



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

Select Legislative Instrument No. 61, 2015

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd),
Governor-General of the Commonwealth of Australia, acting with the
advice of the Federal Executive Council, make the following regulation.

Dated 30 April 2015

Peter Cosgrove
Governor-General

By His Excellency's Command

Fiona Nash
Assistant Minister for Health

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1 Name

This is the *Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulation 2015*.

2 Commencement

This instrument commences on the first day of the month following the day the instrument is registered.

3 Authority

This instrument is made under the *Food Standards Australia New Zealand Act 1991*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments relating to high level health claims applications

Food Standards Australia New Zealand Regulations 1994

1 Regulation 2

Insert:

administration charge has the meaning given by subregulation 8(2).

2 Regulation 2 (definition of *application consideration process*)

Repeal the definition, substitute:

application consideration process means the process undertaken by the Authority in relation to the application under:

- (a) Part 3 of the Act, other than the Authority's dealings with the Council; and
- (b) any other Commonwealth law.

Note: An example for paragraph (b) is a law that requires a new standard to be registered.

3 Regulation 2

Insert:

general procedure level 1 application means an application that the Authority has classified as a general procedure level 1 application under regulation 7.

general procedure level 2 application means an application that the Authority has classified as a general procedure level 2 application under regulation 7.

general procedure level 3 application means an application that the Authority has classified as a general procedure level 3 application under regulation 7.

general procedure level 4 application means an application that the Authority has classified as a general procedure level 4 application under regulation 7.

high level health claims procedure level 1 application means an application that the Authority has classified as a high level health claims procedure level 1 application under regulation 7.

high level health claims procedure level 2 application means an application that the Authority has classified as a high level health claims procedure level 2 application under regulation 7.

high level health claims procedure level 3 application means an application that the Authority has classified as a high level health claims procedure level 3 application under regulation 7.

high level health claims procedure level 4 application means an application that the Authority has classified as a high level health claims procedure level 4 application under regulation 7.

major procedure application means an application that the Authority has classified as a major procedure application under regulation 7.

minor procedure application means an application that the Authority has classified as a minor procedure application under regulation 7.

4 Regulation 2 (definition of procedure)

Repeal the definition.

5 Regulations 7 to 9

Repeal the regulations, substitute:

7 Procedure classification

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 following table.

Schedule 1 Amendments relating to high level health claims applications

Procedure classification				
	Column 1	Column 2	Column 3	Column 4
Item	Procedure	Number of hours the application consideration process is likely to take	Classification	Number of hours to be charged
1	General procedure	A maximum of 350 hours	General procedure level 1 application	350 hours
2	General procedure	More than 350 hours, to a maximum of 650 hours	General procedure level 2 application	650 hours
3	General procedure	More than 650 hours, to a maximum of 1 000 hours	General procedure level 3 application	1 000 hours
4	General procedure	More than 1 000 hours	General procedure level 4 application	The number of hours the application consideration process is likely to take
5	Subdivision E of Division 1 of Part 3 of the Act	Any	Minor procedure application	100 hours
6	Subdivision F of Division 1 of Part 3 of the Act	Any	Major procedure application	Either: (a) 1 200 hours; or (b) if the process is likely to take more than 1200 hours—the number of hours the application consideration process is likely to take
7	Subdivision G of Division 1	A maximum of 350 hours	High level health claims	350 hours

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Procedure classification				
	Column 1	Column 2	Column 3	Column 4
Item	Procedure	Number of hours the application consideration process is likely to take	Classification	Number of hours to be charged
	of Part 3 of the Act		procedure level 1 application	
8	Subdivision G of Division 1 of Part 3 of the Act	More than 350 hours, to a maximum of 650 hours	High level health claims procedure level 2 application	650 hours
9	Subdivision G of Division 1 of Part 3 of the Act	More than 650 hours, to a maximum of 1 000 hours	High level health claims procedure level 3 application	1 000 hours
10	Subdivision G of Division 1 of Part 3 of the Act	More than 1 000 hours	High level health claims procedure level 4 application	The number of hours the application consideration process is likely to take

8 Charges

- (1) For subsection 146(1) of the Act, the charge to be paid by an applicant for an application consideration process mentioned in an item in the following table is the charge set out in that item. (The charge set out in an item has been calculated at the rate of \$115 for each hour to be charged in relation to the application as set out in column 4 of the table in regulation 7).

