	5.9	6	0.9
Guatemala	4	0.7	0	0	4	0.6
New Zealand	2	0.3	0	0	2	0.3
Spain	1	0.2	0	0	1	0.1
Belgium	1	0.2	0	0	1	0.1
Not specified	15	2.5	0	0	15	2.1
Total	**601**	**100**	**101**	**100**	**702**	**100**

3.1.3 Seasonal Distribution

Domestic samples were collected during the summer months (April-September), due to Canada's short domestic growing season. Imported samples were collected throughout the year, but they were primarily collected in the fall, winter, and spring months.

3.2 Results and Assessment

Of the 1423 samples collected, eight were found unfit for analysis because the temperature at reception exceeded the laboratory quality standards/requirements, and one sample was visibly spoiled by the outgrowth of moulds.

The pathogens, *Salmonella, Shigella*, *E. coli* O157:H7 and *E. coli* O157:NM were not detected in any of the 1414 sample analysed.

In addition, generic *E. coli* counts were all below 20 CFU/g. this indicated that neither the direct nor indirect contamination with human or animal excreta was detected.

Consequently, all samples were assessed as "satisfactory" as per the survey's assessment criteria.

In Tables 3.3a, 3.3b and 3.4 the assessment of analysis is shown against each of the four tomatoes' categories sampled and tested in this survey.

Table 3.3a Assessment of Samples Analysed for *Salmonella* spp. and *Shigella* spp. - Imported vs. Domestic

Type of Products		Samples Analysed	Satisfactory	
			(n)	(%)
Imported	Conventional	600	600	100
	Organic	101	101	100
	Subtotal	***701***	***701***	***100***
Domestic	Conventional	611	611	100
	Organic	102	102	100
	Subtotal	***713***	***713***	***100***
Total		**1414**	**1414**	**100**

Table 3.3b Assessment of Samples Analysed for *Salmonella* spp. and *Shigella* spp. - Conventional vs. Organic

Type of Products		Samples Analysed	Satisfactory	
			(n)	(%)
Conventional	Imported	600	600	100
	Domestic	611	611	100
	Subtotal	***1211***	***1211***	***100***
Organic	Imported	101	101	100
	Domestic	102	102	100
	Subtotal	***203***	***203***	***100***
Total		**1414**	**1414**	**100**

Table 3.4 Assessment of Samples Analysed for *E. coli* O157:H7 and *E. coli* O157:NM

Type of Product		Samples Analysed	Satisfactory	
			(n)	(%)
Organic	Imported	101	101	100
	Domestic	102	102	100
Conventional	Domestic	103	103	100
Total		**306**	**306**	**100**

Statistically, based on the negative results obtained for all 1414 samples analysed in this survey, it is possible to infer, with the 95% confidence, that the expected prevalence of *Salmonellae* and *Shigellae* in tomatoes at retail during the fiscal year 2009/10 was lower than 0.2 %. For the imported (701 samples) and domestic (713 samples) tomatoes, due to the lower number of samples tested in each category, the expected prevalence was calculated to be below 0.4% while, for the conventional (1211 samples) and organic (203 samples) tomatoes, it was below 0.3 % and 1.5 %, respectively.

4 Discussion and Conclusion

Surveillance of tomatoes under the FSAP was initiated in the previous fiscal year, 2008-09. Bacterial pathogens and generic *E. coli* were not isolated from any of the total of 676 samples of conventionally grown tomatoes collected and tested that year (33).

Tomatoes are also among the other fresh produce routinely sampled and tested under the CFIA National Monitoring Program for Fresh Fruits and Vegetables. In this program, over the course of several years, neither of the pathogens nor *E. coli* were detected in tomatoes.

Recently, bacterial pathogens and *E. coli* were targeted in surveys of fresh produce, including tomatoes, conducted by Alberta Agriculture and Rural Development (34) and Ontario Agriculture, Food and Rural Affairs (35). While pathogens were not detected in Alberta-grown tomatoes, *Salmonella* Schwarzengrund was isolated from one sample of Ontario-grown conventional Roma tomato. Generic *E. coli* was not isolated from any sample, including the sample positive for *Salmonella*.

In the USFDA survey of domestic, conventionally grown tomatoes *Salmonella*, *Shigella* and *E. coli* O157:H7 were not detected in any of 198 samples analysed (36). Similarly, neither *Salmonella* nor *E. coli* O157:H7 were detected in the 108 samples of organic and conventional tomatoes grown by Minnesota Farmers (9). However, a random sample of pre-packaged organic grape tomatoes collected by the U.S. Department of Agriculture in Michigan was recently found positive for *Salmonella* and triggered recalls of implicated products in the U.S. (37) and Canada (38). In Europe, pathogens were not detected in any of 428 samples of organic tomatoes collected from retail outlets in a survey of organically produced vegetables (39).

