



Review of Agricultural Compounds and Veterinary Medicines (Fees & Charges) Regulations 2002

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Submissions

NZFSA seeks submissions from all interested parties on any aspect of the cost recovery proposals presented in this paper.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section of the document. All major sections are numbered and these numbers should be used to link comments to the document.
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- Your organisation's name (if applicable);
- Your address;
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 26 March 2008

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Table of Contents

1	Introduction	6
2	Background	7
3	The Process of the Review	8
4	Legislative Framework	8
	4.1 Cost Recovery Principles under the Agricultural Compounds and Veterinary Medicines Act	9
	4.2 Government Guidelines.....	9
5	Services Provided	10
	5.1 Standards Setting Services	10
	5.2 Approvals Services.....	12
	5.3 Monitoring and Compliance Services.....	13
6	Cost of Providing Services	14
	6.1 Current Situation.....	14
	6.2 Basis of the Costs Estimates.....	15
	6.2.1 Standards Setting and Compliance and Monitoring Services..	16
	6.2.2 Approvals	16
	6.3 Estimated operating budget 2008/09	17
7	Stakeholder Contributions to NZFSA Costs	17
	7.1 Standards Setting.....	17
	7.2 Approvals.....	18
	7.3 Compliance and Monitoring Services.....	18
8	Charging Mechanisms	19
	8.1 Charging regime should not be overly complex	20
	8.2 Basis of charging for services	20
	8.3 Proposed change to the charging mechanism for the annual fee.....	20
	8.4 Proposed charging mechanism for new services.....	21
	8.5 Proposed change to the collection year	22
9	Proposed Fees and Charges	22
	9.1 Proposed Fees and Charges (GST excl) – Industry Goods	22
	9.2 Proposed Fees and Charges (GST excl) – Private Goods	23
	9.3 Crown Funded Services	26
	9.4 Summary of Proposed Fees and Charges.....	27
	9.4.1 Proposed increase to the hourly rate	27
	9.4.2 Proposed change to the differentiated charging mechanism for registered products used on food animals and feed crops non-food animals and non-feed crops	27

9.4.3	Proposed increase to the border clearance service.....	28
9.4.4	Proposed Annual Fee	28
9.4.5	Proposed Fees and Charges and payment mechanism for the new services provided under the ACVM Act	28
10	Regulatory Impacts and Business Compliance Costs	29
	Appendix 1: NZFSA Fee Calculation Workings	31
	Appendix 2: Approvals and ACVM Group Annual Operating Budget for 2008/09 (GST Exclusive) for services provided under the ACVM Act.....	32
	Appendix 3: Framework for determining service type (Crown, private or industry good)33	
10.1.1	Public Goods	33
10.1.2	Industry Goods	34
10.1.3	Private Goods.....	34

1 Introduction

The purpose of this discussion paper is to present proposals for consideration to amend the cost recovery regulations under the Agricultural Compounds and Veterinary Medicines Act 1997 (as amended 2007) (the ACVM Act). It is proposed that existing fees and charges be increased to recover the full cost of the standards setting, approvals and monitoring and compliance services provided by the New Zealand Food Safety Authority (NZFSA) and Biosecurity New Zealand (BNZ) under the ACVM Act. New fees and charges and payment mechanisms are proposed for the new services to be provided under the ACVM Act. It is proposed to change to the payment mechanism for the differentiated annual fee to a single fixed annual fee and to charge this fee. The single fixed annual fee will be charged to all approval holders including registrants of products (who are currently being charged a differentiated annual fee) and, in the future, “persons” holding specific exemptions, recognised “persons” such as traders and manufacturers, and “persons” with approved operating plans.

The amended ACVM Act incorporates most of the services previously undertaken by NZFSA, however some of these services (such as exemptions in special circumstances from the requirement for registration and standards setting) are more clearly detailed and refined. Other services, such as the approval of operating plans, are essentially new. NZFSA proposes to continue to charge regulated parties¹ via either an hourly rate or where the activity is highly predictable, via a fixed fee; and to recover the costs for general monitoring and standards setting primarily via an annual fee. For approval services where an hourly rate applies, NZFSA will continue to provide a schedule showing the estimated fees for the various types of applications as it does at present. The associated business rules will be updated to reflect the changes as a result of the amended ACVM Act.

It is proposed to change the collection year dates for the annual fees from 1 July – 30 June to 1 October – 30 September and, as a transition, to have a 15 month period in the first year.

¹ Regulated parties include: approval holders (registrants of products, “persons” holding specific exemptions, recognised “persons” e.g. traders and manufacturers, “persons” with approved operating plans), importers (of agricultural compounds), exporters (who require certification), applicants (class determinations, data assessment, and information waivers). Regulated parties also include those “persons” who deal in exempted products (not specific exemptions) e.g. petfood manufacturers (they are regulated but do not pay fees), and users of agricultural compounds.

This paper should be read in conjunction with the NZFSA cost recovery background paper: 'Cost Recovery Policy and Framework' August 2006 (available online at: www.nzfsa.govt.nz), which documents the policy basis for the proposals presented in this paper.

This paper has several key sections:

Section 4

This section details the policy and legislative framework that NZFSA is following.

Section 5

Lists the services NZFSA provides to regulated parties which are subject to the cost recovery proposals in this document.

