



Implementation of the ACVM Act: Regulatory changes

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Submissions

NZFSA seeks submissions from all interested parties on any aspect of the Agricultural Compounds and Veterinary Medicines Act 1997.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section of the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Omissions should be clearly and separately indicated.
- Comments should be to the point and, where possible, reasons and data to support comment are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- The title of the discussion document
- Your name and title (if applicable)
- Your organisation's name (if applicable)
- Your address
- The number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 11 July 2008.

Your comments should be sent to:

Policy Group

New Zealand Food Safety Authority

PO Box 2835, Wellington

Fax: 04 894 2583

Email: policy@nzfsa.govt.nz

Please note that your submission is public information and subject to the Official Information Act (OIA) 1982. The OIA states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are stated in the OIA.

If you consider that any or all information in your submission should be treated as confidential or is commercially sensitive, please state this clearly when making your submission.

NZFSA will take any such indication or request into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

Implementation of the ACVM Act: Regulatory changes

1 Introduction

1.1 Reform of the ACVM Act's administration

The New Zealand Food Safety Authority (NZFSA) has begun a reform of the administration of the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). One of the main reasons for the reform is that some regulatory arrangements need to be updated to reflect amendments that were made to the ACVM Act in 2007. The reform is also an opportunity to reconsider the way that the ACVM Act is implemented and to seek feedback from stakeholders. This discussion document is the first in a series that will be released for public consultation as part of the reform process.

The ACVM Act controls agricultural compounds and veterinary medicines used in association with animals and plants. The ACVM Act's purpose is to:

- prevent or manage risks to public health, trade in primary produce, animal welfare, and agricultural security associated with the use of agricultural compounds
- ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards, and
- ensure the provision of sufficient consumer information about agricultural compounds.

1.2 Purpose of this document

The document focuses on the areas of manufacturing, labelling, advertising and promotion, and own use. "Own use" refers to the practice of using substances (or products) on one's own animals or plants in a manner that has not been specifically authorised. It is distinct from "off-label" use, which is the use of a product that is available as an agricultural compound in an unauthorised way.

Most of the proposed changes in this document are to do with putting existing regulatory obligations that are currently to be found in a number of places into regulations under the ACVM Act. NZFSA is also revising its standards and information requirements at the same time. All regulations will be

subject to consultation during the regulation making process. Where necessary, technical detail will be documented in notices issued after appropriate consultation.

1.3 Background

Manufacturing, labelling, advertising and promotion, and own use are managed in a variety of ways. Conditions of registration are placed on each registered trade name product and also linked to NZFSA standards. Where products are exempt from registration, the conditions are prescribed in regulations. Requirements have also been documented in standards, guidelines and information requirements.

The existing arrangements have been adequate for managing registered trade name products. The regime is not sufficiently flexible to manage the risks that arise around own use. In addition, the relevant exemption from registration does not clearly refer to the *ACVM Standard for Own Use of Agricultural Compounds* – see Schedule 1 of the Agricultural Compounds and Veterinary Medicines Regulations 2001 (the ACVM Regulations). As a result, regulated parties have not always been aware of the regulatory requirements -- increasing the risk that they inadvertently cause negative effects (such as jeopardising animal welfare). Furthermore, in NZFSA's view, the regulations to do with manufacturing, labelling and advertising of products that are exempt from registration do not go far enough in terms of setting appropriate regulatory expectations.

The amendment of the ACVM Act in 2007 has provided a wider range of mechanisms for the regulatory control of agricultural compounds and veterinary medicines. The use of these mechanisms is also more transparent now than would have been the case. The changes include the power to:

- make regulations governing a wider range of activities than the ACVM Act previously covered
- issue notices that set specifications and other detailed requirements
- recognise persons (including a manufacturing entity) to carry out specified functions for the purposes of the ACVM Act, and
- approve operating plans.

1.4 Next steps in the reform process

NZFSA will consider and analyse the feedback received on this document. The outcome of this stage of the consultation will provide the basis for making regulations and notices. A specific area of the NZFSA website has been set aside to provide up to date information throughout the reform process (see <http://www.nzfsa.govt.nz/acvm/subject/acvm-act/>).

NZFSA is also working with other government departments on aspects of the reform, including the scope of the ACVM Act and the risk thresholds and criteria for regulatory intervention. There will be ongoing discussions on the ACVM Act's relationships with other pieces of legislation, and the most suitable approaches to interdepartmental cooperation and communication.

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2 Manufacturing regulations

In brief, NZFSA proposes to make regulations that will:

- apply obligations consistent with the principles of responsible manufacturing to all manufacturers of agricultural compounds and veterinary medicines (see list below under heading 2.3 “Proposed regulatory regime”). These obligations are all existing requirements in the ACVM Standard for Good Manufacturing Practice and the ACVM guidelines for labelling and advertising, but they will be new for manufacturers of products that are exempt from registration.
- change the regulatory mechanism for the formal recognition of manufacturers of certain classes of agricultural compounds. This is not a material change; the only parties that would require formal recognition are those that are already required to be approved as manufacturers.
- set criteria for determining whether products manufactured overseas should be authorised for import, sale, and use in New Zealand.
- create a statutory requirement for all manufacturers of agricultural compounds to have an operating plan that describes how product will be manufactured and assessed as meeting specifications. This is a change in terminology, but as the expectation to have a documented manufacturing plan is not new, the statutory requirement should be no more onerous for manufacturers of registered products than what has always been expected. It will be a new requirement for manufacturers of products that are exempt from registration.
- impose a formal compliance programme on every manufacturer who has to be recognised by NZFSA under section 62 and have an operating plan approved under section 28. This will be new for most manufacturers of agricultural compound products; it is already the case for veterinary medicine manufacturers (see reference to Good Manufacturing Practice below) and manufacturers of restricted sale/restricted use vertebrate toxic agent products.

- administratively link manufacturers to the products being produced.

2.1 Use of terminology and definitions

The below terms and definitions are relevant to NZFSA's manufacturing proposals. Some are currently in use while others are proposed because existing terminology would be inappropriate or confusing under the intended reformed scheme for administering the ACVM Act. Where necessary, some of the terms may be applied in regulations.

Acceptable manufacturer means an overseas-based person/entity for whom there is sufficient evidence (other than an NZFSA assessment) to conclude that they are acceptable and, consequently, that products manufactured by them can be authorised for import, sale, and use (see heading 2.3.2 "Overseas manufacturers" for further information).

ACVM product class refers to the following broad classes of agricultural compounds:

- veterinary medicines
- agricultural chemicals
- oral nutritional compounds
- fertilisers, and
- vertebrate toxic agents.

Approved manufacturer means a manufacturer that holds a current NZFSA approval as a person/entity recognised to manufacture a particular class of agricultural compound.

Approved operating plan means an operating plan approved by NZFSA under section 28 of the ACVM Act.

Authorisation is a term introduced by the ACVM Amendment Bill. It refers to the designations that NZFSA can give to a person or product, including registration, exemption, and provisional registration. These authorisations are required to import, manufacture, sell or use agricultural compounds.

Distribute means to send an agricultural compound that has been manufactured for sale to wholesalers, retailers and/or end users; and includes transport and storage in any intermediate step to the end user. Distribution has a corresponding meaning.

Good Manufacturing Practice (GMP) refers specifically to the approval issued by NZFSA for manufacturers of veterinary medicines. The term has this specific meaning in the current international manufacturing standard, and NZFSA will use GMP only in that context.

Label in relation to any agricultural compound or any container used to contain an agricultural compound, means any written, pictorial, or other descriptive matter under which the trade name product is sold and which purports to give some information about the agricultural compound or veterinary medicine. This includes any information provided with the product at the time it is distributed/supplied. This definition is consistent with the ACVM Act, and explains it further.

Manufacture, in relation to any agricultural compound, includes: acquiring materials, making up, preparing, producing or processing, and assessing the agricultural compound for release; packing and labelling for the purposes of sale. The term relates to any part of the process from manufacture of active ingredients to manufacture of the end-use formulation. NZFSA proposes that “manufacturing” also includes the storage and transport under the direct control of the manufacturer.

Manufacturing operating plan means the minimum required documented description of a manufacturing process, either in general or as it refers to the manufacture of a specific agricultural compound, substance or product. Operating plans are the statutory definition of the Site Master File prepared by the manufacturer. Such files contain specific information about the quality assurance, the production and/or quality control of the manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings.

Responsible manufacture means having a quality assurance system in place when manufacturing any agricultural compound. Responsible manufacturing is fundamentally about ensuring that products are what they are supposed to be. GMP is a sub-set of responsible manufacture, relating specifically to manufacture of veterinary medicines by NZFSA approved manufacturers.

