



Australia New Zealand Food Authority Regulations 1994

Statutory Rules 1994 No. 286 as amended

made under the

Australia New Zealand Food Authority Act 1991

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Australia New Zealand Food Authority Regulations 1994

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1 Name of Regulations [see Note 1]

These Regulations are the *Australia New Zealand Food Authority Regulations 1994*.

2 Interpretation

In these Regulations, unless the contrary intention appears:

Act means the *Australia New Zealand Food Authority Act 1991*.

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

exclusive, capturable commercial benefit has the meaning given by subsection 66 (9) of the Act.

proposal means a proposal prepared under section 21 of the Act.

3 Appropriate government agencies

- (1) For the purposes of paragraph (a) of the definition of *appropriate government agency* in subsection 3 (1) of the Act, the following Departments of the Commonwealth are prescribed:
 - (a) Agriculture, Fisheries and Forestry — Australia;
 - (b) Attorney-General's Department;
 - (c) Department of Foreign Affairs and Trade;
 - (d) Department of Health and Aged Care;
 - (e) Department of Industry, Science and Resources.
- (2) For the purposes of paragraph (d) of the definition of *appropriate government agency* in subsection 3 (1) of the Act, the South Australian Health Commission is prescribed.

4 Section 36 of the Act: application, modification and adaptation of Part 3 of the Act

- (1) This regulation applies if the Authority decides, under subsection 36 (1) of the Act, to omit to do one or more of the matters that the Authority is required to do under Part 3 of the Act in relation to an application or a proposal.
- (2) For the purposes of subsection 36 (2) of the Act, the provisions of Part 3 of the Act apply in relation to the application or proposal subject to the modifications and adaptations set out in the Part of Schedule 1 that relates to the Authority's decision.

5 Section 37 of the Act: application, modification and adaptation of Part 3 of the Act

- (1) This regulation applies if the Authority decides, under subsection 37 (1) of the Act, to omit to do one or more of the matters that the Authority is required to do under Part 3 of the Act in relation to an application or a proposal.
- (2) For the purposes of subsection 37 (2) of the Act, the provisions of Part 3 of the Act apply in relation to the application or proposal subject to the modifications and adaptations set out in the Part of Schedule 2 that relates to the Authority's decision.

6 Disclosure of confidential commercial information

For paragraph 39 (4) (b) of the Act, the following authorities are prescribed:

- (a) for the Commonwealth:
 - (i) Agriculture, Fisheries and Forestry — Australia;
 - (ii) Attorney-General's Department;
 - (iii) Department of Family and Community Services;
 - (iv) Department of Foreign Affairs and Trade;
 - (v) Department of Health and Aged Care;
 - (vi) Department of Industry, Science and Resources;
- (b) for the States and Territories:
 - (i) Department of Health of New South Wales;
 - (ii) Department of Human Services of Victoria;

- (iii) Queensland Health;
- (iv) Health Department of Western Australia;
- (v) South Australian Health Commission;
- (vi) Department of Community and Health Services of Tasmania;
- (vii) Department of Health and Community Care of the Australian Capital Territory;
- (viii) Territory Health Services of the Northern Territory;
- (c) for New Zealand:
 - (i) Environmental Risk Management Authority;
 - (ii) Ministry of Health;
 - (iii) Ministry of Agriculture and Forestry.

7 Additional information about application

For paragraph 12 (2) (b) of the Act, the Authority may request an applicant to give additional information if the application does not contain, or is not accompanied by, sufficient information to enable the Authority to deal with the application in accordance with the Act.

Example

The Authority may request additional information to enable it to determine whether:

- (a) it should make, under section 37 of the Act, a recommendation to the Council as a matter of urgency in relation to the application; or
- (b) the development or variation of a food standard that may result from the application would confer an exclusive, capturable commercial benefit on the person or body that made the application.

8 Application fees

- (1) For paragraph 12 (2) (c) of the Act, the fee for an application for development or variation of a food standard to which paragraph 66 (6) (a) of the Act applies is \$2 800.

