Government of Canada
Canadian Food Inspection Agency
Plant Products Division

Gouvernement du Canada
Agence Canadienne d'inspection des aliments
Division des produits végétaux

Decision Document DD2002-41

Determination of the Safety of Dow AgroSciences Canada Inc. and Pioneer Hi-Bred International's Insect Resistant and Glufosinate - Ammonium Tolerant Corn (*Zea mays* L.) Line 1507

This Decision Document has been prepared to explain the regulatory decision reached under the regulatory directive 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 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, have evaluated information submitted jointly by Dow AgroSciences Canada Inc. and Pioneer Hi-Bred International. This information is in regard to the insect resistant and glufosinate ammonium tolerant corn line 1507. The CFIA has determined that this plant with novel traits does not present a significant risk to the environment, 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 corn line 1507 is therefore authorized as of October 9, 2002. 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, 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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Plant Biosafety Office
Plant Health and Production Division
Plant Products Directorate
59 Camelot Drive, Nepean
Ontario K1A 0Y9
(613) 225-2342

Feed Section
Animal Health and Production Division
Animal Products Directorate
59 Camelot Drive, Nepean
Ontario K1A 0Y9
(613) 225-2342

Table of Contents

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

Designation(s) of the PNT:	Line 1507, OECD identifier DAS-01507-01
Applicant:	Dow AgroSciences Canada Inc. and Pioneer Hi-Bred International
Plant Species:	Corn (*Zea mays* L.)
Novel Traits:	Resistance to lepidopteran pests of corn, including European Corn Borer (*Ostrinia nubilalis.*), corn earworm (*Helicoverpa zea*), fall army worm (*Spodopera frugiperda*) and black cutworm (*Agrotis ipsilon*). Tolerance to glufosinate-ammonium herbicide.
Trait Introduction Method:	Microprojectile bombardment of plant cells.
Proposed Use of PNT's:	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.

II. Background Information

Dow AgroSciences and Pioneer Hi-Bred jointly developed a corn line resistant to certain lepidopteran pests and tolerant to the glufosinate-ammonium herbicide. The corn line, designated as line 1507, was developed to provide a method to control yield losses from insect feeding damage caused by certain lepidopteran pests, and to provide an alternative strategy for weed control.

Line 1507 was developed using recombinant DNA technology, resulting in the introduction of bacterial genes conferring lepidopteran resistance and tolerance to glufosinate-ammonium herbicide.

Dow AgroSciences and Pioneer Hi-Bred have jointly provided data on the identity of line 1507, 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 amino acid sequences of the novel proteins. Each novel protein was identified, the mode of action described, characterized and compared to the original donor bacterial proteins. An evaluation of their potential toxicity to livestock and non-target organisms and potential allergenicity to

humans and to livestock was provided. Relevant scientific publications were also supplied.

Corn line 1507 has been field tested in Canada under confined research field trial conditions from 1999 to 2002. Data generated from field trials in the United States, Chile and Europe was also used to support the application.

Agronomic characteristics of corn hybrids derived from corn line 1507 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.These comparisons contributed to the safety assessment.

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:

- potential of corn line 1507 to become a weed of agriculture or be invasive of natural habitats,
- potential for gene flow from corn line 1507 to wild relatives whose hybrid offspring may become more weedy or more invasive,
- potential for corn line 1507 to become a plant pest,
- potential impact of corn line 1507 or it's gene products on non-target species, including humans, and
- potential impact of corn line 1507 on biodiversity.

The Feed Section, 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 corn line 1507 on livestock nutrition and,
- potential impact of corn line 1507 on livestock

III. Description of the Novel Traits

1. Development Method

Corn hybrid Hi-II hybrid (A188 x B73) was transformed with a vector carrying the synthetic *cry1F* and *pat* genes. The plasmid vector was introduced by microprojectile bombardment into corn embryo tissue. Transformants were selected based on tolerance to the herbicide glufosinate-ammonium in the culture medium. Line 1507 was identified as a successful transformant and was chosen for further development.

