Environment & Public Affairs Committee

Inquiry into

MECHANISMS FOR COMPENSATION FOR ECONOMIC LOSS TO FARMERS IN WESTERN AUSTRALIA CAUSED BYCONTAMINATION BY GENETICALLY MODIFIED MATERIAL

Submission by the Pastoralists & Graziers Association of WA

16 February 2018

The Pastoralists and Graziers Association of WA (PGA) welcomes the opportunity to contribute to the Inquiry being undertaken by the Environment and Public Affairs Committee.

The PGA would welcome the opportunity to appear before the Committee as a witness, should hearings be part of the inquiry process.

PGA

The PGA is a non-profit industry organisation established in 1907, which represents primary producers in the agricultural and pastoral regions of Western Australia. Members include freehold farmers (including grain producers) and pastoral leaseholders, through the full spectrum of some of Australia's largest corporate pastoral groups to family-owned companies and trusts and individual landholders in Western Australia.

The PGA's core and guiding principles are self-reliance, property rights, free markets, competition, small government and reduced regulations.

BACKGROUND

Since the introduction of GM crops in 1996 our grain growing competitors in the United States, Canada, Brazil, Argentina and India have rapidly adopted GM technology.

In Canada the canola grown each year is 98% GM. Their industry has been dramatically transformed by an enviable expansion.

The Canadian canola crop in 1996 was 5.03mmt, in 2006 it was 9.1mmt and in 2016 it produced 18.4mmt. Canola contributes $26.7 billion per annum to the Canadian economy.

Roundup Ready GM canola was approved for use throughout Australia in 2003 by the OGTR but banned in Western Australia from 2003 until 2009.

Our direct Canadian competitors have enjoyed, since 1996, some 20 years of unhindered advances in GM canola varieties while the Australian canola industry was floundering under the weight of State based bans on the production of GM canola.

But since State approval was granted in 2010, GM canola has been widely adopted, now being about 35% of the canola planting in Western Australia. This technology has delivered tangible benefits not only to growers but industry as a whole, including:

- Strong management of herbicide resistant weeds
- Increased farm profitability
- Diversity in crop rotations
- Reduction in herbicide use

Co-existence between producers of GM and non-GM canola producers has been successfully maintained by highly effective segregation practices throughout the supply chain and on farms where many GM canola growers also grow non-GM canola.

MONSANTO INC v. PERCY SCHMEISER

The facts and findings in this case are frequently misrepresented by opponents of GM Canola. In this case, the Canadian Federal Court found that Percy Schmeiser deliberately infringed upon Monsanto's patent by retaining GM Canola seed and planting it without a license.

Mr Schmeiser claimed that in 1997 he sprayed a three acre field of suspected GM Canola with Roundup (if this was true he would have killed the non-GM canola plants and the Roundup Ready plants would have survived). Schmeiser then harvested the remaining plants, segregated the seed and planted the seed without a license in 1998 on just over 1,000 acres of his farm.

He claimed in Court that the plants spontaneously appeared. The trial Judge found:

> *"Mr. Schmeiser complained that the original plants came on his land without his intervention. However, he did not at all explain why he sprayed Roundup to isolate the Roundup Ready plants he found on his land; why he then harvested the plants and segregated the seeds, saved them, and kept them for seed; why he planted them; and why, through his husbandry, he ended up with 1,030 acres of Roundup Ready canola which would have cost him $15,000."*

Mr Schmeiser did not grow just a few Roundup plants as claimed. The trial Judge found that *"tests revealed that 95 to 98 percentage of this 1,000 acres of canola crop was made up of Roundup Ready plants"* and that *"none of the suggested sources [proposed by Schmeiser] could reasonably explain the concentration or extent of Roundup Ready canola of a commercial quality ultimately present in Schmeiser's crop."*
The transcript of the judgment can be found at:

http://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/38991/index.do

http://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/31360/index.do

Monsanto has never taken action for breach of its Roundup Ready patent against any grower in circumstances where the growing of the Roundup Ready canola has been accidental or adventitious (contrary to frequent misrepresentations by the opponents of GM Canola).

