QUESTIONS & ANSWERS ON LICENCE DECISION DIR 108 FOR COMMERCIAL RELEASE OF GENETICALLY MODIFIED CANOLA

What is this licence for?

Bayer CropScience Pty Ltd (Bayer) has received approval for the commercial release of genetically modified (GM) canola into the environment throughout Australia. The GM canola is modified for tolerance to two different herbicides (glyphosate and glufosinate ammonium) and a hybrid breeding system.

How has the GM canola been modified?

The GM canola proposed for commercial release is known as InVigor® x Roundup Ready® canola, and was produced by conventional breeding between GM InVigor® canola lines and GM Roundup Ready® canola, which were separately assessed and approved by the Gene Technology Regulator (the Regulator) in 2003 for commercial release under licences DIR 021/2002 and DIR 020/2002, respectively.

The InVigor® x Roundup Ready® canola contains genes from common bacteria conferring tolerance to the herbicides glufosinate ammonium and glyphosate. In addition, some of the InVigor® x Roundup Ready® canola lines contain genes from common bacteria conferring a hybrid breeding system and/or an antibiotic resistance gene. The antibiotic resistance gene was used to identify genetically modified plants during their initial development in the laboratory.

What is the purpose of the release?

The purpose of the release is to allow commercial production of the GM canola.

The introduced genes for herbicide tolerance enable the GM canola plants to grow in the presence of glufosinate ammonium and/or glyphosate herbicides. These herbicides could then be used for weed control in the GM canola crop.

The introduced genes for a hybrid breeding system facilitate the production of hybrid canola plants. Hybrid plants, produced from crossing genetically distinct parents, are often more vigorous and higher yielding compared to the parental lines.

The GM canola and products derived from the GM canola would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has approved the use of food derived from the parent lines (GM InVigor® canola and GM Roundup Ready® canola) for human consumption. These approvals also cover the GM canola proposed for release.

Where will this GM canola be grown?

Commercial cultivation of GM canola may be subject to restrictions in some Australian States and Territories for marketing reasons. Currently, the commercial cultivation of GM canola licensed by the Regulator is permitted in Victoria, New South Wales, Western Australia and Queensland, but prohibited in the other canola growing states of South Australia and Tasmania.

It is important to note that these requirements do not relate to protection of human health or the environment, and are a matter for State and Territory governments and industry, not the Regulator. Further information should be obtained from the relevant State or Territory.

What controls have been imposed for this GM canola?

The licence is for an ongoing commercial release. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that this release of GM canola poses negligible risks to the health and safety of people or the environment as a result of gene technology. However, general conditions have been imposed to ensure that there is ongoing oversight of the release.

States and Territories may impose measures, such as buffer zones, for marketing reasons (also see above question 'Where will this GM canola be grown?').

Will this GM canola be more weedy than other canola or transfer herbicide tolerance to weeds?

The risk assessment prepared by the Regulator considered the potential for the GM canola itself to become a weed, as well as the potential for the herbicide tolerance traits to be transferred from the GM canola to related plants and lead to increased weediness.

The GM canola is not expected to have any additional weediness traits and will be as susceptible to environmental stresses (such as climate and disease) as non-GM canola. Canola plants with tolerance to both glufosinate ammonium and glyphosate can still be controlled by other approved herbicides or mechanical means.

Some transfer of the introduced genes could occur to a small number of compatible plants at low levels. Even if this does occur, it will not pose a risk to people or the environment. Weeds which acquire the herbicide tolerance genes only have a survival advantage when glyphosate and/or glufosinate ammonium is used to control them. The plants remain susceptible to all other approved herbicides, cultivation practices and other environmental factors.

Will use of herbicide on this GM canola lead to the development of herbicide resistance?

The evolution of resistance to herbicides is not a new phenomenon that has arisen as a result of the development and use of GM crops. Whenever selective pressure is applied by herbicide use, without appropriate resistance management strategies, the development of resistant weeds is a possibility.

Regulation of agricultural chemicals, including insecticides and herbicides, is principally the responsibility of the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA considers a range of issues in assessing agricultural chemicals for registration, including efficacy, resistance management and human health and environmental impacts.

Herbicide resistance management was considered by the APVMA in the registration of Roundup Ready[®] and Liberty[®] herbicides for use on the currently approved GM canola varieties. The APVMA applied registration conditions to provide for responsible use of the herbicides and to minimise the potential for the development of herbicide resistance. Plants which acquire a herbicide tolerance trait can be controlled by other approved herbicides and other management practices.

Want more information?

A number of documents relating to this decision are available on the <u>OGTR website</u> or via Freecall 1800 181 030. These documents include the finalised RARMP, an Executive Summary, a Technical Summary and a copy of the full licence.