Charges		
Item	Application consideration process	Charge
1	The application consideration process for a general procedure level	\$40 250

Schedule 1 Amendments relating to high level health claims applications

Charges		
Item	Application consideration process	Charge
	1 application	
2	The application consideration process for a general procedure level 2 application	\$74 750
3	The application consideration process for a general procedure level 3 application	\$115 000
4	The application consideration process for a general procedure level 4 application	The sum of the following amounts: (a) \$115 000; (b) \$115 for each hour that the process is likely to take above 1 000 hours
5	The application consideration process for a minor procedure application	\$11 500
6	The application consideration process for a major procedure application	The sum of the following amounts: (a) \$138 000; (b) \$115 for each hour that the process is likely to take above 1 200 hours
7	The application consideration process for a high level health claims procedure level 1 application	\$40 250
8	The application consideration process for a high level health claims procedure level 2 application	\$74 750
9	The application consideration process for a high level health claims procedure level 3 application	\$115 000
10	The application consideration process for a high level health claims procedure level 4 application	The sum of the following amounts: (a) \$138 000; (b) \$115 for each hour that the process is likely to take above 1 000 hours

(2) For subsection 146(1) of the Act, a charge (the **administration charge**) of \$10 000 is to be paid by an applicant for the steps in an application consideration process:

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- (a) that are required to be taken under any of the following:
 - (i) the Act or another Act;
 - (ii) regulations or another instrument made under the Act or another Act; and
- (b) for which amounts (however described) are payable by the Authority.

Note: For example, the Authority may be required to publish a notice or register a new standard.

8A Paying charges by instalments

- (1) For subsection 146(1A) of the Act, the charges payable under regulation 8 in relation to the following applications may be paid by instalments in accordance with this regulation:
 - (a) a general procedure level 3 application or a general procedure level 4 application;
 - (b) a major procedure application;
 - (c) a high level health claims level 3 application or a high level health claims level 4 application.
- (2) The first instalment is to consist of the administration charge in relation to the application plus:
 - (a) for a general procedure level 3 application or a general procedure level 4 application—75% of the charge payable under subregulation 8(1) in relation to the application; or
 - (b) for a major procedure application—25% of the charge payable under subregulation 8(1) in relation to the application; or
 - (c) for a high level health claims level 3 application or a high level health claims level 4 application—75% of the charge payable under subregulation 8(1) in relation to the application.
- (3) The first instalment is payable within 20 business days after the day the notice of acceptance of the application is given under section 27 or 48 of the Act.
- (4) Subject to regulation 8B, the second instalment is to consist of:
 - (a) for a general procedure level 3 application or a general procedure level 4 application—25% of the charge payable under subregulation 8(1) in relation to the application; or

- (b) for a major procedure application—75% of the charge payable under subregulation 8(1) in relation to the application; or
 - (c) for a high level health claims level 3 application or a high level health claims level 4 application—25% of the charge payable under subregulation 8(1) in relation to the application.
- (5) The second instalment is payable:
- (a) for a general procedure level 3 application or a general procedure level 4 application—as soon as practicable after the day public notice is given under section 31 of the Act for the application, but not later than the end of the submission period mentioned in the notice; or
 - (b) for a major procedure application—as soon as practicable after the day public notice is given under section 44 of the Act for the application, but not later than the end of the submission period mentioned in the notice; or
 - (c) for a high level health claims level 3 or a high level health claims level 4 application—20 business days after the day a notice is given to the applicant under subregulation (6) in relation to the application.
- (6) When the Authority considers that it is 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 applicant must pay the second instalment.

