

Submission

on Behalf of
The Fertiliser Association of New Zealand

on
**Proposed changes to the
Agricultural Compounds and Veterinary Medicines
(Exemptions and Prohibited Substance) Regulations 2011**
(MPI Discussion paper No. 2017/30)

To
ACVM Regulations proposals
Ministry Primary Industries
Food Policy Team
PO Box 2526
Wellington 6140

E:mail : ACVM.Consultation@mpi.govt.nz

Contact: Greg Sneath
Organisation: The Fertiliser Association of New Zealand
Postal Address: PO Box 11519, Manners St, Wellington, 6142
Phone: (04) 473 6552
E-mail: info@fertiliser.org.nz

Date: 19 October 2017

Introduction

1. The Fertiliser Association of New Zealand ('**FANZ**' or 'the Association'), is a trade organisation representing the New Zealand manufacturers and suppliers of fertiliser. The Association has two 'member companies' – Ballance Agri-Nutrients Ltd and Ravensdown Ltd. Both these companies are farmer co-operatives with some 45,000 farmer shareholders. Between them these companies supply over 98% of all fertiliser used in New Zealand.
2. The member companies have invested significantly in systems and procedures for quality management of fertiliser production and use. The Association supports the provision of robust systems and recommendations for responsible nutrient management to support a viable primary industry and environmental responsibility.
3. The Association takes a particular interest in regional and national policy statements, regulation and guidelines which support sustainable management of natural and physical resources, and seeks that any regulation that may address the use fertilisers is appropriate and necessary to achieve its intent.

Context and background

4. The Fertiliser Association (FANZ) acknowledges the general intent of this proposed amendment to the regulations, which is understood to be to facilitate access to new products, without compromising public health, trade in primary produce and animal welfare. These changes are also intended to reduce costs through less products requiring registration, and increased clarity and certainty about which products are exempt.
5. The proposed changes are understood to:
 - add new compound groups to enable more products to be exempt
 - provide more clarity to existing exemptions
 - amend some individual regulations to incorporate new information such as definitions.
6. MPI is particularly interested in understanding if any additional costs may be imposed through these changes, especially where risk profiles for some product groups are proposed to change.
7. The discussion paper states that the purpose of the ACVM Act is to:
 - a. prevent or manage risks associated with the use of agricultural compounds. This covers risks to public health, trade in primary produce, animal welfare, and agricultural security;

- b. ensure that agricultural compound use does not result in breaches of domestic food residue standards; and
 - c. ensure that consumers are provided with sufficient information about agricultural compounds.
8. The ACVM framework reflects a risk-based approach to managing the use of agricultural compounds, with regulations set at a level commensurate to the risk the compounds pose. The framework provides for three categories of use:
- a. Prohibited from being used as an agricultural compound. These substances are specified in Schedule 1 of the Regulations.
 - b. Able to be used but requires registration (as a trade name product) subject to specifically imposed conditions.
 - c. Able to be used and exempt from requiring registration. Exemption may be provided by one of three routes under section 8A(1) of the Act:
 - i. regulations made under section 75;
 - ii. listed as a substance generally recognised as safe (GRAS) for use under section 8B of the Act;
 - iii. approved on the basis of special circumstances under section 8C of the Act.
9. The regulations for exemption from registration or prohibited substances set specific obligations and responsibilities that apply to importers, manufacturers, sellers and users of exempt compounds.

Key regulations include:

- Regulation 7, which sets out criteria for “fitness for purpose” that applies to any exempt compound imported, manufactured or sold in New Zealand.
- Regulation 8, which requires users of exempt compounds to comply with the requirements for the products ‘fitness for purpose’.
- Regulation 12, which specifies information that must be provided with the product or preparation (that is, labelling requirements).

