

QUESTIONS & ANSWERS ON MONSANTO **ROUNDUP READY**[®] GENETICALLY MODIFIED (GM) CANOLA APPLICATION DIR020/2001

ABOUT THE GM ORGANISM

1. What is Roundup Ready[®] canola ?

Monsanto's Roundup Ready[®] canola has been genetically modified to be tolerant to the widely used, broad spectrum herbicide glyphosate. Glyphosate is the active constituent in a range of herbicides marketed under such trade names as Roundup[®] and Roundup Ready[®]. The genetic modification enables glyphosate to be sprayed on weeds that are growing in Roundup Ready[®] canola crops - without destroying the canola plants.

2. How does it work ?

Two new genes were introduced into an Australian canola variety to produce Roundup Ready[®] canola. One gene produces a version of an enzyme which is essential to the metabolism of the plant that (unlike the plant's own enzyme) can still function in the presence of glyphosate. The other gene expresses a protein that breaks down the glyphosate herbicide into harmless compounds. Neither of the proteins can interfere with the metabolism of humans or other animals.

3. How is Monsanto Roundup Ready[®] canola different from conventional (non-GM) canola ?

Traditional (non-GM) breeding techniques have previously enabled herbicide tolerant genes to be bred into conventional (non-GM) canola. For example, about 60% of all non-GM canola grown in Australia is tolerant to the herbicide atrazine. The main difference between this GM canola and conventional canola is that gene technology has been used to incorporate tolerance to the herbicide glyphosate.

4. How is this (Monsanto) Roundup Ready[®] canola different from the recently approved (Bayer) InVigor[®] canola ?

Roundup Ready[®] canola is tolerant to the widely used herbicide glyphosate whereas Bayer's InVigor[®] canola is tolerant to the less widely used herbicide glufosinate ammonium. InVigor[®] canola also incorporates a hybrid breeding system.

ABOUT THE EVALUATION PROCESS

5. Has the evaluation process 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, as is all relevant independent local and international research. Approximately 400 studies and papers have been reviewed as part of this evaluation, most of which are detailed in the 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 evaluation of applications involving GM canola.

6. Did the Regulator consider the results of the UK Farm Scale Evaluations in her assessment of Roundup Ready® canola?

Yes, the Regulator considered a wide range of information and research from both Australia and overseas including a detailed consideration of 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. In two of three species tested, better weed control was achieved with the GM plants, leading to reductions in insects that rely on those weeds. 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 Roundup Ready 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.

More information on the UK FSE can be obtained at:
www.defra.gov.uk/environment/gm/fse/index.htm

ABOUT THE LICENCE DECISION

7. How soon will Roundup Ready® canola be released on a commercial basis ?

The approval of this application on human health and environmental safety grounds is not expected to result in the immediate large scale commercialisation of GM canola. The extent of Roundup Ready® canola plantings will be limited and determined by consultations between industry and State and Territory governments. This is because the development of the national gene technology regulatory system was undertaken jointly by all Australian jurisdictions and recognised that primary responsibility for economic development issues lies with the States and Territories. Therefore a number of jurisdictions have introduced interim measures pending resolution of market access and segregation issues.

8. Has Roundup Ready® canola received any other approvals ?

Roundup Ready® canola has been approved for a number of trials under limited and controlled conditions in Australia since 1997 and has already been approved for commercial release in Japan, Canada and the USA. Oil from Roundup Ready® canola is approved for food use in these three countries plus Australia and Europe.

9. Why has it taken so long to make a decision ?

The Roundup Ready® canola application was received in June 2002. After a preliminary assessment, the Gene Technology Regulator decided that she required additional information and stopped the 170-day application ‘clock’. The ‘clock’ remained stopped until the Regulator was satisfied that the additional information, particularly on the potential impact of the proposed release on herbicide resistance, had been received. Only after this information had been analysed could the Regulator release the consultation version of *the Risk Assessment and Risk Management Plan*, in October 2003.

An extended consultation period of 8 weeks was provided for public comment and the Regulator held ongoing consultation with the Agricultural Pesticides and Veterinary Management Authority which had been considering a parallel application for permission to use the herbicide Roundup Ready® on Roundup Ready® canola. The Regulator has now completed her consideration of all the comments provided by the public, expert groups and other stakeholders.

