Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

Amended under section 67A of the HSNO Act on 19 August 2014

Date	22 April 2014
Application code	APP201774
Application type	To release any new organism under section 34 of the Hazardous Substances and New Organisms Act 1996
Applicant	Grasslanz Technology Ltd. and AgResearch Ltd.
Date application received	13 November 2013
Hearing and consideration	7 March 2014
Considered by	A decision-making committee of the Environmental Protection Authority (the Committee)[1]; • Shaun Ogilvie (Chair) • Deborah Read • Damian Stone
Purpose of the application	To release non-toxic *Neotyphodium* fungi in order to improve the resistance of rye corn and other annual cereal crops to pests and diseases, reducing pesticide and fungicide use and improving farm productivity.
The new organisms approved for release	45 strains of *Neotyphodium* fungi

1. Summary of decision

1.1. The application to release 45 strains of *Neotyphodium* fungi was lodged under section 34 of the Hazardous Substances and New Organisms Act 1996 (the Act).

1.2. The application was considered in accordance with the relevant provisions of the Act and of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology).

1.3. The Committee has **approved** the application **without controls** in accordance with section 38(1)(a) of the Act.

[1] The Committee referred to in this decision is the subcommittee that has made the decision on this application under delegated authority in accordance with section 18A of the Act.

2. Application process

Application Receipt

2.1. The application was formally received for processing on 13 November 2013.

Public notification

2.2. Section 53(1)(c) of the Act provides that an application under section 34 of the Act must be publicly notified by the Environmental Protection Authority (EPA).

2.3. The application was notified by placing a notice on the EPA website on 18 November 2013.

2.4. In accordance with section 53(4) of the Act, letters or emails were sent notifying the Minister for the Environment, the Ministry for Primary Industries (MPI), the Department of Conservation (DOC), and other government departments, crown entities, and local authorities who have expressed an interest in being notified about applications for non-genetically modified new organisms. Māori organisations, non-government organisations and stakeholders who have expressed an interest in being notified about applications for non-genetically modified new organisms were directly notified. All these parties had an opportunity to comment on the application as per section 58(1)(c) of the Act and clause 5 of the Methodology.

2.5. Section 59(1)(c) of the Act requires an application to be open for the receipt of submissions for 30 working days from the date of public notification. The application was open for submissions from 18 November 2013 until 24 January 2014.

2.6. In regards to alkaloid toxicity in food for human consumption, MPI and Food Standards Australia New Zealand (FSANZ) commented that currently there is insufficient information to be able to conduct a food/feed safety assessment of products derived from *Neotyphodium*-plant host associations. Thereafter, MPI and FSANZ provided the applicant with information on preliminary data requirements for food/feed safety assessments.

2.7. DOC commented that the Department had no cause to disagree with many of the applicant's assertions regarding the 45 strains of *Neotyphodium* fungi, if the host plant is limited to cereal crops. Considering these strains could potentially be inoculated into other host plants under this approval, DOC asked the Committee to "*consider whether there may be potential risks to future plant inoculation research, or a potential for wider exposure of endophyte associated areas to native biota*".

2.8. Nine submissions were received through the public notification pathway. Nursery and Garden Industry New Zealand, Wilderness Trappers, Te Rūnanga o Ngāi Tahu, Foundation for Arable Research, New Zealand Plant Breeding and Research Association (NZPBRA) and Federated Farmers of New Zealand made submissions in support of the application. Len Parker made a submission that neither supported

nor opposed the application. Christopher Bourke and Cliff Mason made submissions opposed to the application.

2.9. Te Rūnanga o Ngāi Tahu and Cliff Mason requested to speak at the hearing. Cliff Mason later withdrew his request and did not speak at the hearing.

Reports sought

2.10. The EPA staff report was provided under section 58(1)(a) of the Act.

2.11. Ngā Kaihautū Tikanga Taiao (NKTT) were given the opportunity to prepare a report and chose not to comment on the application.

2.12. On 21 February 2014, the EPA staff report was published on the EPA website and the applicant and submitters were informed of its availability.

Hearing and Consideration

2.13. Section 59(1)(d) of the Act requires that the hearing commence not more than 30 working days after the closing date for submissions. The hearing was held at the EPA offices, Wellington, on 7 March 2014.

