Risk Assessment Summary Conducted Pursuant to the *New Substances Notification Regulations (Organisms)* of the *Canadian Environmental Protection Act, 1999* NSN 16373: *Phlebiopsis gigantea* strain FTK 897A

This document explains the regulatory decision taken under Part 6 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and its *New Substances Notification Regulations (Organisms)* [NSNR(O)] regarding the import of *Phlebiopsis gigantea* strain FTK 897A by AEF Global Inc. for an experimental field study. *P. gigantea* strain FTK 897A was notified pursuant to subsection 3(5) of the NSNR(O).

Environment Canada and Health Canada have assessed information submitted by AEF Global Inc., as well as other available scientific information in order to determine if *P. gigantea* strain FTK 897A meets the criteria set out in section 64 of CEPA 1999[1].

Regulatory Decision

Based on the hazard and exposure considerations, the risk assessment conducted by Environment Canada and Health Canada concluded that *P. gigantea* strain FTK 897A does not cause harm to the Canadian environment or human health as described in section 64 of the CEPA 1999 when imported for introduction into an experimental field trial. Therefore, import of *P. gigantea* strain FTK 897A for this purpose may proceed after June 20, 2011.

This evaluation does not include an assessment of human health risk in the occupational environment.

NSNR(O) Schedule:	3 (for introduction into an experimental field trial).
Organism Identity:	*Phlebiopsis gigantea* strain FTK 897A
Notifier:	AEF Global Inc., 201, Mgr-Bourget Street, Lévis, Québec G6V 6Z3
Date of decision:	June 20, 2011
Proposed use:	Experimental field trial on efficacy of *Phlebiopsis gigantea* strain FTK 897A to reduce wetwood content of freshly-sawn lumber

IDENTITY / STRAIN HISTORY

P. gigantea is a well-characterized fungal species naturally found in stumps, fallen trunks and other remains of coniferous forest trees. Strain FTK 897A was isolated by a Canadian company from a jack pine log at a sawmill located in St. Lawrence River, Quebec in 1997 and was deposited as FTK 897A to Culture Collection of Wood-Inhabiting Fungi. In 2010, AEF Global Inc. obtained the fungus for testing and commercial production. The notifier intends to import *P.*

[1] In accordance with section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health.

gigantea strain FTK 897A in the commercial product WOODDRY in order to test its effectiveness in reducing the water content of freshly-sawn lumber.

The identification of *P. gigantea* FTK 897A was based on morphological characteristics and on the alignment of rDNA intergenic spacer region sequences with those of other *P. gigantea* environmental isolates.

HAZARD CONSIDERATIONS:

Environmental Hazard Characterization

P. gigantea is a naturally occurring saprophytic fungus that feeds on diseased or dead wooden parts of coniferous trees. *P. gigantea* is ubiquitous in the forest environment, at low concentrations that are at equilibrium with other fungal species. When concentrated and applied to trees, it is an effective bio-control agent against root rot caused by another fungus called *Heterobasidion annosum*. Several products containing various strains of *P. gigantea* have been approved and sold worldwide as biopesticides to control wood-rotting fungi. A closely related strain of *P. gigantea* has been used in Europe for 40 years as a bio-control agent, without any adverse effects, and an assessment of this strain by the State of Estonia concluded that there was little potential for adverse ecological effects (Anonymous, 2008).

P. gigantea has been categorized as a Biosafety Level 1 organism by the American Type Culture Collection (ATCC) and was not found in any databases of plant pathogens, and there are no reports in the published literature of disease associated with *P. gigantea* in wild mammals, birds, earthworms, bees or other arthropods, plants, aquatic invertebrates, fish, algae or aquatic plants.

Based on the above evidence, compiled from information provided by the notifier on the notified strain and surrogate strains and on in-house literature searches on the species, the potential for the notified organism to adversely affect the environment or its biological diversity is considered low.

Human Health Hazard Characterization

In spite of its ubiquity in nature, there have been no reported *P. gigantea* infections in humans. A thorough literature review has not identified any toxic metabolite which is produced either naturally or as a by-product by *P. gigantea* that could be a concern for human health.

