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Canadian Food Inspection Agency
Plant Products Directorate
Plant Biosafety Office

Decision Document DD2003-43

Determination of the Safety of Monsanto Canada Inc.'s Insect Resistant Corn (Zea mays L.) Line MON 863

This Decision Document has been prepared to explain the regulatory decision reached under the guidelines Dir94-08 *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits* and its companion document Dir94-11 *The Biology of Zea mays L. (Corn/Maize)* and the guidelines Dir95-03 *Guidelines for the Assessment of Livestock Feed from Plants with Novel Traits.*

The Canadian Food Inspection Agency (CFIA), specifically the Plant Biosafety Office and the Feed Section of the CFIA, have evaluated information submitted by Monsanto Canada Inc. This information is in regard to the rootworm (*Diabrotica spp*.) resistant corn line MON 863. The CFIA has determined that this plant with a novel trait does not present altered environmental interactions, does not present concerns for the safety of livestock consuming feed derived from this plant with novel traits, when compared to currently commercialized corn varieties in Canada.

Unconfined release into the environment and livestock feed use of the MON 863 is authorized as of March 5, 2003. The authorization is limited to one year. Renewal of the one year authorization is conditional upon the submission of additional information as described in the present document. Any other corn lines and intraspecific hybrids resulting from the same transformation event and all their descendants may also be released and used for livestock feed within the one year conditional authorization, provided (i) no inter-specific crosses are performed, (ii) the intended use is similar, (iii) it is known following thorough characterization that these plants do not display any additional novel traits and are substantially equivalent to currently commercialized corn, in terms of their potential environmental impact and livestock feed safety and (iv) that insect resistance management requirements described in the present document are applied.

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I. Brief Identification of Plant with Novel Traits (PNT)

Designation(s) of the PNT:	MON 863, OECD identifier; MON-00863-5
Applicant:	Monsanto Canada Inc.
Plant Species:	Corn (*Zea mays* L.)
Novel Traits:	Resistance to Western and Northern Corn Rootworms. (*Diabrotica virgifera virgifera and Diabrotica barberi)*; Resistance to aminoglycoside antibiotics
Trait Introduction Method:	Microprojectile bombardment of plant cells.
Proposed Use of PNT:	Production of corn for human consumption (wet mill products, dry mill products and seed oil) and oil, meal, grain, silage and other by-products for livestock feed. These materials are not intended to be grown outside the normal production area for corn in Canada.

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II. Background Information

Monsanto Canada Inc. has developed a corn line resistant to corn rootworm (*Diabrotica spp*.), a periodic pest of corn in Canada. The corn line, designated as MON 863, was developed to provide a method to control yield losses from insect feeding damage caused by rootworm larvae.

MON 863 was developed using recombinant DNA technology, resulting in the introduction of bacterial genes conferring rootworm resistance and resistance to aminoglycoside antibiotics which was used as a selection tool in the development of MON 863.

Monsanto Canada Inc. has provided data on the identity of MON 863, a detailed description of the transformation method, data and information on the gene insertion site, gene copy number, and levels of gene expression in the plant, the role of the inserted genes and regulatory sequences, and the full nucleotide sequence of the Cry3Bb1 gene. Each novel protein was identified, characterized and

compared to the original bacterial protein, including an evaluation of its potential toxicity to livestock and non-target organisms.

These materials have been field tested in Canada from 2000 to 2002 and in Argentina, Japan, and the United States from1998 to 2002.

The CFIA has consulted with the Canadian Corn Pest Coalition on issues related to potential development of rootworm populations resistant to the insecticidal protein produced by the PNT, and the insect resistance management strategy that would significantly reduce and delay the development of rootworm resistance to the Cry3Bb1 protein. The Coalition is a group composed of representatives from academia, government, growers and industry.

Agronomic characteristics of corn hybrids derived from MON 863 such as seed dormancy, vegetative vigour, early stand establishment, time to maturity, flowering period, susceptibilities to various corn pests and pathogens, and seed production were compared to those of unmodified corn counterparts.

Nutritional components of MON 863, such as proximates, amino acids and fatty acids were compared with those of unmodified corn counterparts.

