

EXPLANATORY STATEMENT

Select Legislative Instrument 2007 No. 310

Subject - *Food Standards Australia New Zealand Act 1991*

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

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

The primary business of the Authority 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 purpose of the Regulations is to amend the *Food Standards Australia New Zealand Regulations 1994* (the Principal Regulations) to make changes to the cost recovery procedures including the way in which charges are assessed; bring those provisions of the Principal Regulations that deal with how an application for the development of, or variation to, a standard is progressed into line with recent amendments to the FSANZ Act; update the process by which applications are classified into the appropriate category; and update the list of agencies, authorities and Departments to whom the Authority may refer certain information and from which organisation nominations may be obtained for the Board of the Authority.

The FSANZ Act establishes a food regulatory system for Australia and New Zealand. The object of the FSANZ Act and the Principal Regulations is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of the Authority to achieve the following goals:

- a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
- an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

The impetus for the Regulations was the experience with the system since 2002 (and a review of the standard development and approval process) which confirmed the strengths of the current process including the focus on public health and safety. However, the review also highlighted areas for improvement. The review also made suggestions for improving the coordination of processes within the Authority, better management of issues in relation to food innovation, and better engagement of stakeholders in the standards development process

The Regulations :

- reflect the updated assessment and consultation processes;
- align the process with the nature and scope of the application or proposal under consideration;
- prescribe the time in which applications are to be considered;
- clarify the charges applicable to each procedure classification;
- provide surety to each applicant in terms of costs resulting in the provision of dedicated services and time from the Authority; and
- introduce a system of refund of fees in circumstances where the amount of hours assessed for a paid application have not been used by the Authority.

Consultation

Acknowledging the positive effect the Regulations will have on industry and the benefits which flow from the amendments, the Authority considered that targeted consultation with the representatives of the significant portion of the food industry from which applications to the Authority originate was the most appropriate approach. Further, in recognition of the fact that a RIS was not required, consultation was limited to State and Territory Governments, the New Zealand Government and the Food Regulation Implementation Committee. Wider consultation occurred under the guidance of the Department of Health and Ageing in the development of the changes to the Act which lead to the Regulations and the development of the Guidelines on which applications and other processes will be based. In addition, FSANZ analysed past applications under the current cost recovery regime, the type of application submitted and the level of payments made by all paying applicants.

The regulations will have a positive effect on business, ensuring dedicated time and staff within the Authority to assess paid applications, provide continuity of the current cost recovery arrangements which do not result in an increase in the per hour fee charged by the Authority which remains at \$107 per hour. The Act now provides for shorter consideration periods for certain applications, and the regulations and updated fee structure, provide assurance to industry and applicants generally about dedication of staff and resources, the greater ability to meet the timelines and assurance that the costs involved in progressing an application are known and set. The regulations also provide for refunds of unused fees in circumstances where fees were paid but the time assessed as appropriate for the consideration was not required.

Details of the Regulations are set out in the Attachment.

The FSANZ Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on 1 October 2007.

ATTACHMENT

DETAILS OF THE *FOOD STANDARDS AUSTRALIA NEW ZEALAND AMENDMENT REGULATIONS 2007 (No. 1)*

Regulation 1

Regulation 1 provides that the name of the Regulations is the *Food Standards Australia New Zealand Amendment Regulations 2007 (No. 1)*.

Regulation 2

Regulation 2 provides that the Regulations commence on 1 October 2007.

Regulation 3

Regulation 3 provides that Schedule 1 amends the *Food Standards Australia New Zealand Amendment Regulations 1994* (the Principal Regulations).

Regulation 4

Regulation 4 provides for transitional arrangements. Subregulation 4.1 provides that applications made before 1 October 2007 will continue to be dealt with under the Principal Regulations as in force before 1 October. For the purpose of this regulation, the terms *application*, *former Act* and *proposal* are defined in subregulation 4.2.

Schedule 1 – Amendments

Item 1

Item 1 amends existing regulation 2 (Interpretation). This is a technical amendment to accommodate the substitution of the cross-references in the definitions of *application* and *proposal*. In line with recent amendments to the FSANZ Act, a definition for *procedure* is added to highlight the new process where the Authority assesses which procedure applications must be considered under.

Item 2

This item is a technical amendment to regulation 2 (Interpretation) to omit subregulation 2(2). Recent amendments to the FSANZ Act changed the assessment and consultation process to align the process with the nature and scope of the application or proposal under consideration. This has outdated subregulation 2(2).