Sale includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes delivering or disposing of by way of gift, loan or otherwise; and giving or distributing, in the course of business, as a sample or otherwise, without charge (ref: section 2 of the ACVM Act).

2.2 Current regulatory regime

Agricultural compound and veterinary medicine products are manufactured to meet specifications that have been set by NZFSA. In many cases, NZFSA also officially approves the products. Regulatory control of manufacture is needed for a number of reasons. For example, consumers expect that

products with official authorisation are fit for purpose and appropriate to use. Also, products could be destined for export to jurisdictions that require certain controls on manufacturing as a prerequisite assurance that the products meet their specifications.

2.2.1 Regulatory control of manufacture by product class

Regulatory control varies with the class of product being manufactured.

Veterinary medicines

The registration of all veterinary medicines is dependent on NZFSA approval of New Zealand manufacturers under the Good Manufacturing Practices (GMP) for Veterinary Medicines scheme. The scheme is linked to the conditions of registration for veterinary medicines, because a product cannot be registered unless the manufacturer has GMP approval. The approval does not have a specific statutory basis, but is linked to the conditions of registration of the products being manufactured.

Manufacturers of registered veterinary medicines in New Zealand are subject to formal compliance programmes with entry audits and regular verification audits (every two years) to support renewals (every three years) of their GMP approvals. The *ACVM Standard for Good Manufacturing Practice* is used as the basis for the programmes. NZFSA increases the frequency of audits if confidence in a manufacturer's level of compliance is compromised. NZFSA maintains a separate list of manufacturers who have current GMP approval.

The *ACVM Standard for Good Manufacturing Practice* is aligned with and strongly influenced by international standards (see section 2.2.3 "International agreements" for further details on this).

Veterinary medicine products that are exempt from registration are not subject to any significant manufacturing requirements.

NZFSA does not approve manufacturers of active pharmaceutical ingredients, which leaves it to them to manage the quality of the ingredient. There is pressure on New Zealand to introduce formal approval for these manufacturers to meet international trends, including a changing requirement in the NZ/EU Mutual Recognition Agreement for GMP.

NZFSA considers that current arrangements for veterinary medicines are not well-suited to accommodate the increasing tendency for parties to be involved in contract manufacturing.

Agricultural chemical products

The manufacture of registered agricultural chemical products must comply with the ACVM manufacturing standard, but the manufacturers do not have to have NZFSA approval nor are they

subject to formal verification audits. The manufacturers of active ingredients and products must be specified in the application for registration, and NZFSA will register a product only if it is comfortable with the documentation in support of the capability of the manufacturer. NZFSA's level of comfort is from a general impression rather than an active evaluation or verification. The manufacturer responsible for ensuring that a product meets specifications is included on the registered product's public register. NZFSA does not maintain a separate list of manufacturers because it does not issue manufacturing approvals for them. Agricultural chemical products that are exempt from registration are not subject to any manufacturing requirements.

NZFSA considers that more rigorous consideration of manufacturing practices is justified given recent cases of fraudulent, mislabelled and contaminated products in the market.

Fertilisers

Fertilisers are exempt from registration, but must comply with minimum fit-for-purpose requirements prescribed in Schedule 5 of the ACVM Regulations. Fit-for-purpose guidance is provided in the voluntary Code of Practice. Suspicions and allegations of non-compliance are investigated, and manufacturers are expected to be able to provide evidence that they have taken due care to comply with the ACVM Regulations. There is no register, they do not have to be approved by NZFSA, and are not subject to a formal compliance programme.

As NZFSA holds no information on who is manufacturing fertilisers, there are significant gaps in its knowledge of whether or not people are following current requirements. NZFSA receives occasional complaints about manufacturer non-compliance.

Oral nutritional compounds, including animal feeds

Oral nutritional compounds are mostly exempt from registration, but they must comply with minimum fit-for-purpose requirements prescribed in Schedule 4 of the ACVM Regulations. Fit-for-purpose guidance is provided in voluntary Codes of Practice. Manufacturers do not have to be approved by NZFSA and are not subject to a formal compliance programme. Suspicions and allegations of non-compliance are investigated, and manufacturers are expected to be able to provide evidence that they have taken due care to comply with the ACVM Regulations. There is no register, and NZFSA does not hold information on who is manufacturing oral nutritional compounds. Pet food manufacturers who export pet food must be registered under the Animal Products Act 1999, and manufacturers of ruminant feeds (eg feed for cattle or sheep) who use ruminant protein must be registered under the Biosecurity (Ruminant Protein) Regulations 1999.

There are significant gaps in NZFSA's knowledge about who is manufacturing oral nutritional compounds. NZFSA still finds product in the market place that does not comply with current requirements, and there have been a number of allegations that products are not fit-for-purpose.

Vertebrate toxic agents

All vertebrate toxic agents have to be registered and the control of their manufacture is the same as it is for agricultural chemical products requiring registration – with the exception of restricted sale/restricted use products such as 1080 and cyanide products. For the exceptions, the manufacturers must be approved by NZFSA and are subject to a formal compliance programme. It should be noted that this approval is not called GMP.

Despite the registration requirement for vertebrate toxic agents, NZFSA is aware of occasional complaints of manufacturer non-compliance.

2.2.2 Negative effects

The manufacturing process can involve significant risks that need managing under the ACVM Act. Errors in manufacturing can result in:

- product formulation that does not meet required specifications
- contaminated product
- faulty packaging
- mislabelled product
- deteriorated product.

A range of negative effects can be traced back to errors in manufacturing. Faulty products can cause harm to the animals or plants exposed. They can fail to work, which causes animal welfare or agricultural security problems. They can also result in non-compliant residues in food for the New Zealand domestic or export market, which can in turn jeopardise trade in primary produce. Incorrect labelling could lead to the same negative effects.

2.2.3 International agreements

New Zealand's international agreements on agricultural compound manufacture, which tend to be focused on veterinary medicines, include a:

- Pharmaceutical Inspection Cooperation Scheme (PIC/S)
- Mutual recognition agreement with the European Union
- Memorandum of understanding with the Australian Pesticides and Veterinary Medicines Authority.

Through the arrangements with the European Union and Australia, NZFSA accepts the European and Australian GMP status of veterinary medicine manufacturers. It has also decided to accept the GMP status issued by the Authorities in other countries recognised by PIC/S. In addition, NZFSA informally recognises the equivalence of regulatory control in countries such as Canada, Japan, and the United States via their parallel agreements and commitment to the Veterinary International Cooperation on Harmonisation (VICH) programme.

Manufacturers in all other countries must supply full manufacturing operating plans to NZFSA for consideration, usually via the applicant for a product registration. Although the manufacture of agricultural chemicals and vertebrate toxic agents, fertilisers and animal feeds can pose relevant risks, there is no clear international standard governing manufacture and trade in such products. NZFSA's manufacturing rules for such products are not as stringent as for veterinary medicines. With no international standard to use as a benchmark, New Zealand has to decide the level of control that it considers sufficient to manage risks down to an acceptable level.

2.3 Proposed regulatory regime

The recurrence of cases of contaminated, mislabelled and fraudulent product has convinced NZFSA that the regulation of the manufacture of agricultural compound products should be more rigorous. NZFSA considers that regulatory requirements for manufacturing should focus on outcomes that can be achieved by complying with the principles of responsible manufacturing, such as confidence in the safety and reliability of agricultural compounds. NZFSA therefore proposes that regulations be drafted to apply the following obligations, which are consistent with the principles of responsible manufacturing, to all manufacturers of agricultural compounds and veterinary medicines:

- The manufacturing process must be clearly defined and should be evaluated as being capable of consistently manufacturing product that meets that product's specifications and the required quality standards.
- The manufacturing process must be subject to a clear and unambiguous operating plan (approved by NZFSA for certain products) that specifies procedures and instructions.
- Critical steps in the manufacturing process, and any changes to those steps, must be validated.

