Ministry for Primary Industries
Manatū Ahu Matua

Fertiliser Discussion Document

Proposed changes to regulatory oversight of fertilisers under the Agricultural Compounds and Veterinary Medicines Act 1997 and its Regulations

MPI Discussion Document
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1 Purpose

The Ministry for Primary Industries (MPI) is seeking views on changes to the regulatory oversight of fertilisers and fertiliser additives under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the ACVM (Exemptions and Prohibited Substances) Regulations 2011 (ACVM (E&PS) Regs). Currently, fertilisers are exempt from registration under the ACVM Act via ACVM (E&PS) Regs.

This discussion document identifies some weaknesses (problem identification) with the current level of regulatory oversight, and discusses three options including a more detailed discussion on MPI's preferred option.

A review of the definitions of fertiliser and fertiliser additives as outlined in the ACVM (E&PS) Regs is not within the scope of this discussion document.

2 Submissions

MPI welcomes written submissions on the proposals contained in this document. All submissions must be received by MPI **no later than 18 December 2015**.

Written submissions should be sent directly to:

Fertiliser Consultation
ACVM Programmes and Appraisals
Ministry for Primary Industries
PO Box 2526, Wellington 6140
Email: ACVM.consultation@mpi.govt.nz

We will consider all relevant material made in submissions, so you are welcome to provide information supporting your comments. Please make sure you include the following information in your submission:

- the title of this consultation document;
- your name and title;
- your organisation's name (if you are submitting on behalf of an organisation), and whether your submission represents the whole organisation or a section of it; and
- your contact details (that is, phone number, address, and email).

Submissions are public information

Note, your submission is public information. Submissions may be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available to requesters unless there are sufficient grounds for withholding it, as set out in the OIA. Submitters may wish to indicate grounds for withholding specific information contained in their submission, such as if the information is commercially sensitive or if they wish personal information to be withheld. MPI will take such indications into account when determining whether or not to release the information.

Any decision to withhold information requested under the OIA is reviewable by the Ombudsman. For more information please visit:
http://www.ombudsman.parliament.nz/resources-and-publications/guides/official-information-legislation-guides

3 Background

Under the ACVM Act, fertilisers and fertiliser additives (see Appendix 1 for their meaning as defined under the ACVM (E&PS) Regs) are considered to be agricultural compounds. When considering the level of their risks to the risk areas (public health, agricultural security, animal welfare and trade in primary produce) and the requirement to comply with domestic residue standards under the Act, it was decided that they would not require registration and could be exempted from the requirement from registration via the ACVM Regulations and subsequent amendments. The definition of a fertiliser or fertiliser additive is included under the ACVM (E&PS) Regs to cover the scope of the exemption from registration.

The ACVM (E&PS) Regs is passive regulatory oversight for product groups exempt from registration as the risks in relation to the risks managed under the ACVM Act can be managed appropriately without the need for a higher level of regulatory oversight such as registration. This means the manufacturer/importer has to undertake their own assessment of the requirements of these regulations without any regulator involvement as in the case of registration.

The original Regulations (ACVM Regulations 2001) included a schedule exempting fertilisers and fertiliser additives from registration. In this schedule, specific conditions were placed on this exemption, such as labelling and fit for purpose requirements, at mainly a generic level. However, these specific conditions were largely superseded by Regulations 7-12 of the ACVM (E&PS) Regs.

When fertilisers and fertilisers additives were being proposed for exemption under the ACVM Regulations 2001, a condition would be included as part of the exemption requiring fertilisers to be sold in compliance with a standard. In addition, the standard would provide for codes of practice to be approved under section 28 of the ACVM Act. At that time, it was expected that the codes would specify how manufacturers of fertilisers would ensure compliance with the specifications in the standard. Compliance with an approved code of practice would be deemed to be taking adequate measures to comply with those specifications outlined in the standard. Consequently, prescribing a standard for fertilisers and subsequently exempting them from registration would avoid unnecessary compliance costs, while still maintaining adequate management of the risks relevant to the ACVM Act.

In the end, the exemption from registration for fertilisers and fertiliser additives in the ACVM Regulations 2001 did not reference a standard in the conditions. Instead the industry's Fertmark™ was approved as a Code of Practice (CoP) under section 28 of the ACVM Act, but there was no link in the ACVM Regulations 2001 to this approved CoP. However, there were limitations to this CoP:

1. The focus of Fertmark™ was on conventional fertilisers (e.g. containing N, P, K and other recognised nutrients) - it was less fit for purpose for other types of fertilisers such as those that are biologically based.
2. There was no requirement for a fertiliser manufacturer to obtain a Fertmark™ for fertilisers they marketed.
3. The CoP only applied to manufacturers registered under Fertmark™.

