Environmental Protection Authority
Te Mana Rauhī Taiao

New Zealand Government

Import or manufacture a pesticide

Guide to completing the application form

August 2020

Before you begin

Use this application form to apply for the import or manufacture of pesticides only.

Do not use the application form to apply for approval for more than one formulated hazardous substance, even if the substances and their uses are of a similar nature.

Do not use the form for importing or manufacturing substances for use in emergency, special emergency or containment. See our guidance on:

- emergency or special emergency applications
- applications for hazardous substances in containment, such as in certain laboratories.

Do not use the form for applications for another type of substance (such as a veterinary medicine or industrial chemical). See our guidance on:

- applications for veterinary medicines
- substances other than pesticides and veterinary medicines.

All communication from the EPA about your application will be by email, unless you request otherwise.

Completing the application form

1. Unless otherwise shown, all sections of the form must be completed for the application to be progressed.
2. Please ensure that the information is correct. The information you provide will be used as the basis to make an assessment of the substance.
3. If a section is not relevant to your application, please explain why. If you choose not to provide information for a mandatory section, you must provide a rationale and it may have implications for the ability of the EPA to assess the application.
4. Please provide as much supporting information as possible about the:

- hazard classification
- intended use of the substance
- risks and benefits.

This helps inform the EPA's evaluation and the decision about whether or not to approve the application. If the public are notified about the application, the information gives context for people making submissions about the application.

5. Supporting material must be clearly labelled, cross-referenced and included as an appendix to the application form.
6. You may add extra rows to tables where needed, but please do not add new sections.
7. Please make sure that you have permission to use the data you provide to support this application.
8. You must sign this form.
9. Email the application form and supporting documentation to hsapplications@epa.govt.nz.

Fees

1. A lodgement fee is required, which will be invoiced upon receipt of the application form. This must be paid before work processing the application starts.
2. Once the EPA has determined whether to process the application as a rapid assessment or a category A, B or C (the pathway), you will be invoiced the appropriate application fee. Once the fee is paid, your application can be formally received.
3. For more information about our fees, see our website.

Commercially sensitive information

1. Put commercially sensitive information into a Confidential Appendix to this form and state why you consider it to be confidential, including a detailed basis for any information you regard as commercially sensitive.
    - Find out about supplying confidential information to the EPA: your rights and our obligations.
    - Download the Confidential Appendix template.
2. Any information you supply to the EPA **before** your application is formally received will not be publicly released. Once your application is formally received, all information in the application form, and any non-

confidential appendices, will become publicly available when the application is publicly notified (for notified applications) or when it has been decided (for non-notified applications).

3. Once your application is formally received, all information you have supplied to us at the EPA is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, the request will be considered in a manner that is consistent with the OIA and with section 57 of the Hazardous Substances and New Organisms Act 1996 (HSNO Act). You may be asked to further justify your claim of confidentiality.

Cover page

Name of the substance: this is the name that will be used on the HSNO application register and all documents that will be issued following evaluation of the application by the EPA.

Date: Please type in the date that the application form is submitted to us.

Section 1. Applicant details

1.1. Name and contact details of the applicant

This section identifies the organisation or company lodging the application to import or manufacture a pesticide.

1.2. Contact person details

Complete this section with the details of the person to be contacted for correspondence regarding the application. This includes documents that are issued following evaluation of the application as well as any notifications.

Contact us if the correspondence contact changes while the application is being processed at HSApplications@epa.govt.nz

1.3. Invoice contact

Invoices will be sent to this person. If this section is left blank, invoices will be sent to the contact person in 1.2.

Section 2. General information

2.1. Range of uses

Specify the requested range of uses: **professional** or **domestic**. Tick only one box. Contact us if the substance is intended for both professional and domestic use.

Domestic: the substance is used only by non-professionals, and usually at home. It does not include workers as defined in the Health and Safety at Work Act 2015.

Professional: the substance is used only by professionals, and includes workers as defined in the Health and Safety at Work Act 2015.

2.2. Biopesticides

Specify whether the substance is a **biopesticide**. Tick only one box.

In the rest of the application form, regardless of the box that is ticked, the word “substance” is used.

