Agricultural Compounds and Veterinary Medicines Act 1997 - Proposal to repeal the requirement for product manufacturers' details to be made public

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 a requirement of the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) for product manufacturers' details (in addition to product registrants' and other details) to be included on the public register.

The options are to continue with the status quo or to repeal the requirement by amending the ACVM Act.

The analysis shows that the status quo is unnecessary, inconsistent with international best practice, excessively costly for the industry and creates disincentives around product registration. In terms of compliance costs, a prominent industry association estimates the proposed amendment may save the industry up to $50,000 per year. All submissions received support the proposed amendment.

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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Date: 15/4/2010

Status quo

1. Under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) trade name products are registered on the basis that they will only be manufactured and distributed in accordance with approved manufacturing specifications or 'operating plans' (e.g. for staff training, documentation and systems review).

2. The ACVM Act requires the Director-General of the New Zealand Food Safety Authority (NZFSA) to keep a public register of all registered trade name products; persons responsible for their registration (registrants); and persons who are or will be manufacturing them.

Problem definition

3. Implementation of the ACVM Act has shown that the requirement for manufacturers' details to be included on the public register is both unnecessary and undesirable from a risk management perspective.

4. This requirement is inconsistent with best practice supported by international organisations such as the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the Organisation for Economic Cooperation and Development.[3]

5. The requirement for manufacturer's details to be included on the public register imposes unnecessary costs on the industry. For example, applicants incur additional costs by duplicating or tailoring their manufacturing information so it is in a suitable form for inclusion on the public register. This is particularly problematic and costly when manufacturers do not wish to be publicly named.

6. This requirement represents an unnecessary disincentive for applicants to register agricultural compounds and veterinary medicines in New Zealand.

Background

7. In 2007, the ACVM Act was amended to remove the requirement for the location of every place of business where the registered product is being, or is likely to be, manufactured to be specified on the register. The names and contact details of persons manufacturing the products, however, remained on the register.

8. The public policy objectives of this 2007 amendment (and others in the then ACVM Amendment Act 2007) were to ensure that:

    - **Risks arising from the use of agricultural compounds in New Zealand were managed efficiently and effectively under the Act;**

[3] Best practise is for the registrant to be the responsible person under the Act (and upon whom ongoing duties are imposed in respect of the product), not the manufacturer. Although it is not a mandatory requirement for product labels to include manufacturers' details, some currently do. For those products that do not, members of the public are free to contact the registrant and request this information, if needed (registrants' details are required to be on the public register). The relevant public interest in this area is about who is ultimately responsible for the product, not who manufactures it. It has tended to be businesses, not members of the general public, who have requested manufacturers' details from NZFSA. This is not the main purpose of a public register.

- **Regulatory controls were appropriate for the degree of risk; and**
- **Business compliance costs were minimised.**

9. The rationale for the 2007 amendment was that including all business addresses of manufacturers was out of step with common international practice, especially with regard to safeguarding national security (anti-terrorist protection) around the manufacture of potentially dangerous substances.

10. All submissions received by the Select Committee considering the amendment were in support of the proposal to not require all business addresses of manufacturers' to be on the public register.

11. NZFSA considers that while this 2007 amendment went some way to meeting the public policy objectives of the ACVM Amendment Act 2007, regulatory controls could be made more appropriate for the degree of risk and business compliance costs could be further minimised.

Objectives

12. The analysis within this Regulatory Impact Statement was undertaken in response to the Government's Regulatory Reform Agenda. The objectives of are to:

- **Minimise compliance costs for industry by removing the need for applicants to segregate and duplicate information relating to product manufacturing;**
- **Increase consistency with best/common international practice; and**
- **Remove unnecessary disincentives for registrants and manufacturers.**

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

Regulatory impact analysis

14. The options for addressing the problem are to:

- **Do nothing (continuing with the status quo); or**
- **Amend the ACVM Act to remove the provision that requires the name and contact details of manufacturers of registered products to be included on the public register. This would involve repeal of section 24 (j) of the ACVM Act.**

Status quo

15. Requiring the names of all manufacturers of registered products to be placed on the public register (in addition to registrants' details) does not provide any benefit from a risk management perspective. It is the registrant who is responsible for the product's registration, not the manufacturer. The requirement therefore imposes unnecessary costs on the industry.

16. For some applicants, costs associated with this requirement are the time taken to fill out their manufacturer's (or their own) details on their application. This can take just a minute or two. However, when a registered trade name product is, for example, toll-manufactured (manufactured under contract) and the manufacturer is manufacturing for a number of registrants, they may not wish for such information to be made public. Because of this, some applicants may be deterred from applying for product registration.

