Wine Act 2003, Animal Products Act 1999 and Agricultural Compounds and Veterinary Medicines Act 1997 - Proposal to provide flexible and streamlined 'recognition' of 'agencies' and 'persons'

Regulatory Impact Statement

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the New Zealand Food Safety Authority (NZFSA). It provides an analysis of options to address the need for flexible and streamlined 'recognition' of 'agencies' and 'persons' under the Wine Act 2003, Animal Products Act 1999 and Agricultural Compounds and Veterinary Medicines Act 1997.

The options are to continue with the status quo or to amend the three Acts as a package.

The analysis shows that the status quo sets recognition requirements that are unnecessary, excessively costly and can create disincentives around businesses becoming 'recognised'. The status quo also lacks consistency across legislation and systems administered by NZFSA. The proposed amendments will save potential compliance costs for businesses of approximately $100,000 per year. All submissions received were constructive and supportive of the proposed amendments.

NZFSA confirms that the proposal will have the effect of reducing the compliance burden upon business and certifies that the proposal is consistent with the Government Statement on Regulation.

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Status quo

1. The Animal Products Act 1999 (AP Act), the Wine Act 2003 (Wine Act) and the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) set requirements relating to the 'recognition' of third party 'agencies' and/or 'persons' for the performance of certain necessary functions including sampling, testing, analysing, evaluating and verifying compliance.

2. Recognition requirements are inconsistent across the three Acts. For example:

   - **Under the Wine Act, with the exception of administrative functions and related support matters, any activities of an agency that are specified in the terms of its recognition are to be carried out only by individual persons who have themselves been recognised;**

   - **Under the AP Act this requirement applies to verification functions but is unclear with respect to other functions; and**

   - **Under the ACVM Act 'persons' but not agencies are 'recognised' and, unlike the AP Act and Wine Act, 'persons' is defined to include any 'body' of persons.**

Problem definition

3. Implementation of these Acts has shown that recognition requirements are restrictive and excessively costly for businesses. For example, requirements prevent agencies and persons (including an individual, class, group or type of person) from being recognised to carry out their functions independently.

4. Current recognition requirements results in:

   - **Unnecessary costs being imposed on the industry associated with recognition application, approval, maintenance and renewal[13]; and**

   - **The New Zealand Food Safety Authority (NZFSA) being limited in how it can streamline approval systems based on equivalence; minimise duplication of assessment and enable more efficient whole-of-government regulation.**

5. Any unnecessary disincentives for applicants to seek recognition should be removed as they are counterproductive to the overall risk management system and may limit the availability of recognised third party agencies and persons[14].

Objectives

6. NZFSA has become aware over time of the restrictive nature of relevant recognition requirements. This analysis was progressing but has been advanced as part of the Government's Regulatory Reform Agenda.

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[13] NZFSA collects fees from applicants seeking agency or person recognition. Recognition is granted for a period of time and there is a cost for recognition renewals, if appropriate. This excludes any additional costs associated with achieving and maintaining any accreditation requirements.

[14] In some sectors recognised third party agencies and persons are currently in short supply.

7. The objectives of this proposal are to:

- **Enable NZFSA to apply the best regulatory approaches (i.e. those that manage risks appropriately while minimising compliance costs);**
- **Increase consistency of recognition provisions across all food safety related legislation and enable aligned systems; and**
- **Minimise disincentives for applicants to seek recognition.**

8. NZFSA considers these objectives are consistent with those of this Government's ongoing Regulatory Reform Agenda.

Regulatory impact analysis

9. The options for addressing the problem definition are to:

- **Do nothing (continuing with the status quo); or**
- **Amend the Wine Act, AP Act and ACVM Act to provide:**

  a) **Greater clarity and more consistent flexibility for the Director-General (NZFSA) to approve:**

     - recognition of an agency to perform certain functions:
       i. with all or some persons in that agency also being required to be recognised in order for the agency to carry out its functions; or
       ii. without requiring persons within that agency to be recognised in order for the agency to carry out its functions; or
     - recognition of a person (including an individual, class, group or type of person) to perform functions:
       i. with that person being required to be managed by a recognised agency; or
       ii. without that person being required to be managed by a recognised agency; and

  b) **Greater clarity and consistency in recognised agency and recognised person duties.**

Status quo

10. The status quo can prevent agencies from being recognised to carry out functions unless they also mange persons who are also recognised.