Biopesticide:

- **biological chemicals** (semiochemicals, hormones and growth regulators, enzymes and vitamins)
- **plant and other extracts** (plant extract, essential oils, food products, other extracts derived from organisms)
- **microbial agents** (microbial pesticides (viable), microbial pesticides (nonviable), genetically modified microbial pesticides)
- **other living organisms**.

APVMA Guideline: Australian Pesticides and Veterinary Medicines Authority Guideline for the regulation of biological agricultural products.

2.3. Executive summary

Provide a description of the application. Include only the following:

- substance’s function (eg, herbicide, insecticide, fungicide)
- formulation type (CropLife International code) (see Section 5.1: formulation)
- concentration of active ingredient(s)
- pest or group of pests controlled
- Scenario (see section 3) that approval of the substance in New Zealand would correspond to.

> *Example: Application for Herbicide A containing 200 g/L Active Ingredient X and 100 g/L Active Ingredient Y in the form of a suspension concentrate to control broadleaf weeds in pasture. Herbicide A is a new mixture of active ingredients.*

Note: the executive summary will be used on the HSNO application register and published on the EPA website to refer to the application.

2.4. History of EPA applications

Fill out this section if the substance has been the subject of previous applications with the EPA or ERMA, such as:

- Status of Substance (SOS) Advice
- section 26 statutory determination
- containment application
- application for release approval (eg, a previous application was made for the same substance, but was withdrawn by the applicant before being processed).

Use the confidential appendix if this information is considered confidential. Ignore this section if you did not have any previous application related to the present application.

This information will be helpful to identify the scenario (see section 3) and to process the application.

Section 3. **Scenario**

Fill this in to help you establish what sections of the form you must complete.

It will also help the EPA determine the pathway to use to assess your application (either a rapid assessment or category A, B, or C assessment). Find out more about the process at the process: Rapid Assessment applications and Full Assessment applications

3.1. New substance containing at least one new active ingredient to New Zealand

- **First approval worldwide** *(1)*
- **Active ingredient(s) already approved elsewhere)** *(1)*

If you tick any box, please go to section 4, otherwise go to section 3.2.

First approval worldwide: when approval of the substance would introduce at least one novel active ingredient in New Zealand, and would also represent the first approval of this active ingredient worldwide.

> *Example: Application for Substance A, which contains Active Ingredient Y. Active Ingredient Y is not approved elsewhere in the world at the time of application.*

Active ingredient(s) already approved elsewhere: when approval of the substance would introduce at least one novel active ingredient in New Zealand. Novel active ingredient in New Zealand means that there is no existing approval for a substance containing this active ingredient at the time of application.

> *Example: Application for Substance A, which contains Active Ingredient Y. Active Ingredient Y is not formulated in any approved substance in New Zealand at the time of application. However, Active Ingredient Y is already approved in Europe.*

3.2. New substance containing only active ingredient(s) already approved in New Zealand

Tick the box with the context that approval of the substance in New Zealand would correspond to when compared to other substances that are already approved. Several boxes can be ticked if relevant. Please refer to the definitions included further below:

- New conditions *(2)*
  - **new uses**
  - **new application method**
  - **higher application rates**
- New formulation *(3)*
  - **new mixture of active ingredients**
  - **new concentration of active ingredient(s)**
- New version of an existing substance from the same company *(4)*
  - **composition change**
  - **new data leading to a change of classification**

- Generic substance *(5)*
    - **generic**

Note: the numbers in italics refer to Annex I and Annex II of this document.

New uses: when approval of the substance would introduce at least one novel use (crop) for an existing active ingredient, compared to substances that are already approved and available on the market.

> *Example: Application for Fungicide A, which contains Active Ingredient X, intended to control diseases in potatoes and grapes. Active Ingredient X is already formulated in Fungicide B from Company K and Fungicide C from Company L, to control diseases in potatoes only.*

New application method: when approval of the substance would introduce at least one novel application method for an existing active ingredient, compared to substances that are already approved and available on the market.

> *Example: Application for Fungicide A, which contains Active Ingredient X, intended for both ground-based and aerial application methods. Active Ingredient X is already formulated in Fungicide B and Fungicide C, but with a restriction (control) for ground-based application methods only.*

Higher application rate: when approval of the substance would introduce higher application rate(s) for an existing active ingredient, compared to substances that are already approved and available on the market for the same crops.

