



**Supplement to the
Decision Document**

**DD96-15
Suppl.**

**Determination of Livestock Feed Safety of Dekalb Canada Inc.'s
Glufosinate Ammonium-Tolerant Corn Line DLL25**

Feed Assessment:

This supplement to Decision Document DD96-15 has been prepared to explain the regulatory decision reached under the guidelines Dir95-03 *Guidelines for the Assessment of Livestock Feed From Plants with Novel Traits*.

The Plant Biotechnology Office of the Plant Products Division has evaluated information submitted by Dekalb Canada Inc. regarding the glufosinate ammonium-tolerant corn line DLL25. They have determined that this plant with novel traits does not present altered environmental interactions when compared to currently commercialized corn varieties as explained in decision document DD96-15.

The Feed Section of the Plant Products Division, has evaluated information submitted by Dekalb Canada Inc. regarding the glufosinate ammonium-tolerant canola line DLL25 and has determined that it is substantially equivalent to corn currently approved for use as livestock feed.

Feed use of DLL25 and its byproducts is therefore authorized. Any other *Zea mays* lines and intra-specific hybrids resulting from the same transformation event are also authorized, 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.

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I. Brief Identification of the Plants with Novel Traits (PNTs)

Designation of the PNTs:	DLL25
Applicant:	Dekalb Canada Inc
Species:	Corn (<i>Zea mays</i> L.)
Novel Traits:	Glufosinate ammonium (herbicide) tolerance
Trait Introduction Method:	Microprojectile bombardment
Intended Use of the PNT:	Cultivation as hybrid grain corn for livestock feed use and human consumption.

II. Background Information

Dekalb has developed a corn line tolerant to glufosinate ammonium, a broad spectrum non-residual herbicide. This *Z. mays* line, referred to as DLL25 in the present document, will allow the use of glufosinate ammonium as a post-emergence herbicide, thus providing an alternative for weed control in corn production, and reducing reliance on soil-incorporated herbicides.

The development of DLL25 was based on recombinant DNA technology, by the introduction of a bacterial gene into a line of *Z. mays*. This gene codes for phosphinothricin acetyltransferase, an enzyme that inactivates glufosinate ammonium through acetylation, thereby conferring tolerance to glufosinate ammonium.

Dekalb Canada Inc. has provided data on the identity of DLL25, a detailed description of the modification method and the isolation of transformants, data and information on the donor organisms, the role of the inserted gene and of regulatory sequences in donor organisms, their molecular characterization, and full nucleotide sequences. The novel protein was identified and characterized, including its mode of action, the levels of expression in various tissues, potential effects on plant pathways, toxicity to non target organisms and allergenicity.

Data to support the suitability of line DLL25 as livestock feed was provided. Results from proximate analyses, including crude protein, crude fat, the fatty acid profile, crude fibre, and ash were supplied.

For further information and a more detailed description of the novel trait, please refer to decision document DD96-15.

AAFC has reviewed the information submitted by the company in light of the assessment criteria for determining the safety and efficacy of livestock feed as described in Dir95-03 *Guidelines for the Assessment of Livestock Feed Derived From Plants with Novel Traits*. We have considered the:

- C potential impact on livestock and
- C potential impact on livestock nutrition

III. Nutritional Composition

Analyses of the nutritional composition including protein, oil, fibre and ash were conducted on hybrids derived from line DLL25 and their corresponding non-transformed controls. Oil content was slightly but significantly higher in the grain of DLL25 hybrids compared to the non-modified controls. In contrast, whole plant fibre was lower in the DLL25 hybrid lines compared to the respective controls. Protein content was not significantly different in the hybrid lines compared to the non-modified controls. Overall, nutritional composition of the hybrid lines was shown to be substantially equivalent to non-transformed corn varieties. Occasional significant differences between the PNTs and the controls were apparent but these differences were judged to arise from normal variability rather than as a result of the inserted novel traits. All values were within the normal observed range for these nutrients in corn. AAFC has determined that line DLL25 is substantially equivalent to traditional corn varieties.

IV. Anti-Nutritional Factors

The parent *Zea mays* is not known for the production of anti-nutritional factors and the transformation event which produced line DLL25 would not be expected to induce their synthesis.

V. Regulatory Decision

Based on the review of submitted data and information, the Feed Section of the Plant Products Division has concluded that the novel trait does not in itself raise any concerns regarding the safety or nutritional composition of line DLL25. Corn, corn oil, and meal are currently listed in Schedule IV of the Feeds Regulations and are, therefore, approved for use in livestock feeds in Canada. As line DLL25 has been assessed and found to be substantially equivalent to traditional corn varieties, DLL25 and its byproducts are considered to meet present ingredient definitions and are approved for use as livestock feed ingredients in Canada.

Feed use of DLL25 and its byproducts is therefore authorized. Any other *Zea mays* lines and intra-specific hybrids resulting from the same transformation event are also authorized, 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.