With the amendment to the ACVM Act in 2007, section 28 was amended to replace Codes of Practice with Operating Plans. The CoP for fertilisers was not deemed to fit with the model for an operating plan and therefore was not converted. On 1 October 2010, the CoP lapsed under the ACVM Act. This meant Fertmark™ became industry guidance and therefore no longer had any legal standing under the ACVM Act and its regulations.

4 ACVM risk management framework

An operational policy in the late 1990s was developed on establishing thresholds and criteria for each of the risk areas under the ACVM Act. In summary, the thresholds are based on an unquantified potential for risks in the prescribed areas of trade in primary produce, animal welfare, agricultural security and domestic food residue standards (NB the risk area to public health was added under an amendment to the ACVM Act in 2007). Criteria have been identified as things to be considered when deciding if any of the thresholds have been exceeded.

A risk assessment matrix was developed based on probability x impact recognising that this would be a qualitative assessment and as such a low/medium/high scale was used for both probability and impact.

This matrix was used to determine what groups of agricultural compounds should be exempt from registration under regulations. Based on this, fertilisers were considered of low risk in the ACVM Act risk areas and therefore proposed to be exempt from registration provided a condition of the exemption referenced a standard (as discussed in the background above).

Since that time, the ACVM risk assessment framework has been updated, although the principles are still the same. The current regulatory framework is outlined in the document 'Risk Assessment under the ACVM Act' (http://foodsafety.govt.nz/elibrary/industry/Risk_Assessment-Explains_Nzfsa.pdf).

5 Problem definition

Exemption of product groups from registration under the ACVM (E&PS) Regs is passive regulatory oversight. The exemption and any related conditions are based on MPI's assessment of the risks of the product group in relation to the ACVM Act risk areas. Exemptions from registration for groups of products are considered if the magnitude of their risks, when mitigated by associated conditions, are not considered to reach the threshold for active regulatory oversight, i.e. registration. This is currently the case for the 'fertiliser and fertiliser additive' product group.

For the 'fertiliser and fertiliser additive' product group and all other exempted from registration product groups, the ACVM (E&PS) Regs outlines a number of expectations, in the form of conditions, for importers, manufacturers, distributors and end users. Because these expectations cover all product groups exempted from registration, they are fairly high level and generic in nature.

In addition, as noted above in the Background section, the removal of the Fertmark™ CoP has meant legislative guidance on requirements for fertilisers to ensure compliance with the ACVM (E&PS) Regs is no longer in force. Feedback from some stakeholders has indicated there is less certainty on compliance with these regulations over the manufacture, sale and use of fertilisers and fertiliser additives. This is because the ACVM (E&PS) Regs are generic in nature and provide minimal requirements on those product groups exempt from registration. This makes it difficult for the parties involved to be confident that they have met the conditions, resulting in the risk management being compromised.

To date, no significant compliance issues with fertilisers and fertiliser additives under the ACVM Act and its regulations have occurred. The main type of compliance issue has been around complaints on whether the product is, in fact, an agricultural chemical rather than a fertiliser. It should be noted that the issue with dicyandiamide (DCD)[1] was around its use as a nitrification inhibitor and inhibitors per se are not within the scope of the definition of an

[1] DCD can be used as a fertiliser, but its primary use was as a nitrification inhibitor

agricultural compound under the ACVM Act and hence are not within the scope of the definition of a fertiliser.

The 2009 slice of life review of fertilisers[2] indicated conventional fertiliser manufacturers had good awareness of the ACVM Act and its regulations, while organic and novel fertiliser manufacturers had less awareness of the ACVM Act and its regulations than conventional fertiliser manufacturers.

The review also highlighted that Fertmark™ is principally utilised by conventional fertiliser manufacturers (and not by organic fertiliser manufacturers), but not all conventional fertilisers manufactured are subject to Fertmark™ branding. In relation to the auditing of Fertmark™, the review noted the auditors focused on commercial aspects of it, and not ACVM Act and regulation requirements.

