Ministry for Primary Industries
Manatū Ahu Matua

ACVM Notice

Agricultural Compounds Exempt from Registration

Requirements for conditions of exemption

1 August 2017

Issued under the Agricultural Compounds and Veterinary Medicines Act 1997

New Zealand Government

TITLE

ACVM Notice: Agricultural Compounds Exempt from Registration

COMMENCEMENT

This ACVM Notice comes into force on 1 September 2017

ISSUING AUTHORITY

This ACVM Notice is issued under section 76A of the Agricultural Compounds and Veterinary Medicines Act 1997.

Dated at Wellington this 1st day of August 2017.

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(acting under delegated authority of the Director-General)

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Introduction

This introduction is not part of the ACVM Notice, but is intended to indicate its general effect.

Purpose

This notice specifies in more detail the requirements in the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 for agricultural compounds (including veterinary medicines) exempted from registration under those Regulations. The Regulations specify requirements for the exempt agricultural compound and this notice specifies requirements for the person(s) responsible for the exempt agricultural compound to ensure that those requirements are met.

This notice does not specify the requirements in regard to human medicines used as veterinary medicines by veterinarians (Schedule 2, entry 8) and compounded veterinary preparations used by veterinarians (entry 9). (There is a separate notice for compounded veterinary preparations.)

Background

Agricultural compounds are exempt from registration under the Regulations only if the risks specified in section 4 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 can be managed without regulatory assessment prior to authorising the use of the agricultural compound.

Although regulatory assessment is not necessary for exempt agricultural compounds, it is essential that the person(s) responsible for the agricultural compound takes steps to ensure that it complies with the conditions of exemption specified in the Regulations.

To give effect to and amplify the requirements of the Regulations, these specifications and other detailed requirements are issued to ensure:

- fitness of the exempt agricultural compound for its intended purpose; and
- manufacturing of an exempt compound product in accordance with a documented system; and
- information is provided with an exempt compound product when it is supplied to a user; and
- records are kept:
  - in relation to documented systems; and
  - by importers of exempt compound products.

Who should read this ACVM Notice?

This notice should be read by any person who is responsible for the importation, manufacture, sale, or use in New Zealand of an agricultural compound exempt from registration under the ACVM (Exemptions and Prohibited Substances) Regulations 2011.

Why is this important?

Failure to comply with these requirements may result in in the agricultural compound not being compliant with the conditions of exemption and consequently result in an offence against the ACVM Act being committed if it is imported, manufactured, sold, or used without being registered under the ACVM Act.

Document history

These requirements are being issued for the first time. They do not replace or revoke any other versions.

Part 1: Preliminary Provisions

1.1 Application

(1) This notice applies to every person who is responsible for the importation, manufacture, or sale in New Zealand of an agricultural compound exempt from registration under the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.

(2) This notice does not apply to a compounding veterinarian.

1.2 Interpretation

(1) In this document, unless the context otherwise requires:

Act means the Agricultural Compounds and Veterinary Medicines Act 1997

documented system means a documented system of the kind referred to in regulation 9 of the Regulations and includes the product and manufacturing specifications that govern the manufacture of an exempt compound product

exempt agricultural compound means an agricultural compound that meets the definition of at least one of the entries in Schedule 2 column 1 of the Regulations

fit for purpose means that an agricultural compound, when used as recommended, will not cause any of the harms listed in regulation 7 of the Regulations

Good Manufacturing Practice (GMP) means the procedures or practices that are part of quality assurance that ensure products are consistently produced and controlled to the quality specifications defined by the manufacturer. GMP includes both production and quality control

minimum information means the information required to be provided with a product as per regulation 12 of the Regulations

monitoring means regular assessment that aims to provide early detailed information on the activities being assessed to determine if the outputs, deliveries and schedules planned have been reached so that action can be taken to correct any deficiencies as quickly as possible

product and manufacturing specifications mean the following parts of a documented system:

a) formulation or recipe; and
b) name or description under which the product will be sold; and
c) packaging and labelling; and
d) minimum information to be provided with the product; and
e) manufacturing, quality control and product release processes and procedures; and
f) nominated person responsible for compliance to the documented system

Regulations means the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.

(2) Any words or expressions used but not defined in this notice that are defined in the Act or Regulations have the meaning given to them in the Act or Regulations.