The Plant Biosafety Office, CFIA, has reviewed the above information, in light of the assessment criteria for determining environmental safety of plants with novel traits, as described in the regulatory directive Dir94-08. The following have been considered:

- potential of corn line MON 863 to become a weed of agriculture or invasive of natural habitats,
- potential for gene flow from corn line MON 863 to wild relatives whose hybrid progeny may become more weedy or more invasive,
- potential for corn line MON 863 to become a plant pest,
- potential impact of corn line MON 863 or their gene products on non-target species, including humans, and
- potential impact of corn line MON 863 on biodiversity.

The Feed Section of the Animal Health and Production Division, CFIA, has also reviewed the above information with respect to the assessment criteria for determining the safety and efficacy of livestock feed, as described in Dir95-03. The following have been considered:

- potential impact of MON863 on livestock health and
- potential impact of MON863 on livestock and workers/by-standers.

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III. Description of the Novel Traits

1. Development Method

Inbred corn line A634 was transformed with a vector carrying the *cry3Bb1* and the *nptII* genes. The plasmid vector was introduced by microprojectile bombardment into cultured corn cells. Transformants were selected based on resistance to aminoglycoside antibiotics. MON 863 was identified as a successfully transformed corn line and was chosen for further development.

2. Resistance to the Rootworm (*Diabrotica spp.*)

Bacillus thuringiensis var. *kumamotoensis* is a common gram-positive soil-borne bacterium. In the spore forming stage, it produces several insecticidal protein crystals, including the δ-endotoxin Cry3Bb1 protein

which is active against certain coleopteran insects, such as *Diabrotica spp*. This protein has been shown to be non-toxic to humans, other vertebrates and invertebrates. Foliar insecticides based on Cry endotoxins (generally known as B.t.) have been registered for over 30 years in Canada and have a long history of safe use.

A synthetic *cry3Bb1* gene was developed to maximize it's expression in corn, and was introduced into inbred line A634. The gene codes for a protein similar to the *B. thuringiensis* var. *kumamotoensis* insecticidal crystal protein. The protein expressed by *B. thuringiensis* var. *kumamotoensis* is insecticidal to coleopterans after cleavage in the insect's gut to a bio-active, trypsin resistant core. Insecticidal activity is believed to depend on the binding of the active fragment to specific receptors present in susceptible insects on midgut epithelial cells, forming pores which disrupt osmotic balance and eventually results in cell lysis and insect death.

The *cry3Bb1* gene expressed in corn line MON 863 is linked to a constitutive promoter. Samples of leaf, grain, whole plants, and root were collected from four representative US field trial sites, silk was collected from one US site, and pollen samples were collected from one US site and three sites in Argentina. Average protein expression in micro-grams protein per gram fresh weight tissue as evaluated by ELISA are as follows:

Summary of Cry3Bb1 protein levels measured in tissue collected from MON 863 from various geographic locations and stages of plant development

Tissue	Mean Cry3Bb1 (µmg/g fresh weight)
Young Leaf	81
Grain	70
Pollen	62
Root	41
Silk	10
Forage	39

The Cry3Bb1 protein was shown to degrade readily in the environment. In soil degradation experiments, Cry3Bb1 degradation was assessed by both insect bioassay (insecticidal activity against the target pest and ELISA (presence of immunoreactive protein). Data from insect bioassay and ELISA resulted in mean DT_{50} (average time to degrade 50% of the initial soil concentration of Cry3Bb1 protein) estimates of 2.37 and 2.76 days respectively and DT_{90} (time for 90 % of the Cry3Bb1 protein to degrade) estimates of 7.86 and 9.16 days, respectively.

Protein allergens are normally resistant to digestion and heat processing, unlike the Cry3Bb1 protein which was shown to degrade readily in simulated gastric fluid within 15 seconds, to a faint ~3 kDa band which was digested to below the limits of detection within 15 minutes. As expected, when exposed to simulated intestinal fluid, the Cry3Bb1 protein was digested to the trypsin resistant 57 kDa core within 5 minutes, but was not further digested. The Cry3Bb1 protein was degraded by heat treatment (204 °C for 30 minutes to simulate a heat step in food processing). Unlike many known allergens, the insecticidal protein is not glycosylated, and is present at low levels (≤0.1% total protein) in the tissue of MON 863 corn. A search for amino acid sequence similarity between the Cry3Bb1 protein and known allergens, using a database assembled from the public domain databases GenBank, EMBL, Pir and SwissProt, revealed no significant amino acid sequence homologies (based on sequence identity of 8 or more contiguous amino acids).