11. Currently, when an agency or laboratory with ten staff (e.g. testers, samplers and/or analysts) seeks recognition under the AP Act or Wine Act, in addition to the agency or laboratory recognition fee ($411.75 or $274.50) it would potentially be charged additional fees for each person to be recognised (i.e. $137.25 for each of the ten staff). Total recognition costs could therefore be $1,784.25 per year for such an agency/laboratory.

12. These costs can be excessive and unnecessary when the best approach would otherwise be to regulate an individual person's competency and performance through the:

- **Approval and conditions of their agency/laboratory's recognition, its relevant performance criteria and statutory duties; and**
- **The existing laboratory key technical personnel (KTP) model for gaining accreditation[15].**

13. This flexibility (and cost reduction) is now considered appropriate for the recognition of agencies/laboratories to carry out functions under the Wine Act, AP Act and, potentially, under the ACVM Act. The status quo therefore imposes excessive and unnecessary costs for such agencies and laboratories.

14. Recognition of a person without needing agency recognition is currently provided for under each of the three Acts, with the exception of verifier recognition under the Wine Act and AP Act.

15. NZFSA considers it is timely to provide this flexibility for the recognition of persons for carrying out certain verification functions. For example, for verification services provided to food businesses that may deal with only low-risk products and processes and sell only on the domestic market or export without needing official assurances. This may be the best approach when:

- **The function the person is recognised to carry out does not require the management of a recognised agency; and**
- **Any 'agency' type requirements (e.g. quality management systems) could be more appropriately managed through the approval and conditions of the person's recognition, performance criteria and statutory duties.**

16. Recognition of an individual person is clearly provided for under all three Acts, however recognition of a class, group or type of persons is only a potential option under the ACVM Act. For certain functions to be carried out, recognising a class, group or type of persons may be the best regulatory approach. NZFSA has developed a proposal to recognise equivalence in competency standards and systems requirements by approving:

- **Membership of a profession that has professional standards/adheres to Codes of Ethics (e.g. veterinarians, accountants and pharmacists); and**

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[15] For certain functions, agencies and persons can be required to have quality management systems and be accredited by an accreditation body. For background, while accreditation requirements and costs are not affected by this amendment, costs of gaining accreditation can be disproportionately greater on smaller agencies and on persons who have fewer clients amongst whom to spread/recover their operating costs. For example, single person agencies do not have the option of utilising the signatory or KTP model for gaining more cost-effective accreditation through economies of scale. There is potential for persons operating independently to band together under an umbrella or cluster type agency and derive similar benefits. Experience suggests, however, that independent verifiers for example, who may well be in competition with each other, are unlikely to be comfortable working collectively (accountability and liability issues can also present impediments).

- **Mechanisms that are in place for ensuring compliance to relevant competency standards or systems requirements.**

Amendments

17. In some situations not requiring all or any of the persons managed by the agency or laboratory to be recognised will avoid unnecessary costs to the industry and the clients and food businesses using their services.

18. In total, the amendments would remove unnecessary compliance costs that could potentially equate to approximately $100,000 per year. Without the amendments, such costs and associated NZFSA assessment activity are clearly prohibitive. These potential cost savings are explained in more detail below, but in summary would comprise approximately:

    - **$75,000 per year in total for recognised agencies and laboratories carrying out functions under the AP Act;**
    - **$900 per year in total for recognised laboratories carrying out functions under the Wine Act; and**
    - **$35,000 per year in total for Veterinary Council of New Zealand (VCNZ) and/or its members (registered veterinarians) under the ACVM Act.**

19. There are currently 48 laboratories recognised as agencies under the AP Act for providing functions to the dairy industry. On average such laboratories manage approximately ten staff[16] that would require individual recognition. Total costs for these laboratories would be around $65,880 per year to have individually recognised persons (charged at $137.25 per person for year).