Part 2: Requirements

2.1 Manufacturing exempt agricultural compounds

(1) A person who manufactures an exempt agricultural compound must be able to demonstrate that the product and manufacturing specifications set for the exempt agricultural compound ensure that it is fit for purpose through documentation that shows:

a) consideration has been given as to whether the exempt agricultural compound could cause any of the harms listed in regulation 7 of the Regulations; and
b) due care has been taken when specifying the formulation or recipe, the ingredients and the way they are mixed to ensure the product is fit for purpose; and
c) the exempt agricultural compound does not contain:

i) any of the prohibited substances listed in Schedule 1 of the Regulations; or
ii) plants listed in Schedule 3 of the Regulations if the product is an oral or topical herbal preparation to be used as a veterinary medicine[1].

2.1.1 Specifying packaging and labelling

(1) A person who manufactures an exempt agricultural compound to be offered for sale as an exempt compound product must ensure that:

a) the packaging does not compromise the fitness for purpose of the exempt compound product; and
b) the packaging is appropriate in size, material and quality of material for the kind of exempt compound product to prevent damage, contamination, and limit deterioration of the exempt agricultural compound; and
c) the packaging is large enough to contain (or to have attached to it) the specified label and minimum information to be provided with the exempt compound product so that the information is not likely to get separated from the packaging; and
d) the label and required minimum information is resistant to deterioration (or protected from deterioration) so that it is likely to be readable up to the expiry date of the exempt compound product.

Guidance

- See clause 2.1.2(3) for bulk product requirements.

2.1.2 Specifying the required minimum information

(1) A person who manufactures an exempt agricultural compound to be offered for sale as an exempt compound product must ensure that the information provided with the product provides:

a) the information needed to ensure the product meets the relevant exemption in Schedule 2 of the Regulations; and
b) the information specified in sub-clause (2).

(2) The required information is as follows:

a) **the name (if any) under which the exempt compound product is sold or supplied**
The name under which the exempt compound product is offered for sale and supplied to the user must be the same as the one that is specified in the documented system as a product identity characteristic and must be prominently printed on the label.

[1] If the agricultural compound contains any part or unrefined extract from any of the listed plants, the compound is not exempt and must be registered.

b) **a description of the product or preparation sufficient to enable the user to determine the nature and purpose of it**
The purpose for which the exempt compound product is intended to be used must be within the scope of the definition (i.e. entry in column 1 of Schedule 2 of the Regulations) under which it is exempt from registration. There must not be a purpose statement that is not provided for in the relevant Schedule 2 entry or entries.

c) **name and contact details of the manufacturer or importer**
The name and contact information must be of the manufacturer or importer, depending on who is responsible for preparing the exempt compound product for sale in New Zealand and who is responsible for complying with the requirements regarding fitness for purpose (regulation 7 of the Regulations), manufacturing (regulation 9 of the Regulations), and supplying the required information (regulation 12 of the Regulations).

d) **the active ingredients**
The label must list all the active ingredients (as defined in the Regulations).

e) **directions for use**
The use directions for an exempt compound product that is an exempt agricultural compound described in column 1 of Schedule 2 of the Regulations must define a use that meets the conditions relating to that exempt agricultural compound in column 2 of Schedule 2 of the Regulations.

f) **use-by date or expiry date, if applicable**
The date must reflect the time within which it would be reasonable to expect that the exempt compound product would still conform to its product specifications, and change or deterioration would not likely cause any of the harms listed in regulation 7 of the Regulations.

g) **details of precautions (if any) to be taken to prevent or manage the risks described in section 19 of the Act when using the product or preparation**
The precautions can be limited to the ones posed when using the exempt compound product as recommended.

Guidance
- The harms listed in regulation 7 of the Regulations can be used to identify appropriate precautions to address the risks listed in section 19 of the Act.

h) **the batch number or other information sufficient to allow the date and place of manufacture or preparation to be ascertained**.
The form that the batch number or other information takes should comply with common best practice for industry batch records to enable traceability.

i) **any other information specified in Schedule 2 of the Regulations in relation to the exempt agricultural compound(s) concerned.**

(3) If the exempt compound product is sold in bulk, the minimum information must accompany the consignment, either in hard copy or electronically, and be documented in a way that it can be brought to the attention of the user.