Section 6

Details the costs of providing the services, including how they are calculated.

Section 7

Considers the extent to which each of the outputs provided by NZFSA under the ACVM Act are public, industry or private goods.

Section 8

Details the charging mechanisms.

Section 9

Proposes fees and charges.

Section 10

Identifies regulatory impacts and compliance costs.

2 Background

The Agricultural Compounds and Veterinary Medicines (Fees and Charges) Regulations 2002 (the Regulations) set fees and charges for costs to be recovered under the ACVM Act and specify the timing of annual fee payments.

A number of factors have influenced the need for NZFSA to undertake a review of the ACVM cost recovery regime. These factors include:

- the last amendment to the fees and charges under the ACVM Act took place in 2002. In the past five years operating costs have increased for the Approvals and ACVM Group, including upgrading the Information Technology system, as has the salaries of Approvals and ACVM staff. There has been no corresponding increase in the fees and charges set out in the Regulations;
- more work has been undertaken in the development and review of standards for agricultural compounds and in areas of regulatory control and compliance monitoring;
- recent amendments to the ACVM Act have resulted in some new services to be provided. These new services will need to be cost recovered from the ACVM industry from 1 July 2008.

3 The Process of the Review

It is likely that consultation on the review of the ACVM cost recovery regime will occur in February 2008 (following the release of this discussion paper) by way of a series of workshops.

The next steps in this review process will be to analyse submissions, provide a summary to submitters, and draw on submissions to put forward a proposal to Government. The next stage would be to implement Government decisions that result from this process. The aim is for the new fees and charges to take effect from 1 July 2008.

4 Legislative Framework

Sections 81 to 81(L) of the ACVM Act set out a cost recovery regime for situations where costs are not covered by an appropriation from Parliament. These sections of the ACVM Act set out the principles of how cost recovery will be achieved and the methods of cost recovery.

4.1 Cost Recovery Principles under the Agricultural Compounds and Veterinary Medicines Act

Section 81(2) of the ACVM Act provides the criteria that need to be considered when determining the most appropriate method of cost recovery. The criteria are:

- **Equity** – Users or beneficiaries of a function, power, or service will generally be required to fund the cost of providing the function, power, or service at a level commensurate with their use or benefit
- **Efficiency** – costs should generally be allocated and recovered in a manner that ensures maximum benefits are delivered at minimum cost
- **Justifiability** – the costs (including the indirect costs) associated with providing a function, power or service should be reasonable and justifiable
- **Transparency** – the cost of providing a service, function or power should be identifiable and allocated in a transparent manner.

NZFSA is not required to strictly apportion costs for a particular function, service or power based on usage. Fees or charges may be determined by averaging the costs or potential costs.

Fees and charges may also be set at a level that takes into account costs of services that are not directly provided to the person who pays the fees or charges, but which are indirect arising from the delivery of a service to a class of persons, or all persons, who use the service.

4.2 Government Guidelines

In determining the proposals in this paper, the Treasury document *Guidelines for Setting Charges in the Public Sector* and the Audit Office Guidelines *Costing and Charging for Public Sector Goods and Services* have been taken into account.

In summary, the key Treasury principles for setting the rates for the fees and charges follow:

- Charges should in general be set at the full cost of providing the service, where full cost includes all overheads and non-cash (such as the capital charge), measured in accrual accounting terms
- Charges should not be excessive in relation to the costs incurred

- Charges can be set to vary by the location where the service is provided or by the time at which the service is provided but a balance needs to be struck between the gains from complex fee structures and the costs in terms of a loss of simplicity
- The process for setting charges should be clear and appropriate
- Transaction costs in setting and collecting the charges should be kept as low as practicable
- Appropriate consultation with those affected should be undertaken when setting and changing the charges
- There should be a robust basis for any charges
- There should be fair treatment for taxpayers, beneficiaries of the service and risk exacerbators.

The guidelines and legislative requirements mentioned above have been consolidated into the NZFSA information paper '*Cost Recovery Policy and Framework, August 2006*'. This document may be viewed at: www.nzfsa.govt.nz

5 Services Provided

This section sets out the services provided by NZFSA's Approvals and ACVM Group to regulated parties under the ACVM Act and to interested industry parties, and details the sub-services that the services comprise. Each sub-section also lists and describes the existing and new services which have resulted from the amended ACVM Act.

The NZFSA provides services in three main areas. These areas are:

- Standards Setting
- Approvals
- Compliance and Monitoring

5.1 Standards Setting Services

The setting of standards is comprised of the following services and related advice in policy areas:

- development and review of standards for the regulatory control of agricultural compounds (included generic standards setting work which relates to general operational standards development for approvals under the ACVM Act)
- technical contribution to national and international forums on standards for agricultural compounds²
- technical policy advice.