THE SCOPE OF THE INQUIRY

The wording *"inquiry into mechanisms for compensation of economic loss to farmers in Western Australia caused by contamination by genetically modified material"* appears to proceed on the assumption that the need for a compensation system has been established. In keeping with principles of fairness and natural justice, it is critical that the need for a compensation system is established before the inquiry proceeds to consideration of a compensation system.

In an interview on the ABC Country Hour on 6 February 2018 the Honourable Alannah MacTiernan (Minister for Agriculture and Food) stated that the parliamentary committee has decided to have a look at whether a system which relies on negligence is adequate or whether there should be a system of strict liability.

Accordingly, the Minister for Agriculture is clearly of the understanding that the inquiry should address the first issue which is whether in Western Australia there is a need to change the law as to liability of a GM Canola farmer to a neighbouring farmer for the adventitious entry of GM Canola plant material on to another farm.

In *Marsh v. Baxter [2014] WASC 187* the trial Judge, Justice Kenneth Martin dismissed Mr Marsh's claim for damages on grounds including:

- Mr Baxter's decision to grow and swathe the GM Canola crop was made for sound agricultural reasons, including the control of herbicide resistant weeds, increased yield and as part of a crop rotation programme;
- Mr Baxter in growing GM Canola and in swathing it had acted reasonably;
- Mr Baxter's farming practices were within keeping with farming standards in the district;
- Mr Baxter had not been negligent;
- Mr Baxter could not reasonably foresee before swathing the GM Canola crop that Mr & Mrs Marsh may be decertified and thereby suffer economic loss if GM Canola plant material was carried by strong winds onto their organic farm;
- NCO/NASAA had wrongfully decertified part of Eagle Rest and denied the Marsh's contractual right to use the label 'NASAA Certified Organic' on their Eagle Rest produce by not correctly applying the NASAA Standards (in the subsequent appeal to the WA Court of Appeal Justices Newnes and Murphy held that it was not necessary to rule on the application of the NASAA Standards to the case because the Marsh's appeal was to be dismissed on other grounds);
- GM Canola is not toxic, dangerous or harmful to humans and animals and is incapable of transferring its genetic material to wheat, barley, oats or any crops grown in Western Australia other than canola;
- The Marsh's did not grow canola;
- Mr Baxter was not liable to the Marsh's in the action of nuisance because Mr Baxter's actions in planting, growing and swathing GM Canola on his farm were reasonable and in keeping with farming practice in the district;
- The adventitious entry of the GM Canola plant material onto Eagle Rest did not cause damage to the land, animals or crops on that farm. Accordingly, there was no damage to property and the Marsh's claim was one for pure economic loss only.

The Marsh's had brought actions in nuisance and negligence against Mr Baxter. Justice Martin dismissed both actions. In the nuisance action it was not necessary for the Marsh's to establish that Mr Baxter had been negligent, but it was necessary to establish that Baxter's conduct in growing or swathing GM Canola was unreasonable.

STRICT LIABILITY

Reasonableness is at the very heart of the common law in Australia. In recent years the High Court of Australia has ruled that the general law of negligence applies to claims for damages arising out of the escape of dangerous substances (in *Burnie Port Authority v. General Jones Pty Ltd [1994] 179 CLR 520,* the High Court ruled that the strict liability principle in *Rylands v. Fletcher [1868] UKHL 1* was no longer good law and that the tort of negligence (not strict liability) applied to such cases).

The move in Australia away from strict liability has been brought about by the common laws pursuit of fairness, justice and reasonableness. The introduction of strict liability can have unforeseen consequences e.g., in the case of GM Canola, there is nothing to prevent an idealistic third party from potentially collecting and moving GM plant material from a farm to an organic farm for the purpose of triggering a compensation claim or to attract the media creating adverse publicity for GM Canola farmers etc.

In July 2011 Greenpeace Activists attacked the CSIRO GM wheat trial crop at the Ginnenderra Experimental Station in Canberra inflicting about $300,000 damage. The wheat trial was experimental for the development of a wheat flour suitable for diabetics.

