

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



FORM HS1

Application for approval to
IMPORT OR MANUFACTURE ANY HAZARDOUS
SUBSTANCE FOR RELEASE

under section 28 of the
Hazardous Substances and New Organisms Act
1996

Name of Substance(s): azoxystrobin

Applicant: Nufarm Limited

Office use only

Application Code: Date received: ___/___/___

ERMA NZ Contact: _____ Initial Fees Paid: \$

Application Version No: _____.

IMPORTANT

1. Before you fill in this application form, you may find it helpful to consult the *User Guide to Hazardous Substance Applications under the HSNO Act 1996*. This User Guide can either be downloaded from our website or purchased from ERMA New Zealand. The level of information that you need to provide in this application is dependent upon the scale and the significance of the risks and/or whether these risks are well understood and controlled. The User Guide will offer further advice on this.
2. Part B of the User Guide covers applications under Section 28 of the Act and all of the cross references in this application form are to Part B.
3. You can also talk to an applications officer at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
4. This application form may be used to seek approvals for more than one hazardous substance where the substances are related, for example a concentrated compound (active ingredient) and its related formulations or the two parts of an epoxy glue.
5. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an Appendix to the application form.
6. Commercially sensitive information must be collated in a separate Appendix.
7. Applicants must sign the form and enclose the correct application fee. The initial application fee can be found in our published *Schedule of Fees and Charges*. Make sure that you have an up to date copy of the Schedule. Please check with ERMA New Zealand staff. We are unable to process applications that do not contain the correct fee.
8. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed. Where an applicant is unable to complete the sections marked optional, this information may be derived by ERMA New Zealand and the costs of doing so will be recovered from the applicant as part of the processing costs.

You can get more information at any time by contacting us. One of our staff members will be able to help you.

ERMA New Zealand
20 Customhouse Quay
PO Box 131
Wellington
NEW ZEALAND
Telephone: 64-4-473 8426
Facsimile: 64-4-473 8433
E-mail: info@ermanz.govt.nz
www.ermanz.govt.nz

Section One – Applicant Details

See comments under “Section One of Application Form” in the User Guide for guidance.

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: Nufarm Limited
Address: PO Box 22-407,
Auckland 1640,
Phone: 09 270 4157
Fax: 09 270 4159

1.2 The applicant’s location address in New Zealand (if different from above):

Address: 6 Manu St,
Otahuhu,
Auckland 2024

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

Name: Emma Wilson
Position: Regulatory and Commercialisation Manager
Address: As above
Phone: 09 270 4183
Fax: 09 270 4159
Email: emma.wilson@nz.nufarm.com

Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import and/or manufacture a hazardous substance for 'release' and if it does not meet the requirements for rapid assessment. Please note that it is the substance(s) which is approved, and thus the approval covers both import and manufacture.

If you are making the application for some other reason, you will need a different form.

2.1 Is the information in this application relevant to import, manufacture or both: (See comments under "Section 2.1 of Form" in the User Guide)

- | | |
|--|-----|
| • Import only? | Yes |
| • Manufacture only? | No |
| • Import and manufacture? | No |
| • If import only, indicate whether or not manufacture is likely in New Zealand | No |

2.2 If the information in the application relates to manufacture in New Zealand, provide information on the proposed manufacturing process and any alternatives. (See comments under "Section 2.2 of Form" in the User Guide)

N/A – This substance will be imported from overseas and will not be manufactured in New Zealand.

2.3 If you have reasons for not providing detailed information in this application, explain what they are and provide some justification.

An example of a reason for not giving detailed information is where an approval has been given by another jurisdiction and information that led to that approval can be referenced or the substance will be used in low risk situations or ways.
(See comments under "Section 2.3 of Form" in the User Guide)

We consider this a category A1 application – Limited information package.

Azoxystrobin will have very limited opportunities for exposure in the course of its life-time. It will be imported into New Zealand from the site of manufacture. From the border it will be transported directly to the Nufarm Ltd manufacturing plant in Otahuhu. The carriers used to transport the products will be carriers with experience in transporting pesticide products. Once at the manufacturing plant, the substance will be stored until used in the manufacture of an agricultural product. The manufacturing plant is a secure site and access is restricted to authorised personnel only.