> *Example: Application for Fungicide A, which contains Active Ingredient X, intended to control diseases in potatoes at 50 g ai/ha. Active Ingredient X is already formulated in Fungicide B and Fungicide C, which are both intended for the control of diseases in potatoes, but at the maximum application rate of 30 g ai/ha.*

New mixture of active ingredients: when the substance contains a new combination of existing active ingredients that may or may not introduce new use patterns.

> *Example: Application for Substance A, which contains a combination of Active Ingredient X and Active Ingredient Y. Active Ingredient X and Active Ingredient Y are already formulated in "solo" substances, but have never been combined together within the same substance.*

New concentration(s) of active ingredient(s): when any active ingredient contained in the substance is in higher concentration than in substances that are already approved and available on the market.

> *Example: Application for Substance A 800 WG, containing Active Ingredient X at 800 g/kg. Active Ingredient X is already formulated in Substance B 400 WG and in Substance C 600 WG, however at 400 g/kg and 600 g/kg only.*

New version of an existing substance from the same company – composition change: when the composition of the substance is a variation of an already approved substance from the same company, with the same use pattern, and the composition change involves a classification change of the substance.

> *Example: Substance A, which contains Co-Formulant W, is approved in New Zealand and commercialised by Company K. Company K would like to swap Co-Formulant W with Co-*

Formulant Z, however this composition change leads to a change of classification for Substance A. Company K makes an application to the EPA for Substance B, containing the Co-Formulant Z.

Note: there is no need to make an application if the composition change does not affect the classification of the formulated substance (the same approval number can be used).

Example: Substance A, which contains Co-Formulant W, is approved in New Zealand and commercialised by Company K under approval number HSR000XXX [classification: 6.1C (oral), 6.3B]. Company K would like to swap Co-Formulant W with Co-Formulant Z. This formulation change does not affect the classification of Substance A [classification: 6.1C (oral), 6.3B]. Company K can keep commercialising Substance A with new Co-Formulant Z under the same approval number HSR000XXX.

New version of an existing substance from the same company – new data leading to a classification change: when a company submits new data (generally study data) that support a classification change of an already approved substance from the same company, with the same use pattern.

Example: Substance A is commercialised by Company K under approval number HSR000XXX [classification: 6.1C (oral), 6.3B]. Company K generates formulation data, which indicate that Substance A may have the following classification: 6.1D (oral), 6.3B. Company K makes an application to the EPA for Substance B, which includes the study report supporting the classification downgrade [presumably 6.1D (oral), 6.3B].

Generic substance: substance that has the following characteristics:

- same active ingredient(s) as already approved substance(s) under the HSNO Act
- formulation type is the same as already approved substance(s) under the HSNO Act
- label (ACVM approved or not) refers to the same crops, situations and pests as the reference substance(s) label
- label (ACVM approved or not) includes similar instructions for use as the reference substance
- label claims (ACVM approved or not) are the same, fewer or reduced
- reference substance information is not subject to limit of use of information or the applicant has obtained consent from the owner to use the data from the reference substance.

Example: Application for Fungicide A 200 SC, which contains 200 g/L Active Ingredient X, intended to control diseases in potatoes at 50 g ai/ha. Fungicide A is similar to Fungicide B 200 SC, which also contains 200 g/L Active Ingredient X and which is also intended for the control of diseases in potatoes at 50 g ai/ha.

Reference substance: substance that is already approved and that is used as a reference for the generic substance.

Section 4. Identity of the active ingredient(s)

Complete one section per active ingredient. Please only provide information that is requested here.

Section 5.2 asks for more information about the formulation and concentration of the active ingredients.

Active ingredient name: use the name of the active ingredient not in the amine, ester, acid form, etc (eg, use 2,4-D instead of 2,4-D amine salt, use glyphosate instead of glyphosate potassium).

For stereoisomers, provide the ratio of isomers in the active ingredient (eg, indoxacarb 3:1 mixture of the S-isomer and R-isomer; lambda-cyalothrin 1:1 mixture of (Z)-(1R,3R), S-ester and (Z)-(1S,3S), R-ester).