The full nucleotide sequence of Cry3Bb1 and the corresponding amino acid sequence were provided. A search of a database assembled from the public domain databases GenBank, EMBL, Pir, NRL3D and SwissProt of known toxins indicated no amino acid sequence homologies between known toxins and the Cry3Bb1 protein, with the exception of homologies to other B.t. insecticidal delta-endotoxins.

The inserted, plant expressed *cry3Bb1* gene codes for a 74 kDa protein that is enzymatically converted *in vivo* to 59 and 66 kDa peptides. To obtain sufficient quantities of Cry3Bb1 protein for evaluation of environmental and feed safety it was necessary to express the *cry3Bb1* gene in an *E. coli* production system. The plant produced protein was compared to the bacterial produced protein and shown to be of similar molecular weight and immunological reactivity as the plant produced protein. It was demonstrated that the protein showed similar bioactivity. Matrix assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) and N-terminal sequencing was used to determine the sequence equivalency of the plant and bacterial produced proteins.

Monsanto has provided the CFIA with a method for the detection and identification of corn containing the Cry3Bb1 protein.

3. Resistance to aminoglycoside antibiotics

Aminoglycoside antibiotics bind to bacterial ribosomes, disrupting normal protein synthesis and killing the bacterial cell. The neomycin phosphotransferase II (*nptII*) gene produces an enzyme that phosphorylates aminoglycoside antibiotics, preventing them from binding to ribosomes and thereby rendering the cells resistant. Thus the NPTII protein confers positive selection of genetically transformed plant cells on media containing aminoglycoside antibiotics.

The gene is linked to a constitutive promoter. Average NPTII protein expression from MON863 corn in four different locations in the US was 0.98 µg/g fresh weight (fr. wt.) in leaf tissue, and 0.19 µg/g fr.wt. in forage. NPTII protein levels in grain were below the limit of detection (< 0.076 ug/g fr.wt.)

The *nptII* gene originated from the *E. coli* transposon Tn5. The plant and bacterial produced protein were compared and shown to be of similar molecular weight and immunological reactivity. This protein is produced by many organisms and is therefore ubiquitous in the environment. Previous assessments have shown that NPTII degrades rapidly *in vitro* in simulated mammalian gastric and intestinal fluids and that the NTPII amino acid sequence shows no significant sequence similarity with known protein toxins, allergens or proteins that may result in adverse human or animal health effects.

Due to the use of a unique restriction site for the excision of *nptII* coding sequence from Tn5, the gene cassette also contains a second open reading frame. This open reading frame is composed of a 153 bp portion of the 378 bp bleomycin binding protein gene (*ble*) joined through a 12 bp polylinker to 102 bp derived from the polyadenylation signal. Transcripts encoding the NPTII protein are expected to contain this second open reading frame downstream of the NPTII coding region. The *ble* transcripts are not expected to be translated, and do not display the proper position or context for translation in a eukaryotic organism. Immunoblot analysis did not detect a Ble fusion protein. If a putative fragment of the bleomycin binding protein were to be produced at a level below the limit of detection, the putative product would lack the necessary topology to form the native homodimeric structure and would not yield a structure that could bind bleomycin. The predicted amino acid sequence of the Ble fusion protein was compared to protein sequences in an Allergen, Toxin and Allpeptides database using the FASTA algorithm and to an Allergen database using the IDENTITYSEARCH algorithm. No significant sequence similarity or identity with known protein allergens, toxins or proteins that may result in adverse human or animal health effects were identified.

4. Stable Integration into the Plant's Genome

Southern blot analysis from three generations derived from MON 863 indicated that there is one site of integration of the introduced DNA which includes a single copy of both of the inserted genetic elements.

The backcross data is consistent with that of a single site of insertion that segregates in a Mendelian hereditary fashion. The stability of the insert has been demonstrated through three generations of cross-fertilization.

Southern blot analysis and determination of frequency of insect protected corn in progeny, based on ELISA determination of presence of Cry3Bb1, demonstrated that the traits were inherited in a stable

manner.

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IV. Criteria for the Environmental Assessment

1. Potential of the PNT to Become a Weed of Agriculture or be Invasive of Natural Habitats

The biology of corn, described in the CFIA Biology Document Dir94-11, shows that unmodified plants of this species are not invasive of unmanaged habitats in Canada. Corn does not possess the potential to become weedy due to traits such as lack of seed dormancy, the non-shattering nature of corn cobs, and the poor competitive ability of seedlings. According to the information provided by Monsanto Canada Inc., MON 863 and derived corn hybrids were determined to be similar to their counterparts in this respect.

