Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Special Circumstances Approval

Importing substances under section 8C of the Agricultural Compounds and Veterinary Medicines Act 1997

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Title

Guidance Document: Special Circumstances Approval

About this document

This document provides details of special circumstances approvals under section 8C of the Agricultural Compounds and Veterinary Medicines Act 1997.

Document history

Previous Version Date	Current Version Date	Section Changed	Change(s) Description
Oct 2012	July 2015	All 3.1	Reformatted in new template New subsection (Specified essential animal welfare medications) added.

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1 Purpose

The purpose of this document is to:

- provide details of the framework under which special circumstances approval applications will/will not be considered;
- explain the information required to support an application for approval under section 8C.

2 Background

Section 8C of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 provides the Director-General (DG) of MPI with discretion to approve the importation, manufacture, sale or use of an agricultural compound without registration if the DG considers that special circumstances make it appropriate to grant the approval.

A special circumstances approval under section 8C is required before an unauthorised agricultural compound is used on plants or animals.

3 Framework of approval

The special circumstances scenario determines whether or not a section 8C application will be considered.

The following list of MPI-identified situations is not exhaustive. Applications outside of these situations will be considered and assessed on the basis of the statutory criteria.

Please note that section 8C approval is not a mechanism for circumventing the registration process. Cost of registration of the agricultural compound is not an acceptable rationale for approving the import, manufacture or use of an unauthorised agricultural compound under section 8C.

3.1 Unauthorised veterinary medicine for use by veterinarians

A registered veterinarian must submit an application for approval in special circumstances. There are two general categories of veterinary medicine candidates:

- unregistered veterinary medicines or unconsented human medicines needed to treat a specific case;
- specified essential animal welfare medications.

3.1.1 Unregistered veterinary medicines or unconsented human medicines needed to treat a specific case

An application must be supported by sound argument that the veterinary medicine is essential for the animal(s) being treated. There must be no New Zealand registered or exempt veterinary medicine, or a medicine consented under the Medicines Act that would be effective for that purpose.

For example:

- To confer protection against exotic diseases to animals intended for export if there is no official requirement to do so would be adequate justification to request the import and use of unauthorised veterinary medicines.
- Applications for import and use of unauthorised veterinary medicines from zoo veterinarians for exhibits under their care would be eligible for consideration under this category.

Data on the requested veterinary medicine's chemistry and manufacturing, efficacy, safety and residues would be required only in cases where the ACVM risks are not mitigated via the supervision of the applying veterinarian. The animal(s) to be treated must be under the direct care of the applying veterinarian. The veterinarian must ensure the security of the veterinary medicine and keep adequate records, if needed by MPI, to demonstrate that the compound was not diverted.

The quantity of the veterinary medicine that may be approved at a time will be limited to the amount specified by the veterinarian as being necessary to treat the animal(s). For disease conditions that require lifelong therapy, a request for up to one year's supply of the product will be acceptable. A roll-over request without submitting a new application can be considered for import and use of the medication for subsequent years.

If recurrent requirement for a certain veterinary medicine emerges, the DG may initiate steps to have the product registered.

3.1.2 Specified essential animal welfare medications

The listed unregistered veterinary medicines or unconsented human medicines have been assessed as essential animal welfare medications to avoid unnecessary and unreasonable pain or distress in certain cases. It is considered appropriate and desirable for animal welfare reasons to issue an approval in special circumstances to allow a veterinarian to import and hold them in anticipation of use. The criteria that have been applied in listing a substance are:

- It is needed to avoid unnecessary or unreasonable pain or distress (i.e. animal is likely to die, have to be euthanized, or will suffer significant pain or distress without medication).
- It must be available for immediate use when cases arise.
- There is not likely to be any party who is prepared to register it as a trade name product in New Zealand.
- No practical alternative registered veterinary medicine or consented human medicine is available in New Zealand.

The substances currently listed as essential animal welfare medications for companion animal use only are:

1. Doxapram (e.g. Dopram) 20mg/ml, 5ml injection
2. Phenobarbital (e.g. Phenobsrbitone) 200mg/ml injection
3. Piroxicam 10mg tablets
4. Prednisolone 5mg tablets (28s)
5. Selegeline (e.g. Apo Selegine) 5mg tablets
6. Trazadone tablets (e.g. Desyrel) 50mg and 150mg capsules
7. Zonisamide (e.g. Zonegran) 100mg capsules.

The ACVM Group will consider submissions from expert parties concerning other candidates for essential animal welfare medications. A medication will be listed if, in the opinion of MPI and the New Zealand veterinary community, it meets all of the criteria above. The listing may be subject to conditions, and those conditions may change if the circumstances in which the medication is likely to be used change.

