National Food Authority Amendment Regulations 2000 (No. 1) 2000 No. 122

EXPLANATORY STATEMENT

Statutory Rules 2000 No. 122

Issued by the Authority of the Parliamentary Secretary

to the Minister for Health and Aged Care

Australia New Zealand Food Authority Act 1991

National Food Authority Amendment Regulations 2000 (No. 1)

The Australia New Zealand Food Authority (the Authority) is a statutory body continued in existence by section 6 of the *Australia New Zealand Food Authority Act 1991* (the Act). The Authority was originally known as the National Food Authority and was established in 1991. The Authority recommends amendments to the Food Standards Code, either by proposing new food standards or proposing variations to existing food standards. Under a 1991 Commonwealth, State and Territory agreement, subsequently amended following the signing of a Treaty between the Commonwealth and New Zealand, food standards are recommended by the Authority and adopted by a Ministerial Council called the Australia New Zealand Food Standards Council. Such amendments are adopted by reference and without amendment as food standards in force under State, Territory and New Zealand food laws.

Section 70 of the Act allows the Governor-General. to make regulations 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.

Section 10A of the Act requires the Authority to develop a three year work plan not later than 30 June each year.

Section 66 of the Act enables the fixing of charges by regulation for services and facilities that the Authority provides. Subsection 66(6) of the Act limits the fixing of charges to:

* applications, in relation to the development or variation of a food standard, that would confer an exclusive, capturable commercial benefit on the applicant; or

* the case where an application has been included in the second or third year of the 3 year work plan and the applicant elects to have the application included in the first year of the work plan.

The purpose of the regulations is to among other things, prescribe such charges and related matters as follows:

* an application fee will be charged which will encompass the preliminary assessment and the publishing of the notices relating to preliminary assessment;

* five charging categories are proposed for full assessment fees - based on the amount of work and complexity of applications;

* within each of the five categories charges are fixed for the three main processes that follow preliminary assessment of an application - full assessment, the preparation of a draft food regulatory measure, and inquiry into a draft food regulatory measure;

* refunds of fees will be available only in a limited range of circumstances, and only where a part of the process for which a fee has been paid has not been carried out prior to the withdrawal or rejection of an application;

* provision for review of certain decisions is made.

The regulations also amend the National Food Authority Regulations 1994, so that:

* the name of the regulations is changed from ´National Food Authority Regulations 1994", to "Australia New Zealand Food Authority Regulations 1994", to reflect the name of the Act under which they are made;

* the regulations prescribe the agencies in both Australia and New Zealand to which the Authority may disclose confidential commercial information, such as New Zealand's Environmental Risk Management Agency; and

* the references to the Act in the regulations are updated to take account of the amendments to the Act.

The Regulations commence on 1 July 2000.

Details of the regulations are in the Attachment.

ATTACHMENT

Details of the National Food Authority Amendment Regulations 2000 (No. 1)

Regulation 1 provides that the name of the regulations is the National Food Authority Amendment Regulations 2000 (No. 1).

Regulation 2 provides for that the regulations commence on 1 July 2000.

Regulation 3 provides that the National Food Authority Regulations are amended by Schedule 1 of the regulations.

Details of Schedule 1

Item 1 amends existing regulation 1 (Citation) to provide that the existing regulations are to be cited as the Australia New Zealand Food Authority Regulations 1994.

Item 2 amends existing regulation 2 (Interpretation) to omit the existing definition of Act' and substitute a new definition that refers to the current name of the Act.

Item 3 provides that exclusive, capturable commercial benefit has the same meaning as that contained in section 66(9) of the Act. Such a benefit would apply where the applicant can be identified as deriving a financial gain from the adoption of the standard or variation of a standard, and other persons or bodies would require the agreement of the applicant in order to financially benefit from the approval of the application.

Item 4 amends existing regulation 2 (Interpretation) by omitting the definition of 'the Act´.

Item 5 amends existing regulation 3 (Appropriate government agencies) by substituting new paragraphs 3(1)(a) to 3(1)(e). These amendments are necessary to update the names of two Commonwealth government departments.

Item 6 replaces existing regulation 6 and inserts new regulations 7 to 18.

Regulation 6 -

The existing regulation 6 (Authority or person to whom certain information may be disclosed) is replaced with new regulation 6. Section 39 of the Act imposes upon the Authority, its staff, committee members and consultants a duty not to disclose any confidential commercial information in respect of food that has been acquired by a person because of his or her work with the Authority. Subsection 39(4) of the Act provides that despite this duty of confidentiality, the Chief Executive Officer of the Authority may disclose such confidential commercial information to a prescribed authority or person.