2.14. John Caradus (Grasslanz Technology Ltd.) introduced Tim Chapman from Grasslanz Technology Ltd., and Linda Johnson, David Hume, Wade Mace, Sarah Finch and Wayne Simpson from AgResearch Ltd. as expert witnesses appearing on behalf of the applicant. Thereafter, John Caradus presented the application in person, paying particular attention to the submitters' concerns regarding risk of hybridisation and *Neotyphodium* induced alkaloid toxicity *in planta*.

2.15. Oliver Sutherland and Gerry Coates were present on behalf of Te Rūnanga o Ngāi Tahu. Oliver Sutherland spoke to the Te Rūnanga o Ngāi Tahu submission.

2.16. Leigh Henderson was present on behalf of FSANZ, although she was not required to speak at any point in the hearing.

2.17. Specific points raised by submitters (either in their submission or during the hearing) are addressed where appropriate throughout this decision document.

2.18. The Committee would like to thank all people who submitted the information used in making this decision. Public submissions provide a focus for the Committee on points that need clarification, and the Committee found the submissions and the applicant's responses very helpful in its consideration of the application.

Information available for the consideration

2.19. The information available for the consideration comprised:

- The application;
- The EPA staff advice report peer reviewed by Professor Adrian Leuchtmann (a distinguished fungal ecologist from ETH Zurich university);
- Comments received from MPI, FSANZ and DOC;
- Submissions; and
- Information obtained during the hearing.

Description of the new organisms approved for release

2.20. *Epichloë* and *Neotyphodium* fungi are collectively known as epichloae and have co-evolved with the grass subfamily *Pooideae*. *Epichloë* is a genus comprising sexual species of endophytic fungi, whereas the genus *Neotyphodium* comprises asexual species of endophytic fungi.

2.21. The Committee noted Oliver Sutherland's concerns regarding the applicant's use of reference numbers to identify the 45 strains of *Neotyphodium* fungi (as described in Table 1) rather than species taxonomic classification. None-the-less, the Committee was satisfied the biology of each strain has been characterised in the application (see Table 1 in the application); and accepted John Caradus' position that species classification is currently "*meaningless*" for asexual endophytic fungi as their taxonomy is still being developed due to on-going discoveries and the recent nomenclatural realignment of *Neotyphodium* species with genus *Epichloë*.

Legislative criteria for application

2.22. The application was determined in accordance with section 38 of the Act, taking into account the matters specified in sections 36 and 37, relevant matters in Part 2 of the Act, and the Methodology.

3. Minimum Standards

3.1. The Committee noted that the EPA was not in a position to distinguish between potential species within the 45 strains of *Neotyphodium* fungi (as described in Table 1), and consequently, the EPA risk assessment was conducted on the genus *Neotyphodium* (hereafter referred to as '*Neotyphodium*') to encapsulate all potential risks and benefits associated with this group. However, the Committee limited this approval to the 45 *Neotyphodium* strains in Table 1 and only for non-sporulating members of this group.

3.2. The Committee considered whether *Neotyphodium* meets the minimum standards as specified in section 36(a-e) of the Act; specifically whether it could:

(a) cause any significant displacement of any native species within its natural habitat; or
(b) cause any significant deterioration of natural habitats; or
(c) cause any significant adverse effects on human health and safety; or
(d) cause any significant adverse effects to New Zealand's inherent genetic diversity; or

(e) cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose is to import or release an organism to cause disease, be a parasite, or a vector for disease.

Consideration of section 36(a) of the Act

3.3. The Committee considered whether *Neotyphodium* is likely to cause any significant displacement of any native species within its natural habitat.

3.4. The applicant provided evidence that *Neotyphodium* is an asexual endophyte (non-stroma forming) and is vertically transmitted (via seeds produced by the host) rather than between host plant species.

3.5. The Committee noted concerns raised by Cliff Mason, who 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.*"

3.6. The Committee noted that hybridisation of asexual *Neotyphodium* with stroma forming epichloae competent in horizontal transfer (intragenerational transmission) would first require co-infection of a host plant. However, two different species of epichloae (including closely related species) are rarely found together in the same host; and artificial transfer from the host to other plants only occurs in the laboratory with considerable difficulty.

3.7. Therefore, the Committee considered it extremely unlikely that *Neotyphodium* could displace the native fungus *Neotyphodium aotearoae*, an endophyte within the *E. typhina* complex, or any other fungus, from its natural habitat. The Committee is therefore satisfied that no native fungi will be displaced through the release of *Neotyphodium*.

