Regulatory Impact Statement

Proposed amendments to the ACVM Regulations 2001

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 give effect to NZFSA's review of its administration of the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). The review was partly driven by, and addressed, the need to implement amendments to the ACVM Act made in 2007, in particular the addition of 'public health' as one of the risks to be managed under the Act.

The ACVM Act achieves its purpose by requiring all agricultural compounds to either be registered or exempt from registration. The Agricultural Compounds and Veterinary Medicines Regulations 2001 (the ACVM Regulations) manage product groups that are exempt from the requirement to be registered. NZFSA's review of the administration of the ACVM Act highlighted some areas of inconsistency in the ACVM Regulations. NZFSA also identified four product groups for which new exemptions from registration should be provided. These proposed exemptions would significantly reduce costs for affected parties.

None of the proposals are likely to have effects that the Government has said will require a particularly strong case before regulation is considered. Arguably, any proposal to introduce minimum requirements for the manufacturing, advertising, and own use of exempt products could be seen to impose new costs on business. However, the proposed requirements are no more onerous than what would already be expected of a responsible business. A responsible manufacturing business will already keep written records of its practices. A business that advertises an agricultural compound in a responsible manner will already do so in a way that is consistent with that product's status within the ACVM regulatory framework. The proposed requirements for own use restate existing requirements in the ACVM Standard for Own Use of Agricultural Compounds, and will not change the way in which NZFSA regulates own use activities.

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Status quo and problem definition

1. The ACVM Act provides that all agricultural compounds and veterinary medicines must either be registered as a trade name product or exempt from registration. Its purpose is to prevent or manage risks to public health, trade in primary produce, animal welfare, and agricultural security[3]; to ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards; and to ensure the provision of sufficient consumer information about agricultural compounds.

2. The term 'agricultural compound' covers the following classes of products: veterinary medicines; agricultural chemicals (for example herbicides, fungicides, and insecticides); vertebrate toxic agents (products which kill animals such as possums and rodents); fertilisers and soil conditioners; and animal feeds (including pet food).

3. The ACVM Regulations primarily apply to products that are exempt from registration.[4] The Regulations also state conditions that must be satisfied in order for products to retain their exemption from registration. These conditions are set on a product group basis, and are the means by which the risks associated with exempt products are managed.[5]

ACVM Amendment Act

4. Government action is required to implement changes introduced by the Agricultural Compounds and Veterinary Medicines Amendment Act 2007 (the ACVM Amendment Act). During the development of the ACVM Amendment Act, the Legislation Advisory Committee raised concerns about a lack of clarity in the way the ACVM Act worked. One of NZFSA's main objectives in giving effect to the ACVM Amendment Act is to increase transparency.

5. The ACVM Amendment Act introduced three key changes:

i. Adding a description of the scheme of the Act in section 4A. This effectively states, amongst other things, that the ACVM Act should work transparently.

ii. Providing for 'standards' to be set in regulations. This change enabled requirements that have statuary effect to be moved into the ACVM Regulations. It was introduced in response to the key concern raised by the Legislation Advisory Committee, which was that the application of the ACVM Act was made unnecessarily complex by provisions variously relating to codes of practice; standards; conditions; and regulations. The ACVM Act did not originally provide an explicit power to set standards, yet some administrative documents had been referred to as 'standards'. This had increased the potential for confusion. The distinction between requirements with statutory consequences (or intended to have statutory consequences) and guidance on how to comply with such requirements was unclear.

iii. Adding a new public health risk area. This requires NZFSA to take a role in managing risks to public health associated with the use of agricultural compounds and veterinary medicines. It was not intended to put NZFSA's statutory functions in conflict with other agencies' public health responsibilities. It is for other government

[3] Being the risks listed in section 4 of the ACVM Act.
[4] There are exceptions where the regulations apply to agricultural compounds more generally, for example regulation 10 which prohibits the use of certain substances as agricultural compounds.
[5] Risks associated with registered products are managed through product-specific conditions of registration.

agencies to indicate whether they wish NZFSA to use the ACVM Act to manage risks within their core areas of responsibility.