Note 1 The fee comprises \$2 576 (charge under section 66 of the Act for the making of a preliminary assessment) and \$224 (for the giving of notices under section 14 of the Act).

Note 2 Paragraph 66 (6) (a) of the Act provides that a charge may only be fixed if, in relation to the development or variation of a food standard, the

development or variation of that food standard would confer an exclusive, capturable commercial benefit on the person or body that made the application.

- (2) The application fee (if any) for an application is taken to accompany the application if it is paid without delay when the applicant receives notification, under paragraph 13A (2) (a) of the Act, that the application has been accepted.
- (3) For subsection 35 (1) of the Act, an application is taken not to have been received until the application fee (if any) has been paid.

9 Refunds — withdrawal before preliminary assessment

If an applicant withdraws an application before preliminary assessment of the application commences, the Authority must refund the application fee, if any, paid under section 12 of the Act.

10 Refunds — withdrawal after preliminary assessment

- (1) This regulation applies if an applicant withdraws an application after preliminary assessment.
- (2) If the application is withdrawn before full assessment of the application commences, the Authority must refund any amounts paid, in relation to the application, under section 15 of the Act.
- (3) If the application is withdrawn after full assessment of the application commences but before half of the work required for full assessment is completed, the Authority must refund:
 - (a) half of any amounts paid, in relation to the application, under section 15 of the Act; or
 - (b) if the inquiry mentioned in subsection 16 (3) of the Act has not been held — all of the charge paid under paragraph 15 (2) (b) of the Act and half of all other amounts paid.
- (4) If the application is withdrawn after half of the work required for full assessment is completed but before an inquiry under

section 16 of the Act commences, the Authority must refund any amount paid in relation to the holding of the inquiry.

11 Refunds — no request for inquiry

If the applicant to whom subsection 16 (3) of the Act applies gives the Authority notice that the applicant will not be asking the Authority to hold an inquiry under that subsection, the Authority must refund any amount paid, in relation to the application, under subsection 16 (4) of that Act.

12 Preliminary assessment — relevant matters

For paragraph 13 (2) (e) of the Act, relevant matters include:

- (a) the category of assessment (as set out in Part 1 of Schedule 3) that will be required if the application proceeds to full assessment; and
- (b) for an application that relates to the development or variation of a food standard — whether the development or variation would confer an exclusive, capturable commercial benefit on the applicant.

13 Outcome of preliminary assessment

- (1) A notification by the Authority, under subsection 13A (2) of the Act, must include the following information:
 - (a) the decisions made by the Authority in relation to the matters mentioned in regulation 12, and the reasons for those decisions;
 - (b) advice that the applicant may seek review under regulation 14 if the applicant does not agree with any of those decisions;
 - (c) the amount of any further charge payable by the applicant under section 15 of the Act;
 - (d) advice that, until amounts payable under section 15 of the Act are paid, full assessment cannot proceed.

Note For the amount of further charges, see regulations 15, 16 and 17.

- (2) A notification by the Authority, under subsection 13A (3) of the Act, must include advice that the applicant may seek

review under regulation 14 if the applicant does not agree with the decision.

14 Review of decisions

- (1) Following receipt of a notification under subsection 13A (2) or (3) of the Act in relation to an application, the applicant may apply to the Authority, in writing, for reconsideration of a decision mentioned in the notification.
- (2) After reconsideration, the Authority must make a decision:
 - (a) confirming the decision; or
 - (b) setting aside the decision and substituting for it another decision.
- (3) Subject to the *Administrative Appeals Tribunal Act 1975*, an applicant may make an application to the Administrative Appeals Tribunal for review of a decision under subregulation (2).

Note Under section 27A of the *Administrative Appeals Tribunal Act 1975*, the decision-maker must give to persons whose interests are affected by the making of the decision notice of the decision and of their right to have the decision reviewed. In notifying such a person, the decision-maker must have regard to the Code of Practice determined under section 27B of that Act (see *Gazette* No. S 432, 7 December 1994).

