



Food Standards Australia New Zealand Amendment Regulations 2007 (No. 1)¹

Select Legislative Instrument 2007 No. 310

I, PHILIP MICHAEL JEFFERY, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Food Standards Australia New Zealand Act 1991*.

Dated 26 September 2007

P. M. JEFFERY
Governor-General

By His Excellency's Command

BRETT MASON
Parliamentary Secretary to the Minister for Health and Ageing

1 Name of Regulations

These Regulations are the *Food Standards Australia New Zealand Amendment Regulations 2007 (No. 1)*.

2 Commencement

These Regulations commence on 1 October 2007.

3 Amendment of *Food Standards Australia New Zealand Regulations 1994*

Schedule 1 amends the *Food Standards Australia New Zealand Regulations 1994*.

4 Transitional

4.1 The *Food Standards Australia New Zealand Regulations 1994* as in force immediately before 1 October 2007 continue to apply to an application or a proposal made before 1 October 2007.

4.2 In this regulation:

application means an application made under section 12 of the former Act.

former Act means the *Food Standards Australia New Zealand Act 1991* as in force immediately before 1 July 2007.

proposal means a proposal prepared under section 12AA of the former Act.

Schedule 1 Amendments

(regulation 3)

**[1] Subregulation 2 (1), definitions of *application*,
category, *exclusive*, *capturable commercial benefit*
and *proposal***

substitute

application means an application made under section 22 of the Act.

procedure, for an application, means the procedure of assessment into which the application is classified under section 25 of the Act.

proposal means a proposal prepared under section 55 of the Act.

[2] Subregulation 2 (2)

omit

[3] Subregulations 3 (1) and (2)

omit each mention of

3

insert

4

[4] Regulations 4 and 6

substitute

6 Disclosure of confidential commercial information

For paragraph 114 (4) (b) of the Act, each authority mentioned in Schedule 2 is prescribed.

[5] Regulation 6A, including the heading

omit each mention of

40

insert

116

[6] Regulations 7 to 14

substitute

7 Charges

- (1) For subsection 146 (1) of the Act, a body or person must pay to the Authority the charges mentioned in Schedule 3 for services and facilities the Authority provides to the body or person.
- (2) For subsection 146 (1A) of the Act, the charge for an application that has been classified as a major procedure under Schedule 4 is payable in the following 2 instalments:
 - (a) 25% — within 20 business days after the notice of acceptance is given under section 27 of the Act;
 - (b) 75% — as soon as practicable after the public notice given under section 44 of the Act and before the assessment of the submissions under section 45 of the Act.
- (3) However, the Authority must repay to the body or person \$107 for each hour, if any, by which the time taken to assess the application is less than the hours mentioned in Schedule 4 for the category of application.

8 Refunds

For subsections 24 (2) and 110 (3) of the Act, the refund is \$107 for each hour, if any, by which the time taken to assess the application is less than the hours mentioned in Schedule 4 for the category of application.

Example

If an application is withdrawn after 350 hours of work done on an application which is calculated to take 500 hours to process, the refund

amount is \$16 050, being the 150 unused hours paid at the rate of \$107 per hour.

9 Procedure classification

- (1) This regulation applies to an application for which charges are payable.
- (2) If the Authority accepts an application under section 26 of the Act, the Authority must:
 - (a) classify the application in accordance with section 25 of the Act and Schedule 4; and
 - (b) if the application is classified as a major procedure application, determine:
 - (i) whether the full assessment of the application is likely to require more than 1 050 hours; and
 - (ii) if so, how many hours are likely to be required.

10 Period within which consideration of proposal must be complete

For section 83 of the Act, the consideration period ends 9 months after it begins.

11 Period within which consideration of applications for standards or variations must be complete

For subsection 109 (3) of the Act, the consideration period ends:

- (a) for a general procedure in Subdivision D of the Act — 9 months after it begins; and
- (b) for a minor procedure in Subdivision E of the Act — 3 months after it begins; and
- (c) for a major procedure in Subdivision F of the Act — 12 months after it begins.

