Re: Application for importation and trial release of Roundup Ready canola line RT73.

With reference to Monsanto's application for importation and trial release of Roundup Ready canola RT73, reference number 17/3/1 – Monsanto – 09/673. Kindly find herewith our response to the objections received.

Response to potential food and feed safety concerns:

This is an application for trial release and use as food or feed in South Africa is not within the scope of this application. However, as was indicated in the application, extensive studies confirmed that there are no toxic or allergenic risks associated with RT73 and that RT73 canola is compositionally equivalent to conventional. The safety of RT73 canola is further supported in the fact that Roundup

Ready canola varieties are commercially cultivated in various countries. Extensive food, feed and environmental safety reviews have therefore been conducted by numerous global regulatory authorities prior to the commercial introduction of RT73. A summary of the global regulatory approval status of RT73 is provided below.

- Agriculture and Agri-Food Canada and Health and Welfare Canada were responsible for assessing the safety of agricultural and food products derived from Roundup Ready canola. Agency reviews followed a strict process consistent with international standards for safety assessment of food and feed derived from plants with novel traits. Food and feed products derived from RT73 canola were reviewed by the Canadian Food Inspection Agency and approved for human and animal consumption in Canada in November 1994. Agriculture and Agri-Food Canada also granted unconfined environmental release for RT73 in November 1994. Commercial introduction of RT73 was approved in Canada in 1996. Links to the decision documents can be found at: [http://www.agbios.com/docroot/decdocs/ofb-094-325-a.pdf];

  http://www.inspection.gc.ca/english/plaveg/bio/dd/dd9502e.shtml

- RT73 canola falls within the scope of the U.S. Food and Drug Administration (FDA) policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering (FDA, 1992). Monsanto voluntarily completed a consultation process with FDA in September of 1995.

- The Japanese Ministry of Health and Welfare and the Ministry of Agriculture, Forestries and Fisheries cleared food and feed products containing event RT73 for importation into Japan in September 1996.

- Mexico's Secretary of Health has granted Roundup Ready canola RT73 approval for use in food (September, 1996).

- The United Kingdom's Ministry of Agriculture Fisheries and Food's Advisory Committee on Novel Foods and Processes (ACNFP) has reviewed a notification for import of oil derived from Roundup Ready canola. In January of 1996, the ACNFP stated that there were no safety concerns with oil produced from RT73 and acknowledged that the oil was substantially equivalent to oil produced by conventional canola. A similar notification was reviewed and acknowledged by the European Commission in November 1997.

- Prior to its deregulation by the U.S. Department of Agriculture (USDA), Roundup Ready canola RT73 was subject to regulations (7 CFR Part 340) administered by the Animal and Plant Health Inspection Service based on its authority under the Plant Protection Act. The USDA granted Monsanto's request for a determination of non-regulated status for canola event RT73 in January of 1999. A link to the decision document can be found at:

  [http://www.aphis.usda.gov/brs/aphisdocs2/98_21601p_com.pdf]

- The Australia New Zealand Food Authority has approved Roundup Ready canola RT73 for import and food use in July, 2000. A link to the decision document can be found at:

  [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir0204/$FILE/dir020finalrarmpsum.rtf]

- The Philippines Department of Agriculture and Bureau of Plant Industries have granted Roundup Ready canola RT73 approval for food, feed and processing use in October, 2003.

- Korea's Food and Drug Administration granted approval of Roundup Ready canola RT73 for import for food in December, 2003.

- The European Food Safety Authority has published a positive scientific opinion regarding the safety of Roundup Ready canola for feed use in March, 2004 and the European Commission authorized import of GT73 grain for crushing and feed use in

May of 2007. A link to the decision document can be found at: [http://www.efsa.europa.eu/en/scdocs/scdoc/29.htm]

- China's Ministry of Agriculture has granted a safety certificate allowing for food and feed import of Roundup Ready canola RT73 in April, 2004 (renewed in April, 2007 and December, 2009).

Summaries of the safety reviews of RT73 conducted by several global regulatory authorities are publically available, as provided above. In addition to these approvals, the safety of RT73 continues to be monitored through mandatory product renewals required by several regulatory authorities, such as China's Ministry of Agriculture, Korea's Food and Drug Administration, Philippines Department of Agriculture and Bureau of Plant Industries and the European Food Safety Authority.

Therefore, considering that RT73 has been grown on millions of hectares since its first commercial introduction, without a single incident of adverse impact to human or animal health or to the environment, it provides indisputable support for the conclusions of safety reached in the studies and in reviews by numerous regulatory authorities.

Response to potential concerns related to gene escape:

Field trials are a necessary component of the safety assessment process. Field trialing with GM crops has a history of safety that dates more than 20 years. The OECD provided guidance on the safe conduct of field trials in a document published in 1992 (OECD, 1992). Based on this guidance, most OECD countries developed field trial programs with application processes and standards for confinement and compliance. All these systems are based primarily on three key safety factors described in 1992, which are (i) the characteristics of the organism(s) used including the introduced gene/genetic material, (ii) the characteristics of the research site and surrounding environment and (iii) the use of appropriate experimental conditions (OECD, 1992).