Approval will be to import as a veterinary medicine and to hold in anticipation of use. It will be site-specific (i.e. confined to a single veterinary practice and geographical location). The approval will be specific to the veterinarian requesting the approval. The animal(s) to be treated must be under the direct care of the applying veterinarian or another veterinarian in the same practice.

The veterinarian granted the approval will be responsible for:

- importing the medication and controlling its storage and security; and

- use of the medication in the practice (including use by any other veterinarian in the same practice); and
- reconciliation of use/stock; and
- disposal after expiry.

The medication must not be supplied to any party outside the practice except to another veterinarian in a specific animal welfare emergency as judged by the responsible veterinarian.

A request for up to one year's supply of the product (based on a reasonable justification in the application for approval of the quantity that is likely to be needed at that site during the year) will be acceptable. A roll-over request without submitting a new application can be considered for import and use of the medication for subsequent years.

3.2 Official export requirement

Request for import and use of unauthorised agricultural compounds for official export certification of animals and plants will be considered. For example, animals being exported may need to be vaccinated against a disease that is not present in New Zealand while they are in pre-export quarantine so that they will be resistant to the disease when they arrive at their destination. The vaccine, which is unauthorised in New Zealand, could be imported under this provision.

These requests must be submitted by the relevant Animal or Plant Exports team in MPI or by the exporter endorsed by MPI. The use and security of the product will be the direct responsibility of either the MPI requesting group or the MPI-approved handler.

3.3 Post-entry quarantine use

The relevant Animal or Plant Imports group of MPI must apply to import and use the unauthorised agricultural compound if it is required to treat an imported animal or plant held in quarantine under MPI's supervision.

3.4 Urgent biosecurity use

This request for approval must be submitted by the Operations Branch of MPI or by a party endorsed by that branch.

This approval should be for the import, manufacture or use of an unauthorised agricultural compound for management and control of a biosecurity outbreak, or for the preventative administration in case of an imminent or anticipated biosecurity outbreak.

Note: Section 8C approval may not be the preferred route for importing and using unauthorised agricultural compounds if there is either a 'declared emergency' for the purposes of the Biosecurity Act or a 'special emergency' for the purposes of the HSNO Act. In these situations, it should be possible to invoke provisions of those Acts to override the requirements set under the ACVM Act.

The following information must be provided with the application to enable MPI to make a satisfactory technical appraisal and risk assessment of the unauthorised agricultural compound (unless the information deficiency is adequately justified).

Target species	Information required
Plant species – non-food producing	Chemistry & manufacturing

Plant species – food/feed crops	Chemistry & manufacturing Efficacy Residues
Animal – non-food species	Chemistry & manufacturing Efficacy Target animal safety
Animal – food-producing species	Chemistry & manufacturing Efficacy Target animal safety Residues

An Operating Plan/Technical Programme outlining the strategy to manage the outbreak/biosecurity risk must be included with the application, and this must be in sufficient detail to allow the selection of the appropriate conditions on the approval. Additional information required will be dependent on the degree to which the Operating Plan/Technical Programme manages the ACVM risks.

The quantity of the agricultural compound approved will be limited to the amount likely to be needed to meet the urgent biosecurity need as specified in the Operating Plan/Technical Programme.

You will be responsible for oversight of the import, manufacture or use of the unauthorised agricultural compound, and for maintaining records of the administration of the operating plan/technical programme in regards to the security and use of the agricultural compound.

Amendments to the Operating Plan/Technical Programme that will alter the need for the agricultural compound, or the manner in which it will be used, may prompt adjustments in the special circumstances approval or even withdrawal of approval.

If you anticipate that the agricultural compound will need to be used for more than a year, the DG may advise you to register it.

3.5 Other circumstances

If you think your special circumstances situation fits within the scope of a section 8C approval but it does not fit any of the situations described above or in 4.1 below, contact us to discuss your proposed application and likely information requirements.

Contact us at approvals@mpi.govt.nz

4 Information requirements

As an applicant, you are responsible for providing us with all information required by MPI to make a decision on the application. If your application does not contain the required information, the request is likely to be declined.