- The personnel involved in the manufacturing process must be appropriately qualified and trained.
- Responsibilities must be clearly defined.
- The premises and space must be suitable for the manufacturing process undertaken.
- The equipment and services must be suitable for the manufacturing process undertaken.
- All formulation materials and processing chemicals must be of a suitable quality; sourced from a competent and reliable source; and managed in a manner that is suitable for the products and the manufacturing process undertaken.
- Product containers and other packaging must be appropriate for the product, such that it can be stored, transported and handled without posing unacceptable ACVM risks.
- The part of the label attached to the container and packaging must be durable enough to be in good condition through to the expiry date of the product, and the label as a whole must be clearly printed with all the minimum required information about the product.
- Product must not be released for sale until the quality of the product has been confirmed. This includes sampling (starting materials, packaging materials, intermediate, bulk and finished product as appropriate), testing to written specifications, and a formal approval by an authorised person that the final product contains the active ingredient(s) as per the marketing authorisation (both qualitative and quantitative) and is packed and labelled correctly.
- Manufactured product must be stored (and transported within the manufacturer's operation) in a manner that ensures it remains consistent with its specifications (this does not include storage and transport beyond the control of the manufacturer).
- Records which demonstrate that all the required steps were followed must be made during manufacture. Any significant deviations must be fully recorded and investigated.
- Records of manufacture (including initial distribution arranged by the manufacturer) must be retained so that the history of any batch of product can be traced.
- The manufacturing process must include a system to recall any batch of product from sale or supply.
- Complaints regarding manufacturing must be investigated and appropriate corrective action taken to prevent recurrence.
- The manufacturer must notify NZFSA if their product poses immediate and unacceptable risks that would require product recall.

The above bullet points are all existing requirements in the *ACVM Standard for Good Manufacturing Practice* and the ACVM guidelines for labelling and advertising.

2.3.1 Status of manufacturers

NZFSA proposes to formally recognise manufacturers of certain classes of agricultural compounds under the ACVM Act. This will mean that mandatory performance and technical standards would likely be set by NZFSA, both as a measure for the compliance programme and as a means to confirm acceptable performance for the purposes of investigations. This is not a material change; it is only a change in the regulatory mechanism. The only parties that would require formal recognition are those that are already required to be approved as manufacturers.

Veterinary medicines and restricted sale/restricted use vertebrate toxic agents

NZFSA considers that manufacturers of veterinary medicines and restricted sale/restricted use vertebrate toxic agents should be formally recognised and required to comply with certain minimum performance and technical standards. All such products have significance in regard to the risk areas specified in the ACVM Act. Because of overseas jurisdictions' views on the control of veterinary medicines and the potential for significant negative effects, NZFSA considers it should have evidence readily at hand to address suspicions or allegations of non-compliant product. NZFSA's proposal for veterinary medicines reflects an international expectation, a bilateral requirement in the NZ/EU Mutual Recognitions Agreement and a memorandum of understanding with the Australian Pesticides and Veterinary Medicines Authority.

Section 75 of the ACVM Act has been amended to allow the regulation of people's behaviour (as opposed to just the regulation of products). As a result, the GMP approvals will be issued as statutory recognition under section 62 of the ACVM Act. This will create a list of GMP approved manufacturers.

The existing ACVM standard and guidelines for GMP will be converted into performance and technical standards. This will involve no material change to the requirements imposed; the existing vague administrative approval will become a transparent statutory one. Recognitions will be contingent on compliance with the standards. Whether or not the standard and guidelines will be re-issued as notices under section 76A will depend on discussions with affected parties. It is NZFSA's view that such notices will be used as guidance rather than as instruments to impose regulatory requirements. Such requirements should be imposed via regulations, with reference to notices if necessary.

NZFSA proposes to convert the requirement for restricted sale/restricted use vertebrate toxic agent products to comply with the ACVM manufacturing standard into a requirement to be recognised under

section 62 with an operating plan approved under section 28. This will automatically create a list of approved manufacturers for such products.

Other product groups

NZFSA is considering whether manufacturers of all other classes of agricultural compounds (agricultural chemicals, oral nutritional compounds, fertilisers and the remaining vertebrate toxic agents) should be on an NZFSA list. If so, name and contact details should be sufficient in most cases. Such a list, which would not be published on the NZFSA website, could be used to facilitate investigations of non-compliance or product recall.

NZFSA will not be formally recognising manufacturers of such products, or requiring compliance with performance and technical standards, or requiring operating plans to be approved except on a case by case basis. The minimum labelling requirement to identify the manufacturer would link products on the New Zealand market to the appropriate manufacturer listed with NZFSA.

NZFSA will conduct occasional compliance checking programmes (“slice of life” reviews) to check whether industry sectors’ programmes are performing as expected.

Active ingredient manufacturers

NZFSA proposes to provide recognition for active ingredient manufacturers if they need official assurances for exports, in the context of issuing certificates of compliance under section 35A of the ACVM Act. While it is not within the scope of this paper, it should be noted that NZFSA will have to consider whether it should require an approved status for active ingredient manufacturers as a prerequisite of product registration.

Export-only products

NZFSA proposes that all export-only products be exempt from registration with conditions, including the condition that the manufacturers are recognised under section 62 of the ACVM Act. That recognition will be contingent on compliance with performance and technical standards which will require the manufacturer to operate in a manner that is equivalent to that required under the manufacturing regulations, with particular emphasis on preventing the diversion of export-only product onto the New Zealand market.

2.3.2 Overseas manufacturers

NZFSA proposes to set criteria to determine whether or not products manufactured outside New Zealand's jurisdiction should be authorised for import, sale and use in this country. The criteria will be based on EITHER the:

- status given to the manufacturer by the competent authority (recognised by NZFSA) in the country in which the manufacture occurs OR
- information provided to or held by NZFSA (including its knowledge about the relevant competent authority) on the acceptability of the manufacturer and the manufacturing process for the product in question.

NZFSA will not use the term "approved" unless an approval was issued by NZFSA. As NZFSA does not have the capacity to assess and approve overseas manufacturers, it will not be able to audit them. It intends to use the term "acceptable manufacturer" to describe a party for whom there is sufficient evidence (other than an NZFSA assessment) to conclude that they are acceptable and, consequently, that products manufactured by them can be authorised for import, sale and use.

Manufacturing information requirements will be specified for veterinary medicines from countries that NZFSA informally recognises as having equivalence to New Zealand's regulatory control. NZFSA intends to create criteria for other classes of agricultural compounds based on these requirements.

2.3.3 Use of operating plans

NZFSA proposes to require all manufacturers of agricultural compounds to have an operating plan. An operating plan will describe how product will be manufactured and assessed as meeting specifications. NZFSA would ask to examine operating plans for the purposes of confirming compliance, investigating non-compliance, and supporting recalls. NZFSA will impose formal recognition and approval of operating plans only when there is a need to give official assurances of compliance, or to assure Government or the public that the regulated parties are complying.

Although the term "operating plan" is not usually used in agricultural compound manufacture, the expectation that manufacturing should be subject to a documented system is not new. A documented manufacturing plan is a fundamental part of responsible manufacturing. A statutory requirement to have such a plan should be no more onerous for businesses than what has always been expected.

NZFSA considers it will need to approve operating plans for registered veterinary medicines, registered restricted sale/restricted access vertebrate toxic agent products, and any products requiring NZFSA certification of matters relating to the manufacturing process specified in the plan. Other

manufacturers will make and implement their operating plans, except when there is an international expectation that must be met or where risks are so significant that assurances to the public must be given. NZFSA will make it very clear to affected parties when operating plans need to be approved.

2.3.4 Compliance programme

NZFSA proposes to impose a formal compliance programme on every manufacturer who has to be recognised by NZFSA under section 62 and have an operating plan approved under section 28. This would include manufacturers of:

- registered veterinary medicines
- registered restricted sale/restricted use vertebrate toxic agent products, and
- any manufacturer who wants NZFSA to issue certificates of compliance concerning aspects of the manufacturing process.

All other manufacturers will be subject to compliance activity through intermittent checks or investigation of suspicions or allegation of non-compliance.

When NZFSA imposes the approval requirements mentioned above in section 2.3.3 “Use of operating plans”, it will also impose a formal compliance programme. Manufacturers will otherwise be subject to the minimum requirements in the Regulations, with guidance from NZFSA when necessary. During any investigations of non-compliance, the manufacturing operation will be examined in light of the operating plan and the conditions of authorisation for the products being manufactured.

2.3.5 Linking products to manufacturers

There is an insufficiently close administrative relationship between manufacturer performance and the authorisation of the products being manufactured. Where manufacturers are required to be approved prior to product registration, the approval is not linked specifically to the particular product but rather granted on the basis of the general manufacturing capability of the person/entity. For other products there is no formal approval of the manufacturer, and the authorisation of the products is based on a level of comfort associated with information provided to or held by NZFSA.

NZFSA proposes to administratively link all manufacturers to the products being manufactured. NZFSA also proposes that verification audits should include specific verification of the products and substances that a manufacturer has authorisation to manufacture, to ensure that they align either with the data held by NZFSA (if registered) or with the company’s operating plan (if exempt from registration).

It should be noted that verification audits for companies whose products are exempt from registration will not be carried out by NZFSA, as they will be part of each such company's operating plan.

