EXPLANATORY STATEMENT

Select Legislative Instrument No. 61, 2015
Food Standards Australia New Zealand Act 1991

Food Standards Australia New Zealand Amendment
(High Level Health Claims and Other Measures) Regulations 2015

Authority and Background

Food Standards Australia New Zealand (the Authority) is a body corporate continued in existence by section 12 of the *Foods Standards Australia New Zealand Act 1991* (the Act). The primary function of the Authority is to develop, vary and review food regulatory measures, being food standards and codes of practice for industry. Food standards developed by the Authority comprise the *Australia New Zealand Food Standards Code* (the Code).

Food regulatory measures are developed or varied by the Authority, either as a result of an application from a body or person, or as a result of a proposal prepared by the Authority on its own initiative. Applications to amend the Code are assessed by the Authority under one of four statutory procedures – general, minor, major or high level health claim variation. The choice of which procedure is used depends on factors such as the complexity of the application, how many hours the assessment is likely to take and the type of amendment that is being proposed.

Food Standard 1.2.7 – Health, Nutrition and Related Claims took effect in January 2013. The Act's provisions provide that the regulations may fix charges for applications to vary specific Schedules within this Standard. (Such variations are referred to as high level health claims variations.) No such regulations have been made to date.

Section 153 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters required or permitted by the Act to be prescribed or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Act does not specify any conditions that must be satisfied before the power to make a regulation may be exercised.

Section 146 of the Act provides that the *Food Standards Australia New Zealand Regulations 1994* (the Principal Regulations) may fix charges to be paid to the Authority by a body or person for services and facilities the Authority provides to the body or person. A charge may be fixed in relation to an application to develop or vary a standard if the development or variation of the standard will confer an exclusive capturable commercial benefit on the applicant, or the applicant has elected to have consideration of their application expedited.

Subclause 109(3) provides for the regulations to prescribe a period of consideration for applications to develop or vary standards that is shorter than 12 months.

Section 33(3) of the *Acts Interpretation Act 1901* provides that, where an act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

The repeal of regulation 10 also relies on the necessary and convenient power in paragraph 153(b) of the Act.

The *Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulations 2015* (the 'Amending Regulation') is a legislative instrument for the purposes of the *Legislative Instruments Act 2003.*

Purpose and operation

The Amending Regulation amends the Principal Regulations to:

- prescribe a period of consideration for applications for high level health claims
- prescribe a charging regime for applications for high level health claims
- repeal regulation 10 as it is no longer relevant
- make technical amendments, which will not change the effect of the Principal Regulations, to bring the format of the Principal Regulations into line with current drafting practice, clarify their meaning and minimise the need for future amendments.

Detailed explanation of the Amending Regulation's provisions

Regulation 1 – Name of Regulation
Regulation 1 provides that the title of the Amending Regulation is the *Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulations 2015.*

Regulation 2 – Commencement
Regulation 2 provides that the Amending Regulation commences on the first day of the month following the day of registration.

Regulation 3 – Authority
Regulation 3 provides that the legislative authority for the making of the Amending Regulation is the *Food Standards Australia New Zealand Act 1991.*

Regulation 4 – Schedules
Regulation 4 provides that each instrument that is specified in a Schedule is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

Schedule 1 – Amendments relating to high level health claims applications

Item [1] – Regulation 2

Item [1] of Schedule 1 inserts a definition of 'administration charge' into Principal Regulation 2. This term is referenced elsewhere in the Principal Regulations. The definition refers to subregulation 8(2) which sets the amount of the charge.

Item [2] – Regulation 2

Item [2] amends Principal Regulation 2 by repealing and replacing the definition of 'application consideration process' with a new definition that includes the process undertaken by the Authority in relation to an application for a high level health claim variation.

Item [3] – Regulation 2

Item [3] amends Principal Regulation 3 by inserting new definitions for the ten cost recovery classifications for assessment procedures that are referenced in Principal Regulations as amended by the Amending Regulations. These classifications include four cost recovery levels for the general and high level health claims procedures.