Note: We may require a certificate of analysis, especially in the case of stereoisomers.

Substance's function: specify the substance's function (eg, herbicide) and use 'other' box to add a function not appearing in the proposed list (if a biopesticide, use the corresponding group).

Manufacturer development code(s): provide the active ingredient's code(s), if applicable. Provide any code used in study reports provided in support of the application, if any (use the confidential appendix if this information is deemed confidential).

CAS No: use the CAS number corresponding to the active ingredient not in the amine, ester, acid form, etc.

Pending approval(s): provide jurisdictions (eg: EU, USA, Canada, Australia, Japan) where approval of the active ingredient(s) is (are) pending (under evaluation by the regulatory authorities), if applicable.

Section 5. Substance description

5.1. Formulation

Formulated substance name: if available/applicable, provide the name that will be used for ACVM registration.

Formulation type (CropLife International code): enter the acronym and name of the code from the CropLife International Catalogue of pesticide formulation types and international coding system [CropLife International Technical Monograph No. 2].

Manufacturer development code(s): provide the substance's code(s). Provide any code used in study reports provided in support of the application, if any (use the confidential appendix if this information is deemed confidential).

Density: for liquids only. Provide the total weight/volume (g/L) value.

5.2. Active ingredient(s) and content

Complete one row per active ingredient in the substance. Fill out boxes with the information requested in *italics*.

Provide only the level of pure active ingredient (ai) as well as:

a) The name of the active ingredient (common name).

b) If applicable, provide the name of the active ingredient, including where relevant its form as acid, salt, ester or stereoisomer.

5.3. Regulatory status of the formulated substance

Tick boxes depending on the regulatory status of the formulated substance in the listed jurisdictions. Use the Comment column to provide further information, such as under which regulation(s) or directive(s) the formulated substance is approved or the approval number of the formulated substance.

Section 6. Lifecycle of the substance

6.1. Transport

Specify how the formulated substance will be transported within New Zealand. Tick as many boxes as you need.

Provide additional information related to the transport of the formulated substance.

UN Packing Group Number: please refer to the UN Model Regulations (UN Model Regulations mean Model Regulations annexed to the most recently revised edition of the Recommendations on the Transport of Dangerous Goods published by the UN).

IMDG Code: International Maritime Dangerous Goods Code, as amended.

6.2. Packaging

Type of packaging and nature of packaging material: provide the type of packaging (eg bottle, can, sachets, tube, barrel, tank) as well as the packaging material (eg, high-density polyethylene [HDPE]).

Pack sizes: provide the volume or mass for each type of packaging (eg: 1L [bottle]).

Type of closure: provide the type of closure (consider opening size, type of cap, child-resistant packaging).

Mixing/loading: indicate whether the substance is ready-to-use or requires mixing and loading with a solvent (eg, water).

Additional information: provide any additional information relating to the packaging of the substance.

Note: the rules for the packaging of hazardous substances are set out in the Hazardous Substances (Packaging) Notice 2017.

6.3. Storage

Provide details of recommended storage. Provide also details on the facilities the substance will be stored in (including warehouse storage).

6.4. Disposal

Provide details of recommended disposal of damaged packaging, contaminated absorbents and other materials.

Provide instructions for safe disposal of the formulated substance and its packaging.

Section 7. Intended uses of the formulated substance

Note: If the substance is envisioned for both crop and non-crop use, use both GAP tables:

- GAP table (a) for plant protection products
- GAP table (b) for pesticides not used as plant protection products.

7.1. Good agricultural practices (GAP) table for plant protection products

Add as many lines as necessary. If one section cannot be completed because it does not apply to the corresponding use, enter N/A.

Refer to the notes underneath the table to help you understand what is being requested.

Number of applications: if the number of applications is more than one, indicate the maximum seasonal application rate in addition to the single maximum application rate per treatment (in the application rate per treatment column).

Growth stage and season:

- Provide the BBCH stage corresponding at first and at last treatment of the crop.
- If a herbicide is applied in pre-emergence, indicate whether it is applied in pre-emergence of the weeds or of the crop.