P. gigantea has an optimal growth temperature range of 20-25°C which is well below human body temperature (37°C). *P. gigantea* ceases to grow at 30°C and dies at 40°C (Yang, 2007). *P. gigantea* is not capable of colonizing or invading humans or animals (Anonymous, 2008) and has even been considered as an edible fungus by Worgan (1968).

Two strains of *P. gigantea* are categorized as Biosafety Level 1 organisms by the ATCC. Based on the information provided by the notifier and on in-house literature review of scientific literature, *P. gigantea* is considered to be a low human health hazard.

EXPOSURE CONSIDERATIONS

Environmental and Human Exposure Characterization

Approximately 50-100 kg dried spores and mycelia containing 2 x 10^7 living spores per gram will be imported to AEF Global Inc. in Levis, Quebec, then transported to a 1 km^2 field trial site situated at a sawmill in Saint-Pamphile, Comté de l'Islet, Quebec.

The notifier provided detailed information on the protocols that will be used to formulate the product, to dip the lumber into a tank containing the formulated product, and on the methods to test for wood dampness, drying time, wood quality and wood yield.

Containment of the organism is achieved through controls applied to the dipping process and storage of the treated lumber, the use of high temperatures during the drying process, and the procedures for handling any residual material containing *P. gigantea* strain FTK 897A and accidental spills. These measures were deemed sufficient to confine the organism within the experimental field location. Furthermore, the product containing *P. gigantea* strain FTK 897A is rapidly absorbed into the lumber, making it unlikely that the organism will enter water or soil. The notified organism is unlikely to spread from treated lumber to the neighbouring environment because the formulated dipping suspension contains only asexual spores, which are incapable of long-distance migration (Vainio, 2008); treated wood will be covered and wrapped to contain any released spores during storage before kiln drying, and spores are expected to be killed during kiln drying; no sexual fruiting bodies or spores were detected on the treated, kiln-dried lumber in preliminary studies (Yang, 2010).

Fewer than fifty individuals will be directly exposed to the organism during the experimental study. Human exposure is further mitigated with the use of personal protective equipment, such as suitable protective clothing, rubber boots, rubber or plastic gloves (e.g., nitrile), and respiratory masks with dust filters. Unintended exposure of the general population to *P. gigantea* strain FTK 897A is limited by the nature of the experimental trial and by the containment procedures that are in place.

Given that safety and containment measures are in place to prevent or minimize its release into the environment, and given its limited potential for dispersal, the potential environmental and human exposure to *P. gigantea* strain FTK 897A is considered to be low.

RISK CHARACTERIZATION

P. gigantea strain FTK897A is well characterized, and has a history of safe use as a biocontrol agent. It is a saprophytic fungus and is not associated with disease in plants, animals or humans. Furthermore, the notified strain FTK 897A will be used at an experimental field under strictly controlled conditions where adequate measures are in place in case of accidental releases. Based on these hazard and exposure considerations, the risk assessment conducted by Environment Canada and Health Canada concluded that *P. gigantea* strain FTK 897A does not cause harm to the Canadian environment and human health and thus does not meet any of the criteria described in section 64 of CEPA 1999.

REFERENCES

Anonymous, (2008) Draft Assessment Report (DAR) Initial risk assessment provided by the rapporteur Member State Estonia for the existing active substance *Phlebiopsis gigantea* of the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC, Volume 1

Worgan, J.T. (1968) Culture of the higher fungi, in Progress in Industrial Microbiology. (Hockenhull, D.J.D., Ed.) J.&A. Churchill Ltd, London.

Vainio, E.J. (2008) Ecological impacts of *Phlebiopsis gigantea* against *Heterobasidion* spp. as revealed by fungal community profiling and population analyses. Academic dissertation, Dissertationes Forestales 63. Yang, D. (2010) Promoting Natural Biocontrol of Wetwood General Revenue Report Project NO. 201000571. Forintek Canada Corp.

Yang, D. (2007) Biological Method to Pre-dry Lumber with Wetwood. Forintek Canada Corp.

Yang, D. (2010) Promoting Natural Biocontrol of Wetwood General Revenue Report Project NO. 201000571. Forintek Canada Corp.