Environmental Protection Authority
Te Mana Rauhī Taiao

# EPA staff report

# Import and release of *Neotyphodium*

**March 2014**

**Advice to the Decision Making Committee on application APP201774: – To import and release strains of *Neotyphodium*, an endophytic fungus, under section 34 of the Hazardous Substances and New Organisms Act 1996**

# Executive Summary and Recommendation

In November 2013, Grasslanz Technology Ltd. made an application to the Environmental Protection Authority (EPA) seeking to import and release 45 strains of *Neotyphodium*, an endophytic fungus. These strains act to protect their host plants from invertebrate pests and drought.

Evidence in the application shows that no native and/or taonga plants will be adversely affected, no organisms will be displaced by the introduction of these fungi, and no valued animals will be harmed. We therefore recommend that they be approved for release.

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# 1.The application process

## Purpose of this document

1.1. This document has been prepared by EPA staff; Asela Atapattu (Manager, New Organisms), Kate Bromfield (Senior Advisor, New Organisms) and Sean Rangiwhetu (Advisor, Māori Policy and Operations), to advise the HSNO Decision Making Committee on the results of our risk assessment of this application to import and release 45 strains of *Neotyphodium*, an endophytic fungus that contributes to plant persistence by protecting the plants from invertebrate pests and drought. The document discusses information provided in the application and other readily available sources.

1.2. In response to the recommendation from DOC that "*the Authority seeks input from an independent pathologist who could provide more qualified feedback than what we can offer*", this document has been peer reviewed by independent expert Professor Dr Adrian Leuchtmann, Institute of Integrative Biology, Plant Ecological Genetics, ETH Zurich. Professor Dr Leuchtmann is a distinguished fungal ecologist, and was among the researchers who first characterised and described *N. siegelii* in 2001.

## Submission process

1.3. Grasslanz Technology Ltd lodged an application with the EPA on 13 November 2013 to import and release specified strains of *Neotyphodium* under section 34 of the Hazardous Substances and New Organisms (HSNO) Act (the Act).

1.4. Application APP201774 was publicly notified as required by section 53(1)(b) of the Act. The 30 working day notification period began on 18 November 2013 and closed on 24 January 2014.

1.5. Submitters were asked to provide information, make comments and raise issues, particularly with regard to, but not limited to the following matters:

- adverse effects[1], especially adverse effects not identified in the application, and
- positive effects[2], especially positive effects not identified in the application.

## Submissions

1.6. Nine submissions were received in response to public notification of the application. The submissions are summarised in Appendix 1. The following five submitters supported the application: Nursery and Garden Industry New Zealand, Foundation for Arable Research, Ngai Tahu, the New Zealand Plant Breeding and Research Association and Federated Farmers. Two submitters, Len Parkes and Paul

[1] Adverse effects can include any risks and costs associated with approving the release of these organisms.

[2] Positive effects can include any benefits associated with approving the release of these organisms.

Elwell-Sutton, neither supported nor opposed the application. Two submitters, Chris Bourke and Cliff Mason, opposed the application. Ngai Tahu and Cliff Mason requested to be heard in support of their submissions.

### Submissions from MPI and DOC

1.7. As required by the Act and the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology), the Ministry for Primary Industries (MPI) and the Department of Conservation (DOC) were advised of the application and provided with the opportunity to comment. We gave particular regard to the comments provided by DOC, and these full comments are provided in Appendix 2. MPI commented that they suggest specific "*data should be sent in to the Agricultural Compounds and Veterinary Medicines Group at MPI with a request for a class determination*". Their full comments are provided in Appendix 3.

## Application summary

1.8. The application seeks to import and release 45 strains[3] of *Neotyphodium,* a genus of endophytic fungus that is largely considered to be safe to animals and the environment, and contributes to plant persistence by protecting the plants from invertebrate pests and drought.

## Background

1.9. *Neotyphodium* endophytes are asexual fungal symbionts of cool season grasses that form long term associations with their grass hosts. They live in a symbiotic[4] relationship with their hosts, growing in the intercellular spaces between the plant's cells in all above-ground tissues of the grass. Through this association, the endophyte gains access to nutrients and an exclusive biological niche, while producing bioactive alkaloid compounds which can protect the grass host from insect and mammal herbivory, drought stress, and other abiotic factors (Kuldau and Bacon 2008). Host grasses infected with *Neotyphodium* are asymptomatic, and most pasture grasses in New Zealand are host to one of several *Neotyphodium* endophyte species.

1.10. *Neotyphodium* endophytes are not passed between grass species, or between individual plants, but transmitted vertically. That is, the fungus grows into the reproductive tissues and seeds of the host grass, and is transmitted asexually to the next generation through the seeds produced. Endophyte

[3]The collective descendants produced from common ancestors that share a uniform morphological or physiological character (Usher 1996).