The key services undertaken by the Approvals and ACVM Group under each of these service areas follow:

- provision of public information in relation to standards, guidelines and related information for regulated parties
- representation of the New Zealand position at Codex Alimentarius Commission (CODEX), OECD and other international standard setting forums
- representation at relevant Trans-Tasman forums
- technical support and advice for the development, review and maintenance of regulations under the ACVM Act
- technical support and advice for the NZFSA Chemicals Coordination Group
- technical support and advice on market access issues
- development and review of standards for agricultural compounds including regulatory control and compliance monitoring
- support for and co-ordination of the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC)
- technical contribution to international fora e.g. Trans-Tasman harmonisation, New Zealand and European Union (NZ:EU) mutual recognition arrangements, OECD pesticides forum, Veterinary

² Examples of multilateral work are CCPR (Codex Committee on Pesticide Residues), CCRVDF (Codex Committee on residues of veterinary drugs in food) and the Codex antimicrobial task force. An example of the bi-lateral work is the work that the ACVM Group does to support the Mutual Recognition Agreement with the European Union (EU) on Good Manufacturing Practice for selected veterinary medicine products.

co-operation on International Harmonisation (VICH) meetings, CODEX meetings and bilateral relationships

- consider residue and trade implications in relation to applications for registration and for exemption under special circumstances
- process applications for class determination
- process applications for waivers.

5.2 Approvals Services

The approvals programme provides the following services to regulated parties under the ACVM Act:

- considers applications for approval of agricultural compounds and other related approvals such as those related to manufacture, sale and use
- recognition of persons to undertake some services relating to ACVM Act functions
- maintains public registers of agricultural compounds and other relevant approvals
- clearance of agricultural compounds at the border
- considers applications for the exemptions from the requirement to register certain products³
- considers application for exemptions to register products in special circumstances⁴. **This is a new service** which has resulted from recent changes made to the ACVM Act.
- considers applications for the approval of operating plans. **This is a new service** which has resulted from recent changes to the ACVM Act.
- suspends and/or cancels approvals in certain circumstances. **This is a new service** which has resulted from recent changes to the ACVM Act.

³ Certain products (such as oral nutrition compounds where there is no nutrition claim and fertilizers etc) do not need to be registered because they are of low level regulatory interest or concern.

⁴ Special circumstances may include trial work for generating registration data, drug shortages, and outbreak of disease.

- issues and withdraws certificates of compliance. **This is a new service** which has resulted from recent changes to the ACVM Act.

The key services undertaken by the approvals programme under these service areas follow:

- processes enquiries relating to regulatory control under the ACVM Act
- processes applications for registration of trade name products and other approvals
- provides for clearance of agricultural compounds at the border (this activity is provided by the Ministry of Agriculture and Forestry Biosecurity New Zealand (MAFBNZ) personnel)
- recognises persons to undertake ACVM related activities such as data assessors, traders, manufacturers, facilities and systems. **This is a new service** which has resulted from recent changes to the ACVM Act.
- develops and maintains a public register for registered trade name products and for other approvals
- provides a register inspection service.

5.3 Monitoring and Compliance Services

The monitoring and compliance service area under the ACVM Act is provided by the Approvals and ACVM Group, the Compliance and Investigation Group and Biosecurity New Zealand. The following services are provided:

- border services for controlling the importation or agricultural compounds (provided by Biosecurity New Zealand)
- monitoring activities related to the manufacture of agricultural compounds
- provision and operation of compliance programmes for monitoring compliance with legislation and or conditions
- appointment of ACVM Act Officers
- investigation and enforcement of the provisions of the ACVM Act

The key services undertaken by the Approvals and ACVM Group and the Compliance and Investigation Group for regulated parties under the ACVM Act in this area are:

- providing monitoring for importation of agricultural compounds
- auditing and monitoring ACVM Officers and regulated parties and /or activities
- conducting monitoring and audit of manufacturers, distributors, traders wholesalers and users of agricultural compounds
- conducting monitoring and audit of persons approved to provide authorisation for agricultural compounds
- resolving complaints related to compliance
- managing recalls of agricultural compounds. **This is a new service** which has resulted from changes to the ACVM Act.
- applying appropriate sanctions in the event of non-compliance with the ACVM Act
- conducting investigations and prosecuting illegal activities associated with the use of agricultural compounds

6 Cost of Providing Services

This section details the current and future costs to NZFSA of providing services to regulated parties under the ACVM Act and to interested parties. Budget information is provided on the proposed allocation of direct and indirect costs to each area of service.

6.1 Current Situation

The current fees and charges were set in 2002/03 when NZFSA's budget expenditure for the services under the ACVM Act was \$3,266,718. The expected cost of providing services to regulated parties under the ACVM Act for 2008/09 is \$3,917,887 which represents an increase of \$651,169.

In the last five years there has been a great deal more work undertaken in the development and review of standards for agricultural compounds and in the areas of regulatory control and compliance monitoring. As a result, NZFSA has needed to increase the number of full time staff (FTE's) to provide these services.

There have also been increases to the salary and operating costs. There has been a 9% increase to the hourly rate. The change in the hourly rate is reflected in the increase in the cost of providing services.

The NZFSA Information Technology (IT) system which supports the services delivered by the Approvals and ACVM Group (and other NZFSA Groups) is being upgraded so that services delivered under the several Acts administered by NZFSA will be cost recovered through one IT system. The estimated operating cost of this system for the Approvals and ACVM Group is \$100,000 OPEX (operating expenditure) per annum. Increases have also occurred in indirect costs, such as corporate Information technology costs, personal computer costs, building rental and other costs in line with budget assumptions.

The reasons for the increase in budgeted expenditure for 2008/09 is mainly due to the additional services provided, more work being done under existing services and to the upgrading of the IT system which supports the NZFSA services delivered under the ACVM Act.

