

FOOD SAFETY SYSTEMS RECOGNITION ARRANGEMENT BETWEEN THE CANADIAN FOOD INSPECTION AGENCY AND THE DEPARTMENT OF HEALTH OF CANADA AND THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES

The United States Food and Drug Administration (FDA), the Canadian Food Inspection Agency (CFIA), and the Department of Health of Canada (Health Canada), (hereafter collectively referred to as “the Participants”):

Recognizing existing arrangements between FDA and the CFIA and between FDA and Health Canada;

Desiring to safeguard public health as it relates to the safety and integrity of food traded between the United States and Canada (hereafter referred to as “the two countries”);

Noting that reciprocal food safety Systems Recognition Assessments have been carried out regarding the operation and oversight of the food safety system of the United States, as implemented by FDA, and the food safety system of Canada, as implemented by CFIA and Health Canada (“the Canadian Participants”), through the application of the following standards, as identified in the Participants’ respective international comparability assessment tools: Regulatory Foundation; Training Program; Inspection Program; Program Assessment and Inspection Audit Program; Food-related Illness and Outbreaks; Compliance and Enforcement Program; Industry and Community Relations; Program Resources; International Communication and Harmonization; and Laboratory Support;

Desiring greater regulatory cooperation, collaboration, partnership and information exchange between FDA, on the one hand, and the Canadian Participants, on the other hand, relating to these standards;

Having determined, based on the successful outcome of the food safety Systems Recognition Assessment and on existing knowledge, confidence and experience, that the United States and Canada have comparable control measures and systems as they relate to the safety of Food; and

Noting that this Food Safety Systems Recognition Arrangement (“Arrangement”) offers benefits for public health, consumer protection and trade, including the use of Systems Recognition as an important tool for enhancing the safety of imported Food;

Have reached the following understandings:

Section I **Purpose and Scope**

1.1 This Arrangement sets out the principles and areas of cooperation between FDA and the Canadian Participants with respect to public health and consumer protection relating to Food traded between the two countries, and to any food safety-related areas of mutual interest.

1.2 This Arrangement covers articles regulated as Food by FDA and one or both of the Canadian Participants, but does not include the articles listed in the Annex.

Section II Definitions

2.1 For the purpose of this Arrangement:

“Food” includes (1) any article used as food or drink for humans, (2) chewing gum, and (3) any article used for components of any such article;

“Food Safety Concern” refers to a situation where there is a reasonable probability that the use of, or exposure to, a Food will cause acute or chronic deleterious health consequences or death;

“Systems Recognition” means that, following successful completion of a Systems Recognition Assessment, a determination has been made that (1) a country’s food safety system provides a similar, though not identical, system of food safety protection as does that of the other country, and (2) the Participants provide similar oversight and monitoring activities for Food that they regulate; and

“Systems Recognition Assessment” means an evaluation of the overall food safety system to determine whether the systems provide a comparable degree of food safety control.

Section III General Principles

3.1 Systems Recognition allows for: more efficient and effective use of resources; collaboration on risk-informed decision-making about activities that may be carried out in each country; and enhanced regulatory cooperation, improved coordination and greater reliance on the other country’s Participant(s) for follow-up and coordination when a Food Safety Concern arises. It may also result in reductions in the type and frequency of verification activities.

3.2 The Participants intend that exchanges of non-public information pursuant to this Arrangement be done in accordance with appropriate Confidentiality Commitments, including:

- *The 2003 Confidentiality Commitment Statement of Legal Authority and Commitment from Canadian Food Inspection Agency Not To Publicly Disclose Non-Public*

Information Shared by the U. S. Food and Drug Administration (US FDA), U.S. Department of Health Human Services;

- *The 2003 Confidentiality Commitment Statement of Legal Authority and Commitment from the United States Food and Drug Administration (US FDA) United States Department of Health and Human Services Not To Publicly Disclose Non-Public Information Shared by the Canadian Food Inspection Agency;*
- *The 2003 Confidentiality Commitment Statement of Legal Authority and Commitment from Health Canada Not To Publicly Disclose Non-Public Information Shared by the U.S. Food and Drug Administration (USFDA), U.S. Department of Health and Human Services; and*
- *The 2003 Confidentiality Commitment Statement of Legal Authority and Commitment from the United States Food and Drug Administration (USFDA) United States Department of Health and Human Services Not To Publicly Disclose Non-Public Information Shared by the Health Products and Food Branch (HPFB) of Health Canada.*

3.3 If the level of food safety control required under the domestic law administered and enforced by, or if the level of food safety control achieved by, FDA or the Canadian Participants significantly changes, the Participants may carry out a follow-up Systems Recognition Assessment of the affected standards of the food safety systems. Systems Recognition continues while any such assessment is carried out.

3.4 This Arrangement does not create legally binding obligations under domestic or international law. The Participants intend that activities under this Arrangement be in accordance with applicable domestic laws, regulations and policies, and subject to the availability of personnel and resources.

3.5 The Participants may mutually determine to invite other U.S. or Canadian national and sub-national government organizations (including, but not limited to, the Public Health Agency of Canada) to participate in activities under this Arrangement, as appropriate.