[7] Schedule 1, Part 2*substitute***Part 2 State and Territory authorities**

| Item | Authority |
|-------------|---|
| 1 | Department of Primary Industries (NSW) |
| 2 | NSW Food Authority |
| 3 | NSW Health |
| 4 | Department of Primary Industries (Vic) |
| 5 | Department of Sustainability and Environment (Vic) |
| 6 | Department of Innovation, Industry and Regional Development (Vic) |
| 7 | Department of Human Services (Vic) |
| 8 | Department of Primary Industries and Fisheries (Qld) |
| 9 | Queensland Health |
| 10 | Safe Food Queensland |
| 11 | Department of Agriculture and Food (WA) |
| 12 | Department of Health (WA) |
| 13 | Department of Primary Industries and Resources South Australia |
| 14 | Department of Health (SA) |
| 15 | Department of Primary Industries and Water (Tas) |
| 16 | Department of Health and Human Services, Tasmania |
| 17 | ACT Health |
| 18 | Department of Business, Economic and Regional Development of the Northern Territory |
| 19 | Department of Health and Community Services (NT) |

[8] Schedule 1A

omit

[9] Schedule 2, Part 1, item 4

substitute

4 Department of Families, Community Services and Indigenous Affairs

[10] Schedule 2, Part 2, items 1 and 2

substitute

1 Department of Primary Industries (NSW)

2 NSW Health

[11] Schedule 2, Part 2, item 4

substitute

4 Department of Human Services (Vic)

[12] Schedule 2, Part 2, item 8

substitute

8 Department of Primary Industries and Fisheries (Qld)

[13] Schedule 2, Part 2, items 11 to 13

substitute

11 Department of Agriculture and Food (WA)

12 Department of Health (WA)

13 Department of Health (SA)

[14] Schedule 2, Part 2, item 15

substitute

15 Department of Health and Human Services, Tasmania

[15] Schedule 2, Part 2, items 18 and 19

substitute

- 18 Department of Business, Economic and Regional Development of the Northern Territory
- 19 Department of Health and Community Services (NT)

[16] Schedule 2, Part 3, after item 3

insert

- 4 New Zealand Food Safety Authority

[17] Schedule 2A, Part 1, column 3, heading

substitute

Subparagraph of paragraph
116 (3) (a)

[18] Schedule 2A, Part 1, item 102, column 2

substitute

CHOICE

[19] Schedule 2A, Part 2, column 3, heading

substitute

Subparagraph of paragraph
116 (4) (a)

[20] Schedule 2A, Part 2, item 209, column 2

substitute

Restaurant and Catering Australia

[21] Schedules 3 and 4*substitute***Schedule 3 Charges**

(regulation 7)

| Item | Service or facility provided by the Authority | Provision of the Act | Charge (\$) |
|-------------|---|-----------------------------|--------------------|
| 1 | Assessing the application under section 29 of the Act and preparing a draft regulatory measure under section 30 of the Act for: | subparagraph 27 (c) (i) | |
| | (a) a minor procedure application | | 18 725 |
| | (b) a general procedure level 1 application | | 53 500 |
| | (c) a general procedure level 2 application | | 90 950 |
| | (d) a major procedure application: | | |
| | (i) base charge; and | | 112 350 |
| | (ii) if the Authority determines, under regulation 9, that the full assessment of the application is likely to require more than 1 050 hours — for each hour that the assessment will require after the first 1 050 hours | | 107 |

Schedule 4 Procedure classification

(regulations 7, 8 and 9)

1 General procedure

- 1.1 This procedure applies to applications that are not being considered under the minor procedure or the major procedure.

Note The general procedure is the default procedure for considering an application for the development of a food regulatory measure or a variation to a food regulatory measure.

General procedure level 1

- 1.2 A general procedure application that is likely to require up to 500 hours to fully assess is to be classified as a general procedure level 1 application.