Changes have been made to rationalise existing processes, an example being the introduction of the "Smart Track"⁵ system to reduce the time taken to provide technical assessment, administration and approval services.

In regard to the border clearance work carried out by the Ministry of Agriculture and Forestry Biosecurity New Zealand (MAFBNZ) personnel under the ACVM Act, the existing fee of \$57.38 was set under the Biosecurity Act in 1993 and has never been revised under the ACVM Act. The proposed change is required in order to align the hourly rate charge for providing this service under the ACVM Act with the hourly rate charge of \$100.00 per hour set in the Biosecurity (Costs) Regulations 2006. MAF BNZ is therefore currently under recovered for providing this service. (The costs relating to this service are not allocated to the NZFSA operating budget as they are cost recovered by MAF BNZ).

6.2 Basis of the Costs Estimates

In delivering the services that are to be cost recovered from regulated parties under the ACVM Act, NZFSA incurs direct and indirect costs.

⁵ The Approvals and ACVM Group has recently revised its processes for number of application types, such as those that do not require as much time in respect to technical assessment, administration and approval processes. This is known as the "Smart Track" system and has reduced the fees to registrants accordingly.

Direct costs include personnel and operating costs.

Indirect costs include management, a share of NZFSA management and support services and NZFSA corporate overhead costs, such as accommodation, equipment and communications. NZFSA fixed costs are allocated to NZFSA outputs each year and form part of the cost of producing these outputs.

6.2.1 Standards Setting and Compliance and Monitoring Services

The steps undertaken by NZFSA in calculating the costs of the services provided to regulated parties under the ACVM Act for 2008/09 are as follows:

- estimates of time spent by each staff member on a full-time equivalent-basis (FTE) on NZFSA's different outputs for each service area (standard setting, approvals and monitoring and compliance) covered under the ACVM Act in 2007/08 have been made by the Director Approvals and ACVM Group
- these estimates of the FTE time spent by staff for each service area have then been pro-rated against the total level of personnel costs expected to be incurred for each output in 2008/09, to obtain an expected level of personnel cost per service area for 2008/09
- the estimates of the FTE time spent for the ACVM industry service area have also been pro-rated against the total level of operating and indirect costs expected to be incurred for each output in 2008/09 to obtain an expected level of operating and indirect cost per output per sector for 2008/09
- the cost of specific programmes are allocated directly to the service areas to which they apply. For example, the alignment work being undertaken with the Environmental Risk Management Authority (ERMA) New Zealand has been applied to the standards setting function, and the work to support the approval of prescription veterinary medicines will be charged against approvals activities.

6.2.2 Approvals

The total direct and indirect costs of the services, has been built into an hourly rate which has been apportioned to particular services based on the estimated time taken.

6.3 Estimated operating budget 2008/09

The estimated operating budget (GST Excl) for 2008/09 follows:

Services	NZFSA Budget 2008/09
Standards Setting	\$982,732
Approvals	\$2,338,873
Monitoring and Compliance	\$596,282
Total	\$3,917,887

7 Stakeholder Contributions to NZFSA Costs

This section considers the extent to which each of the outputs provided by NZFSA under the ACVM Act, are public, industry or private goods. The framework for determining the service type is described in Appendix 3. Based on these criteria, the relative Crown and industry contributions are proposed.

7.1 Standards Setting

In the case of the development, setting and review of standards and guidelines for the ACVM industry, NZFSA considers that these services are industry goods and therefore it is quite feasible to charge regulated parties for such services. Regulated parties under the ACVM Act need to obtain appropriate approvals to import, manufacture, sell and use agricultural compounds. The cost of developing and maintaining standards and guidance information could be included as part of the costs of the registration/approvals and/or the annual fee. Generally these standards are put in place as part of a risk management system. In the case of the development and setting of ACVM standards, use by one regulated party does not detract from its use by another (i.e., consumption is non-rival, like a public good), but it is possible to exclude regulated parties at a low cost (unlike a public good).

There are some components of Standards Setting services that are more properly regarded as public goods, as consumption of this good is both non-rival and non-excludable. These components are technical input to policy, technical advice for communication, and participation in international and national fora. NZFSA considers that it would be appropriate for these costs to be taxpayer funded.

Technical input into policy activities should be regarded as a public good as this advice should take a national (rather than a sectoral) interest perspective and often considers competing claims. To maintain independence of advice, NZFSA's policy advice activities should be regarded as public goods and taxpayer funded.

7.2 Approvals

Approvals services are a private good as these services are provided specifically to regulated parties, such as approval holders, and the costs can be attributed on an enterprise-by enterprise basis. That is, regulated parties under the ACVM Act can be excluded from the benefits of the Approvals service at low cost and its use by one regulated party conflicts with its use by another. NZFSA therefore considers that it is quite practical to charge for approval services on an individual enterprise basis.

NZFSA has identified the following five new services under the amended legislation to be private goods as the regulated party in each case can be excluded from the benefits of each service at low cost and the use of these services by one regulated party conflicts with its use by another. Therefore NZFSA considers that it is feasible to charge the applicant or identified party for these services.

