Guideline for Registrants: Request to release your non-complying batch of an ACVM registered product (Batch Specific Variation - BSV)

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Contents

1 Purpose

This document is for registrants, New Zealand agents or other authorised entities that require a Batch Specific Variation (BSV) to release non-complying batch(es) of an ACVM registered product to the New Zealand market.

This document is intended to:

- provide guidance on applying for a BSV.
- provide guidance on completing the application form correctly.
- provide guidance on mitigating the risks associated with the release of non-complying product to the New Zealand Market.

2 Definitions and abbreviations

Batch means a defined quantity of a formulated trade name product produced in one process or a series of processes so that it could be expected to be homogeneous within specified limits.

Batch number means a unique combination of numbers and/or letters that specifically identifies a batch.

Bulk product means any product that has completed all processing stages up to, but not including, final primary packaging.

Bulk product batch number means a unique combination of numbers and/or letters that identified a batch prior to being packed into its final primary packaging. This may be the same as the packed batch number.

Corrective action(s) means actions taken to correct the non-compliance and manage the immediate risk.

Implicated batch(es) means the identified batch(es) of an ACVM registered product that are impacted by the identified non-compliance.

Non-compliance means failure to comply with the ACVM Act or Regulations including the conditions of registration or conditions of exemption. A non-compliance may also be referred to as a non-conformance, a quality defect, or defective product. These terms are intended to have the same meaning.

Non-complying batch means a batch that have been identified as not meeting the expected quality standard and/or registration particulars, including those specified on the approved label, approved product and manufacturing specifications, and conditions of registration.

Out of specification (OOS) means the results of finished product release testing do not comply with the limits specified in the registration.

Packed batch number means a unique combination of numbers and/or letters that specifically identifies a batch once it has been packed into finished primary packaging, i.e., the batch number specified on the marketed unit. For some companies this may be the same as the bulk batch number.

Preventative action(s) means actions taken to eliminate the cause of the non-compliance and prevent the non-compliance from reoccurring. This also includes action(s) taken to prevent similar non-compliances in other products and/or batch(es) from occurring.

3 Introduction

Products registered under section 21 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 are required to comply with the conditions of registration applied under section 23 of the ACVM Act.

All ACVM registered products must be manufactured and labelled in accordance with the product and manufacturing specifications approved as part of the registration. These are enforced through the applicable conditions of registration.

It is expected that the conditions of registration are always complied with. However, it is acknowledged that occasionally things can go wrong unintentionally. As a result, conditions of registration may not be complied with. In some circumstances the risks may be negligible, and/or the risks associated with the non-compliance may outweigh the risk of not having a certain batch available at all.

In exceptional circumstances, where an unexpected event or result has occurred leading to a batch that needs to be released that is non-complying, a Batch Specific Variation (BSV) can be requested and will be assessed on a case-by-case basis.

BSVs are limited in duration and may be accepted for specific batches of ACVM registered products to ensure maintenance of supply, when supply of product in compliance with the products' registration particulars is temporarily and unavoidably affected, or to bring a batch into compliance with the products' registration particulars providing the risks can be justified, mitigated and/or the risks outweigh the product not being available for use in the market.

Note: BSVs are granted under the ACVM Act only. The registrant is responsible for ensuring other legislative requirements for the batch(es) are current and valid (including HSNO or Biosecurity approval (if applicable)).

Registrants are strongly discouraged from applying for a BSVs when batch(es) are not in line with the product's approved specifications. However, in exceptional circumstances non-critical non-compliances may be considered on a case-by-case basis. Where feasible and applicable, it is expected that non-complying batches are reworked in accordance with defined and validated procedures. However, where this is not possible or the non-compliance does not significantly impact the risk areas managed under the ACVM Act, then a BSV may be accepted.

BSVs should generally be applied for by the product registrant. However, in instances where the applicant is an entity other than the registrant, such as a third-party consultant or manufacturer, the registrant must be informed and agree with the proposed request.

If a non-compliance has been identified with a product or batch **already on the market,** complete the Non-compliance Report: Notification of your non-complying ACVM registered product on the market (ACVM 41) form. See our website for more information.

4 BSV request process

A BSV is considered on a case-by-case basis and should only be applied for in exceptional circumstances for a specific batch. It is not intended to:

- facilitate a permanent change, or
- be used as a temporary measure when a permanent change is required urgently, or
- circumvent, replace, or fast-track the registration variation process.

