



Application Form (HS6C)
*Notification of changes to formulations or uses of
vertebrate toxic agents*

Send by post to: ERMA New Zealand, PO Box 131, Wellington OR
email to sos@ermanz.govt.nz

| | | |
|---|------|--|
| Company name: | | |
| Company address: | | |
| Postal address [if different to company address] | | |
| Contact name: | | |
| Job title | | |
| Contact person phone / e-mail: | (0) | |

1 Product name:

2 HSNO Approval number:

3 Full composition (attach if insufficient room.)

3.1 Existing formulation

| CAS number | Component name | Function of component | Concentration (g/L or g/kg) |
|------------|----------------|-----------------------|-----------------------------|
| | | | |
| | | | |
| | | | |

3.2 Modified formulation

| CAS number | Component name | Function of component | Concentration (g/L or g/kg) |
|------------|----------------|-----------------------|-----------------------------|
| | | | |
| | | | |
| | | | |

4 Reason for change to formulation

5 Is the modified formulation intended to replace the existing formulation?
Yes/No



6 Formulation type

[Identity whether there is change between the existing and the modified formulation type – see notes to this form for formulation codes]

7 Source of active ingredient

[If there has been a change in source of the active ingredient, name the manufacturer and the location of the manufacturing plant]

8 Impurity profiles of active ingredients:

[If there has been a change in source of the active ingredient, list all impurities present in the active ingredient(s) at levels greater than or equal to 0.1%, and at any level for toxic / ecotoxic impurities or where the toxicity / ecotoxicity is unknown]

9 Information on the use pattern of the product

9.1 Methods of release

| | Existing formulation | Modified formulation |
|--------------------------------------|----------------------|----------------------|
| Contained ground-based application | | |
| Uncontained ground-based application | | |
| Aerial application | | |

9.2 Bait size

| | g/bait [specify all sizes for the product] |
|----------------------|---|
| Existing formulation | |
| Modified formulation | |

9.3 Food bait [only applies to soluble concentrate containing 200g sodium fluoroacetate/L]

[Identify the proposed new food bait, and include description of bait preparation and steps taken to minimize particles <0.5 g]

10 Additional information

[refer to guidance on information requirements]

[List studies attached to this notification and provide a summary of the findings, including your assessment of whether the modified formulation is likely to present a greater risk to non-target species and/or people than the existing formulation]

Instructions to complete form

You need to ensure that all relevant information is provided in full before you send in the form. If the form is incomplete, we will be unable to process your application and will need to contact you to fill in the missing information.

Full composition – existing and new

If you do not have access to the full composition of the substance, you will need to ask the company who does to supply the information to ERMA New Zealand directly, with an appropriate cover letter to ensure that we can link your notification to that information.

Please ensure that the composition totals 100%. If it doesn't we will not be able to start work on your application. If the composition of your substance includes ranges [e.g. 5-10%] for different components, please indicate where possible if some ingredients are optional, or are not always present. In the column headed 'function' please indicate what the purpose of the component is within the mixture.

Please check that the names of components and their accompanying CAS numbers match. A useful website for checking these details is ChemID Plus <http://chem.sis.nlm.nih.gov/chemidplus/>. If these details don't match, we will need to ask you for more information i.e. to confirm whether the name or the CAS number is correct.

Formulation type - please choose the most appropriate international¹ bait type code from the list below and note whether changes to the composition have resulted in a change of formulation type

AB – grain bait [ie treated grain]

BB – block bait

CB – bait concentrate – a solid or liquid intended for dilution before use as bait, ie mixing with food

CL - contact liquid or gel for direct application

CP – contact powder (formerly known as tracking powder)

GB – granular bait

GS – grease, very viscous formulation based on oil or fat

PA – paste

PB – plate bait

SB – scrap bait

XX – other [please specify]

¹ "Catalogue of Pesticide Formulation types and International Coding Systems", GCPF (Crop Life) Technical Monograph No 2. 5th Edition, 2002

Guidance on information requirements for notification of changes of formulation or uses of vertebrate toxic agents

1 Background

Changes to non-hazardous ingredients in baits may increase the risk profile of a product by increasing the palatability or toxicity to non-target species, or increasing the time for the bait to degrade in the environment. Other factors such as bait size and placement may also alter the risk profile of the product. These guidance notes are intended to assist with completion of the HS6C form used to notify changes to VTA products.

2 Information requirements

Table 1 sets out the information which will be required when notifying a formulation change to an existing HSNO approved substance. A tiered approach will be taken in determining what level of information is required. This approach is described in further detail below.

If the method of release for the ‘new’ formulation is different to that which is already approved, then a different process will need to be followed, most likely leading to a full application or modified reassessment being required.

In all cases, it is advisable to contact ERMA staff to discuss the requirements which may apply to your circumstances.