Remarks:

- Indicate other relevant information.
- Indicate the droplet size of the spray for each application method (only applicable for scenarios *(1)* and *(2)*).

Additional comments: use the comment field to enter any other relevant information that might be useful.

7.2. GAP Table pesticides not used as plant protection products

Add as many lines as necessary. If one section cannot be completed because it does not apply to the corresponding use, enter N/A.

Refer to the notes underneath the table to help you understand what is being requested.

Application rate per treatment: the expression of the application dose must be adapted for use by a professional or domestic (eg, for a product intended for domestic use, the applicant can use a unit such as grams / m^2).

Additional comments: use the comments field to enter other relevant information.

Section 8. HSNO hazard classification of the active ingredient(s)

This section is only required for new active ingredients (scenario *(1)*).

There is one sub-section/page per active ingredient. Only complete the information as per the number of active ingredients in your substance.

Please consider each of the hazardous properties in the table and provide information on those properties that trigger any threshold level for the active ingredient. Use the justification column to record the reason for your classification. If endpoints are provided, provide the reference of the study in the justification column.

Please use the following abbreviations if needed:

NA: Not Applicable – For instance when testing is technically not possible: testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the active ingredient.

ND: No Data or poor quality data (according to Klimisch criteria) – where there is a lack of data.

No: Not Classified based on actual relevant data available for the active ingredient – the data is conclusive and shows the threshold for classification is not triggered.

Section 9. HSNO hazard classification of the formulated substance

Please consider each of the hazardous properties in the table and provide information on those properties that trigger any threshold level for the substance. Use the justification column to record the reason for your classification. If your substance is a mixture, you can apply mixture rules to the hazardous components of the mixture. If you do this, you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.

See Assigning your product to an individual approval on our website for more information. If endpoints are provided, provide the reference of the study in the justification column.

NA: Not Applicable – For instance when testing is technically not possible: testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: eg very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible.

ND: No data or poor quality data (according to Klimisch criteria) – where there is a lack of data.

No: Not classified based on actual relevant data available for the substance – the data is conclusive and shows the threshold for classification is not triggered.

Note: You can chose to **self-classify** your product, or ask for help to do this from either a consultant or an advisor at the EPA. To classify your product, you will require information on the hazards. It could be either from hazard data (such as toxicity data) on the product or the components, or information from the SDS of either the product or the components of the product.

Read the HSNO Assigning a Product to a HSNO Approval.

Search the EPA Chemical Classification and Information Database (CCID).

The **classification system for hazardous substances** in New Zealand is set out in the Hazardous Substances (Classification) Notice 2017, and provides the criteria for each hazard classification.

The **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** will be adopted by the EPA (implementation date is, at this stage, intended to be 1 April 2021). A new EPA Classification Notice will be issued following the implementation of GHS. This Notice will align with the EPA Labelling and Safety Data Sheet Notices, which already require compliance with the GHS.

WorkSafe New Zealand (WorkSafe) may be consulted regarding the management of risks to human health from the use of hazardous substances as WorkSafe is the regulator for the purposes of the Health and Safety at Work Act 2015 (HSWA). Under section 30(1)(a) of HSWA, the Person Conducting a Business or Undertaking (PCBU) must eliminate risks to health and safety so far as reasonably practicable. If this is not reasonably practicable, the PCBU must minimise the risks so far as is reasonably practicable. Risks are to be minimised following the **hierarchy of controls** set out in regulation 6 of the Health and Safety at Work (General Risk and Workplace Management) Regulations 2016. Here is a link to WorkSafe's website regarding hazardous substances risks in a workplace and the hierarchy of controls: WorkSafe - Risk management.

Section 10. **Statutory considerations**

In order to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances (the purpose of the HSNO Act), the decision maker is required to take into account the following matters:

(a) the sustainability of all native and valued introduced flora and fauna:

(b) the intrinsic value of ecosystems:

(c) public health:

(d) the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga:

(e) the economic and related benefits and costs of using a particular hazardous substance: and

(f) New Zealand's international obligations.

The EPA addresses each of these matters when assessing an application to import/manufacture a hazardous substance for release. As such, information is requested for each one of these categories:

- Effect on the environment [(a) and (b) above];
- Effect on public health [(c) above];
- Effect on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga [(d) above];
- Costs and benefits [(e) above];
- New Zealand's international obligations [(f) above].