3.8. After assessing all the information, the Committee is satisfied that *Neotyphodium* is not likely to cause any significant displacement of any native species within its natural habitat.

Consideration of section 36(b) of the Act

3.9. The Committee considered whether *Neotyphodium* is likely to cause any significant deterioration of natural habitats.

3.10. *Neotyphodium* endophytes are obligate symbionts. They have no capacity to exist independently of their host plants in nature. Therefore, *Neotyphodium* itself cannot cause any significant deterioration of natural habitats.

3.11. Under section 58(1)(c) of the Act, the Committee paid particular regard to the request from DOC to "*consider whether there may be potential risks to future plant inoculation research, or a potential for wider exposure of endophyte associated areas to native biota*" associated with *Neotyphodium* release.

3.12. The Committee noted that considering *Neotyphodium* cannot pass between hosts horizontally without artificial assistance using specialised techniques, *Neotyphodium* is unlikely to be inoculated into native or naturalised biota under natural conditions. Furthermore, *Neotyphodium* are host specific and inoculation is limited to one or few members within the grass subfamily *Pooidae*.

3.13. It is possible that the increased resistance to pests and disease afforded by *Neotyphodium* infection may make host plants more persistent in the environment, and may result in the plants becoming invasive weeds. However, Sarah Finch stated during the hearing that any benefit from a novel *Neotyphodium*-plant host association is not expected to increase fitness of material over and above pesticide/fungicide treated plants.

3.14. After assessing all the information, the Committee considered it very unlikely that association with *Neotyphodium* will cause any host plant to become more invasive.

3.15. Therefore, the Committee is satisfied that *Neotyphodium* is not likely to cause any significant deterioration of natural habitats.

Consideration of section 36(c) of the Act

3.16. The Committee considered whether *Neotyphodium* is likely to cause any significant adverse effects on human health and safety.

3.17. The applicant, EPA staff advice report and submitters did not identify any examples of *Neotyphodium* acting as a human pathogen or posing a threat of any kind to human health or safety.

3.18. Te Rūnanga o Ngāi Tahu submitted that farmed animals fed grasses containing peramine or loline alkaloid inducing endophytes have shown no ill-effects, but "*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*." Similarly, Christopher Bourke submitted food safety concerns regarding endophyte derived alkaloids ending up "*in your breakfast cereal, your bread sandwich at lunch, your cakes or biscuits at afternoon tea and your pasta and pudding at dinner*".

3.19. The Committee noted that the neurotoxin lolitrem B (causal agent of ryegrass staggers in animals) and the vasoconstrictive toxin ergovaline (can result in reduced milk production and general ill-thrift of grazing animals) are alkaloids that have not been identified as being induced by the 45 *Neotyphodium* strains *in planta* (see Table 1 of the application).

3.20. The Committee noted that the alkaloids produced by the 45 *Neotyphodium* strains *in planta* (Table 1 of the application: peramine; chanoclavine; terpendole E and lolines) are produced by epichloae already

present in New Zealand, and that novel New Zealand epichloae-plant host associations are not regulated.

3.21. The Committee acknowledged the applicant has found no evidence to indicate the four alkaloids produced by the 45 *Neotyphodium* strains (peramine; chanoclavine; terpendole E and lolines) are toxic to animals. In their response to submitters' concerns about alkaloid toxicity, the applicant stated 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*". During the hearing, John Caradus reiterated that NANL, NAL, NFL (loline alkaloids) and peramine alkaloid toxicity testing performed by the applicant using mice models, following OECD guidelines, raised no concerns for food safety or livestock health. The Committee noted that tests for bioactivity using mice models are an accepted, cost effective method of assessing possible mammalian toxicity.

3.22. In horse grazing trials, the applicant observed severe Equine Fescue Oedema (EFO) in horses grazing Mediterranean-Max P fescue (plant-endophyte association) containing NANL at 1141 parts per million (ppm) in the leaf, but no signs of EFO in horses grazing meadow fescue containing NANL at 699 ppm in the leaf (61% of Mediterranean-Max P fescue pasture). Only an incredibly steep dose response curve would present severe adverse effects at 1141 ppm concentration yet show no adverse effects at 699 ppm. The applicant considers such a steep dose response curve to be highly improbable, and as such, the results suggest that NANL is not the causal agent of EPO. John Caradus suggested a Max P endophyte allergen may be responsible.