[4] A close, prolonged, and usually obligatory association of two organisms of different species that live together, often to their mutual benefit.

growth is synchronised with the host plant tissues, and when the leaf tissues hosting the endophyte senesce and die, the endophyte dies with them. However, some of the endophyte strains listed in the application have a relationship to sexually reproducing *Epichloë* species in their original host, and therefore have the potential to produce contagious ascospores[5], thus allowing for horizontal transmission (Leutchman pers. comm. 2014).

1.11. There are 43 taxa recognised in the entire group, of which 22 have been described as *Neotyphodium* (see Leuchtmann et al 2014). Seven of these species of *Neotyphodium* endophytes are considered present in New Zealand, including the native *N. aotearoae* which lives within the endemic grass species *Echinopogon ovatus* (Forest hedgehog grass) (Moon et al 2002). Other introduced species; *N. coenophialum*, *N. lolii*, *N. occultans*, *N. typhinum*, and *N. uncinatum;* are found in the following pasture grasses: tall fescue; perennial ryegrass; Persian, Italian, Wimmera; and Canary Islands ryegrasses; and meadow fescue respectively (Clay & Schardl 2002, Moon et al 2000, Moon et al 2002). *Neotyphodium siegelii* was approved for release by the EPA in June 2013 (Approval code NOR100004).

1.12. In association with grasses, these endophytes produce a wide range of bio-active alkaloid compounds, including peramine, ergovaline, lolitrems and lolines. All of these compounds deter insect feeding, protecting the plant against a wide range of insect pests including Argentinean stem weevil, black beetle, root aphid, and grass grub. However, high concentrations ergovaline and lolitrem B cause neurological disorders known as ryegrass staggers and fescue toxicosis in cattle and sheep. These and other livestock illness caused by some endophyte-grass associations present a significant problem to New Zealand's agricultural industry.

1.13. *Neotyphodium* endophytes are derived from the closely related *Epichloë* endophytes. *Epichloë* are sexual fungal endophytes that form associations in hosts that range from mutualistic[6] to parasitisitic[7], with some species causing 'choke' disease[8].

[5] An ascospore is a spore contained in, or produced inside, an ascus. This is specific to fungi classified as ascomycetes.

[6] A symbiotic relationship between individuals of different species in which both individuals benefit from the association.

[7] A form of symbiosis in which one organism benefits at the expense of another organism of a different species.

[8] 'Choke' arises when some *Epichloe* endophytes enter the sexual stage of their lifecycle, and the rapidly growing fungal stroma engulfs the grass inflorescence, 'choking' seed production of the grass.

# 2. The organisms proposed for release

2.1. This organism has the following taxonomy:

Kingdom = Fungi

Phylum = Ascomycota

Class = Ascomycetes

Order = Hypocreales

Family = Clavicipitaceae

Genus = *Neotyphodium*

2.2. The 45 strains of endophyte proposed for release (referred to as *Neotyphodium*) form asymptomatic mutualistic symbioses with their host. They reproduce asexually, by infecting the seeds of the host plant, and are transmitted vertically. However, it is possible that some of the strains are capable of sexual reproduction on their natural hosts. Therefore the organism description that is covered in this advice refers only to the specific strains named in the application, if they are non-sporolating.

2.3. There are no inseparable organisms associated with *Neotyphodium.* EPA staff note that due to the mutualistic relations *Neotyphodium* has with its host plant, it cannot persist naturally outside of the host and is therefore inseparable itself. However, some members of the genus can live outside the host in culture and may grow and sporulate for a limited time on plant litter (Leutchman pers. comm. 2014).

# 3. Risk and benefit assessment

3.1. We have conducted a risk benefit assessment for the import and release of *Neotyphodium.* This includes risks and benefits to the environment, human health and safety, Māori culture and spiritual values, society and community, and the market economy.

3.2. The applicant has asked for a large number of strains from the genus. They have provided the EPA with commercial identifiers for those strains (Table 1; page 6 of the application), but we are not in a position to distinguish between potential species within the genus *Neotyphodium* that might be included in that list, or whether these identifiers represent strains of a single species. We have therefore conducted our risk assessment on the endophyte group referred to *Neotyphodium*, so as to encapsulate all potential risks and benefits associated with this group. However, the final recommendation resulting from the risk assessment concerns only the 45 strains requested by the applicant.

3.3. Our risk assessment takes into account the effects of the organism "*Neotyphodium*" on its original host in the first instance, how it interacts with any new potential hosts in the second instance, and how any risks compare to those from endophytes already present in New Zealand.

3.4. In performing this assessment, EPA staff conducted a literature review in addition to reviewing the information provided by the applicant and submitters.

## Minimum standards

3.5. Prior to approving any new organism the EPA is required to ensure that if the organism were to be released, it would meet the following minimum standards set out in section 36 of Act.

### Section 36 (a): whether *Neotyphodium* is likely to cause any significant displacement of any native species within its natural habitat

3.6. The applicant has provided evidence that *Neotyphodium* is an asexual endophyte and is vertically transmitted. It can only pass between plants by colonisation of seeds produced by the host. However, sexual reproduction cannot be ruled out for all strains that originated from hosts where stroma formation is regularly observed. For example, *Hordeum bogdanii* is known to host a hybrid (*E. bromicola* x *E. typhina*) (Moon et al 2004), whereas *Hordeum brevisubulatum* is reported to be host of a non-hybrid endophyte that is sexually compatible with *E. bromicola* (Leuchtmann et al 2014).