If the proposed change(s) in the application will be permanent, (e.g., change of the approved manufacturing process, change in raw material suppliers etc.) then the registrant must apply for a variation to the product registration. It is expected that registration variation applications for permanent changes be made with sufficient time for the application to be processed and approved prior to implementation of the change.

If a BSV is requested for the same reason as a variation application already in the queue or for a change that will become permanent; the BSV will not be granted.

Requests for registration variation applications to be expedited may be considered in exceptional circumstances if a permanent change is required urgently. Any permanent variation applications

(including requests for expediting) should be submitted to approvals@mpi.govt.nz. BSVs will not be considered to release a batch for a product wide change that is considered permanent.

Requests for a BSV should be submitted using the BSV request form. The form should be completed in full and all relevant support information provided. If the form is not fully completed, the request will not be accepted for assessment.

Once a request has been received, an assessment will be conducted using the information and risk assessment provided along with any information held on file (if applicable).

The assessment takes into consideration:

- the risks to one or more matters referred to in section 4
- the impact of the non-compliance on the quality and sterility of the product
- the market distribution of the batch(es)
- the impact on the market i.e. will a product shortage be likely and potential risk to animal welfare or crop safety if the batch(es) are not released
- the cause(s) of the non-compliance
- the actions that have been or will be taken to prevent the non-compliance from reoccurring.

MPI will review the BSV request and aim to inform the applicant of the decision to approve or decline the request within five working days.

If further information is required to decide on the application, MPI will contact the applicant with this request.

If the risks are too great and/or cannot be mitigated the BSV will be declined. Where the application has been declined, the applicant will be informed by email with details as to why the application was declined.

Examples of when a BSV request may be declined include:

- Lack of information or incomplete form
- Instances where a BSV is not appropriate, for example:
  - A variation to registration is in progress (e.g. C1, C2)
  - If the issue is deemed to be a matter for compliance
- Evidence that the risk(s) has not been mitigated or are not acceptable
- Where an X-Variation is applicable
- Where it's apparent that relevant product approvals under the Hazardous Substances and New Organisms (HSNO) Act 1996 or Biosecurity Act 1993 are not valid for the batch(es).

5 Guidance to complete the ACVM 68 form

This guidance should be used to help complete the Batch Specific Variation (BSV) request form.

Email the completed form and supporting documents to ACVM-recallsandcompliance@mpi.govt.nz.

5.1 Registered product details

Complete the trade name, registration number (AXXXXXX, PXXXXXX or VXXXXXX) and product type of the product affected by this non-compliance.

5.2 Address and contact details for this request

Specify whether you are the Registrant, NZ Agent/Consultant, or another authorised party, and provide your contact details and postal address for this request.

Where a third party or the manufacturer (i.e., the registrant is not the manufacturer) is acting on behalf of the registrant for the BSV, please provide evidence this has been agreed by both parties.

Provide the current accounts payable email address to which invoices should be emailed. Where a purchase order number is needed when invoicing, please add the P.O. number in the Active billing details dialog box.

5.3 Details of implicated batch(es)

Multiple batches: In general, BSVs are only considered for one batch at a time. However, if a non-compliance has been identified for multiple batches of the same product and the risk assessment is the same, one form can be used for multiple batches.

Multiple products: If the same non-compliance affects batches of several registered products, complete one form for each product.

Provide full details of the following:

- Specify the name and site address of the manufacturer who manufactured the implicated batch(es) and select whether this manufacturer is listed on the approved PDS.
    - Often there is more than one manufacturer listed on a PDS. It is important to state the manufacturer of the implicated batch(es) only.
- Specify the name and address of the repacker/relabeller and select whether this repacker/relabeller is listed on the approved PDS.
    - Only include the repacker/relabeller if the implicated batch(es) were repacked/relabelled. Write N/A if the batch(es) were not repacked/relabelled.
- Specify the name and address of the QC testing laboratories that have performed finished product release testing of the batch(es) (if different from the manufacturer). And select whether they are listed on the approved PDS.
- Provide details of the batch as stipulated on the form:
    a) Bulk batch number (or batch numbers affected as applicable)
    b) Bulk batch size in applicable units such as Litres, Kilograms etc.
    c) Packed batch number (if different to bulk batch number)
    d) The unit sizes (i.e. the pack size such as 1kg, 1L, 500mL etc.)
    e) The number of units per marketed pack (e.g., one box containing 5 x 500mL bottles)
    f) Number of packs that are planned to go to market
    g) Date of manufacture in DD Month Year (e.g. 25 March 2020)
    h) The expiry date (currently approved expiry date) in Month Year format (e.g., March 2022). **Note:** For agricultural chemicals, the approved shelf-life should be specified in the Batch expiry section.