Item [4] – Regulation 2

Item [4] omits the definition of 'procedure' from Principal Regulation 2.

Item [5] – Regulations 7 to 9

Item [5] amends the Principal Regulations by repealing and replacing regulations 7 (Charges – General), 7A (Charges – instalments for general procedure level 3 and 4 applications), 7B (Charges – instalments for major procedure applications) and 8 (Refunds). They are replaced with regulations 7 (Procedure classification), 8 (Charges), 8A (Paying charges by instalments), 8 (Second instalments for certain withdrawn or rejected applications) and 9 (Refunds).

Regulation 8 (Charges) now contains the charges table that is currently located in Schedule 3 of the Principal Regulations, with amended wording to clarify how the regulations apply. The Principal Regulations have also been reordered to reflect the fact that an application must be classified before charges can be worked out (currently the provisions setting out how applications are classified (regulation 9) comes after the provisions setting out the charges and refunds (regulations 7 and 8)).

Regulation 7 (Procedure Classification)

Regulation 7 provides that, if the Authority accepts an application under section 26 or 47 of the Act and charges are payable in relation to the application under regulation 8, the Authority must classify the application in accordance with the table to regulation 7.

Regulation 8 (Charges)

Subregulation 8(1) provides that, for the purposes of subsection 146(1) of the Act, the charge to be paid by an applicant for an application consideration process that is mentioned in an item in the table in that Regulation is the charge set out in that item.

Subregulation 8(1) also clarifies that the charge set out in the table in regulation 8 has been calculated at the rate of $115 for each hour to be charged in relation to an application as set out in the table in regulation 7. The fact that charges were calculated by this hourly rate was implicit in the current Principal Regulations, but not articulated.

Subregulation 8(2) provides that an administrative charge of $10,000 is to be paid by an applicant for the steps in an application consideration process that the Act, another Act or regulations made under the Act or another Act require to be taken and for which an amount is payable by the Authority. Two examples of such steps are the Authority's obligations to publish a notice in a newspaper in accordance with paragraph 34 (1)(c) of the Act and to register a new standard under the *Legislative Instruments Act 2003.*

Regulation 8A (Paying charges by instalments)

Item [5] consolidates into new regulation 8A all the provisions in the Principal Regulations relating to paying charges by instalment.

The process for paying the charges by instalments (currently outlined in regulations 7A and 7B of the Principal Regulations) is now set out in regulation 8A. For general procedure applications and major procedure applications, the process remains unchanged. Regulation 8A includes additional provisions for paying charges by instalments for high level health claims level 3 and level 4 applications. The payment regime for general procedure level 3 and level 4 applications and major procedure applications remains unchanged with the second instalment payable as soon as practicable after public notice is given under the Act, but not later than the end of the submission period mentioned in the notice.

Regulation 8A requires that, in the case of high level health claims level 3 or level 4 applications, the second instalment is due 20 business days after the day a notice is given to the applicant under subregulation 8A(6). Subregulation 8A(6) provides that, when the Authority considers it appropriate for the second instalment to be paid given the stage that the application consideration process has reached, the Authority must notify the applicant in writing that the second instalment is payable. The reason that payment of the second instalment in the case of high level health claims level 3 and 4 applications is not linked to the giving of public notice, as in the case of general and major procedure applications, is because the high level health claims procedure does not allow for public submissions to be called for unless the applicant has requested it.

Regulation 8B (Second instalments for certain withdrawn or rejected applications)

Regulation 8B provides for the payment of a second instalment for certain withdrawn or rejected applications. This process is currently contained within regulation 7A and 7B of the Principal Regulations. Regulation 8B also sets out the process for payment of the second instalment in the case of a high level health claims procedure level 3 or 4 application that has been rejected or withdrawn.

Regulation 9 (Refunds)

Regulation 9 provides for refunds to applicants. The process is identical to the one currently provided in regulation 8 of the Principal Regulations, but the wording has been revised to improve clarity.