Azoxystrobin is already present in New Zealand as a component of a number of currently registered agricultural products. At present these products are manufactured overseas and imported into New Zealand as a fully formulated products. Nufarm Limited would like to manufacture a new product containing azoxystrobin in New Zealand.

The hazards associated with this substance can be adequately managed by the Nufarm Limited manufacturing plant. This plant and the staff are experienced in the management, storage and use of similar chemicals.

2.4 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?
(Optional) (See comments under "Section 2.4 of Form" in the User Guide)

Name of Approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	Yes
Food Act 1981	NA
Medicines Act 1981	NA
Chemical Weapons (Prohibition) Act 1996	NA
Radiation Protection Act 1965	NA
Biosecurity Act 1993	NA
Resource Management Act 1991	NA
Other (please specify):	No

Section Three – Information on the Substance(s)

Note all information that is commercially sensitive must be attached as an Appendix. The application form should be cross-referenced to the Appendix but should be able to be read as a stand-alone document which will be publicly available.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; in-house data, research, technical literature, etc. See the introductory comments under “Section Three of the Form” in the User Guide for more details.

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1 State the unequivocal identification of the substance(s).

This section should include all information necessary to unequivocally identify the substance(s) and may include:

- Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name)
- Common Name
- Synonyms
- Trade Names
- CAS Registry Number
- Molecular Formula
- Structural Formula
- Significant impurities

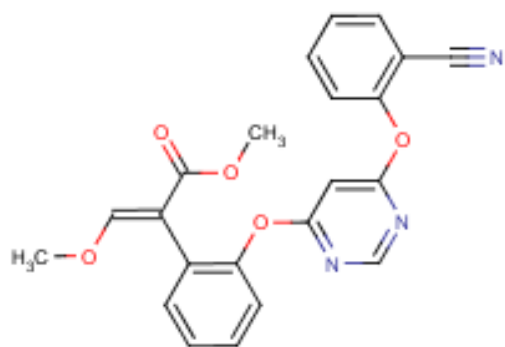
For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture ie the chemical name, CAS number, function (eg active ingredient, emulsifier, surfactant, filler) and percentages of **ALL** components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

If there are commercial reasons for not providing full information in the main part of the form, alternative approaches must be discussed with and agreed by ERMA New Zealand. These must include the provision of a unique identifier of some kind.

(See comments under “Section 3.1 of Form” in the User Guide)

IUPAC Chemical Name:	Methyl (E)-2-(2-[6-(2-cynophenoxy)pyrimidin-4-yloxy]phenyl)-3-methoxyacrylate
Common Name:	azoxystrobin
CAS Number:	131860-33-8
Empirical Formula:	C ₂₂ H ₁₇ N ₃ O ₅
Molecular Weight:	403.4
Significant Impurities:	No significant impurities of toxicological importance (APVMA standards)

Structure:



3.2 Provide information on the chemical and physical properties of the substance(s).

Provide as much information as possible on the chemical and physical properties of the substance(s) [at 20°C and 1 atmosphere unless otherwise stated] eg

- Appearance (colour, odour, physical state or form)
- pH
- Density
- Vapour pressure
- Boiling/melting point
- Solubility in water
- Water/octanol partitioning co-efficient

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture

(See comments under “Section 3.2 of Form” in the User Guide)

Appearance:	White solid
Density:	1.34
Melting Point:	114-116°C
Vapour pressure:	1.1×10^{-7} mPa (20°C)
K_{ow}:	logP = 2.5
Solubility:	In water 6mg/L (20°C). Low solubility in hexane, <i>n</i> -octanol; moderate solubility in methanol, toluene, acetone; high solubility in ethyl acetate, acetonitrile, dichloromethane

3.3 Provide information on the hazardous properties of the substance(s).

Information should be provided on the hazardous properties of the substance(s) known to the applicant. You must consider each of the six hazardous properties below and provide information on those hazardous properties that trigger any threshold level. If you wish, you may assign the relevant HSNO classification category to each hazardous property that exceeds these threshold levels.

- explosiveness
- flammability
- oxidising properties
- corrosiveness
- toxicity
- ecotoxicity

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings. (See comments under "Section 3.3 of Form" in the User Guide).