3.23. Furthermore, John Caradus and Sarah Finch described the grass endophyte testing program that all novel endophyte-plant host associations are subjected to prior to commercialisation by Grasslanz Technology Ltd. (self-regulated testing). The testing program involves, but is not limited to: molecular screening for alkaloid biosynthesis genes; chemotype testing; and livestock toxicity testing using endophyte treated pasture and grazing sheep.

3.24. The Committee noted that should any food or feed product derived from, or containing, the 45 *Neotyphodium* strains (Table 1) become commercially available (i.e. cereals), the safety of those products will need to be assessed under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the Food Act 1981; and the appropriate approvals will need to be sought, if required, before a food or feed product is commercialised.

3.25. After assessing all the information, the Committee is satisfied that *Neotyphodium* poses no increased risk of alkaloid toxicity in food products above the present risk associated with unregulated novel New Zealand epichloae-plant host associations.

Consideration of section 36(d) of the Act

3.26. The Committee considered whether *Neotyphodium* is likely to cause any significant adverse effect on New Zealand's inherent genetic diversity.

3.27. The Committee is satisfied that hybridisation of asexual *Neotyphodium* with New Zealand epichloae is highly unlikely.

3.28. Oliver Sutherland expressed concern over the genetic stability of the asexual nature of *Neotyphodium*. The Committee noted that the evolutionary changes required for this to occur happen over hundreds and thousands of generations, even under positive selective pressure. This equates to hundreds, or even thousands of years, and cannot be considered as part of the HSNO risk assessment.

3.29. After assessing all the information, the Committee is satisfied that *Neotyphodium* is not likely to cause any significant adverse effects on New Zealand's inherent genetic diversity.

Consideration of section 36(e) of the Act

3.30. The Committee considered whether *Neotyphodium* is likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease.

3.31. The applicant, EPA staff advice report and submitters did not identify any examples of *Neotyphodium* acting as a pathogen, parasite, or vector of human, animal, or plant disease.

3.32. Therefore, the Committee considers 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

3.33. After assessing all the information, the Committee considers that *Neotyphodium* meets the minimum standards, as specified in section 38(a)(i) of the Act.

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

4.1. Section 37 of the Act requires the Committee 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.

4.2. The Committee considered the biological characteristics of *Neotyphodium* presented by the applicant, submitters and detailed in the EPA staff advice report. The Committee acknowledged that *Neotyphodium* is a symbiotic fungal endophyte that lives between the cells of its plant host, and that it is incapable of existing as a free-living organism. They also note *Neotyphodium* cannot be passed from plant to plant other than inter-generationally (via seeds) or via deliberate inoculation.

4.3. Therefore, the Committee considered that *Neotyphodium* could not establish a self-sustaining population, but that its plant host could establish such a population. However, given deliberate inoculation of *Neotyphodium* into a plant host is technically difficult, the Committee considered that only desirable *Neotyphodium*-plant host associations are likely to be pursued.

4.4. The Committee acknowledged Gerry Coates' query regarding what "*checks and balances will be taken if a negative aspect does arise*", and noted that the eradication of *Neotyphodium*, if required, would involve the eradication of the endophyte in association with the plant host. The Committee noted eradication could be easily achieved by: removing plant seeds from sale; heat treating seeds; prolonged seed storage (viability of endophyte decreases with seed storage); or spraying *Neotyphodium*-plants with herbicide.

5. Effects of any inseparable organism

5.1. No inseparable organisms associated with *Neotyphodium* were identified.

6. Assessment of adverse effects

6.1. The Committee considered the potential adverse effects of the organism, including any risks and costs associated with the release of the organism, on human health and safety, the environment, society and communities, Māori culture and traditions, the principles of the Treaty of Waitangi (Te Tiriti o Waitangi), and the market economy.

6.2. The Committee noted the potential adverse effects outlined in the application, EPA staff report and hearing, which included:

- Risk of morbid/lethal EFO reported to be concomitant with horses grazing plants containing NANL inducing endophytes after protracted periods of dry weather (4-6 weeks);
- The possibility of adverse effects on native insects; and
- The possibility of adverse effects from alkaloid compounds leaching into the soil.

