microscopic examination of all major organs of the surviving mice revealed no treatment-related abnormalities. Body weight, body weight gain and organ weights (brain, liver, kidneys, and spleen) were comparable in the control and test groups. There was no evidence of toxicity. Accordingly, the LD_{50} value for MCRY3A–0102 in male and female mice is greater than 2,632 mg/kg body weight, and the LD_{50} value for pure mCry3A protein is greater than 2,377 mg/kg body weight, the single dose tested.

Extensive bioinformatics searches of public protein data bases revealed that the mCry3A protein shows no significant amino acid homology to proteins known to be mammalian toxins or known or suspected to be human allergens. Additional information and testing indicate that the mCry3A protein does not have properties that would suggest it has the potential to become a food allergen. The source of native Cry3A protein (*Bacillus thuringiensis*) is not known to produce food allergens. Unlike allergenic proteins, which typically are present at 1–80% of the total protein in an offending food, the average mCry3A concentration measured in raw grain derived from Event MIR604 corn represents less than 0.0001% of the total protein. This calculation is based on corn grain containing 10% total protein by weight, and assumes less than 1 ppm mCry3A in the grain. Additionally, due to degradation *via* food processing methods, mCry3A will not likely be present in processed food products, or will be present in only trace quantities. The mCry3A protein produced in transformed corn plants is not targeted to a cellular pathway for glycosylation, and shows no evidence of post-translational glycosylation. Bioactivity of mCry3A is lost upon heating at 95 °C for 30 minutes. Upon exposure to simulated mammalian gastric fluid containing pepsin, mCry3A rapidly degrades.

The native Cry3A protein has had a history of safe use as a component of spore preparations of the microbial insecticide *Bacillus thuringiensis* subsp. *tenebrionis*, as an encapsulated component of a microbial insecticide derived from *Bacillus thuringiensis* subsp. *san diego*, and as a plant-incorporated protectant in *Bacillus thuringiensis* potato.

The genetic material occurring in the subject plant-incorporated protectant active ingredient has been adequately characterized. This genetic material (*i.e.*, the nucleic acids DNA and RNA), including regulatory regions, necessary for the production of mCry3A in all corn will not present a dietary safety concern. ''Regulatory regions'' are the DNA sequences such as promoters, terminators, and enhancers that control the expression of the genetic material encoding the protein. Based on the ubiquitous occurrence and established safety of nucleic acids in the food supply, a tolerance exemption under the FFDCA regulations has been established for residues of nucleic acids that are part of plant-incorporated protectants in 40 CFR 174.475 (66 FR 37817 July 19, 2001) (FRL–6057–5). Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of mCry3A protein in all corn.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Average mCry3A levels measured in grain from Event MIR604-derived hybrid field corn plants were less than 1 ppm on a dry-weight or fresh-weight basis. Processed corn products or by-products used in food are unlikely to have measurable mCry3A protein, or will have only trace amounts. Oral exposure is not expected to result in adverse health effects, because of a demonstrated lack of toxicity to mammals and the rapid digestibility of the mCry3A protein. It is expected that any mCry3A protein consumed will be digested as conventional dietary protein.

ii. *Drinking water*. Little to no exposure *via* drinking water is anticipated. Due to the demonstrated mammalian safety profile of mCry3A, such exposure would not present a risk.

2. *Non-dietary exposure*. Non-dietary exposure is not anticipated, due to the proposed use pattern of the product. Exposure *via* dermal or inhalation routes is unlikely because the active ingredient is contained within plant cells. However, if exposure were to occur by non-dietary routes, no risk would be expected because the mCry3A protein is not toxic to mammals.

E. Cumulative Exposure

Because there is no indication of mammalian toxicity of the mCry3A protein or the genetic material necessary for its production, it is reasonable to conclude that there will be no cumulative effects for this active ingredient.