Registrants and persons responsible for substances or products exempt from registration will need to be aware that unacceptable performance of the manufacturer could have an impact on the authorisation of their products. This is relatively clear in regard to veterinary medicines now, and will become more significant for the other classes of products as these proposals are put into effect.

3 Labelling

In brief, existing minimum label information requirements and labelling specifications will be transferred into the manufacturing regulations. NZFSA proposes to impose a condition on all exempt product groups to comply with the manufacturing regulations. This is only a change in regulatory mechanism; the requirements themselves will not change.

3.1 Current regulatory regime

Label content for products exempt from registration is currently not subject to NZFSA approval, but it is subject to minimum label information requirements in Regulation 6 of the ACVM Regulations. Registered products are subject to the ACVM labelling and advertising guidelines, which set out what an applicant for registration needs to state on the label. In addition, the label content for registered products is approved by NZFSA. The conditions of registration require compliance with the labelling and advertising guidelines. The current minimum labelling requirements are to ensure that labels contain sufficient information to facilitate the safe and appropriate use of the product, and any investigation of the products in regard to compliance with regulatory requirements.

3.2 Proposed regulatory regime

NZFSA proposes to transfer existing minimum label information requirements and labelling specifications from the ACVM Regulations into the manufacturing regulations. A condition will be imposed on all exempt product groups to comply with the manufacturing regulations. Label content for registered products will continue to be approved as part of the registration process. Compliance with the labelling requirements will be additional to the label content approval. This will require a minor adjustment in the conditions of registration, to align labelling with manufacturing rather than with advertising.

The minimum labelling requirements, which are currently in the ACVM guidelines for labelling and advertising, are listed below in no particular order:

- Mandatory label information imposed via the conditions of authorisation must be specified (eg “for the treatment of animals only”).
- Primary and secondary packaging must comply with the minimum labelling requirements.
- Label components attached to restricted size primary packaging must include the active ingredient and trade name, and must always be supplied in secondary packaging with all the required information.
- Outers must identify the product with its trade name, registration statement and number, active ingredients and net contents.
- Packaging and labelling must be defined in the manufacturing specification. This will be considered by NZFSA when approval is required for an operating plan.
- All products must be supplied with a label (or if supplied in unpackaged bulk form must have documentation) containing the following minimum information:
 - trade name, if any
 - the ACVM authorisation statement and identification number if one has been issued for the product
 - the name and address of the manufacturer/producer (and/or registrant if the product is registered)
 - active ingredients
 - net contents
 - use claims
 - directions for safe use
 - any applicable information specified in its authorisation
 - details of any precautions to be taken to prevent or manage the risks described in section 19 of the ACVM Act when using it, particularly potential hazards to animals treated with or exposed to it
 - batch number, date of manufacture, or any equivalent information used to link the product to its manufacture
 - shelf-life statement, use by date or expiry date, or any equivalent information used to specify the period in which the product should be used

- storage and transport instructions, if necessary
- disposal instructions, if necessary.

4 Advertising and promotion regulations

Advertising and promotion is the least-regulated area under the ACVM Act. As NZFSA has little information to go on, some of its proposals are more in the nature of options for discussion than fully-considered approaches. In brief, NZFSA is tentatively considering the merits of:

- requiring warning information to adequately reflect the significance of the regulatory warnings. This would be a new, more stringent requirement; it is contrary to current practice and would impose costs on some businesses.
- treating all communication practices concerning agricultural compounds as relevant to the risks specified in section 4, regardless of whether the party providing communication has a vested interest in the product or not. This approach may have implications for freedom of speech that will need to be taken into consideration.

In terms of more formal proposals around advertising and promotion, NZFSA proposes to make regulations that will:

- effectively apply the current requirements around advertising, promotion, and information transfer for registered products to both registered products and products exempt from registration. The impact on registered products will be very minor, but products that are exempt from registration will need to meet certain new requirements.
- require advertising and promotion to be consistent with each product's authorisation. This reflects an existing expectation that parties should not make claims that are outside the scope of a product's authorisation.
- impose an obligation on parties to support their products with adequate, reliable and readily available consumer information. There has always been an obligation under the ACVM Act to supply "adequate consumer information", but no definition of what constitutes "adequate".
- allow information to be communicated about off-label uses by third parties, with a prescribed obligation to warn potential users of the uncertainty, potential risks and consequential liability. This proposal effectively clarifies NZFSA's current practice by putting it into regulations.

4.1 Use of terminology and definitions

The below terms and definitions are relevant to NZFSA's advertising and promotion proposals. Some are currently in use, while others are proposed because existing terminology would be inappropriate or confusing. Where necessary, some of the below terms may be applied in regulations.

Scope of "communication" for the purposes of this paper

"Communication" includes the transfer of facts about products and the companies that supply them, as well as encouragements via advertising and promotion to purchase the products. Because all communications can pose relevant risks, they are all considered in this paper.

Advertising and promotion

"Advertisement" is defined in the ACVM Act as "any publication to the community or to any section of the community of any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device, used to promote the sale of any agricultural compound".

"Promotion" is not defined in the ACVM Act, but is understood to mean "encouraging parties to purchase particular agricultural compounds via advertising or any other type of encouragement including but not limited to offering special concessions on price, quantity or additional goods". Both terms relate to communications that have as their primary intent the desire to sell products.

Information transfer

"Information transfer" is not defined in the ACVM Act, but it has been used by NZFSA in the past. NZFSA proposes that it means "to provide information (in any of the same forms listed in the definition of advertising) about agricultural compounds or about circumstances in which agricultural compounds are likely to be used". While information transfer may influence purchasing decisions, that is not its primary objective. The aim is to educate or train people. Likely topics of information transfer include disease state awareness, animal/plant management potential, and alternative means of management.

Labelling product

The label is the primary and most immediate source of information about a product. "Label" is defined in the ACVM Act, and understood to mean "all the information provided with the product when it is made ready for initial distribution". This includes:

- the immediate packaging
- any outer packaging

- any leaflet, flyers, pamphlets, and
- any other informational material provided with the product by the registrant/manufacture for marketing (it does not include any additional informational material prepared by the wholesaler or retailer for distribution with the product).

NZFSA considers the label to be a fundamental characteristic of the product set at the time of manufacture. Consequently, proposals about regulating labelling can be found in the manufacturing section of this document. On the other hand, advertising and promotional information about the product is not and cannot be governed by the label content approval at registration (or any prescribed minimum labelling requirements for products exempt from registration). Such information, which includes television/radio or magazine advertisements, material prepared for sales campaigns, and in-store advertising prepared by third parties, is relevant to this section of the document.

Primary message

NZFSA considers that certain warnings should be part of “the primary message”, to make it clear that putting important warnings in the “small print” to meet minimum requirements does not give those warnings the consideration they deserve. NZFSA proposes that “the primary message” mean “that part of a communication containing the essential information to be communicated and which is the focus of the communication”.

4.2 Current regulatory regime

All ACVM product authorisations can be issued with conditions that define the acceptable circumstances under which a product can be imported, manufactured, sold or used. All registrations have a condition that requires compliance with the relevant ACVM guidelines for labelling and advertising. When NZFSA considers a product or group of products for authorisation, it assesses the risks posed. The relevant areas to be considered are risks to:

- trade in primary produce
- public health
- animal welfare
- agricultural security.

Products are also assessed and managed to ensure that their use will not result in non-compliant levels of residues. The information to be provided with the product is also assessed to ensure it

provides sufficient consumer information to allow the product to be used appropriately and safely. These assessments are carried out in the context of the product's intended use.

Products that are exempt from registration have no regulatory controls placed on them with respect to advertising or information transfer. If they were advertised or promoted for uses that were not exempt from registration, such products would need to be registered.

Communications surrounding off-label use

The use of products that are available but not authorised for the purpose is commonly referred to as off-label use or minor use/minor species (MUMS). It is not the same as own use of generic chemicals or substances, which is discussed in the next section of this document. Communications about off-label use are usually made (or commissioned) by users or special interest groups, consultants, or even members of the public. Such communications are almost always outside the sphere of control of the person responsible for the manufacture of the product. Although a condition allowing off-label use is imposed on most product registrations, the labelling and advertising guidelines prohibit advertising off-label uses and, consequently, discourage the transfer of information on those uses. So while off-label uses are permissible, it is not possible to legitimately promote those uses. It is also unclear as to who must comply with the condition. It is obvious that a registrant must do so, but registrants do not usually promote off-label uses because of the associated liability that would be incurred if something goes wrong.