Existing regulation 6 lists the names of the prescribed authorities. New regulation 6 updates the names of some of those authorities and adds the following New Zealand agencies to the list of prescribed authorities: the Ministry of Health, the Environmental Risk Management Authority and the Ministry of Agriculture and Forestry. These authorities were not included in the original list because the list was developed before the Australia New Zealand Food Authority partnership was formed in 1996. Subsection 39(6) of the Act provides that these prescribed authorities must treat the released information in-confidence.

New Regulation 7

New regulation 7 provides that the Authority may request additional information from an applicant in order to enable it to deal with the application in accordance with the Act.

New Regulation 8

New regulation 8 provides for the fixing of a charge of $2,800 as the application fee for an application that would confer an exclusive, capturable commercial benefit on the applicant. The fee will comprise the charge for the preliminary assessment and the charge for giving of notices inviting submissions (under section 14 of the Act).

Subregulation 8(2) constitutes a deeming provision in relation to acceptance of an application fee because a determination as to whether a charge is applicable is not made until after the acceptance of an application.

The application will not be deemed to have been received until payment of the fee is received.

New Regulation 9

New Regulation 9 provides for the refund of the application fee in the event that an applicant withdraws an application prior to the commencement of a preliminary assessment of the application.

Note: Subsection BA(4) of the Act provides for the refund of that part of the fee that relates to the giving of section 14 notices in the event of an application being rejected at preliminary assessment

New Regulation 10

New regulation 10 makes provision for the refund of fees where an application is withdrawn after its preliminary assessment has been made. The proportion of the amount of the charge that is to be refunded is dependent upon the stage of the process at which the application is withdrawn.

Subregulation *10(2)* provides that if an application is withdrawn before a full assessment commences, any money that has been paid in relation to full assessment, drafting and inquiry must be refunded.

Subregulation *10(3)* provides that if an application is withdrawn after full assessment has commenced and before half of the work required for a full assessment been carried out, the Authority must refund half of the money that has been paid in relation to full assessment and drafting and the full amount of money that has been paid for inquiry.

Subregulation 10(4) provides that if an application is withdrawn after half of the work required for full assessment has been carried out and before inquiry, the Authority must refund the money that has been paid in relation to the holding of an inquiry.

New Regulation 11

New regulation 11 provides for refund of the monies paid in relation to the holding of an inquiry in the event that an applicant advises that the Authority will not be requested to hold an inquiry.

The combined effect of subsection 16(4) and subsections 1713(1), 18(1) and 19(1) is that the application will progress no further, that is, development of a food regulatory measure will cease

and no recommendations will be made by the Authority to the Ministerial council regarding the application.

New Regulation 12

New regulation *12* provides that, in making a preliminary assessment, the Authority must also decide the category of assessment that will be required for the application and whether the application is one that could confer an exclusive, capturable commercial benefit.

These requirements are in addition to those matters (required by subsection *13(2)* of the Act) that the Authority must have regard to in the making of a preliminary assessment.

New Regulation 13

New Regulation 13 requires the Authority, when notifying the applicant of the results of the preliminary assessment, to also notify the applicant of the category that the application falls into, whether the application is considered as one that may confer an exclusive, capturable commercial benefit and that the application may seek a review of these decisions under regulation 14.

The applicant must also be advised of any further charge payable and that no further processing of the application will occur until payment of the charge has been received by the Authority.

New subregulation 13(2) would require the Authority to notify the applicant that the applicant may seek an internal review of the decision to reject the application at preliminary assessment.

New Regulation 14

New Regulation 14 makes provision for the review of decisions regarding the category of assessment of an application and decisions as to whether an application would confer an exclusive, capturable commercial benefit on an applicant.

An applicant would be able to apply to the Authority for reconsideration of such decisions and the Authority would then be required to either confirm the decision or set aside the decision and substitute with another decision.

If an applicant is dissatisfied with the outcome of the Authority's reconsideration the applicant may make an application to the Administrative Appeals Tribunal for review of the decision made in relation to the reconsideration.

New Regulation 15

New regulation 15 provides for the fixing of charges for the full assessment of five different categories of applications. The categories are set out in Part 1 of proposed new Schedule 3 to the regulations. The charges are set out in Part 2 of that schedule.

New Regulations 16 and 17

New regulations 16 and 17 provide for the fixing of charges in relation to an inquiry relating to a food regulatory measure and the drafting of a food regulatory measure respectively. The charges are fixed for the five categories of application and are set out in Part 2 of the proposed new Schedule 3 to the regulations.

New Regulation 18

New Regulation 18 provides for the fixing of a charge of $2,800 to. be payable by an applicant who elects to have an application that has been included in the second or third year of the work plan included in the first year of the work plan.