'Effect' includes: any potential or probable effect; any positive or adverse effect; any temporary or permanent effect; any past, present, or future effects; any acute or chronic effect; and any cumulative effect which arises over time or in combination with other effects.

All these matters will need to be addressed, although the level of detail and focus will depend on the scenario envisaged (eg new conditions, generic substance, etc.).

For all the scenarios, except for a new substance containing at least one new active ingredient to New Zealand, the focus should be on the incremental effects, costs and benefits (including non-monetary) that the new substance would bring to New Zealand, including any risks if the substance was approved. See the examples below:

> **Example 1**: Application for a substance containing at least one new active ingredient (*scenario: new substance containing at least one new active ingredient to New Zealand*). The applicant should address the matters above associated with the new active ingredient being available in New Zealand. Please refer to our data requirements document for further guidance. We request a full data package on

the active ingredient and the associated substance containing that active ingredient (please contact us if you would like to discuss data requirements) and, if a quantitative risk assessment is available to support your application, we request that you provide it to us.

Example 2: Application for a substance intended to be used on a new crop / with higher application rate(s) / new application method than already approved substances (*scenario: new conditions*). All matters need to be addressed associated with the introduction of the novel use (crop / application method) or higher application rate(s). There is no need to address the matters associated with the use of the substance on crops that are already treated with the same active ingredient(s) / application rate(s).

Example 3: Application for a substance that contains a new combination of existing active ingredients (*scenario: new formulation*). All matters need to be addressed associated with combining the active ingredients, as compared to approved substances that may contain those active ingredients separately (solo products).

Example 4: Application for a new version of an existing substance from the same company which contains a new co-formulant (composition change), leading to a classification change of the substance (*scenario: new version of an existing substance from the same company*). All matters need to be addressed associated with the composition change as compared with the existing substance.

Example 5: Application for a generic substance (*scenario: generic substance*). All matters need to be addressed associated with the introduction of the generic substance in New Zealand, as compared with the reference substance. All available studies on the formulated substance need to be provided.

In some cases, it will not be possible to fit all the information (such as study summaries, risk assessment, etc.) in the application form, in which case, a separate document should be attached and cross referenced in the application form.

10.1. Effects on the environment

You should identify the effects (note the definition above) on the environment from introducing the hazardous substance to New Zealand, as well as any measures (controls) to mitigate any effect.

Particular attention should be given to how specific environmental aspects/hazards of the substance can be addressed. For instance, for a herbicide used in an agricultural setting, explanation should be given as to how risks to non-target vegetation will be addressed. This may include, specific language for the label or recommendation of spray drift reduction technology.

In the case of a substance toxic to the aquatic environment, an overview of measures taken to reduce risks to non-target organisms should be provided, such as drift reduction measures (droplet size, buffer zones, etc.).

In the case of aerial application, specifically address the risks associated to this application method.

All aspects of the lifecycle of the substance should be covered, including, for example, use, disposal and measures taken in case of accidental spillage.

Please cross-refer to the EPA Notices (see link here) and suggest additional controls where relevant.

10.2. Effects on public health

You should identify the effects on public health from introducing the hazardous substance to New Zealand, as well as any measures (controls) to mitigate any effect.

Risks to the following groups should be addressed: operators (users of the substance), workers (for instance, for agricultural pesticides, farmers/operators re-entering a field after spraying), bystanders (members of the public potentially exposed to a substance either during spraying or after spraying).
Please cross-refer to the EPA Notices (see link here) and suggest additional controls where relevant. For example, proposed restricted entry intervals, buffer zones for bystanders or specific language for the label.
Note: some effects are regulated by the Health and Safety at Work Act 2015 (for instance the setting of restricted entry intervals).

Consideration should be given to the use pattern associated with the substance. For instance, if the substance is intended for domestic use, how risks to that particular group of users will be addressed (for example, child-resistant packaging).

10.3. Effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga

We recommend you contact the EPA to discuss this aspect of the application, as there may be ways we can assist. Consideration will need to be given to the type of information needed and where/who to obtain that information from.

