
MEMORANDUM OF UNDERSTANDING**BETWEEN****THE FOOD STANDARDS AGENCY OF THE UNITED KINGDOM OF GREAT BRITAIN
AND NORTHERN IRELAND****AND****FOOD STANDARDS AUSTRALIA NEW ZEALAND**

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 Food Standards Australia New Zealand (FSANZ), sometimes collectively referred to as the Participants, recognise the benefits of sharing information on a range of food issues. The sharing of such information will increase the ability of both organisations 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*. Food Standards Australia New Zealand is a statutory authority established under section 6 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ 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 or policy activities.
- 3.2 Subject to paragraph 6, the Participants will exchange information, some of which may not be in the public domain, on risk assessments and risk management options in respect of foods and food processes over which they both have jurisdiction under their respective legislation, regulations or guidelines, and will work concurrently to conduct scientific risk assessments in relation to specific food regulatory issues. 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);
 - (ii) Measures to reduce food incidents² and emergency response measures; and
 - (iii) Consumer research with particular relevance to health claims or food fortification.
- 3.4 This 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 Australia or New Zealand;
 - (ii) The development of a joint work program with a set of defined time-specified activities over a three (3) year period. This work program will aim towards the harmonisation 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 national and international fora, such as sessions of the Codex Alimentarius Commission and its Committees, and other 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 September 2007, and may be completed by August 2008.

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.

- 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 and added to the joint work program.
- 3.7 The Participants will endeavor to facilitate an exchange of staff or staff secondment if an approach is made, subject to relevant Civil Service Nationality Rules and the appropriate administrative and immigration procedures.

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 FSANZ, information is often required and obtained from persons, groups of persons or organisations (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 FSANZ about disclosure of information it has provided and give FSANZ ten (10) working days in which to comment. The Food Standards Agency will take account of any comments received from FSANZ 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 FSANZ 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 FSANZ in advance, it may not do so.
- 4.5 The Participants acknowledge that under the FSANZ Act, all information provided by an applicant in support of an application to FSANZ, except for confidential commercial information, is a matter of public record and is subject to requests under the *Freedom of Information Act 1982*. Similarly, all of FSANZ's assessment reports, including the safety assessment reports, are also a matter of public record. FSANZ is acting in accordance with the FSANZ Act in committing to provide such information to the Food Standards Agency and is not committed to inform the applicant about the provision of such 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 FSANZ of any applications received or proposals initiated relating to, but not limited to, those food regulatory matters listed under paragraph 3.3. Notification will involve the Food Standards Agency providing an information summary to FSANZ describing the nature of the application or proposal.
- 5.1.2 At the request of FSANZ, and subject to paragraph 6.1, the Food Standards Agency will provide further information to FSANZ 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) verbal or written reports and discussions with the assessing officers regarding issues of concern that arose during an assessment.
- 5.1.3 The Food Standards Agency will inform FSANZ of the outcome of the Food Standards Agency's final assessment, made in respect of any application or proposal notified to FSANZ 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 Standards Australia New Zealand

- 5.2.1 Subject to paragraph 6.2, FSANZ 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 FSANZ 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, FSANZ will provide further information to the Food Standards Agency regarding FSANZ's assessment of any application or proposal notified under paragraph 5.2.1. Such information may include:
- (i) full copies of Food Standards Australia New Zealand'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) verbal or written reports and discussions with the assessing officers regarding issues of concern that arose during an assessment.
- 5.2.3 FSANZ will inform the Food Standards Agency of the outcome of FSANZ's final assessment in relation to draft standards and variations, and the outcome of the Australia and New

Zealand Food Regulation Ministerial Council process in relation to FSANZ's notification of approved draft standards and variations, made in respect of any application or proposal notified to the Food Standards Agency under paragraph 5.2.1.

5.2.4 FSANZ will provide such information under paragraph 5.2.2 free of charge.

6. CONFIDENTIALITY

6.1 Information Supplied by the Food Standards Agency to Food Standards Australia New Zealand

6.1.1 The Food Standards Agency will not disclose to FSANZ 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 FSANZ 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 FSANZ may use the information, and of FSANZ's commitments and information policy as outlined in paragraph 4.5.

6.1.3 The Food Standards Agency will notify FSANZ when information the Food Standards Agency considers is confidential is provided to FSANZ and identify the confidential information. The Food Standards Agency will also notify FSANZ of the Third Party's consent to the disclosure of the information.

