



**MEMORANDUM OF UNDERSTANDING
BETWEEN**

THE FOOD STANDARDS AGENCY

OF

**THE UNITED KINGDOM OF GREAT BRITAIN AND
NORTHERN IRELAND**

AND

THE FOOD DIRECTORATE

HEALTH PRODUCTS AND FOOD BRANCH

HEALTH CANADA

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1. BACKGROUND

- 1.1 International trade in food is increasing year on year. This brings with it new food safety challenges. The Food Standards Agency of the United Kingdom of Great Britain and Northern Ireland¹ (the Food Standards Agency) and the Food Directorate, Health Products and Food Branch, Health Canada (the Food Directorate), sometimes collectively referred to as the Participants, recognize the benefits of sharing information on a range of food issues. The sharing of such information will increase the ability of both organizations to respond rapidly to emerging food related issues.

2. AUTHORITY

- 2.1 The Food Standards Agency is a non-ministerial government department established and given statutory functions and legal powers under the *Food Standards Act 1999*. The Food Directorate is part of a federal government department granted authority under the *Food and Drugs Act* and the *Department of Health Act*. The Participants have similar approaches to regulation of foods in the broad policy sense and at the practical level in relation to the type of data they require.
- 2.2 This Memorandum of Understanding (MOU) comprises this document and any schedules, as amended from time to time.

¹ Elsewhere in this document referred to by the conventional short form: "United Kingdom"

3. PURPOSE AND OVERVIEW

- 3.1 This MOU establishes a voluntary arrangement under which the Participants do not intend to create legally binding commitments or obligations between them. However, the Participants intend to strengthen the exchange of knowledge and expertise to enhance the efficiency and effectiveness of their respective roles. Nothing in this MOU prevents or derogates from the ability of either Participant to carry out its regulatory, legislative and policy activities.
- 3.2 Subject to paragraph 6, the Participants will exchange information on risk assessments and risk management options in respect of foods and food processes over which they both have jurisdiction under their respective legislation or regulations, and will work concurrently to conduct scientific risk assessments in relation to specific food regulatory matters. The MOU specifies a number of aspects of the arrangement between the Participants, to fulfill these general objectives.
- 3.3 The exchange of information and cooperative action between the Participants relates to food regulatory matters of mutual interest, with early focus on, but not limited to, applications received or proposals initiated by the Participants regarding:
- (i) Chemical safety (e.g., contaminants, food allergens); and
 - (ii) Measures to reduce food incidents² and emergency response measures.
- 3.4 The arrangement also comprises the following elements:
- (i) A system for early information exchange on emerging food safety issues and food regulatory problems that may impact on the United Kingdom and Canada;
 - (ii) The development of a joint work program with a set of defined time-specified activities over a three (3) year period. The work program will aim towards the harmonization of risk assessment methods and processes and the conduct of concurrent assessments in relation to food regulatory matters; and
 - (iii) A mutual determination to take advantage of international fora, such as sessions of the Codex Alimentarius Commission and its Committees, and other international fora or conferences as appropriate, for face-to-face meetings between staff, as an important mechanism for advancing the work program that the Participants mutually determine.
- 3.5 As an initial activity of the work program, the Participants will cooperate on at least one assessment in relation to a food regulatory matter identified under paragraph 3.3. It is envisioned that this activity will begin in mid 2006, and may be completed by mid 2007.
- 3.6 As additional activities of the work program are developed and mutually determined by officers responsible for this MOU, these will be exchanged in writing.

² "Food incident" means any event where, based on the information available, there are concerns about actual or suspected threats to the safety or quality of food that could require intervention to protect consumers' interests.

4. ACKNOWLEDGEMENT OF THE PARTICIPANTS' COMMITMENTS AND INFORMATION POLICIES

- 4.1 In support of an application received or proposal initiated by the Food Standards Agency or the Food Directorate, information is often required and obtained from persons, groups of persons or organizations (Third Parties).
- 4.2 The Participants acknowledge that the Food Standards Agency may publish any information in its possession in accordance with Section 19 of the *Food Standards Act 1999*. As a government department, the Food Standards Agency may be obliged to publish or disclose information under the following legislation governing access to information held by public authorities:
- (i) *The Data Protection Act 1998*;
 - (ii) *The Freedom of Information Act 2000*;
 - (iii) *The Environmental Information Regulations 2005*;
 - (iv) *The Environmental Information (Scotland) Regulations 2005*; and
 - (v) related European Union legislation, as amended from time to time.
- 4.3 Subject to the enactments mentioned in paragraph 4.2, the Food Standards Agency has a general policy of openness and transparency with regard to information it holds. All of the Food Standards Agency's assessment reports, including safety assessment reports, are published.
- 4.4 The Food Standards Agency will consult the Food Directorate about disclosure of information it has provided and give the Food Directorate ten (10) working days in which to comment. The Food Standards Agency will take account of any comments received from the Food Directorate when reaching its decision on whether to publish or disclose information under any of the enactments mentioned in paragraph 4.2. However, where the Food Standards Agency is deciding whether to publish information received from the Food Directorate using powers granted to it under the *Food Standards Act 1999*, and it considers that an urgent public health issue makes it impractical to consult the Food Directorate in advance, it may not do so.
- 4.5 The Participants acknowledge that it is the current policy of the Food Directorate to treat all information received from a Third Party as if it were confidential information for the purposes of the *Access to Information Act* and the *Privacy Act*. All the Food Directorate's assessment reports are also considered as confidential information.