Item 7 inserts a new Schedule 3 into the regulations. Schedule 3 contains two parts.

Part 1 of Schedule 3 sets out and defines the five categories of assessment.

A category 1 application is one that relates to a simple variation to a food regulatory measure requiring limited public consultation.

A category 2 application is one that merely requires the updating of standard methods of analysis in the Australian New Zealand Food Standards Code.

A category 3 application is one that requires an updated risk assessment for an existing standard.

A category 4 application is one that requires a new risk assessment for a new food regulatory measure but does not require a category 5 assessment.

A category 5 application is one that would require a new risk assessment of a higher degree of complexity because it would require a high degree of external scientific and technical input and/ or protracted negotiation of outcomes with stakeholders.

Part 2 of Schedule 3 sets out the charges payable for each of the five categories in relation to full assessment, drafting and inquiry. These charges have been based on the average cost to the Authority of processing each type of category.

REGULATIONS FOR COST RECOVERY

OUTLINE

The Australia New Zealand Food Authority Amendment Bill 1999 amended the *Australia New Zealand Food Authority Act 1991* (the Act). The Bill was passed by Parliament in December 1999 and proclaimed on 23 December 1999. The amended Act requires the Authority to establish a threeyear work plan and to recover the costs of processing applications for which the applicant has an *exclusive capturable commercial benefit.*

Applications will no longer have to be completed within a twelve-month period, but can instead be allocated to the second or third year of the work plan, although they will still have to be completed within 12 months of commencement as required by the Act. The work plan will enable the Authority to better prioritise its work of reviewing, modifying and developing the Food Standards Code especially as the number of applications is expected to increase over the next few years as a result of rapidly changing food technologies and industry innovations such as biotechnology and novel foods.

These regulations establish the framework for the work plan and cost recovery mechanism.

FINANCIAL IMPACT

As a result of introducing cost recovery and the work plan the Authority will be able to process certain additional food standards applications by taking on additional resources to complete the work.. This will enable the Authority to continue to meet its statutory obligations by ensuring that its appropriated resources are spent on issues of greatest priority to the community, rather than being required to divert these resources to applications of lower public health and safety merit.

REGULATION IMPACT STATEMENT

Background

The amended Act is quite specific about what ANZFA can do. Section 10A of the Act establishes that ANZFA must develop and publish a three year forward plan for applications, proposals and types of applications and proposals for which it intends to develop standards or variations to standards. A regulation impact statement was prepared as part of amendments to the Act. The regulations set out the circumstances under which ANZFA can recovery the costs of processing food standards applications.

For a number of years prior to the 2000-01 Budget, ANZFA was required to seek additional funding on an annual basis. However, in the 2000-01 Budget the Government agreed to provide ANZFA with an additional $25.8m over four years to establish its base funding at $12m pa. Any funds received through cost recovery will be in addition to those received through the Budget.

It is always difficult to be certain how many applications will be received annually but it is expected to be between 30 and 50 of which 5 to 10 might attract a charge providing fees of $0.25 to $0.5 m.

Problem

At a time of increasing industry innovation and technological advances and Increased demands from consumers for new products and high levels of safety assurance; funding standards development work from government appropriations is problematic. At the same time, establishment of any industry charging regime needs to be done equitably and effectively.

Objective

To establish a work program that meets the Authority's public health and safety and consumer protection requirements and to institute a charging regime that fairly and efficiently recovers costs for processing those applications that have an exclusive capturable commercial benefit or where an applicant opts to pay for an earlier assessment than would otherwise occur.

Options

<u>Work plans</u>

Prior to the December 1999 amendments to the Act, the Authority had a statutory responsibility to process all applications within a twelve-month period on a first come first served basis. Large numbers of applications in any one year has meant that the Authority has had to divert limited resources away from other core activities to complete these applications within the statutory timeframe.

The amendments to the Act require ANZFA to introduce a 3 year work plan. Whilst the Act does not specify the format of the work plan, the key objective will be to provide at least as much

information as is currently provided publicly plus an indication of starting dates, expected completion dates and the amount of work that has been completed on each application.

Proposals and applications will be assessed and divided into three categories. Those which have a high public health or safety component or are of an emergency nature, will be given priority on the work plan and placed in category one. Other applications which do not have a significant health and safety component and do not provide an exclusive financial benefit to a particular company or group of related companies, win be included in the work plan on a first come, first served basis and placed in category two. All proposals and applications in categories one and two will be processed at no cost to the applicant. The Act requires the Authority to set aside l0 per cent of the budget for processing food standards applications each year to ensure that applications in category two continue to be processed and are not delayed unnecessarily. All applications whether from industry, both Australian and New Zealand, State or Territory governments or consumers will be treated equally.