The introduction of strict liability will increase the likelihood that an organic farmer's certifying organisation may unnecessarily decertify the organic farmer as occurred in *Marsh v. Baxter.*

There are very few examples of strict liability law surviving in Australia. The *Civil Aviation (Carriers' Liability) Act* is one such example, but it is complimentary to the International Warsaw System Conventions. It remains to be seen whether the common law strict liability rule for cattle trespass (where cattle stray from one farm to another and do damage) will survive *Burnie Port Authority v. General Jones Pty Ltd.*

STANDARDS FOR ORGANIC AND BIO-DYNAMIC PRODUCE

The National Standard for organic and biodynamic produce (last updated 1 September 2016) is the Australian Export Standard for Products Labelled Organic or Biodynamic administered by the Commonwealth Department of Agriculture and Water Resources.

Section 1.1.9:

> *"Where product has been contaminated with non-permitted substances as a result of factors beyond the control of the certified operator, then ...*
> *product known to be contaminated by genetically modified organisms, or their by-products must be excluded from sale."*

Section 1.3.1:

> *"The use of genetically modified organisms or their derivatives is prohibited. This includes but is not limited to, animals, seed and farm inputs such as fertilisers, soil conditioners, vaccines, crop production materials, food additives or processing aids."*

Section 1.3.2:

> "*Operators shall implement a risk management process to assess how they will avoid the accidental introduction of genetically modified organisms to the organic farm. These actions may include, but are not limited to:*
>
> - *knowing about contaminant risks*
> - *implementing distances / buffer zones from potential contaminants*
> - *implementing special handling, transport and storage arrangements*
> - *maintaining samples*
> - *testing a crop perceived at risk."*

Section 1.3.5:

> *"The certification of organic crops, livestock or agricultural products will be withdrawn where genetically modified crops, live stock or agricultural products are grown or produced on the same farm."*

Section 4.2.6:

> *"Sampling and analytical testing will be conducted by the certifying organization as part of the certification process. This may be soil or product, or both.*

Section 4.3:

*"**Sanctions***

General Principles

- *Sanctions are imposed on certified operators for any breach of this Standard. Depending on the severity of the breach, the sanctions may range from a direct instruction to correct a minor discrepancy; additional inspections; suspension of operations; or de-certification of the certified operation where the infringement is significant."*

Standards

4.3.1 An inspection report may result in a condition or conditions being imposed on the operator with timelines for compliance.

4.3.2 Failure of the certified operator to comply with any condition may result in additional inspections as determined by the approved certifying organisation.

4.3.3 Suspension may be applied at any time to the certified operator by the approved certifying organisation where there is reason to believe that the organic or bio-dynamic integrity of the product has been compromised."

THE NATIONAL GUIDELINE

On 4 January 2018 the Commonwealth Department of Agriculture and Water Resources released *"A Guideline for Responding to Contamination by Prohibited Substances or Materials in the Organic Export Supply Chain (2018-01)".* The guideline is attached (**Attachment 1**).

The notice *"provides guidance in responding to unnecessary intentional use, negligent introduction and accidental introduction or necessary intentional use of prohibitive substances or materials, including the presence of genetically modified materials and organisms."*

The guidelines in essence recommend moderation in the appliance of sanctions.

Principle 4:

> *"Sanctions applied in response to contamination by prohibitive substances or materials, including the presence of genetically modified materials and organisms, should be proportional to the instance of contamination."*

Principle 10:

> *"Repetitive contamination incidents that result from unnecessary intentional use of prohibitive substances or materials or negligent introduction of prohibitive substances or materials may result in the application of higher grade sanctions. An incident is considered repetitive if the same non-compliance occurs within three years of the previous incident."*

Action 12:

> *"When contamination by prohibitive substances or materials is evident, including the presence of genetically modified materials and organisms, the operator must take immediate corrective action to ensure the integrity of the organic production system is not further compromised."*

Action 14:

> *"The approved certifying organisation should assess the contamination incident against its approved QM manual to determine the appropriate response."*

Accordingly, the adventitious entry of GM Canola plant material onto on organic farm should not lead to decertification. There are six Australian organic certifying organisations including NAASA approved by the Department of Agriculture and Water Resources.

THE NAASA ORGANIC STANDARD

The NAASA Organic Standard has been amended since the *Marsh v. Baxter* trial.