3.7. Many species of *Neotyphodium*, for example *N. aotearoae*, *N. typhinum, N. siegelii* (Moon et al 2002, Tadych et al 2007, Craven et al 2001) produce extensive mycelia[9] on the underside of host plant leaf surfaces, and can produce conidia[10] in plants. However, when *N. siegelii* was artificially cultured on potato dextrose agar, although it produced abundant conidia, these were not interfertile with either of its hybrid parent's *E. festucae*, and *E. bromicola*, and did not reproduce (Craven et al 2001). From this we infer that *N. siegelii* is not likely to hybridise with other fungi. Other *Neotyphodium* strains are non-hybrids or are even identical to *Epichloë* spp. and have at least the potential to hybridise. We therefore consider that this application will be limited only to those strains that are not sexually compatible with other species and therefore cannot have the potential to hybridise.

3.8. Two grass endophytes are native to New Zealand: *N. aotearoae*, which colonises only *Echinopogos ovatus* (Hedgehog grass), and a second endophyte, from the *E. typhina* complex, is endemic to the native *Poa mathewsii*. Because this approval would be limited to *Neotyphodium* that cannot be

[9] Masses of fine branching tubes that make up the body of a fungus.

[10] An asexually produced fungal spore.

transmitted between hosts, we do not consider that it will displace either native endophyte in their natural habitat.

3.9. Cliff Mason submitted that there is a "*potential route for the acquisition of the ability for stromal growth and dispersal by means other than direct vertical transmission….This would presumably require the infection of the host plant by a species that is competent in horizontal transmission.*"

3.10. We consider that *Neotyphodium* forms a relationship with its host such that it protects the host from fungal infection, even from related fungi that might be transmitting horizontally. Two different, even closely related, species of Eplichloae are rarely found together in the same host and artificial "*co-infections of plants have been unsuccessful, indicating that hybridisation is not the inevitable or frequent outcome of interaction between Epichloe/Neotyphodium species*" (Moon et al 2004; and references therein). The New Zealand Plant Breeding and Research Association (NZPBRA) submitted that "*Transfer from the host to other plants is considered extremely unlikely under natural conditions and only occurs in the laboratory with considerable difficulty*." While this may be true for *N. lolii* and *N. coenophialum*, it is certainly not true for all strains infecting *Elymus* and *Hordeum* hosts. There is evidence of horizontal transmission from plant to plant of an endphyte infecting *Elymus europaeus* mediated by conidia formed on host leaf surface (Leutchman pers. comm. 2014).

3.11. None-the-less, we consider that the potential for *Neotyphodium* to colonise another host species by any means is low. We therefore consider it unlikely that *Neotyphodium* would cause significant displacement of any native species within its natural habitat.

### Section 36 (b): whether *Neotyphodium* is likely to cause any significant deterioration of natural habitats

3.12. *Neotyphodium* is not a free-living organism. It lives only within the tissues of its host and is not exposed to the environment. The organism itself cannot cause any significant deterioration of natural habitats.

3.13. DOC notes that "*it ostensibly appears that if the release of these 45 fungi strains is limited to cereal crops, they will not cause significant displacement of native species, deterioration of natural habitats or adversely affect New Zealand's inherent genetic diversity*". However, they asked "*the Committee to consider whether there may be any potential risks to future plant inoculation research, or a potential for wider exposure of endophyte associated areas to native biota, given that once these strains are released into New Zealand they can then be used for any host plant, not just cereal crops*".

3.14. We consider that as *Neotyphodium* cannot pass between hosts without artificial assistance (although we note that *Epichloë* can); it is unlikely to be inoculated into the native biota. *Neotyphodium* (and most *Epichloë* species) are host specific, and inoculation is limited to one or few members within the

sub-family Pooidae. Even artificial inoculation into novel plants within that family has thus far proven difficult. We consider that inoculating outside the family would never have any commercial benefits that would make it a cost effective exercise. In addition, we do not consider that any of these strains pose a greater risk from this type of deliberate inoculation than any of the species' or stains already present in the country.

3.15. It is possible that the increased drought tolerance and pest resistance conferred by *Neotyphodium* may make the host plants more persistent in the environment. However, the applicant states that this is unlikely because "*Cereals crops are grown under conditions that provide tilled and fertile soils along with intensive management of weeds, and pests and soil nutrients are annuals grown in cultivated land and there is little contact with native species. Cereals are poor performers in wild environments and are quickly outcompeted*". In addition, they argue that "*Cereals are also grown as an annual crop, at the end of the season no plants are left remaining in the field*".

3.16. We agree with this with regards to the endophyte-cereal relationship. In terms of any potential future endophyte/novel host relationship, we expect drought tolerance and pest resistance to be desirable qualities. It is unlikely that any new relationships would cause the new host to be persistent in such a way that would enable *Neotyphodium* to cause any significant deterioration of natural habitats.

