



RIGOROUS ASSESSMENT CONFIRMS GM INVIGOR[®] CANOLA SAFE AS NON-GM CANOLA

Following extensive evaluation and extended public consultation, the Australian Gene Technology Regulator, Dr Sue Meek, announced today that she has decided to issue a licence for the commercial release of Bayer CropScience's InVigor[®] hybrid canola.

"The Australian public can be assured that our rigorous independent assessment of potential health, safety and environmental impacts has found InVigor[®] canola as safe to humans and the environment as conventional (non-GM) canola," Dr Meek said.

This decision is the first step in the phased commercial release of InVigor[®] canola in Australia. Bayer CropScience will continue to work with farmers, industry groups and State and Territory governments to ensure a staged and orderly commercial roll-out of InVigor[®] canola.

InVigor[®] canola has been genetically modified (GM) to contain two new characteristics – a hybrid breeding system and tolerance to the herbicide glufosinate ammonium.

Dr Meek paid tribute to the thoughtful feedback from the public on the Risk Assessment and Risk Management Plan released for public consultation in April 2003 and the input from expert groups and authorities.

"Many submissions raised concerns about the spread of genetically modified canola, the development of herbicide tolerant weeds and the consequences to herbicide use," Dr Meek said.

"I assure the public that my office (the Office of the Gene Technology Regulator) and the Australian Pesticides & Veterinary Medicines Authority (APVMA) which regulates herbicide use, have comprehensively considered these issues.

"The final version of the Risk Assessment and Risk Management Plan has been expanded to more comprehensively address issues raised, to further explain the conclusions and to incorporate the most up-to-date international research."

Dr Meek said a number of submissions questioned the feasibility of industry proposals to segregate GM canola from non-GM canola for marketing purposes.

"I reiterate that as Gene Technology Regulator, I am part of the Australian Department of Health and deal exclusively with risks that may be posed by genetically modified organisms (GMOs) to human health and safety or to the environment.

“When the Gene Technology Act was created it was a deliberate measure, agreed to by all Australian governments and Opposition parties, to confine the Regulator’s powers to deal exclusively with health, safety and environment issues. This ensures that the assessment of health and environmental risks cannot be compromised by economic issues, matters that may impact on people’s incomes or the marketability of crops.

“Clearly the marketing implications of my decision regarding the commercial release of canola do not represent a risk to human health or the environment and these issues need to be addressed separately by industry and State governments.”

Dr Meek said the Office of the Gene Technology Regulator has reporting systems in place to identify any human health and safety or environmental issues with any GMO licence and also has the powers to investigate and redress them.

“The APVMA similarly has review systems to deal with chemical use issues should they arise,” she said.

“In addition to these safeguards, and because this is the first licence issued for the commercial release of GM canola in Australia, I intend to report on the implementation of the InVigor® canola release after three years of commercial plantings.

“I will call for public input to the proposed report which I consider to be part of the responsible oversight of the progress of this and other licences for genetically modified crops,” Dr Meek said.

The Regulator’s full determination on the Bayer licence can be found on the Office of the Gene Technology website: www.ogtr.gov.au.

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Background on Gene Technology Regulator's decision on InVigor® canola

In July 2002 Bayer CropScience Pty Ltd applied for a licence (application number DIR 021/2002) for the commercial release of genetically modified (GM) canola.

Following thorough evaluation, the Gene Technology Regulator, Dr Sue Meek has issued a licence for seven similar GM 'lines' of Bayer canola: T45, Topas19/2, MS1, RF1, RF2, RF3 and MS8. The MS1, MS8, RF1, RF2 and RF3 lines, and hybrids derived from MS and RF crosses, are covered by the registered trade name InVigor® hybrid canola.

All seven GM canola lines are approved for growing and human consumption in the USA and Canada. They have all been trialled previously in Australia under limited and controlled conditions, and oil derived from all seven canola lines has been approved by Food Standards Australia New Zealand (FSANZ) for use in human food in Australia. Only lines derived from Ms8 and Rf3 combinations will be taken forward for commercialisation in Australia.

The InVigor® hybrid canola is intended to be used as oil in human food, or in animal feed, in the same way as conventional (non-GM) canola.

Following extensive assessment, expert independent advice and extended public consultation, the Gene Technology Regulator has concluded that the seven lines of GM canola are as safe to humans and the environment as non-GM canola.

The approval of this application will not result in the immediate large scale commercialisation of GM canola. Bayer's phased-in release of InVigor® hybrid canola will be undertaken in consultation with growers, industry bodies and State governments.

The reasons for the Regulator's conclusion are thoroughly detailed in the final Risk Assessment and Risk Management Plan available on the Gene Technology Regulator's website: www.ogtr.gov.au (see under the 'What's New' section)

The main conclusions from the evaluation are:

- InVigor® hybrid canola is no more toxic or allergenic than non-GM canola;
- InVigor® hybrid canola will not become any more of a weed than non-GM canola and can be effectively managed with the wide range of herbicides already used to control non-GM plants and weeds; and
- InVigor® hybrid canola will only cross with a small group of related plant species at a *very low level* and which would not cause a weed problem.

The Australian Pesticides & Veterinary Medicine Agency (APVMA) has concurrently approved the use of the Liberty® glufosinate ammonium herbicide on InVigor® hybrid canola. Both the Gene Technology Regulator and the APVMA are confident in their assessments and proposed conditions to manage the commercial release of InVigor® hybrid canola and the use of Liberty® herbicide in Australia.

Further information is available on the Questions & Answer sheet. from the OGTR website: www.ogtr.gov.au