2.1.3 Manufacturing for sale

(1) A person who manufactures an exempt agricultural compound to be offered for sale as an exempt compound product must ensure that the product and manufacturing specifications, which have been set and recorded in the documented system, meet the conditions of exemption.

(2) A person who manufactures an exempt agricultural compound to be offered for sale as an exempt compound product must manufacture it in accordance with the following requirements:

a) a person manufacturing an exempt compound product must have and comply with a documented system that includes all the requirements in clause 2.1.4; and
b) the exempt compound product must conform to the product and manufacturing specifications in the documented system before it is released for sale.

2.1.4 Documented system for manufacturing

(1) The documented system must include the product and manufacturing specifications.

Guidance

- For manufacturers such as pet food manufacturers operating under a Risk Management Programme (RMP) approved under the Animal Products Act 1999, it is not necessary to create a documented system if it duplicates the information in the RMP. It is only necessary to document required details that are not covered by the RMP.
- Manufacturers of exempt veterinary medicine products may be operating under an ACVM GMP approval for veterinary medicines. If they use the same manufacturing infrastructure and procedures for veterinary medicines that are exempt from registration, it is not necessary to duplicate these in a documented system specific for the exempt compound products. It is only necessary to document the product-specific details that are not covered by the GMP approval.

Guidance

- If more than one product is manufactured at the same premise, the documented system for an exempt compound product should address the capability to manufacture the range of products and the equipment used as well as the manufacture of specific products.
- The documented system should also describe how cross-contamination is to be avoided to keep each product fit for purpose.

Plant/premise/site/manufacturing area

(2) For every site where any step of the manufacturing of an exempt compound product occurs, the following information must be included in the documented system:

a) information on the manufacturing site, including name, physical and postal address, contact details; and
b) name and contact details of the nominated person with overall responsibility for manufacturing at that site; and
c) outline of the manufacturing activities undertaken at that site; and
d) types of products routinely manufactured.

Guidance

- Information on the types of products routinely manufactured should be either a list of individual trade name products or categories of products with similar characteristics.

(3) The documented system must include an appropriate description of the plant or premise. This may include such things as a line diagram of the buildings, and indication of their use.

(4) Manufacturing areas must not be a source of hazards that compromise the fitness for purpose of the exempt compound product.

(5) Personal hygiene facilities must be located away from the manufacturing area to ensure fitness for purpose of the exempt compound product is not compromised.

(6) The premise must be designed and built or modified to prevent the entry of vertebrate or invertebrate pests that could result in hazards that compromise the product's fitness for purpose.

(7) Exempt compound products must not be manufactured in an area, or using the same equipment, where contamination would compromise conformity to the product specifications of the exempt compound products.

(8) Equipment used in the manufacture of exempt compound products must be designed so it doesn't present a risk to the exempt compound product (e.g. equipment must not shed paint, plastic, or metal into a product).

(9) Surfaces in the manufacturing area must be able to be cleaned to prevent contamination.

(10) Premises and equipment in the manufacturing area must be cleaned according to a regular cleaning schedule.

(11) Cleaning chemicals must not compromise conformance to the product specifications.

Personnel

(12) The documented system must specify personnel (by job title or name) engaged in the manufacturing process, including product release, and the roles that they perform (e.g. manufacturing, quality control, warehousing).

(13) The responsibilities of personnel engaged in the manufacturing process must be defined, including responsibilities for critical steps (e.g. releasing raw materials for use in manufacture, testing, checking, or releasing finished product for sale) and for monitoring compliance to the documented system.

(14) A personnel organisational diagram must be included in the documented system.

(15) A person who manufactures an exempt compound product must take all reasonable steps to ensure that personnel:

a) are not a source of hazards that compromise the fitness for purpose of the exempt compound product (e.g. personnel may need to wear protective clothing to protect the product); and
b) comply with personal hygiene requirements, which must be sufficient to prevent contamination of the exempt compound product; and
c) notify the person nominated in sub-clause (2b) if they are diagnosed with an infectious disease (such as Salmonellosis or Campylobacteriosis) and are not be involved in manufacture if this compromises the fitness for purpose of the exempt compound product; and
d) do not eat or smoke in the manufacturing area; and
e) are trained to ensure manufacturing requirements are understood and followed.

Materials

(16) The documented system must specify how the contact details of all raw material suppliers are recorded to ensure traceback is possible if needed.