Relevant clauses of the NAASA Standard are:

Section 1.1: Definitions

> *"**Contamination:** Contact of organic crops, animals, land or products with any substance that would compromise the organic integrity."*

Section 2.10:

> *"**SANCTIONS***
> ***GENERAL PRINCIPLES***
> *Sanctions may be imposed when there are non-compliances or non conformities to this Standard. An operator unable to demonstrate compliance with this Standard may be subject to the following:*
> • *Suspension: A defined period, ordinarily no greater than two weeks, during which an operator must provide verification of compliance with this Standard following notification of non-compliance with any section of this Standard. During this period an operator must not sell produce with reference to certification.*
> • *Decertification: Either partial or total withdrawal of certification as a result of ongoing non-compliance with the Standard, following a period of suspension.*
> • *Termination: cancellation of the operators contract following a period of suspension or decertification*
> ***STANDARDS***
> *2.10.1 Manifest non-compliance with this Standard such as mixing organic and conventional products will result in decertification.*
> *2.10.2 Failure to observe contract conditions will result in suspension until compliance is demonstrated.*
> *2.10.3 Ongoing failure to observe contract conditions will result in decertification.*
> *2.10.4 Additional inspections will be scheduled at the operator's cost where previous serious non-compliance has been observed.*
> *2.10.5 Failure to complete the Annual Return, complete a certification contract, pay levies and/or associated costs of certification will result in suspension and possible decertification."*

Section 3.2:

*"**GENETICALLY MODIFIED ORGANISMS***

GENERAL PRINCIPLES

Organisms, which are derived from recombinant DNA technology, are genetically modified organisms and have no place in organic production and processing systems. The NASAA Organic Standard prohibits the presence of GMO's either deliberate or accidental in any segment of the organic food chain.

RECOMMENDATIONS

Every potential source of GMOs in the supply and input chain, and any sources from historic or adjacent usage, should be identified and operators should familiarise themselves with the vectors and modes of potential transfer of material with modified DNA to avoid contamination.

STANDARDS

3.2.1 The accidental, deliberate use and/or the negligent introduction of genetically engineered organisms or their derivatives to organic farming systems or products are prohibited. This includes, but is not limited to:

- *seed*
- *feed*
- *propagation material*
- *farm inputs such as fertilisers and compost*
- *vaccines*
- *crop protection materials*
- *Downstream products*

3.2.2 Operators using input materials at risk of containing GMOs must obtain signed statements from the suppliers of these materials that they do not contain GMOs or their derivatives, backed up by laboratory analysis where deemed necessary.

3.2.3 <u>The certification of organic crops will be withdrawn where genetically engineered crops are grown on the same farm</u>.

3.2.4 Operators must not use ingredients, additives or processing aids derived from GMOs in certified products. Processing operations that handle GMOs in conventional products will need to develop a detailed risk strategy for prevention of contamination of certified product.

3.2.5 <u>Operators must not knowingly permit exposure or fail to take action against the application of or exposure to GMOs. The NASAA Organic Standard, December 2004, Amended 06/02/2012, February 2016 Page 26 of 120</u>.

3.2.6 Inputs, processing aids and ingredients shall be traced back one step in the biological chain to the direct source organism from which they are produced to verify that they are not derived from GMOs.

3.2.7 Operators must conduct an assessment of risks from contamination with GMOs and take action where appropriate. These actions may include, but are not limited to:

- *knowing about contaminant risks*
- *implementing distances/buffer zones from potential contaminants*
- *implementing special handling, transport and storage arrangements*
- *maintaining samples*
- *testing of crops perceived at risk*

3.2.8 Planting or sowing for organic production will not take place until 5 years after the harvest (or removal) of any genetically engineered crop that may have been planted on the land.

3.2.9 Contamination by GMO's that results from circumstances beyond the control of the operator may alter the organic status of the operation.

3.2.10 Any products that are tested and reveal the presence of GMO's will be decertified."

It is clear that the Standards in section 3.2 do not require the withdrawal of organic certification unless the operator intentionally grows GM crops on the organic farm or testing of the organic produce reveals the presence of GMO's (Standards 3.2.3, 3.2.9, 3.2.10).