CLASS	Azoxystrobin	Hazard Classification
Class 1. Explosiveness	Not Explosive ¹	Not triggered
Class 2. Flammability	Not Flammable ²	Not triggered
Class 5. Oxidising	Not an Oxidising substance ¹	Not triggered
Class 8. Corrosive	Not Corrosive	Not triggered
Class 6. Toxic		
- Acute oral	LD ₅₀ for rats >5000 mg/kg b.w ³	Not triggered
- Acute dermal	LD ₅₀ for rats > 2000mg/kg body weight ³	Not triggered
- Acute inhalation	LC ₅₀ = 0.69mg/L Female rat ³	6.1C
- Skin irritation	Not a skin irritant ³	Not triggered
- Eye irritation	Not an eye irritant ³	Not triggered
- Sensitisation	Not a sensitiser ¹	Not triggered
- Mutagenic	In vivo tests all negative ³	Not triggered
- Carcinogenic	Azoxystrobin at doses up to the maximum tolerated in rat and mouse provided no evidence for carcinogenicity ³	Not triggered
- Reproductive/developmental	Shown not to interfere with reproduction in animal studies ²	Not triggered
- Target organ / systemic	Chronic systemic effects: Long term feeding studies with azoxystrobin in animals causes liver damage ¹	6.9B
Class 9. Ecotoxic		
- Aquatic	LC ₅₀ (96 h) for rainbow trout 0.47mg/l ¹	9.1A
- Soil	LC ₅₀ (earthworms) 283mg/kg (14 d) ¹	Not triggered
- Terrestrial vertebrates	Bobwhite quail acute LD50>2000mg/kg/bw/day ³	Not triggered
- Terrestrial invertebrates	LD ₅₀ >25µg ai/bee ³	Not triggered

¹ Azoxystrobin MSDS

² Council Directive 91/414/EEC Azoxystrobin Volume 3 Annex B to the Report and Proposed Decision of the United Kingdom made to the European Commission under Commission Regulation 737/2007/EC. Summary, Scientific Evaluation and Assessment May 2009 (not supplied)

³ FAO Specifications and Evaluations for Agricultural Pesticides - Azoxystrobin

Summary of Hazard Classifications

6.1C, 6.9B, 9.1A

3.4 Identification of the default Controls on the substance(s).

A range of default controls are triggered by the hazardous property classification(s) attached to the substance. If you wish, you can list what these default controls are. If you don't provide this information, ERMA New Zealand will do it for you. Regardless, you need to be aware of what the default controls are so that you can take them into account when assessing risks – see Section 4.

(Optional) (See comments under “Section 3.4 of Form” in the User Guide)

Toxicity	T1, T2, T3, T4, T5, T6, T7, T8
Ecotoxicity	E1, E2, E5, E6, E7
Identification	I1, I3, I8, I9, I11, I16, I17, I18, I19, I20, I21, I23, I28, I29, I30,
Packaging	P1, P3, P13, P15, PG3, PS4
Disposal	D4, D5, D6, D7, D8
Emergency Management	EM1, EM6, EM7, EM8, EM11, EM12, EM13
Tracking and Approved Handlers	TR1, AH1

3.5 Provide information on what will happen to the substance throughout its whole life from its introduction into New Zealand, its uses, through to disposal.

This information is used in the development of exposure scenarios and the assessment of risks, costs and benefits and should therefore be as expansive as possible.

(See comments under “Section 3.5 of Form” in the User Guide)

Transport and Storage Information: The azoxystrobin technical will be packaged in fibreboard drums with Low Density Polyethylene (LDPE) inner liners. It will be imported into New Zealand and transported to the Nufarm manufacturing site in Otahuhu where it will be stored until used in manufacturing. It will be transported within New Zealand as a Class 9 DG with relevant labelling, signage and documentation.

The Intended Use of the Substance: Azoxystrobin technical will be blended into a formulation with other ingredients to form a fungicide product. Azoxystrobin is currently available in New Zealand but only in the form of fungicide formulations which are manufactured overseas and imported into New Zealand as finished products.

Who may use the substance: The azoxystrobin technical will only be used by fully trained and competent manufacturing staff.

Storage: Storage will be at the Nufarm manufacturing plant, a secure site with appropriate signage, and bunding.

Disposal: Disposal of the technical is not likely to occur. It will only be used for the formulation of a fungicide product.