6.3. The Committee acknowledged Christopher Bourke's concern regarding EFO, but noted that trials with the NANL inducing Mediterranean-Max P fescue combination in Mississippi have reported no confirmed cases of EFO; and western Texas and Oklahoma landowners are successfully using this

endophyte-fescue combination to raise cattle and sheep. Moreover, the Committee considered that with knowledge of EFO outbreaks occurring under specific environmental conditions, farmers and growers can take preventative measures to protect the health of their livestock from potential novel plant-endophyte toxicity.

6.4. The Committee considered that the introduction of *Neotyphodium* is very unlikely to have any adverse effects on native insects because novel *Neotyphodium*-host plant associations deter insect feeding rather than kill insects (unlike pesticide sprays). The latter assumption is based on the applicant's choice feeding trials performed using *Rhopalosiphum padi* (bird cherry oat aphid), *Aceria* mites and meadow fescue plants infected with the endophyte *Neotyphodium uncinatum*; and no choice feeding trials performed using *Epiphyas postvittana* (light brown apple moth) and *Elymus mutabilis* plants infected with endophyte strain AR3046.

6.5. The applicant explained that the *Neotyphodium* derived loline alkaloids responsible for deterring insect pests are produced and accumulate in all above ground parts of the host grass, and the root system. The Committee is satisfied that alkaloids leaching from decomposing plant debris will likely break down in the soil.

6.6. After assessing all the information, the Committee did not identify any adverse effects from the release of *Neotyphodium* on human health and safety, the environment, society and communities, Māori culture and traditions, the principles of the Treaty of Waitangi (Te Tiriti o Waitangi), and the market economy.

Effects on Māori and their culture and traditions and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

6.7. The Committee took into account the possible effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga, and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

6.8. After assessing all the information, the Committee did not identify any adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga, as it is highly unlikely that there will be any impacts on native flora or fauna.

6.9. Given the absence of identified effects to the outcomes of significance to iwi/Māori (as outlined in the Protocol '*Incorporating Māori perspectives in HSNO Act decision making*') the Committee considers the application to be broadly consistent with the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

Conclusion

6.10. After considering the information, the Committee did not identify any adverse effects, risks or costs from the release of *Neotyphodium*. The Committee therefore considers the risks to be **negligible**. Since the Committee did not identify any adverse effects, the Committee was not required to take into account the probability of occurrence or magnitude of any adverse effects.

6.11. In addition, the Committee noted that New Zealand has no international obligations relevant to the application.

7. Assessment of positive effects

7.1. The Committee considered the potential positive effects (including benefits) of the organism on human health and safety, the environment, society and community, relevant aspects of Māori culture and traditions, and the market economy.

7.2. Novel *Neotyphodium*-host plant associations may increase host plant resistance to insect pests and disease, which the Committee noted has potential flow on beneficial effects, including:

- Improved farm productivity, specifically due to reduced costs of applying synthetic chemicals (currently estimated at $22 million per year), and increased cereal crop yields; and
- Environmental and human health benefits may occur as a result of reduced agrichemical use.

7.3. Based on Australian pasture trials, David Hume (AgResearch Ltd.) explained that he expected a 20 – 50% reduction in pesticide use from the release of *Neotyphodium*.

7.4. Cliff Mason submitted that he considers the applicant's claim that the release of endophytes will reduce the use of chemical pesticides "*is a highly questionable claim"*. Conversely, NZPBRA and Te Rūnanga o Ngāi Tahu commented in their submission that "*genus Neotyphodium has already proven to be of significant economic benefit to New Zealand farmers through enhanced pasture productivity and animal performance*" and "*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*", respectively. Furthermore, DOC commented in their submission that the Department supported "*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*".

7.5. *Neotyphodium* may also provide host plants with protection against pest soil-borne nematodes - pests that either feed on plant roots directly or vector plant disease. Farmers currently have few viable tools for managing pest soil-borne nematodes.

7.6. Furthermore, *Neotyphodium* may provide improved drought tolerance to the host plant as endophytic plants have been shown to produce more biomass and increased plant height and tiller numbers under low water treatment.

7.7. The Foundation for Arable Research submitted that they held the applicant's *Neotyphodium* research team in extremely high regard and therefore considered that the positive effects stated by the applicant are likely to accrue.

7.8. After assessing all the information, the Committee considered a reduction in agrichemical use from *Neotyphodium* release is likely to be beneficial to the environment and human health. Accordingly, the Committee is satisfied that the benefits are **non-negligible**.