6.1.4 When FSANZ 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, FSANZ will take all reasonable steps to protect the confidentiality of that information. FSANZ will not release the information to any person other than its employees, agents or contractors who need to know the information for work purposes. FSANZ 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 FSANZ is required by applicable law to disclose the information, or where the information is already in the public domain, FSANZ will inform the Food Standards Agency of this as soon as is reasonably practicable.

6.1.6 Where FSANZ is notified pursuant to paragraph 6.1.3 that information provided is confidential, if FSANZ 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 FSANZ need no longer 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 Food Standards Australia New Zealand to the Food Standards Agency

- 6.2.1 FSANZ will not disclose to the Food Standards Agency information received in confidence from other Governments.
- 6.2.2 FSANZ will not disclose to the Food Standards Agency information that FSANZ considers is confidential without first obtaining the consent of the Third Party from whom the information was received. When seeking consent, FSANZ 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 FSANZ will notify the Food Standards Agency when information FSANZ considers is confidential is provided to the Food Standards Agency and identify the confidential information. FSANZ 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 FSANZ 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 FSANZ that either (i) the information or an identified part of it has been made public, or (ii) FSANZ consents to the disclosure of the information or an identified part of it, then the Food Standards Agency need no longer 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 FSANZ from proceeding with its own assessment of the application or proposal.

7. ADMINISTRATIVE ARRANGEMENTS

- 7.1 Changes by either Participant in legislation, operational policies, guidelines, 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 Chief Executive Officer, Food Standards Australia New Zealand.
- 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 General Manager, Office of Food Standards at Food Standards Australia New Zealand.
- 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. DISPUTES

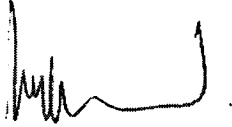
- 9.1 Any dispute about the interpretation or application of this MOU will be resolved by consultations between the Participants, and will not be referred to any national or international tribunal or third party for settlement.

10. COMMENCEMENT AND TERMINATION OF THIS MOU

- 10.1 The MOU will commence on the day on which it is signed by the latter of the Participants.
- 10.2 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.
- 10.3 Notwithstanding termination of this MOU, paragraphs 6 and 9 of this MOU will still remain in effect unless the Parties mutually arrange otherwise.

SIGNED AT

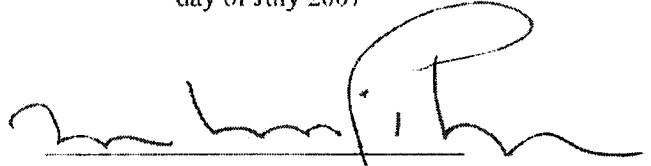
10 day of July 2007



John Harwood
Chief Executive
Food Standards Agency
United Kingdom

SIGNED AT

day of July 2007



Melanie Fisher
Acting Chief Executive Officer
Food Standards Australia New Zealand

ANNEX A

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.

"claim" means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;

"nutrient" means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances which belong to or are components of one of those categories:

"other substance" means a substance other than a nutrient that has a nutritional or physiological effect;

"nutrition claim" means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- (a) the energy (calorific value) it
 - (i) provides,
 - (ii) provides at a reduced or increased rate, or
 - (iii) does not provide, and/or

- (b) the nutrients or other substances it
 - (i) contains,
 - (ii) contains in reduced or increased proportions, or
 - (iii) does not contain:

"health claim" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

"reduction of disease risk claim" means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease;

Food Standards Australia New Zealand's Definitions:

"Health claim" means a claim that a relationship exists between the consumption of a food or component in a food and a disease or health related condition, and includes -

- (a) an enhanced function claim³;
- (b) a reduction of disease risk claim⁴;
- (c) a claim that a food will assist in weight reduction;
- (d) a claim that could be interpreted as advice of a medical nature;
- (e) the name of, or any reference to, any disease or physiological condition.

Food includes:

³ "Enhanced function claim" means a claim that a relationship exists between the consumption of a food or component in a food and the reduced risk of developing a disease or health related condition.

⁴ "Reduction of disease risk claim" means a claim that a relationship exists between the consumption of a food or component in a food and the reduced risk of developing a disease or health related condition;

- (a) any substance or thing of a kind used, capable of being used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared); and
- (b) any substance or thing of a kind used, capable of being used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a); and
- (c) any substance used in preparing a substance or thing referred to in paragraph (a); and
- (d) chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum; and
- (e) any substance or thing declared to be a food under a declaration in force under section 3B.

(It does not matter whether the substance, thing or chewing gum is in a condition fit for human consumption.)

However, **food** does not include a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*.

To avoid doubt, **food** may include live animals and plants

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.