Health claims and enforcement—how regulators will enforce the nutrition and health claims standard

Implementation Subcommittee for Food Regulation

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Introduction

This publication, developed by the Implementation Subcommittee for Food Regulation (ISFR), outlines the documents food regulators will use in implementing Standard 1.2.7 – Nutrition, Health and Related Claims (Standard 1.2.7) of the *Australia New Zealand Food Standards Code* (the Food Standards Code).

ISFR is made up of representatives from government agencies and departments in Australia and New Zealand who are responsible for monitoring implementation and compliance of food laws. These agencies and departments work together through ISFR to ensure standards are implemented and enforced consistently.

All food sold in Australia and New Zealand must comply with Standard 1.2.7 when making nutrition content claims and health claims on food labels, in advertisements and in endorsements on food from 18 January 2016.

You can find Standard 1.2.7 and the explanatory statement, which provides detail about the purpose and intent of the Standard and its associated clauses, online.

Purpose

This publication seeks to:

1. Promote a consistent enforcement response from food regulators in relation to non-compliance with Standard 1.2.7.

2. Provide guidance on the application of the Australia and New Zealand Food Regulation Enforcement Guideline to nutrition, health and related claims.

3. Describe how food regulators will prioritise implementation and compliance activities for Standard 1.2.7 in a way that is consistent with the Food Labelling Policy *Conceptual Framework* (the Conceptual Framework).

4. Describe the documents that food regulators will use to guide:
   (i) assessment of compliance with Standard 1.2.7;
   (ii) collection of data that will inform assessment of compliance with Standard 1.2.7; and
   (iii) conduct of implementation and compliance activities.
5. Provide an outline of all relevant publically available information that may be used by food industry in complying with Standard 1.2.7, including ISFR and FSANZ publications.

Working towards consistent implementation and enforcement of Standard 1.2.7

Government agencies and departments in Australia and New Zealand that are responsible for implementing and enforcing food laws will implement Standard 1.2.7 in a way that is consistent with The Australia and New Zealand Food Regulation Enforcement Guideline, including Appendix 1 which contains a description of enforcement tools.

The home jurisdiction rule will also apply for the implementation of Standard 1.2.7 by food regulators.

Enforcement Guideline - application to enforcement of nutrition, health and related claims

The objectives of the Australia and New Zealand Food Regulation Enforcement Guideline (page 4) apply:
- compliance with the legislative provisions of Australian and New Zealand food law;
- a consistent approach to the application of enforcement provisions by food regulators;
- a risk based approach to compliance and enforcement activities through adoption of a graduated and proportionate response to legislative non-compliance;
- transparency in the decision making processes used by food regulators to determine enforcement responses to legislative non-compliance;
- use of compliance and enforcement strategies in such a way as to best achieve legislative compliance;
- a cooperative and collaborative approach with businesses or between jurisdictions to legislative compliance, and one that does not place an unnecessary impost on food businesses in Australia;
- protection for consumers from inappropriate and/or misleading trade practices.

The enforcement guideline advocates the graduated application of enforcement measures against food businesses, commencing with milder measures such as
warnings and progressing to more severe measures such as prosecution, should milder measures not address the issue of concern.

The enforcement toolbox, appended to the enforcement guideline, provides details on the range of different enforcement tools available and some examples of the situations in which these would be appropriately employed.

An example of application of the enforcement toolbox to an initial breach of Standard 1.2.7 is provided:

Example
A nutrition content claim is made on a product and the claim fails to meet the conditions of Schedule 1 of Standard 1.2.7. There is no evidence of intentional misleading conduct and it is a first-time offence. An appropriate enforcement approach would involve mediation, possibly combined with a written warning. Monitoring of the relevant food category may be undertaken to gain an indication of the level of compliance in the market.

Assigning priority to implementation and compliance activities for Standard 1.2.7

In the Conceptual Framework, food regulators prioritise food labelling activities in the following descending order:

i. Food safety
ii. Preventative health
iii. Consumer values issues.

Nutrition, health and related claims are categorised as ‘preventative health’.

Documents that food regulators will use to guide the assessment of compliance with Standard 1.2.7

To supplement existing ISFR guidance material, for the implementation of Standard 1.2.7, food regulators have agreed on approaches to: managing imported foods in Australia; collating data on complaints received about nutrition content or health claims; and a process for assessing self-substantiation dossiers for food-health relationships established by systematic review.

In Australia, the Department of Agriculture has prepared an approach for managing health claims made on imported food.
Data will be collected from jurisdictions on complaints received about nutrition, health and related claims on a 6-monthly basis, commencing with 1 January – 30 June 2015. This data will be collated and examined on a regular basis by ISFR to improve consistency of compliance.

ISFR has developed a process for assessing self-substantiation dossiers for food-health relationships established by the process of a systematic review. In New Zealand, a process for evaluating systematic reviews of substantiated food-health relationships has also been developed and used.

**Industry guidance – getting your claims right**

The primary resource for industry stakeholders in ensuring compliance with Standard 1.2.7, is the document ‘Getting your claims right: A guide to complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code’ ([Getting your claims right](#)) on the FSANZ website or via the food regulation website: [Getting Your Claims Right](#).

This guidance document includes:

- flow diagrams to help food businesses navigate in the document;
- information on general conditions and restrictions on making nutrition, health or related claims;
- information on building nutrition content claims, general-level health claims (pre-approved), general-level health claims (systematic review) and high-level health claims;
- compliance templates that can be completed for nutrition content claims, general-level health claims (pre-approved), general-level health claims (systematic review), high-level health claims and endorsements – these templates are intended to help food businesses to build the claim and demonstrate due diligence in attempting to comply with the Food Standards Code; and
- checklists to assist food businesses to comply with the Food Standards Code.

Stakeholders are encouraged to use this guidance document and its associated templates and checklists when making a claim. Food regulators will use this guidance document and its components as a resource in monitoring compliance with the Food Standards Code.
Additional resources to assist food business to comply with Standard 1.2.7

The FSANZ website contains information prepared for both consumers and food industry. The information on the consumer pages on nutrition content claims and health claims consists of the following:

- a general overview of the types of claims that are permitted;
- a link to further detail about the notification process for food health relationships established by systematic review;
- a history of the development of the Standard;
- a question and answer section;
- information about the High Level Health Claims Committee; and

The information on the FSANZ website on the industry pages on nutrition, health and related claims consists of the following:

- a general overview of Standard 1.2.7 and the types of claims that are permitted;
- guidance on establishing a food-health relationship by systematic review;
- details on the process for notifying the FSANZ CEO of a food-health relationship established by the process of systematic review;
- information about the Nutrition Information Panel and the Nutrition Panel Calculator; and
- information about the Nutrient Profiling Scoring Criterion and an online calculator.

The New Zealand Ministry for Primary Industries (NZ MPI) website will contain information on health claims prepared for the NZ food industry:

- a general overview of Standard 1.2.7;
- a brief description of self-substantiation of a food-health relationship and the role of MPI in evaluating systematic reviews;
- links to legislative documents (Standard 1.2.7; NZ Supplemented Foods; Dietary Supplements) and guidance documents developed by ISFR and FSANZ;
- a description of regulations applicable to health claims in other countries / areas (e.g. EU, Canada, US and China); and
- information on how to seek regulatory and technical advice in NZ.
Further assistance

For further assistance, contact the food regulatory agency in your state or territory in Australia or in New Zealand.

Full details of state and territory and New Zealand agencies responsible for administering and enforcing the Food Standards Code can be found on the FSANZ website under food enforcement contacts.