### Section 36 (c): whether *Neotyphodium* is likely to cause any significant adverse effects on human health and safety

3.17. We have searched the literature, and there are no examples of *Neotyphodium* acting as a human pathogen or posing a threat of any kind to human health or safety. However, Ngai Tahu submitted that "*To date, only farmed animals have been fed peramine- or loline-containing grasses and these have been shown to be safe. But we can foresee objections to the production of loline-containing cereals for human consumption, and suggest that research on public attitudes to this form of modification of staple human foods be undertaken*."

3.18. Chris Bourke submitted that *"Endophyte alkaloids will in this way end up in your breakfast cereal, your bread sandwich at lunch, your cakes or biscuits at afternoon tea and your pasta and pudding at dinner*", and we take this concern very seriously. Even though we consider that all plants have associated endophytic relationships (Saikkonen et al 1998 and references therein), there are not many endophytes that colonise the seed with such high amount of mycelium and the potential to produce toxins. Genes for toxin production may be upregulated in unforeseen ways within a new association (Leutchmann pers. comm. 2014).

3.19. The applicant has stated in their response to submissions that in terms of loline toxicity *"All literature except the Bourke paper refers to loline produced by Neotyphodium endophytes as insecticidal and*

*deterrent to a broad range of insects…and provides no evidence of mammalian toxicity issues*"; in terms of peramine toxicity "*There is no published evidence of mammalian toxicity to this compound and we have dosed mice at the OECD limit dose of 2000 mg/kg with no adverse effects*"; in terms of chanoclavine toxicity "*there is no evidence that chanoclavine will cause a food safety issue"* and in terms of terpendole E, they "*stand by* [their] *position that terpendole E is non-tremorgenic*". We consider therefore that it is unlikely that human toxicity will result from new associations between these endophytes and cereal hosts.

3.20. However, the presence of toxins in potential food pathways is regulated by the New Zealand Food Standards Association. They complete a risk assessment on the potential for toxic compounds to enter human food chains, and if there is a significant change in composition, or safety concerns in relation to exposure to alkaloids through food, then crops produced in this way could be considered to be a novel food. An application to the Advisory Committee on Novel Foods could provide an opinion on this, once data were available (L. Henderson pers. comm. 2014).

3.21. We therefore consider that *Neotyphodium* is not likely to cause significant adverse effects on human health and safety.

### Section 36 (d): whether *Neotyphodium* is likely to cause any significant adverse effect to New Zealand's inherent genetic diversity

3.22. The introduction of any new organism to New Zealand has the potential to cause harm to New Zealand's genetic diversity. However, the taxonomic classification and characterised biology of *Neotyphodium* indicates that this potential is highly unlikely to eventuate.

3.23. We therefore consider that *Neotyphodium* is unlikely to cause any significant adverse effects to New Zealand's inherent genetic diversity.

### Section 36 (e): whether *Neotyphodium* is likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease

3.24. We have searched the literature, and there are no examples of *Neotyphodium* acting as a pathogen, parasite, or vector of human, animal, or plant disease, although sexually reproducing *Epichloë* is considered a plant disease. We therefore consider that *Neotyphodium* is not likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

### Conclusion on the minimum standards

3.25. We consider that *Neotyphodium* is unlikely to cause significant displacement of other organisms, cause significant deterioration of natural habitats, have any significant adverse effects on human health and safety, or have significant adverse effects on New Zealand's inherent genetic diversity. It is unlikely to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

3.26. We therefore consider that *Neotyphodium* meets the minimum standards as stated in the Act.

## The ability to establish an undesirable self-sustaining population and the ease of eradication

3.27. Section 37 of the Act requires EPA staff to have regard to the ability of the organism to establish an undesirable self-sustaining population and the ease with which the organism could be eradicated if it established such a population.

3.28. We note that the purpose of introducing *Neotyphodium* is to provide protection to annual cereal crops. We consider that *Neotyphodium* endophytes could not form a self-sustaining population, as it cannot effectively propagate outside of its plant host, although we understand that if any of these strains were to become stroma forming, then contagious aspcospores could be dispersed from crops to wild grasses and back. In addition, we consider that the annual crops for which this approval is intended do not form self-sustaining populations. However, if in the future *Neotyphodium* endophytes were inoculated into a novel plant host that was able to form a self-sustaining population, we consider that the *Neotyphodium* contained within this population would not be undesirable.

3.29. We therefore consider that *Neotyphodium* is unlikely to require eradication. If eradication became necessary, it would be simple to spray crops with herbicide, as the endophyte can only live if the host plant is living.

## Adverse effects

3.30. The applicant has identified potential adverse effects associated with the release of *Neotyphodium* (see pages 15-18 of the application). In particular, they discuss the potential for *Neotyphodium* to cause harm to birds and mammals by introducing them to toxic alkaloids.