A section 8C request for the import, manufacture or use of an unauthorised agricultural compound must be supported by the following:

- The application form. An appropriately completed application form will contain all the information necessary to process the section 8C request **except for the three situations given in 4.1 below.** Special circumstances import approval request

- Other supporting documents (if applicable):
  - HSNO approval(s) (see 5.1 of this document);
  - Approval under the Misuse of Drugs Act (see 5.3 of this document);
  - Biosecurity Clearance (see 5.4 of this document);
  - Safety Data Sheet: This document, which is produced by the manufacturer, contains information about the product's physical and chemical properties. It also includes information on the product's storage, disposal and procedures for its safe handling. The Safety Data Sheet must be included by the product's supplier in a re-sealable plastic pouch attached to the outside package of the product so that it can be accessed by anyone handling the product. Supplying the Safety Data Sheet is a requirement under the ACVM Special Circumstances Group Standard 2011 (see 5.1.2 of this document).
- The appropriate fee (see application form).

4.1 Exceptions to information requirements

4.1.1 Product not to be used as an agricultural compound

If the product in question is not going to be used as an agricultural compound, ACVM Act requirements are irrelevant so a section 8C approval is not required. In this case, to facilitate border clearance complete Declaration: Imported Product Not to Be Sold or Used as an Agricultural Compound.

4.1.2 Medication accompanying an imported animal

Approval for import and use of unauthorised veterinary medicines accompanying an imported animal will deem to have been granted if the importer/agent or kennel hand completes the Declaration for Importation of Veterinary Medicines for Use Only on Accompanied Animals.

The quantity of imported medications that can be authorised via the declaration is generally limited to a three months' supply. If more than this quantity of the overseas medication is required, the request must be made by a New Zealand-based veterinarian and it must meet the criteria set for 'unauthorised veterinary medicine for use by veterinarians' (see 3.1 of this document).

4.1.3 Research use

Section 8C approval for import, manufacture and use of unauthorised agricultural compounds for research use on animals and plants will be considered by MPI as per the procedures laid out for research approvals. For this, you must complete the Research Approval application form, following the requirements described in Research Approval in New Zealand: ACVM Information Requirements

5 Other statutory requirements

As with the usual process for ACVM Act registration of a trade name product, an approval cannot be given under section 8C unless certain requirements have been met, if applicable.

5.1 Hazardous Substances and New Organisms (HSNO) Act 1996

The HSNO Act has a hazardous substances component and a new organism component. Depending on the nature of the agricultural compound in question, HSNO approval under both components may be required.

5.1.1 Hazardous substances component

All agricultural compounds, irrespective of their regulatory status under the ACVM Act, require approval under the HSNO Act for their hazard status before they can be imported, manufactured or used in New Zealand.

For certain approvals under section 8C of the ACVM Act, MPI has developed the Agricultural Compounds Special Circumstances Group Standard 2011, which has been approved by the Environmental Protection Authority (EPA). This standard allows the import, manufacture and use of unauthorised agricultural compounds without requiring additional approval under the HSNO Act, provided the unauthorised agricultural compound conforms to its scope.

The scope of this Group Standard is expected to cover most applications submitted for the following special circumstances situations:

- post-entry quarantine use;
- official export requirements;
- medications accompanying imported animals;
- unauthorised veterinary medicines for use by veterinarians.

If your request for the importation, manufacture or use of an unauthorised agricultural compound for any of the above special circumstances situations is not covered by the scope of the Group Standard, we will advise you to support your application with the appropriate HSNO approval.

The Group Standard does not apply to research work or urgent biosecurity use. For these situations, you must support your 8C application with appropriate HSNO approval.

5.1.2 Conditions

The Group Standard places conditions that section 8C applicants must comply with. MPI has designed the special circumstances approval process to make compliance with these conditions as easy as possible.

- **Label information:** The Group Standard requires the following to be included as part of the agricultural compound's label information: (a) hazard classification information relevant to the compound, (b) contact details of the importer, and (c) a 24-hour emergency telephone number.

  For agricultural compounds imported from Australia, USA, Canada, and the European Union, the hazard classification information requirement on the authorised label is met. The section 8C application form asks applicants to name the country the compound will be imported from. If it is not from one of the above countries, contact us for advice on providing evidence that the Group Standards labelling requirements are met.

  The EPA has determined that requirements (b) and (c) above will be met if the address on the parcel has the importer's contact details plus the importer's cell phone number. The special circumstances approval certificate will have a condition about meeting the contact details requirement.

- **Safety data sheet:** The Group Standard places an obligation for agricultural compounds with certain hazard properties to be supplied with safety data sheets, which must be accessible for the compounds' handlers. The special circumstances approval certificate will have a condition requiring you to ask the exporters of the agricultural compounds to include the safety data sheet for all compounds (irrespective of their hazard classification) in a re-sealable pouch attached to the outside of the parcel.

  The safety data sheet requirement does not apply to veterinary medicines accompanying an imported animal.