F. Safety Determination

1. *U.S. population*. The lack of mammalian toxicity at high levels of exposure to the mCry3A protein demonstrates the safety of the product at levels well above possible maximum exposure levels anticipated *via* consumption of all food commodities produced from corn plants that produce mCry3A. Moreover, little to no human dietary exposure to mCry3A protein is expected to occur via transformed corn. Due to the digestibility and lack of toxicity of the mCry3A protein, and its very low potential to become an allergen in food, dietary exposure is not anticipated to pose any harm for the U.S. population. No special safety provisions are applicable for consumption patterns or for any population sub-groups.

2. *Infants and children*. Based on the mammalian safety profile of the active ingredient and the proposed use pattern, there is ample evidence to conclude with a reasonable certainty that no harm will result to infants and children.

G. Effects on the Immune and Endocrine Systems

The active ingredient is derived from sources that are not known to exert an influence on the endocrine or immune systems.

H. Existing Tolerances

The registrant is not aware of any existing tolerances or tolerance exemptions for mCry3A protein and the genetic material necessary for its production as an active ingredient.

However, exemptions from tolerances exist for use of the native form of Cry3A protein as a plant-incorporated protectant in Bt potato (40 CFR 180.1147) and as a component of an encapsulated *Bacillus thuringiensis* microbial insecticide (40 CFR 180.1108).

I. International Tolerances

No Codex maximum residue levels exists for the plant-incorporated protectant modified Cry3A *Bacillus thuringiensis* protein and the genetic material necessary for its production in corn.

[FR Doc. 04–19719 Filed 8–30–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7807–9]

Receipt of an Application From the State of Ohio to Declare Its Waters of Lake Erie a No Discharge Zone for Vessel Sewage

AGENCY: Environmental Protection Agency (EPA).

ACTION: Receipt of a petition from the State of Ohio for determination as to the adequacy of facilities on Lake Erie for the disposal of vessel sewage.

SUMMARY: Notice is hereby given that a petition has been received from the State of Ohio for a determination by the Administrator of Region 5 that there is a reasonable availability of adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels on its waters of Lake Erie.

SUPPLEMENTARY INFORMATION: On June 23, 2004, the State of Ohio, Department of Natural Resources, submitted a petition requesting the EPA to declare the Ohio waters of Lake Erie a No Discharge Zone under section 312(f)(3) of the Clean Water Act (33 U.S.C. 1322(f)(3) and 40 CFR 140.4(a). Section 312(f)(3) states that ''After the effective date of the initial standards and regulations promulgated under this section, if any State determines that the protection and enhancement of the quality of some or all of the waters within such State require greater environmental protection, such State may completely prohibit the discharge from all vessels of any sewage, whether treated or not, into such waters, except that no prohibition shall apply until the Administrator determines that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for such waters to which the prohibition would apply.''

The petition states that there are 81,371 licensed watercraft in the counties bordering Lake Erie with 22% of the motorized boat users having either a portable or permanent toilet on board and that approximately 353 marinas are located with access to the lake. Of these, 121 marinas have pumpout and/or dump stations for vessel sewage. A listing of these facilities and their location has been submitted with the petition. In addition, there are over 700 shoreline public restrooms available at public boat launches, docks and parks. Also, there are nine ports with 35 commercial docking facilities with no pumpout stations. However, the petition states that these ports are serviced by private septage tanker trucks. Once the Regional Administrator determines that adequate facilities are available, the State of Ohio has the authority pursuant to section 312(f)(3) of the Clean Water Act and 40 CFR 140.4(a) to completely prohibit the discharge of sewage, whether treated or not, from all vessels into the waters of Lake Erie under its jurisdiction.

Comments and views regarding this petition, pending a determination by the Regional Administrator, may be filed within 30 days of publication of this notice. These should be addressed to Irvin J. Dzikowski P.E. at U.S. Environmental Protection Agency, Region 5 WN–16J, 77 West Jackson Blvd, Chicago, Illinois 60604.