3.31. Chris Bourke submitted that "*Alkaloids that were present in only small amounts in "wild" endophyte infected plants for example can suddenly be produced in very large amounts in plants inoculated with a "selected strain" of an endophyte*". He cites an example where "*the Mediterranean tall fescue grass plus Max P (or sometimes Max Q) endophyte combination (found after release to produce a new form of lethal toxicity in horses, most likely due to the very high levels of a particular loline compound that are produced by this combination)"*.

3.32. Dr Bourke also commented that he "*would like to be able to challenge the applicants over their farm animal/livestock risk assessment statements* (C. Bourke pers. comm. 2013)". He defined and named the syndrome Equine Fescue Oedema (EFO) (Bourke et al 2009), after 48 horses in Australia ate Mediterranean tall fescue infected with *Neotyphodium coenophialum* and became intoxicated. Four animals died in that instance. The applicant states that all *"endophyte and cereal host plant*

*combinations will be tested for bioactivity using mice models which are accepted as indicating possible mammalian toxicity…..We have reviewed the evidence around the toxicity of each of the four alkaloids produced by these strains* [and] *we find that there is no evidence to indicate they are toxic to any animals except insects. They therefore pose no risk to…the welfare of livestock".*

3.33. EPA staff note that Bourke et al (2009) reported that "*It is significant that the period of pasture toxicity …followed a protracted period of dry weather that ended with sufficient rainfall to initiate pasture growth. In all the outbreaks* [of EFO] *so far there has been an extended period of dry weather, varying in length from 4 to 6 weeks, prior to toxicity developing*". The implication from this is that the toxins are produced under specific environmental conditions, and we consider that with knowledge of these conditions, toxicity resulting from new host/endophyte relationships can be managed.

3.34. Furthermore, no confirmed cases of EFO have been reported in the U.S. Several years of trials with the Max P (Max Q)/Mediterranean-type fescue combination in Mississippi have failed to duplicate the Australian experience, according to Dr Ray Smith (forage extension specialist at the University of Kentucky). If Mediterranean fescue in association with *N. coenophialum* is the culprit in EFO, (and we consider that there may be alternative explanations; agrichemical poisoning for example), "*Horse owners and advisors have developed ways to protect their horses from EFO and there are no reported cases in cattle. In short, they are making sure not to graze horses in pastures with Neotyphodium strains introduced into Mediterranean tall fescue*" (Smith pers. comm. 2013). Smith noted that in the U.S., Mediterranean-type tall fescues have been sown in areas of western Texas and Oklahoma with full awareness of potential horse health issues and landowners are successfully using this fescue to raise cattle and sheep with no ill effects.

3.35. We therefore consider that although there may be questions around the genuine effects of new host/endophyte associations; a) the applicant intends to carry out further mammalian testing prior to commercialisation, b) farmers and growers can take preventative measures to protect the health of their livestock and c) we do not consider that these effects are more plausible than the potential for future research to be developed that enables novel hosts to be inoculated with strains of *Neotyphodium* already present in New Zealand, as long as this approval is limited to strains that are non-stroma forming.

3.36. We consider that the introduction of *Neotyphodium* in association with cereals is very unlikely to have any adverse effects on beneficial insects. We also consider that *Neotyphodium* is very unlikely to confer such host advantages that the host could become an invasive pest. Therefore, we consider that the adverse effects associated with the release of *Neotyphodium* are **negligible.**

## Positive effects

3.37. The applicant has identified potential positive effects on the environment, on society and communities, and on the market economy, associated with the release of *Neotyphodium* (see pages 13-15 of the application). They consider that approval of *Neotyphodium* will result in improved farm productivity, specifically via reduced costs of applying synthetic chemicals and increased cereal crop yields.

3.38. The applicant states that "*Worldwide crop loss due to animal pests and pathogens has been estimated at 18% and 16% respectively (Oerke 2006). Cereal crops in New Zealand are no different, suffering attack from plant pathogens, insects and other invertebrates. In cereal crops losses are reduced through the regular applications of fungicides and insecticides, accounting for 30 tonnes and 9 tonnes of active ingredient applied each year respectively (Manktelow et al 2005). The cost* [of] *synthetic chemicals and their application has been estimated at $22 million per year (data sourced from FAR)".*

3.39. The applicant presented a number of case studies demonstrating the efficacy of *Neotyphodium* endophytes in pest management. We consider that some benefits to farm pest management practices are likely.

3.40. The applicant also states that environmental and human health benefits may occur as a result of reduced agrichemical use. "*In particular, accumulation of toxic pesticides in humans and animals can lead to serious health issues for individuals, particularly during early development. For example, pesticide exposure has been linked to respiratory disorders, developmental cancers and shown to have lasting effects on the development of mental abilities (Zejda et al 1993)*".

3.41. DOC commented that "*In general and where adverse impact to conservation values has been mitigated, the Department supports such innovation that would reduce the amount of pesticides used that may, at some point, enter natural pathways (soil and water) in native ecosystems thereby negatively impacting New Zealand's environmental values"*.