15 Charges — full assessment

For paragraph 15 (2) (a) of the Act, the charge payable for full assessment of an application is the amount specified in column 2 in the Table set out in Part 2 of Schedule 3 in relation to the category of assessment mentioned in the Table that the Authority has determined applies to the application.

16 Charges — inquiry relating to food regulatory measure

For paragraphs 15 (2) (b) and (c) of the Act, the charge payable for the giving of notices in relation to an application is the amount specified in column 3 in the Table set out in Part 2 of Schedule 3 in relation to the category of assessment mentioned

in the Table that the Authority has determined applies to the application.

17 Charges — preparing drafts

For paragraph 15 (2) (d) of the Act, the charge payable for the preparation, under section 15A of the Act, of a draft food regulatory measure, or a draft variation of a food regulatory measure, in relation to an application is the amount specified in column 4 in the Table set out in Part 2 of Schedule 3 in relation to the category of assessment mentioned in the Table that the Authority has determined applies to the application.

18 Charges — election

A charge of \$2 800 is fixed for an election under paragraph 66 (6) (b) of the Act.

Note Paragraph 66 (6) (b) of the Act states a charge may only be fixed if an application has been included in the second or third year of a three year plan and the applicant elects to have the application included in the first year of the work plan.

Schedule 1	Modifications or adaptations of Part 3 of the Act under subsection 36 (2) of the Act
Part 1	Modifications and adaptations if the authority decides not to invite submissions after it accepts an application

Schedule 1 Modifications or adaptations of Part 3 of the Act under subsection 36 (2) of the Act

(subregulation 4 (2))

Part 1 Modifications and adaptations if the authority decides not to invite submissions after it accepts an application

1 Section 13 (Authority to make preliminary assessment of application)

1.1 Subparagraph 13 (4) (a) (iii):

Omit the subparagraph, substitute:

“(iii) that the Authority will not invite submissions on matters relevant to the application; and”.

2 Section 14 (Authority to invite public submissions)

2.1 Paragraph 14 (1) (a):

Omit “and”.

2.2 Paragraph 14 (1) (b):

Omit the paragraph.

2.3 Paragraph 14 (1) (g):

Omit the paragraph, substitute:

“(g) stating that the Authority will not invite submissions on matters relevant to the application.”.

3 Section 15 (Full assessment of application)

3.1 Paragraph 15 (2) (a):

Omit the paragraph.

**4 Section 16 (Notice following preparation of draft
standard or variation)**

4.1 Paragraph 16 (a):

Omit

“, to each appropriate government agency, and to each other body or person who made a submission in response to a notice sent or published under section 14”, substitute “and to each appropriate government agency”.

5 Section 17 (Notice following rejection of application)

5.1 Paragraph 17 (a):

Omit the paragraph, substitute:

“(a) by writing sent to the applicant and to each appropriate government agency; and”.

**Part 2 Modifications and adaptations if the
Authority decides not to give notice that
it will hold an inquiry to consider a draft
standard, or a draft variation of a
standard, prepared in relation to an
application**

**6 Section 16 (Notice following preparation of draft
standard or variation)**

6.1 Paragraph 16 (a):

Omit “and” (last occurring).

6.2 Paragraph 16 (b):

Omit the paragraph.

6.3 Paragraphs 16 (e) and (f):

Schedule 1	Modifications or adaptations of Part 3 of the Act under subsection 36 (2) of the Act
Part 2	Modifications and adaptations if the Authority decides not to give notice that it will hold an inquiry to consider a draft standard, or a draft variation

Omit the paragraphs, substitute:

“(e) stating that the Authority will not hold an inquiry to consider that draft.”.

7 Section 18 (Authority must make recommendation to Council)

7.1 Subsection 18 (1):

Omit

“After holding an inquiry to consider a draft standard or a draft variation of a standard, the Authority”, substitute “If the Authority prepares a draft standard, or a draft variation of a standard, under section 15, it”.