- approval of specific special exemptions (Section 8C of the ACVM Act)
- approval of operating plans (Section 28 of the ACVM Act)
- suspension of registration (applies to identified party) (Section 30A of the ACVM Act)
- certificates of compliance (Section 35A – 35D of the ACVM Act)
- appointment of recognised persons (Section 62 of the ACVM Act).

7.3 Compliance and Monitoring Services

The area of Compliance and Monitoring services are mainly industry goods.

Regular compliance programmes (such as those operating for manufacturers of registered veterinary medicine products) are defined as industry goods as regulated parties can be excluded from their benefits at low cost and the use of these programmes by one regulated party does not conflict its use

by another. Therefore, NZFSA considers that it is quite feasible to charge regulated parties for the use of these programmes.

In other areas where there is no established programme, but where surveys are undertaken from time to time, this type of activity is defined as an industry good as consumption, or use of the findings by one regulated party does not detract from its use by another, but a regulated party can be excluded from the benefits of the information at low cost. NZFSA, therefore considers that it is also quite feasible to charge regulated parties for these types of activities.

In the case of the new service for the recall of an agricultural compound (Section 35G of the ACVM Act) which has resulted from recent amendments to the legislation, even though this service is identified as a public good (as it is the public who ultimately benefit from this service), NZFSA considers that it is feasible to charge the identified party for the use of this service as they caused the risk.

Enforcement services are 100% Crown funded as the use of this service is both non-rival and non-excludable.

8 Charging Mechanisms

This section outlines the policy for determining the basis for charging, including the mechanisms and methods for calculating fees and charges.

The Audit Office Guidelines are used to determine the basis for charging, and suggest the following steps:

- identification of outputs and their associated costs
- forecasting the volume of these outputs to be produced during a period
- determination of the costs and resources required to produce these outputs
- calculation of cost for each unit of output.

8.1 Charging regime should not be overly complex

Total costs to be recovered by regulation are \$3,276,848⁶ from regulated parties under the ACVM Act from 1 July 2008. Providing a cost recovery system where small units of service are individually calculated for each regulated party would be costly to set up and administer in comparison with the estimated costs to be recovered. In some cases, the costs of obtaining the necessary information and keeping track of various components may outweigh the direct cost of providing the service.

The current charging mechanisms used to recover costs under the Regulations are a differentiated fixed annual fee mechanism and a time-based charge.

8.2 Basis of charging for services

It is proposed that functions and services that can be divided into homogeneous units, and where there is little variation in the cost of providing the unit of service, will be charged at an average cost (direct and indirect) per unit of output. Fixed fees and annual charges are proposed. This will assist in minimising transaction costs and providing certainty over fees and charges.

Where there is a large variation in the cost of individual outputs, for example in the time taken to perform the service, average costing through fixed fees is not an appropriate charging option. In these circumstances it is proposed that the hourly rate be used. Where hourly rates are used, disbursements covering items such as (but not exclusively) travel, accommodation and communication will be charges at cost.

8.3 Proposed change to the charging mechanism for the annual fee

It is proposed to change the differentiated annual fee charging mechanism to a single fixed annual fee and to charge this fee to all approval holders, including registrants of products (who are currently paying a differentiated annual fee), and in the future "persons" holding specific exemptions, recognised "persons" e.g. traders and manufacturers, and "persons" with approved operating plans.

⁶ \$3,276,848 is the result of removing the Crown funding of \$641,039 from the total operating budget of \$3,917,887 for 2008/09.

Currently registrants of registered products used on food animals or food crops and registrants of registered products used on non-food animals and non-food crops are paying a differentiated annual fee. Under the current cost recovery regime a separate annual fee is provided for registered products used on food producing animals and crops, which has incorporated the addition of residues surveillance monitoring. This separate fee has reflected the additional work needed for products used on food producing animals and food crops.

However, since the initial setting of the annual fee that differentiated between food and non food producing animals and crops, the distinction has become less clear. Crops that were previously considered non-food in New Zealand are now being used as animal feed (grain or parts of grain grown in New Zealand for instance), and products used on beehives outside of the production season have also caused non-compliant residues in honey. Situations such as this have meant that of the almost 3000 products currently registered, only a small proportion (estimated at approximately 420⁷) fit the broader non-food definition. NZFSA considers that it is inefficient to maintain a separate charge and billing system for these two types of product registrations and proposes a single fixed annual fee mechanism to cover both.

8.4 Proposed charging mechanism for new services

The costs of providing these services are currently recovered through a combination of fixed and time based charges.

It is proposed to cost recover the new approval services (identified as private goods) which have resulted from recent changes to the ACVM Act, by way of the hourly rate charge as the time taken to perform each of these services is likely to vary depending on the type and complexity of the application.

It is proposed to cost recover the new monitoring and compliance service (product recall service - identified as a public good) by way of the hourly rate charge plus disbursements (actual and reasonable where appropriate) as each situation could take different amounts of time to perform the service.

⁷ In 2002 the number of registrants for products used non-foods animal and non-food crops were 777 out of a total number of 2550 registrants.

8.5 Proposed change to the collection year

It is proposed to change the collection year for annual fees from 1 July – 30 June to 1 October – 30 September and as transition have a 15 month period in the first year. This will mean that these fees will be collected from regulated parties such as the registrants of products, on 1 October 2009.

