In Confidence

Office of the Minister for Food Safety
Chair, Cabinet Economic Development Committee

Proposed amendments to the ACVM (Exemptions and Prohibited Substances) 2011 Regulations

Proposal

1. This paper seeks Cabinet's agreement on proposals to amend the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 [ACVM Regulations].

Executive Summary

2. Under the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act) all agricultural compounds and veterinary medicines must be registered unless expressly exempted from registration. The default position is for agricultural compounds and veterinary medicines to be individually registered with the Ministry for Primary Industries (MPI).

3. The ACVM Act allows for exemption from registration through the inclusion of exempt product 'groups' (e.g. fertiliser and fertiliser additives) in the ACVM Regulations. These exemptions were included in the ACVM Act to recognise that some products have a risk profile not requiring a high level of regulatory oversight and compliance costs.

4. Following a risk assessment, only low-risk compounds or products whose risks can be managed down to acceptable levels are authorised for exemption. While exempt from registration, they must meet a number of requirements in the ACVM Regulations. By satisfying these requirements, products are able to retain their exempt status.

5. All products being imported, manufactured or sold in New Zealand also have to comply with relevant legislation. Products may be subject to the Hazardous Substances and New Organisms Act 1996 (HSNO Act) and may also require a biosecurity assessment under the Biosecurity Act 1993. For products subject to the above legislation, they can only be cleared for entry into New Zealand once they have gained the appropriate authorisation.

6. Being exempt from the requirement to register a product with MPI has distinct advantages for the producer. Registration is subject to fees and levies and is required on a product-by-product basis, which requires significant amount of

information to prove the product is safe and to support registration. Products exempt from registration are not subject to these compliance costs.

7. Since the ACVM Regulations were last amended in 2011, there are a number of new ACVM products entering the market that have a low risk profile and should therefore be exempt from registration according to the framework under the ACVM Act. However, until the ACVM Regulations are amended to allow for new groups of low-risk products, they still require registration.

8. The main proposal is to exempt six new groups of products, from registration. Substances in these groups have been determined to have risk profiles not requiring their registration when used in compliance with the ACVM Regulations. Products within these new exemption groups deal with pest control and animal welfare.

9. Other proposed changes to the ACVM Regulations are to improve the clarity of descriptions and conditions in a number of product groups, consolidate some exemption groups, and reduce the reliance on prescriptive requirements in favour of emphasising the obligation and responsibilities on importers, manufacturers, and sellers.

10. The objectives of the proposed changes are to:

    - reduce compliance and operational costs;
    - improve readability of the Regulations;
    - create greater certainty and confidence in the Regulations; and
    - improve fairness by providing a more flexible and effective exemption regime.

11. Public consultation on the proposals occurred between September and October 2017. Producers and importers of agricultural compounds support these amendments as compliance will be cheaper and easier. Industry welcomes the addition of six new exemption groups and the clarification of conditions that must be met to retain exempt status.

Background

The ACVM Act

12. The purpose of the ACVM Act is to prevent or manage the risks associated with the use of agricultural compounds. These are risks to public health, trade in primary produce, animal welfare, and biosecurity. A further purpose of the

ACVM Act is to ensure that the use of agricultural compounds do not result in breaches of domestic food residue standards.

13. Agricultural compounds as defined under the ACVM Act cover a wide range of products including animal feeds and pet food, pesticides, veterinary medicines, vertebrate toxic agents, and fertilisers.

14. To manage the risks, the ACVM Act requires all agricultural compounds imported, manufactured, sold or used in New Zealand to be registered unless expressly exempt from registration. Registration requires providing costly technical information about the product, its method of production, its safety and efficacy, and how these risks are being managed.

15. Initial registration for each individual product is approximately $4,000 and once registered, there is an annual levy of $540 plus GST. Registration can also involve the generation of data from trials and completion of documentation; together these could add between $10,000 and $500,000 to the costs.

The ACVM Regulations list product groups that are exempt from registration

16. The ACVM Act allows exemptions from registration due to the recognition that some products have risk profiles not requiring the high level of regulatory oversight and compliance costs associated with registration. Exemptions are for product groups, rather than individual products. The advantage of exemption, for product manufacturers, is there is no time involved or ongoing costs in registering a product.

17. The ACVM Act requires that the Minister should recommend an exemption if he or she considers the likely cost of assessing and registering an agricultural compound is greater than the likely risks from the use of that agricultural compound without registration, or the risks are already adequately managed under other legislation (section 76 of the ACVM Act refers).

18. Exemption from the requirement to be registered does not mean that a product does not need to meet any obligations under the ACVM Act or Regulations. Exempt products may still pose some risk, if minimum requirements or obligations are not met. Therefore, exempt products must satisfy any conditions of use that are set out in the ACVM Regulations.

19. Some of the products, regardless of being given exempt status, may require approval under the Hazardous Substances and New Organisms Act 1996, which includes an assessment of risks to human health and the environment. Compounds being imported may also require a biosecurity assessment (whether registered or exempt from registration) under the Biosecurity Act 1993 if the products contain ingredients of biological origin.