Section Four: Risks, Costs and Benefits

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

You will need to consider the effects on the environment and human health and welfare, including any social effects.

In each section set out below, it might be easier for you, and most useful for ERMA New Zealand, if the information is set out under the following three sub sections:

- Costs and benefits which can be stated in monetary (dollar) terms
- Non-monetary risks and costs
- Non-monetary benefits.

Complete this section as far as you can. If the analysis provided is incomplete, then it will be completed by ERMA New Zealand. However, the costs of doing this will be chargeable.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; in-house research, independent research, technical literature, community or other consultation.

(See comments under “Section 4 of Form” in the User Guide)

4.1 Identify all of the potential risks, costs and benefits of the substance(s)

Identification is the first step in assessing risks, costs and benefits. The introductory part of “Section 4 of Form” in the user Guide provides detailed guidance on what kinds of costs, risks and benefits should be thought about. It is important to think about the source of the risk, ie the way in which the risk is created (the exposure pathway), and then the consequences and likelihood of exposure.

You should try to think as widely as possible about every potential risk, cost and benefit and give a brief description. The range of matters that you will need to think about is discussed in the User Guide. You must also decide how significant that risk, cost or benefit is likely to be. If the risk, cost, or benefit is obviously not significant (and you can give reasons), then there is no need to further assess that risk, cost, or benefit.

(See comments under “Section 4.1 of Form” in the User Guide)

Identification of the Risks with azoxystrobin technical

Source of Risk Event / Incident		Adverse Effects	Potential Significance of Risk
Transport and Storage	Occupational exposure	Inhalation toxicity	Significant
	Public exposure		Significant
	Discharge to water	Death of aquatic organisms	Significant
Incorrect disposal of packaging	Occupational exposure	Inhalation toxicity	Significant
	Public exposure		Significant
	Discharge to water	Death of aquatic organisms	Significant
Handling during manufacture	Occupational exposure	Inhalation toxicity	Significant

Source	Lifecycle	Event
Spillage	Transport Storage	An incident during shipping including unloading. Transport or handling incidents on roads or during loading/unloading. Damage to packaging in warehouse.
Manufacture of end use product	Use Disposal	Exposure of workers during opening of packaging, measurement of required quantities, pouring into mixing tank, and disposal of used containers.

Hazardous property	Impact	Exposure pathway	Adverse effect
Toxicity	Worker & Public health	Inhalation	Moderate inhalation toxicity
Ecotoxicity	Environment	Water - from spillage	Toxic to aquatic organisms

1. Primary risk is to Human exposure and its consequences during occupational use.

The risks to human health from exposure to the active ingredients relates largely to:

- *Inhalation:* Toxic if inhaled.
- *Ingestion:* Small amounts not likely to cause injury. Liver damage is a possible chronic long term effect.

2. Secondary risk is to contamination of the Environment.

The risks to the environment from exposure would relate to the contamination of -

- *Water:* Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Source of the Risks:

Spillage: Accidental spillage may occur during storage at or transport between the ship, port, and manufacturing site. Accidents in storage situations could arise from forklift use or improper and unrealistic stacking of containers. Other possible spillage situations could arise during transportation involving vehicular accidents on public roads or rail. The physical handling of smaller containers in any situation could also lead to spillage. Spillage is possible at the time of manufacture of the end-use product during the opening of the container, measuring and pouring the correct amount of the substances into the mixing tank.

BENEFITS - Identification

The approval of this active ingredient will allow the end use product to be manufactured in New Zealand instead of overseas where similar end use products are currently manufactured. This will create extra work and potentially more jobs for New Zealanders.

COSTS

No new costs are likely to be associated with the approval of this active ingredient.

4.2 Provide an assessment of those risks, costs, and benefits identified in Section 4.1 which might be significant.

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 4.3 and 4.4 below for those aspects.

Assessments only need to be done for those risks, costs and benefits which Section 4.1 shows might be significant. Section 4.2 in the User Guide provides a detailed explanation of how to do an assessment. Remember that assessments can be qualitative ie based on judgements, if there is no analytical information available. But it is essential that a firm conclusion is drawn about the size and likelihood of the risks, costs or benefits, and also about the certainty of the assessment.