Reviewing the administration of the ACVM Act

6. NZFSA reviewed the administration of the ACVM Act, both to give effect to the ACVM Amendment Act, and to update operational decisions made in the late 1990's and early 2000's. Also, some guidance material issued under the Act had taken on implied statutory effect. This had effectively created quasi-regulatory requirements without due process having been followed. Key issues associated are summarised below.

Manufacturing

7. Manufacturers usually operate to a good practice system for quality purposes. NZFSA expects all agricultural compounds to be manufactured in accordance with good practice, and be fit for purpose. Most manufacturers of exempt products are thought to be manufacturing in a responsible way. However, the condition of exemption that products 'must be manufactured in accordance with good manufacturing practice' does not apply to all exempt products. This has created inconsistencies between groups of exempt products and NZFSA's ability to take compliance action against products to which this condition does not apply is very limited.

Advertising

8. Advertisements often misrepresent products or overstate claims. NZFSA has operated on the basis that advertising should be consistent with the relevant conditions of a product's exemption from registration. This is not explicitly stated in the ACVM Act. The Fair Trading Act 1986 prohibits misleading and deceptive conduct, false representations, and unfair practices. However, the Fair Trading Act has a broad consumer focus; it covers all advertising and selling of goods and services. The ACVM Act has a specific risk focus; it is intended to prevent or minimise particular risks associated with the use of agricultural compounds. For example, a misleading advertisement for a veterinary medicine could have implications for risks to animal welfare, in that the product may have detrimental effects on a treated animal.

Agricultural compounds that are made for a persons' own use on their own property or animals

9. 'Own use' is when someone uses a non-agricultural compound substance on their own land/animals in such a manner as to make it an agricultural compound or veterinary medicine. For example using a domestic flyspray on sheep to prevent flystrike, or using superglue to close a minor wound and honey as a dressing, or using salt to kill weeds. The requirements in the ACVM Standard for Own Use of Agricultural Compounds have not been effective, as regulated parties have generally not been aware of their existence (this 'standard' is currently issued below the level of regulation). NZFSA has no evidence of irresponsible 'own use', but the risks around 'own use' are increasing as chemicals (and information about their use) become more readily available, for example copper sulphate can be purchased and then made into an animal dip or footbath. As the consequences of misuse may take some time to be known, it would not be an appropriate risk management action to remove the requirements for own use altogether.

Potential for exemptions from registration

10. NZFSA considers certain registered products may not pose risks of a kind or magnitude that require their registration. For example, compounds used in commercial plant production must be registered under the ACVM Act at a direct cost of $500-$1,500, along with indirect costs from $5,000-$10,000 for generating data and preparing an application. Even though the only registration information required for such compounds is to do with product quality, an application for registration still takes significant time and resources. This product group includes compounds used in forestry, turf farming, and plant nurseries (including products used in bulb production and products used post-harvest on cut flowers).

11. NZFSA realised certain products that were not considered agricultural compounds do fit within the scope of the term when used for certain purposes. For example, products with claims to control pathogens on equipment, facilities, or the environment in which animals or plants are managed have not previously been considered agricultural compounds. However, these sterilisers, sanitisers, and disinfectants have always fitted the definition of 'agricultural compound' when used for pest management. NZFSA came to a similar conclusion about water conditioners with claims to control the quality of water in which animals or plants are managed; when used for pest management purposes or to control certain characteristics of water that can jeopardise animal welfare, these products also fit the definition. The risks posed by the use of sterilisers, sanitisers, disinfectants, and water conditioners are, for the most part, adequately controlled under other legislation.[6] However, risks posed by hazards introduced during the manufacture of these products are not managed. This leaves the users exposed to potential breaches, through no fault of their own. Should such products be exempt from registration, the risks associated with their manufacture would be managed through NZFSA's proposed manufacturing requirements.