20. For all agricultural compounds imported into New Zealand, the importer must provide documentation showing their product is authorised for entry. Without the appropriate documentation they will not be cleared for entry. The ACVM act contains a number of compliance and enforcement measures, including product recalls and investigations, or seizure and disposal.

The problem

21. The ACVM Regulations were last amended in 2011. Exempt groups set out in the ACVM Regulations can no longer accommodate the full range of products that are available on the agricultural compound market. Off-shore companies own most agricultural compound products in the market, therefore product development is largely driven by overseas markets and the advances in technology in those countries.

22. Some advances involve novel technologies not previously considered by the regulator before as they didn't needed to be considered at the time the Regulations were last amended. Furthermore, some of these novel technologies have a risk profile that indicate registration should not be required. However, because of their novel use they do not fit existing exemption categories and therefore, require registration.

23. Registration can result in delays in bringing products to market, as it involves compiling an application package and obtaining supporting data. Companies will forego bringing novel products into New Zealand because of the time and costs involved resulting in less product choice for producers, and users of agricultural compounds.

24. Some Regulations and exemption groups are also unclear and do not provide sufficient certainty for both industry and government. For example, it is uncertain where some products fit within the regulatory framework meaning costs to business and delays to consumers having access to products.

Comment

The proposed amendments to the ACVM Regulations

25. Each of the primary proposed changes to the ACVM Regulations are described below. In summary it is proposed to:

    a. Add new exempt product groups whose low risk profile indicate they do not require registration;

b. Amend existing exempt product groups to improve consistency and provide new consolidated groupings to better align with reassessed risk profiles; and
c. Amend some specific Regulations including information requirements and documented systems.

Proposed new product groups to be exempted from registration

26. The MPI ACVM technical team has identified several new groups that it considers meets the criteria for exemption. Substances in these proposed new groups have been determined as carrying a risk profile not requiring their registration when used in compliance with the ACVM Regulations (the general provisions as well as any specific conditions proposed).

27. It is estimated that around 60-90 products could become exempt if the proposed groups are finalised. This would save industry thousands of dollars and give consumers more access to a variety of products.

28. It is proposed that the following additional agricultural compound groups be exempted from registration:

    a. agricultural compounds that act mechanically to control pests in the environment;
    b. semiochemical preparations that modify animal behaviour;
    c. biologically active agricultural compounds, applied to the contained environment in which non-food producing animals are kept, to control invertebrate pests of animals;
    d. topically absorbable animal nutrient substances;
    e. substances with a purely mechanical mechanism of action used on animals; and
    f. agricultural chemical products used in empty structures to remove infestations of diseases or pests of plants.

29. **Appendix One** provides a table with further information on the proposed new exemption groups and the conditions that have to be met, along with some examples of the products that would fit under the new exemption groups. The table also outlines the rationale for how the proposed new groups meet the criteria for exemption.

Proposed amendments to existing exemptions

30. Schedule 2 of the ACVM Regulations currently contains 41 exemption groups of agricultural compounds. The main benefit to having a large number of groups is that specifically formulated substances requiring precise conditions for exemption status can be readily accommodated. However, specifically and narrowly defined groups may exclude new products from exemption if these

products vary in some small way from the specific group description, even if, in other respects, they have a similar low risk profile.

31. MPI is proposing to make technical changes to rationalise some exemption groups and standardise conditions so that groups sharing common factors are treated consistently. This rationalisation would improve the readability and understanding of the ACVM Regulations. **Appendix Two** provides a table with the proposals and rationale for change.

Further amendments to Schedule 2 exemption groups to clarify and improve risk management

32. In addition to the above proposed amendments, it is proposed to further amend a number of specific exemption groups in Schedule 2. Amendments are proposed to better align with re-assessed risk profiles, delete redundant provisions, and provide better clarity for the exemption groups. The table in **Appendix Three** sets out the proposals and the rationale for change for a number of specific exemption groups.

Proposed changes to specific Regulations

Documented system for compounded veterinary preparations

33. Regulation 10 of the ACVM Regulations specifies that compounded veterinary preparations must be prepared in accordance with a documented system for that preparation, and sets out a number of requirements that must be contained in the documented system. It is proposed to add words to the effect that the compounding veterinarian must be satisfied that the documented system is suitable and fit for purpose.

34. The proposed change would address concerns that the current regulation is silent on who should take responsibility for ensuring the documented system is fit for purpose. By limiting the proposed change to specifying an oversight role for the compounding veterinarian, the preparation of the documented system is left flexible. This enables a documented system to be prepared by, for example a product manufacturer, an agent under the supervision of a compounding veterinarian, or the compounding veterinarian.

How information requirements must be supplied on label of exempt product

35. Regulation 12 states how information must be supplied on the label of an exempted product administered by the user. The proposed amendment clarifies when labelling is not required, such as where a veterinarian who compounded a veterinary product and administered it themselves. In all other circumstances label information will be required.