2. Resistance to Lepidoperan pests of Corn

Bacillus thuringiensis var. *aizawai* is a common gram-positive soil-borne bacterium. In its spore forming stage, it produces several insecticidal protein crystals, including the δ-endotoxin Cry1F protein that is active against certain Lepidopteran insect pests, such as European Corn Borer. This protein has been shown to be non-toxic to humans, other vertebrates and non-lepidopteran 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 *cry1F* gene was developed to maximize it's expression in corn, and introduced into the Hi-II hybrid. The gene codes for a protein with a high degree of similarity to the *B. thuringiensis* var. *aizawai* insecticidal crystal protein. The protein expressed by *B. thuringiensis* var. *aizawai* is insecticidal to some lepidopteran species 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 *cry1F* gene expressed in corn line 1507 is linked to a constitutive promoter, (ie. results in expression in all corn tissues). Cry1F protein expression was determined from plants grown in Canada, USA, Europe and Chile. The levels of Cry1F protein detected in corn grown in these locations shows a range of values. Differences in protein expression is expected due to differences in the climate and environment at these locations. Values ranged from 61 to 348 picograms of Cry1F protein per micro gram of plant protein in leaf, 126 to 190.5 picograms of Cry1F protein per micro gram of plant protein in pollen, 37 to 133 picograms of Cry1F protein per micro gram of plant protein in silk, 550 to 1450 picograms of Cry1F protein per micro gram of plant protein in stalk and 89.8 to 116 picograms of Cry1F protein per micro gram of plant protein in grain. The Cry1F protein was shown to degrade readily in the environment. In soil degradation experiments, Cry1F was found to have a mean DT_{50} value (time to degrade to 50% of the original insecticidal properties) of 3.13 days.

Protein allergens are normally resistant to digestion and heat processing unlike the Cry1F protein which was shown to degrade readily in simulated gastric fluid (digested within 1 minute at a molar ratio of 1:100 Cry1F:pepsin), and be deactivated after exposure to 75 ^{0}C for 30 minutes.

The full nucleotide sequence of *cry1F* and corresponding amino acid sequence of Cry1F were provided. A search for amino acid sequence similarity between the Cry1F protein and known allergens which included food allergens, as well as non-food and wheat gluten allergens, using a database assembled from the public domain databases GenBank, EMBL, Pir-Protein and SwissProt, revealed no significant amino acid sequence homologies (based on sequence identity of 8 or more contiguous amino

acids). A search of a similarly constructed database of known toxins indicated no amino acid sequence homologies between known toxins and the Cry1F protein, with the exception of homologies to other B.t. insecticidal delta-endotoxins. Additionally, the insecticidal protein was demonstrated not to be glycosylated, as many known allergens are, providing additional evidence that Cry1F does not have the properties of known allergens.

The inserted, plant expressed *cry1F* gene codes for a 68 kDa protein which was compared to the bacterial produced protein and shown to be of similar molecular weight and immunological reactivity. Matrix assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) was used to determine the sequence equivalency of the two proteins. The protein showed similar bioactivity and host range specificity to the native protein.

Dow AgroSciences and Pioneer Hi-Bred have provided to the CFIA a method for detection and identification of corn specifically containing the Cry1F protein.

3. Glufosinate-Ammonium Herbicide Tolerance

Phosphinothricin, the active ingredient of glufosinate-ammonium herbicide, inhibits the plant enzyme glutamine synthetase, resulting in the accumulation of lethal levels of ammonia in susceptible plants within hours of application. Ammonia is produced by plants as a result of normal metabolic processes.

The glufosinate-ammonium tolerance gene engineered into corn line 1507 codes for the enzyme phosphinothricin acetyltransferase (PAT). This enzyme detoxifies phosphinothricin by acetylation into an inactive compound. PAT has extremely high substrate specificity and data included in the submission indicates that it does not acetylate other enzymes or proteins.

The *pat* gene was originally isolated from *Streptomyces viridochromogenes*, an aerobic soil actinomycete bacterium. The PAT enzyme is therefore naturally occurring in the soil. More generally, acetyltransferase enzymes are ubiquitous in nature.

The *pat* gene is linked to a constitutive promoter. The expression of the *pat* gene in hybrid line 1507 was evaluated in leaf, pollen, silk, stalk and grain. For all tissue samples taken in Canada, Chile and the US, the levels of PAT protein were below the limit of detection. The LOD is 7.5 pg/µg total protein for samples tested from Canada, and 20 pg/µg total protein for samples from the other locations. The PAT levels in Europe were all below the LOD except for in leaf which had a mean PAT expression level of 42 pg/µg total protein (LOD is 20 pg/µg total protein).