12. Parties that regularly use agricultural compounds for research, testing, or training purposes asked NZFSA to consider an exemption from the need to seek an authorisation for such activities.[7] Under the ACVM Act, an organisation is obliged to obtain an authorisation from NZFSA for each such proposed use. NZFSA considers the risks relevant to the ACVM Act could be managed without the need to obtain a separate authorisation for each intended use, so long as appropriate conditions applied to the exemption from registration. NZFSA took into account existing regulatory and non-regulatory considerations that apply to the use of agricultural compounds for research, testing, or training. These include the requirement for every use of animals in research, testing, or teaching to be approved by an animal ethics committee (acting according to an approved code of ethical conduct). Also there are various protocols on what constitutes good practice in respect of the activities relating to research, testing, and training. A relevant statutory precedent is the provision for containment approvals under the Hazardous Substance and New Organisms Act 1996 (the HSNO Act) for specified purposes of a research and development nature. Such approvals are conditional on the product being used in containment and not for commercial release.

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[6] Under the Animal Products Act 1999, or a Food Safety Programme under the Food Act 1981, operators need to specify chemicals that have been used. A company needs to have confidence that products will manage relevant risks.

[7] Examples of organisations that routinely use agricultural compounds for these purposes include: universities (for research); companies (for chemical tests on animals); and veterinary colleges (which use veterinary medicine products as part of students' training).

Objectives

13. The objectives of the proposals are, in respect of products covered by the ACVM Regulations, to:

14. The ACVM Act specifies that where the likely cost of product assessment and registration is considered to be greater than the risk(s) use of the product without registration will cause, or the risk are already adequately managed under other legislation, then the Minister must recommend that the product be exempt from registration (section 76 of ACVM Act refers).

    - give effect to the ACVM Amendment Act, including a general objective of making the ACVM regulatory framework more transparent and accessible for regulated parties;
    - ensure consistency around manufacturing, advertising, and own use; and
    - enable NZFSA to more effectively manage relevant risks.

Regulatory impact analysis

Alternative option: new sets of regulations

15. NZFSA considered three new sets of regulations to respectively manage the manufacturing, advertising, and 'own use' of all agricultural compounds and veterinary medicines (including both registered and exempt products). This option was set out in an NZFSA discussion paper, entitled *Implementation of the ACVM Act: Regulatory changes*, and released for public consultation in May 2008. NZFSA decided to continue to manage registered trade name products through conditions on registration, and to manage exempt products by way of the ACVM Regulations. Separate sets of regulations, each of which dealt with both registered and exempt products, could have made the ACVM regulatory framework less transparent and less readily accessible for regulated parties.

Preferred option: amend the ACVM Regulations

Giving effect to the Scheme of the Act

16. It is proposed that any existing requirements for exempt products that are intended to have statuary effect be moved into the ACVM Regulations. This will separate them from guidance material, and will increase transparency and accessibility for regulated parties.

Public health risk area

17. It is proposed to add a public health 'fit for purpose' requirement, which will apply to exemptions from registration for oral nutritional compounds, fertilisers/fertiliser additives, and oral gastrointestinal-acting microflora-enhancing compounds. The requirement will be that products do not:

    - compromise public health programmes;
    - spread organisms that could be harmful to humans; or
    - compromise the efficacy of human medicines.

18. This will require manufacturers to take due care to avoid hazards that will have a negative effect on human health, such as contamination with substances harmful to

humans (for reasons other than hazard characteristics of the intended ingredients, which are regulated under the HSNO Act). It will not change the nature of the controls that businesses are required to have around product safety. Those manufacturers with operating plans (descriptions of how they will comply with regulatory requirements) will need to consider risks to public health when setting up their operating plans. This may mean that spot samples need to be checked for human pathogens before going on sale.

19. The 'fit for purpose' requirement will enable NZFSA to take action if a risk to public health arises, either through an act of gross negligence or through someone knowingly operating outside the exemption requirements.

Manufacturing

20. It is proposed to apply minimum manufacturing requirements around product specifications, labelling, process specifications, and records to all products that are covered by the ACVM Regulations (except for the 'own use' category, discussed below). The proposed requirements will support the consistent, controlled manufacture of exempt products.