In assessing risks especially, it is important to take account of the extent to which risks will be reduced by the default or other controls (see Section 3.4 above and 4.5 below).

(See comments under “Section 4.2 of Form” in the User Guide)

RISKS - Assessment

The potentially significant risks with toxic hazardous properties and the possible adverse effects on human health and the environment have been considered.

Human Health Risks:

Azoxystrobin triggers the following HSNO toxicity classifications:

- 6.1C – acute oral toxicant
- 6.9B – target organ toxicant

Accordingly, they can have an effect on human health through:

- Transportation
- Storage
- Formulation of the end use product
- Disposal of substance and containers

Transportation:

Accidental spillage may occur during transport between the port and manufacturing site. The possibility of adverse human health effects occurring as a result of exposure to spillage is **very unlikely** if the proposed default controls are in place.

In the event of a transport accident, people would need to ingest or inhale large quantities of the substance to suffer any injury. Drivers and emergency workers attending the spill should be wearing appropriate protective clothing and be trained in emergency management procedures to contain the spill. In extreme cases, the general public may be exposed but normally the public would be excluded from the accident area. The magnitude of any ingestion or inhalation effects is considered to be **minimal** as the individual container will limit the amount released (assuming not all packages are damaged) and the packaging controls will provide a barrier against damage. The resulting risk is considered **insignificant**.

Storage

Accidental spillage may occur during storage at the port or manufacturing site. Accidents in storage situations could arise from forklift use or improper stacking of containers. The physical handling of smaller containers in any situation could also lead to spillage. All storage sites are secure and access is restricted to authorised personnel only.

It is possible that any of these incidents could occur, but if the proposed default controls are in place it is **unlikely** that an adverse effect would occur as a result. The magnitude of ingestion or inhalation effects is considered minimal, as any exposure will be sporadic. The resulting risk is considered **insignificant**.

The assessment of the risks to human health after controls are imposed are summarised in the table below.

Table 1: Assessment of Human Health Risks with controls in place

Exposure route	Potential effect	Likelihood of Adverse Effect Occurring	Magnitude of Adverse Effect	Level of Risk
Release during transport resulting in the substance being ingested or inhaled	- Ingestion - Inhalation	Very unlikely	Minimal	Insignificant
Release during dispensing, measuring and mixing of the substances resulting in substance being ingested or inhaled	- Ingestion - Inhalation	Unlikely	Minimal	Insignificant
Inappropriate disposal of substance or containers with the substance being released and being ingested or inhaled	- Ingestion - Inhalation	Unlikely	Minimal	Insignificant

Overall the level of risk to human health arising from the import of azoxystrobin is considered to be **insignificant**.

Biological and Physical Environment

Azoxystrobin triggers the following HSNO ecotoxicity classification:

- 9.1A – very ecotoxic in the aquatic environment

As identified in the risk assessment table in section 4.1, the potentially significant risks to the environment would relate to the contamination of –

- *Water*. This may occur from spillage into drains and waterways.

Transportation:

A transport accident resulting in a fire or the spillage of this particular substance is considered improbable. The possibility of adverse environmental effects occurring as a result of any spillage is **very unlikely** if the proposed controls are in place. Drivers and emergency workers attending the spill should be trained in emergency management procedures to contain a fire or spill and prevent it from reaching sensitive environments eg waterways. The magnitude of any effect is considered to be **minimal** as any effects will be acute and localised and the size of the individual containers will limit the amount released (assuming not all packages are damaged). The resultant risk is thus considered **insignificant**.

Storage:

As above, a fire or spillage in the storage facility is considered *unlikely*. HSNO controls should ensure that any effects of any spillage at storage facilities are *minimal*. The resultant risk is thus considered *insignificant*.

The assessment of the risks to the environment after HSNO controls are imposed are summarised in the table below.

Table 2 Assessment of Environmental Risks with controls in place

Lifecycle	Event	Likelihood of Adverse Effects	Magnitude	Risk
Transport	Accident during transport and handling - on ship, at port, in land vehicle, to and from storage.	Very unlikely	Minimal	Insignificant
Storage	Spillage	Unlikely	Minimal	Insignificant
Use in Manufacture	Spillage when opening container, and pouring into mixing tank	Unlikely	Minimal	Insignificant
Disposal	Inappropriate disposal	Unlikely	Minimal	Insignificant

Overall the level of risk to the biological and physical environment arising from the import of azoxystrobin is considered to be *insignificant*

COST / BENEFITS - assessment

Costs:

The direct costs to consider are medical costs and productivity losses from ingestion or inhalation of the substance. General first aid procedures of flushing the affected areas with water would reverse the effects of exposure. Medical attention should be sought if the substance is inhaled or ingested. Follow-up medical examinations and or treatment may be necessary but not expected.