8 Section 19 (Authority must notify outcome of inquiry)

8.1 Subsection 19 (1):

Omit the subsection, substitute:

“(1) The Authority must:

- (a) by writing sent to the applicant and to each appropriate government agency; and
- (b) by advertisement published in the *Gazette*, and in a newspaper circulating in each State and Territory;

give notice setting out the nature of the recommendation made to the Council under section 18.”.

Part 3 Modifications and adaptations if the Authority decides not to invite submissions in relation to a proposal

9 Section 22 (Authority to invite public submissions on proposal)

9.1 Paragraph 22 (1) (a):

Omit “and”.

9.2 Paragraph 22 (1) (b):

Omit the paragraph.

9.3 Paragraph 22 (1) (f):

Omit the paragraph, substitute:

“(f) stating that the Authority will not invite
submissions on matters relevant to the
proposal.”.

10 Section 23 (Full assessment)

10.1 Paragraph 23 (2) (a):

Omit the paragraph.

11 Section 24 (Notice following preparation of draft standard or variation)

11.1 Paragraph 24 (a):

Omit

“, and to each other body or person who made a
submission in response to a notice sent or published
under section 22”.

12 Section 25 (Notice following abandonment of proposal)

12.1 Paragraph 25 (a):

Omit the paragraph, substitute:

Schedule 1	Modifications or adaptations of Part 3 of the Act under subsection 36 (2) of the Act
Part 4	Modifications and adaptations if the Authority decides not to give notice that it will hold an inquiry to consider a draft standard or a draft variation

“(a) by writing sent to each appropriate government agency; and”.

Part 4 Modifications and adaptations if the Authority decides not to give notice that it will hold an inquiry to consider a draft standard or a draft variation of a standard prepared in relation to a proposal

13 Section 24 (Notice following preparation of draft standard or variation)

13.1 Paragraph 24 (a):

Omit “and” (last occurring).

13.2 Paragraph 24 (b):

Omit the paragraph.

13.3 Paragraphs 24 (e) and (f):

Omit the paragraphs, substitute:

“(e) stating that the Authority will not hold an inquiry to consider that draft.”.

14 Section 26 (Authority must make recommendation to Council)

14.1 Subsection 26 (1):

Omit

“After holding an inquiry to consider a draft standard or a draft variation of a standard, the Authority”, substitute “If the Authority prepares a draft standard, or a draft variation of a standard, under section 23, it”.

15 Section 27 (Authority must notify outcome of inquiry)

15.1 Subsection 27 (1):

Omit the subsection, substitute:

“(1) The Authority must:

- (a) by writing sent to each appropriate government agency; and
- (b) by advertisement published in the *Gazette*, and in a newspaper circulating in each State or Territory;

give notice setting out the nature of the recommendation made to the Council under section 26.”.

Schedule 2	Modifications or adaptations of Part 3 of the Act under subsection 37 (2) of the Act
Part 1	Modifications and adaptations if the Authority decides not to invite submissions after it accepts an application

Schedule 2 Modifications or adaptations of Part 3 of the Act under subsection 37 (2) of the Act

(subregulation 5 (2))

Part 1 Modifications and adaptations if the Authority decides not to invite submissions after it accepts an application

1 Section 13 (Authority to make preliminary assessment of application)

1.1 Subparagraph 13 (4) (a) (iii):

Omit the subparagraph, substitute:

“(iii) that the Authority will not invite submissions on matters relevant to the application; and”.

2 Section 14 (Authority to invite public submissions)

2.1 Paragraph 14 (1) (a):

Omit “and”.

2.2 Paragraph 14 (1) (b):

Omit the paragraph.

2.3 Paragraph 14 (1) (g):

Omit the paragraph, substitute:

“(g) stating that the Authority will not invite submissions on matters relevant to the application.”.