Table 1 Information to be provided with HS6C form

| Requirement | Application method | | |
|--|--|--------------------|--------|
| | Contained ground | Uncontained ground | Aerial |
| 1 Notification of formulation change [old and new] <ul style="list-style-type: none"> • Formulation details • Physical form • Bait colour • Bait size • Intended use; method of release, target species | Yes | yes | Yes |
| 2 Evaluation of palatability (relative to the reference substance) to non-target species which may be exposed to the bait <ul style="list-style-type: none"> • Cage/pen trials • Field trials¹ | Must be satisfied that the method of containment minimizes exposure to non-target species – otherwise palatability and toxicity to non-target species must be assessed | yes | Yes |
| 3 Demonstration of no increase in toxicity to non-target species which may be exposed to the bait <ul style="list-style-type: none"> • Desk study • Cage/pen trials • Field trials | | yes | Yes |
| 4 Efficacy against target species [related to benefits] <ul style="list-style-type: none"> • Cage/pen trials • Field trials | Yes | yes | Yes |
| 5 Demonstration of no increase in risks to people <ul style="list-style-type: none"> • Desk study | Yes | Yes | Yes |

| Requirement | Application method | | |
|--|---|--------------------|--------|
| | Contained ground | Uncontained ground | Aerial |
| 6 Degradation of the new bait formulation in the environment relative to the reference substance | No – containment will protect bait from the weather | Yes | yes |

3 Tiered approach to assessing changes in the risk profile of a substance

3.1 Contained ground based application

Where a substance has been used for contained ground based application only and will continue to be used in the same way, generally the only information requirement will be to provide the formulation details noted in Table 1 [also see form].

An assessment will be made by ERMA New Zealand to ensure that there is no change in the hazard classification of the substance or that any changes in bait size or physical form preclude ‘matching’ with the original substance according to the ERMA Status of Substance policy. If this information results in a ‘no match’ an application for HSNO approval may be required.

If the method of containment does not adequately restrict access to the bait by non-target species, assessment of palatability and/or toxicity may be required.

3.2 Uncontained application: ground and aerial

Due to greater potential exposure resulting from uncontained application, a greater level of information will be needed to demonstrate that the reformulated product is of no greater risk to non-target species than the original product.

3.2.1 Palatability trials

These trials are to be conducted on the non-toxic bait in the first instance to determine whether the changes to the bait matrix have altered the palatability to both target and non-target species.

Pen/cage trials should be undertaken first and the results evaluated to determine whether field trials are needed to determine more realistic exposures.

3.2.2 Toxicity testing; non-target species

Given the ethical issues associated with animal toxicity testing, there are progressive steps to be taken in determining whether such testing is warranted.

If there is no reason to believe that a change in formulation will affect the toxicity of the baits, then no testing is required. Technical justification should be provided as part of the notification.

In the event that there is reason to believe the formulation change is likely to alter the toxicity of the bait, such as addition of a synergist, then further investigation may be required.

In the first instance, a desk study/literature review should be undertaken to assess the changes in toxicity on the basis of the information already available. If there is evidence in the literature of increased toxicity then some level of toxicity testing may be necessary to clarify the scope of the changes. In the absence of information in the literature it may be appropriate to seek an expert opinion from a toxicologist or ecotoxicologist on potential effects.

Where indications are that testing may be warranted this should be discussed with ERMA New Zealand staff at the scoping stage to ensure that proposed protocols are suitable and justified.

3.2.3 Efficacy testing; target species

It is anticipated that efficacy testing against target species will be necessary to gain ACVM approval in terms of animal welfare requirements. This information should also be provided to ERMA New Zealand as it may assist in assessing potential changes in toxicity of the bait, and the benefits of the substance, ie if not efficacious then little value in using the substance.

3.2.4 Degradation of bait in the environment

Where change to the formulation is likely to increase the resistance of bait to degradation in the environment, such information must be provided with the notification.



4 Risks to people

If there is reason to believe that the change in formulation may alter the risks to people handling the product, or the general public, then this needs to be discussed in the notification of the substance. This aspect may potentially require consideration if for some reason exposure may be increased as a result of increased dust content [inhalation hazard], change in consistency making the product more viscous or likely to adhere to skin, increase dermal absorption etc.

5 HSNO approvals

Pen/cage and field trials need to be conducted under a HSNO containment approval where a hazardous substance is being trialed. The exception to this is where the trials are being conducted within the confines of a s33 exempt laboratory. If only the non-toxic formulation is being assessed, no approval is required to conduct the trial.

Field trials must include adequate replication of non-target monitoring to demonstrate no greater risk to non-target species and no reduction in efficacy to target species.

There may be a need to continue field trials into subsequent years/different sites depending on the scope and outcomes of monitoring. Statistically robust monitoring is essential.

On completion of field trials, the monitoring data needs to be reviewed and provided to ERMA New Zealand with an assessment as to whether there is evidence that the risk profile of the substance is no greater than the original product.

If the risks are no greater, then there may be no need for a new HSNO approval. If the formulation change is outside the bounds of 'same as' policy, then a rapid assessment application may be appropriate.

In the event the risks are greater, then a full Part V HSNO application may be required to ensure that identified risks can be adequately managed.