Contamination of waterways would affect aquatic organisms. Costs are hard to quantify but would include cleanup of damage to waterways through spillage, release or misuse of the product.

Benefits:

The introduction of azoxystrobin would allow a number of currently registered and approved fungicide products to be manufactured in New Zealand. This will create extra work for the New Zealand manufacturing plant which could have flow on benefits in the form of extra jobs for New Zealanders.

Manufacturing the end use fungicide product in New Zealand will eliminate the need and the cost of transporting the product from overseas. The ability to manufacture the product in New Zealand will also allow Nufarm Limited to respond to quickly to the needs of the market.

4.3 Provide an assessment of any particular risks, costs and benefits which arise from the relationship of Māori and their culture and traditions with their taonga, or which are, for other reasons, of particular relevance to Māori.

We have asked for a separate response in this area because these requirements are different to other risks, costs and benefits. These are explained in more detail in Section 4.3 of the User Guide. Please note that if there are potentially significant risks in this area, it will almost certainly be necessary to consult with Māori in preparing an assessment.

(See comments under “Section 4.3 of Form” in the User Guide)

The approval of azoxystrobin technical should have no effect on Maori, their culture, traditions or taonga. The technical will not be released into the environment. The only possible exposure would be in the case of a road accident during transportation from the port to the manufacturing plant. If an accident occurred, the emergency procedures for this substance would minimise any possible adverse effects.

4.4 Provide an assessment of any risks, costs or benefits to New Zealand’s international obligations.

This is a specialist area which ERMA New Zealand will handle. However, any information you are able to provide on relevant international agreements would help us and save time and cost.

(Optional) (See comments under “Section 4.4 of Form” in the User Guide)

Azoxystrobin is currently present in New Zealand as a component of a number of fungicide products registered with the ACVM Group.

There are no known international obligations that will be affected by this application.

4.5 Provide information on the proposed management of the substance.

This section should provide information on managing the effects identified and assessed in Sections 4.1 - 4.4 above. The starting point for this is the range of default controls triggered by the hazardous property classification(s) attached to the substance (see Section 3.4). You should describe how these controls would be implemented and indicate other mean of managing risks. The information provided must be specific to the substance(s) and cover all areas of intended use. Reference should be made to Codes of Practice or standard operating procedures that will be followed. If changes to the default controls triggered by the substance classification are proposed, the reasons for these changes should be provided.

Please note that you will find it easiest to complete this section in conjunction with section 4.2. That is because the management of risks will influence their residual level.

(See comments under “Section 4.5 of Form” in the User Guide)

Using the proposed hazard classifications and HSNO matrix, 48 default controls are identified as being required to manage the risk associated with azoxystrobin.

The following default controls are considered inappropriate:

T7 Azoxystrobin will not be transported on passenger service vehicles

T8 Azoxystrobin will not be used as a vertebrate poison.

The remaining default controls as listed in section 3.4 will be managed using the following reference publications:

Codes of Practice:

- Signage for Premises Storing Hazardous Substances and Dangerous Goods (HSNO CoP 2-1 09-04), NZCIC.
- Preparation of Safety Data Sheets (ACoP SDS), NZCIC

NZ Standards:

- NZS 8409:2004: Management of Agrichemicals
- NZS 5433:2007: Transport of Dangerous Goods on Land

Other References:

- United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations
- Land Transport Rule, Dangerous Goods 2005 Rule 45001/1
- In house quality control procedures and SOPs in use at the manufacturing plant

4.6 Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 4.2, 4.3 and 4.4.

Doing this overall evaluation is the main task of the Authority. However, you may wish to express a view on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision.