CFIA evaluated data submitted by Monsanto Canada Inc. on the reproductive and survival biology of corn hybrids derived from MON 863, and determined that flowering period, vegetative vigor, time to maturity and seed production were within the normal range of expression of these traits currently displayed by commercial corn hybrids.

No competitive advantage was conferred to these plants, other than that conferred by resistance to rootworm. These traits were demonstrated not to render corn weedy or invasive of natural habitats since none of the reproductive or growth characteristics were modified.

The above considerations, together with the fact that the novel traits have no demonstrable effects on weediness or invasiveness, led the CFIA to conclude that MON 863 has no altered weed or invasiveness potential compared to currently commercialized corn.

2. Potential for Gene Flow to Wild Relatives Whose Hybrid Offspring May Become More Weedy or More Invasive

The biology of corn, as described in Dir94-11, indicates that there are no wild relatives in Canada that can hybridize with corn. None of data submitted by Monsanto Canada Inc. on the physiological characteristics of MON 863 indicated any changes in sexual compatibility as a result of the gene insertions.

CFIA therefore concludes that gene flow from MON 863 to wild corn relatives is not possible in Canada.

3. Altered Plant Pest Potential

The intended effects of both novel traits are unrelated to plant pest potential, and corn is not a plant pest in Canada (Dir94-11). In addition, agronomic characteristics of the modified corn hybrids were shown to be within the range of values displayed by currently commercialized corn hybrids, and indicate that the growing habit of corn was not inadvertently altered. Field observations did not indicate modifications of disease and pest susceptibilities, other than to rootworm, which is not known to be a principal factor restricting the establishment or distribution of corn in Canada.

Some of the genetic elements introduced into MON 863 were derived from known plant pathogens, but in all cases the genes responsible for the pathogenic qualities of the pathogen were not introduced. Therefore, the introduction of genetic material for *Diabotica spp.* resistance would not be expected to result in MON 863 expressing novel pathogenic characteristics.

CFIA has therefore determined that MON 863 does not display any altered pest potential.

4. Potential Impact on Non-Target Organisms

The history of use and literature suggest that the bacterial B.t. *-endotoxins are not toxic to humans, other vertebrates, and non-coleopteran invertebrates and the B.t. protein produced in corn was shown to be equivalent to the original microbial protein. This protein is active only against specific coleopteran insects. There are no coleopteran species currently listed by the Committee on the Status of Endangered Wildlife in Canada as being a threatened or endangered species. (Please refer to http://www.cosewic.gc.ca/index.htm for more information)

Monsanto Canada Inc. has submitted data from dietary toxicity studies on the effect of the *Bacillus* bacterial B.t. protein on non-target invertebrates, including honeybees, ladybird beetles, daphnia, collembola and earthworms. Data was also submitted on the non-target vertebrates catfish and quail. In all cases, MON 863 was demonstrated to be safe to these indicator species.

Monsanto Canada Inc. submitted field based observational studies on the stability and abundance of non-target organism communities (arthropods, earthworms and soil microbes) where MON 863 is grown. The species studied were representatives of several Coleoptera families, including Carabidae, Staphylinidae and Coccinellidae. The studies demonstrated that MON 863 does not have a negative impact on the abundance of these non-target organisms relative to the control (non-Bt) hybrid.

The CFIA also considered whether or not it is likely that fireflies (family Lampyridae) would be exposed to the Cry3Bb1 toxin from MON 863 because fireflies are coleopterans, and may be susceptible to the toxic effects of Cry3Bb1 if they were exposed. Larvae and adults of these insects typically occur on or above the soil surface, with larvae generally feeding on rotting wood. Therefore, fireflies would rarely be found in corn fields and exposure to Cry3Bb1 protein from MON 863 would be very unlikely.

In addition, Monsanto Canada Inc.submitted a study on the potential toxicity of Cry3Bb1 protein to green lacewing larvae (Neuroptera: Chrysopidae). The data submitted by Monsanto Canada Inc. did not demonstrate any adverse effects of MON 863 on this species; however the study protocol was not of an optimal design. The CFIA has requested that Monsanto Canada Inc. submit a new beneficial insect study within one year of the authorization of this corn line. Authorization beyond one year is contingent on a satisfactory submission of this information

Unmodified corn is known to produce low levels of trypsin inhibitor and phytic acid and the levels of these compounds in MON 863 were demonstrated to be equivalent to levels found in the control lines. Therefore the genetic modification did not alter the expression of endogenous anti-nutritional factors.