Applications with an exclusive capturable commercial benefit or those opting to pay will be included in category 3 of the work plan and will be processed separately using additional resources acquired with the fees that are paid. Processing of applications will commence on payment of the fee and will be conducted concurrently.

Cost Recovery

In relation to charging for its services, the Act states that the Authority "may fix charges" in certain situations, which are specified in the Act. Currently there are no charges imposed for processing applications. However, the Act prescribes that those applicants who derive an exclusive capturable commercial benefit should pay the M cost of processing that application. In addition, the Act also allows an applicant in category two to elect to have the processing of their application commenced prior to its allocated starting date on the work plan by meeting the full cost of processing that application. A business will make a commercial decision on whether it opts to pay based on the perceived financial benefits to itself knowing that its place in the work plan is secure as similar applications will be processed in the order in which they were received.

The definition of an exclusive capturable commercial benefit is included in the Act and is intended to apply to those applicants *who* would be the only ones to gain a real financial benefit from having a food standard varied or created. Of the 30 to 50 applications that might be expected to be lodged each year only between five and ten are likely to fall into this category and be subject to a fee.

Proposed Options

Option 1 - sliding fee scale

The Authority would have a sliding scale of fees based on the turnover of the business or some other method for determining the size of a business.

Option 2 - charge each applicant the full cost of processing their application

Charge applicants the full cost of processing an application based on an average cost within a five-tier fee structure.

Impact analysis

The following groups were identified as likely to be affected by the proposed options and were consulted:

* **Consumers** - who want to be assured that the food they consume is safe and that the regulatory process is open and they are able to participate in the decision making process either as individuals or representing a specific or general interest group. Better allocation of resources will ensure that the Authority can give greater priority to public health and safety matters. On the negative side there is the potential for the cost of processing an application to be passed on to consumers by industry depending on the competition in the market. This will be a commercial decision based on the likely acceptance of those costs by consumers. However, the cost of processing an application would in general represent only a very small part of the overall development costs of a new product. A concern of consumers is that ANZFA will be "captured" by applicants because of cost recovery. The Act does not allow this to happen as exactly the same stringent objectives, public consultation periods and approval processes will apply to these applications as to all others. Payment of the fee will ensure timely processing of the application, it will not affect the outcome of the decision.

* The **food industry** generally - which relies on consumer confidence in safe food to sell their products and who bear the cost of implementing the regulatory system and who want costs, including fees minimised. Applicants will have the option of having their applications processed promptly by payment of a fee. There will be improved accountability and transparency of the applications processing system, as industry will be consulted in the development of the work plan. On the negative side industry may have to pay for certain applications that in the past would have been completed using public resources. There is also the potential that small business might find the costs significant when introducing a new product to the extent that the product did not reach the market although based on past experience, only large businesses are expected to submit such applications. In fact over the past three years there has been only one application submitted by a small business and this is not expected to change.

* **Governments** - the governments of Australia and New Zealand have responsibility for protecting public health and safety in relation to food as well as bearing the cost of administering and enforcing legislation from limited public .resources. By being able to prioritise its work the Authority will be able to achieve a better balance in its outcomes and be more responsive to the development of food standards which involve a high health and safety component or can be classed as an emergency application. The receipt of fees will also help partially defray the costs of the regulatory system, though Governments will continue to meet the bulk of the costs.

These regulations would have no differential social or economic impact on rural or regional Australia.

Costs and Benefits of each Option

Option

Option 1 involving a sliding fee scale based on the size of a business would impose a significant administrative cost on both the Authority and the applicants themselves. Initially, an appropriate methodology for measuring the size of a business would need to be developed. It could be based on criteria such as turnover, taxable income, floor space or the number of employees. None of these were assessed as being entirely equitable. Whichever method was chosen, it would require applicants to supply additional financial information and the Authority would have to have staff skilled in undertaking such an assessment and setting fees. Most of Australia's major food producers, who are the ones most likely to submit applications for which a charge could be levied, are part of large multinational companies, which could make the gathering and

confirmation of financial information difficult. The cost of undertaking such financial analysis would add significantly to the cost of processing an application.

A graduated fee structure might also encourage fee minimisation by large companies lodging applications through small subsidiaries, associates or through consultants.

A further concern would be that a graduated fee system based on some measure of size of the company would of necessity involve the cross subsidisation of small businesses by large businesses if the system was to be cost neutral to the Authority. This might legitimately be viewed as a tax by large business and would, therefore, not only be unfair but illegal. Charging a fee on the basis of a "capacity to pay" could constitute a levy for which separate taxation legislation would be required. This has already been rejected by Government as an option and is strongly opposed by industry.