20. In 2008 AsureQuality (a prominent agency recognised under the AP Act) managed 59 staff that carried out sulphonamide-on-site (SOS) sampling and testing. In 2009 it managed 66 SOS sampling and testing staff. Costs to AsureQuality would have been at least $8,097 in 2008 and $9,058 in 2009 to have individually recognised persons.

21. Under the Wine Act, there are currently four recognised laboratories that together manage approximately 20 staff. Without the amendments, unnecessary compliance costs of $2,745 would be imposed on them (charged at the minimum $137.25 per person) for three-yearly periods.

22. Under the ACVM Act NZFSA proposes to recognise registered veterinarians (i.e. with current VCNZ practising certificates) for carrying out the function of ensuring the authorised purchase and use of restricted veterinary medicines.[17] VCNZ has advised that they have 2,350 practising veterinarians. Requiring each veterinarian to be individually recognised under

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[16] *Source:* Extrapolated from a survey of a sample of recognised laboratories and agreed by industry as an appropriate average.

[17] Relevant experience, technical competence and/or qualification requirements are to be demonstrated with evidence of valid certificates (i.e. gained through compliance with the VCNZ's professional Code of Conduct). For assessment purposes, NZFSA intends to ensure any necessary competency standards or systems requirements are considered and delivered by VCNZ through, for example, negotiations on the Memorandum of Understanding between NZFSA and VCNZ.

the ACVM Act (at the current minimum charge rate of $149.60) would cost $351,560. Because recognition could be approved for an indefinite period, as is currently provided for under the ACVM Act, costs to VCNZ and/or its members could be spread over a number of years (e.g. $35,000 per year over ten years).

23. The amendments would instead enable all practicing vets to be collectively recognised at a minimal cost of approximately $900 (e.g. 6 hours assessment charged at $149.60 per hour) and remove potential upfront costs of $350,000.

24. Compliance costs can be further reduced if equivalence could be applied between Acts for the purpose of recognition. Streamlining recognition requirements and procedures would allow recognition under one Act administered by NZFSA to be sufficient for equivalent recognition under a different Act. This would reduce the assessment process and be particularly beneficial for applicants seeking recognition to provide services to food businesses/sectors that are regulated under more than one Act (e.g. food businesses that manufacture mixed-food products comprising of food, animal-material and/or wine ingredients).

25. Aligning the three Acts will allow for greater economic efficiency in recognition procedures (e.g. application, assessment (both desktop and on-site), approval, renewal, suspension, surrender and cancellation), and the administrative systems that underlie them.

26. Any reduction in costs associated with businesses being recognised may:

- **Lead to an increase in the availability of third party agencies and persons within New Zealand;**
- **Provide more choice and competition for service provision; and**
- **Lead to lower operating/compliance costs being passed on from third parties to their clients and food businesses.**

27. The amendments are not anticipated to have any negative impact on fiscal, compliance, social, cultural or environmental matters.

Consultation

28. NZFSA consulted on the proposals by emailing a public discussion document to relevant stakeholders. The discussion document was posted on the NZFSA website (subscribers to the website's updates were then automatically notified of this via email) and formed the basis of this Regulatory Impact Statement.

29. Formal consultation was from 21 January 2010 to 18 February 2010[18]. Industry organisations consulted include Agcarm, Animal Remedy and Plant Protectant Association, Egg Producers Federation of New Zealand, Federated Farmers of New Zealand, Fonterra, Horticulture New Zealand, International Accreditation New Zealand, Joint Accreditation System of

[18] While this consultation period was not as long as usual, this was necessary to ensure that this Regulatory Impact Statement could be sufficiently developed and provided to the Ministry of Economic Development in accordance with the agreed timeline.

Australia and New Zealand (JASANZ), Meat Industry Association, National Beekeepers Association, New Zealand Feed Manufactures Association, New Zealand Pork Industry Board, New Zealand Wine Growers, Pork New Zealand, Poultry Industry Association of New Zealand, Seafood Industry Council, Veterinary Association of New Zealand and Veterinary Council of New Zealand. The discussion document was also emailed to all recognised agencies and persons for which NZFSA had email addresses.

