



Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

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RE: Docket No. 2004N-0258

Please find attached the Government of Canada's comments on the document "Produce Safety From Production to Consumption: An Action Plan to Minimize Food borne Illness Associated With Fresh Produce," as notified under Docket No. 2004N-0258 and published by the Food and Drug Administration, Department of Health and Human Services, in the Federal Register of June 15, 2004 (Volume 69, Number 114).

If you require further information, please do not hesitate to contact me.

Yours truly,

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Comments of the Government of Canada on the United States Food and Drug Administration's "Produce Safety From Production to Consumption: An Action Plan to Minimize Food borne Illness Associated With Fresh Produce"

Docket No.: 2004N-0258

The Government of Canada welcomes the opportunity to provide comments on key elements of the Food and Drug Administration's proposed produce safety action plan entitled "Produce Safety From Production to Consumption: An Action Plan to Minimize Food borne Illness Associated With Fresh Produce," (Proposed FDA Action Plan) as notified under Docket No. 2004N-0258 and published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the Federal Register of June 15, 2004 (Volume 69, Number 114).

The Government of Canada shares and supports the objectives of the proposed FDA Action Plan. Safeguarding Canada's food supply is one of the Canadian Government's top priorities. In carrying out this objective, the Canadian Government is committed to: contributing to the protection of Canadian consumers from preventable health risks; delivering a fair and effective regulatory regime; fostering strong partnerships with its stakeholders and its trading partners; and promoting the security of the Canadian food supply. Canada shares the view with the FDA that any initiative or system put in place must be designed and implemented based on science and effective risk management principles and practices.

Canada is currently implementing national food safety systems on the farm and throughout the agri-food chain - from the field to the fork under the Canadian Agricultural Policy Framework. Specifically, in the area of fresh produce, the Government of Canada is working with farmers and the industry to build on existing food safety measures while undertaking new measures to enable the tracing of food products back to the point of contamination, implement Hazard Analysis Critical Control Point (HACCP) plans, improve food quality and share critical information. These measures will improve the sector's ability to identify and respond to food safety issues and concerns.

Canada believes that it is critical that guidelines developed under the proposed FDA Action Plan take into consideration the successful joint "FDA/CFIA Action Plan on Food Safety" initiated by the FDA and the Canadian Food Inspection Agency (CFIA) in 2000 (Annex 1). The overall purpose of this program is to ensure and enhance the high level of consumer health protection, in both countries, in the most efficient and effective manner while maintaining FDA's ability to ensure product safety. This initiative is reflective of the high level of confidence our two countries have in each other's inspection systems.

Similar to the "FDA/CFIA Action Plan on Food Safety", any guidelines which are developed under the proposed FDA Action Plan must take into consideration the large volume of fresh produce that crosses our shared border and the importance of this trade to producers and consumers in both countries. On average, Canada exports US\$ 507 million worth of fresh

produce to the United States annually and imports US\$1.4 billion worth of fresh produce from the United States.

It is important that we continue to work together to develop initiatives and systems to achieve our regulatory objectives in a manner that reflects the scale of our bilateral trade relationship and the increased integration of our two economies. Therefore, it is Canada's view that, the proposed FDA Action Plan take into account the "FDA/CFIA Action Plan on Food Safety", which could be extended to products covered by the proposed FDA Action Plan.

**Year 2000 Accomplishments and Next Steps Under
The U.S. Food and Drug Administration and
The Canadian Food Inspection Agency
Action Plan on Food Safety**

In April, 2000, the U.S. Food and Drug Administration (FDA) and the Canadian Food Inspection Agency (CFIA) began work on an "Action Plan on Food Safety" to consider how entry of fresh Canadian produce into the United States could be facilitated while maintaining FDA's ability to ensure product safety. This document is a summary of the accomplishments achieved during calendar year 2000 to implement the Action Plan and future activities to be implemented under the Action Plan.

INFORMATION EXCHANGE

Food safety experts from FDA and CFIA exchanged technical information about each country's respective food safety programs for fresh produce regarding microbiological contaminants, pesticide residues, tracebacks, good agricultural practices, recalls, and food irradiation. The country experts then met to discuss this information in light of the objectives of the Action Plan, i.e., to facilitate trade of safe fresh fruits and vegetables between Canada and the U.S. and further enhance food safety. Areas for future collaborative exchange on fresh produce safety were also discussed.

IMPLEMENTATION PLAN

As a result of the FDA-CFIA Action Plan on Food Safety and the exchange of technical information, the FDA and CFIA intend to take the actions below pertaining to certain fresh fruit and vegetable commodities shipped between Canada and the United States.

A. Scope of the Current Plan

1. The plan covers fresh fruits and vegetables that are shipped between the United States and Canada. The commodities currently under consideration are: Fresh Blueberries, Cantaloupe, Celery, Cilantro/ Coriander, Green Onion/Scallions, Honeydew, Loose-leaf Lettuce, Parsley, Raspberries, Strawberries, and Tomatoes.
2. Canada and the United States intend to consider additional commodities at a later date as warranted by information generated by FDA and CFIA on the incidence of microbial and chemical contaminants and pesticide residue food safety concerns.
3. The plan does not apply to products from other countries that are transhipped through Canada or through the United States.