Section IV **Intentions of the Participants**

4.1 To the extent reasonably possible, FDA and the Canadian Participants intend to:

- (a) Continue to cooperate on food safety and to facilitate regular communications related to their countries' respective food safety systems;
- (b) Promote the management of food safety risks prior to export;

(c) Consistent with any applicable domestic laws and regulations, consult and collaborate on the development of changes to their food safety policies and regulatory approaches as they impact the standards that have been assessed under this Arrangement in order to optimize the prospects for continued comparability of degree of food safety control;

(d) Encourage early discussion of respective policy approaches when faced with similar food safety issues and challenges, which will allow for the exchange of best practices and approaches and enhance the likelihood for similar or complementary approaches to be considered, where applicable;

(e) Work cooperatively to ensure prompt notification of a Food Safety Concern regarding Food traded between the two countries, and, as may be mutually determined, Food originating from a third country that may have been shipped to either of the two countries;

(f) Work cooperatively when investigating a Food Safety Concern associated with Food that is traded between the two countries to facilitate appropriate risk management interventions; and

(g) Collaborate, as appropriate, on foreign inspections and foreign audits and, as mutually determined, share results to support the effective use of the Participants' resources.

4.2 The Participants may consider broadening the scope of this Arrangement based on additional assessments at a future date.

Section V

Reassessment, Review and Audit

5.1 FDA and the Canadian Participants may periodically reassess, review or audit the operation of the other country's regulatory systems as they relate to food safety for the purpose of maintaining knowledge of and confidence in the other country's systems. It is intended that the content and extent of any such reassessment, review or audit be based on discussions and mutually determined and coordinated through the Contact Points.

5.2 It is intended that any such reassessment, review or audit focus on significant changes in food safety systems. Each Participant intends to fund its own expenses relating to such reassessment, review or audit.

5.3 To support continued confidence in the countries' food safety systems, the Participants intend to discuss Systems Recognition reassessments, reviews or audits, at least once every five years.

5.4 It is intended that determinations regarding the type and frequency of reassessments, reviews or audits reflect the high level of knowledge, experience and confidence that each Participant has in the other country's food safety system.

5.5 The Participants intend to cooperate to ensure that responses to any issues that arise during such reassessments, reviews or audits are risk-based, outcome-focused and reflect the high level of knowledge, confidence and experience each has in the other country's food safety system.

Section VI

Cooperation and Technical Information Exchange

6.1 FDA and the Canadian Participants intend to further cooperate and exchange information on at least an annual basis on regulatory and scientific issues related to food safety. Such cooperation may include, but is not limited to:

- (a) The scheduling of meetings, including annual meetings as well as urgent meetings, to resolve in a mutually acceptable manner issues of significance to the Participants;
- (b) Scientific exchange and collaboration on food safety hazards, including emerging hazards, such as: scientific reviews, development of surveys/monitoring, and procedures for sampling and analysis;
- (c) Collaboration on and/or sharing of regulatory assessments, pertinent laws, regulations, policies and guidance information, where appropriate; and
- (d) Cooperation in other food safety-related areas of interest as mutually determined.

Section VII

Contact Points and Notification

7.1 The Participants intend to identify Contact Points for the activities associated with this Arrangement.

7.2 Each Participant intends to provide written notification to the other Participants within 30 days of relevant changes in the names of its organization, the structure of its organization, or its Contact Points. The updating of such administrative aspects does not constitute a change in the terms of this Arrangement.

Section VIII

Implementation

8.1 Activities under this Arrangement may be carried out through existing collaboration mechanisms or new mechanisms, as considered appropriate by the Participants.

8.2 The Participants understand that activities under this Arrangement may involve only those Canadian Participants whose involvement is appropriate given the scope of the activity.

8.3 This Arrangement is intended to take effect on the date of the last signature of the Participants.

8.4 Participants may amend this Arrangement, including the Annex, by mutual consent in writing.

8.5 A Participant may withdraw from this Arrangement or discontinue an activity under this Arrangement by giving at least 60-days' written notice to the other Participants.

8.6 The Participants understand that withdrawal from this Arrangement or discontinuation of an activity under this Arrangement is not intended to affect ongoing cooperative activities.

Signed in the English and French languages.

**For the CANADIAN FOOD
INSPECTION AGENCY**

_____/s/_____
Paul Mayers
Vice President
Policy and Programs
Canadian Food Inspection Agency

Date: 04/25/2016

**For the FOOD AND DRUG
ADMINISTRATION OF THE
UNITED STATES OF AMERICA**

_____/s/_____
Michael Taylor
Deputy Commissioner
Foods and Veterinary Medicine
United States Food and Drug Administration

Date: 04/25/2016

**For the HEALTH PRODUCTS AND
FOOD BRANCH, HEALTH CANADA**

_____/s/_____
Anil Arora
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

Date: 04/25/2016

**For the FOOD AND DRUG
ADMINISTRATION OF THE
UNITED STATES OF AMERICA**

_____/s/_____
Howard Sklamberg
Deputy Commissioner
Global Regulatory Operations and Policy
United States Food and Drug Administration

Date: 04/25/2016

ANNEX

ARTICLES EXCLUDED FROM THE SCOPE OF THIS ARRANGEMENT

- Meat;
- Poultry;
- Processed egg products;
- Farmed catfish and catfish products;
- Grade “A” milk and Grade “A” milk products;
- Raw bivalve molluscan shellfish; and
- Dietary supplements and natural health products.