Item [6] – Paragraph 11(c)

Item [6] repeals paragraph 11(c) of the Principal Regulations 11 and replaced it with a new paragraph. The current paragraph specifies a consideration period for a major procedure application as being 12 months. This is the default period under the Act and was therefore considered to be unnecessary to have the period also specified in this paragraph. In its place, a prescribed consideration period of nine months for high level health claim applications has been specified.

Item [7] – After Regulation 11

Item [7] amends the Principal Regulations by inserting Regulation 12 after Regulation 11. Regulation 12 provides that Schedule 1 of the Amendment Regulations only applies to applications received on or after that commencement of the Schedule.

Item [8] – Schedules 3 and 4

Item [8] repeals Schedules 3 and 4 of the Principal Regulations. The information contained in these two Schedules has been included in the Principal Regulations by the Amending Regulations. This reflects current drafting practice which is to avoid the use of Schedules to Legislative Instruments.

Schedule 2 – Other amendments

Item [1] – Regulation 2

Item [1] of Schedule 2 amends Regulation 2 of the Principal Regulations by inserting new definitions for certain Commonwealth and State Government Departments and specific State Government agencies (currently listed in Schedules 1 and 2). The new definitions are designed to reduce the need for future amendments when and if departmental names and responsibilities change.

Item [2] – Regulation 3

Item [2] repeals and replaces Principal Regulation 3 to reflect the definitions inserted into Regulation 2 by Item [1] of Schedule 2. Regulation 3 prescribes certain agencies as 'appropriate government agencies' for the purposes of paragraphs (a) and (d) of the definition of that term in section 4 of the Act. The departments and agencies prescribed by new regulation 3 also include departments and agencies that are currently prescribed in Schedule 1 of the Principal Regulations, which will be repealed. New subregulation 3(2) also does not list the State and Territory Departments of Health, as these are already covered by paragraph 4(1)(c) of the definition of 'appropriate government agencies' in the Act.

These amendments will reduce the need for future amendments when and if departmental names and responsibilities change. They also reflect current drafting practice, which is to avoid the use of Schedules to Legislative Instruments.

Item [3] – Regulations 6 and 6A

Item [3] repeals and replaces regulations 6 and 6A of the Principal Regulations.

New regulations 6 and 6A are the same in substance, but include the authorities currently mentioned in Schedule 2 of the Principal Regulations, and the organisations and public bodies currently mentioned in Schedule 2A. Item [7] below will repeal Schedule 2 and 2A. The new regulations also list authorities by their current names and in alphabetical order.

Regulation 6 prescribes those authorities to which confidential commercial information may be disclosed for the purposes of paragraph 114(4)(b) of the Act. Regulation 6 has been replaced to reflect the new definitions provided under Item 1 of Schedule 2 of the Amendment Regulations and to update the list of prescribed State, Territory and New Zealand Departments of State and other relevant agencies.

Regulation 6A prescribes Australian and New Zealand organisations and public bodies from which nominations for appointment to the Authority's Board may be sought for the purposes of section 116(4)(b) of the Act. The Regulation has been replaced to include an updated list of organisations and public bodies currently contained in Schedule 2A and to list these organisations and bodies in alphabetical order.

These amendments will reduce the need for future amendments when and if departmental names and responsibilities change. They also reflect current drafting practice, which is to avoid the use of Schedules to Legislative Instruments.

Item [4] – Regulation 10

Item [4] repeals regulation 10 of the Principal Regulations. Regulation 10 prescribes a period for the purposes of section 83 of the Act. Section 83 of the Act was replaced in 2010.

Items [5] and [6] – Paragraphs 11(a) and (b)

Item [5] omits the words *a general procedure in Subdivision D of the Act* from paragraph 11(a) of the Principal Regulations and substitutes the words *an application to which Subdivision D of Division 1 of Part 3 of the Act (general procedure) applies*.

