



**Australian Government**  

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**Department of Health**  
Office of the Gene Technology Regulator

**QUESTIONS & ANSWERS ON BAYER CROPSCIENCE GENETICALLY MODIFIED (GM)  
INVIGOR<sup>®</sup> HYBRID CANOLA DECISION**

**1. What is this decision about ?**

Bayer CropScience Pty Ltd (formerly Aventis CropScience Pty Ltd) applied to the Gene Technology Regulator in July 2002 for approval to commercially release seven similar types of genetically modified canola (application DIR21). All of the lines have been previously trialed under limited and controlled conditions in Australia and are approved for commercial release and food use in Canada and the USA and for food use in Australia. Bayer sought approval of all seven types of GM canola to ensure consistency of Australian and overseas approvals. However in Australia, Bayer only intends to commercialise two of the seven GM canola types as InVigor<sup>®</sup> hybrid canola seed (Ms8 and Rf3).

**2. How is Bayer InVigor<sup>®</sup> hybrid canola different from conventional (non-GM) canola?**

Traditional (non-GM) breeding techniques have previously enabled the production of both hybrid seed and the incorporation of herbicide tolerance into conventional (non-GM) canola (about 60% of Australian non-GM canola is tolerant to the herbicide atrazine). The main difference between this GM canola and conventional canola is that gene technology has been used commercially for the first time to incorporate a hybrid breeding system and tolerance to a different herbicide (glufosinate ammonium).

**3. What issues were raised in feedback on the Risk Assessment & Risk Management Plan ?**

The key human health and environmental issues raised in submissions from key stakeholders and the public were: health concerns such as toxicity or allergenicity; GM canola becoming a problem weed; transfer of herbicide resistance to other weeds; and transfer of introduced genes to other organisms. While these issues were examined in the consultation Risk Assessment and Risk Management Plan, the finalised document has been revised to address these issues more comprehensively and to incorporate the most up-to-date international research.

**4. Has the assessment relied only on industry data and information ?**

No. The Gene Technology Regulator requires extensive data as part of any application and often asks applicants for new and additional information. All data supplied by applicants is reviewed by OGTR staff and independent experts, together with relevant independent local and international research. Around 400 studies and papers have been reviewed in this evaluation, most of which are detailed in the extensive Reference section of the Risk Assessment & Risk Management Plan. In addition, the OGTR has prepared the literature review *The Biology and Ecology of Canola (Brassica napus)* as a reference document for the risk assessment process.

**5. Do the results of the UK Farm Scale Evaluations affect the Regulator's decision on InVigor<sup>®</sup> hybrid canola ?**

No, the Regulator has considered in detail the results of the [UK "Farm Scale Evaluations \(FSE\)](#) of Genetically Modified Herbicide Tolerant Crops".

The study compared the environmental effects of weed management practices on selected GM herbicide tolerant crops and conventional crops. Not unexpectedly, the results showed that different herbicide use can affect the abundance of weeds. InVigor<sup>®</sup> hybrid canola when used with glufosinate ammonium herbicide resulted in better weed control than the conventional non-herbicide tolerant canola variety, leading to reductions in insects that rely on those weeds. This was also the case in one of the other two GM species tested. It was also postulated (but not tested) that animals that prey on these insects could also be adversely affected.

In-crop biodiversity is considered important in the UK, as weeds are often remnant native vegetation that is critical to the survival of wildlife. In contrast, Australia's fauna has a much greater reliance on native bushland and forest in the off farm environment. In addition, weeds controlled on Australian farms are usually exotic and are not considered environmentally valuable or important in maintaining biodiversity.

Therefore, the results from the UK Farm Scale study cannot be used as evidence that InVigor<sup>®</sup> hybrid canola will have a detrimental effect on the Australian environment. They do, however, demonstrate the need for the regulatory system's careful case by case assessment of GM crops using scientific data that is relevant to the Australian environment.