10. Why couldn't just one regulator make a decision on the use of Roundup Ready® Canola ?

The *Gene Technology Act 2000* is designed to operate in a cooperative legislative framework with other regulatory authorities that have complementary responsibilities and specialist expertise. As well as enhancing coordinated decision making, this arrangement avoids duplication.

The Gene Technology Regulator is responsible for the evaluation of all applications for contained research and early stage trial work with GMOs in Australia. However, once a GMO reaches later stage development or commercial application, other product approval authorities also have a role. For example Food Standards Australia New Zealand (FSANZ) sets the standards for safety and labelling of foods for human consumption, irrespective of whether they are, or were produced by, GMOs. Approvals may be sought for imported foodstuffs, prior to seeking approval from the Regulator to grow the crop in Australia. Similarly, the APVMA is responsible for assessing the safety and ensuring the efficacy of all agricultural chemicals and veterinary medicines. Insecticidal GM crops must also be registered by the APVMA and the use of herbicides on GMOs (such as Roundup Ready® herbicide on Roundup Ready® canola) requires assessment and registration.

HUMAN HEALTH & SAFETY

11. How can we be sure that the Monsanto Roundup Ready® canola is safe for humans ?

The detailed assessment of the Monsanto Roundup Ready® canola application looked at the differences between this GM canola and non-GM canola *ie.* whether the new proteins expressed by the introduced genes were toxic or likely to trigger allergies. The assessment also looked at other changes that might result from the genetic modifications (as detailed in the *Risk Assessment and Risk Management Plan*). None of the new proteins were found to be toxic or allergenic and the nutrient composition of this GM canola is the same as that of non-GM canola.

12. How is GM food assessed for safety ?

Food Standards Australia New Zealand (FSANZ) assesses, approves and sets standards for food and food ingredients and is responsible for food labelling. Food produced using gene technology is required to undergo a mandatory pre-market safety assessment by FSANZ. More information is available at www.foodstandards.gov.au/whatsinfood/gmfoods/index.cfm. Only the oil from canola seeds (for both GM and non-GM) is used in human food. Canola oil is highly refined during processing which removes both GM and non-GM genetic material (DNA) and proteins. The remaining canola meal is used as a high protein animal feed. FSANZ approved the use in food of oil derived from Roundup Ready® canola in 2000 (see <http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa363foodp951.cfm>)

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 mammalian digestive systems. 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 or any other animal genome. 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 or animals.

ENVIRONMENT

14. How can we be sure that the Monsanto Roundup Ready® canola is not harmful to the environment ?

Monsanto's proposal to commercially release Roundup Ready® canola has been thoroughly assessed by a wide range of independent specialists with skills in many disciplines, including ecology, biochemistry, agronomy, biology, molecular biology, genetics and agricultural science. The evaluation has involved months of detailed assessment, including input from a wide range of expert groups and authorities and detailed reviews of Australian and overseas research, all of which are discussed in the *Risk Assessment and Risk Management Plan*.

15. Will the Monsanto Roundup Ready® canola harm grazing / native animals ?

No. The proteins produced by the introduced genes in Roundup Ready® canola are not toxic, nor are the compounds into which the herbicide is broken down. The Risk Assessment has found that canola seed and meal derived from Roundup Ready® canola is as safe as non-GM canola seed and meal.

16. Will the commercial release of Roundup Ready® canola result in increased use of glyphosate and promote development of resistance ?

Glyphosate is a very important agricultural chemical with a broad spectrum action, low toxicity to animals and microbes, and minimal persistence in the environment. Glyphosate was not previously registered for use on canola crops and therefore separate approval was required from the APVMA before Roundup Ready® herbicide could be used on Roundup Ready® canola for weed control. The APVMA intends to ensure that glyphosate (and all approved herbicides) remains effective for as long as possible. Therefore the risk of herbicide resistance was comprehensively assessed and addressed by the APVMA placing registration conditions on the uses of the herbicide including:

- implementation of Monsanto's Roundup Ready® canola resistance management plan;
- reporting of resistance incidents to the APVMA; and
- establishment of an industry/expert/government herbicide resistance consultation group.

17. Will the commercial release of Roundup Ready® canola result in increased use of more toxic or persistent herbicides ?