3 Section 15 (Full assessment of application)

3.1 Paragraph 15 (2) (a):

Omit the paragraph.

**4 Section 16 (Notice following preparation of draft
standard or variation)**

4.1 Paragraph 16 (a):

Omit

“, to each appropriate government agency, and to each other body or person who made a submission in response to a notice sent or published under section 14”, substitute “and to each appropriate government agency”.

5 Section 17 (Notice following rejection of application)

5.1 Paragraph 17 (a):

Omit the paragraph, substitute:

“(a) by writing sent to the applicant and to each appropriate government agency; and”.

**Part 2 Modifications and adaptations if the
Authority decides not to give notice that
it will hold an inquiry to consider a draft
standard, or a draft variation of a
standard, prepared in relation to an
application**

**6 Section 16 (Notice following preparation of draft
standard or variation)**

6.1 Paragraph 16 (a):

Omit “and” (last occurring).

6.2 Paragraph 16 (b):

Omit the paragraph.

6.3 Paragraphs 16 (e) and (f):

Schedule 2	Modifications or adaptations of Part 3 of the Act under subsection 37 (2) of the Act
Part 3	Modifications and adaptations if the Authority decides not to invite submissions in relation to a proposal

Omit the paragraphs, substitute:

“(e) stating that the Authority will not hold an inquiry to consider that draft.”.

7 Section 18 (Authority must make recommendation to Council)

7.1 Subsection 18 (1):

Omit

“After holding an inquiry to consider a draft standard or a draft variation of a standard, the Authority”, substitute “If the Authority prepares a draft standard, or a draft variation of a standard, under section 15, it”.

8 Section 19 (Authority must notify outcome of inquiry)

8.1 Subsection 19 (1):

Omit the subsection, substitute:

“(1) The Authority must:

- (a) by writing sent to the applicant and to each appropriate government agency; and
- (b) by advertisement published in the *Gazette*, and in a newspaper circulating in each State and Territory;

give notice setting out the nature of the recommendation made to the Council under section 18.”.

Part 3 Modifications and adaptations if the Authority decides not to invite submissions in relation to a proposal

9 Section 22 (Authority to invite public submissions on proposal)

9.1 Paragraph 22 (1) (a):

Omit

“and”.

9.2 Paragraph 22 (1) (b):

Omit the paragraph.

9.3 Paragraph 22 (1) (f):

Omit the paragraph, substitute:

“(f) stating that the Authority will not invite
submissions on matters relevant to the
proposal.”.

10 Section 23 (Full assessment)

10.1 Paragraph 23 (2) (a):

Omit the paragraph.

11 Section 24 (Notice following preparation of draft standard or variation)

11.1 Paragraph 24 (a):

Omit

“, and to each other body or person who made a
submission in response to a notice sent or published
under section 22”.

12 Section 25 (Notice following abandonment of proposal)

12.1 Paragraph 25 (a):

Omit the paragraph, substitute:

“(a) by writing sent to each appropriate
government agency; and”.

Schedule 2	Modifications or adaptations of Part 3 of the Act under subsection 37 (2) of the Act
Part 4	Modifications and adaptations if the Authority decides not to give notice that it will hold an inquiry to consider a draft standard or a draft variation

Part 4 Modifications and adaptations if the Authority decides not to give notice that it will hold an inquiry to consider a draft standard or a draft variation of a standard prepared in relation to a proposal

13 Section 24 (Notice following preparation of draft standard or variation)

- 13.1 Paragraph 24 (a):
Omit “and” (last occurring).
- 13.2 Paragraph 24 (b):
Omit the paragraph.
- 13.3 Paragraphs 24 (e) and (f):
Omit the paragraphs, substitute:
“(e) stating that the Authority will not hold an inquiry to consider that draft.”.

14 Section 26 (Authority must make recommendation to Council)

- 14.1 Subsection 26 (1):
Omit
“After holding an inquiry to consider a draft standard or a draft variation of a standard, the Authority”,
substitute “If the Authority prepares a draft standard, or a draft variation of a standard, under section 23, it”.