8B Second instalment for certain withdrawn or rejected applications

- (1) This regulation applies to the following applications:
- (a) a general procedure level 3 application or a general procedure level 4 application that has been withdrawn under section 24 of the Act before the Authority has made a decision under subsection 33(1) or 35(1) of the Act;
 - (b) a major procedure application that has been withdrawn under section 24 of the Act before the Authority has made a decision under subsection 33(1) or 35(1) of the Act;
 - (c) a high level health claims procedure level 3 application or a high level health claims procedure level 4 application that

- has been withdrawn under section 24 of the Act before the Authority has made a decision under subsection 52(1) of the Act;
- (d) an application that is rejected by the Authority under paragraph 30(1)(b) or subparagraph 52(1)(a)(ii) of the Act.
- (2) The second instalment is to consist of \$115 for each hour (if any) taken for the application consideration process that:
 - (a) has not been paid for by the applicant under paragraph 8A(2)(a), (b) or (c); and
 - (b) occurs before notice of the withdrawal of the application is given to the Authority, or notice of the rejection of the application is given to the applicant.
 - (3) The Authority must give the applicant a written notice that sets out the time taken for the application consideration process and the amount of the second instalment.
 - (4) The second instalment is payable within 20 business days after the day the notice of withdrawal or rejection is given.

9 Refunds

For subsections 24(2), 110(3) and 149(2) of the Act, the amount to be refunded to an applicant in relation to an application is the total of:

- (a) the balance, if any, of the administration charge paid by the applicant after the Authority has paid any required amounts; and
- (b) if the application consideration process has taken less time than the hours charged in relation to the application (as set out in column 4 of the table in regulation 7)—\$115 for each unused hour.

Example: The Authority classifies an application as a general procedure level 2 application because the application consideration process is likely to take more than 350 hours but not more than 650 hours. The application is withdrawn after the applicant has paid \$84 750 (consisting of the administration charge (\$10 000) plus the charge for a general procedure level 2 application (\$74 750)), and after 500 hours of work have been done. The Authority has not been required to pay any amounts covered by the administration charge. The refund amount is \$27 250 (consisting of the administration charge (\$10 000) plus the 150 unused hours paid at the rate of \$115 per hour (\$17 250)).

6 Paragraph 11(c)

Repeal the paragraph, substitute:

- (c) for an application to which Subdivision G of Division 1 of Part 3 of the Act (high level health claims) applies—9 months after it begins.

7 After regulation 11

Insert:

12 Application of the *Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulation 2015*

Schedule 1 to the *Food Standards Australia New Zealand Amendment (High Level Health Claims and Other Measures) Regulation 2015* applies to an application received by the Authority on or after the commencement of that Schedule.

8 Schedules 3 and 4

Repeal the Schedules.

Schedule 2—Other amendments

Food Standards Australia New Zealand Regulations 1994

1 Regulation 2

Insert:

Agriculture Department means the Department administered by the Minister administering the *Imported Food Control Act 1992*.

Foreign Affairs Department means the Department administered by the Minister administering the *Diplomatic Privileges and Immunities Act 1967*.

Health Department means the Department administered by the Minister administering the Act.

Industry Department means the Department administered by the Minister administering the *Industry Research and Development Act 1986*.

Treasury Department means the Department administered by the Treasurer.

2 Regulation 3

Repeal the regulation, substitute:

3 Appropriate government agencies

- (1) For paragraph (a) of the definition of *appropriate government agency* in subsection 4(1) of the Act, the following are prescribed:
 - (a) the Agriculture Department;
 - (b) the Foreign Affairs Department;
 - (c) the Health Department;
 - (d) the Industry Department;
 - (e) the Treasury Department.
- (2) For paragraph (d) of the definition of *appropriate government agency* in subsection 4(1) of the Act, the following are prescribed:

- (a) the Department of State of each State and Territory that is primarily responsible for primary industries in that State or Territory;
- (b) NSW Food Authority;
- (c) the Department of State of Victoria that is primarily responsible for the food and beverage industry;
- (d) Safe Food Production QLD.