(Optional) (See comments under “Section 4.6 of Form” in the User Guide)

Evaluating all the risks associated with azoxystrobin and taking into account the controls that will be put in place it is considered that the following risks either do not apply, or can be managed:

- | | |
|---|------------------|
| • The risk of involuntary exposure | – managed |
| • The risk is relatively persistent | – not applicable |
| • The risk could spread uncontrollably | – not applicable |
| • The potential adverse effects are irreversible | – not applicable |
| • The risk is not understood by society | – not applicable |
| • There are risks to human health | – managed |
| • There are risks to the survival of native species or their habitats | – not applicable |

Section Five – International Considerations

- 5.1 ERMA New Zealand is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand or by any other country. If you are aware of this, please provide details of the results of such consideration.**
(Optional) (See comments under “Section 5.1 of Form” in the User Guide)

Azoxystrobin has already been approved for use in New Zealand as the active ingredient in a number of fungicide products approved under the HSNO Act and registered under the ACVM Act. It is also used and registered widely throughout the rest of the world.

Section Six – Miscellaneous

6.1 Provide a glossary of scientific and technical terms used in the application.
(See comments under “Section 6.1 of Form” in the User Guide)

Active ingredient	The component in a formulation that is biologically active as a pesticide
ACVM	Agricultural Compounds and Veterinary Medicines
APVMA	Australian Pesticides and Veterinary Medicines Authority
CAS	A unique number assigned to a specific chemical by the Chemical Abstracts Service.
CoP	Code of Practice
Emergency management	Requirements to manage any emergency involving a hazardous substance. Includes the provision of information, equipment or for high-hazard situations, specific emergency management plans.
Fungicide	A substance intended for use in the management of diseases of crops
MSDS	Material Safety Data Sheet. A document that describes the properties and uses of a substance, that is, identity, chemical and physical properties, health hazard information, precautions for use and safe handling information.
NZCIC	New Zealand Chemical Industry Council
SOP	Standard Operating Procedure

6.2 Provide here any other information you consider relevant to this application not already included.
(See comments under “Section 6.2 of Form” in the User Guide)

None

Section Seven – Summary of Public Information

The information provided in this section may be used in the Authority's public register of substances required under Section 20 of the HSNO Act.

This summary information will be used to provide information for those people and agencies (eg Ministry for the Environment, Department of Conservation, Regional Councils, etc), who will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

7.1 Name of the substance(s) for the public register:

Please use a maximum of 80 characters.
(See comments under "Section 7.1 of Form" in the User Guide)

Azoxystrobin

7.2 Purpose of the application for the public register:

This should include (in a maximum of 255 characters) an abstract giving information on the intended use of the substance and why an application is needed based on its hazardous properties.
(See comments under "Section 7.2 of Form" in the User Guide)

To import azoxystrobin technical for the purpose of using in the manufacture of a fungicide product in New Zealand.

7.3 Use Categories of the substance(s):

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

- Main category: There are four main categories - see User Guide for details.
- Industry category: There are 16 industry categories - see User Guide for details.
- Function/Use category: There are 55 function/use categories - see User Guide for details.

(Optional) (See comments under "Section 7.3 of Form" in the User Guide)

Main Category: 4 (non-dispersive use)

Industry Category: 1 (agricultural industry)

Function/Use Category: 38 (pesticide)

7.4 Executive Summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties and intended uses
- an assessment of the risks, costs and benefits
- the methods implemented to manage the risks, particularly in relation to emergency management and disposal.

(See comments under “Section 7.4 of Form” in the User Guide)

This application seeks approval to import the active ingredient azoxystrobin for the purpose of formulating into a fungicide product. This active ingredient is currently present in New Zealand as a component of a number of fungicide products registered under the ACVM Act and approved under the HSNO Act. These products are currently manufactured overseas and imported into New Zealand fully formulated. Nufarm Limited would like to have the option of formulating similar products at the Nufarm manufacturing plant in New Zealand. The manufacturing plant currently manufactures a number of other agricultural chemicals.

Azoxystrobin triggers the following hazard classifications: 6.1C, 6.9B, 9.1A

The controls derived from the above classifications should ensure that any risks associated with the active ingredients will be adequately managed throughout the life cycle.

CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes
Fees enclosed	Nufarm is an approved creditor – please invoice
Application signed and dated	Yes

Signed

Date:

Emma Wilson

Regulatory and Commercialisation Manager