Studies showed that the enzyme was digested within 5 seconds when subjected to typical mammalian stomach conditions.

The enzyme amino acid sequences for the PAT protein was provided in the submission. The amino acid sequence showed no significant homology to toxins in the Genbank database or allergens (based on sequence identity of 8 or more contiguous amino acids) from standard DNA and protein sequence databases.

The *pat* gene was expressed experimentally in a bacterial expression system and the resulting enzyme was used to evaluate it's enzyme kinetics, to perform toxicology studies and as a standard in the determination of protein expression from the modified plant. The inserted plant expressed *pat* gene codes for a 22 kDa protein which was compared to the bacterial produced protein and shown to be of similar molecular weight and immunological reactivity. Peptide mass fingerprinting by matrix assisted laser desorption ionization time-of-flight mass spectrometry (MALDI-TOF MS) was used to determine the sequence equivalency of the two proteins.

4. Stable Integration into the Plant's Genome

Southern blot analysis of different generations derived from line 1507 indicated that there is one site of integration of the introduced DNA which includes a single copy of both of the inserted genetic elements in addition to a short, non-coding fragment of the *cry1F* element.

The backcross data is consistent with that of a single locus behaving in a Mendelian hereditary fashion. Mendelian segregation data provides evidence of the stable inheritance of the genetic elements introduced into corn line 1507. Segregation analysis was performed on two stages in the breeding process, designated as the F1 generation and the BC2F1 generation. Southern blot analysis and determination of frequency of glufosinate-ammonium herbicide tolerance and ECB resistance in progeny demonstrated that the traits were inherited in a stable manner.

IV. Criteria for the Environmental Assessment

1. Potential of Corn Line 1507 to Become a Weed of Agriculture or be Invasive of Natural Habitats

The biology of corn, described in 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 poor competitive ability of seedlings. According to the information provided by Dow AgroSciences and Pioneer Hi-Bred, corn line 1507 and derived hybrids were determined not to be significantly different from their counterparts in this respect.

CFIA evaluated data submitted by Dow AgroSciences and Pioneer Hi-Bred on the reproductive and survival biology of corn hybrids derived from line 1507, and

determined that flowering period, vegetative vigour, 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 the target pests and tolerance to glufosinate-ammonium herbicide. 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 corn line 1507 has no altered weed or invasiveness potential compared to currently commercialized corn.

2. Potential for Gene Flow from line 1507 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 Dow AgroSciences and Pioneer Hi-Bred indicated any changes in sexual compatibility as a result of the gene insertions.

CFIA therefore concludes that gene flow from line 1507 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 itself 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 to disease and pest susceptibilities, other than to ECB and other lepidopteran pests of corn which are not known to be limiting factors in the establishment and spread of corn in Canada.

Some of the genetic elements introduced into corn line 1507 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 lepidopteran resistance and herbicide tolerance would not be expected to result in corn line 1507 expressing novel pathogenic characteristics.

Based on these points, the CFIA has determined that line 1507 does not display any altered plant pest potential.

4. Potential Impact on Non-Target Organisms

The history of use and available literature indicate that, with the exception of certain insect pests, bacterial B.t. δ-endotoxins are not toxic to humans, other vertebrates and non-lepidopteran invertebrates.

The B.t. protein produced in line 1507 corn was shown to be equivalent to the original bacterial protein. This protein is active only against specific lepidopteran insects; no lepidopteran species which are listed as threatened or endangered species in Canada will have significant exposure to the Cry1F protein produced by widespread cultivation of corn line 1507.

In addition, Dow AgroSciences and Pioneer Hi-Bred have submitted data from dietary toxicity studies on the effect of the microbial Bt protein on non-target organisms, including lepidoptera (monarch butterfly larvae), pollinators (honeybees), predaceous insects (green lacewing larvae, ladybird beetles), fresh water invertebrates (daphnia), soil insects (collembola) and beneficial insects (parasitic hymenoptera). Dietary toxicity studies were also conducted with ~~the~~ earthworm and bobwhite quail. In addition, an acute oral gavage study was used to test the toxicity of Cry1F to mice.

Studies submitted by Dow AgroSciences and Pioneer Hi-Bred demonstrated that the Cry1F protein expressed by corn line 1507 exhibits virtually no toxicity to larvae of the monarch butterfly at levels as high as 10 mg toxin/ml diet, a level which greatly exceeds anticipated environmental exposure, based on field trial data.

