



**Supplement to the
Decision Document**

**DD96-11
Suppl.**

**Determination of Livestock Feed Safety of AgrEvo Canada Inc.'s
Glufosinate Ammonium-Tolerant Canola Line HCN28**

Feed Assessment:

This supplement to Decision Document DD96-11 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 described has evaluated information submitted by AgrEvo Canada Inc. regarding the glufosinate ammonium-tolerant canola line HCN28. They have determined that this plant with novel traits does not present altered environmental interactions when compared to currently commercialized canola varieties as explained in decision document DD96-11.

The Feed Section of the Plant Products Division, AAFC, has evaluated information submitted by AgrEvo Canada Inc., regarding the glufosinate ammonium-tolerant canola line HCN28 and has determined that it is substantially equivalent to canola currently approved for use as livestock feed.

Feed use of HCN28 and its byproducts, its descendants and any derived sister lines, but without the introduction of any other novel trait, is therefore authorized.

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

Designation of the PNTs:	HCN28
Applicant:	AgrEvo Canada Inc.
Species:	Canola (<i>Brassica napus</i> L.)
Novel Traits:	Glufosinate ammonium (herbicide) tolerance
Trait Introduction Method:	<i>Agrobacterium tumefaciens</i> -mediated transformation
Intended Use of the PNT:	Production of <i>B. napus</i> for seed oil for human consumption and seed oil and meal for livestock feed. These materials will not be grown outside the normal production area for canola.

II. Background Information

AgrEvo has developed a *Brassica napus* canola line tolerant to glufosinate ammonium, a broad spectrum non-residual herbicide. This *B. napus* line, referred to as HCN28 in the present document, will allow the use of glufosinate ammonium as a post-emergence herbicide, thus providing an alternative for weed control in canola production, and reducing reliance on soil-incorporated herbicides.

The development of HCN28 was based on recombinant DNA technology, by the introduction of a bacterial gene into a line of *B. napus*. This gene codes for phosphinothricin acetyltransferase, an enzyme that inactivates glufosinate ammonium through acetylation, thus conferring tolerance to glufosinate ammonium. It is the same as the gene inserted in HCN92, a glufosinate ammonium tolerant canola line that was authorized for unconfined release and feed use on March 10, 1995 (see DD95-01).

AgrEvo has provided data on the identity of HCN28, a detailed description of the modification method, data and information on the gene insertion, 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 the levels of expression in seed, its potential toxicity and allergenicity.

Data to support the suitability of line HCN28 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 DD96-11.

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 :

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

III. Nutritional Composition

Analyses of the nutritional composition including protein, fat, fatty acid profile, fibre and ash were conducted on samples of line HCN28, line HCN92 (Innovator) and three non-transformed commercial canola varieties (Excel, Cyclone, Legend). Overall, nutritional composition of HCN28 was shown to be substantially equivalent to non-transformed canola varieties. There were no differences among lines in crude fat, fatty acid profile, crude fibre or ash content. At one location, protein content was significantly lower in line HCN28 than two of the non-transformed controls while at the other two locations, there were no significant protein content differences among lines. In all locations, protein content was within the normal range for canola.

IV. Anti-Nutritional Factors

The phytosterol, erucic acid and glucosinolate content of line HCN28 was substantially equivalent to the levels determined for the non-transformed controls. All values were below the prescribed maximum levels for these anti-nutritional factors in canola as set out in the Feeds Regulations.

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 HCN28. Canola oil, seed 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 HCN28 has been assessed and found to be substantially equivalent to traditional canola varieties, HCN28 and its byproducts are considered to meet present ingredient definitions and are approved for use as livestock feed ingredients in Canada.

Feed use of the HCN28 line and its byproducts, its descendants and any derived sister lines, but without the introduction of any other novel trait, is therefore considered safe.

