



# Suspension of Registration of a Trade Name Product

ACVM Operational Interpretation No 187

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# Suspension of Registration of a Trade Name Product

## 1 Introduction

The purpose of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 (ACVM Act), as stated in section 4 is to:

- prevent or manage risks associated with the use of agricultural compounds; being:
  - risks to trade in primary produce; and
  - risks to agricultural security; and
  - risks to animal welfare; and
  - risks to public health; and
- 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.

Conditions are imposed on the registrations of trade name products to ensure that the above risks are mitigated. Compliance with these conditions is mandatory.

Section 30A of the ACVM Act 1997 provides that the Director-General may suspend the registration of a trade name product (TNP) for a period of three months if the Director-General has reasonable grounds to believe that any condition of registration is not being complied with.

Suspension of the registration of a TNP prevents the import, manufacture, sale or use of the relevant TNP (unless a condition of the suspension allows otherwise) until the registration is restored.

### 1.1 Scope

This interpretation states the principles to be used by the ACVM Group when registration of a TNP is suspended.

The document also outlines the circumstances of imposing such a suspension.

## 1.2 Definitions and abbreviations

Remedial action means the actions specified by the Director-General in the conditions or requirements imposed under section 30A(2) and directions imposed under section 30A(7) that must be complied with by the registrant (or any party contracted by the registrant) before a suspension can be lifted.

# 2 Interpretation

## 2.1 Consideration of Suspension

Suspension may be considered when there are reasonable grounds to believe that:

- a TNP itself is non-compliant with any condition of registration in a manner that is under the control of the registrant (or any party contracted by the registrant); or
- the actions of the registrant (or any party contracted by the registrant) are not compliant with the conditions of registration; and
- action could be taken by the registrant in a relatively short time to correct the non-compliance.

In such cases, the registrant may be given an opportunity (via suspension of registration) to comply with the conditions of registration within a specified period rather than have the registration immediately reassessed under Section 29.

Suspension of registration is not appropriate in cases in which the product and the registrant are compliant with the conditions of registration but the conditions of registration do not fit the risk management needs. In such cases reassessment is the most appropriate action. This includes cases in which:

- a condition imposed upon registration is no longer considered appropriate or in an appropriate form by the ACVM Group
- the ACVM Group identifies a significant change to the risk profile of a TNP that brings into question the current conditions of registration.

Suspension of registration is not necessary (and most likely not appropriate) in cases in which the non-compliance with a certain condition of registration is the fault of some other party than the registrant. In such a case a prohibition notice may be issued under Section 65 to restrict the product and the activity of the non-compliant party.

## 2.2 Advising Registrant of Intention to Suspend

The decision to suspend must be made by the Director-General or a person with the delegated authority under Section 30A.

The suspension may be based on evidence of reasonable grounds to believe that the product or the actions or inactions of relevant parties are not compliant with the conditions of registration. However, suspension should not be progressed until the case is investigated to confirm the non-compliance and the remedial action directions can be specified.

Notification must be provided to the registrant that the Director-General or their delegate proposes to suspend the registration. This must be done prior to the start of the suspension period as specified under Section 30A(3) of the ACVM Act. The notice should contain:

- the reason for suspension
- the period of suspension (up to three months)
- the date or time of commencement (which must not be earlier than the date of notification)
- the remedial action that must be taken before a suspension can be lifted
- any other conditions or requirements and directions in relation to the suspension.

Where appropriate, conditions of suspension may specify certain aspects of the suspension with regards to sale and use of product, including but not limited to;

- continued use of the products in the market place
- continued sale and use of a limited quantity under specified circumstances, including urgent situations.

The notification must advise the registrant of their right to request a statutory review of the decision made under delegated authority. Information on the review process, particularly how to initiate a statutory review, should also be provided.

## 2.3 Initiation of Product Suspension

Suspension of registration will commence immediately following public notification in the *Gazette*. The registrant will be notified directly regarding the suspension and the date on which it will come into force.

Suspension will commence through 'flagging' on the ACVM register which will indicate the suspended status. Conditions of suspension and a brief description of the reasons for the suspension must be noted on the register.

If the situation warrants wider coverage and exposure, NZFSA may advertise suspension through any mechanism it considers appropriate.

## 2.4 Suspension

The Director-General or the delegate will specify the conditions or requirements and directions but it will also state its intended actions. This may include:

- auditing facilities/records
- prohibitions on import, manufacture, sale and/or use
- forced site closure.

## 2.5 Removal of Suspension

In a situation where a registrant has provided sufficient evidence to indicate remedial action has been completed, or has initiated a remedial action program that The Director-General or delegate considers is sufficient to address the non-compliance, then the suspension status will be removed and the register amended accordingly. The conditions and restrictions applied during suspension will cease with the removal of the suspension status, unless the Director-General or delegate states otherwise as in the case of an extended remedial action program.

Public notification of the removal of the suspension will be considered, if appropriate.

## 2.6 Extending the Suspension Period

It is expected that a registrant will complete the remedial action within the three month period of the suspension. However, if the registrant advises that some actions cannot be completed in the three month time frame the delegate may consider, after discussion with the registrant, extending the suspension for a further period of up to three months. The extension notification should again contain;

- the reason for extended suspension
- the period of extended suspension (up to three months)

- any other conditions or requirements and directions in relation to the extended suspension.

In the event an extension is not granted and the remedial action has not been completed, the registration may be reassessed under section 29.

## **2.7 Recall**

If the non-compliance is so crucial that product that has already been sold poses a serious risk, the Director-General may direct a recall of that product under Section 35G of the ACVM Act.

## **2.8 Consequences of failure to take remedial action**

Failure to complete the necessary action in the allotted timeframe may result in the reassessment of the registration. This may lead to changes in the conditions of registration or even cancellation of the registration. Re-activation of a cancelled registration will not be permitted. An application for a new registration will have to be lodged.

To knowingly allow or cause a product to be non-compliant with the conditions of registration or knowingly failing to comply with the conditions of registration is an offence under Section 55(1)(c). A prosecution may be taken in addition to suspension of registration.