- **Advertisement:** Agricultural compounds imported under the provisions of the Group Standard are prohibited from being advertised. A similar prohibition is in place under the ACVM Act for special circumstances approvals.
- **Site and storage requirements:** The Group Standard requires agricultural compounds above certain quantities (minimum trigger quantity is 100L or 100kg) to be stored in specified ways. The special circumstances approval certificate will have a condition about this requirement.
- **Approved handler requirement:** For agricultural compounds with HSNO 6.7A (carcinogenicity) classification and exceeding 10L or 10kg in quantity, the handler must hold appropriate EPA test certification. There is an exemption for this requirement for the following two special circumstances approval scenarios:
  - *Medications accompanying imported animals*: A specific exemption has been built into the Group Standard for this scenario.
  - *Unauthorised veterinary medicine for use by veterinarians*: The Group Standard recognises veterinarians holding a current practising certificate as being compliant with the approved handler requirement.
  - For the other two scenarios (post-entry quarantine use and official export requirements), the special circumstances approval certificate will have a condition about this requirement.
- **Packaging requirement:** The Group Standard's packaging requirements are met if the regulated parties import agricultural compounds from Australia, USA, Canada and the European Union. If it is not from one of the above countries, contact us for advice on providing evidence that the Group Standard's labelling requirements are met.
- **Personal protective equipment**: The Group Standard's requirement for handlers to wear personal protective equipment applies to agricultural compounds with certain hazard classifications. As this requirement is not applicable for compounds in closed packaging and complying with the Group Standard's packaging requirement, regulated parties are not expected to be affected by this condition. The special circumstances approval certificate will have a condition about this requirement.
- **Passenger service vehicle restriction**: The Group Standard prohibits agricultural compounds above certain weights or volumes per package (the limit depends on the compounds hazard classification) from being carried on passenger service vehicles. As the imported compounds are intended to be delivered via goods vehicles, this requirement is unlikely to impact on special circumstances approvals.
- **Disposal of unused agricultural compounds and packaging**: The Group Standard requires agricultural compounds and the packaging to be disposed of in ways that render the compounds non-hazardous. Instructions for safe disposal are included as a condition on the special circumstances approval certificate.
- **Record keeping**: Section 8C applicants are required by the Group Standard to keep records of their imports via the special circumstances approval process as EPA may want to verify if requirements under the Group Standard have been adhered to. The special circumstances approval certificate will have a condition about record keeping.

If you have a query regarding the Group Standard contact us at approvals@mpi.govt.nz.

5.1.3 New organism component

If the requested agricultural compound is intended to be imported and it contains a live organism (including spores, DNA or plasmid components), your special circumstances approval application must be supported by an EPA determination of whether or not the organism is new to New Zealand. If the determination indicates that the organism is new to New Zealand, MPI will process your special circumstances application only after EPA has given its approval to import.

EPA's new organism approval is in addition to the EPA's hazardous substances approval.

If the EPA imposes any restrictions as part of the approval, it is your responsibility to comply. MPI will not monitor their observance.

Environmental Protection Authority (External website)

5.2 Medicines Act 1981

Applications for importing and using agricultural compounds containing active ingredients that are prescription medicines under the Medicines Act may require the approval of the Ministry of Health before section 8C approval can be granted. MPI will contact the Ministry of Health for the approval.

If the Ministry of Health imposes any restrictions as part of the approval, it is your responsibility to comply. MPI will not monitor their observance.

5.3 Misuse of Drugs Act 1975

If the product contains a controlled drug as defined under the Misuse of Drugs Act, you must include an approval from the Ministry of Health.

If the Ministry of Health imposes any restrictions as part of the approval, it is your responsibility to comply. MPI will not monitor their observance.

Ministry of Health (External website)

5.4 Biosecurity Act 1993

If the requested agricultural compound contains an ingredient originating from an organism (such as plant, animal, fungus) a Biosecurity Clearance must be included along with the section 8C application.

Information on obtaining the clearance is available under “Importing” on the MPI website. Alternatively, contact the Animal Imports Team by email animalimports@mpi.govt.nz or phone 04 894 0304.

6 When section 8C approvals will not be granted

6.1 Registered agricultural compounds

Approval under section 8C cannot be granted to registered agricultural compounds. If a registered agricultural compound must be considered under section 8C, the trade name product must first be de-linked from its conditions of registration. One way of achieving the registration de-linking is by re-branding the registered trade name product.

6.2 Prohibited substances

Special circumstances approval cannot be granted to substances listed in Schedule 1 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011. (External website)