Today, the common elements among all the regulatory systems approving field trials are -

1. Recognition that field trials are necessary for the country to evaluate new technologies that are regulated and may have adverse impacts on their environment 1.

2. Acceptance that little information on the environmental risks associated with the GM plant maybe available at the time of the first field trial. But, when there is a history of releases, including previous field trials in other world areas, this experience is valuable in establishing conditions for confined trials.

3. A need for information on a case-by-case basis, and is used primarily to assign appropriate conditions of confinement (risk management). As noted by OECD (1992), the characteristics of

the trial location and experimental conditions will ensure safety. As such, field trials are conducted under confinement; that is the focus of the decision is on risk management-1.

4. A focus on ensuring safety using a compliance program involving appropriate inspection and monitoring of trials-2.

1. According to Canada's directive 2000-07. Conducting Confined Field Trials with Plants with Novel Traits (PNT) in Canada: "In Canada, a confined research field trial of PNTs is the release of a PNT in the environment, for research purposes, under terms and conditions of confinement. These terms and conditions of confinement include, but are not limited, to reproductive isolation, site monitoring, and post-harvest land use restrictions and are designed to minimize the exposure of the PNT to the environment. The confined research field trial program provides developers with the opportunity to (i) evaluate the performance of PNTs, (ii) study the environmental safety of these modified plants, (iii) address the criteria and information requirements considered in the environmental safety assessment of PNTs for unconfined releases and (iv) generate data for variety registration purposes."

2. According to the USDA APHIS "BRS works to ensure the safe and confined introduction of regulated GE organisms. This is achieved in large part through BRS' Compliance and Inspection Branch (CIB). CIB is dedicated to ensuring that developers of regulated GE organisms maintain and adhere to Federal regulations and all permit conditions."

We also highlight the conclusions of a report from the US National Academy of Sciences, "Field Testing Genetically Modified Organisms, Framework for Decisions, 1987, National Academy Press. Washington DC".

- Plants modified by classical genetic methods are judged safe for field testing on the basis of experience with hundreds of millions of genotypes field-tested over decades. They are, in the terms used by the plant subcommittee, "manageable by accepted standards" The committee emphasizes that "the current means for making decision about the introductions of classically bred plats are entirely appropriate and no additional oversight is needed or suggested in this report"

- Crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits. As the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants. Traits that are unfamiliar in a specific plant will require careful evaluation in small-scale field tests where plants exhibiting undesirable phenotypes can be destroyed.

- At this time, the potential for enhanced weediness is the major environmental risk perceived for introductions of genetically modified plants. The likelihood of enhanced weediness is low for genetically modified, highly domesticated crop plants, on the basis of our knowledge of their morphology, reproductive systems, growth requirements, and unsuitability for self-perpetuation without human intervention.

- Confinement is the primary condition for ensuring safety of field introductions of classically modified plants.

- Depending on the crop species, proven confinement options include biological, chemical, physical, spatial, environmental, and temporal isolation, as well as sized of field plot.

- Plants grown within field confinement for experimental purposes rarely, if ever, escape to cause problems in the natural ecosystem.

- Established confinement options are as applicable to field introductions of plants modified by molecular and cellular methods as to introductions of plants modified by classical genetic methods.

The Republic of South Africa recognizes the key safety factors described in the OECD document of 1992 and applies many of these principles in their approach to field trials for genetically modified plants. Application of these principles have resulted in no adverse impact to the environment or to food and feed safety over the period of time that genetically modified plants have been tested in South Africa and globally.

Taking into consideration the key safety factors, a field trial with RT73 in South Africa is proposed based on the following principles (i) measures that will be taken to confine the transgene within the boundaries of each location as described in the application, (ii) utilization of containment methods to assure that seed is contained prior to planting and after harvest, (iii) spatial isolation of the plants from other B. napus and related Brassica species to assure that there is no unintentional release of the transgene into the environment and (iv) post harvest monitoring of the field site locations to assure that no volunteer plants remain in the environment after harvest and in subsequent seasons. Effective use of these measures addresses the

potential concerns regarding contamination of South Africa's canola industry and the potential unintentional release of the transgene into the environment.

Thus, given the data available and the history of safe use established for RT73 canola, the proposed field trail poses no concerns to human and animal health. Furthermore, on the basis of the extensive body of research regarding gene movement in B. napus and the potential crossing to related relatives, the isolation measures proposed during implementation of the field trial will predictably mitigate any unintended movement of the transgene from the trial sites, resulting in minimal risk to the environment.

We trust that the information provided addresses the potential concerns raised.

Reference

OECD (1992) Safety Considerations for Biotechnology 1992. OECD. Paris. http://www.oecd.org/dataoecd/8/3/2375496.pdf