SUBMISSION

The intent of the proposed amendments:

Comment

10. FANZ supports a risk based approach to managing the use of agricultural compounds, with the controls applied being commensurate with the level of risk the agricultural compounds may present.
11. FANZ recognises that new product groups are being brought to the market with new applications, and internationally the laboratory test methods for detecting contaminants and is becoming more sophisticated and more stringent. These new products groups and new detection risks must be managed, while enabling industry to benefit from application of new and improved agricultural compounds. To that end, FANZ supports the general intent of the proposed changes to the ACVM Regulations.
12. However, caution is also raised that the broad categories, such 'Plant biostimulants' for example, should not be so open as to allow new product to be introduced under the fertiliser/biostimulant category without adequate assessment, information and understanding of the management of potential risks. To this end adequate resourcing and monitoring will be required by the regulator.
13. Without adequate resourcing for enforcement and clear specification of requirements for exemption, the proposed regulation may not achieve the objectives of proposed regulation
14. Specific comment on the detail of the proposed amendments are considered primarily with respect to the manufacture, importation and use of fertiliser products.

Section 5.3 Clarifying entries in Schedule 2 and improving risk management

5.3.1 Substances with no agricultural compound claims

15. FANZ is concerned that this section, (Section 5.3.1) of the discussion document, is headed by a statement that Entry 2 of Schedule 2, that it applies to "*generic substances with no agricultural compound claims but are used as such*". This interpretation does not seem to be consistent with the text in the regulations which reference Schedule 2 or in Schedule 2 Entry 2, itself.
16. It is proposed to:

change the 2nd entry description in Schedule 2, columns 1 and 2 as follows:

Product Description	Conditions
<p>Substance or compound (not being an agricultural compound described elsewhere in this schedule)—</p> <p>(a) prepared by a person (person A) for use on animals or plants owned by person A, or in any land, place, or water owned or occupied by person A (and not for sale); or</p> <p>(b) used by person A, or a person employed or engaged by person A, or another person expressly authorised by person A, as described in paragraph (a)</p>	<p>If the substance or compound is used by a person employed or engaged by person A or another person expressly authorised by person A, the use must be in accordance with written instructions from person A about—</p> <p>(a) how the substance or compound is to be stored, prepared for use, administered, applied, and (if applicable) disposed of; and</p> <p>(b) how the safety and welfare of any person or animal who may come into contact with the substance or compound is to be protected and how any pain or distress of an animal is to be mitigated; and</p> <p>(c) how third parties are to be contacted or advised of the use of the substance or compound and warned of any hazards relating to the use of the compound</p> <p>The following substances or compounds may be prepared or used as described in column 1 only in compliance with an approved operating plan:</p> <p>(a) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981);</p> <p>(b) antibiotic active ingredients;</p> <p>(c) hormones;</p> <p>(d) substances that are prohibited by countries importing New Zealand primary produce;</p> <p>(e) vertebrate toxic agents</p> <p><i>Unless there is an approved operating plan, ingredients the compounds must not contain:</i></p> <ul style="list-style-type: none"> • <i>antibiotic substances</i> • <i>hormones</i> • <i>pharmacological substances</i> • <i>solvents or penetrating agents</i> • <i>active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981)</i> • <i>substances that are prohibited by countries importing New Zealand primary produce</i>

Comment:

17. The rationale presented in the discussion document for the proposed change is that currently entry 2 creates uncertainty about the appropriate exemption group for some compounds. *“This could mean a substance that should be solely subject to entry 2 (and its conditions) could be subject to other entries. This is not the intention. For example, the exemption allows a person to buy a shampoo sold for human use and use it to wash their dog as long as they take care not to harm the dog and the shampoo is not medicated with, for example, a prescription medicine. However, because cleaning products, including shampoos, are described in entry 13, entry 2 might not apply, which is not the intention.”*
18. The deletion of the proposed wording (*not being an agricultural compound described elsewhere in this schedule*) for entry 2 will require that entry 2 applies to all substances or compounds exempt from registration, prepared by a person **or used** by a person in any land, place, or water owned or occupied by that person.
19. The condition for this entry requires that for all exempt substances or compounds, if the product is *“used by a person employed or engaged by person A or another person expressly authorised by person A, the use must be in accordance with written instructions from person A”*.

While it is accepted that minimum information is required (as described in Regulation 12, *ACVM (Exemptions and Prohibited Substances) Regulations 2011*, and Section 2.1.2 in the *ACVM Notice: Agricultural Compounds Exempt from Registration.1 August 2017*), the proposed requirement that express written instructions must be provided by person A, will be onerous in the case of application of many fertiliser products, or indeed for the example provided in the discussion document. (i.e. where a human shampoo product is used to wash a dog, provided it does not contain a prescription medicine.)