Question to submitters

Should this change to the collection year be adopted, what impact will this have on your business?

9 Proposed Fees and Charges

This section proposes fees and charges for Standards Setting services and Compliance and Monitoring services and Approvals services.

The total direct and indirect costs of the approval services have been built into an hourly rate. The hourly rate calculation is detailed in Appendix 1.

Should the proposal to change the collection year dates be adopted, the annual fee collected on 1 July 2008 will therefore be \$606.25 (calculation based on proposed annual fee rate of \$485.00 plus \$121.25 (3 months or $\frac{1}{4}$ of the 12 month annual fee rate)). The proposed annual fee of \$485.00 will then be charged from 1 October 2009.

9.1 Proposed Fees and Charges (GST excl) – Industry Goods

The table below lists the industry good services provided to regulated parties under the Regulations and describes who pays the proposed fixed annual fee of \$485.00. The proposed single fixed annual fee will be charged to all approval holders including registrants of products (who are currently being charged a differentiated annual fee) and, in the future, “persons” holding specific exemptions, recognised “persons” such as traders and manufacturers, and “persons” with approved operating plans.

Service Area	Who Pays	Cost recovery mechanism	Proposed (new) single fixed annual charge rate (GST excl)
Standards Setting Activities			
ACVM specific standards	regulated parties such as registrants of products	Part of fixed annual charge	
Generic (or general) standard setting under the ACVM Act	regulated parties such as registrants of products	Part of fixed annual charge	
Monitoring and Compliance			
Monitoring Compliance with the ACVM Act	regulated parties such as registrants of products	Part of fixed annual charge	
Total	Total payable annually by regulated parties such as registrants of products	The costs of the three specific services detailed above make up the proposed fixed annual fee	\$606.25 will be collected on 1 July 2008 then \$485.00 annually from 1 Oct 2009

9.2 Proposed Fees and Charges (GST excl) – Private Goods

The table below sets out the private good services provided by NZFSA under the ACVM (Fees and Charges) Regulations 2002, who pays, the payment mechanism and what the current fees and charges are as set under the current regulations. The last column in the table describes the proposed fees and charges.

Service Area	Activity	Who Pays?	Payment mechanism	Current Fees and Charges (GST incl)	Proposed Fees and Charges (GST excl)
Fees and Charges payable for Compliance and Monitoring					
For an application for an inspector to give authority	For an application for clearance	(a) Importer	(a) Hourly charge	\$57.38 per hour	\$100.00 per hour (GST incl)

or clearance					
For monitoring compliance with conditions imposed under the Act or regulations made under the Act	For monitoring compliance with conditions	Person to whom the conditions apply	Hourly charge plus actual cost of disbursements	\$121.50 per hour	\$133.00 per hour
For inspection for the purpose of enforcing provisions of the Act or regulations made under the Act	For inspection services	Person being inspected	Hourly charge plus actual cost of disbursements	\$121.50 per hour	\$133.00 per hour
Recall of Product	For recall of a non-compliant product from the market place	Company/ enterprise responsible for product	Hourly charge		New \$133.00 per hour plus disbursements
Fees and Charges payable for Applications, Accreditations and Registers					
For responding to enquiries about form and content of applications	Responding to enquiries re application	Payable by the enquirer	Hourly charge plus actual cost of disbursements	\$121.50 per hour	\$133.00 per hour
For considering applications for waiver of notice under the Act	Considering applications for waiver of notice	Payable by the applicant	Hourly charge plus actual cost of disbursements	\$121.50 per hour	\$133.00 per hour
For assessing whether an application to register a trade name product complies with	Assessment of application for a trade name product	Payable by applicant	Fixed charge plus actual cost of disbursements	\$346.50 per assessment	\$485.00 per assessment

the Act					
For considering an application to register a trade name product or to vary 1 or more conditions on a registered trade name product	Application to register or to vary 1 or more conditions on a registered trade name product	Payable by the applicant	Hourly charge plus actual cost of disbursements	\$121.50 per hour	\$133.00 per hour
For considering an application for approval of, amendment to, or revocation of a operating plan under the Act	Consideration of an application for approval	Payable by the applicant	Hourly charge plus actual cost of disbursements		New \$133.00 per hour
For considering an application to be appointed as a recognised person under the Act	Consideration of an application for recognised persons	Payable by the applicant	Hourly charge		New \$133.00 per hour
For specifying a listed product in the register of registered trade name products	Specifying details of a trade name product into a register	Payable by the applicant	Hourly charge	\$121.50 per hour	\$133.00 per hour
For maintaining the register of registered trade name	Up-dating of a register of trade name products	Payable by the applicant	Hourly charge	\$121.50 per hour	\$133.00 per hour

products					
For inspecting the register of registered trade name	Inspection of the register	Payable at completion of the inspection by the person inspecting the register	Hourly charge for each inspection plus disbursements	\$121.50 per hour for each inspection	\$133.00 per hour for each inspection
Approval with special circumstances	To be used for circumstances such as: - permits for exemption in the ACVM Regs - Research approvals - product specific exemptions - short term deviations from existing authorisations	Payable by the applicant	Hourly charge plus disbursements		New \$133.00 per hour
Suspension of registration	This activity allows a registration to be suspended without revoking it all together	Payable by the registrant	Hourly charge plus disbursements		New \$133.00 per hour
Issuing certificate of compliance	Provide specific power to issue such certificates and creates specifications and due process	Payable by the applicant	Hourly charge plus disbursements		New \$133.00 per hour

9.3 Crown Funded Services

The costs of services identified as public goods supplied to the ACVM industry (and therefore paid by the Crown) are estimated for 2008/09 to be \$641,039 (included in the 2008/09 estimated operating budget). These services are delivering technical input into policy advice and technical advice to the Communications Group, participation in international and national fora and enforcement services.