Public Consultation

36. The ACVM Act requires that, before recommending that Regulations be made, the Minister must be satisfied that appropriate consultation with affected stakeholders has taken place and the results of the consultation have been taken into account.

37. Public consultation on the proposals started with the release of the discussion document on 7 September 2017 and closed on 19 October 2017. The public were invited to make submissions. The consultation was publicised through a media release, MPI's website, and emails to industry associations, businesses, and individuals. MPI received 15 submissions. Some submissions were deemed out-of-scope. MPI will address these matters separately with the submitters.

38. A number of submitters agreed with the proposed new exemption groups and changes. Submitters included agricultural industry professional organisations, fertiliser and pesticide businesses, and individuals.

39. Before consultation began, MPI engaged with the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC). AVMAC consists of industry groups, producer sectors involved in the sale or use of agricultural compounds, and a consumer representative. AVMAC's purpose is to provide balanced advice to MPI on matters relating to the regulatory control of agricultural compounds and veterinary medicines. AVMAC was provided with a draft discussion document for comment and they supported the draft proposals.

40. MPI proposes to release an exposure draft of the amended ACVM Regulations to AVMAC. Testing an exposure draft with AVMAC will ensure that the policy decisions have been translated accurately and in a way that can be readily understood and implemented. The exposure draft will be released on an in confidence basis and subject to professional legal privilege.

Departmental Consultation

41. The following government agencies have been consulted on this paper: Ministry for the Environment, Environmental Protection Authority, Department of Conservation, The Treasury, Te Puni Kōkiri, and Work Safe New Zealand. The Department of the Prime Minister and Cabinet was informed.

Financial Implications

42. There are no financial implications arising from these proposals.

Human Rights

43. There are no implications under the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Legislative Implications

44. The proposals will result in amendments to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.

Regulatory Impact Analysis

45. A Quality Assurance Panel from the Ministry for Primary Industries reviewed the Regulatory Impact Assessment "Proposed amendments to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 [ACVM Regulations]" produced by the Ministry for Primary Industries. The Panel considers that it meets the Quality Assurance criteria. The Impact Summary Assessment is attached as **Appendix Four.**

46. The Regulatory Quality team at the Treasury has determined that the regulatory decision sought in this paper relating to categories one and three are exempt from the requirement to provide an Impact Assessment as they have only minor impacts on businesses, individuals or not-for profit-entities.

47. Category one relates to the proposal to amend existing exempt product groups to improve consistency and better align with reassessed risk profiles and category three relates to the proposals to amend some specific Regulations including information requirements and documented systems.

Publicity

48. A summary of submissions has been prepared and will be published on MPI's website.

Proactive Release

49. Following Cabinet consideration I intend to consider the release of this paper in full.

Recommendations

The Minister for Food Safety recommends that the Committee:

1. **Note** that the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 set out conditions that must be satisfied if products are to be manufactured, sold and used in New Zealand without registration under the Agricultural Compounds and Veterinary Medicines Act 1997;
2. **Note** that the proposed amendments to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 will clarify regulatory requirements, provide for more exempt product groups based on their low risk profile, and reduce costs for businesses;
3. **Note** that consultation was undertaken between September and October 2017 on proposed changes to the ACVM Regulations and no concerns were raised in submissions;
4. **Agree** to add six new exemption groups for compounds that have been assessed as having a low risk profile not requiring their registration;
5. **Agree** that the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 be amended to:
    a. Delete Schedule 3: plants not to be included in oral and topical preparations, and any reference to it;
    b. Remove reference to substances generally recognised as safe in Schedule 2;
    c. Consolidate topical veterinary preparations into a single entry with a common set of conditions;
    d. Extend the labelling information requirements for animal preparations to other exemption groups that relate to animal preparations, to provide a consistent approach;
    e. Remove references to non-medicated in exemption groups;
    f. Amend exemption groups dealing with topically applied preparations to state the compound must not be used on the udders and teats of animals whose milk is being collected for human consumption; and
    g. Consolidate compounds used for protecting plants from climatological conditions into a single group;
6. **Agree** to amend specific exemption groups and conditions to better align with re-assessed risk profiles, delete redundant provisions and provide better clarity for the exemption groups;
7. **Agree** to amend regulation 10 to ensure that the compounding veterinarian must be satisfied that the documented system is suitable and fit for purpose;
8. **Agree** to amend Regulation 12 to clarify when labelling of exempt compounded veterinary preparations is not required, such as where a veterinarian who compounded a vet product and administers it themselves;
9. **Agree** to release an exposure draft of the amended ACVM Regulations to the Agricultural Compounds and Veterinary Medicines Advisory Council;

10. **Authorise** the Minister for Food Safety to issue drafting instructions to the Parliamentary Council Office to implement the above policy decisions;
11. **Authorise** the Minister for Food Safety to make final decisions on minor and technical issues and make changes consistent with the policy intent described in this paper on any issues that arise during the drafting process.

Authorised for Lodgement

Hon Damien O'Connor
Minister for Food Safety