B. General Principles

1. CFIA and FDA understand that increased information exchange about their respective regulatory systems provides a basis for a clear understanding of the likelihood that exported fresh fruits and vegetables would comply with the other country's food safety requirements. CFIA and FDA intend to take this understanding into account in facilitating the entry of the designated fresh produce when these agricultural products are offered for entry into their respective countries. Each agency intends to conduct sampling of the other's exports at a rate commensurate with its level of confidence in the exporting country's system for the commodities covered.

2. Based on discussions on implementing the Action Plan, CFIA and FDA intend to cooperate as described below.

a. CFIA and FDA plan to meet as needed in order to determine that the basis for the current plan for fresh fruits and vegetables continues to exist.

b. In cases of serious and immediate concern with respect to public health or safety regarding the designated commodities and contaminants, CFIA and FDA intend to notify the designated agency contacts, herein included, immediately. Written confirmation would follow within 48 hours.

c. Where either CFIA or FDA has concerns regarding a potential risk to public health with respect to the designated commodities and contaminants, consultations regarding the situation should, upon request of that agency, take place no later than the next working day. CFIA and FDA intend to provide in such situations all legally discloseable information deemed by each respective Party necessary to reach a mutually acceptable solution.

3. Nothing in the current plan for fresh fruits and vegetables would in any way abrogate the responsibility or authority of FDA under section 801 of the Federal Food, Drug and Cosmetic Act to examine any food product offered for entry into the United States or under any other law administered by FDA. Neither would it abrogate the responsibility or authority of the Canadian Food Inspection Agency pursuant to the *Food and Drug Act* and any other pertinent Canadian legislation.

4. Nothing in the current plan precludes either the U.S. or Canada from exercising their respective mandates with respect to the safety of fresh produce being allowed to enter that country's commercial marketing channels.

5. All activities, including the sharing of non-public information, undertaken pursuant to the current plan are to be conducted in accordance with the laws and regulations of the United States and of Canada.

6. FDA and CFIA intend to address any technical issues that may arise concerning this plan through bilateral consultations between FDA and CFIA and, as appropriate, through relevant Technical Working Groups of the North American Free Trade Agreement Committee on Sanitary and Phytosanitary Measures (NAFTA SPS Committee).

7. The current plan demonstrates progress in implementing the Action Plan on Food Safety. This document is not a binding international agreement nor is it intended to

create any private rights of action.

C. Specific CFIA and FDA Actions

CFIA Actions

1. CFIA intends to inform the FDA on a quarterly basis¹ that:
 - CFIA is using appropriate methodologies that are adequate to detect *Salmonella*, *E. coli* 0157 and *Shigella*.²
 - CFIA is continuing to sample and test the identified commodities for the above mentioned microbial contaminants to maintain confidence in product safety.
2. CFIA intends to share on an annual basis all monitoring results relevant to the three microbial pathogens described in CFIA Action 1.
3. CFIA intends to notify FDA (no later than the next working day) should CFIA detect a microbial pathogen in any of the identified commodities imported from, or that could be present in products exported to, the U.S..
4. CFIA intends to investigate the cause of any finding of a microbial pathogen in any of the identified commodities reported by FDA on a Canadian shipment and intends to facilitate any necessary FDA regulatory action pertaining to that finding.

FDA Actions:

1. FDA intends to share on an annual basis all domestic monitoring results relevant to the three microbial pathogens described in CFIA Action 1.
2. FDA intends to notify CFIA (no later than by the next working day) should FDA detect a microbial pathogen in any of the identified commodities imported from, or that could be present in products exported to, Canada.
3. FDA intends to investigate the cause of any finding of a microbial pathogen in any of the identified commodities reported by CFIA on a U.S. shipment and intends to facilitate any necessary regulatory action pertaining to that finding.

CFIA and FDA Actions:

FDA and CFIA intend to inspect and sample imports of the identified commodities at a rate and in a manner commensurate with their respective levels of confidence in the effectiveness of each other's food safety monitoring program. Currently, both these levels of confidence are high. When something occurs that might affect CFIA's or FDA's level of confidence in the other's monitoring program, CFIA and FDA intend to

¹On or about February 1, May 1, August 1, and November 1 of each year.

²The Parties recognize that currently, with respect to *Shigella*, the appropriate methodology is the methodology acceptable to both parties pursuant to their respective existing testing methodologies.

immediately notify each other and, when possible without compromising either side's ability to protect public health, provide an opportunity to resolve the situation before confidence in the other's system is lessened. FDA and CFIA intend to give prior notice of future program changes. Further, FDA and CFIA intend to share sampling plans, inspection procedures, methods of analysis, and information on commodities of current focus.

D. Next Steps

1. Cooperation under the current plan is intended to begin as of the date of the signing of the letters to be exchanged between the U.S. FDA and the CFIA, as would the collaborative evaluation described under Section D.2. After the first year, CFIA and FDA plan to evaluate annually the effectiveness and practicability of the actions described here as well as progress achieved in further implementation of the Action Plan.

2. FDA and CFIA are evaluating information on chemical contaminants and pesticide residues for fruit and vegetable commodities, and intend to do the same for other food commodities, as agreed to by the U.S. FDA and the CFIA, with the goal of including them within the scope of the Action Plan on Food Safety.

E. Agency Contacts

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