9.4 Summary of Proposed Fees and Charges

9.4.1 Proposed increase to the hourly rate

It is proposed to increase the hourly rate from \$108.00 (GST exclusive) per hour to \$133.00 (GST exclusive) per hour.

9.4.2 Proposed change to the differentiated charging mechanism for registered products used on food animals and feed crops non-food animals and non-feed crops

It is proposed to change the payment method for the differentiated fixed annual charge to a single fixed annual charge of \$485.00 and to charge this fee to all approval holders including registrants of products (currently paying a differentiated annual fee), and, in the future to, “persons” holding specific exemptions, recognised “persons” e.g. traders and manufacturers, and “persons” with approved operating plans.

Registrants for registered products used on **food animals or food crops** will have their annual fee changed from \$405.50 to \$485.00.

Registrants for registered products used on **non-food animals or non-food crops** will have their annual fee changed from \$335.56 to \$485.00.

(Due to the proposed change to the collection year from 1 July – 30 June to 1 October – 30 September, as a transition to the new collection year registrants will be required to pay \$606.25 on 1 July 2008 (from 1 July 2008 - 1 Oct 2009 = 15 month period) and \$485.00 annually from 1 October 2009)

Questions for submitters

Should the proposal to change the charging mechanism for registered products be adopted, what impact will this have on your business and those with whom you do business?

Will there be any impact on your business or those you do business with should the proposed change to the collection year be adopted?

9.4.3 Proposed increase to the border clearance service

It is proposed to increase the hourly rate charge for clearance of imported agricultural compounds under the ACVM Act from \$57.38 (GST incl) per hour to \$100.00 (GST incl) per hour. The proposed change is required in order to align the hourly rate charge for border clearances under the Regulations to the hourly rate charged to provide the same activities under the Biosecurity (Costs) Regulations 2006. Border clearance services of agricultural compounds are provided by MAF Biosecurity New Zealand personnel as they are warranted under the ACVM Act to perform these activities.

Question for submitters

Should this proposal be adopted what impact will this have on your business and those with whom you do business?

9.4.4 Proposed Annual Fee

It is proposed that the single fixed annual fee of \$485.00 (GST excl) be charged to all approval holders including registrants of products (who are currently being charged a differentiated annual fee) and, in the future, “persons” holding specific exemptions, recognised “persons” such as traders and manufacturers, and “persons” with approved operating plans.

Question for submitters

Should this proposal be adopted what impact will this have on your business and those with whom you do business?

9.4.5 Proposed Fees and Charges and payment mechanism for the new services provided under the ACVM Act

- **Approval in special circumstances.** It is proposed that this service is cost recovered by way of the proposed new hourly rate of \$133.00 per hour.
- **Approval of operating plans.** It is proposed that this service is cost recovered by way of the proposed new hourly rate of \$133.00 per hour.
- **Suspension of registration without revocation.** It is proposed that this service be cost recovered by way of the proposed new hourly rate of \$133.00 per hour.
- **Certificates of compliance.** It is proposed that this service be cost recovered by way of the proposed new hourly rate of \$133.00 per hour.

- **Recall of a non-compliant product.** It is proposed that this service be cost recovered by way of the proposed new hourly rate of \$133.00 per hour.
- **Recognised persons.** It is proposed that this service be cost recovered by way of the proposed new hourly rate of \$133.00 per hour.

Question to submitters

Should the new fees and charges and payment mechanism be adopted what impact will these new costs have on your business and those with whom you do business?

10 Regulatory Impacts and Business Compliance Costs

Some of the proposals will have a cost impact on some regulated parties under the ACVM Act. It is anticipated that the main impacts are likely to be:

- The proposed hourly rate charge will increase from \$121.50 per hour to \$133.00 per hour. This represents a 9% increase for regulated parties such as approval holders (including registrants of products, third party agencies, traders, recognised people), exporters (who require certification) and applicants (for class determinations, data assessments and information waivers).
- The level of cost impact on most regulated parties paying a fee for service (hourly rate charge) may not be as significant as the “Smart Track” system has already reduced the costs of using these services. For example, the charge for a simple addition to a registered product “pre-Smart Track” system was \$911.75, with the “Smart Track” system the current charge is \$303.75. The proposed hourly rate charge will increase the cost of this service to \$332.50. Another example is for a complicated veterinary medicine application or approval. This service currently costs \$3857.75. The proposed hourly rate charge will increase the cost of this type of application or approval to \$4256.00.
- The proposed hourly rate charge for clearances of imported agricultural compounds under the ACVM Act will increase from \$57.38 per hour to \$100.00 per hour (a 74% increase). Therefore the importers of these types of goods will be affected by the proposed cost increase for the clearance service provided by MAF BNZ personnel under the ACVM Act.