Conclusion

7.9. After considering the information, the Committee considered that there are benefits to be gained from the release of *Neotyphodium*. Accordingly, the Committee is satisfied that these benefits are likely to be achieved in the foreseeable future and will be **non-negligible**.

8. Achieving the purpose of the Act

8.1. The purpose of the Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms (section 4 of the Act).

8.2. The Committee took into account the following matters when considering the application to achieve the purpose of the Act:

- The sustainability of all native and valued introduced flora and fauna;
- The intrinsic value of ecosystems;
- Public health;
- The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga;
- The economic and related benefits and costs of using a particular hazardous substance or new organism;
- New Zealand's international obligations;
- The need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- The principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

8.3. The Committee is satisfied that this decision is consistent with the purpose of the Act and the above principles and matters. Any substantive issues arising from the legislative criteria and issues raised by submitters have been discussed in the preceding sections of this decision.

9. Evaluation and weighing of positive and adverse effects

9.1. The Committee took into account all the effects of *Neotyphodium*, and concluded that *Neotyphodium* poses negligible risks, and that the benefits are non-negligible. It is therefore evident that the positive effects of releasing *Neotyphodium* outweigh the adverse effects.

10. Recommendation

10.1. In response to public engagement advice raised by Te Rūnanga o Ngāi Tahu, the Committee recommends that the applicant explores ways to raise public awareness on feed and food products containing alkaloid producing endophytes.

11. Decision

11.1. After reviewing all of the information contained in the application, the Committee was satisfied that the application met the requirements of section 34 of the Act. In any event, in accordance with section 59(3)(a)(ii), the Committee waives any information requirement that has not been met as requested by the applicant in its application.

11.2. The Committee considered that the threshold for approval under section 38 of the Act had been met. The Committee concluded that the organisms meet the minimum standards set out in section 36 of the Act and that the positive effects of the organisms outweigh the adverse effects of the organisms, taking into account all of the following:

- All the effects of the organisms;
- The matters in section 37 of the Act;
- The relevant matters in Part 2 of the Act; and
- The Methodology.

11.3. The Committee decided to exercise its discretion and **approve** the release of 45 non-sporulating strains of *Neotyphodium* (as described in Table 1) under section 38(1)(a) of the Act. The Committee noted that in accordance with section 38(2) of the Act, the approval has been granted **without controls.**

11.4. The Committee noted that under section 38(3) of the Act, if the 45 strains of *Neotyphodium* (Table 1) have not been released within five years of the date of this decision, this approval for release will lapse. However, any person may apply before the expiry of the time limit for an extension of that time limit for a further period of up to five years.

11.5. The Committee has waived the requirement under section 38(4) of the Act, to notify the Authority of the release of the 45 strains of *Neotyphodium* (Table 1).

11.6. The Committee would like to thank all people who provided information that has been used in making this decision.

21 April 2014

Signed

Shaun Ogilvie **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date**

Amendment August 2014

- To assign the correct approval numbers to the new organisms approved for release

19 August 2014

Louise Malone **Chair, Decision Making Committee** **Environmental Protection Authority**	**Date**

Table 1: The organisms approved for release and corresponding approval codes

***Neotyphodium* strain reference number**	**Approval code**
AR3002	NOR100130
AR3005	NOR100086
AR3007	NOR100087
AR3013	NOR100088
AR3014	NOR100089
AR3015	NOR100090
AR3017	NOR100091
AR3019	NOR100092
AR3020	NOR100093
AR3023	NOR100094
AR3029	NOR100095
AR3035	NOR100096
AR3039	NOR100097
AR3042	NOR100098
AR3045	NOR100099
AR3046	NOR100100
AR3048	NOR100101
AR3049	NOR100102
AR3050	NOR100103
AR3051	NOR100104
AR3052	NOR100105

AR3053	NOR100106
AR3054	NOR100107
AR3055	NOR100108
AR3059	NOR100109
AR3061	NOR100110
AR3064	NOR100111
AR3065	NOR100112
AR3068	NOR100113
AR3070	NOR100114
AR3071	NOR100115
AR3073	NOR100116
AR3074	NOR100117
AR3075	NOR100118
AR3076	NOR100119
AR3078	NOR100120
AR3079	NOR100121
AR3080	NOR100122
AR3081	NOR100123
AR3082	NOR100124
AR3083	NOR100125
AR3084	NOR100126
AR3087	NOR100127
AR3088	NOR100128
AR3089	NOR100129