Engagement with Māori may be appropriate for this application, especially if the substance contains a new active ingredient to New Zealand. Please refer to the EPA guidelines 'Māori engagement guideline for hazardous substances notified applications'. If you engage with Māori, you should tell us who you engaged with and why, the process for that engagement and the outcome.

An example of the issues to consider is whether the substance will impact any native or valued species, or waterways.

Incorporating Māori Perspectives into Decision Making Protocol

The following aspects are key to address:

- Impact on the relationship Māori have with their environment and taonga, more specifically
    - Papatūānuku (Soil environments)
    - Ngā wai koiroa (Aquatic habitats)
    - Otaota (Plants)

  - Ngā manu (Birds)
  - Te Aitanga Pepeke (Arthropods)
  - Taha hauora (Human health and well-being)
  - Ngā hua (Benefits)
- Impact on Māori economic wellbeing (arising from the impact on the environment and taonga)
- Impact on Māori social wellbeing (arising from the impact on the environment and taonga)
- Impact on Māori cultural wellbeing (arising from the impact on the environment and taonga)

Please note that any claim made regarding the above aspects should be substantiated.

10.4. New Zealand's international obligations

Please state any international obligations you are aware of that may be relevant (such as the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 1998 (the Rotterdam Convention)), and why.

Signature of applicant or person authorised to sign on behalf of applicant

The form must be dated and signed either by the applicant or person authorised to sign on behalf of the applicant.

Annex 1. Preparation of dossiers to obtain approval to import or manufacture a pesticide - Sections of the application form to be completed

The following sections need to be completed in full for every application scenario:

- **Section 1 – (Applicant details)**
- **Section 2 - (General Information)**
- **Section 3 - (Scenario)**
- **Section 4 - (Identity of the active ingredients)**
- **Section 5 - (Substance description)**
- **Section 6 – (life cycle of the substance)**
- **Section 9 - (HSNO classification for the substance)**
- **Section 10 – (Statutory considerations)**

Number in the form	Scenario	Sections to be completed for each application		
		Section 7 – intended uses		Section 8 – Classification for active ingredients
		a	b	
1	New substance containing at least one new active ingredient in New Zealand (including all sub-scenarios)	Yes	Yes	Yes
2	New conditions (including all sub-scenarios)	Yes	Yes	-
3	New formulation (including all sub-scenarios)	Yes	Yes	-
4	New version of an existing substance from the same company (including all sub-scenarios)	-	-	-
5	Generic substance	-	-	-

Annex 2 – documents to be provided

The following documents must be provided for all applications types / scenarios:

- **Co-formulant SDSs**
- **Proposed label**
- **Confidential appendix**

Number in the form	Scenario	Documents to be provided for each application	
		Statutory declaration	Study reports/data
1	New substance containing at least one new active ingredient in New Zealand	-	Yes
2	New conditions	-	Yes (if available)
3	New formulation	-	Yes (if available)
4	New version of an existing substance from the same company	-	Yes (if available)
5	Generic substance	Yes	Yes (if available)

Safety Data Sheet (SDS)

SDSs according to the Hazardous Substances (Safety Data Sheet) Notice 2017.

SDSs for all the co-formulants from your supplier (including active substances) must be provided.

The EPA may request the full composition of any co-formulant that is a mixture. The information contained in the SDSs must be consistent with the information given in the full composition (CAS No of the substance(s), etc.).

Proposed label

The information contained in the proposed label must be consistent with the information given in the GAP table.

Confidential appendix

Link to confidential appendix template on our website

This form should be used to provide confidential information for your application.

Statutory declaration

For applications for generic substances only. Physical or scan copy of the statutory declaration to be sent to the EPA.

Study reports / data

For applications for substances containing at least one new active ingredient to New Zealand:

Data requirements for Hazardous Substances Application

The EPA can advise you about the data requirements for an application for a substance that contains a new active ingredient, other than a chemical pesticide (eg a new veterinary medicine, pure chemical, or biopesticide).

Study reports can be provided for other application types / scenarios, if available, to support the application of the substance.

Other documents

Other documents may include letter(s) of access, copies of additional references, relevant correspondence, etc.