

Agricultural Compounds and Veterinary Medicines Act 1997 - Proposal to provide for the cancellation of non-compliant and obsolete product registrations

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 cancellation of non-compliant and obsolete product registrations under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).

The options are to continue with the status quo or to amend the ACVM Act.

The analysis sets out scenarios in which registration cancellation is the most appropriate action, but is not provided for with the status quo. The analysis shows that enabling the cancellation of non-compliant and obsolete product registrations will minimise compliance costs, increase consistency across legislation administered by NZFSA and increase certainty around the status of registered products.

In terms of compliance costs, the analysis demonstrates that the proposal may eliminate unnecessary costs upwards of \$10,000 per year (these costs are otherwise recovered from the industry as a whole). 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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Status quo

1. Among the purposes of the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) is to manage risks associated with the use of agricultural compounds.
2. Under the ACVM Act, product registration can only be cancelled:
 - Following a formal reassessment by the Director-General of the New Zealand Food Safety Authority (NZFSA) in consultation with the trade name product's registrant;
 - When requested by the registrant; or
 - When ordered by a Court following the conviction of the registrant.

Problem definition

3. The ACVM Act does not provide for non-compliant and obsolete product registrations to be cancelled in the most efficient or effective way in the following situations:
 - When any required prerequisite approval for the product or a specific component or ingredient of a product has been revoked under other legislation (e.g. by the Environmental Risk Management Authority New Zealand (ERMA NZ) under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act);
 - When the registrant, following investigation and due process by NZFSA, cannot be located meaning there is inappropriate stewardship and risk attached to their registered product; or
 - When non-compliance continues following suspension of a product's registration or the issuance of a prohibition notice.
4. Maintaining registrations for non-compliant and obsolete products imposes additional costs to the risk management system. These costs are incurred by the industry and government and are unnecessary given cancellation of registration would otherwise be the best regulatory action.

Objectives

5. The analysis within this Regulatory Impact Statement was undertaken in response to the Government's Regulatory Reform Agenda. The objectives of this proposal are to:
 - Add efficiency to risk management under the ACVM Act by reducing costs for the industry and government;
 - Increase consistency between provisions of other Acts administered by NZFSA that relate to cancellation and surrender

of various types of registration and subsequent removal from public registers⁵; and

- Increase industry and public certainty around the registration status of products (e.g. clutter should be removed from the public register).
6. NZFSA considers these objectives are consistent with the objectives of this Government's ongoing Regulatory Reform Agenda.

Regulatory impact analysis

7. The options for addressing the problem are to:
- Do nothing (continuing with the status quo); or
 - Amend the ACVM Act to:
 - a) Provide for the cancellation of non-compliant and obsolete product registrations and subsequent update of the public register when:
 - i. Any required prerequisite approval for the product or a specific component or ingredient of a product has been revoked under other legislation;
 - ii. The registrant, following due process by NZFSA, cannot be located; or
 - iii. Non-compliance continues following suspension of a product's registration; and
 - b) Provide for a right of review and/or appeal procedure.

Status quo

8. For certain products to be registered under the ACVM Act, specific components or ingredients of them may need prior approval from another agency under other legislation. Consequently, even if approvals for these products, components or ingredients under other legislation are revoked by the other agencies, the relevant products remain registered under the ACVM Act until the registrants apply to NZFSA for cancellation of the registration (i.e. they actively surrender it). For example, in 2008 ERMA NZ revoked the approval of endosulfan under the HSNO Act. At the time several products containing endosulfan were registered under the ACVM Act but, based on ERMA NZ's revocation, they could not be imported, manufactured or sold in New Zealand. Without a clear mechanism for cancelling such registration, NZFSA had to encourage relevant registrants to actively surrender their registration or undertake a formal reassessment. Neither approach is efficient as the outcome will always be cancellation of registration.

⁵ I.e. under the Animal Products Act 1999, Wine Act 2003, and Food Act 1981.

9. "The Director-General [NZFSA] may, after consultation with the registrant, decide to reassess a trade name product..." Formal reassessment is ordinarily triggered when NZFSA receives significant new information, for example, of a change in the use of the product, new technical information or anything that alters the risk profile of the product and, consequently, means the conditions of registration may need to be altered (or its registration cancelled). The purpose of the formal reassessment process is not to remove obsolete products from the market (particularly when there is no registrant to engage with) or remove unnecessary clutter from the public register.
10. Consultation with the registrant is not always possible. There are several instances each year when registrants cannot be contacted or located or are unwilling to engage with NZFSA. In these situations it can only be assumed by NZFSA that the registrant has relinquished their responsibility for their product and its registration. This represents a risk to the system. For example, products receive registration on the basis that they will only be manufactured and distributed in accordance with approved manufacturing specifications or 'operating plans'. To ensure that products do not 'drift' away from these specifications there needs to be a steward (the registrant, who may or may not be the manufacturer) who is legally responsible for a product's continued compliance.
11. If, after adequate investigation and due process by NZFSA, registrants cannot be contacted, prohibition notices are issued that restrict the importation, manufacture, sale and use of the product. This is not an effective solution as the non-compliant product remains registered under the ACVM Act and businesses (particularly suppliers of registered products) are faced with unnecessary costs associated with administering prohibition notices. Other mechanisms are for NZFSA to suspend registration⁶ or for a Court to order registration cancellation⁷. Neither of these mechanisms effectively addresses the problem either (i.e. no Court has cancelled a product's registration).
12. Each year several registrants do not pay fees⁸, and some have a number of product registrations. The status quo necessitates NZFSA invoicing and trying to track down registrants each year until registrations expire (a registration is typically valid for 3 years). Total sunk costs and lost revenue equate to \$13,324.12 (\$1,496 plus \$11,828.12⁹) for the 08/09 financial year. Costs

⁶ NZFSA has the ability to suspend product registration. When registration is suspended, NZFSA provides the registrant with certain steps that need to be taken for the suspension to be removed. If the registrant does not follow these steps the product no longer complies with the conditions of registration. However, this suspension has a limited duration and can be extended only once.