CONTAMINATION OF ORGANIC PRODUCE

Uncontradicted expert evidence given at the *Marsh v. Baxter* by Dr Patrick Rudelsheim (a world renowned expert) established that the produce on Mr Marsh's organically certified produce could not contain genetically modified material or residue because GM Canola is incapable of transferring its genetic material or residue to plants (other than members of the Brassica family of plants. Canola is a member of the Brassica family) or animals. Mr Marsh did not grow canola. A copy of Dr Rudelsheim's expert report is attached (**Attachment 2**). Dr Rudelsheim's expert evidence was accepted by Justice Martin at the trial and was not contradicted by Dr Rene Van Acker (world renowned scientist), who was called to give expert evidence at the trial by Marsh. It emerged at trial that Dr Van Acker had been requested not to answer a question which had been raised in the letter of instruction from Mr Marsh's lawyers as to whether GM

Canola was toxic or in any way harmful to the land, people, animals or plants. The explanation as to why he was requested not to answer the question is obvious.

Canola is not suitable for organic farming in Western Australia because without the application of herbicides and pesticides (which are prohibited by Organic Standards) the crop will be incapable of successfully competing with weeds and susceptible to insect attack.

DECERTIFICATION FOR ADVENTITIOUS ENTRY OF GMO'S

Accordingly, it is open to NASAA and other organic certifying organisations not to decertify an organically certified farm in response to the adventitious entry of GM Canola plant material and it is consistent with the National Guidelines not to do so.

The solution is in the hands of the organic certifying organisations. To the extent (if any) that organic standards make decertification a mandatory sanction in the event of the adventitious entry of GM Canola plant material, such standards should be amended to remove the mandatory decertification sanctions consistent with the National Guides.

NON-GM CANOLA FARMERS

An expert report from Dr Christopher Preston who gave evidence in the *Marsh v. Baxter* trial is attached (**Attachment 3**). In that report Professor Preston states at:

6. "*The research I have been involved in discussed above has demonstrated that GM Canola can cross pollinate with other varieties of canola. On a field basis, the rates of cross pollination are typically low, but can be as high as 0.8%. Cross pollination is more likely when the crops are planted within 10 mm and declines rapidly with distance. There has not been one incident when non-GM canola crop seed grown in Western Australia has on testing been rejected for reason of GM Canola cross pollination. GM Canola has now been grown in Western Australia for seven years without any adverse impact on the canola produced by non-canola farmers. The same result can be said for experience in the other Australian States where the growing of GM Canola is permitted.*"

And at:

7. *"The Australian Oilseed Federation (AOF) produces oilseed delivery standards for Australia under the auspices of Grain Trade Australia, previously NACMA. The AOF canola delivery standard for non-GM canola CSO 1-a, states that under the standard:*

> *"The adventitious presence of up to 0.9% of GM events approved by the Australian Government Office of the Gene Technology Regulator is permitted".*

This value was set in order to meet international market requirements for non-GM canola. The value is consistent with the EU requirements for adventitious presence in canola seed."

Approximately 34% of the Canola grown in Western Australia in 2017 was GM Canola (Emma Field Weekly Times 11 July 2017 - **Attachment 4**).

CO-EXISTENCE

There has been no reported incident in Australia of the entry of GM Canola material onto an organic farm since *Marsh v. Baxter.* There is a long history in Australia that within a farming community, farmers freely and willingly go to the aid of other members of the community in their hour of need. Voluntary fire fighting, seeding, harvesting, lending of equipment, provision of grain and other forms of voluntary assistance too numerous to mention are a regular part of the exchange between farmers.

There is nothing to prevent the co-existence of organic farming, and conventional farming (including the growing of GMO crops) in Western Australia.

Had commonsense prevailed in *Marsh v. Baxter* NASAA would have advised the Marsh's to collect and remove the GMO plant material which had blown onto Eagle Rest. Mr Baxter would have assisted them to do so (and did offer to do so). NASAA, on the correct interpretation of its Standards, would not have removed the Marsh's organic certification and the produce of Eagle Rest could have gone to the market as certified organic (and with zero GM presence).

As matters transpired the GM plant material remained on Eagle Rest ungathered for weeks.

It was established by expert evidence at the *Marsh v. Baxter* trial that GM volunteer plants can be readily identified and removed before harvest. As it was very few GM volunteer plants appeared on Eagle Rest. It is the spirit and good will of the farming tradition through which problems such as the adventitious arrival of GM plant material on an organic farm should be resolved not litigation, harsh and unjust interpretation of organic standards and the introduction of an inequitable strict liability compensation scheme which will create division and ill feeling within the farming community.