In the last 3-4 years, some stakeholders (such as producer sector groups and industry associations) have raised concerns over the level of regulatory oversight of product groups (and particularly fertilisers) exempted from registration under the ACVM (E&PS) Regs. These concerns relate to the lack of traceability should a compliance issue arise from the use of a fertiliser both for the industry and regulator, and insufficient details on requirements to ensure compliance with the ACVM (E&PS) Regs. The latter concern was focused around residue management to ensure food based animal or plant commodities complied with residue standards set by MPI. While MPI recognises there is some merit to some of these concerns, there have been few compliance issues reported to MPI (note that absence of reporting does not always equate to absence of issues).

However, the lack of reported compliance issues indicates that in general the exemption from registration for fertilisers and fertiliser additives appears to be meeting MPI's expectations on the level of regulatory oversight. In stating this, it is acknowledged that the approved CoP (Fertmark™) as part of the package to facilitate such an exemption no longer has any regulatory underpinning. Some stakeholders (as stated above) have concerns over this lack of clarity. Furthermore, the slice of life audit indicated that the CoP (now industry guidance) does not apply to all fertiliser manufacturers.

Consequently, MPI considers compliance in the future could be compromised without further clarity, which will ensure that the fertiliser industry (including importers, manufacturers, distributors, retailers and end users) can comply with the ACVM (E&PS) Regs, and which will enable MPI to enforce these regulations.

6 Options

We have identified the following three options to address the problem above.

Option 1: Exemption by regulation from ACVM registration with conditions (status quo)
Fertiliser products would remain exempt from the requirement for ACVM registration under the ACVM (E&PS) Regulations 2011, with conditions as stated in the ACVM (E&PS) Regulations 2011.

Option 2: Registration with specified requirements
Each fertiliser product would require registration. However, registration requirements for the group of products can be reduced based on a risk assessment of the fertiliser product group. Reduced chemistry and manufacturing requirements, efficacy and plant safety, or residue requirements may be considered appropriate.

[2] See http://www.foodsafety.govt.nz/elibrary/industry/Slice_Life-Chemicals_Medicines.htm

Option 3: Exemption under the ACVM (E&PS) Regulations 2011, with specific requirements included in legislative notice

Fertiliser products would remain exempt from the requirement for ACVM registration under the ACVM (E&PS) Regulations 2011. High level conditions would remain as set out in the ACVM (E&PS) Regulations 2011, with the addition of a legislative notice under section 76(A) of the ACVM Act[3] which would give specific and clear expectations to importers, manufacturers, distributors and end users on complying with the ACVM (E&PS) Regulations with respect to fertilisers. The notice, or a series of notices, can apply to all fertilisers and fertiliser additives or to a reduced scope. The high level conditions in the ACVM (E&PS) Regulations would still apply to fertiliser and fertiliser additive products outside the scope of the notice.

We would like to hear what your views are on these three options, and their advantages and disadvantages. If you would like to suggest another option, please provide a description of that option, why you consider that to be a better option, and any advantages and disadvantages.

[3] Under section 76(A) of the ACVM Act:
The Director-General may from time to time issue notices setting specifications and other detailed requirements that—
(a) are specified or contemplated by or necessary to give effect to any regulation made under section 75; or
(b) are necessary or desirable to amplify the manner in which the requirements of any such regulation may or must be achieved.

7 Analysis of options

Table 1: Advantages and Disadvantages of Options on the Regulatory Oversight of Fertilisers under the ACVM Act and its Regulations