4.2.1 Negative effects

NZFSA is concerned that some communications may negate or reduce the effectiveness of the risk management mechanisms imposed on products in the form of conditions on authorisations. Products could be misrepresented in the marketplace, or parties could be encouraged to use them in an inappropriate manner. If a product is represented in a way not anticipated when its authorisation was issued, negative effects can include:

- non-compliant residues in food from animals or plants treated
- harm to animals or plants either via toxic/undesirable side effects or failure to work
- spread of diseases, pests or unwanted organisms
- development of resistance jeopardising animal, plant and human health
- restrictions imposed on New Zealand exports of primary produce.

These effects could cause significant personal losses and/or compromise New Zealand's reputation as a trusted supplier of food and food-related products. They could also seriously damage the public's confidence in the implied official assurances that authorised agricultural compound products are safe and reliable.

4.3 Proposed regulatory regime

NZFSA proposes to make new regulations that will largely reproduce current requirements for advertising, promotion, and information transfer. This will make the regulatory arrangements clearer. A key feature of the proposed new regulations is that they will apply to all products authorised under the ACVM Act, whether registered or exempt from registration. The impact on registered products will be very minor, but the regulations will set new requirements for products that are exempt from registration.

4.3.1 Warning information

NZFSA is aware that in some instances it is common advertising practice to do the bare minimum to meet statutory obligations. Warning information is often not presented in a way that would encourage the audience to think of it as important. For example, the warnings are placed in small print at the bottom of a communication, or delivered rapidly at the very end of the communication.

To address this practice, NZFSA is considering whether it would be appropriate to set a minimum requirement for warning information at a level that adequately reflects the significance of the regulatory warnings. NZFSA considers that, in principle, crucial regulatory information should be made as obvious as any other part of a communication about a product. However, it should be noted that this proposal would be contrary to current advertising practice. It would also create a new, more stringent requirement that would impose increased costs on some businesses.

4.3.2 Obligation to represent the product as authorised

NZFSA proposes that regulatory control should focus as much as practical on the desired outcome, rather than on specifying the arbitrary boundary between advertising and information transfer. No matter what the intent of the communication, products should always be represented in the market place in a manner that is consistent with the assessment that was the basis for their authorisation in the first place. Parties responsible for preparing products for market or for selling them should be made accountable for ensuring that products are always presented in a manner that is consistent with their authorisation. When advertising or promoting products, parties should not make claims for their

products that are beyond the scope of their authorisations. Neither should parties represent their products in a manner that has not been adequately substantiated with reliable evidence, given the potential risks. In addition, parties should have an obligation to support their products with adequate, reliable and readily available consumer information.

4.3.3 Information transfer versus advertising/promotion

Current regulatory control under the ACVM Act is partly based on the boundary between advertising/promotion and information transfer, but that boundary is not clear.

Parties have often attempted to pass off advertising as information transfer. NZFSA has not formed a clear view on how best to manage this problem.

In NZFSA's view, those who pay for responsible communications that encourage safe and appropriate use of products should benefit, through brand recognition or awareness of their products. Even where rigorous care is taken to avoid advertising/promotion, information transfer is likely to influence the audience's purchasing decisions. It is when a communication's intention is primarily to sell products that it should be considered advertising/promotion.

4.3.4 Obligations on parties with no vested interest in the products

Some parties who impart information about agricultural compounds may be promoting the products with no vested interest in them. They could be communicators (magazine editors, health care advisors etc) to the public in general or special interest groups. Such parties can misrepresent the products or impart information that is contrary to the authorisations of the products, or that nullifies the risk management role of persons recognised to control access to certain products (such as veterinarians or approved traders). This causes the same negative effects on risk management as would have prompted regulatory intervention, and even prosecution, if the communication had been made by parties who had vested interests in the agricultural compound.

The regulation making powers in the ACVM Act expressly state the power to make rules about how parties directly involved with importing, manufacturing, selling or using those products can carry out those activities, including the communication of information about the products. The ACVM Act is not so clear that communications by other parties can also be regulated; it could be argued that parties with no vested interest in products are outside the scope of the regulation making powers.

The ACVM Act does provide the power to make regulations for the purpose of any other matter relevant to the management of products, activities, or behaviours to minimise the risks specified in section 4 of the ACVM Act. It is NZFSA's view that, in principle, all communication practices

concerning agricultural compounds are relevant to the risks specified in section 4, regardless of whether the party providing communication has a vested interest in the product or not.

It should also be noted that this proposal may have implications for the freedom of speech guaranteed under the New Zealand Bill of Rights Act 1990. NZFSA is particularly interested in feedback on this proposal, as options other than regulations may be the most appropriate response to the issue.

4.3.5 Communication about off-label uses

One option is to prohibit any communication by any person containing information about a use that is not specifically approved in a product's registration. Such a prohibition would not be practical and would certainly be breached on a daily basis.

NZFSA proposes to allow information to be communicated about off-label uses by third parties, with an obligation to warn potential users of the uncertainty, potential risks and consequential liability. Such warnings would need to be part of the primary message. NZFSA considers that the potentially significant implications of using products in a manner that has not been assessed must be made explicit and tied to the ability to take legal action against any person who breaches regulatory requirements. Consistently including warnings will be far cheaper than getting a use approved (which involves incurring significant costs associated with providing efficacy data and assessment).

5 Own use/off-label regulations

This section is about managing the use of substances as agricultural compounds that have not been assessed and authorised by NZFSA, and the use of authorised products in a manner that has not been assessed.

Substances used as agricultural compounds have often not been sold for that use. They become agricultural compounds because of the way they are used. For the purposes of this discussion document the practice will be considered in three forms:

- own use
- off-label/MUMS use
- provision of professional services.

Own use is currently covered under the first entry in Schedule 1 of the ACVM Regulations 2001.

For own use, NZFSA proposes to make regulations that will:

- include the existing requirements that apply to persons who use generic substances, mixture of substances or biological compounds as an agricultural compound
- include an exemption from registration, and prescribe an obligation to take due care to ensure that the relevant risks are kept to an acceptable level
- prohibit marketing, manufacture, sale or distribution that states or implies in any way that the substance, mixture of substance or biological compound can be used as an agricultural compound.

For off-label/MUMS use, NZFSA proposes to:

- place a condition on the registration of most products that allows off-label use, but imposes requirements on responsible parties and on users to take due care to avoid negative effects, tying the use to the same requirements for own use of generic substances.. These requirements will, for the most part, not be new. The main change will be in the type of regulatory mechanism, in line with the revised, more transparent scheme of the ACVM Act.

For the provision of professional services, NZFSA proposes to:

- exempt from registration preparations compounded as part of specified professional services, and prescribe minimum requirements that must be complied with. These will be new requirements, as the specified professional services have not been regulated under the ACVM Act to date.

5.1 Use of terminology and definitions

Agricultural compound as per section (2) of the ACVM Act, but focusing on the regulatory control of persons who, by their actions:

- convert non-agricultural compound substances or products into agricultural compounds, or
- use agricultural compound products in a manner that was not specifically assessed and authorised under the ACVM Act.

Compounding means preparing a substance (or mixture of substances) to be used as an agricultural compound to treat animals or plants on a small scale. The term is used with reference to herbalists, homeopathic practitioners and veterinarians who prepare medications to use as veterinary medicines or as preparations to manage plants. It is also used when referring to contract chemists/pharmacists commissioned by those practitioners. It is not used when referring to the manufacture of herbal, homeopathic or chemical preparations for sale as proprietary products (ie preparations offered for sale

to the public outside the context of a professional service). The manufacture of proprietary products offered for sale is covered under the manufacturing section of this paper.

Contract application refers to the use of agricultural compounds by persons who provide an application service to clients. For example this includes spray contactors, who provide aerial or ground application (and may provide the product along with the application service).

Distribute means to send an agricultural compound that has been manufactured for sale to wholesalers, retailers and/or end users; and includes transport and storage in any intermediate step to the end user. Distribution has an impact on the status of both the substance/product and the actions of the parties involved. If a non-agricultural compound is used by a party only on their own animals or plants the activity would be relevant to this section. However, if that person distributes it to other parties to be used as an agricultural compound it would not be considered "own use". Such distribution implies sale and, if the product is not properly authorised, the action would be an offence under the ACVM Act.

Label in relation to any agricultural compound or any container used to contain an agricultural compound, means any written, pictorial, or other descriptive matter under which the compound is sold or to be sold and which purports to give some information about the compound (ref: section 2 ACVM Act). Labelling requirements have no practical meaning when a party converts a non-agricultural compound for use on their own animals or plants. However, labelling is relevant when a professional practitioner prepares a preparation to be used as an agricultural compound as part of a service, as is done by herbalists, homeopathic practitioners and some veterinarians.