Item 3

Due to the renumbering of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), ***appropriate government agency*** is now defined in section 4 of the FSANZ Act (previously section 3). This item amends regulation 3 to omit each mention of 3 and insert 4.

Item 4

Item 4 substitutes existing regulations 4 and 6 with an amended regulation 6. Recent amendments to the FSANZ Act omitted section 36 and therefore made regulation 4 which deals with section 36 of the FSANZ Act redundant. Confidential Commercial Information is now renumbered as section 114 in the FSANZ Act. This item amends the reference in regulation 6 from paragraph 39(4)(b) to paragraph 114(4)(b).

Item 5

Due to the renumbering of the FSANZ Act, section 40 (Constitution of the Board) will be renumbered as section 116. This item amends regulation 6A to omit each mention of 40 where occurring and insert 116.

Item 6

This item substitutes existing regulations 7 to 14 with new regulation 7 (Charges), regulation 8 (Refunds), regulation 9 (Procedure Classification), regulation 10 (Period within which consideration of proposal must be complete), regulation 11 (Period within which consideration of applications for standards or variations must be complete).

Regulation 7 Charges

This new regulation 7 substitutes the previous regulation 8 (Charges) and provide for the payment of charges mentioned in Schedule 3 to the Principal Regulations for the services and facilities the Authority provides to a person or body in accordance with section 146 (charges relating to the authority's costs) in the FSANZ Act. Subregulation 7(1) provides that the charges to be paid to the Authority by a body or person are set out in Schedule 3. The charge for the provision of such services and facilities remains at \$107 per hour.

Subsection 146(1A) of the FSANZ Act provides that the regulations may provide for charges to be paid by instalments and may fix the times at which instalments are due to be paid. Subregulation 7(2) provides that a charge for an application that has been classified as a major procedure under Schedule 4 (Procedure Classification) is payable by way of two instalments. The first instalment which represents 25 per cent of the full charge is payable within 20 business days after the notice of acceptance is given under section 27 of the FSANZ Act. The balance of the charge, being 75 per cent of the full charge, is payable as soon as practicable after public notice given under section 44 of the FSANZ Act and before the assessment of the submissions under section 45 (matters to which the Authority must have regard in making a decision) occurs.

Charges for all other procedures as classified under Schedule 4 are payable by way of one payment.

Subregulation 7(3) provides that the Authority must repay to the person or body \$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.

Regulation 8 Refunds

Regulations 9, 10 and 11 of the existing regulations provided for refunds of fees in particular circumstances. Those regulations are substituted with regulation 8 which provide for a refund of fees in two circumstances.

Subsections 24(2) (withdrawal of applications) and 110(3) (rejection of application) provide that the Authority must refund to the applicant so much of the charge as is equivalent to the sum paid by the applicant but not expended by the Authority from the charge, calculated in accordance with the regulations. Regulation 8 provides for the calculation of the refund in such circumstance. For example, if an application is withdrawn after 350 hours of work done on what was calculated to be a 500 hour assessment, the refund will be calculated at 150 hours paid at the rate of \$107 per hour and total \$16,050 in that circumstance.

Regulation 9 Procedure classification

This new regulation provide that if the Authority accepts an application, it must classify the application in accordance with the procedure classification in section 25 of the FSANZ Act and Schedule 4. Paragraph 9(2)(b) requires the Authority to determine how many hours are likely to be required if an application is classified as a major procedure.

Regulation 10 Period within which consideration of proposal must be complete

This new regulation provides that consideration of a proposal in relation to the variation of the Maximum Residue Limits standard, in accordance with section 83 of the FSANZ Act (Authority to complete its consideration of the proposal within prescribed period), ends 9 months after it begins.

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

Subsection 109(3) of the FSANZ Act provides that the consideration period of an application or variation ends 12 months after it begins or, if a shorter period is prescribed, at the end of that shorter period. Regulation 11 prescribes those shorter times.

Consideration of an application for development of, or variation to, a food regulatory measure that is assessed as a general procedure ends 9 months after it begins. An application which is assessed under the minor procedure will end 3 months after it begins, while an application that is assessed under the major procedure ends 12 months after it begins.

The consideration period for those applications classified as minor procedure and general procedure consideration periods may not be extended. The consideration period for those applications for the development of a new standard or a major variation, being assessed under the major procedure, may be extended by a maximum period of 6 months in accordance with the provisions of subsections 109(4) and (5) of the FSANZ Act.