In summary, up-to-date laboratory results obtained by monitoring tomatoes for the presence of pathogens at various levels of distribution indicates that the contamination can occur but is sporadic and the expected prevalence can be considered low. The results of this survey clearly indicates that in 2009-2010 the tomatoes available to Canadians at retail were produced under GAP and maintained in sanitary conditions after harvest and during transportation and storage. However, the link between the outbreaks of foodborne gastroenteritis to tomatoes cannot be ignored and should be monitored. The importance of GAP and sanitary handling along the whole food continuum, including in consumers households remain crucial for minimizing the potential for contamination and consequently the risk of foodborne illness.

5 Future Considerations

In the remaining three years of enhanced surveillance under the FSAP, tomatoes will continue to be targeted, with a possible increase in focus placed on organic products, as they constitute an increasing share of the market. In addition to bacterial pathogens,

consideration may also be given to testing for viral hazards such as hepatitis A and Norovirus, because of their association with outbreaks linked to tomatoes.

6 Acknowledgment

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Appendix A: Glossary of Terms

[a] Health risk: Levels of health risk are determined by a health risk assessment, Health Canada characterizes health risks into three categories:

- **Health risk 1**: The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

- **Health risk 2**: The health risk identified represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to temporary or non-life threatening health consequences, or that the probability of serious adverse consequences is considered remote.

- **Helath risk category 3** (HRC 3): This represents a situation where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequence.

[b] Recall is an action by a manufacturer, importer, distributor or retailer to remove unsafe food products from the market to help protect the public. In Canada, food recalls are coordinated by the CFIA. The CFIA classifies recalls into three classes (Class I, Class II or Class III) based on the level of health risk of the food product being recalled.

- **Class I recalls (High risk)**: The CFIA will request a Class I recall for a food product when there is a high risk that eating or drinking that product will lead to serious health problems or death. The CFIA issues a public warning for all Class I recalls when the product is available for sale or could be in the consumer's home.

- **Class II recalls (Moderate risk)**: The CFIA will requests a Class II recall for a food product when eating or drinking that product will most likely lead to short-term or non-life threatening health problems. The chance of any serious health symptoms is low in healthy populations. The CFIA issues a public warning for some Class II recalls based on the risk assessment and other criteria, such as the severity of symptoms in vulnerable populations (children, pregnant women, seniors, etc.)

- **Class III recalls (Low and no risk)**: The CFIA will request a Class III recall when eating or drinking that product will not likely result in any undesirable health effects. Class III recalls can include food products that pose no health and safety risk, but do not follow federal food regulations.

[c] Foodborne disease is defined as a disease, caused by infectious or toxic agents that enter the body through the ingestion of food.

[d] Disease outbreak is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season.

[e] Incidence is the number of cases of a disease, arising in a defined population during a stated period, expressed as a proportion, such as x cases per 1000 persons per year.

[f] Cytotoxin: any substance that poisonous to living cells

Appendix B: List of Acronyms

CDC: Centres for Disease Control and Prevention

CFIA: Canadian Food Inspection Agency

CFU: colony forming unit

E. coli: *Escherichia coli*

FDA: Food and Drug Act

FCSAP: Food and Consumer Safety Action Plan

FSAP: Food Safety Action Plan

GAP: Good Agricultural Practice

GMP: Good Manufacturing Practice

HC: Health Canada

MPN: Most Probable Number

PCR: Polymerase Chain Reaction

PHAC: Public Health Agency of Canada

***Salmonella* spp.**: *Salmonella* species

***Shigella* spp.**: *Shigella* species

USFDA: the United States Food and Drug Administration

(%): (percentage)

(n): (number)

°**C**: degrees Celsius

g: gram(s)