Manufacture means to make up, prepare, produce, or process an agricultural compound and includes packing and labelling for the purposes of sale. The term relates to any part of the process from manufacture of the active ingredients to the end-use formulation. NZFSA considers that "manufacturing" also includes storage and transport by the manufacturer. The definition is also relevant to the activities of parties who compound a preparation as part of a service. The principles of responsible manufacturing are the same, and all parties should be subject to those principles.

Operating plan refers to the documented description of a process, either in general or as it refers to the compounding or use of a specific agricultural compound substance or product. There may be circumstances in which the activities of people may have to be subject to operating plans to ensure that due care is taken to keep risks relevant to the ACVM Act down to an acceptable level. The use of this term in this section is most relevant to the recognition of professional practitioners.

Own use refers to persons using agricultural compounds (generic chemical or off-label use of registered products) to manage their own animals or plants (or animals or plants that they are responsible for) either by direct applications to those animals or plants or application to land, places or

water that are also under the control of that person, for any of the purposes listed in the definition of an agricultural compound. It usually refers to the use of generic chemicals or other substances or biological compounds that have been sold without any agricultural compound use claim or instruction. Off-label or minor use/minor species (MUMS) use is sufficiently similar to warrant discussion in this section.

Own use includes contract application when the application remains the responsibility of the owner, as opposed to responsibility being transferred to the person providing the application service.

It is recognised that the criteria for own use does not fit very well in regard to the activities of professional practitioners providing product with services to third parties. For this reason the activities of some professional groups have been considered in separate proposals in this section. At this stage the proposals relating to the activities of professional groups do not include spray contractors.

Sale includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes delivering or disposing of by way of gift, loan or otherwise; and giving or distributing, in the course of business, as a sample or otherwise, without charge (ref: section 2 of the ACVM Act). The proposals in this section prohibit sale, except in the very limited context of providing a professional service as is done by herbalists, homeopathic practitioners and some veterinarians.

5.2 Own use

5.2.1 Current regulatory regime

“Own use” as specified in schedule 1 of the ACVM Regulations 2001 refers to the use of a substance/product by persons on their own animals or plants on land or water or in a place under their own control. It does not include the sale of such substances as agricultural compounds to third parties. Own use is managed through a combination of regulations, conditions of registration and standards.

The generic chemicals or substances involved in own use are usually readily available. Their use as agricultural compounds has not been assessed by NZFSA. Technically, it could be an offence under the ACVM Act to intentionally use them as agricultural compounds. However, due to the frequency of own use practices, they have been covered by an exemption from registration. Examples of own use of generic chemicals include:

- epsom salts (magnesium sulphate) to control the colour of hydrangea flowers

- copper sulphate footbaths to prevent/treat footrot in sheep
- zinc oxide to prevent facial eczema
- tincture of iodine or solutions of potassium permanganate to treat minor wounds
- garlic oil to repel undesirable insects away from fruit/vegetable crops
- seaweed or greenwaste compost to be used as fertilisers.

In the past, own use was limited to simple, traditional uses based on a narrow range of readily available chemicals. The risk of causing harm was small and regulatory control was not considered necessary. In addition, there was an expectation that persons engaged in own use would comply with the rules. The technical breaches that occurred before an exemption was included in the ACVM Regulations 2001 were overlooked because the common own use practices at the time were not likely to exceed acceptable risk thresholds in trade in primary produce, animal welfare or agricultural security, and unlikely to lead to breaches of the domestic residue standard.

With the increasing availability of a vast range of quite sophisticated chemicals, the potential for harm from own use now poses risks far beyond acceptable thresholds. NZFSA does not consider that, in general, a system of permits for own use is practical under New Zealand conditions. Furthermore, prohibiting own use is neither practical nor desirable.

5.2.2 Proposed regulatory regime

NZFSA proposes to set regulatory requirements that must be complied with by any person who uses generic substances, mixture of substances or biological compounds as an agricultural compound.

The requirements to be prescribed will, for the most part, not be new. The main change will be that the regulatory mechanism will be made consistent with the revised, more transparent scheme of the ACVM Act.

All affected parties are already regulated through requirements in the *ACVM Standard for Own Use of Agricultural Compounds* (the approved code of practice for own use).

NZFSA considers that putting requirements around own use into regulations is the most transparent and effective way to minimise non-compliance. People will be held accountable for their actions when converting generic substances into agricultural compounds or when using a registered product in a manner that has not been assessed. It might be possible to deal with both these issues in the same regulations, but it seems clearer to NZFSA to promulgate two sets of regulations – one for own use and one for off-label/MUMS use.

The current requirements in the *ACVM Standard for Own Use of Agricultural Compounds* include:

- prohibition on use of specified substances as agricultural compounds
- prohibition on use of new organisms, including genetically modified organisms, unless approved by ERMA NZ under the HSNO Act
- obligation to ensure that maximum residues limits set under the Food Act (and maximum permissible limits set under the Animal Products Act) are not exceeded
- obligation to ensure that treated (exposed) animals are not subjected to unnecessary or unreasonable pain or distress
- obligation to make the use known when animal products are collected for human consumption
- prohibition on sale of the substances as an agricultural compound, and
- obligation to ensure the compound is fit for purpose and due care is taken when using it.

NZFSA proposes that the regulations will include an exemption from registration. This would provide the authorisation required under the ACVM Act, and create the mechanism by which the minimum requirements could be imposed. The proposed regulations would place an obligation on every person to take due care to ensure that the relevant risks are kept to an acceptable level. They would also prescribe what constitutes due care, such as a proactive effort to gather information to support a particular use pattern. They would restrict the use to animals or plants that are owned by that person. They would also restrict the location in which the use can occur to land, water or a place owned (or managed) by that person. This would ensure that the risks are contained, and that third parties would not be involved or inadvertently exposed to potential harm. The proposed regulations would address the circumstances in which responsibility has been conferred on a person but actual ownership is not involved.

The proposed regulations would prohibit marketing, manufacture, sale or distribution that states or implies in any way that the substance, mixture of substance or biological compound can be used as an agricultural compound.

It would be an offence not to comply with the proposed regulations. Compliance would not be an excuse to justify non-compliance with any other regulatory requirements, such as those set under the Animal Welfare Act, Biosecurity Act, Hazardous Substances and New Organisms Act, Resource Management Act or any maximum residue limits under the Food Act or maximum permissible limits under the Animal Products Act.

5.3 Off-label use or MUMS

NZFSA proposes to place a condition on the registration of most products that allows off-label use (specifically prohibiting in the conditions of registration uses that it considers would pose significant risks), but imposes requirements on responsible parties and on users to take due care to avoid negative effects.

As is the case for own use, the requirements will, for the most part, not be new. The main change will be in the type of regulatory mechanism, in line with the revised, more transparent scheme of the ACVM Act.

Current regulatory regime

New Zealand producers are forced to consider off-label uses because no one is pursuing registration for products to meet their particular needs. Off-label or MUMS use is a reflection of the mismatch between overseas authorisation of trade name products for common livestock and crop species, and the focus in New Zealand agriculture on minor crops and minor animal species. Off-label uses include:

- pest control in herbs, unusual tree crops and other minor crops
- cattle or sheep vaccines used on ratite birds such as emu and ostrich
- therapeutic products for cattle or sheep used on deer, pigs, goats and other animals.

Currently, off-label use is authorised via a condition of registration. The off-label condition refers to use on animals or plants or, very rarely, on both. If use on neither animals nor plants is specifically referred to, off-label use is not authorised. The off-label condition states minimum requirements. For products used to manage plants, the minimum requirement is to take due care to avoid non-compliant residues. For products used on animals there is also a requirement to avoid unnecessary or unreasonable pain or distress in the treated animals, and to seek veterinary advice if necessary before use. If NZFSA considers off-label/MUMS use cannot be allowed, then the off-label use condition is not applied or is specifically restricted (which can require a specific permit from NZFSA).

In New Zealand, off-label use is allowed as a general rule, and only restricted where there are regulatory concerns to be managed. Managing off-label use is an international problem. Some countries manage it via special authorisations or permits, while others prohibit it. NZFSA considers neither of these solutions to be practical under New Zealand conditions. New Zealand often has no specifically authorised products when it comes to minor uses or in minor animal/plant species. There are so many MUMS circumstances that it is highly unlikely that anyone would want go to the expense and trouble to register products dedicated to those uses. Prohibition of off-label use would have

serious negative effects on business – and a permits system could introduce a costly level of regulatory intervention.