15 Section 27 (Authority must notify outcome of inquiry)

- 15.1 Subsection 27 (1):
Omit the subsection, substitute:
“(1) The Authority must:

Modifications or adaptations of Part 3 of the Act under subsection 37 (2) of the Act	Schedule 2
Modifications and adaptations if the Authority decides not to give notice that it will hold an inquiry to consider a draft standard or a draft variation of a standard prepared in relation to a proposal	Part 4

- (a) by writing sent to each appropriate government agency; and
 - (b) by advertisement published in the *Gazette*, and in a newspaper circulating in each State or Territory;
- give notice setting out the nature of the recommendation made to the Council under section 26.”.

Schedule 3 Charges

(regulations 15, 16 and 17)

Part 1 Categories of assessment

For regulation 12, the categories of assessment that may apply to an application under section 12 of the Act are as follows:

Category 1 — for an application relating to a simple variation to a food regulatory measure requiring limited public consultation;

Category 2 — for an application requiring only the updating of standard methods of analysis set out in the Australia New Zealand Food Standards Code in relation to a food;

Category 3 — for an application requiring only an updated risk assessment in relation to an existing standard;

Example

A Category 3 assessment is required for applications that will achieve any of the following outcomes:

- extension to other foods of the permission for use of a permitted food additive or processing aid
- introduction or variation of a labelling requirement that affects a particular food or class of foods
- permission to add a new ingredient to a standardised food;
- allowing simple food irradiation for a food
- recognition of a new, simple processing technology.

Category 4 — for an application requiring a risk assessment for a new food regulatory measure, but not a Category 5 assessment;

Example

A Category 4 assessment is required for applications that will achieve any of the following outcomes:

- allowing a food additive or processing aid that is not currently permitted
- a new standard for a food

- review of a food standard or part of a food standard
- introduction or variation of a labelling requirement that affects a food generally
- allowing complex food irradiation for a food
- recognition of a new, complex processing technology
- establishment or variation of a maximum permitted concentration for an environmental contaminant or heavy metal
- regulation of a new micro organism in food
- regulation of an allergen in food.

Category 5 — for an application requiring a new risk assessment that is of a higher degree of complexity than that required for Category 4, because of the need for:

- increased external scientific and technical input; or
- extensive negotiation of relevant issues with stakeholders such as relevant government agencies, consumer groups and industry associations.

Example

A Category 5 assessment will be required for applications that involve any of the following:

- evaluation of a complex toxicology data package for new food additives
- a highly complex food irradiation for a food
- recognition of a new, highly complex processing technology
- preparation of detailed exposure estimates.

Part 2 Charges for full assessments, inquiries and draft food regulatory measures

Category of assessment	Charge under regulation 15	Charge under regulation 16	Charge under regulation 17
Category 1	2 142	420	238
Category 2	10 710	2 100	1 190
Category 3	25 704	5 040	2 856
Category 4	42 840	8 400	4 760
Category 5	64 260	12 600	7 140

Table of Statutory Rules

Notes to the *Australia New Zealand Food Authority Regulations 1994*

Note 1

The *Australia New Zealand Food Authority Regulations 1994* (in force under the *Australia New Zealand Food Authority Act 1991*) as shown in this compilation comprise Statutory Rules 1994 No. 286 amended as indicated in the Tables below.

Table of Statutory Rules

Year and number	Date of notification in <i>Gazette</i>	Date of commencement	Application, saving or transitional provisions
1994 No. 286	23 Aug 1994	23 Aug 1994	
2000 No. 122	22 June 2000	1 July 2000	—

Table of Amendments**Table of Amendments**

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 1	rs. 2000 No. 122
R. 2	am. 2000 No. 122
R. 3	am. 2000 No. 122
R. 6	rs. 2000 No. 122
Rr. 7–18	ad. 2000 No. 122
Schedule 3	ad. 2000 No. 122