3 Regulations 6 and 6A

Repeal the regulations, substitute:

6 Authorities to which confidential commercial information may be disclosed

- (1) For paragraph 114(4)(b) of the Act, the following Commonwealth authorities are prescribed:
 - (a) the Agriculture Department;
 - (b) the Foreign Affairs Department;
 - (c) the Health Department;
 - (d) the Industry Department;
 - (e) the Treasury Department.
- (2) For paragraph 114(4)(b) of the Act, the following State or Territory authorities are prescribed:
 - (a) the Department of State of each State or Territory that is primarily responsible for public health in that State or Territory;
 - (b) the Department of State of each State and Territory that is primarily responsible for primary industries in that State or Territory;
 - (c) NSW Food Authority;
 - (d) the Department of State of Victoria that is primarily responsible for the food and beverage industry;
 - (e) Safe Food Production QLD.
- (3) For paragraph 114(4)(b) of the Act, the following New Zealand authorities are prescribed:
 - (a) the Department of State of New Zealand that is primarily responsible for public health;

- (b) the Department of State of New Zealand that is primarily responsible for primary industries;
- (c) Environment Protection Authority.

6A Organisations and public bodies from which nominations for Board members may be sought

Australian science and public health organisations and bodies

- (1) For paragraph 116(3)(b) of the Act, an Australian organisation or public body mentioned in an item in the following table is prescribed for the purposes of each subparagraph of paragraph 116(3)(a) of the Act mentioned in that item.

Australian science and public health organisations and bodies		
Item	Organisation or body	Subparagraph of paragraph 116(3)(a)
1	Australian Academy of Science	Subparagraph (vi)
2	Australian Institute of Environmental Health	Subparagraphs (i), (iii), (vii) and (viii)
3	Australian Medical Association	Subparagraphs (i) and (vi)
4	Australian Society for Biochemistry and Molecular Biology	Subparagraphs (vi), (vii) and (ix)
5	Australian Veterinary Association	Subparagraph (x)
6	CHOICE	Subparagraphs (i) and (ii)
7	Consumers Health Forum of Australia	Subparagraphs (i) and (ii)
8	Dietitians Association of Australia	Subparagraphs (i), (iii), (iv), (v) and (viii)
9	Food Science Australia	Subparagraphs (iii), (iv), (v), (vii) and (viii)
10	National Aboriginal Community Controlled Health Organisation	Subparagraphs (i) and (ii)
11	Nutrition Australia	Subparagraphs (i), (ii) and (v)
12	Nutrition Society of Australia (Inc)	Subparagraphs (iii), (iv), (v) and (viii)
13	Public Health Association of Australia	Subparagraphs (i), (ii), (iii), (iv), (v) and (viii)

Schedule 2 Other amendments

Australian science and public health organisations and bodies		
Item	Organisation or body	Subparagraph of paragraph 116(3)(a)
14	Royal Australian Chemical Institute Incorporated	Subparagraph (iii)
15	The Australian Institute of Food Science and Technology Incorporated	Subparagraphs (i), (iii), (vi), (v), (vii) and (viii)
16	The Australian Society for Microbiology	Subparagraph (vii)
17	The Royal Australasian College of Physicians (Faculty of Public Health Medicine)	Subparagraphs (i), (v) and (vi)

New Zealand science and public health organisations and bodies

- (2) For paragraph 116(3)(b) of the Act, an organisation or public body of New Zealand mentioned in an item in the following table is prescribed for the purposes of each subparagraph of paragraph 116(3)(a) of the Act mentioned in that item.