**6. What impact do recent State Governments agreements and legislation have on this decision?**

None. The national gene technology regulatory system is designed to address risks to human health, safety and the environment and this assessment has confirmed that Bayer InVigor<sup>®</sup> hybrid canola is as safe as non-GM canola. However, the *Gene Technology Act 2000* anticipated that State and Territory governments may respond to market access issues in relation to the commercial introduction of GM crops.

**7. When are we likely to see the commercial release of 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<sup>®</sup> hybrid canola will be undertaken in consultation with growers, industry bodies, State and Territory governments. Bayer has advised that no commercial scale plantings will occur in 2003.

**8. What happens to the Bayer CropScience GM field trials now this decision is made ?**

Bayer has a licence (DIR10) to undertake field trials until 2005 which it may choose to retain. Although there are no health, safety or environmental concerns that require continued monitoring by the OGTR, Bayer CropScience is obliged to comply with all relevant government requirements. States, Territories and industry are currently considering various market-related management options.

**9. Why do you have a 3 year report if the commercial release is safe ?**

The Regulator is taking a responsible approach in overseeing the progress of this and other licences for genetically modified crops. The Regulator will call for public input to the report.

## HUMAN HEALTH & SAFETY

### 10. How can we be sure that the Bayer InVigor<sup>®</sup> hybrid canola is safe for humans ?

The detailed assessment of the Bayer InVigor<sup>®</sup> hybrid canola application looked at the differences between these GM canola lines and non-GM canola *eg.* whether the new proteins were toxic or likely to trigger allergies. The assessment also looked at other changes that might result from the genetic modifications. The assessment (detailed in the *Risk Assessment and Risk Management Plan*) found that none of the new proteins were toxic or allergenic and the nutrient composition of this GM canola is the same as that of non-GM canola.

### 11. How is GM food assessed for safety ?

Food Standards Australia New Zealand (FSANZ) assesses, approves and sets standards for food and food ingredients. For more information see the [FSANZ website](#) and their information sheets.

Only the oil from (GM and non-GM) canola is used in food. Canola oil is highly refined during processing which removes all (GM and non-GM) DNA and the proteins it produces (the remaining canola meal is used as a high protein animal feed). FSANZ has approved the oil from all seven lines of Bayer's canola for human food use. The Final Assessment on the Bayer canola can be found on the [FSANZ website](#).

### 12. Do antibiotic resistant marker genes pose any health risks ?

No. Naturally occurring antibiotic resistance genes are often used as marker genes to help identify and select plants that have been successfully genetically modified.

The InVigor<sup>®</sup> hybrid canola which Bayer CropScience proposes to commercialise in Australia does not contain any antibiotic resistance genes. However, four of the seven GM canola types included in the application do contain an antibiotic resistance gene. The antibiotic resistance gene in the GM canola already occurs naturally in a wide range of bacteria. In addition, transfer of antibiotic resistance genes from GM plants to other organisms is considered highly unlikely.

### 13. Is there any risk from transfer of the introduced genes to humans or animals?

No. Most things that humans and animals eat contain millions of genes but they are broken down by the human digestive system. Even though we all eat plant genes in vegetables each day, no study has been able to demonstrate conclusively the presence of functional plant genes (or even plant gene fragments) in the human genome or that of any other animal. In the case of canola, the oil is highly refined which removes DNA in the process. Therefore it is extremely unlikely that any of the introduced genes could become incorporated into food and then transferred to humans.

## ENVIRONMENT

### 14. How can we be sure that the Bayer GM canola is not harmful to the environment?

The Bayer GM canola has been thoroughly assessed by a wide range of independent specialists with skills in ecology, biochemistry, agronomy, biology, molecular biology, genetics and agricultural science.

- The evaluation involved months of detailed assessment, including reviews of Australian and overseas research which is discussed in the *Risk Assessment and Risk Management Plan*.
- The *Risk Assessment and Risk Management Plan* received input from a wide range of experts and was made available for public scrutiny over a two month period. All health and environmental issues raised have been investigated.

- Despite every attempt to identify detrimental health or environmental hazards, the conclusion is that the Bayer GM canola is as safe as non-GM canola.