Appendix C: Outbreaks Associated with Tomatoes *

Microorganism	Location	Cases	Source	Narrative
Campylobacter	Ohio, 2004	13	CDC line list 2004	
Hepatitis A virus	France, 2010	55	French institute of Public Health	Dried tomatoes, used in sandwiches and salads.
Hepatitis A virus	Australia, 2009	200	South Australian director of public health	On-going outbreak of HAV in Australia that has sickened about 200 people and appears to be linked to semi-dry tomatoes.
Hepatitis A virus	Netherlands, 2009	13	Eurosurveillance, Volume 15, Issue 20, 2010	Imported product-source not reported: semi-dried tomatoes in oil.
Hepatitis A virus	Tennessee, 2005	23	CDC line list 2005	
Norovirus	Ohio, 2000	31	CDC line list 2000	
Norovirus	California, 2002	50	CDC line list 2002	
Norovirus	Connecticut, 2004	92	CDC line list 2004	
Norovirus	Colorado, 2005	17	CDC line list 2005	
Norovirus	Colorado, 2007	33	CDC line list 2007	
Salmonella	Multiple US states, 2004	429	MMWR 2005/54(40);325-328.	129 hospitalized; 9 states (Maryland, Michigan, Missouri, North Carolina, New Hampshire, Ohio, Pennsylvania, Virginia, & West Virginia) associated with dining at delicatessen chain A. These cases yielded S. Javiana (383), S. Typhimurium (27), S. Anatum (5), S. Thompson (4)
Salmonella	Minnesota, 2007	22	Post-Bulletin, Rochester MN	1 hospitalized; Tomatoes were contaminated before they got to the restaurant.
Salmonella Baildon	Multiple US states, 1998	86	Emerg Infect Dis. 2001 7(6):1046-8	Raw restaurant-prepared tomatoes likely contaminated on the farm or during packing were implicated in outbreak. Traceback identified tomato grower/packer cooperatives, in Florida, & a tomato dicing operation in California. Dicing & pooling may have played a role.
Salmonella Berta	Multiple US states, 2006	16	CDC linelist 2006	4 hospitalized;
Salmonella Braenderup	Multiple US states, 2004	137	MMWR 2005/54(40);325-328.	25 hospitalized;16 states (Delaware, Connecticut, Georgia, Iowa, Kansas, Maryland, Massachusetts, Missouri, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Virginia, West Virginia, & Wisconsin) Roma tomatoes
Salmonella Braenderup	Multiple US states, 2005	84	CDC line list 2005	

Microorganism	Location	Cases	Source	Narrative
Salmonella Norfolk	Multiple US states, 2006	106	CDC	37 hospitalized; Federal officials are investigating a second Salmonella outbreak linked to restaurant tomatoes that has sickened 106 people in 19 states.
Salmonella Javiana	Ontario, 2004	7	MMWR 2005/54(40);325-328. CCDR Volume 31-21 2005	1 hospitalized; Indistinguishable PFGE patterns, but with patterns distinct from the multiserotype Salmonella outbreak, were identified from Ontario. All patients ate at the same restaurant. Roma tomatoes
Salmonella Javiana	Multiple US states, 1990	176	Epidemiol Infect 1999 122(3):385-93	Illinois, Michigan, Minnesota and Wisconsin - 1990 (176 cases of S. javiana) Case-control studies & traceback implicated consumption of tomatoes from a single South Carolina tomato packer. Contamination likely occurred at the packing shed.
Salmonella Javiana	Florida, 2002	159	MMWR 2002 51(41):683-4; Emerg Infect Dis. Vol 11 2005; 610-612	3 hospitalized; Transplant Games, an Olympics-style athletic competition among recipients of solid organ & bone marrow transplants in Orlando, Florida: 75 reported eating food items at specific food courts in theme park. Illness associated with eating dishes containing diced Roma tomatoes.
Salmonella Montevideo	Multiple US states, 1993	100	Epidemiol Infect 1999 122(3):385-93	Illinois, Michigan, Minnesota and Wisconsin - Case-control studies & traceback implicated consumption of tomatoes from a single South Carolina tomato packer. Contamination likely occurred at the packing shed.
Salmonella Newport	Multiple US states, 2002	510	CDC line list 2002	
Salmonella Newport	Multiple US states, 2005-2006	459	MMWR Weekly Volume 56, No. 35 2007	During 2005--2006, four large multistate outbreaks of Salmonella infections associated with eating raw tomatoes at restaurants occurred in the United States. The four outbreaks resulted in 459 culture-confirmed cases of salmonellosis in 21 states.
Salmonella Newport	Multiple US states, 2007	65	CDC line list 2007	11 hospitalized; beefsteak tomatoes
Salmonella Newport	New York, 2007	10	CDC line list 2007	unspecified type; 1 death; 4 hospitalized;
Salmonella Thompson	Multiple US states, 2000	43	CDC line list 2000	
Salmonella Typhimurium	Minnesota, 2007	23	CDC line list 2007	1 hospitalized;
Salmonella virchow	California, 2003	11	CDC line list	
Salmonella virchow PT8	Australia, 1998	32	Epidemiology and Infection Volume 131, Issue 3 (pp 1041-1048)	S. Virchow (42) was cultured from 2 brands of semi-dried tomatoes associated with cases in 2 states. 1 death; 12 hospitalized

Microorganism	Location	Cases	Source	Narrative
Shigella flexneri 2a	New York, 2001	886	Clinical Infectious Diseases 2006;42:163-9	22 hospitalized; Outbreak involved 5 local restaurants under the same ownership. Consumption of tomatoes was the only exposure that remained significant in multiple multivariable models.

* Information in the Appendix C is prepared by Judy D. Greig, Laboratory for Foodborne Zoonoses , PHAC (Public Health Agency of Canada)