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# Novel Food Information - Food Biotechnology

## Imidazolinone Tolerant Clearfield™ Lentil (RH44)

July, 2004

Health Canada has notified BASF Canada Inc. that it has no objection to the food use of Clearfield lentil (*Lens culinaris*) variety RH44 derived through mutation breeding, which is tolerant to imidazolinone herbicides. The Department conducted a comprehensive assessment of this lentil according to Health Canada's Guidelines for the Safety Assessment of Novel Foods. These Guidelines are based upon internationally accepted principles for establishing the safety of foods with novel traits.

### Background:

The following provides a summary of the BASF Canada Inc. notification to Health Canada and the results of the safety assessment. This summary contains no confidential business information.

### 1. Introduction

BASF Canada developed lentil line RH44, which is tolerant to imidazolinone herbicides. It joins a family of imidazolinone tolerant crops produced in a similar way and previously reviewed by Health Canada, namely imidazolinone tolerant corn, canola, rice, and wheat. The decision documents for these novel foods are available at  <http://www.novelfoods.gc.ca> under the heading "Decisions on Novel Foods". Clearfield lentil variety RH44 is intended solely for breeding stock and only the imidazolinone resistance trait will be selected for in the progeny of crosses involving RH44. Other progeny traits (including composition) would be characteristic of the material used for backcrossing.

### 2. Development and Production of the Modified Plant

Lentils (*Lens culinaris*) and other pulse crops are grown on the Canadian prairies primarily for the export market. Lentils are self-pollinating, are well adapted to cooler climates and have a reputation for improving soil fertility. Most lentil seed is produced for food and undergoes little processing before being eaten as lentil or split lentil.

The petitioner has provided information describing the methods used to develop lentil line RH44 and data that characterizes the genetic change which confers tolerance to imidazolinone herbicides. BASF developed this lentil variety through a process of mutagenesis combined with conventional breeding. No novel DNA has been introduced into the lentil line to achieve the herbicide tolerant phenotype.

The mutation responsible for imidazolinone tolerance is a point mutation of a single nucleotide in one of the acetohydroxyacid synthase (AHAS) genes found in Clearfield lentil variety RH44. The petitioner has identified the mutation in the AHAS gene by sequencing, and shown it to be a single base pair change that codes for a single amino acid change in the AHAS protein. As with the previously approved imidazolinone tolerant wheats, rice, corn and canola, the single amino acid change alters the binding site for the herbicide on the AHAS enzyme without affecting the normal functioning of the enzyme.

### **3. Product Information**

Theoretically, a mutation in the AHAS enzyme in lentil could affect the biosynthesis of the essential amino acids isoleucine, leucine, and valine. The amino acid composition of Clearfield lentil line RH44 was compared to commercial cultivars, confirming that the AHAS activity of the imidazolinone-tolerant lentil was not affected by the mutation.

### **4. Dietary Exposure**

Imidazolinone tolerant Clearfield lentil line RH44 is expected to be used in the same applications as other lentil varieties by the food industry.

### **5. Nutrition**

The nutrient data pertaining to Clearfield lentil variety RH44 comprised two data sets which were obtained through two different studies. Both studies included the analyses of nutritional composition of Clearfield lentil variety RH44 and of currently registered commercial varieties. Samples of grain for both studies were collected from trials using randomized complete block design. The results of these studies indicate that the proximate analysis, amino acid profile, fatty acid profile, and magnesium, zinc, iron,

phosphorous, niacin, pantothenic acid, vitamin B6, thiamine and concentrations of the antinutrients phytic acid and trypsin inhibitor of Clearfield lentil variety RH44 were within the same range as commercial lentil varieties currently registered in Canada.

Although these studies included the analysis of many nutrients and antinutrients, some other key micronutrients (folacin, vitamin C, riboflavin, copper, potassium and manganese) and lectin were not included. Health Canada reviewed a rationale provided by the petitioner stating that there is a high degree of certainty that the above components would not have changed significantly in the lentil variety RH44 because the source of herbicide tolerance (a single amino acid substitution in the AHAS enzyme) is unrelated to vitamin or mineral metabolism. In addition, secondary phenotypic effects (including biochemical effects) have not been observed in this and other crops developed using a similar mutagenesis approach that have been approved in Canada. Moreover, Clearfield lentil variety RH44 is intended for breeding stock only and will be subjected to further genetic crossing. Only the imidazolinone resistance trait will be selected for in the progeny of crosses involving RH44. Other progeny traits (including composition) would be characteristic of the material used for backcrossing. As a result it was concluded that further testing of Clearfield lentil variety RH44 for additional parameters was not warranted.

Based on the nutrient data provided in this submission, it was considered there was no reason to object to imidazolinone tolerant lentil variety RH44 and progeny containing this mutation, being sold for food use in Canada.

## **6. Toxicology**

The weight of evidence suggests that the mutant AHAS enzyme from lentil variety RH44 is unlikely to be a toxin or allergen under normal conditions of consumption. This conclusion is based on the observations that the protein is present in very low amounts in the edible part of the lentil, its activity is heat-labile and would be destroyed during normal food preparation processes, and the protein is as sensitive to degradation in the human gastrointestinal tract by trypsin as the native protein. Consequently, systemic exposure to the intact AHAS was considered negligible. Further, the modified AHAS protein is not homologous to known allergens and did not differ from native AHAS in its similarity to known food allergens. In addition, lentil variety RH44 does not express any new major proteins or altered amounts of other proteins, which includes endogenous allergens.

## **Conclusion:**

Health Canada's review of the information presented in support of the

food use of imidazolinone tolerant lentil line RH44 concluded that the food use of this lentil line does not raise concerns related to safety. Health Canada is of the opinion that lentil line RH44 is as safe and nutritious as current commercial lentil varieties.

Health Canada's opinion deals only with the food use of imidazolinone tolerant lentil variety RH44. Issues related to its use as animal feed have been addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.

For more information, please contact: [food-aliment@hc-sc.gc.ca](mailto:food-aliment@hc-sc.gc.ca)

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