Dated: August 23, 2004.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 04–19819 Filed 8–30–04; 8:45 am]

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FEDERAL MARITIME COMMISSION

[Docket No. 04 –10]

Agreement No. 201158; Docking and Lease Agreement by and Between City of Portland, Maine and Scotia Prince Cruises Limited; Order of Investigation and Hearing

Agreement No. 201158 is a ''docking and lease agreement'' between the city of Portland, Maine (''Portland''), a municipal corporation organized under the laws of Maine, and Scotia Prince Cruises Limited (''Scotia Prince''), a Bermuda corporation. Under the Agreement, effective this date, Scotia Prince leases certain docking and terminal facilities from Portland for purposes of operating a daily passenger and passenger vehicle service between Portland and Yarmouth, Nova Scotia.

Ordinarily, a docking and lease agreement would be classified as a ''marine terminal facilities agreement'' exempt by regulation from the filing and waiting period requirements of section 5 of the Shipping Act of 1984, as amended (''Shipping Act''), 46 U.S.C. app. § 1704. *See* 46 CFR § 535.311. Agreement No. 201158, however, contains exclusive use and non-compete provisions which cause it to be classified as a cooperative working agreement under section 4(b)(2) of the Act, 46 U.S. app. 1705(b)(2). Specifically, in sections 15 and 16 of the Agreement, Portland has agreed not to grant to any other operator permission to use its terminal premises for passenger or passenger vehicle service to or from Portland during Scotia Prince's scheduled season.[1] In return, Scotia Prince has agreed not to operate or participate in the operation of any competitive passenger or passenger vehicle service operating between any New England port and any port in Nova Scotia.

The effect of sections 15 and 16 of the agreement is to grant Scotia Prince a monopoly on passenger and passenger vehicle service between Portland, Maine and all ports in Nova Scotia, including Yarmouth. At the same time, Portland is protected from possible competition from Scotia Prince at nearby Portsmouth, NH, Bar Harbor, ME or any other New England port. Inclusion of these restrictive provisions in an otherwise routine agreement raises serious concerns under section 10(d) of the Shipping Act, 46 U.S,C. app. 1709(d). Section 10(d)provides, as pertinent:

(1) No common carrier, ocean transportation intermediary, or marine terminal operator may fail to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property.

(2) No marine terminal operator may agree with another marine terminal operator or with a common carrier to boycott, or unreasonably discriminate in the provision of terminal services to, any common carrier or ocean tramp.

(3) The prohibitions in subsections (b)(10) and (13)of this section apply to marine terminal operators.

(4) No marine terminal operator may give any undue or unreasonable preference or advantage or impose any undue or unreasonable prejudice or disadvantage with respect to any person.

The restrictions on competitive service at Portland may also contravene section 10(b)(10), made applicable to marine terminal operators by section 10(d)(3), which makes it unlawful to ''unreasonably refuse to deal or negotiate.''

Background

Scotia Prince's service to Portland is provided by the M/V Scotia Prince, a 485 foot cruise vessel which accommodates approximately 1200 passengers and 200 vehicles. The Scotia Prince, which was extensively renovated in 2003, offers passengers restaurant dining, a casino, a café and bars, live entertainment, duty free shopping, a skydeck, and a massage and beauty spa, among other amenities. Overnight berths for 1,054 are provided in 174 cabins and staterooms.

The Scotia Prince operates on a daily basis carrying passengers and passenger vehicles between Portland and Yarmouth in southern Nova Scotia. The vessel departs Portland each evening, sails overnight and arrives at Yarmouth the next morning, eleven hours later. After an hour in port to disembark and embark passengers and vehicles, the Scotia Prince sails for Portland, arriving in the early evening. Approximately 153,000 passengers were boarded in 2003.[2]

[1] Approximately May 1–October 31.

[2] Scotia Prince Cruises is separately regulated by the Commission as a passenger vessel operator under 46 CFR part 540.