Corn is not known for the production of significant levels of endogenous toxins and the transformation event that produced line 1507 would not be expected to induce their synthesis. Additionally, corn line 1507 was demonstrated not to be toxic to non-target organisms indicating that the insertion of genetic elements did not result in unexpected toxicity. Corn is however, known to produce low levels of trypsin inhibitor and phytic acid and the levels of these compounds in line 1507 were found to be equivalent to levels found in the control lines. The genetic modification, therefore did not alter the expression of endogenous toxins.

Based on the above, the CFIA has determined that the unconfined release of line 1507, when compared with currently commercialized corn, will not result in altered impacts on non-target organisms.

5. Potential Impact of Corn Line 1507 on Biodiversity

Corn line 1507 has no novel phenotypic characteristics that would extend its use beyond the current geographic range of corn production in Canada. Since there are no wild relatives of corn in Canada, there will be no transfer of novel traits to unmanaged environments.

With the exception of certain lepidopteran pest species, corn line 1507 has been demonstrated to be safe for non-target organisms. 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 corn line 1507 does not present a significant change from existing agricultural practices.

The use of broad spectrum herbicides has the intended effect of reducing local weed populations within agricultural fields and this may reduce local weed species biodiversity, and possibly other trophic levels which utilize these weed species. It must be noted however that reduction in weed biodiversity in agricultural fields is not unique to the use of herbicide tolerant crops, and is a common factor in virtually all modern agricultural systems.

The CFIA has therefore concluded that the potential impact on biodiversity of corn line 1507 does not present a significantly altered impact in comparison to corn varieties currently being grown in Canada.

6. Potential for Development of Target Pest Resistance to Corn Line 1507

The following IRM design is intended to reduce or delay European corn borer resistance to the Cry1f protein. Corn line 1507 also targets corn earworm, black cutworm and fall armyworm, however no modification is required to the present IRM design to address resistance in these pests since there are no significant overwintering populations of these insects in Canada.

Lepidopteran insects have a significant ability to develop resistance to conventional chemical insecticides, therefore it is reasonable to expect that resistance to the insecticidal properties of corn line 1507 may develop. *B. thuringiensis* var *aizawai* preparations are commercially available for control of various lepidopteran pests and the development of resistance to Cry1F due to the environmental release of corn line 1507 may result in the reduction or loss of efficacy of the foliar spray Bt products. Corn line 1507 produces Cry1F throughout the growing season therefore target insects will be exposed to significantly higher levels of Cry1F than through the current foliar spray treatments, leading to high selection pressures for resistant ECB individuals.

In order to significantly minimize the likelihood of the development of insect pest resistance to PNTs expressing novel insect resistance, the CFIA requires that an insect resistance management (IRM) plan be implemented for these products. A component of the IRM strategy that will be used with corn line 1507, is the establishment of structured refugia (unmodified corn) arranged in strip rows or blocks within or near the insect pest resistant corn field. Should resistant insects occur, they would then be able to mate with susceptible insects to keep the frequency of resistance genes diluted in the insect population.

CFIA believes that sound management practices and IRM strategies can significantly reduce and delay the development of Cry1F resistant ECB populations, however the ECB populations must be monitored for the development of resistance in a regular and consistent manner. CFIA understands that Dow AgroSciences and Pioneer Hi-Bred have developed and will implement an insect resistance management plan that includes the following key components:

(i) The use of structured refugia to provide a population of insects that have not been exposed to the Cry1F protein and are available to reproduce with potentially resistant insects that may emerge from the Bt crop.

(ii) The early detection of ECB populations resistant to the corn-expressed insecticidal protein is extremely important. Close monitoring for the presence of such populations, in ECB-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 individuals, instructions to contact Dow AgroSciences and Pioneer Hi-Bred, and strategies to be followed if unexpected levels of lepidopteran pest damage occur.

(iv) Dow AgroSciences and Pioneer Hi-Bred will have procedures in place for responding to these reported instances of unexpected target pest damage. These procedures will include, where warranted, the collection of plant tissue and pest insects and use of appropriate bioassays to evaluate suspected Cry1F resistant individuals, and a protocol for immediate action to control resistant individuals.

(v) Detection of confirmed resistant lepidopteran pest populations and subsequent action plan will immediately be reported to CFIA.