Decision sought:

20. Make it clear that the conditions of Entry 2 require that “minimum information” must be provided by person A to a person using the product who is employed or engaged by person A. (Where it is expected that product groups will require more than the minimum information, this would be covered by the conditions in column 2, of schedule 2, under the entries 3-41.)
21. In the alternative, if it is not the intention that Entry 2 requires minimum information to be provided to the user, retain the clarification that the Entry, and conditions apply only to agricultural compounds which are not addressed by other entries in Schedule 2.

22. If it is the intention to provide regulatory controls for generic substances which do not have agricultural compound claims, then further consultation is required on how such products should be captured under the Agricultural Compound and Veterinary Medicines Act, or by some other mechanism.

Section 5.3.12 Entry 41- Fertilisers and fertiliser additives

23. It is proposed to amend entry 41, in Schedule 2, to read:

“Fertilisers and plant bio-stimulants”

24. The condition applicable to this entry is proposed to be altered to include ‘active ingredients’ so that it reads as follows:

“The label must specify nutrient content, active ingredients and modifying pH value, as applicable”

25. The interpretation and application of this entry is also influenced by the amendments whereby; the definition of ‘fertiliser’ is to be amended, definition for ‘fertiliser additive’ deleted, definition for ‘plant bio-stimulant’ introduced, definition for ‘plant nutrient’ introduced and definition for ‘animal nutrient’ introduced. (These definitions will each be submitted on separately.)
26. The rationale presented in the discussion document states that removal of reference to ‘fertiliser additive’ and removal of the definition for ‘fertiliser additive’ does not remove the exemption status for fertiliser additives, as these are anticipated to be addressed under Entry 28 of Schedule 2.
27. Entry 28 of Schedule 2 states in column 1 (agricultural compound):
- “Agricultural chemical synergists and other adjuvants, including wetting and sticking agents, pH buffers, drift retardants, and water conditioners”*

There are no conditions which apply to Entry 28, in column 2 (conditions)

Comment:

28. The nature and action of ‘fertilisers’ which provide essential nutrients, is very different to the nature and action of ‘plant bio-stimulants’ which enhance plant growth (the definition of which excludes plant growth regulators but includes other “*substances or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural growth processes or enhance/benefit plant nutrient uptake, plant nutrient efficiency, tolerance to abiotic stress, or crop quality*”
29. Presumed examples of bio-stimulants under this definition may include: water gel crystals to alleviate water stress, mycorrhizal fungi, composts or

organic matter or other substances which might ameliorate toxicity of contaminants, substances which alleviate effects of salinity, pH (Lime) etc.

30. There are no specific reasons why this wide range of substances with a variety of mechanisms for supporting plant growth should not be introduced under the group name 'Plant biostimulants' and addressed in Schedule 2. However, given the very different nature of action compared to fertilisers, and to future proof the regulation, with potentially different treatment of fertilisers and plant biostimulants, it would be sensible to provide a new entry, Entry 42, specifically for 'Plant bio-stimulants'.
31. A separate entry for Plant biostimulants would retain a clear distinction between fertiliser and plant biostimulants, which would be consistent with other statutory regulation, such as HSNO regulations and Fertiliser Group Standards.
32. Hence inclusion of plant bio-stimulants to Schedule 2 is supported, however, it should be as a new Entry 42.
33. Costs introduced to the industry may be incurred through new documentation required for products such as lime, which might be introduced as 'Plant biostimulants'.
34. In consideration of the proposal to delete reference to 'fertiliser additives', the range of products which may be considered fertiliser additives, may not necessarily be covered adequately by Entry 28, Schedule 2. If fertiliser additives are intended to be addressed by the exemption status, it may be best to retain reference to fertiliser additives in Entry 41.
35. The definition of a fertiliser additive may be defined as something a little more specific, but still providing for a range of products. For example, being a substance or compound, which is sold or supplied separately to the fertiliser product, but applied with the fertiliser. (Hence this definition would exclude fertiliser coatings or free-flow agents which would be captured by the fertiliser product itself, as "*non-plant nutrient attributes of the materials used in fertiliser*". Fertiliser additives could however include selenium selenate, iodine or cobalt should they be excluded from the definition of fertiliser as proposed. There may be other examples of products which could be described as fertiliser additives, but not fit the description under Schedule2, Entry 28).
36. In relation to the conditions proposed for entry 41, 'Fertiliser and Plant biostimulants', the addition of a requirement for the label to specify 'active ingredients', is probably redundant, as it is already a requirement under Reg 12, minimum information. If required for this entry, then it should probably also be specified for all other entries. However, to rationalise, and improve consistency in Schedule 2, the specific requirement should be removed from the proposed wording for this condition.