⁷ Under the ACVM Act a Court can order the cancellation of a product's registration if the registrant is convicted of an offence, as defined under the ACVM Act. This mechanism for cancellation of registration is not always effective or efficient (or even possible) as:

- Costs involved with prosecutions are prohibitive;
- The registrant is not always the cause of the suspension of their product's registration; and
- Registrants who are unable to be contacted or have had prerequisite approval revoked under other legislation may not have committed an offence in the ACVM Act.

⁸ The current annual fee for product registration is \$485 per product. For all registered products, NZFSA invoices registrants for annual fees. The cost of raising an invoice is \$149.60 per hour and takes approximately half an hour on average (i.e. costs \$75).

⁹ In the 08/09 financial year 21 registrants failed to pay their fees on time, totalling \$32,137.45. NZFSA spent approximately 10 hours tracking these registrants (charged at \$149.60 per hour, costing \$1,496). Following due process NZFSA could not locate seven registrants, representing a total of \$11,828.12 in unpaid fees for 23 registered products.

associated with these administrative actions, sunk costs and lost revenue are unnecessary and can be charged to the industry via product registration fees.

Amendment

13. Providing for NZFSA to cancel non-compliant and obsolete registrations in the situations described will reduce unnecessary compliance costs and add efficiency to the ACVM Act. For example, costs associated with administrative activities will be minimised¹⁰.
14. The amendment fits with the New Zealand food safety regime's underlying principle of making individuals responsible for ensuring they are compliant and is consistent with other legislation administered by NZFSA. It should not be the responsibility of NZFSA to ensure registrants pay their fees or can be contacted. The amendment will provide more certainty to industry and the public around the status of registered products.
15. The amendment is not anticipated to have any negative impact on fiscal, compliance¹¹, social, cultural or environmental matters.

Consultation

16. 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.
17. Formal consultation was from 23 December 2009 to 26 January 2010¹². Key stakeholders were advised through the Agricultural Compounds and Veterinary Medicines Advisory Council of this timeframe and reasons for it.
18. 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 Manufacturers Association.
19. Government departments consulted include 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 Minister and Cabinet.
20. All ten submissions received support the proposed amendment. A summary of submissions received follows:

¹⁰ E.g. tracking down and invoicing registrants (who cannot be contacted/located or will not engage); undertaking inefficient or ineffective formal reassessments; disseminating and enforcing unnecessary prohibition notices; and maintaining data for the public register (e.g. obsolete data will be removed).

¹¹ The amendment may provide an incentive for registrants to notify NZFSA of any change in contact details which may enable greater compliance monitoring and enforcement.

¹² 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.

Submitter	Comment
ERMA NZ	"ERMA has broad agreement with the outcomes of the paper"
Ministry for the Environment	"We obviously support the revocation proposal in regard to revocation of required prerequisite approvals under other legislation, including the HSNO Act"
<ul style="list-style-type: none"> • Privacy Commissioner; and • Ministry of Consumer Affairs. 	"No comment"
Agcarm	"Agcarm members support the proposal"
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: <ul style="list-style-type: none"> • Poultry Industry Association of New Zealand; • Egg Producer's Federation of New Zealand; and • New Zealand Feed Manufacturers' Association. 	"have no opposition"
ARPPA	"happy with the...proposal" and note "suspension is considered a more desirable first step"

Conclusions and recommendations

21. NZFSA considers that making the legislative amendment is preferred to maintaining the status quo because it will:

- Add efficiency to risk management under the ACVM Act by reducing costs to the industry and government;
- Increase consistency between provisions of other Acts administered by NZFSA that relate to cancellation and surrender of various types of registration and subsequent removal from public registers; and
- Increase certainty around the registration status of products.

Implementation

22. Implementation of this proposal would require NZFSA to update the registration status of non-compliant and obsolete products and remove applicable prohibition notices. NZFSA will inform the public and industry of the change but may not be able to inform effected registrants directly (as the fact that they cannot be contacted or located following investigation may be the basis for the cancellation of their product registration).

23. The Director-General of NZFSA will need to ensure delegated authority is in place. This would be consistent with delegated authorities for cancellation of other forms of registration under other Acts administered by NZFSA.

Monitoring, evaluation and review.

24. NZFSA does not consider that the implementation of this proposal would require any evaluation or review as it only involves administrative changes (i.e. there will be no impact on food safety or suitability outcomes). However, for monitoring purposes NZFSA will maintain information on all decisions to cancel non-compliant and obsolete product registrations under the amended provisions (such as the justification, and evidence of due process).