3.42. The NZPBRA submitted that "*The Association considers that the release of the endophytic fungus, Epichloe/Neotyphodium could confer important advantages for cereal crops against insect pests, disease and drought. The endophyte genus Neotyphodium has already proven to be of significant economic benefit to New Zealand farmers through enhanced pasture productivity and animal performance. Use of Epichloe/Neotyphodium in cereal crops has the potential to continue improving New Zealand production as well as reducing pesticide use."*

3.43. Ngāi Tahu submitted that they have "*concerns over the longstanding and widespread use of toxic chemicals and other agrichemicals in the horticultural and agricultural sectors*". They consider that "*The development of pest resistant pasture grasses through the utilization of endophytic fungi has transformed pastoral farming, at least from the pest management point of view. As the applicant*

*explains, pest-resistant ryegrass and fescue cultivars have been incorporated in pastoral systems for some years with considerable benefit to production, reduced use of pesticides, and no apparent adverse effects. The present application seems to us to offer similar benefits to the arable sector*."

3.44. We consider that reducing the use of agrichemicals in the rural sector is likely to benefit the environment, and to have human health benefits.

3.45. Cliff Mason submitted that he considers that the claim that the release of endophytes will reduce the use of chemical pesticides "*is a highly questionable claim, largely because of the unrealistic assessment of the agronomic situation in which the agent will be employed. There is an unsupported assumption of proportionality between the reduction in pest damage that can be achieved in the presence of the endophytes and the reduced use of pesticides*". He contends that "*because of the economic pressures to maximise production volume and quality, pressures that a market economy ensures are unrelenting, there is unlikely to be any significant reduction in pesticide use because pest damage is not eliminated but only marginally diminished by the presence of the endophytes*."

3.46. However, New Zealand is considered the world leader when it comes to the endophyte research. The Foundation for Arable Research submitted that they consider that "*The research team are of extremely high calibre and are world leading in their field thus any research undertaken on endophyte in cereals will be of high quality*." Therefore, we consider that the positive effects stated by the applicant are likely to accrue.

3.47. Having evaluated the information, we consider that the beneficial effects that can be accredited to the release of *Neotyphodium* are **non-negligible**.

## Relationship of Māori to the Environment

3.48. The potential effects on the relationship of Māori to the environment have been assessed in accordance sections 6(d) and 8 of the HSNO Act. Under these sections all persons exercising functions, powers, and duties under this Act shall take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of the Treaty of Waitangi (te Tiriti o Waitangi).

3.49. In consideration of these functions and duties, this section of the report will provide an overall evaluation of the consultation process with Māori that was undertaken by the applicant and their response to issues that were raised from this. Finally an assessment of the impact this application may have on the principles of te Tiriti o Waitangi will be provided.

### Consultation

3.50. The EPA policy on engagement with Māori requires that consultation be undertaken by the applicant in the first instance, and should lead to the effective exchange of information between the applicant

and Māori as appropriate. In addition, another purpose of consultation in this context is to lead to the provision of information to the decision makers to enable them to evaluate risks, costs and benefits and make informed decisions in accordance with its legal duty under the HSNO Act.

3.51. To fulfil this requirement the applicant sent letters and emails to members of the EPA's Te Herenga Network[11] which outlined the purpose of the application, proposed research they would undertake and an invited comment/queries. The applicant responded to queries as required.

3.52. In addition, the applicant received nine responses to the public notification of the application. One response of relevance to Māori was via Ngāi Tahu in support of the application. Ngāi Tahu mentioned;

- Urging reduction in use of agrichemicals;
- Encouraging further development of new technologies;
- Unsure of the stability of plant/endophyte associations.

### Impact on the Principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

3.53. Under section 8 of the Hazardous Substances and New Organisms Act (1996), all persons exercising powers and functions under the Act are to take into account the principles of the Treaty of Waitangi (te Tiriti o Waitangi).

3.54. The principles we have assessed as relevant are partnership, participation and protection.

3.55. The principles of partnership and participation refer to the shared obligation on both the Crown and iwi/Maori to act reasonably, honourably and in good faith towards each other to ensure the making of informed decisions on matters affecting the interests of Māori. In fulfilment of these principles, as previously stated, the applicant has completed a consultation program for the application and responded to queries.

3.56. The principle of active protection refers to the Crown's obligation to take positive steps to ensure that Māori interests are protected. Taking into account this principle requires this application to provide sufficient evidence to show that the introduction of *Neotyphodium* does not pose a significant risk to native or taonga species, ecosystems and traditional Māori values, practices, health and well-being.

3.57. As outlined in more detail in section 3, *Neotyphodium* is unlikely to cause significant displacement of other organisms, cause significant deterioration of natural habitats, have any significant adverse effects on human health and safety, or have significant adverse effects on New Zealand's inherent genetic diversity. It is unlikely to cause disease, be parasitic, or become a vector for human, animal, or plant disease other than the plant disease for which it is intended for release.