30. Government departments consulted include the Environmental Risk Management Agency New Zealand; the Ministry for the Environment, Ministry of Economic Development, Ministry of Health, Ministry of Foreign Affairs and Trade and the Ministry of Agriculture and Forestry (Biosecurity New Zealand (MAF BNZ)); the Treasury and the Department of Prime Minster and Cabinet.

31. NZFSA received nine submissions in total. All were constructive and supportive of the proposed package of amendments. Many made comments that were outside the scope of the proposals (e.g. by expressing concerns over accreditation requirements and associated costs). These comments are being addressed in separate NZFSA work programmes. A summary of submissions received follows:

Submitter	Comment
AsureQuality	• "In summary, AsureQuality is very supportive of the proposals" • "The alleviation of the need for every individual to be a Recognised Person would reduce cost by several tens of thousands." • "Dual [agency and person] approval, over and above organisational approval as a Recognised Agency, adds little that could not be achieved through internal systems" • "AsureQuality agrees that the degree of flexibility [for recognising a body of persons] provided by the ACVM Act would be desirable across all areas" • "In relation to...equivalent recognitions, AsureQuality would suggest that recognitions in addition to those identified might also be considered. For example, these might include recognitions by other agencies such as MAF BNZ for IVA [Independent Verification Agency] and/or live animals and germplasm" • "In regard to...taking equivalence into account. AsureQuality is very supportive of this opportunity to rationalise costs. Many of the core auditing/inspection skills are common"
Verification New Zealand	"I am very much in favour of anything that will harmonise, streamline or simplify the processes administered by any Government department. Savings to the taxpayer or to industry are most welcome...My estimation is the savings to industry might be in the order of $100,000 per year"
JASANZ	"JAS-ANZ ... supports NZFSA in their initiatives ...Consideration should be given to the full approval process and the cost implications of that additional costs...include[ing] the onsite assessment component of the approval ... (Dairy, Organics)"
SGS	"SGS believe the proposal is positive for the industry generally. It will achieve the aim of reduced compliance costs and remove complexity and inconsistencies that currently exist. Operations

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Submitter	Comment
	for the Recognised Agencies will be simplified and this will benefit industry as a whole"
Federated Farmers	"In the longer term, NZFSA should ensure that legislative and regulatory developments are, as far as is practicable, future-proofed"
Bureau Veritas New Zealand	"the method of assessment and length of time the approvals are valid [should] be reviewed and be consistent"
Avivet Ltd	• "[The proposal] brings about a great potential for reduction in costs for a variety of non-export businesses, as they will have greater flexibility over their choice of verifier" • "I have no problem with the principle of the flexibility to include recognition of certain classes of persons" • " [the objectives of the Government's ongoing Regulatory Reform Agenda]...are to be applauded – all we have to do is get the implementation correct" • "All the above [objectives] are likely [to be met]"
Norris Environmental	"As one of the single-person verification agencies registered under the Wine Act 2003 I agree with the proposals...The reasons for agreeing with this proposal are...costs for both my agency and myself as a recognised person under the Wine Act. This dual cost would obviously be passed onto my clients and therefore any reduction of fees by reducing the requirement for when dual recognition is required would, in the long term, benefit my clients"
MAF BNZ	"No concerns identified in the proposal from MAFBNZ's perspective"

Conclusion and recommendation

32. NZFSA considers that making the legislative amendments to the AP Act, Wine Act and ACVM Act is preferred to doing nothing (continuing with status quo) because, as a package, the amendments will:

- **Enable NZFSA to apply the best regulatory approaches (i.e. the approach that manages risks appropriately while minimising compliance costs associated with businesses' being recognised);**
- **Minimise disincentives for applicants to seek recognition; and**
- **Increase consistency of recognition provisions across food safety and related legislation and enable more aligned systems.**

Implementation

33. Implementation of these amendments would require NZFSA to inform the public and industries of the changes and create a more streamlined recognition application form.

34. NZFSA would need to allocate time and resource if Regulations and/or Specifications (Director-General Notices) need amending to reflect the amended Acts. This would be resourced from existing baseline funding.

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Monitoring, evaluation and review

35. NZFSA considers that two to three years after implementation of this proposal, an evaluation would confirm the cost savings and identify any increase in business activity as a result.