Examples

1 An application for the variation or development of a food regulatory measure involving:

- (a) allowing a processing aid that is currently not permitted; or
- (b) extending permission for use of a food or a food additive; or
- (c) making a minor change to a labelling requirement; or
- (d) making a minor change to a compositional requirement for a food; or
- (e) granting a permission involving a pre-market safety assessment similar to a previous assessment; or
- (f) reducing a maximum residue limit.

2 This kind of application is likely to:

- (a) involve an assessment of the risk to public health and safety of average complexity; or
- (b) have only a limited social or economic impact; or
- (c) require a simple toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- (d) require a simple assessment of risk management requirements; or
- (e) involve any other matter of similar complexity.

General procedure level 2

- 1.3 A general procedure application that is likely to require up to 850 hours to fully assess is to be classified as a general procedure level 2 application.

Examples

1 An application for the variation or development of a food regulatory measure involving:

- (a) allowing a food or food additive that is not currently permitted; or
- (b) changing a compositional requirement for a food; or
- (c) establishing or increasing a maximum permitted concentration for an environmental contaminant or heavy metal; or
- (d) changing permission to add a nutritive substance; or
- (e) changing a labelling requirement for a food; or
- (f) granting a permission involving a pre-market safety assessment similar to a previous assessment; or
- (g) regulating a new micro-organism.

2 This kind of application is likely to:

- (a) involve a more complex assessment of the risk to public health and safety; or
- (b) have a broader social or economic impact; or
- (c) require a complete toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- (d) require targeted consultation with key stakeholders, special interest groups; or
- (e) require the provision of advice to advisory groups, peak organisations or other stakeholders; or
- (f) require comprehensive consideration of risk management requirements; or
- (g) insert and amend maximum residue limit; or
- (h) require the establishment of high level advisory groups to discuss and interpret scientific evidence and social perceptions; or
- (i) involve the development of a community communications strategy to address public concern; or
- (j) involve any other matter of similar complexity.

2 Minor procedure

2.1 This procedure applies to an application for a variation of a food regulatory measure that, if made, would not directly or indirectly:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of the measure.

Examples

A variation would fall within this procedure if its only effect would be:

- (a) correcting a typographical error; or
- (b) updating a reference to another document; or
- (c) amending a cross-reference within a food regulatory measure; or
- (d) omitting provisions of a food regulatory measure that has ceased to have effect; or
- (e) any other matter of similar complexity.

2.2 An application that has been classified as a minor procedure is likely to require up to 175 hours to fully assess.

3 Major procedure

3.1 This procedure applies to:

- (a) an application for the development of a new food regulatory measure; and
- (b) an application for the variation of a food regulatory measure that:
 - (i) involves scientific or technical complexity that makes it necessary to adopt this procedure for its assessment; or
 - (ii) involves a significant change to the scope of the food regulatory measure that makes it necessary to adopt this procedure for its assessment.

Examples

1 An application for the development of, or a major variation to, a new food regulatory measure involving:

- (a) the development of a new Standard; or
- (b) a change to a labelling requirement affecting a wide range of foods; or
- (c) a change to a compositional requirement for a food affecting a wide range of foods; or
- (d) a change to a nutritive substance permissions affecting a wide range of foods; or
- (e) the granting a permission involving a pre-market safety assessment, with no similar previous assessments; or
- (f) any other matter of similar complexity.

2 This kind of application is likely to:

- (a) require the use of community meetings including public hearings; or

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- (b) involve the development of a complete community communications strategy to address public concern; or
 - (c) require the development and distribution of community education material; or
 - (d) require representation at international forums; or
 - (e) require extensive consultation with government agencies, industry, health professionals and consumer groups; or
 - (f) require establishment of external working parties and advisory groups; or
 - (g) require a comprehensive assessment of risk management requirements; or
 - (h) involve any other matter of similar complexity.

Note A minimum of 2 rounds of public comment is likely to be required and consultation might also require the establishment of external working parties or advisory groups to assist with the assessment.

- 3.2 An application that has been classified as a major procedure application is likely to require more than 1 050 hours to assess fully.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See www.frli.gov.au.