[11] Te Herenga is made up of Māori resource and environmental managers, practitioners, or experts who represent their iwi, hapū or Māori organisation on matters of relevance to the activities and decision-making of the EPA.

3.58. Consequently, it is considered that the application provides sufficient information to take into account the principle of "active protection" and is considered to be consistent with the principles of the Treaty of Waitangi. Having considered this assessment we consider the application to be consistent with the principles of the Treaty of Waitangi.

### Conclusion on adverse and positive effects

3.59. After completing our risk assessment and reviewing the relevant information, we consider that the adverse effects of releasing *Neotyphodium* are negligible and the positive effects are non-negligible. Therefore the positive effects from the import and release of *Neotyphodium* outweigh the adverse effects.

## 4. Recommendation

4.1. After weighing the adverse and positive effects, the EPA recommends that the import and release of 45 strains of *Neotyphodium* be approved.

4.2. However, we recognise that *Epichloë* and *Neotyphodium* cannot easily be distinguished, and in fact, new nomenclatural rules (one-fungus-one-name concept) require that all species be unified in a single genus (Leuchtmann et al 2014). We therefore recommend that this approval be limited to a) the strains listed in the application, and b) to those that have been diagnosed as being non-sporolating and cannot transmit sexually.

4.3. We recommend that the applicant use the trials they intend to carry out in New Zealand to generate the data required to enable MPI to clearly determine what, if anything, needs to be done to comply with legislation administered by MPI. Depending on the claims made for any product containing the endophyte, it may need registration under the Agricultural Compounds and Veterinary Medicines Act 1997.

4.4. Further, as food producing animals will potentially be fed treated plant material, Food Safety Australia and New Zealand (FSANZ) and MPI would also need to know the level of alkaloids that could get into foods (meat and milk). If residues were detected, depending on the level of the residues found, maximum residue limits may need to be set in New Zealand Food Standard legislation.

4.5. We therefore recommend that the applicant begin communications with MPI and FSANZ to establish the level of information required to get approvals and permits for the commercialisation of their product once field trials have been finalised.

4.6. We are cognisant of the fact that the applicant has undertaken to do additional toxicity trials and we trust they will do so. However, we recommend this approval be granted on the basis of the information

already provided to the Authority, and that any additional information (results from field trials, genetic identity of strains etc.) be provided to the other regulatory bodies for their evaluation.

| | | |
|---|---|---|
| Asela Atapattu | Sean Rangiwhetu | Dr Kate Bromfield |
| **Manager** | **Advisor** | **Senior Advisor** |
| **New Organsims** | **Māori Policy and Operations** | **New Organism** |

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# Appendix 1 Summary of Submissions

| Submission | Submitter/ organisation | Support/ Oppose | Submitter comments |
|---|---|---|---|
| 103680 | Len Parkes | Neither support nor oppose | • Appreciated precautionary approach taken by applicant |
| 103681 | Nursery and Garden Industry New Zealand | Support | • NZ has a long history of utilising endophyte science for the benefit of pasture production<br>• Support the introduction of endophytes where sound science is available to prove the benefits |
| 105350 | Paul Elwell-Sutton | Neither support nor oppose | • No concerns regarding release from containment |
| 106209 | Dr Christopher Bourke | Oppose | • The risks have not been fully disclosed<br>• The research has not been peer reviewed, and is insufficient to support the 'reasonable doubt' required by HSNO<br>• More research is required |
| 108125 | Foundation for Arable Research | Support | • Significant potential to reduce agrichemical use<br>• Viable and sustainable pest management technique |
| 108115 | Ngai Tahu | Support | • Urge reduction in use of agrichemicals<br>• Encourage development of new technologies<br>• Unsure of the stability of plant/endophyte associations |
| 108127 | New Zealand Plant Breeding and Research Association | Support | • *Neotyphodium* could confer important advantages for cereals against insect pests, disease and drought<br>• Already has a proven economic benefit<br>• Transfer between plants extremely unlikely and only occurs with difficulty in laboratories |
| 108443 | Cliff Mason | Oppose | • Concern that *Neotyphodium* could develop an ability for stromal growth and dispersal by means other than vertical transmission<br>• Unrealistic assessment of the agronomic situation thus that *Neotyphodium* will not actually result in reduction of agrichemicals |
| 108450 | Federated Farmers | Support | • Endophytes already proven to significantly increase production potential in pastures by deterring pests |

# Appendix 2 Comments from DOC

19 December, 2013

**Application number:** Application APP201774

**Applicant:** Grasslanz Technology Ltd & AgResearch Ltd

**Application purpose:** to provide pest and disease resistance and drought tolerance to populations of rye-corn (*Secale cereale*), and other annual cereal crops, by infecting with non-stroma forming epichloae (*Epichloe/Neotyphodium* spp.) fungal endophytes that have been isolated from wild relatives of modern cereals

**Submission period closes:** 24 January 2014

Thank you for the opportunity to comment on this application, the primary aim of which is to release up to 45 strains from the class of fungus (*Neotyphodium* spp.) for the purpose of improving cereal crops' resistance to insects and plant pathogens and tolerance to drought.