Based on the above, CFIA has determined that the unconfined release of MON 863 will not result in altered impacts when compared with currently commercialized corn on interacting organisms, including humans, with the exception of specific coleopteran insect pest species.

5. Potential Impact on Biodiversity

MON 863 has no novel phenotypic characteristics which would extend its use beyond the current geographic range of corn production in Canada. Since corn does not out cross to wild relatives in Canada, there will be no transfer of novel traits to unmanaged environments.

MON 863 provides an alternative method to existing methods of control of rootworms, an important agricultural pest of corn in Canada. The control of agricultural pest species is a common practice in Canada that is not restricted to the environmental release of PNTs. Therefore, the reduction in local pest species as a result of the release of MON 863 does not present a significant change from existing agricultural practices. At present, the use of chemical insecticides to control rootworm is permitted in Canada. Currently, crop rotation represents the principal method of rootworm control.

CFIA has therefore concluded that the potential impact on biodiversity of MON 863 is equivalent to its unmodified counterparts.

6. Potential for Development of Rootworm Resistance to MON 863

The Plant Biosafety Office requires the implementation of an insect resistance management (IRM) plan when plants expressing novel insect resistance are grown in fields greater than one hectare in size. IRM is intended to significantly reduce or delay the development of insect resistance to plants expressing novel insect resistance traits. Monsanto Canada Inc. has developed an IRM plan for MON 863 that has been reviewed by the CFIA and the Canadian Corn Pest Coalition. The plan was determined to be acceptable for the initial one year period of the conditional authorization.

Research related to the proposed IRM plan is ongoing, and as research progresses, the new information will be used to determine if the present IRM plan should be maintained in its present form, or if it will be modified. Therefore, the renewal of the present one year authorization will be contingent upon Monsanto Canada Inc. demonstrating significant progress in research related to insect resistance management. The elements of the present IRM plan are described below.

CFIA believes that sound management practices can reduce and delay the development of resistant rootworm populations, and that rootworm populations must be monitored for the development of resistance in a regular and consistent manner. Monsanto Canada Inc. has developed, and will implement an insect resistance management plant that includes the following key components:

i. The use of structured, in-field refugia to provide a population of insects that have not been exposed to the Cry3Bb protein and are available to reproduce with potentially resistant insects which may emerge from the Bt crop. The refuge shall be arranged within, or adjacent to, the Bt crop and consist of a minimum of 20 per cent non-Bt corn. The refuge and Bt corn planting areas will both have the same crop rotation histories. The refuge may be treated with a soil insecticide for larval rootworm control if economic thresholds prescribe it; however, insecticides must not be used for adult control.
ii. The early detection of rootworm populations resistant to the corn-expressed insecticidal protein is extremely important. Close monitoring for the presence of such populations, in rootworm-resistant corn fields and surrounding areas, is therefore warranted. Monitoring includes the development of appropriate detection tools such as visual field observations and laboratory bioassays, education of growers, reporting schedules, and enforcement procedures in case of resistance development.
iii. Education tools will be developed and provided to all growers, district managers and field managers. These will include information on product performance, resistance management, monitoring procedures and timetables, detection protocols for resistant rootworm individuals, instructions to contact Monsanto Canada Inc. and strategies to be followed if unexpected levels of rootworm damage occur.
iv. Monsanto Canada Inc. will have documented procedures in place for responding to these reported instances of unexpected rootworm damage. These procedures will include, where warranted, the collection of plant tissue and rootworms and use of appropriate bioassays to evaluate suspected Cry3Bb resistant individuals, and a protocol for immediate action to control resistant individuals.
v. Detection of confirmed resistant rootworm populations and mitigation measures will be immediately reported to CFIA.
vi. Integrated Pest Management practices will be promoted, such as prediction of infestation problems from field histories.

Note: The Plant Biosafety Office periodically audits compliance with the IRM requirements.