17. In these situations, applicants may alternatively nominate themselves (or other parties) as the publicly named manufacturer (despite not being the actual manufacturer) after allocating resources and putting in place an operating plan. This is required by NZFSA for assessment purposes under the ACVM Act. The cost to these parties incurred in developing such operating plans is dependent on their experience. It is estimated that this could take up to five hours and that it may necessitate the employment of a consultant. If this work was charged at, for example $150 per hour, then applicants would incur additional costs of $750. Industry has submitted that these costs have already been incurred by some registrants.

18. NZFSA considers that these costs (which can be passed on to consumers) are unnecessary and a disincentive for businesses to register agricultural compounds and veterinary medicines in New Zealand. Any unnecessary disincentives for applicants to register products in New Zealand should be removed, particularly when taking into account the comparatively small market size for these products in New Zealand.

Amendment

19. This amendment will enable greater economic efficiency, minimising costs associated with the registration process. Applicants will no longer be required to duplicate and tailor information relating to the manufacture of trade name products and segregate it into that which is commercially sensitive and that which is for the public register. Applicants will be free to develop and submit operating plans they have in place with any manufacturer (i.e. not only with those willing to be publicly named).

20. Although NZFSA has not been able to identify any parties that have chosen not to register products in New Zealand or that may choose not to in future due to the status quo, less compliance costs and disincentives may lead to a marginal increase in product registrations (and lower costs to consumers).

21. Agcarm, a prominent industry association, estimates that the total time and resource savings for the industry in the future may be up to $50,000 per year.

22. The amendment will not have any negative impact on fiscal, compliance, environmental, social or cultural matters.

Consultation

23. 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.

24. Formal consultation was from 23 December 2009 to 26 January 2010[4]. Key stakeholders were advised through the Agricultural Compounds and Veterinary Medicines Advisory Council of this timeframe and reasons for it.

25. Industry organisations consulted include Federated Farmers of New Zealand, New Zealand Pork Industry Board, Animal Remedy and Plant Protectant Association (ARPPA), Agcarm, Veterinary Council of New Zealand, Veterinary Association of New Zealand, Fonterra, Horticulture New Zealand, Poultry Industry Association of New Zealand, Egg Producers Federation of New Zealand and New Zealand Feed Manufactures Association.

26. Government departments consulted include the Environmental Risk Management Agency New Zealand (ERMA NZ); the Ministries for the Environment, Economic Development, Health, Consumer Affairs and Agriculture and Forestry (Biosecurity New Zealand); the Treasury, Privacy Commissioner and the Department of Prime Minster and Cabinet.

27. All ten submissions received support the proposed amendment. A summary of submissions received follows:

Submitter	Comment
Ministry for the Environment	"We have no issues with the proposal"
ERMA NZ	"ERMA has broad agreement with the outcomes of the paper"
• Privacy Commissioner; and • Ministry of Consumer Affairs.	"No comment"
Agcarm	Agrees status quo is difficult as required information is often commercially sensitive, increases compliance costs and acts as a disincentive for new product registrations - "Agcarm members support the proposal and stated objectives" citing potential annual savings to industry of up to $50,000
Federated Farmers of New Zealand	"supports this proposal" noting that reducing costs associated with regulation could reduce costs for users of agricultural compounds and veterinary medicines
Joint submission: • Poultry Industry Association of New Zealand; • Egg Producer's Federation of New Zealand; and	"we wish to note that because of the small size of the poultry industry in New Zealand, any disincentives to the introduction of new products are not welcomed, and we feel the proposed changes will help erode these

[4] While this consultation period was not as long as usual, and ran over the Christmas holiday period, this was necessary in order 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.

• New Zealand Feed Manufacturers' Association.	disincentives"
ARPPA	"happy with the...proposal"

Conclusions and recommendations

28. NZFSA considers that making the legislative amendment is preferred to continuing with the status quo because it will:

    - **Remove an unnecessary regulatory requirement;**
    - **Reduce compliance costs for industry (and government);**
    - **Be consistent with best/common international practice; and**
    - **Reduce disincentives for products to be registered in New Zealand.**

Implementation

29. Implementation of this proposal would require NZFSA to create a more streamlined application form (by no longer requiring applicants to complete section A9 'Responsible Manufacturer of the Formulated Product' as this information will be already provided in section B).

30. Minot IT changes to the product data sheets will also need to be made.

Monitoring, evaluation and review

31. NZFSA does not consider that the implementation of this proposal would require any monitoring, evaluation or review as it only involves the repeal of a an administrative requirement (i.e. there may be no measurable impact on achieving the purposes of the ACVM Act).