Please note we do **not** wish to be heard at a public hearing in support of our comments.

### *Disclosure of DOC'S knowledge precincts*

1. The Department does not have endophytic expertise or capability and as such we can only offer very limited appraisal and comment to this application.
2. We note the EPA's adverse effects assessment relies on the evidence provided by the applicant, references cited within the application, and additional information available in the public domain and that raised through public engagement, and as such we ask that the Authority takes our knowledge precincts into account when deciding whether suitable assessment has been done on this new organism's potential adverse effects to the environment.
3. There is a concern that if EPA publicly notify such applications but do not receive any feedback from experts the default perception is that the application poses little or no risk. Within this context we recommend the Authority seeks input from an independent pathologist who could provide more qualified feedback than what we can offer. This approach would enable an appropriately informed, objective and independent decision on this application.

### *Comments on potential adverse effects to conservation values*

4. We have no cause to disagree with the applicants' assertions that:
    - the 45 fungi strains pose no hybridisation risk with native New Zealand *Neotyphodium* fungi, given the species is asexual
    - the fungus does not survive independently of its host plant and is incapable of spreading to other species
    - the improved cereal plants' competitive ability is unlikely to increase their advantage to the point where they could outcompete native species, because of the nature and biology of cereal cropping
    - the insect deterring chemicals inherent in the cereal crops will not substantially increase the pressure on native invertebrates given relative large scale pastoral farming infected with insect deterring endophytes (10.1 million hectares) compared to the release of endophytes in cereal crops (121,000 hectares) (noting this is qualified by the considerations in 6. below), and
    - the combination of less invertebrate species in areas infected with endophytes along with learnt aversion to the plants should help protect avian species from adverse effects of grazing infected biota.

5. As such, it ostensibly appears that if the release of these 45 fungi strains is limited to cereal crops, they will not cause significant displacement of native species, deterioration of natural habitats or adversely affect New Zealand's inherent genetic diversity.

*Other considerations*

6. We ask the Committee to consider whether there may be any potential risks to future plant inoculation research, or a potential for wider exposure of endophyte associated areas to native biota, given that once these strains are released into New Zealand they can then be used for any host plant, not just cereal crops. Reiterating our knowledge precincts above, we do not have the capability to assess these likelihoods or consequences in-house.
7. In general and where adverse impact to conservation values has been mitigated, the Department supports such innovation that would reduce the amount of pesticides used that may, at some point, enter natural pathways (soil and water) in native ecosystems thereby negatively impacting New Zealand's environmental values.

*Comments co-ordinated on behalf of the Department of Conservation by:*

**Verity Forbes**

Technical Advisor (Biosecurity), Science and Technical Group, Wellington

*Contributors:*

*Kate McAlpine (Science Advisor – Threats), Science & Capability, Wellington*

*Chris Green (Technical Advisor – Threats), Science & Capability, Hamilton (based in Auckland)*

# Appendix 3 Comments from MPI

Further to our meeting today, the MPI comments on the application for approval are:

Similar to FSANZ, MPI cannot be definitive as to whether a product with the endophyte in it needs registration or not without more information. In particular we would need to have data on the levels of alkaloids present in the plant both with and without treatment, so the increase in alkaloids under New Zealand growing conditions can be determined. This would assist in our determining whether the use of the product has any animal welfare or food residue issues.

As food producing animals will be fed treated plant material, we would also need to know the level of alkaloids that get into foods (meat and milk). If residues are detected, depending on the level of the residues found, maximum residue limits may need to be set in New Zealand Food Standard legislation. I am aware that some data has been submitted and shows a very low acute toxicity, and no effects in a 28-day feeding study. However, many alkaloids are potential genotoxic carcinogens (depends on their core chemical structure), and the short term testing described will not inform as to the potential for carcinogenicity. This might be resolvable if the chemical structure of the alkaloids was disclosed. (The presence of a potential carcinogen in food that is sold would be likely to breach Section 9 of the Food Act 1981).

Depending on the claims made for any product containing the endophyte, it may need registration under the Agricultural Compounds and Veterinary Medicines Act 1997.

For MPI, the best way forward for the applicant would be to use the trails they intend to carry out in New Zealand to generate the data required to enable us to clearly determine if they need to do anything to comply with legislation administered by MPI.

In summary, we suggest the trials determine the levels of alkaloids in both treated and untreated crop plants grown in New Zealand conditions, and residue levels in food (milk and meat) from animals fed the treated plant material, and also information on the chemical structures of the alkaloids induced in the plant by the endophyte. Summarised toxicity data would also be helpful. A copy of the labels of intended products (with the claims being made and recommended method of use clearly stated) would also be required. This data should be sent in to the Agricultural Compounds and Veterinary Medicines Group at MPI with a request for a class determination. There may be more data required after the data sent in has been assessed.

With regards

**John Reeve** | Principal Adviser (Toxicology)
Science and Risk Assessment Directorate | Standards Branch
Ministry for Primary Industries - Manatū Ahu Matua