The current regulatory regime has been satisfactory for the most part but specific cases of non-compliance have lead NZFSA to the conclusion that it does not provide sufficient instruction to regulated parties about what they have to take into consideration when choosing to use a registered product in a manner that has not been specifically authorised. The negative effects can be very significant; for example, a farmer recently used a product on his cattle and deer that had only been approved for use on plants. This resulted in millions of dollars in trade losses and seriously undermined international confidence in New Zealand as a source of safe food.

Proposed regulatory regime

NZFSA would prefer to manage the risks associated with uses that have not been assessed by placing a condition on the registration of most products that allows off-label use (specifically prohibiting in the conditions of registration uses that it considers would pose significant risks), but imposes requirements on responsible parties and on users to take due care to avoid negative effects. The proposed minimum requirements would be similar to those that would be imposed for the use of generic chemicals as agricultural compounds because it cannot be presumed that assessment and authorisation for one use provides a sound platform for a different use.

NZFSA proposes to place an obligation to comply with the regulations in the conditions of registration, while retaining the practice of specifying in the conditions of registration any specific limitations on off-label/MUMS use.

It should be noted that this proposal does not relate to the off-label/MUMS use of most products that are currently exempt from registration in the ACVM Regulations 2001 because the use is fundamental to the exemption. For example, if therapeutic claims are made about an oral nutritional compound product, then that product no longer fits the definition of an oral nutritional compound and is not exempt. This means that a person may not be able to use a product that is exempt from registration in an off-label manner without nullifying the exemption and making him/herself liable to register the product.

5.4 Provision of professional services

The third activity relevant to the own use proposals relates to certain professional groups who offer services to manage the health and productivity of animals and plants.

NZFSA proposes to exempt from registration preparations compounded and provided in conjunction with specified professional services. NZFSA also proposes to prescribe minimum requirements that practitioners must comply with in the provision of these specified services.

Compounding as part of a service is not regulated at the moment because the outcome cannot practically be managed via registration. Nevertheless, parties must be responsible for the way they manufacture their preparation just like any other manufacturer.

The professional services that have been identified as relevant at this stage are:

- herbalists
- homeopathic practitioners
- pharmacists
- veterinarians.

Current regulatory regime

These professional groups compound their own preparations as needed in the services they provide. The preparations are not manufactured and sold as trade name products, but prepared to meet a particular case or patient's needs. In most cases, it is the service that is sold, not the preparation. The preparations are agricultural compounds, but they cannot practically be regulated via registration. An exemption from registration has been prescribed for some of these preparations, but the conditions do not adequately address the potential for harm across the wide range of relevant preparations.

Currently there are exemptions from registration for oral and topical homeopathic and herbal veterinary medicines, and homeopathic products used to manage plants. Minimum requirements are specified in the exemption, but NZFSA considers that these are too generic for the wide range of preparations that are made by practitioners in the course of providing professional services.

Proposed regulatory regime

The conditions on the proposed exemption will require practitioners to be recognised by NZFSA under section 62 of the ACVM Act to carry out compounding of the relevant kinds of products. Either minimum requirements for compounding will be incorporated into technical and professional standards, which can be issued under section 62, or there will be a requirement to comply with a section governing compounding in the proposed manufacturing regulations. If the former mechanism is used, failure to comply will result in loss of recognition. Without recognition the preparation used will not comply with the conditions of exemption and administering them will be an offence. If the latter mechanism is used, failure to comply with the regulations will also be an offence.

NZFSA is considering the role of operating plans in the regulatory control regime. It proposes to require that these professionals must have operating plans to cover their compounding activities and the link with their professional services. It has not been decided whether such plans would need NZFSA approval. NZFSA needs to discuss the matter with industry groups before that decision is made, and the decision may not be the same for all of the groups in every case.

This proposal does not make a distinction about mode of administration. The current exemptions limit administration to topical or oral. This proposal could cover all modes of administration, and set minimum requirements as necessary based on the risks posed. This would mean that preparations could be compounded by these practitioners even for injection or for application to eyes and ears. NZFSA also needs to discuss this with industry groups to ensure that the minimum requirements are necessary, sufficient and relevant to the affected parties.

This proposal will not cover the manufacture of products to be sold to the public outside the context of providing a specified professional service. Such products will be subject to the rules of registration or relevant exemption from registration, and to the proposed manufacturing regulations.

6 Regulatory impact statement

Executive Summary

The New Zealand Food Safety Authority (NZFSA) is updating the administration of the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act). This regulatory impact statement pertains to the discussion paper on proposals for manufacturing, labelling, advertising and promotion, and own use. Some arrangements, particularly around products that are exempt from registration, are not as rigorous or clear as they need to be in order to manage risks. A key objective is to use existing powers to set regulatory control at a level that is neither more nor less than what is required. Most of the proposals contemplate shifting existing requirements from a range of regulatory frameworks into regulations. This would increase transparency as the regulations will be more comprehensive. Although the proposals will create some new obligations for parties associated with products that are exempt from registration, there will be very little change for existing registrants.

Adequacy Statement

NZFSA has prepared this draft regulatory impact statement for the purposes of public consultation. When consultation is finished, NZFSA will confirm whether it meets the adequacy criteria.

Status Quo and Problem

NZFSA has begun a reform of the administration of the ACVM Act, which controls agricultural compounds and veterinary medicines used in association with animals and plants.

Regulatory requirements under the ACVM Act are not clearly set down in one place. Various tools have been used to manage manufacturing, labelling, advertising and promotion, and “own use” (the use of a substance/product by persons on their own animals or plants on land or water or in a place under their own control). Conditions of registration are placed on each registered trade name product and linked to standards. Where products are exempt from registration, the conditions are prescribed in regulations. Regulatory requirements have also been documented in standards, guidelines and information requirements. Since 2007 the ACVM Act has included powers that allow for more rigorous and transparent regulatory control.

The regulatory regime has been adequate in cases involving trade name products, but it is insufficiently flexible to manage risks when people sell or use substances as agricultural compounds. In addition, obligations for regulated parties have not always been clear. While New Zealand is party to a number of international agreements focused on veterinary medicines, there is no clear international standard for trade in agricultural compounds. New Zealand must set a sufficient level of control to manage risks in relation to agricultural compounds down to an acceptable level.

Insufficiently-managed risks can result in negative effects such as non-compliant residues in food, which can in turn jeopardise New Zealand's reputation as a trusted supplier of food and food-related products. The frequency of cases of contaminated, mislabelled or fraudulent product has indicated to NZFSA that some risks relevant to the ACVM Act have not been sufficiently managed.

Manufacturing

Products are manufactured to meet specifications. Errors in the manufacturing process can lead to such things as contaminated, deteriorated or mislabelled product. Regulatory control of manufacture varies by class of product as discussed below.

Veterinary medicines: NZFSA approves New Zealand manufacturers under the Good Manufacturing Practices (GMP) for Veterinary Medicines scheme prior to registering products. The scheme has no specific statutory basis. Manufacturers are subject to formal compliance programmes with entry audits and regular verification audits to support renewals of their GMP approvals. Veterinary medicines that are exempt from registration are not subject to any manufacturing requirements.

Manufacturer performance is not administratively linked to the veterinary medicine products being manufactured. Where manufacturers are required to be approved prior to product registration, the approval is not linked specifically to the product. If an approved manufacturer does not maintain approved status, the product registrants who have registered the manufacturer's products may not necessarily be affected (if the manufacturer is the sole registrant of the product, this is not an issue).

Manufacturers of other products do not require formal approval, and the authorisation is based on a level of comfort associated with information provided to or held by NZFSA.

Registered agricultural chemical products: Must comply with the ACVM manufacturing standard.

Manufacturers do not need NZFSA approval and are not subject to formal verification audits.

Manufacturers of active ingredients and products must be specified in the application for registration. NZFSA has no formal process for assessing whether to register products, and does not maintain a separate list of manufacturers. Agricultural chemical products that are exempt from registration are not subject to any manufacturing requirements. There have been a number of recent cases of fraudulent, mislabelled and contaminated products in the market.

Fertilisers: Must comply with minimum fit-for-purpose requirements prescribed in the ACVM Regulations 2001. Fit-for-purpose guidance is provided in a voluntary Code of Practice. NZFSA holds no information on who is manufacturing fertilisers. Manufacturers are expected to be able to provide evidence that they have taken due care to comply with the Regulations. They do not have to be approved by NZFSA, and are not subject to a formal compliance programme. There are both gaps in NZFSA's awareness of compliance and occasional complaints about manufacturer non-compliance.