21. All manufacturers of products covered by the ACVM Regulations will need to hold evidence of compliance with the new requirements that can be produced on request. This will have little impact on most manufacturers. A responsible manufacturing business will keep track of its practices. Should a manufacturer be required to demonstrate that they were responsible, for example in a civil suit in Court, they would need to use records to do so.

22. Those manufacturers of products covered by the Regulations that require official assurances for export purposes will be subject to requirements depending on the overseas markets to which they require access. Other manufacturers will not be subject to any regular monitoring or compliance intervention, except in circumstances involving suspected non-compliance.

23. The manufacturing requirements will provide a basis for NZFSA to take compliance action against manufacturers who are not taking an appropriate level of care. Knowingly contravening any conditions that apply to any product is an offence under Section 55(1)(d) of the ACVM Act, liable to a term of imprisonment of up to two years or a fine of up to $30,000 (or in the case of a corporation, up to $150,000).

Advertising

24. It is proposed to apply minimum advertising requirements to all products covered by the ACVM Regulations (except for the 'own use' category, discussed below). The proposed requirements are that advertisements:

    - neither infer nor make false or misleading statements about an exempt product's regulatory status;
    - are consistent with an exempt product's conditions of exemption, and with the definition of its product group.

25. These requirements will not change the way that NZFSA has been regulating the advertising of products that are exempt from registration. The ACVM Regulations will clearly state what has been an implied expectation, and NZFSA will have a more secure basis on which to take compliance action. Although the Fair Trading Act 1986

applies to the sale of agricultural compounds, the existence of an explicit offence provision in the ACVM Regulations around false or misleading statements about the regulatory status of a product that is exempt from registration may deter businesses from making such statements. This will help achieve two aspects of the ACVM Act's purpose; it aims to ensure the provision of sufficient consumer information about agricultural compounds, as well as preventing and minimising specific risks associated with their use.

Agricultural compounds that are made for a persons own use on their own property or animals

26. It is proposed to set out in the regulations the conditions that would apply to any compound made/prepared by the person who is going to use it on their own land or animals. It would not apply to compounds sold with no associated agricultural compound claim (because they are not agricultural compounds at the time they are sold). It would also not cover the off-label use of registered agricultural compounds, or the use of an agricultural compound that is not authorised but should be.

27. The proposed minimum requirements for 'own use' are all drawn from the existing ACVM Standard for Own Use of Agricultural Compounds. They include a prohibition on the sale of non-agricultural compound substances as agricultural compounds, and set out an obligation to ensure the compound is fit for the purpose to which it is being put and due care is taken when using it as an agricultural compound. There are also obligations to ensure that maximum residue limits are not exceeded, and to make the use known when animal and plant products are sold for human or animal consumption. It is also proposed to prohibit any advertising associated with 'own use'.

28. NZFSA considers the proposed requirements for 'own use' will not impose any additional regulatory burden. Many affected parties have been unaware of their obligations with regard to own use of agricultural compounds, and stating those obligations in regulations should improve transparency. The main impact is that a statutory mechanism will be in place to manage any future incidents associated with 'own use'. This is considered necessary because of the increasing risk posed by greater access to generic chemicals and information about their use. Non-compliance with the own use requirements will be an offence under existing provisions of the ACVM Act. However, NZFSA will continue to provide information and advice about the offence in the first instance, and only consider prosecution where an 'own use' offence is knowingly continued.

Exemptions from registration

29. It is proposed to create four additional categories of exemption from the requirement for registration. Existing registrants will cease to incur the costs of registration requirements (a direct cost of $500-$2,000 and indirect costs ranging from $5,000-$10,000 for generation of data and completion of documentation). No person who is making a fit for purpose product will incur extra cost or be required to do extra work as a result of any of these proposed exemptions.

    Exemption from registration for compounds used in commercial plant production, where the plants are not used in the production of food or animal feed

30. The proposed exemption will reduce costs, as approximately 20 products will no longer need to be registered. NZFSA estimates this proposed exemption result in

saving to registrants as a whole of around $9,700 plus GST per year in annual fees and around $2,700 plus GST every three years to renew registration. Registrants will also not have to spend considerable time on the renewal process.