New Zealand science and public health organisations and bodies		
Item	Organisation or body	Subparagraph of paragraph 116(3)(a)
1	Consumer NZ	Subparagraphs (ii), (v) and (viii)
2	Dietitians NZ	Subparagraphs (i), (ii), (iii), (iv), (v) and (viii)
3	Health Research Council of New Zealand	Subparagraphs (i), (iv), (v), (vi), (vii) and (ix)
4	Maori Women's Welfare League Inc	Subparagraphs (i), (ii) and (viii)
5	National Council of Women of New Zealand	Subparagraph (ii)
6	New Zealand Medical Association	Subparagraphs (i) and (vi)
7	NZ Nutrition Foundation	Subparagraphs (v), (vi) and (viii)
8	NZBIO	Subparagraph (ix)
9	Public Health Association of New Zealand Inc	Subparagraphs (i), (ii), (iii), (iv), (v), (vi), (vii), (viii) and (ix)
10	Science New Zealand	Subparagraphs (i), (ii), (iii), (vi),

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New Zealand science and public health organisations and bodies

Item	Organisation or body	Subparagraph of paragraph 116(3)(a)
		(vii), (viii) and (ix)
11	The New Zealand Institute of Food Science and Technology Inc	Subparagraphs (iii), (viii) and (ix)
12	The Royal Australasian College of Physicians, New Zealand Committee, Faculty of Public Health Medicine	Subparagraphs (i), (v) and (vi)
13	The Royal Society of New Zealand	Subparagraphs (vii) and (ix)

Australian food industry organisations and bodies

- (3) For paragraph 116(4)(b) of the Act, an Australian organisation or public body mentioned in an item in the following table is prescribed for the purposes of each subparagraph of paragraph 116(4)(a) of the Act mentioned in that item.

Australian food industry organisations and bodies

Item	Organisation or body	Subparagraph of paragraph 116(4)(a)
1	Australian Chamber of Commerce and Industry	Subparagraphs (i), (ii), (iv), (vi) and (vii)
2	Australian Food and Grocery Council	Subparagraphs (i), (ii), (v), (vi) and (vii)
3	Australian Hotels Association	Subparagraphs (i), (iv), (vi) and (vii)
4	Council of Small Business Australia	Subparagraphs (iv) and (vi)
5	National Association of Retail Grocers of Australia Pty Ltd	Subparagraphs (ii) and (iv)
6	National Farmers' Federation Limited	Subparagraphs (iii), (iv), (v) and (vi)
7	Restaurant and Catering Australia	Subparagraphs (i), (iv), (vi) and (vii)
8	The Australian Industry Group	Subparagraphs (i), (iv), (v), (vi) and (vii)
9	The Australian Retailers Association	Subparagraphs (i), (ii), (iv), (vi) and (vii)

New Zealand food industry organisations and bodies

- (4) For paragraph 116(4)(b) of the Act, an organisation or public body of New Zealand mentioned in an item in the following table is prescribed for the purposes of each subparagraph of paragraph 116(4)(a) of the Act mentioned in that item.

New Zealand food industry organisations and bodies		
Item	Organisation or body	Subparagraph of paragraph 116(4)(a)
1	New Zealand Food and Grocery Council	Subparagraphs (i), (ii), (iv), (v), (vi) and (vii)
2	New Zealand Retailers Association	Subparagraph (ii)
3	The Grocery Retailers Association	Subparagraphs (i), (ii) and (iv)

4 Regulation 10

Repeal the regulation.

5 Paragraph 11(a)

Omit “a general procedure in Subdivision D of the Act”, substitute “an application to which Subdivision D of Division 1 of Part 3 of the Act (general procedure) applies”.

6 Paragraph 11(b)

Omit “a minor procedure in Subdivision E of the Act”, substitute “an application to which Subdivision E of Division 1 of Part 3 of the Act (minor procedure) applies”.

7 Schedules 1, 2 and 2A

Repeal the Schedules.