Item 7

This item amends existing Schedule 1, Part 2 (Appropriate government agencies – State and Territory authorities) to update the names of authorities and to expand the list, mentioned in Part 2 to reflect changes of name or division responsibilities within those authorities. The existing list is expanded from 11 to 19 to include additional authorities with which the Authority engages. Existing subregulation 3(1) provides that for the purpose of paragraph 4(1)(a) of the FSANZ Act (definition of appropriate government agency) each State and Territory authority mentioned in Part 2 of Schedule 1 is prescribed. Each such authority is prescribed for the purpose of receiving official notification from the Authority in relation to the progress of applications and proposals under consideration.

Item 8

This item omits Schedule 1A which is no longer required as a result of amendments to the FSANZ Act. Recent amendments to the FSANZ Act omitted section 36 and therefore Schedule 1A which deals with section 36 of the FSANZ Act is no longer required.

Items 9 to 16

Items 9 to 16 amend, update, or insert the correct names of Commonwealth authorities, State and Territory authorities, and New Zealand authorities to reflect change of names of Departments or division of responsibilities within each such authority at Commonwealth or State and Territory level. Section 114 of the FSANZ Act imposes a duty upon members of the Board, the Authority, its staff, committee members and consultants to not disclose any confidential commercial information in respect of food, which has been acquired in the course of his or her work with the Authority. However, the Chief Executive Officer of the Authority may disclose any such confidential commercial information to a prescribed authority or person. For this reason it is necessary to update and maintain the names of prescribed authorities in Schedule 2 to which such information may be disclosed.

Items 17 to 20

Section 116 of the FSANZ Act establishes the Board of the Authority and paragraphs 116(3)(a) and 116(4)(b) provide that the Minister may appoint persons to the Board subject to having expertise in particular fields. For the purpose of such appointments, the Minister may seek nominations from such bodies and organisations as may be prescribed in the regulations. Schedule 2A (Board – prescribed organisation and public bodies from which nominations may be sought) lists those organisations and bodies from which nominations may be sought.

Items 17 and 19

Item 17 amends the heading to column 3, Part 1 of Schedule 2A, while item 19 amends the heading to column 3, Part 2 of Schedule 2A. As a consequence of the renumbering of the FSANZ Act, section 40 is now renumbered as section 116. These items amend the heading to substitute 40 and insert 116.

Item 18

This item amends item 102 (Australian Consumers' Association), column 2 of Part 1 to Schedule 2A (prescribed organisations and public bodies from which nominations may be sought) to reflect a change in name of that organisation to CHOICE.

Item 20

This item amends item 209 (Restaurant and Catering Industry of Australia Inc), column 2 of Part 2 to Schedule 2A (prescribed organisations and public bodies from which nominations may be sought) to reflect a change in name of that organisation to Restaurant and Catering Australia.

Item 21

This item substitutes Schedule 3 (Charges) and Schedule 4 (Categories of assessment) which is renamed Procedure Classification.

Schedule 3 Charges

Item 21 replaces existing Schedule 3 to update the charges payable to the Authority. Under section 146 of the FSANZ Act, the 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 if it relates to an application to develop or vary a standard and the development or variation of the standard confers an exclusive capturable commercial benefit on the applicant, or the applicant has elected to have the consideration of the application expedited.

Item 1 of Schedule 3 sets out the charges payable for each procedure as classified in relation to an application to develop a standard, or a variation to a standard for which charges may be payable. These charges are based on the cost to the Authority of processing each category of application. The charges have not been increased and remain at \$107 per hour. The charges incorporated in Schedule 3 are applied depending on the procedure which the application is classified as appropriate.

The FSANZ Act provides for three procedure classifications: general as the default procedure, minor and major as determined by the Authority. The Authority, in recognising the complexity of some applications which may be assessed under the general procedure has determined that it is appropriate to have two levels of classification within that one procedure classification.

Charges determined for applications assessed under the minor and general procedures are payable in one fee. Charges as assessed for the major procedure are payable by way of two instalments as provided in regulation 7.

Schedule 4 Procedure classification

Item 21 replaces the existing Schedule 4 (categories of assessment) to provide for procedure classification linked to the new procedures in the FSANZ Act. The procedures contain

expanded examples of those matters which typically satisfy the classification of each procedure and those factors which the Authority may take into account when considering which procedure an application should be classified as. These examples are provided as guidance only. Though not contingent on the number of hours likely to be required to fully complete the assessment of each application, each procedure does provide an indication of the likely number of hours which will be required for the assessment.