Exemption from registration for sterilisers, sanitisers, and disinfectants, where the products are used for pest management purposes

31. The conditions of the proposed exemption are to comply with minimum fit for purpose, manufacturing, and advertising requirements. NZFSA considers that these requirements will not have a significant impact on products that are made well and used in a responsible manner. 'Fit for purpose' relates both to the toxicity to animals exposed to a particular steriliser, sanitiser, or disinfectant, and to its effectiveness against the biological contamination that it is supposed to control. The exemption will provide NZFSA with a statutory basis upon which to take action if necessary, and will also complement requirements in other legislation administered by NZFSA, for example approvals for agricultural chemicals under the Food Act 1981.

Exemption from registration for water conditioners (products used to maintain the quality of water in which animals and plants are managed for the purposes of pest management, or to control characteristics of water that are crucial to animal welfare)

32. The conditions of the proposed exemption are to comply with minimum fit for purpose, manufacturing, and advertising requirements. These requirements will not have a significant impact on products that are made well and used in a responsible manner. 'Fit for purpose' relates both to the potential toxicity to animals exposed to a water conditioner, and to its effectiveness in regard to the claims being made. It will provide NZFSA with a statutory basis upon which to take action if necessary.

33. The proposed exemptions for sterilisers, sanitisers, disinfectants, and water conditioners will mean around 40 products will not require registration. This would save industry around $40,000 plus GST in application fees, plus savings around data generation and preparing application submissions. The industry would also save around $19,400 plus GST per year in annual fees and $5400 plus GST every three years for renewing registrations.

Exemption from the requirement to seek an authorisation for agricultural compounds used for research, testing, and training purposes

34. The proposed exemption would require the organisation to: have an operating plan approved by NZFSA; comply with specific research, testing, or training protocols that provide an adequate substitute for the conditions that would have been applied; briefly notify NZFSA of the intended use; not use any substance prohibited for use as an agricultural compound unless its use was specifically approved by NZFSA; and ensure that no animal or plant produce treated with the agricultural compound could be used for human or animal consumption or for the manufacture of human pharmaceutical products.

35. The exemption would allow organisations to undertake activities in a regulated manner without having to make repeated applications for authorisations. The relevant ACVM risks would be managed by the existing combination of regulatory and non-regulatory requirements. As the exemption would only apply to the requirement to obtain separate authorisation under the ACVM Act for each use, it would not affect other obligations that apply to the use of agricultural compounds for research, testing, and training/teaching purposes.

36. Affected organisations' costs would be significantly reduced. NZFSA receives around 40-50 applications annually for provisional registration. This would equate to savings of around $24,000-30,000 plus GST per year. It would also save companies considerable time and costs around data generation and preparing application submissions. Current costs include: a one-off fee of between approximately $300 and $400 per research approval; the two to three hours that it could take to fill in an application form; and possible subsequent time spent interacting with NZFSA. A requirement to notify NZFSA would simply involve a brief statement as to intended use.

37. The research, testing, and training exemption would also ensure that regulation under the ACVM Act was not disproportionate to the approval issued by the Environmental Risk Management Authority New Zealand (ERMA) for the use of hazardous substances in containment for research and development purposes. This would reduce the impact of having to obtain approvals under the ACVM Act and the HSNO Act for the same activity.

38. This exemption would also contribute to New Zealand's existing reputation as a cost-effective place for research, particularly for out-of-season field research trials for compounds that are under development in the northern hemisphere.

Minor exemptions from registration

39. A number of technical amendments are proposed, most of which are the consequence of the amendments discussed above. Of note, these include three proposed exemptions from registration.

Exemption for plant products that provide a physical barrier to infestation or infection

40. This applies to products that, when spread on foliage in the absence of wounds or pruning, produce a physical barrier to protect plants. This is a new product group, which probably includes two current products.

Exemption for agricultural chemical synergists

41. This would clarify that products used to assist the performance of agricultural chemicals to control pests are exempt from registration.