(vi) Integrated Pest Management practices will be promoted, such as prediction of infestation problems from previous years and crop rotation.

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

7. Potential for the development of multiple herbicide tolerant volunteers and herbicide tolerant weeds

If there is general adoption of several different crop species with novel herbicide tolerances, then the potential exists for the development of crop volunteers with a combination of tolerances to different herbicides. Therefore, this technology should be managed as part of an integrated approach which may include currently available weed control products with alternate modes of action, or alternative methods of weed control. Of additional note is the use several crop species in rotation which all rely on tolerance to the same herbicide. Another potential concern is that the continued use of a specific herbicide may provide significant selective pressure for the potential development of herbicide tolerant weeds. Therefore, agricultural extension personnel in both the private and public sectors should promote careful management practices for growers who use these herbicide-tolerant crops to minimize the development of multiple herbicide tolerant crop volunteers as well as tolerant weed populations. The CFIA is currently working with the Pest Management Regulatory Agency of Health Canada to develop strategies which address the issues of multiple herbicide tolerant volunteers and herbicide tolerant weeds in a broad industry led stewardship program.

V. Criteria for the Livestock Feed Assessment

1. Potential Impact on Livestock Nutrition

Nutritional Composition of corn line 1507

Composition of grain and whole plant from Line 1507 was compared with an unmodified control corn line with the same genetic background. Data were obtained from trials conducted in four locations in Chile, with sufficient replication to allow for statistical analysis. Whole plant analysis included proximates, acid digestible fibre (ADF) and neutral digestible fibre (NDF). Grain analysis included proximates, major fatty acids, amino acids, tocopherols, B vitamins and minerals. Slight but statistically significant differences in ADF in whole plant were reported. No other differences in whole plant were observed. In grain, there was significantly lower fat, lower manganese and higher potassium in line 1507 compared to the control. These differences were not of significant nutritional consequence, and were likely due to normal variability. There were no other differences between Line 1507 and control grain. All nutrients measured were within the normal range for corn. Additional supporting data from agronomic trials of Line 1507 grown in Ontario was submitted. A study conducted in Italy and France on the nutrient composition in grain and forage of line 1507 and Mycogen Inc. brand hybrid 2722 (a corn variety with similar genetic background as line 1507), showed no difference in proximate analysis for both grain and forage between the two corn lines. The CFIA therefore concludes that line 1507 has equivalent nutritional composition to commercial current corn.

2. Potential Impact on Livestock

Corn is not known for the production of endogenous allergens and the transformation event which produced line 1507 would not be expected to induce their synthesis. Additionally, the non-target toxicity studies did not demonstrate any unexpected toxicity of corn line 1507.

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.

A mouse acute oral toxicity test and a bobwhite quail dietary toxicity study using Cry1F protein were conducted. No adverse effects were demonstrated.

A mouse acute oral toxicity test was performed using PAT protein. No adverse effects were demonstrated.

Based on the expected exposure levels and the results of the above tests, the CFIA concludes that there is not expected to be any significant risk to livestock from dietary exposure to the Cry1F and PAT proteins in livestock feed.

VI. New Information Requirements

If at any time, Dow AgroSciences and Pioneer Hi-Bred become aware of any information regarding risk to the environment, including the development of lepidopteran pest resistance, or risk to human or animal health that could result from release of these materials in Canada, or elsewhere, Dow AgroSciences and Pioneer Hi-Bred will 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.

VII. Regulatory Decision

Based on the review of data and information submitted by Dow AgroSciences and Pioneer Hi-Bred, and through comparisons of corn line 1507 with unmodified corn counterparts, 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 significant environmental effects following unconfined release. Dow AgroSciences and Pioneer Hi-Bred have developed and will implement a resistance management plan.

Based on the review of submitted data and information by Dow AgroSciences and Pioneer Hi-Bred, including comparisons of corn line 1507 with unmodified corn counterparts, 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 corn line 1507 for livestock animals. 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. Corn line 1507 has been assessed and found to be substantially equivalent to traditional corn varieties, with respect to safety and nutritional quality. Corn line 1507 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 line 1507 is therefore authorized as of October 9, 2002. 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.

The corn line 1507 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 corn line 1507. The food safety decisions are available at the following Health Canada web site:

http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novel_foods_and_ingredient.html