Mixtures of herbicides are commonly used to achieve effective weed control. The adoption of Roundup Ready® canola may mean that different herbicides may need to be used, particularly where glyphosate is currently the only herbicide used for weed control. Over-reliance on any one herbicide is not good agricultural practice. Integrated weed management practices *eg.* alternating herbicides and using mechanical methods, are preferable to avoid resistance development. The APVMA assesses all herbicides used in Australia for safety and sets their conditions of use. The APVMA can also undertake a review of herbicides. For example, the herbicides 2, 4-D (one of the most commonly used tank-mix herbicides) and atrazine (currently used with TT Canola) are currently under review by the APVMA.

18. Will the Roundup Ready® canola genes spread to other canola crops ?

Some transfer of the herbicide tolerance gene will occur to other canola at a low level. Like non-GM canola, Roundup Ready® canola is not invasive and remains susceptible to all approved non-glyphosate herbicides, cultivation practices and other environmental factors (such as climate). Therefore, conventional canola plants that acquire the herbicide tolerant gene can be controlled, if necessary, in the same way as Roundup Ready® canola.

19. Will the Roundup Ready® canola genes spread to other plants and create ‘super weeds’ ?

Some transfer of the herbicide tolerance gene will occur to a small number of compatible plants but at a lower level and over a longer timeframe than to other canola. Even if this does occur, it will not pose an environmental risk. Weeds which acquire the herbicide tolerance gene only have a survival advantage when glyphosate is used to control them. The plants remain susceptible to all approved non-glyphosate herbicides, cultivation practices and other environmental factors (such as climate). A number of weeds cannot be controlled by glyphosate. Therefore it is not uncommon for mixtures of herbicides to be used in this situation. The conditions of use of all registered chemicals are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

MARKETING & SEGREGATION

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.

For this reason, the *Gene Technology Act 2000* anticipated that these governments may choose to respond to market access issues in relation to the commercial introduction of GM crops. The recently enacted *Gene Technology (Recognition of Designated Areas) Principle 2003* allows for recognition of GM or non-GM designated areas under State or Territory legislation for marketing purposes. The Principle is designed to ensure the valid operation of these State and Territory laws. More information on the policy principle is available from the Gene Technology Ministerial Council's website at www.tga.gov.au/gene/gtmc.htm#policy

21. Why hasn't the Gene Technology Regulator imposed conditions on the Monsanto Roundup Ready® canola licence to separate GM canola from other plants ?

Licence conditions are imposed by the Gene Technology Regulator where there are risks to human health and safety or the environment that need to be managed. The occurrence of glyphosate tolerant plants (both canola and related weedy species) as a result of transfer of the herbicide tolerance gene from Roundup Ready® canola does not pose an environmental risk. This is because unwanted canola and related weeds can be effectively managed by using approved herbicides and mechanical controls already in common use. The introduction of genetically modified canola will require economic decisions to be made by farmers. However, potential economic implications are excluded from consideration in assessments conducted under the *Gene Technology Act 2000*. The costs incurred will depend on the management methods, segregation thresholds and supply chain management processes adopted by the sector to meet perceived market access requirements.

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

The Australian Bureau of Agricultural & Resource Economics (ABARE) has issued two relevant reports on market impacts: *Market Access Issues for GM Products* and *Australian Grains Industry 2003-GM Canola. What are its economics under Australian conditions ?*. These reports are available free from www.abareonlineshop.com/product.asp?prodid=12559 and www.abareonlineshop.com/product.asp?prodid=12526 respectively. ABARE has also produced a report entitled *Agricultural Biotechnology: Potential for use in developing countries* available from www.abareonlineshop.com/product.asp?prodid=12594

The Department of Agriculture, Fisheries and Forestry has a number of papers available including Gap analysis of existing quality assurance systems for handling GM and non-GM products and Genetically Modified Organisms and Liability Issues. These and other papers may be found at <http://www.affa.gov.au/content/output.cfm?ObjectID=5A53B336-FC4E-411E-8C06A9D82C6AE0C9&contType=outputs>

The Productivity Commission has issued a report *Modelling Possible Impacts of GM Crops on Australian Trade* available at www.pc.gov.au/research/staffres/gmcrops/index.html.

Information on industry initiatives to promote co-existence of agricultural production systems is available at http://www.avcare.org.au/default.asp?V_DOC_ID=887

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