Exemption for compounds used as media for animal ova and embryos

42. This extends an existing exemption for compounds used as media for animal ova. It will not alter NZFSA's current actions, and will have no impact on compliance costs for the two operators in this market.

Revocation of Schedule 7 of the ACVM Regulations

43. A further technical amendment will be to revoke the Schedule 7 to the Regulations. Prior to the 2007 amendment of the ACVM Act substances generally recognised as safe (GRAS) and that could be used as an agricultural compound (together or separately) could be exempt from registration by being included in a schedule to the ACVM Regulations. The amendment of the ACVM Act in 2007 replaced this requirement with a provision for the Director-General to maintain and publish a GRAS list. The existing schedule to the Regulations was not revoked because the Director-General list did not exist at the time the Act amendment was passed. However there are now two lists, the schedule to the ACVM Regulations, which has no legal status and could be considered *ultra vires*, and the Director-General list on the NZFSA

website. Revocation of the schedule in the regulations is therefore required to address its legal status and remove confusion.

Consultation

44. Information about NZFSA's review of the administration of the ACVM Act has been published on the NZFSA website since 2007. NZFSA discussed its proposed amendments to the ACVM Regulations at a number of meetings of the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC). The NZFSA discussion paper Implementation of the ACVM Act: Regulatory changes was released for public consultation in May 2008. This paper proposed new sets of regulations for all agricultural compounds and veterinary medicines. NZFSA then decided it was preferable for registered products to continue to be managed through conditions on registration. This decision was initially socialised with AVMAC.

45. The NZFSA discussion paper *Implementation of the ACVM Act: changes to the ACVM Regulations 2001* was released for public consultation in September 2009. Five submissions were received. Four were from industry representative organisations, and one from a business.

46. Two submitters offered unqualified support and, with regard to the proposed exemption for research, testing, and training purposes, urged NZFSA to work with ERMA. NZFSA has been working with ERMA to make this proposed exemption as seamless as possible, and will continue to do so (while noting that such an approach is not viable for products that will enter the food chain, because they pose greater food safety risks).

47. One submitter was supportive, and sought clarification around how three types of agricultural compound use situations would be managed, namely:

    - own use;
    - inadvertent spraying of ground cover that is subsequently grazed by stock; and
    - large-scale spraying of forest and waste land for pest management purposes.

48. NZFSA's approach to 'own use' will not change. The proposed amendments increase the transparency of the context in which own use occurs.

49. NZFSA notes that any spraying of ground cover grazed by stock would be outside the scope of the proposed exemption for products used in the commercial production of plants, as it involves the use of agricultural compounds on animal feed. Nevertheless, NZFSA considers there could be a labelling requirement on products being exempt on the condition that they are not used in a food/feed context. This would warn users not to allow livestock that may enter the food chain to access the treated area.

50. With regard to the large-scale spraying of forest and waste land for pest management purposes, it is also relevant to note that the proposed exemption for products used in the commercial production of plants only applies if the agricultural compound is not used in a food or feed context. When public land is being treated, a failure to post warnings and to prevent livestock access is likely to create circumstance in which a product's conditions of exemption could be breached. The obligation in this instance is on the party responsible for the treatment to address the potential risk, or to use some other product for which livestock exposure in a food/feed context is acceptable.

51. Two submitters raised concerns based on industry-specific considerations to do with animal feed and petfood. For reasons discussed below, NZFSA's view is that such concerns are appropriately addressed through communication and do not require any changes to the proposed amendments.

52. Requirements that apply to all groups of product exempt from registration must be expressed in terms that are suitably flexible to cater for all affected parties. While some of the proposed amendments create rules that apply to all product groups, the interpretation of those rules will take into account the differences between such groups. For example, 'fit for purpose' does not have the same meaning for all products covered by the Regulations, because they do not share a common purpose.