37. It is recognised the term 'active ingredient' might not be directly applicable to some plant biostimulants, (e.g. where it is a biological agent such as rhizobia). For clarity, identifying 'mode of action' could be specified as condition for plant biostimulants.
38. Furthermore, it may be useful to address the manner in which impurities are managed. An industry voluntary limit could still be applied without regulation of a threshold level, but how best to address how impurities are managed, by all importers or manufacturers to ensure products are 'fit for purpose' is something that requires more detailed consultation and discussion.

Decisions sought:

39. Include the proposed amendment to add 'Plant Bio-stimulants' to Schedule 2, however, it should be included as a new entry, "Entry 42" and
40. The associated condition for the new entry Plant biostimulants should be amended to read:

"The label must specify ~~nutrient content, active ingredients~~ mode of action and modifying pH value, as applicable"

41. Reject the proposed deletion of the term 'fertiliser additives' from Entry 41, and
42. Seek a modified definition of 'Fertiliser Additive' e.g. substance or compound, which is sold or supplied separately to the fertiliser product, but applied with the fertiliser, as follows:

Fertiliser additive—

- (a) means a non-nutrient substance ~~added to a sold separately to the fertiliser, or applied by itself~~ but applied with the fertiliser 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

The associated condition for entry 41, Fertiliser and Fertiliser additive, should be amended as follows:

"The label must specify nutrient content, ~~active ingredients~~ mode of action and modifying pH value, as applicable."

Engage with further consultation and discussion with industry on how to best address the manner with which impurities are addressed to ensure the products are 'Fit for purpose'.

Section 7.1 Regulation 3 - Interpretation

Definition of Fertiliser

43. The proposed definition for fertiliser is as follows:

- (a) means a substance or biological compound or plant material or mix of substances or biological compounds or plant material 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 plant nutrients; and*
- (b) includes non-plant 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*

Comment:

44. It should be considered that because the definition only applies to plant nutrients, it explicitly excludes some elements applied to soils or pasture for the indirect benefit of animals. The definition will exclude elements such as cobalt, copper, iodine or selenium if applied in fertiliser for the benefit of livestock. Of these, only copper is an essential element for plants.

45. These elements applied with fertiliser, for the indirect benefit of animals do not need to be considered in the definition of fertiliser if they are supplied through some other pathway. The Schedule 2, Entry 28 is intended to include all fertiliser additives. Entry 28 applies as follows, and is probably not broad enough to include these essential elements for animal health:

“Agricultural chemical synergists and other adjuvants, including wetting and sticking agents, pH buffers, drift retardants, and water conditioners”

46. For this reason, it is considered that the proposed definition for fertiliser does not adequately apply for essential elements for animal health, and so the reference, *“indirectly, animals”* could be deleted without changing the proposed meaning. Conversely, if the definition of fertiliser is intended to include application of elements essential for animal health, then this should be provided for specifically.

For example:

Fertiliser -

- (a) means a substance or biological compound or plant material or mix of substances or biological compounds or plant material 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 ~~plant nutrients~~; and

(i) nitrogen, phosphorus, potassium, sulphur, magnesium, calcium, chlorine, and sodium as major essential elements;

or

(ii) manganese, iron, zinc, copper, boron, cobalt, molybdenum, iodine, and selenium as minor essential elements; and

(b) includes non-plant 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

Definition of Plant Nutrient

47. A new definition, that of “plant nutrient” is proposed as follows:

chemical elements and compounds necessary for plant growth, including, but not limited to—

a) macronutrients (nitrogen, phosphorous, potassium, calcium, sulphur and magnesium); and

b) micronutrients (boron, chlorine, manganese, iron, zinc, copper, molybdenum, and nickel)

Comment:

48. As discussed above, the proposed definition of fertiliser excludes essential elements for animals. The proposed definition for Plant nutrients is much wider than essential elements, and includes, and is not limited to “*Compounds necessary for plant growth*”.