Option	Compliance	Advantages	Disadvantages
Option 1: Exemption by regulation from ACVM registration with conditions (status quo)	No information about products is submitted to or held by MPI. Involved parties are responsible for determining whether they are complying with conditions. Compliance action by MPI may be taken if conditions are knowingly not met.	• Requirements for compliance are very outcome focused allowing the responsible party more flexibility and adaptability in terms of how they are addressed. • No change in compliance costs to company • No significant change required to current MPI resourcing.	• As conditions are generic and fairly high level, companies (especially smaller operators) may not interpret conditions consistently. • MPI does not hold information to identify products or responsible parties should an issue arise, or if consultation is required.
Commentary: A preference for this option would suggest the current regulatory oversight is sufficient and clear to regulated parties and compliance with them in the future should not be a significant issue.			
Option 2: Registration with Specified Requirements	Each product would be managed under the ACVM Act, and compliance identical to that of other ACVM registered products. Every product would be recorded on the ACVM register, requiring any changes to be approved and registrations are renewed on a 3-yearly basis to ensure compliance. As regulatory conditions would be imposed, compliance can be taken against any person knowingly contravening the conditions.	• The ability to place a range of controls of a trade name product covering importation, manufacture, sale and use. • Each product would be appraised individually. • Potential issues involving efficacy, plant safety, residues and potential organic or inorganic contamination could be identified and managed on a case-by-case basis. • Industry sectors and other stakeholders would have greater visibility of fertilisers on the market via a public register. This would assist them in managing any risks they associate with fertilisers.	• Increased compliance cost to registrant (both initial registration, and ongoing, including annual fees, renewal fees, and applications to change any aspect of the registration) with the benefit of such increased compliance costs not significantly outweighing the current low regulatory oversight. • Some fertiliser products do not lend themselves to the registration model as they are either sold in bulk or made to order. • Would require a change to the regulations.
Commentary: A preference for this option would suggest the current regulatory oversight is insufficient and unclear to regulated parties and compliance with them in the future is likely to be a significant issue if registration was not in place.			

Option 3: Exemption under the ACVM (E&PS) Regulations 2011, with specific requirements included in legislative notice	No information about products is submitted to or held by MPI. Manufacturers, importers, and sellers are responsible for determining whether they are complying with the ACVM (E&PS) Regs and notice. Compliance action by MPI may be taken if conditions are knowingly not met.	• Re-introduces a similar level of requirements as originally conceived when this product group was considered for exemption from registration. • Provides clarity and certainty to regulated parties regarding requirements (and reduce the likelihood of mis-interpretation). • Low additional compliance cost to fertiliser owners and regulators (when compared to the registration option). • Would reduce reliance on industry bodies to interpret conditions. • The notice may specify requirements which are outcome based, prescriptive or a mixture of both. • Would allow compliance by MPI to be more effective due to the specific nature of the notice. • Scope could be amended to include only fertilisers sold in commercial quantities and/or non-biological fertilisers. To accomplish this, the ACVM (E&PS) Regulations would not need to be amended. The notice (or a series of notices if required) could be written specifically for the subset chosen, and these would be additional to the conditions under the ACVM (E&PS) Regulations. All other fertilisers or fertiliser additives would still be exempt under the ACVM Regulations (E&PS) and subject to the conditions specified.	• MPI does not hold information to identify products or responsible parties should an issue arise, or if consultation is required. • Industry sectors and other stakeholders would not have greater visibility of fertilisers on the market via a public register. • Requires development of a notice.

Commentary: A preference for this option would suggest the current regulatory oversight is insufficient and unclear, and compliance with them in the future could be a significant issue if they are not clarified.

8 MPI's preferred option

MPI' prefers option 3 because MPI considers the current passive regulatory oversight of fertilisers and fertiliser additives is sufficient provided further clarity of the rules is introduced. This option reflects the original thinking of MPI when the fertiliser and fertiliser additives were considered, and it is considered to still be of relevance.

The addition of a legislative notice under section 76(A) of the ACVM Act would give specific and clear expectations to importers, manufacturers, distributors and end users on complying with the ACVM (E&PS) Regs with respect to fertilisers. The notice, or a series of notices, can apply to all fertilisers and fertiliser additives or to a reduced scope. The high level conditions in the ACVM (E&PS) Regs would still apply to fertiliser and fertiliser additive products outside the scope of the notice.

It should be noted that section 76(A) was not in the original ACVM Act, so it was not available as a regulatory tool when the Act commenced back in 2001. This section, which was added by an amendment to the Act in 2007, provides a more appropriate regulatory tool to the type of situation identified in this discussion document compared to the tools (e.g. CoP) available when the Act commenced.

9 Elements of a possible ACVM Fertiliser (Specifications) Notice

Should there be support for option 3, but further details on a notice would be helpful in reaching this support, MPI can elaborate on some key specifications that could be included in the notice. Feedback on these elements would be beneficial to MPI on the development of this notice.

These are outlined in Appendix 2.

10 Next steps

Subject to submissions received as part of this consultation, if options 2 or 3 are considered the preferred option, then the following steps would be required.

Option 2 – Registration
This would require amendment to the ACVM (E&PS) Regs to remove fertilisers and fertiliser additives from schedule 2. This would involve a public consultation process to allow comment on the proposal to amend the regulations, drafting by Parliamentary Counsel Office (PCO) of amended regulations, and then sign off by the Government. In parallel to this process MPI would need to develop forms and information requirement documents and consult with industry on them.