5. ROLES AND RESPONSIBILITIES

5.1 Food Standards Agency

- 5.1.1 Subject to paragraph 6.1, the Food Standards Agency, where it is able, will notify the Food Directorate of any applications received or proposals initiated relating to, but not limited to, those areas listed under paragraph 3.3. Notification will involve the Food Standards Agency providing an information summary to the Food Directorate describing the nature of the application or proposal.
- 5.1.2 At the request of the Food Directorate, and subject to paragraph 6.1, the Food Standards Agency will provide further information to the Food Directorate regarding the Food Standards Agency's assessment of any application or proposal notified under paragraph 5.1.1. Such information may include:

- (i) full copies of the Food Standards Agency's assessment reports, including the safety assessment information;
- (ii) information about the type and scope of data submitted with or related to the application or proposal, including copies of specific study reports; and
- (iii) discussions with the assessing officers regarding issues of concern that arose during an assessment.

5.1.3 The Food Standards Agency will inform the Food Directorate of the outcome of the Food Standards Agency's final assessment, made in respect of any application or proposal notified to the Food Directorate under paragraph 5.1.1.

5.1.4 The Food Standards Agency will provide information under paragraph 5.1.2 free of charge.

5.2 Food Directorate

5.2.1 Subject to paragraph 6.2, the Food Directorate will notify the Food Standards Agency of any applications received or proposals initiated relating to, but not limited to, those areas listed under paragraph 3.3. Notification will involve the Food Directorate providing an information summary to the Food Standards Agency describing the nature of the application or proposal.

5.2.2 At the request of the Food Standards Agency, and subject to paragraph 6.2, the Food Directorate will provide further information to the Food Standards Agency regarding the Food Directorate's assessment of any application or proposal notified under paragraph 5.2.1. Such information may include:

- (i) full copies of the Food Directorate's assessment reports, including safety assessment information;
- (ii) information about the type and scope of data submitted with or related to the application or proposal, including copies of specific study reports; and
- (iii) discussions with the assessing officers regarding issues of concern that arose during an assessment.

5.2.3 The Food Directorate will inform the Food Standards Agency of the Food Directorate's final decision made in respect of any application or proposal notified to the Food Standards Agency under paragraph 5.2.1.

5.2.4 The Food Directorate will provide such information under paragraph 5.2.2 free of charge.

6. CONFIDENTIALITY

6.1 Information Supplied by the Food Standards Agency to the Food Directorate

6.1.1 The Food Standards Agency will not disclose to the Food Directorate information received in confidence from other Governments, or from institutions of the European Union.

- 6.1.2 The Food Standards Agency will not disclose to the Food Directorate information that the Food Standards Agency considers is confidential without first obtaining the consent of the Third Party from whom the information was received. When seeking consent, the Food Standards Agency will inform the Third Party of the purposes for which the Food Directorate may use the information, and of the Food Directorate's commitments and information policy as outlined in paragraph 4.5.
- 6.1.3 The Food Standards Agency will notify the Food Directorate when information the Food Standards Agency considers is confidential is provided to the Food Directorate and identify the confidential information. The Food Standards Agency will also notify the Food Directorate of the Third Party's consent to the disclosure of the information.
- 6.1.4 When the Food Directorate is notified pursuant to paragraph 6.1.3 that information provided is confidential, then unless otherwise required by applicable law, and except in so far as the information is already in the public domain, the Food Directorate will take all reasonable steps to protect the confidentiality of that information. The Food Directorate will not release the information to any person other than its employees, agents or contractors who need to know the information for work purposes. The Food Directorate will take all reasonable steps to ensure that its employees, agents and contractors with access to the information protect its confidentiality.
- 6.1.5 If the Food Directorate is required by applicable law to disclose the information, or where the information is already in the public domain, the Food Directorate will inform the Food Standards Agency of this as soon as is reasonably practicable.
- 6.1.6 Where the Food Directorate is notified pursuant to paragraph 6.1.3 that information provided is confidential, if the Food Directorate obtains written confirmation from the Food Standards Agency that either (i) the information or an identified part of it has been made public, or (ii) the Food Standards Agency consents to the disclosure of the information or an identified part of it, then the Food Directorate shall no longer be obliged to protect the confidentiality of that information.
- 6.1.7 Refusal of the Third Party's consent to disclose information as outlined in this MOU will not preclude the Food Standards Agency from proceeding with its own assessment of the application or proposal.