(17) Raw materials must be sourced from suppliers who can supply raw materials to the required quality specifications.

(18) Raw materials must be checked on arrival to ensure identity and conformation to quality specifications.

(19) Raw materials must not be entered into stock without identification.

(20) Packaging materials must be of a quality and standard to have no detrimental effect on the exempt compound product (e.g. packaging for animal foods must be food grade).

(21) The packaging must sufficiently protect the exempt compound product from contamination and moisture to ensure that it remains fit for purpose and unspoilt throughout its shelf life.

(22) The product labelling must be of a quality and standard to ensure that attached labels stay attached and readable throughout product shelf life.

Guidance

- If a formulation includes a pre-manufactured ingredient the manufacturing process for that ingredient does not have to be included in the documented system, but the quality check on that ingredient as appropriate in the exempt compound product must be included.
- Depending on the raw materials, they may require testing to verify conformance or checking for contamination. For example, ingredients in animal feeds may need to be tested for:
  - microorganisms (e.g. bacteria, mould, grains contaminated with aflatoxin or mycotoxin)

- chemicals that may cause detectable residues in finished product (e.g. herbicides, pesticides, trace metals)
- substances produced by plants in concentrations that would be harmful to treated/exposed animals or plants (e.g. alkaloids)
- substances capable of causing harm to the target species (e.g. feeds for dogs or horses contaminated with ionophores)
- anti-fungal agents (in grain originally intended as seed grain)
- faecal matter or ingestor contents (if carcasses are being used as raw material)
- putrefaction, deterioration or fermentation that would make the exempt compound product not fit for purpose (e.g. when food by-products such as bread, fruit, and dairy products are used in feed)
- adulterants (e.g. melamine where protein content is a specification of the raw material)
- physical contaminants (e.g. pieces of metal and broken plastic or glass).

Storage and transport

(23) The documented system must detail how raw materials, work in progress, and finished goods are stored in a way that prevents contamination or spoiling. For example, products must be kept away from any other compounds that could contaminate them, and some materials may require refrigeration.

(24) If transport of the finished product is under the control of a person who manufactures an exempt compound product, transport conditions must meet storage requirements.

Manufacturing process

(25) The manufacturing process must be described adequately in the documented system, including step-by-step descriptions of the manufacturing steps with emphasis on specified monitoring points.

(26) Any contractors involved must be specified, with a description of how activities of the contractor are monitored or how their input is confirmed as satisfactory in regard to its impact on the conformance of the final exempt compound product.

(27) Appropriately designed and documented procedures of the equipment cleaning (and cleaning schedules), set-up, manufacturing, packing, and labelling steps must be included in the documented system and followed to enable the process to be conducted consistently and accurately.

Guidance

- The description may include a flow diagram to show the production process from the raw material stage to the finished product stage. If several products are involved, different diagrams should be included if processes are not the same.

Quality control

(28) The documented system must detail the quality checks throughout manufacturing and of the finished product that must be made before each batch is released for sale. This must include a review of the batch records to ensure each step of manufacture has been carried out correctly and recorded.

(29) The physical condition of the exempt compound product, packaging, and labelling (i.e. batch number, expiry, product name, use instructions, storage information on the label) must be checked before the product is released for sale.

(30) If necessary to verify conformance with product specifications, quality control checks must include laboratory testing to verify conformance to product specifications or to check for microbial contamination, or the presence of toxins or residues.

2.1.5 Compliance with the documented system

(1) A person who manufactures an exempt compound product must ensure that a designated person(s):

a) compiles and maintains the documented system; and
b) ensures that the person specified in the documented system as responsible for a function or task complies with the system; and
c) records the performance at the specified monitoring points in the manufacturing process.

(2) A person who manufactures an exempt compound product must ensure that procedures and schedules for internal audits for compliance with the documented system are in place and are carried out as specified.

2.1.6 Record keeping for compliance to documented system

(1) A person who manufactures an exempt compound product must keep records of the application of the documented system, including a record of performance/conformance monitoring data, for 5 years from date of release for sale.

(2) All records must be available and readily accessible for inspection by an ACVM Officer on request.

2.2 Importing exempt agricultural compounds

2.2.1 Importing for sale

(1) A person who imports an exempt compound product, i.e. to be offered for sale, in its imported form, must be able to demonstrate through records that they have sufficient information about the product to be able to determine that:

a) the exempt agricultural compound is fit for purpose; and
b) it complies with any other conditions of exemption.

