

**Risk Assessment Summary Conducted Pursuant to the
New Substances Notification Regulations (Organisms) of the
Canadian Environmental Protection Act, 1999
NSN 16243: *Rhynchosporium secalis***

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 manufacture of *Rhynchosporium secalis* by Agriculture and Agri-Food Canada (AAFC) for introduction into the AAFC Lacombe Research Centre where it was originally isolated. *R. secalis* was notified pursuant to subsection 3(6) of the NSNR(O).

Environment Canada and Health Canada have assessed the information submitted by Agriculture and Agri-Food Canada and other available scientific information in order to determine if *R. secalis* meets the criteria set out in section 64 of CEPA 1999¹.

Regulatory Decision

Based on the hazard and exposure considerations, the risk assessment conducted by Environment Canada and Health Canada concluded that *R. secalis* is not suspected to cause harm to the Canadian environment or human health as described in section 64 of the CEPA 1999 when manufactured at the site where isolated, for introduction into the same site. Therefore, the manufacture of *R. secalis* for introduction into the AAFC Lacombe Research Centre may proceed after December 18, 2010.

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

NSNR(O) Schedule: 4 (micro-organisms manufactured at the site from which they were isolated, for introduction into the same site).
Organism Identity: *Rhynchosporium secalis*
Notifier: Agriculture and Agri-Food Canada Lacombe Research Centre, 6000 C&E Trail, Lacombe, AB T4L 1W1
Date of decision: December 18, 2010
Proposed use: Barley disease-resistance screening research

IDENTITY / STRAIN HISTORY

R. secalis is a naturally occurring ubiquitous micro-organism. The notifier, Agriculture and Agri-Food Canada (AAFC), isolated this species from barley cultivars exhibiting scald lesions at the Lacombe Research Centre in Lacombe, Alberta.

¹In 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.

Identification of this organism was based on conidial morphology and disease symptomology on inoculated barley plants. Since all *R. secalis* isolates share the same morphological features, they are routinely distinguished from other pathogenic species through inoculation onto barley plants and confirming the infection with easily recognized distinctive lesions or scalds formed on the host plant. This is a standard approach to substantiating the identification of *R. secalis* in plant pathogen research because disease symptoms are distinctive for the pathogen on barley (Gilchrist-Saavedra et al., 2006). Isolates covered in this notification include any isolate collected from diseased leaf material from the scald nursery plots at the Lacombe Research Centre.

R. secalis has a history of use in agricultural field trials in many countries, including Canada. Tekauz (1991) provides evidence for use of *R. secalis* isolates in field trials at the AAFC Winnipeg Research Station from 1971-1991.

HAZARD CONSIDERATIONS:

Environmental Hazard Characterization

R. secalis is the causative agent of scald in barley and is considered to be an indigenous plant pathogen commonly found in many regions of Canada. It has the ability to infect and cause disease on cultivated barley, rye and triticale, as well as a range of wild grass species. A literature search did not reveal any reports of outbreaks in natural ecosystems, even though the disease is commonly present within barley fields in agricultural ecosystems. The notifier indicated that while scald has been observed in some grassy areas near the research field, no epidemic has been reported in adjacent commercial barley fields.

Because of their high genetic diversity, populations of *R. secalis* can quickly adapt to and overcome resistant crop cultivars, especially when crops are planted continuously without rotation (Zhan et al., 2008; Sharma et al., 2006; Xi et al., 2002; Tekauz, 1991; Mathre, 1982). However, given that plots are rotated yearly, selective pressure within the scald nursery site is expected to be minimal.

As well, since the Canadian Grain Commission's Official Grain Grading Guide does not identify *R. secalis* infection as a grading factor, it can be inferred that the organism is not known to affect grain quality for use in food and feeds through infections of the grain that would render it unpalatable or toxic. However, a literature search revealed that *R. secalis* secretes a small group of necrosis-inducing peptides that appear to be host specific phytotoxic with no reported effects on other plants or animals (Hahn, *et al.*, 1993; Wevelsiep *et al.*, 1993 and 1991).

Based on the above characteristics, the potential for the notified organism to cause adverse effects on the environment or its biological diversity is very limited since it appears to exclusively affect only a number of certain plant species.

Human Health Hazard Characterization

In spite of its ubiquity in nature, there have been no case reports of *R. secalis* infection in humans. A thorough review of the literature has not identified toxic metabolites that are either

naturally produced by *R. secalis* or as a consequence of any by-products resulting from plant infections that could be a concern for human health.

Based on information provided by the notifier and an in-house review of scientific literature, *R. secalis* is considered to be a low human health hazard.

EXPOSURE CONSIDERATIONS

Environmental and Human Exposure Characterization

Annually, approximately 10 L of a suspension of 10^5 *R. secalis* conidiospores per mL will be produced. The notifier intends to manufacture and use two to three different isolates per year for both laboratory studies and field trials.

Containment of the organism is achieved through sanitation of all field and laboratory equipment, consumables and left over spore suspension and by cultivation of soil, crop rotation, and spatial isolation from nearby commercial barley fields. These measures are in keeping with the Canadian Food Inspection Agency (CFIA) Basic Containment standard for facilities handling plant pests. Basic containment is applicable for work with plant pests posing low risk, as is the case for *R. secalis*.

Field inoculation via spraying on plants will occur yearly in June in the scald nursery plots (~1 ha) of the Lacombe Research Centre which is located at least 25 m away from the border of the Lacombe Research Centre and 1 to 4 km away from commercial barley fields. These isolation distances are sufficient to minimize spread from the nursery site given the limited dispersal abilities of this pathogen. The physical location of the field trials and the operational measures put in place adequately contain the potential dispersal of the micro-organism given that the principal source of primary infection is believed to be from infected host residue (Mathre, 1982) with secondary spread of the disease through dissemination of asexual conidia by rainsplash and wind during rainfall and irrigation events, usually less than 1-2 m away (Tekauz, 2003; Mathre, 1997; Shipton et al. 1974; Ayesu-Offei and Carter, 1971; Stedman, 1980; Fitt et al., 1986; Fitt et al., 1988).

It is expected that less than ten individuals would be directly exposed to the organism during isolation, culturing, inoculum production, inoculation and trial rating phases. Exposure will be limited by following the CFIA Basic Containment Standard for facilities handling plant pests, including use of a bio-containment laminar flow hood and aseptic techniques in the laboratory. During the inoculation phase, a maximum of four individuals will be directly involved in the application of inoculum to nursery plots. Exposure is further mitigated by the use of personal protective equipment including safety boots, rain slickers (jacket and pants), and nitrile or equivalent gloves. Unintended exposure to *R. secalis* of the general population is limited by the above-described containment procedures and the geographic location of the research facility.

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 for environmental and human exposure to *R. secalis* is considered to be low.

RISK CHARACTERIZATION

Based on the hazard and exposure considerations described above, the risk assessment conducted by Environment Canada and Health Canada concluded that *R. secalis* is not suspected to cause harm to the Canadian environment and human health as described in section 64 of CEPA 1999 when manufactured at the site where isolated for introduction into the same site.

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