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V. Criteria for the Livestock Feed Assessment

1. Potential Impact on Livestock Nutrition

Nutritional Composition of MON 863

Comparisons of protein, fat, acid digestible fibre (ADF) neutral digestible fibre (NDF), amino acids, minerals, and fatty acids in corn grain, and protein, fat, fibre (ADF, NDF) in forage from the PNT line and a sister line that does not express Cry3Bb1 (MON846) were made. Controlled trials of MON 863 vs MON846 in four locations in the US were conducted. There were no differences between the lines for protein, fat, or fibre in either the grain or the forage. In the grain there were some significant differences between the PNT and the control in some amino acids and minerals, but there was no consistent pattern of differences from the control for any nutrient, and the concentrations of these nutrients in both lines were within the published range for corn grain.

The observed variations in nutritional composition were judged to arise from normal variability rather than as a result of the inserted novel traits. CFIA has determined that line MON 863 is substantially equivalent to traditional corn varieties.

Anti-Nutritional Factors

Corn is not known for the production of significant levels of anti-nutritional factors and the transformation event which produced MON 863 would not be expected to induce their synthesis. Nevertheless, grain phytic acid content was monitored and was shown to be slightly lower in MON 863 than the parental line.

2. Potential Impacts on Livestock and Workers/By-standers

Corn is not known for the production of endogenous allergens and the transformation event which produced MON 863 would not be expected to induce their synthesis.

The history of use and literature suggest that the bacterial B.t. δ-endotoxin is not toxic to humans and other vertebrates. The B.t. protein produced in corn was shown to be equivalent to the original microbial protein. No receptors for the Cry3Bb1 delta-endotoxin are present on the surface of mammalian intestinal cells, therefore livestock and workers/by-standers are not expected to be susceptible to these proteins.

A mouse acute oral toxicity test and a bobwhite quail and catfish dietary toxicity study using Cry3Bb1 were conducted and no adverse effects on growth or survival were observed.

Based on the predicted exposure levels and the results of the above tests, no significant risk to livestock and workers/by-standers is expected from exposure to the Cry3Bb1 proteins.

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VI. New Information Requirements

If at any time, Monsanto Canada Inc. becomes aware of any information regarding risk to the environment, including the development of rootworm resistance or risk to plant, animal or human health that could result from release of these materials in Canada, or elsewhere, Monsanto Canada Inc. must immediately provide such information to the CFIA. On the basis of such new information, the CFIA will re-evaluate the potential impact of the proposed feed use and environmental release and will re-evaluate its decision with respect to the livestock feed use and environmental release authorizations of this corn line.

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VII. Regulatory Decision

Based on the review of data and information submitted by Monsanto Canada Inc., and through comparisons of corn hybrids derived from MON 863 both with unmodified corn counterparts and the sister line MON 864, the Plant Biosafety Office, CFIA, has concluded that the novel genes and their corresponding traits do not confer to these plants any characteristic that would result in intended or unintended environmental effects following unconfined release. Monsanto Canada Inc. has developed and will implement a resistance management plan.

Based on the review of submitted data and information by Monsanto, including comparisons of corn MON 863 with unmodified corn counterparts, and the sister line MON 864, the Feed Section, CFIA, has concluded that the modified gene and its corresponding novel trait will not confer to these plants any characteristic that would raise any concerns regarding the safety or nutritional composition of MON 863. Grain corn, its byproducts and corn oil are currently listed in Schedule IV of the *Feeds Regulations* and are therefore approved for use in livestock feeds in Canada. MON 863 has been assessed and found to be as safe as and as nutritious as traditional corn varieties. MON 863 and its products are considered to meet present ingredient definitions and are approved for use as livestock feed ingredients in Canada.

Unconfined release into the environment and livestock feed use of the corn MON 863 is therefore authorized as of March 5, 2003. The authorization is limited to one year. Renewal of the one year authorization is conditional upon the submission of additional information as described in the present document. Any other corn lines and intraspecific hybrids resulting from the same transformation event, and all of their descendants, are also approved, provided no inter-specific crosses are performed, provided the intended use is similar, provided it is known following thorough characterization that these plants do not display any additional novel traits and are substantially equivalent to currently grown corn, in terms of their potential environmental impact and livestock feed safety and provided that pest resistance management requirements described in the present document are applied.

MON 863 is subject to the same phytosanitary import requirements as its unmodified counterparts

Please refer to Health Canada's Decisions on Novel Foods for a description of the food safety assessment of MON 863. The food safety decisions are available at the following Health Canada web site: http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_novel_foods_and_ingredient.html

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