In cases of multiple batches, enter each batch on a different line as per the example below:

Provide details of the batch(es) applicable to this BSV							
Bulk batch number *(a)*	**Bulk batch size (kg or L)** *(b)*	**Packed batch number** (if different to bulk batch) *(c)*	**Unit size** *(d)*	**Number of units in each marketed pack** (Enter 1 if each unit is sold individually) *(e)*	**Number of packs available for sale** *(f)*	**Date of manufacture** *DD MM YY (g)*	**Batch expiry date** (as currently approved) *DD MMM YY or MMM YY (h)*
B135813	100L	B135814	500mL	5	20	25 Mar 20	Mar 22
B135813	100L	B135815	1L	1	50	25 Mar 20	Mar 22
B213455	100kg	B213456	1 kg	1	100	14 Jul 20	Jul 21
B89144	20L	B89145	10mL	10	200	07 Apr 20	Apr 22

5.4 Details of the BSV request

- Describe the issue(s) with the batch(es). Provide details of the parameters that are not in accordance with the approved registered particulars specified in the PDS. Include the following where applicable:
    - laboratory testing results
    - certificates of Analysis
    - photographs/pictures
- Provide a clear explanation of the rationale for the BSV. Include full details of why the implicated batch(es) should be released to the New Zealand market. For example, is there an urgent need or a shortage of product such as the release is required to meet seasonal demand that may otherwise result in lack of availability adversely affecting animal welfare.
- Identify the risks and include a detailed risk assessment and justification for the release of the batch(es). Include details such as:
    - root cause analysis
    - comparison to other batches
    - trending data
    - subject matter expert input etc.
    - details of CAPAs (etc.) to correct the issue and prevent it from happening again
    - examination and retesting of retained samples
    - identify the possible outcomes for the risk(s) identified
    - identify the control measures in place to manage the risk(s)
    - provide stability data or retention sample testing data if the shelf life is to be extended.
- Provide details of the forecasted sales and supply, for example:
    - How long is the implicated material expected to be on the market?
    - Is there a risk that the product could expire before sale?
    - Is the product for seasonal or year-round use?
- Confirm you have checked that all other specifications and registration particulars (other than those detailed above) comply with the approved registration. If you identify that other parameters do not comply with the registration, include these above and document as part of the risk assessment.
- Provide any additional clarifying information as applicable which may assist in the assessment of your BSV request. If you have provided attachments, include a list of all the documents here.

5.5 Impacts to other legislative requirements

In some situations, the non-compliance may also impact approvals or permits under other legislation such as the HSNO Act 1996 or Biosecurity Act 1993.

As part of your BSV request, you need to determine if the non-compliance affects the HSNO or Biosecurity approval (where applicable) for the product and provide evidence of the new approval if necessary. If it becomes apparent that the batch(s) do not meet HSNO or Biosecurity approval for the product, the BSV request will likely be declined.

Examples that may affect the HSNO status include:

- Change in formulation (such as contamination, change in amount of active ingredient, or change in excipients)
- Change in impurity profile of actives or excipients (if the Environmental Protection Authority (EPA) has set limits on purity or impurities of concern).
- **Note:** this is not an exhaustive list and there may be other situations that may result in a change to the HSNO status. If in doubt you should discuss the proposed changes with the EPA directly.

Examples that may affect the biosecurity status include:

- Contamination (including active ingredient/raw material contamination)

- There is a change in the formulation, source and/or manufacturing process of any biological ingredient (other than those listed in the Negligible Risk Ingredient Schedule).
- **Note:** this is not an exhaustive list and there may be other situations that may result in a change to the biosecurity approval. If you are uncertain if your biosecurity approval is affected, contact Animal Imports (animal.imports@mpi.govt.nz) for veterinary medicines and VTAs, or Plant Imports (plant.imports@mpi.govt.nz) for agricultural chemicals.