Item [6] omits the words *a minor procedure in Subdivision E of the Act* from paragraph 11(b) of the Principal Regulations and substitutes the words *an application to which Subdivision E of Division 1 of Part 3 of the Act (minor procedure) applies.*

These amendments are a consequence of the amendments made by Item 3 in Schedule 1 of these Amendment Regulations which include the new definitions of assessment procedures in Regulation 2. The amendments also better reflect the language used in the Act.

Item [7] – Schedules 1, 2 and 2A

Item [7] repeals Schedules 1, 2 and 2A of the Principal Regulations. The Amending Regulations have included the information contained in these Schedules in the Principal Regulations themselves. This reflects current drafting practice which is to avoid the use of Schedules to Legislative Instruments.

Consultation

A consultation paper which canvassed public comment on an increased hourly charge for cost recovery and changes to levels within the general procedure was issued on 18 June 2012 with a four-week deadline for submissions. The deadline for lodgement of submissions was subsequently increased to six weeks.

The Authority received 12 submissions from industry, government, a public health organisation and an individual. The submissions commented on all aspects of the review and a number of broader policy issues which were beyond the scope of the review and the Authority's responsibilities.

Submissions on the proposed arrangements for high level health claim variations were then called for on 8 November 2012 with a four-week deadline for lodgement of submissions. At that time, the Authority proposed to apply the cost recovery arrangements for the general procedure to applications for high level health claim variations. The Authority also proposed to apply an administrative charge of $14,000. The existing refund policy was also to apply. The Authority received six submissions from industry and government. The submissions commented on a number of aspects of the proposed charging regime and a number of broader issues which were beyond the scope of the review and the Authority's responsibilities.

The Office of Best Practice Regulation has considered the impact analysis for these changes and has advised that a regulation impact statement is not required as the cost of standards development is machinery in nature and does not appear to change the regulatory burden placed on businesses or the non-profit sector.

The above proposals did not eventually proceed. Instead, it was decided to retain the existing cost recovery arrangements and to address the absence of cost recovery arrangements for high level health claim variation applications, and in doing so, also improve the clarity of the Principal Regulations. It was also decided that a further review of the Authority's cost recovery arrangements would occur later in 2015.

The Authority will inform stakeholders and industry of the changes made by the Amending Regulations prior to their taking effect by posting an update on its website.

Statement of compatibility with human rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulations 2015

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Regulation

The purpose of the *Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulations 2015* ('Amending Regulation') is to amend the *Food Standards Australia New Zealand Regulations 1994* ('Principal Regulations'). The Principal Regulations provide details that allow for the effective administration of the *Foods Standards Australia New Zealand Act 1991* ('the Act').

The Act provides for the existence of Food Standards Australia New Zealand (the Authority), the primary function of which is to develop, vary and review food regulatory measures, being food standards and codes of practice for industry. Food regulatory measures are developed or varied by the Authority, either as a result of an application from a body or person, or as a result of a proposal prepared by the Authority on its own initiative.

The Act provides that the Principal Regulations may fix a charge in relation to an application to develop or vary a standard where the development or variation of the standard will confer an exclusive capturable commercial benefit on the applicant, or the applicant has elected to have consideration of their application expedited

The Amending Regulation will fix such a charge in relation to future applications for amendment of Food Standard 1.2.7 – Health, Nutrition and Related Claims. This Standard took effect in January 2013. No charges have yet been fixed for applications relating to this Standard. The Amending Regulation also makes minor amendments of a technical or clarifying nature.

Human rights implications

The Amending Regulation does not give rise to any human rights implications. The Amending Regulation does not engage any of the applicable human rights and freedoms. As explained above, the Legislative Instrument only fixes the charges for future applications to amend Standard 1.2.7 and these are based on or reflect current charging arrangements for applications. The other amendments do not alter the current legal effect of the Regulations. Therefore, the amendment of the Principal Regulations will not affect any of the applicable human rights and freedoms.

Conclusion

The Amending Regulation is compatible with human rights as it does not raise any human rights issues.