Such an assessment process might also attract a significant number of appeals against a decision of the Authority.

Option 2

Option 2 involving charging each applicant a fixed fee representing the full cost of processing an application would be much simpler to administer and be more equitable.

Once it were determined that an application had an exclusive capturable commercial benefit, a small flat fee would be charged by the Authority to undertake a preliminary assessment to determine the scale and likely cost of processing the application and the applicant advised of the total cost.

As the time and resources taken to process each application can vary significantly, it is proposed to use a five tier scale that has been developed based on past experience of processing applications. The five tiers, will be:

* **Very simple** - requiring only a limited amount of work, such as changing a simple procedural matter; where no public consultation is required or where the safety assessment has been carried out by another agency. The fee will be $2,800 plus GST.

* **Simple** - where a risk assessment does not have to be prepared; or where issues are raised that are uncomplicated and can be dealt with quickly; where standard methods are updated or where the assessment process is simple. The fee will be $14,000 plus GST.

* **Average** - is more complicated than a simple application but is still straightforward or requires a revision of a previously undertaken risk analysis. The fee will be $33,600 plus GST.

* **Complex** - requires an additional degree of assessment such as where a new risk assessment is required for a new food additive or processing aid not currently used; an entirely new standard or where the work required is complex and extensive. The fee will be $56,000 plus GST.

* **Highly Complex** - requiring an additional degree of assessment such as a higher degree of external scientific and technical input; the evaluation of complex toxicology data for new food additives; the preparation of detailed exposure estimates or protracted negotiations of outcomes with stakeholders. The fee will be $84,000 plus GST.

The fee would be based on an estimate of anticipated costs. A five tiered fee structure applying equally to all applicants would allow each applicant to be advised of the cost that they would face before the full assessment of their application begins.

Consumers' concerns that the fee will influence the outcome is addressed by clearly prescribing the circumstances in which fees are paid and making it clear that the fee pays for the processing, not the outcome. The fee would also cover the administrative costs of collecting fees.

The costs for a small business submitting an exclusive capturable commercial benefit application could be significant but on examining applications received by the Authority over the past three years, only one out of the 56 applications received could have been defined as coming from a small business. In reality it is the cost of developing and marketing a new product requiring a change to a food standard, rather than a fee charged by the Authority, that would act as a disincentive to small business to launch a new product. Small businesses are more likely to try to break into an existing market rather than introducing new food technologies that would require a new food standard.

Consultation

Extensive consultation was undertaken with key stakeholders. Consultation took the form of a detailed policy paper being sent to industry associations (Australian Food and Grocery Council, Food Industry Conference of Australia, Australian Supermarket Institute), consumer groups (Australian Consumers' Association, Consumer Food Network, New Zealand Consumers' Institute), public health professionals (Public Health Association of Australia) and government agencies (including the Departments of Prime Minister and Cabinet, Agriculture, Fisheries and Forestry -Australia, Health and Aged Care, agencies such as the Office of Regulation Review and Office of Small Business, and the New Zealand Officials Committee of Food Administration). The paper was also circulated amongst interested members of peak organisations and in addition a number of inquiries were received from individual companies.

The paper was followed up with meetings, telephone discussions and a teleconference with New Zealand Government officials. Most of these involved responding to queries and clarifying detailed working arrangements. As a result the paper was amended to reflect a number of the suggestions received.

Responses fell into three broad categories. Industry associations gave qualified support to the introduction of the work plan and limited cost recovery to those applications that had an exclusive capturable commercial benefit. Consumer groups were opposed to the Authority imposing charges because of concerns that the Authority's independence might be compromised, preferring instead to see the Authority funded directly from the Budget. Government agencies either supported the proposed approach or did not oppose it.

Conclusion and preferred Option

Option 2 is the preferred option as it is the simplest to administer and represents an efficient, cost-effective and fair method of recovering the costs of processing applications. Option 1 was rejected as it would have added considerably to the cost of processing each application, been administratively complex and raised serious legal concerns about the issue of cross-subsidies.

Implementation and Review

It is intended to have these regulations in place by 1 July 2000 and charging commence from that date. Industry has been consulted on the development of the work plan.

The work plan will be reviewed mid way through each year as required by the Act. At this stage it is difficult to be certain how many fee-paying applications will be received and the level of fees that this will generate. ANZFA will monitor the cost recovery system closely during its first twelve months of operation, including the levels of the fees, to ensure that the system is the most efficient and effective possible.