49. ‘Plant nutrient’ compounds necessary for plant growth could be very wide and varied. For example, it could be argued the definition for “Plant nutrients” captures water, glucose, plant growth regulators or many other compounds necessary for plant growth.

50. There seems to be no particular advantage for including a wide range of compounds as plant nutrients. The specific term ‘Plant nutrient’ does not seem to appear in the current wording of the ACVM Exemption and Prohibited substances regulations. In the proposed new wording for the regulation, the term ‘Plant nutrient’ appears only in the definition of fertiliser, conditions under entry 41, Schedule 2, and the definition of Plant bio-stimulant.

51. The proposed changes do not make it clear why any compound necessary for plant growth (and not limited to these) should be included in the definition of Plant nutrients.

Recommendation:

52. Delete the definition for plant nutrient and specifically reference essential elements for plants and animals in the definition of fertiliser as shown above in paragraph 42.
53. In the alternative,
delete the reference to “compounds” in the definition of ‘Plant nutrients’, so that the definition explicitly applies to essential elements necessary for plant growth, as follows:

chemical elements ~~and compounds~~ necessary for plant growth, including, but not limited to—
a) *macronutrients (nitrogen, phosphorous, potassium, calcium, sulphur and magnesium); and*
b) *micronutrients (boron, chlorine, manganese, iron, zinc, copper, molybdenum, and nickel)*

(if not included in the definition of fertiliser, essential elements for livestock applied with fertiliser would need to be recognised through some other mechanism e.g. fertiliser additive).

Definition of Plant biostimulant

54. A new definition, that of “Plant biostimulant” is proposed as follows:
- contains substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural growth processes or enhance/benefit plant nutrient uptake, plant nutrient efficiency, tolerance to abiotic stress, or crop quality. It does not include substances that are plant growth regulators that modify the physiological functions of plants*

Comment:

55. As discussed in paragraphs 28 and 29 above, the definition for ‘Plant biostimulants,’ excludes plant growth regulators but captures a wider range of other compounds, including lime. For example, this definition may include: water gel crystals to alleviate water stress, mycorrhizal fungi to enhance nutrient uptake and provide symbiotic benefits to plant growth, rhizobium inoculants, composts or organic matter or other substances which might ameliorate toxicity of contaminants, substances which alleviate effects of salinity, pH etc.
56. It is presumed products like urease inhibitors are considered to improve plant nutrient efficiency by providing for better availability of nitrogen applied to the soil, however, it is not necessary for these products or some of the other products listed in paragraph 50 above, to be applied to the plant or rhizosphere for their activity. Exemption from registration might instead be provided, if they are accepted as ‘agricultural chemical

synergists' as per Entry 28 Schedule 2. This may be a grey area if the products are applied on their own and not in combination with another product (e.g. fertiliser). Another example might be nitrification inhibitors. If not 'agricultural chemical synergist', these and other products listed in paragraph 50 may be considered a 'plant biostimulant', enhancing plant nutrient efficiency. In this case, such a product would be addressed under a new entry for plant biostimulants, Entry 42, Schedule 2.

Recommendation:

57. Amend the definition for 'Plant biostimulant' as follows, to give effect to products which are not fertilisers, but may provide these benefits if not applied specifically to the plant or rhizosphere.

contains substance(s) and/or micro-organisms whose function when applied to plants, ~~or the rhizosphere, or soil,~~ is to stimulate natural growth processes or enhance/benefit plant nutrient uptake, plant nutrient efficiency, tolerance to abiotic stress, or crop quality. It does not include fertilisers nor substances that are plant growth regulators that modify the physiological functions of plants

Concluding comment:

58. The Association is grateful for the opportunity to comment and provide feedback on the proposed amendments to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.
59. The Association recognises the issues being addressed are complex and options and solutions are difficult to resolve. The Association and its member companies seek to further discuss and address matters of interest or concern raised in this submission, to assist in seeking the most satisfactory solutions, to achieve the intended purpose.



Greg Sneath

Executive Manager

Fertiliser Association of New Zealand

19 October 2017