6.2 Information Supplied by the Food Directorate to the Food Standards Agency

- 6.2.1 The Food Directorate will not disclose to the Food Standards Agency information received in confidence from other Governments.
- 6.2.2 The Food Directorate will not disclose to the Food Standards Agency information that the Food Directorate considers is confidential without first obtaining the consent of the Third Party from whom the information was received. When seeking consent, the Food Directorate will inform the Third Party of the purposes for which the Food Standards Agency may use the information and of the Food Standards Agency's commitments and information policy as outlined in paragraphs 4.2, 4.3 and 4.4.
- 6.2.3 The Food Directorate will notify the Food Standards Agency when information the Food Directorate considers is confidential is provided to the Food Standards Agency and identify

the confidential information. The Food Directorate will also notify the Food Standards Agency of the Third Party's consent to the disclosure of the information.

- 6.2.4 When the Food Standards Agency is notified pursuant to paragraph 6.2.3 that information provided is confidential, then unless otherwise required or permitted by applicable law, and except in so far as the information is already in the public domain, the Food Standards Agency will take all reasonable steps to protect the confidentiality of that information. The Food Standards Agency will not release the information to any person other than its employees, agents or contractors who need to know the information for work purposes. The Food Standards Agency will take all reasonable steps to ensure that its employees, agents and contractors with access to the information protect its confidentiality.
- 6.2.5 If the Food Standards Agency is required or permitted by applicable law to disclose the information, or where the information is already in the public domain, the Food Standards Agency will inform the Food Directorate of this as soon as is reasonably practicable.
- 6.2.6 Where the Food Standards Agency is notified pursuant to paragraph 6.2.3 that information provided is confidential, if the Food Standards Agency obtains written confirmation from the Food Directorate that either (i) the information or an identified part of it has been made public, or (ii) the Food Directorate consents to the disclosure of the information or an identified part of it, then the Food Standards Agency shall no longer be obliged to protect the confidentiality of that information.
- 6.2.6 Refusal of the Third Party's consent to disclose information as outlined in this MOU will not preclude the Food Directorate from proceeding with its own assessment of the application or proposal.

7. ADMINISTRATIVE ARRANGEMENTS

- 7.1 Changes by either Participant in legislation, operational policies, practices and procedures which relate to matters covered by the MOU, and which would impact on the arrangement established by the MOU, will be notified to the other Participant and any consequential changes necessary to the MOU will be subject to consultation between the Participants.
- 7.2 Either Participant may propose a variation to the provisions of this MOU, but any variation must be mutually determined in writing by both Participants.
- 7.3 The officers responsible for the administration of this MOU are:
- (i) the person holding the position of Chief Executive, Food Standards Agency; and
 - (ii) the person holding the position of Director General, Food Directorate.
- 7.4 The officers responsible for the day-to-day operations under this MOU are:
- (i) the person holding the position of Head of Chemical Safety Division at the Food Standards Agency; and
 - (ii) the person holding the position of Director, Bureau of Food Regulatory, International and Interagency Affairs, Food Directorate.

7.5 Changes of contact officers will be notified within ten (10) working days and transitional arrangements put in place to deal with correspondence received in the interim. The Participants will assist each other when requested to identify sources of expertise to review applications or proposals, or to review or provide other information.

8. REVIEW OF THIS MOU

8.1 On, or shortly after, the first anniversary of the date of commencement of this MOU, representatives of the Participants will review the flow of information between the Participants, the costs incurred by each Participant in providing information, and the scope of the MOU and consider, if appropriate, amendment of this MOU. Thereafter, periodic review of this MOU may take place on request from either Participant.

8.2 Nothing in paragraph 8.1 precludes the Participants from mutually determining to amend this MOU at any time.

9. COMMENCEMENT AND TERMINATION OF THIS MOU

9.1 The MOU will commence on the day on which it is signed by the latter of the Participants.

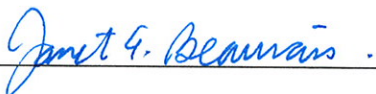
9.2 Either Participant may terminate this MOU by written notice to the other Participant. The MOU will terminate thirty (30) calendar days after the date upon which the other Participant receives written notice of the intention to terminate.

SIGNED AT

SIGNED AT

5 day of April 2006

31 day of March 2006





Janet Beauvais

Jon Bell

Director General, Food Directorate,

Chief Executive

Health Products and Food Branch

Food Standards Agency

Health Canada

United Kingdom

DEFINITIONS & INTERPRETATION**In this MOU:****Food Standards Agency's Definitions:**

"Food" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EC and 98/83/EC.

"Food" shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EC and 92/73/EC;
- (e) cosmetics within the meaning of Council Directive 76/768/EC;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EC;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

Health Canada's Definitions:

"Food" includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

Application of Definitions:

For the purposes of this MOU, each Participant will apply its own definitions of terms used in the MOU, in accordance with its domestic laws or internal common usage, and will have regard to the definitions of terms used by the other Participant.