53. Several of the industry-specific issues raised appeared to be driven by concern that the proposed amendments would impose more onerous formal regulatory requirements. NZFSA notes that there is nothing in the proposals that signals increased regulatory intervention. For example, a concern was expressed that as the manufacture of compound feed does not conform to the same parameters as found in the manufacture of other exempt products, the proposed amendments would unnecessarily increase compliance measures and costs for feed manufacturers. This concern appears based on a perceived discrepancy in the manufacturing parameters between those for feed manufacture and those for other products under the ACVM Regulations. NZFSA considers that there is no discrepancy between the parameters; there must always be a person responsible, and a plan to manage risks down to an acceptable level. NZFSA agrees that what specifically needs to be addressed varies greatly between kinds of products. NZFSA expects each industry sector will address manufacturing in a way that is most appropriate to manage the ACVM risks as they relate to that industry.

54. Several of the industry-specific concerns can be addressed through the provision of guidance that clarifies certain terms. For example, a concern was expressed about the impracticality of 'preventing' some contamination occurring in an animal feed mill. Part of the purpose of process specifications is to prevent contamination or cross-contamination. This does not mean that the only acceptable target is zero risk of contamination. It is impossible to prevent all forms of contamination, and some kinds of contamination pose insignificant or irrelevant risks. Manufacturers should be aware of the risks, and take reasonable steps to avoid relevant manageable risks.

55. Also, a concern was raised that animal feeds do not have a 'master formulation', in that their ingredient profile is likely to change regularly – and that it is not correct for the public discussion document to have stated that "if products are not manufactured consistently, they are likely to pose issues for the risk areas listed in the ACVM Act." NZFSA notes that nothing in the manufacturing regulations prevents a master formulation from specifying variability in ingredients. NZFSA did not intend 'manufactured consistently' to be understood as meaning 'always manufactured with exactly the same ingredients'; the phrase is intended to refer to a product being consistently manufactured in accordance with its manufacturer's quality system.

56. Subsequent to the 2009 consultation process, two additional submissions have been received in support of the amendments proposed. These are from Federated Farmers and Agcarm. Federated Farmers noted that the proposals will allow for simplification of regulation, allowing ease of use, better entry by suppliers and manufacturers and decreases in costs, which have the potential to filter back to end users. They consider the proposed changes are based on common sense and that

the safeguards proposed (minimum manufacturing and advertising requirements) should protect farmers from substandard or potentially damaging products. Agcarm note their membership's unequivocal support for the proposed exemption from the requirement to seek an authorisation for agricultural compounds used for research, testing, and training purposes. One of their members has advised that they currently make about 15 research authorisation applications per year with only a third of these actually taken to the testing stages – they estimate each application costs them $2,000 - $3,000 in fees and time and they would therefore expect to gain significant savings from the proposed exemption. Agram also support the introduction of minimum requirements for manufacturing, advertising and own use that would apply to all exempt products. They see this as creating a level playing field for all manufacturers and ensuring an appropriate level of product stewardship (taking responsibility for your products).

57. The following government agencies were consulted on the attached Cabinet paper and this regulatory impact statement: the Ministry for the Environment, ERMA, MAF, the Ministry of Economic Development, the Ministry of Health, the Department of Conservation, the Department of Labour, the Department of Prime Minister and Cabinet, and The Treasury.

Conclusions and recommendations

58. Giving effect to the ACVM Amendment Act requires changes to regulations. No feasible alternative options that will fully meet the objectives were identified. The outcome of NZFSA's options analysis was to recommend amendments to the ACVM Regulations.

Implementation

59. It is intended that the regulations be implemented as soon as they are promulgated. The ACVM Group will implement the new regulations. NZFSA will develop industry-specific guidance material on the changes in discussion with affected parties. NZFSA will also rely on industry to help ensure that the guidance material continues to be fit for purpose.

60. NZFSA does not expect to change its approach in enforcing the new requirements. The changes will not lead to any more proactive or urgent compliance activity, but will clarify the basis on which NZFSA can take action.

Monitoring, evaluation and review

61. NZFSA has not set a time to review the new regulations. Their effectiveness will be considered during assessment of the administration of the ACVM Act. NZFSA regularly proposes refinements to the ACVM Regulations as and when prompted by new technology and product development.