Oral nutritional compounds, including animal feeds: Must comply with minimum fit-for-purpose requirements prescribed in Schedule 4 of the ACVM Regulations 2001. Fit-for-purpose guidance is provided in the voluntary Code of Practice. Manufacturers do not have to be approved by NZFSA, are not subject to a formal compliance programme, and are expected to be able to provide evidence that they have taken due care to comply with the Regulations. Pet food manufacturers must be registered under the Animal Products Act 1999, and manufacturers of ruminant feeds who use ruminant protein must be registered under the Biosecurity (Ruminant Protein) Regulations 1999. NZFSA has little information on who is manufacturing oral nutritional compounds that do not contain animal products.

Vertebrate toxic agents: Must be registered, and the control of their manufacture is the same as it is for agricultural chemical products requiring registration – with the exception of restricted sale/restricted use products such as 1080 and cyanide products. For the exceptions, the manufacturers must be approved by NZFSA and are subject to a formal compliance programme. NZFSA is aware of occasional complaints of manufacturer non-compliance in respect of vertebrate toxic agents.

Labelling

Label content is subject to minimum requirements in the ACVM Regulations 2001. Registered products are subject to the ACVM labelling and advertising guidelines. Conditions of registration require compliance with the labelling and advertising guidelines.

Advertising and promotion

The regulation making powers in the ACVM Act expressly state the power to make rules about how parties directly involved with importing, manufacturing, selling or using products can carry out those activities, including the communication of information about the products. The ACVM Act is not so clear around whether communications by other parties can also be regulated.

Products are at risk of misrepresentation in the marketplace regardless of whether communications are made by parties with vested interests or not. Some communications marginalise important warning information (for example by putting it in very small print), which reduces its effectiveness. Risks arising from advertising and promotions can cause significant personal loss, and damage public confidence in the implied official assurances that authorised agricultural compound products are safe and reliable.

Own use

Own use involves people managing their own animals or plants through the use of substances that have not been assessed and authorised by NZFSA as agricultural compounds, as well as the use of authorised products in a manner that has not been assessed. It used to be limited to simple, traditional uses based on a narrow range of readily-available chemicals. The risk of causing harm was low and regulatory control was not considered necessary. The potential for harm from own use has increased

as sophisticated chemicals become increasingly available, to the extent that it now poses risks far beyond acceptable thresholds. "Own use" includes certain professional groups who compound their own preparations as part of services offered to manage the health and productivity of animals and plants. Oral and homeopathic and herbal veterinary medicines and homeopathic plant products are exempt from registration, with specified minimum requirements. These requirements are considered to be too generic for the range of preparations covered.

Objectives

The objective is to efficiently and transparently administer manufacturing, labelling, own use, advertising and promotion through the use of existing powers under the ACVM Act.

Alternative Options

Generally, no alternative options were considered sufficiently feasible to merit discussion. Two exceptions are the options around:

- products manufactured outside New Zealand's jurisdiction, which are set out under the subheading *Manufacturing* below.
- the provision of professional services, which are set out below under the subheading *Own use and off-label/MUMS use*.

Preferred Option

NZFSA's key proposed changes to regulatory arrangements are discussed below.

Manufacturing

Make regulations that require all manufacturers to comply with minimum obligations in line with the principles of responsible manufacturing. The majority of the obligations would be no more onerous than would previously have been expected.

A sample low-impact proposal is that all manufacturers will need an operating plan that describes how product will be manufactured and assessed as meeting specifications. The term "operating plan" is new, but the expectation that manufacturing should be subject to a documented system is not. Most businesses will be left to make and implement their own operating plans. Operating plans will probably need to be approved for any products requiring NZFSA certification of matters relating to the process specified in the plan, as well as for all veterinary medicines and restricted sale/restricted access vertebrate toxic agent products.

By contrast, a proposed requirement for critical steps in the manufacturing process (and any changes to those steps) to be validated is likely to result in costs. NZFSA is not dictating how validation is done

or who must do it, so managing the costs is to some extent in the hands of the manufacturer. NZFSA has not yet determined whether it will need to set some expectations in regard to validation.

Under the proposed regulations, manufacturers of veterinary medicines and restricted sale/restricted use vertebrate toxic agents will be formally recognised and required to comply with certain performance and technical standards. Other manufacturers' names and contact details will be kept on a list, for the purposes of investigations of non-compliance or product recall. NZFSA will conduct occasional reviews to monitor the performance of industry sectors' programmes.

All export-only product will be exempt from registration, with conditions including a requirement that manufacturers are recognised under the ACVM Act. That recognition will depend upon compliance with standards equivalent to the requirements under the manufacturing regulations.

There will be criteria for authorising products that have been manufactured outside New Zealand's jurisdiction for import, sale and use in this country. Option One: use criteria based on the status given to the manufacturer by the recognised authority in the country in which the manufacture occurs. Option Two: use criteria based on NZFSA's information on the acceptability of the manufacturer and the manufacturing process for the product in question.

The regulatory control of manufacturers will be administratively linked to the products. Verification audits will include specific verification of the products and substances that a manufacturer has authorisation to manufacture, to ensure that they align either with the data held by NZFSA (if registered) or with the company's operating plan (if exempt from registration). Unacceptable performance by manufacturers could have an impact on the authorisation of their products. This was relatively clear with veterinary medicines, and will become more significant for the other classes of products as these proposals are put into effect.

Labelling

Transfer labelling requirements and specifications into the manufacturing regulations. A range of minimum labelling requirements is under consideration as set out in the discussion paper. Compliance with the labelling requirements will be in addition to the label content approval.

Advertising and promotion

Make new regulations that will largely reproduce current requirements and will effectively make existing regulatory arrangements clearer. Apply the requirements that currently apply to registered products to both registered products and those exempt from registration. Products that are exempt from registration will therefore need to meet some new requirements.

As regards communication about off-label use, NZFSA proposes to place a condition on the registration of most products that allows off-label use, but imposes requirements on responsible parties and users to take due care to avoid negative effects. This will mean that communications about off-label uses will need to include warnings as part of the primary message (see above paragraph), which will increase the requirements around and costs of off-label uses.

NZFSA is considering treating all communication practices as relevant to the risks to be managed under the ACVM Act, regardless of whether the party providing communication has a vested interest in the product or not.

NZFSA is considering increasing the profile of warning information, by establishing that it should be part of the primary message of a communication. NZFSA proposes to define “the primary message” as “that part of a communication containing the essential information to be communicated and which is the focus of the communication”. By requiring it to be included in the primary message, NZFSA will require warning information to adequately reflect the significance of the warning. The relationship with provisions in the Fair Trading Act 1986 on “fine print” has yet to be explored.

Own use and off-label/MUMS use

Make two sets of regulations, one for own use and one for off-label/MUMS use. The own use regulations will require any person who uses generic substances, mixtures of substances, or biological compounds as an agricultural compound to comply with minimum requirements. The off-label/MUMS use regulations will require any person who uses a registered trade name product as an agricultural compound in a manner that is not specifically assessed and approved as part of the registration to comply with minimum requirements. For the most part, both sets of requirements will not be new.

Compounding as part of professional services

NZFSA needs to discuss with industry groups the proposals that involve preparations compounded in conjunction with certain professional services. The intention is to exempt from registration herbalists, homeopathic practitioners, pharmacists and veterinarians – and to set some minimum requirements that must be complied with. NZFSA is considering requiring these practitioners to have operating plans to cover their compounding activities and the link with their professional services. The decision may not be the same for all of the groups in every case. The practitioners will need to be recognised by NZFSA under the ACVM Act. Option One: minimum requirements for compounding will be incorporated into technical and professional standards, which can be issued under section 62. Failure to comply would result in loss of recognition. Without recognition, the preparation would not comply with the conditions of exemption and administering it would be an offence. Option Two: add a requirement to comply with a section governing compounding in the proposed manufacturing regulations. Failure to comply with the regulations will also be an offence. While current exemptions

limit administration to topical or oral, this proposal does not make a distinction about mode of administration. It could cover all modes of administration, and set minimum requirements as necessary based on the risks posed. This would mean that preparations could be compounded by these practitioners even for injection or for application to eyes and ears.

Implementation and Review

The Approvals and ACVM Group within NZFSA is responsible for administering the ACVM Act and will implement the proposals.

Consultation

Stakeholders

The reform of the ACVM Act was socialised initially with the industry body, AVMAC. NZFSA held targeted consultation on an overview of the reform process with key industry sectors in Auckland and Wellington in December 2007. Public consultation in New Zealand and Australia will begin with the release of the attached discussion paper in May 2008, and continue in relation to subsequent discussion papers.

Government agencies

The following government agencies were sent draft copies of the Cabinet paper and discussion paper: the Departments of Conservation and Labour, ERMA New Zealand, the Ministries of Agriculture and Forestry, Economic Development, Health and the Ministry for the Environment.