(2) The information about the product that must be known is:

a) the name of the person responsible for the exempt agricultural compound; and
b) the intended use within the scope of use in the relevant entry in Schedule 2 of the Regulations; and
c) the exempt agricultural compound's formulation or recipe; and
d) the packaging in which the exempt agricultural compound is to be contained; and
e) the name under which it is to be sold or supplied; and
f) any label and minimum information to be provided with the exempt compound product.

Guidance: Importing

- All the above information about the exempt agricultural compound may not be readily available to the importer. Nevertheless, the importer is still responsible for ensuring that, if the exempt agricultural compound is to be offered for sale or supplied to a user as an exempt compound product, it is fit for purpose.
- If the importer cannot obtain sufficient information to confirm that it is fit for its intended purpose (regulation 7, and Schedules 1 and 3 of the Regulations), the importer should presume that it is not fit for purpose and should not import it as an exempt agricultural compound product. An importer cannot assume that a product manufactured overseas is fit for purpose or meets New Zealand regulatory requirements.

Guidance: Providing information

- If the minimum information provided with the product does not comply with regulation 12 of the Regulations, the importer will have to provide the information. If that requires relabelling, the importer must comply with the requirements in this notice for persons who manufacture exempt agricultural compounds.
- If the agricultural compound is in bulk form, the importer will have to provide the required information either electronically or in hard copy.

2.2.2 Record keeping for importers

(1) A person who imports an exempt compound product must keep the records described in clause 2.2.1 and regulation 15 of the Regulations for 5 years after importing the product.

(2) All records must be available and readily accessible for inspection by an ACVM Officer on request.

2.2.3 Altering imports

(1) A person who imports:

a) an exempt agricultural compound to be made into an exempt compound product; or
b) an exempt compound product and alters it in any way, including relabelling

must comply with the requirements in this notice for persons who manufacture exempt agricultural compounds.

Guidance: Importing for own use

- A person who imports an exempt agricultural compound for their own use should have sufficient information about the product to be able to determine that:
  a) the exempt agricultural compound is fit for purpose; and
  b) it complies with any other conditions of exemption.
- Although there are no minimum information/labelling requirements for 'own use' product, MPI recommends that a user identifies any compound by what it is and how to contain, store, and use it appropriately.
- If you are not confident that a product is fit for purpose, don't import it.

2.3 Selling exempt compound products

(1) A person who sells an exempt compound product must ensure that the product is protected from damage and deterioration while it is in their care.

(2) To ensure fitness for purpose is maintained, a person selling an exempt compound product must not alter any aspect of the product, the information provided with it, or the scope of its intended use.

Guidance

- A person who purchases an exempt compound product in New Zealand to on-sell it can assume that the seller has ensured that it is fit for purpose and it is still fit for purpose as long as the exempt compound product, the information provided with it, and the intended use of the exempt compound product is not altered in any way.

2.3.1 Altering exempt compound products

(1) A person who intends to sell an exempt compound product and alters any aspect of it before sale (e.g. packaging) must comply with the requirements in this notice for persons who manufacture exempt agricultural compounds.

Guidance: Using exempt agricultural compounds

- A person who uses an exempt agricultural compound should have sufficient information about the product to be able to determine that:
  a) the exempt agricultural compound is fit for purpose; and
  b) it complies with any other conditions of exemption.
- If a person uses an exempt agricultural compound in a manner other than as directed by the information provided with the product, the product is not exempt from registration unless the different manner is within the scope of one of the exempt compound groups in Schedule 2 of the Regulations. Also, the person cannot presume the assessment of the exempt agricultural compound as fit for purpose when used as recommended is at all relevant to the use in a different manner.
- A person who alters an exempt agricultural compound for their own use should confirm that the resulting compound:
  a) is fit for purpose; and
  b) complies with any other conditions of exemption.
- A person who prepares an exempt agricultural compound for their own use should ensure it is fit for purpose before using it, but that person is not subject to the requirements for the manufacture of an exempt compound product to be offered for sale.
- Although there are no minimum packaging and information/labelling requirements for 'own use' product, MPI recommends that a user identifies any compound by what it is and how to contain, store, and use it appropriately.