Does the non-compliance affect the **HSNO approval** of the batch(es)?

- Yes - If the non-compliance means that the batch(es) no longer meet the current HSNO approval of the product, select yes and provide details of the change and evidence of the new HSNO approval. Evidence may take the form of a new HSNO approval or, where appropriate, declaration of self-assignation to a different approval.
  Note: You will also need to ensure that all of the controls imposed by the new HSNO approval have been met for this batch.
- No - If the non-compliance does not affect the HSNO approval of the batch(es), select no and provide details including:
  - declaration that you have self-determined that the batch(es) still meets the current HSNO approval; or
  - evidence from EPA that the HSNO approval is still valid (this may be an email).

Does the non-compliance affect the **biosecurity approval** of the batch(es)?

- Yes - If the non-compliance affects the biosecurity approval, provide details of the change and evidence that:
  - The current biosecurity approval is still valid for the batch(es) (this may be an email), or
  - Obtain a new biosecurity approval for the implicated batch(es).
- No - If the non-compliance does not impact the biosecurity approval.
- N/A - Select not applicable if the product does not require biosecurity approval.

Important note: Authorisation to release your non-complying batch(es) is granted under the ACVM Act only. The registrant is responsible for ensuring other legislative requirements for the batch(es) are current and valid (including HSNO or Biosecurity approval (if applicable)). However, if it becomes apparent that the batch(s) do not meet HSNO or Biosecurity approval for the product, the BSV request will likely be declined.

5.6 Additional actions

- If there any additional proposed manufacturing steps (such as over-labelling with an extended expiry date) to be performed, provide full details of the intended process. Including details such as:
  - the labelling and procedures to be followed and the entity that will be performing the additional steps. Include full details of the steps performed, include attachments such as photographs, intended procedure, batch records of the packing process and label reconciliation.
  - If over-labelling is required, it must not obliterate required original text. If placed to cover incorrect or outdated text, the over-label should not permit the underlying text to be visible. The over-label must have permanent adhesive.
  - A documented record on the activities performed should be prepared and retained at the manufacturing site for review upon request.
  - If no additional actions are required, write N/A and proceed to section 7.
- Specify the name of the entity performing any additional manufacturing steps.
- Specify the address of the entity performing any additional manufacturing steps.
- If the entity performing the additional steps is not approved on the PDS for this product provide details as to why this entity is fit for purpose and appropriate to perform these steps.

- If the entity has GMP approval a copy of the GMP approval held by the site which will be performing the additional steps should be submitted (for veterinary medicines and vertebrate toxic agents).

5.7 Reoccurrence

Provide details regarding the actions that have been taken or are proposed to prevent this non-compliance reoccurring. For example, preventative actions, supplier evaluations, testing, training, or validation.

If a similar BSV has been requested for this product previously, provide the BSV number.

If in the past twelve months, there has been a similar BSV requested for another product provide the number of the BSV (include declined BSVs).

5.8 Additional supporting information

Provide details of any attachments to support your request.

5.9 Signature and date of request

Electronically sign and date the form.

5.10 Fees, charges and BSV outcome

Complete the appropriate section to notify us of your payment details. Please provide your customer number if you are an approved creditor.

The costs incurred by MPI will be charged in accordance with schedule 1 of the Agricultural Compounds and Veterinary Medicines (Fees, Charges and Levies) Regulations 2015.

To reduce the likelihood of additional time being charged, registrants should:

- promptly provide as much information with your request. If information is still pending, state when the outstanding information will be provided.
- respond to requests for additional information or clarification promptly.

Where the BSV request has been approved the applicant will be sent a BSV letter of authorisation.

If the BSV request has been declined, the applicant will be notified of the decision via email. Note that the fee may still be charged where the request is declined. Where a request has been declined:

- There will not be a charge where no appraisal is performed (such instances may include where the request should be a compliance matter or where a BSV can't be considered). Such cases would generally be decided in less than fifteen minutes.
- Where the application has been assessed/appraised, the appraisers time and assessors time (if applicable) will be cost recovered and the applicant will be invoiced where the application has been declined**.**

Email the completed form and all supporting documents to ACVM-recallsandcompliance@mpi.govt.nz

6 Document History

Version Date	Sections Changed	Description of Changes
July 2021	New document.	New document.
March 2024	All	Formatting and minor wording amendments. Additions to incorporate impacts to other legislative requirements.