- The proposed change to the annual differentiated charging mechanism to a single fixed annual charge of \$485.00 for registrants of registered products used on food animals or food crops and for registrants of products used on non-food animals or non-food crops means that there is a significant increase in the annual charge for both types of registered products. For the registrants of products used on food animals or food crops the annual fee will increase from \$405.50 to \$485.00 (a 20% increase) and for the registrants of non-food animals or non-food crops the annual fee will increase from \$335.56 to \$485.00 (a 45% increase). The regulated party that will be most impacted by the proposed single annual flat fee charge will be registrants of companion animal products. Currently there are approximately 30 registrants of companion animal products.
- Approval holders such as “persons” holding specific exemptions, recognised “persons” e.g. traders and manufacturers, and “persons” with approved operating plans will in the future be subject to the proposed annual fee charge of \$485.00.

Business Compliance Costs

Government requires business compliance costs to be explicitly considered in the development of any regulatory proposals,

Compliance costs are the administrative paper work costs to business in meeting government requirements. They include the costs associated with identifying and understanding regulatory requirements. Compliance costs are not the direct costs of the provision of a good or service.

The costs of complying with cost recovery requirements would be minor and relate to administrative responsibilities such as paying invoices and supplying data.

Appendix 1: NZFSA Fee Calculation Workings

Proposed Hourly Rate Calculation (GST exclusive) for 2008/09: ACVM Approvals Group

Chargeable Hours: (based on 2007/08 budgeted expenditure and FTE's)			
	Personnel	\$2,155,349	
	Operational	\$ 421,207	
	Contractors	\$271,000	
	Indirect costs	\$1,878,266	
		\$4,725,821	
	FTEs:	30	
Billable Hours Per FTE:			
		Hours	
Working Year		1,566.00 (at 75%)	
Less:			
Statutory Holidays			78
Annual Leave			150
Sick leave			60
Courses and conferences			30
Technical Training			60
Annual Billable Hours			1,188.00 per FTE
Total Billable Hours		35,640 (over 30 FTEs)	
		\$133/hour	

Appendix 2: Approvals and ACVM Group Annual Operating Budget for 2008/09 (GST Exclusive) for services provided under the ACVM Act

Services	NZFSA Budget 2008/09
Standards Setting	\$982,732
Approvals	\$2,338,873
Monitoring and Compliance	\$596,282
Total	\$3,917,887

The total of **\$3,917, 887** includes the Crown funding component of \$641,039.

Appendix 3: Framework for determining service type (Crown, private or industry good)

In principle, the appropriate source of funding of an activity depends on the nature of the good or service. Economic theory distinguishes between three types of goods or service: public goods (or services), industry goods (or services) and private goods (or services). The Treasury document *Guidelines for Setting Charges in the Public Sector* defines these types of 'goods' for the purpose of determining the appropriate source of funding. The key characteristics of these three categories and their appropriate sources of funding are considered below.

10.1.1 Public Goods

The classic definition of a public good or service is where consumption of the good or service is both:

- non-rival: where consumption of the good or service by one party does not reduce the amount of the good or service available to other potential consumers. An example is radio broadcasting because one person listening to the channel doesn't reduce the ability of others to tune in; and
- non-excludable: where it is not possible (or too costly) to prevent a party from freely consuming the good or service. For example, in the case of public radio broadcasts, anyone with a suitable receiver can listen in.

Examples of pure public goods are rare. For example, some have argued that a lighthouse is a public good, as use by one ship of the light does not diminish the ability of another ship to use the light and it is generally difficult or impossible to prevent a ship from benefiting from the service. However, it has been noted that original lighthouse services were in fact provided by private operators who funded the activity by charges on ships entering the harbour. Similarly, in the case of radio broadcasting, while it may meet the criteria for a public good, there are ways other than general taxation of funding the activity (i.e., advertising).

In practice, the distinction between a public good, industry good and private good is not black and white. The issue is more one of degree, with the practical question being how costly it is to charge (or exclude) a user of the publicly provided service.

10.1.2 Industry Goods

In the case of an industry (or club) good, use by one person does not detract from its use by another (i.e., consumption is non-rival, like a public good), but people can be excluded from the benefits at low cost (unlike a public good).

Industry goods can, in principle, be provided by member-owned 'clubs' (eg, an industry organisation), by a separate organisation or by the public sector.

There are typically advantages in an industry good being funded by the industry (rather than by the taxpayer). These advantages can include:

- more equitable outcomes, as those who impose the cost of supplying the good or service, or who benefit from it (rather than the general taxpayer) pay for the costs of supplying the good or service
- better incentives for the industry to moderate its demand for the publicly-provided services and to minimise the activities that give rise to the cost or risk associated with the activity
- better incentives for efficiency in the provision of the good or service, as the industry is likely to have better ability and greater incentives than the general taxpayer to monitor the performance of the supplier.

Where a publicly provided activity is industry (or privately) funded, the charging mechanisms used should be consistent, transparent, and be able to be implemented. The charges set should not over-recover the cost of the service.

10.1.3 Private Goods

In the case of private goods, people can be excluded from its benefits at low cost and its use by one person conflicts with its use by another.

Private goods are far the most common. There is a strong case for recovering the costs of a private good from those who benefit from it.