**15. Will the introduced Bayer InVigor<sup>®</sup> hybrid canola genes spread to other plants ?**

Yes. Some transfer of the herbicide tolerance gene will occur to other canola at a low level, and to a small number of related plants at an even lower level. Even if this does occur, it will not pose an environmental risk. Agricultural impacts can be managed by usual agricultural practices (including using the wide range of herbicides already used to control non-GM plants and weeds). The likelihood of the Bayer GM canola ‘outcrossing’ to unrelated plants is negligible.

**16. Will the Bayer InVigor<sup>®</sup> hybrid canola create ‘super weeds’ ?**

No. Like non-GM canola, the Bayer InVigor<sup>®</sup> hybrid canola is not invasive. The introduced hybrid breeding system cannot be transferred to other plants and tolerance to the herbicide glufosinate ammonium does not convey any competitive advantage unless that specific herbicide is used. Bayer’s InVigor<sup>®</sup> hybrid canola is the only broadacre crop on which glufosinate ammonium is registered for use in Australia. Any plant that acquired the glufosinate ammonium tolerance gene from the Bayer canola will be just as susceptible to all the other control measures that are currently used in agriculture.

**17. Will the Bayer InVigor<sup>®</sup> hybrid canola harm grazing / native animals ?**

No. The assessment of the Bayer GM canola is that it is as safe to humans and animals as conventional (non-GM) canola.

**18. Why haven’t you imposed any conditions on the Bayer InVigor<sup>®</sup> hybrid canola to protect against the development of herbicide resistance ?**

The Australian Pesticides and Veterinary Medicines Authority has conditions in place to deal with any possible future herbicide resistance issues (which for glufosinate ammonium are considered very low).

**MARKETING & SEGREGATION**

**19. Why haven’t you imposed any conditions on the Bayer InVigor<sup>®</sup> hybrid canola licence to separate GM canola from other plants ?**

Licence conditions are only imposed by the Gene Technology Regulator if there are risks to human health and safety or the environment that need to be managed.

Proposed industry supply chain management strategies (*eg. Gene Technology Grains Committee Canola Industry Stewardship Protocols for Co-existence of production Systems and Supply Chains* and *Bayer’s Canola Crop Management Plan*) promote good agricultural practice in relation to seed purity, cultivation, handling, transport *etc.* They are intended to enable the segregation of GM and non-GM canola to the level required by markets.

The risk assessment process considered the risks that might occur without *any* control measures and concluded that InVigor<sup>®</sup> hybrid canola is as safe for human health, safety and the environment as non-GM canola.

**20. Why doesn’t the OGTR assess marketing, trade or economic impact ?**

Feedback from extensive stakeholder consultation during the development of the *Gene Technology Act 2000* made it clear that the community wanted the regulatory system to focus exclusively on the protection of human health and safety and the environment. This is to prevent the possibility of decisions being influenced by economic considerations. This was agreed to by all Australian governments and Opposition parties. The States and Territories are

primarily responsible for economic development and market access issues in their respective jurisdictions.

**21. How do I find out more about marketing, trade or economic issues ?**

The Productivity Commission has issued a report [\*Modelling Possible Impacts of GM Crops on Australian Trade\*](#). [\*The Australian Bureau of Agricultural & Resource Economics \(ABARE\)\*](#) has also issued a report *Australian Grains Industry 2003-GM Canola. What are its economics under Australian conditions ?* .

Information on industry initiatives to promote co-existence of agricultural production systems is available from AVCARE.

**22. What has happened to the Monsanto Roundup ready GM canola commercial release application ?**

The Gene Technology Regulator still requires additional information about herbicide use issues related to the Monsanto GM canola application (DIR20). As soon as this information is provided and assessed, the Gene Technology Regulator can then release the Monsanto DIR20 Risk Assessment and Risk Management Plan.

**NOTE:** This document is intended as a guide only, for more detailed information please refer to the full *Risk Assessment and Risk Management Plan* and other associated documents available on the OGTR website.