Option 3 – Notice
MPI would develop a draft notice which would be subject to public consultation. Once finalised, the notice would be signed off by the Director-General of MPI (or a person acting under delegated authority).

Questions for Feedback

1. Do you agree with MPI's characterisation of the problem identified in section 5 above? If not, why not?

2. What are your views on the three options discussed in this paper, and what you consider to be the costs and benefits of the three options?

3. Would you like to suggest another option? If so, please provide a description of that option, reasons for supporting that option and its advantages and disadvantages.

4. Do you currently import or manufacturer fertilisers and/or fertiliser additives? How would the three options impact on your business practice?

5. What are your views on MPI's preferred option in section 8 above?

6. Do you have any other comments on the proposed specifications for a fertiliser notice in Appendix 2? Have specifications been missed or are those included considered inappropriate?

NB: Feedback does not have to be limited to answering these questions.

Appendix 1: Definition of Fertiliser and Fertiliser Additive under the ACVM (E&PS) Regs

Fertiliser:
(a) means a substance or biological compound or mix of substances or biological compounds that is described as, or held out to be suitable for, sustaining or increasing the growth, productivity, or quality of plants or, indirectly, animals through the application to plants or soil of—
(i) nitrogen, phosphorus, potassium, sulphur, magnesium, calcium, chlorine, and sodium as major nutrients; or
(ii) manganese, iron, zinc, copper, boron, cobalt, molybdenum, iodine, and selenium as minor nutrients; or
(iii) fertiliser additives; and
(b) includes non-nutrient attributes of the materials used in fertiliser; but
(c) does not include substances that are plant growth regulators that modify the physiological functions of plants

Fertiliser Additive:
(a) means a non-nutrient substance added to a fertiliser, or applied by itself to land or plants, that—
(i) improves the supply and uptake of nutrients; or
(ii) increases biological activity; or
(iii) modifies the physical characteristics of a fertiliser to make it more fit for its purpose; but
(b) does not include substances that are plant growth regulators that modify the physiological functions of plants

Appendix 2: Key specifications for a possible ACVM Fertiliser (Specifications) Notice

The requirements under section 76(A) of the ACVM Act for issuing a notice must be within the scope of the relevant regulations, in this case the ACVM (E&PS) Regs. The notice cannot state specifications outside this scope as this would be ultra vires.

Therefore, the relevant regulations in the ACVM (E&PS) Regulations with respect to fertilisers and fertiliser additives are:

Reg 7 Fit for purpose
Reg 8 Fit for purpose: use of exempt agricultural compound
Reg 9 Manufacture of exempted compound product to be in accordance with documented system
Reg 11 Regulations 9 and 10 to apply if operating plan required
Reg 12 Information requirements
Reg 13 Misleading statements about exempt compound product or compounded veterinary preparation
Reg 14 Recording of documented system and of actions taken in accordance with documented system
Reg 15 Records to be kept to importer in relation to exempt compound products

In addition, the fertiliser and fertiliser additive exemption from registration under schedule 2, 41 places a condition of a requirement to state on the label the nutrient content and modifying pH value, if applicable.

With these regulations as the basis for specifications of the notice, the following areas are contemplated for inclusion into the notice for fertilisers and fertiliser additives:

Reg	Suggested inclusions
7	Fertilisers 1. Particle size 2. Clarification on macro and micro nutrients 3. Minimum levels of N, P, K, S 4. Level of selenium 5. Allowable ranges of stated nutrients Fertilisers and Fertiliser Additives 1. Levels of impurities, e.g. lead, cadmium, micropathogens 2. Contamination limits, e.g. seeds (particularly bulk fertilisers), pests, diseases, ruminant protein (blood and bone) 3. Compliance with Import Health Standards issued under the Biosecurity Act 1993
8	Follow label instructions
9	1. Details on facility hygiene and maintenance, process controls, calibration control points 2. Product recall
11	Not applicable
12	1. Clarity on labelling of bulk fertilisers

	2. Clarity on the nutrient content (as specified in the condition) 3. Consistency of representation of nutrients 4. Clarity on misleading trade names
13	1. Clarity on the scope of this regulation 2. Clarity on what is considered acceptable advertising 3. Clarity on what is considered unacceptable advertising
14	Nothing specific
15	Nothing specific