A COMPENSATION SCHEME IS NOT THE SOLUTION

It will be practically impossible to develop a strict liability compensation scheme which is not unfair and inequitable. Such a scheme will be open to exploitation and will require one section of the farming community to become the insurer of another farmers business if GM farmers are required to contribute directly or indirectly to a compensation fund (and in a setting where strict liability for pure economic loss is unwisely proposed). This will represent an added cost to their farming operations when GM Canola seed is relatively expensive but an essential tool for many farmers in their fight against herbicide resistant weeds and their pursuit of higher yields and more efficient farming practices.

A compensation scheme is unnecessary because with a proper and fair application of organic standards and commonsense an organic operator should be able to present certified organic produce to the market regardless of the adventitious arrival of GM plant material onto his organic farm.

The incidence of adventitious entry of GM Canola onto organic farms in Western Australia is extremely rare. Response to the risk of such adventitious entry by the establishment of a compensation scheme is a gross overreaction which if implemented will come at a great cost to GM farmers and the farming community generally.

Submitted on behalf of the PGA

Mr Gary McGill
Chairman - PGA Western Graingrowers Committee

Guideline for responding to contamination by prohibited substances or materials in the organic export supply chain - (2018-01)

Date of issue: 4 January 2018

Attention:

- Organic Industry Standards and Certification Council
- Organic Federation of Australia
- Organic Certifying Organisations
- Organic and Biodynamic Exporters

Purpose

1. This notice provides guidance in responding to unnecessary intentional use, negligent introduction and accidental introduction or necessary intentional use of prohibited substances or materials, **including the presence of genetically modified materials and organisms.**
2. This guideline is to be read in conjunction with the **Export Control (Organic Produce Certification) Orders, the National Standard for Organic and Bio-Dynamic Produce and the Government Administrative Arrangements for Approved Certifying Organisations Managing Inspection and Certification Programs for the Export of Certified Australian Organic and Biodynamic Produce.**
3. This guideline replaces Industry Advice Notice 2015/04 and Industry Advice Notice 2016/02.

Principles

4. Sanctions applied in response to contamination by prohibited substances or materials, including the presence of genetically modified materials and organisms, should be proportional to the instance of contamination.
5. Sanctions applied in response to a contamination incident should take into account:
    a. the cause of the contamination. Sanctions should consider whether the contamination resulted from unnecessary intentional use, negligent introduction, accidental introduction or necessary intentional use of prohibited substances or materials.
    b. the extent of the contamination. Sanctions should consider whether the contamination affects the organic production unit, the off production unit procedures or the organic produce itself.
    c. the permanence of the contamination. Sanctions should consider whether the contamination has a permanent effect, a persistent effect or no persistent effect.
    d. the treatment of the contamination. Sanctions should consider whether the contamination is rectifiable. For example, whether the contamination can be removed, isolated or contained.
6. Graduated sanctions available in response to a contamination incident include corrective action requests (CARs), suspension and decertification.
7. Suspension may be applied to an entire organic production system (full suspension) or parts of an organic production system (partial suspension). Partial suspension should be applied where the contamination can be isolated or contained from compliant elements of an organic production system.
8. Decertification only applies to an entire organic production system; an organic production system cannot be partially decertified. Where part of an organic production system is considered to be permanently ineligible, the affected part of the system should be permanently removed from the operator's approval.
9. Following an identified or reported contamination incident, it may be necessary for an approved certifying organisation to apply an interim suspension on the organic production system to allow for the extent, severity and treatment of the contamination incident to be investigated.
10. Repetitive contamination incidents that result from unnecessary intentional use of prohibited substances or materials or negligent introduction of prohibited substances or materials may result in the application of higher grade sanctions. An incident is considered repetitive if the same non-compliance occurs within three (3) years of the previous incident.
11. Not addressing a corrective action request within the stipulated terms may result in the application of higher grade sanctions.

Actions

12. When contamination by prohibited substances or materials is evident, including the presence of genetically modified materials and organisms, the operator must take immediate corrective action to ensure the integrity of the organic

production system is not further compromised.

13. When contamination by prohibited substances or materials is evident, including the presence of genetically modified materials and organisms, the operator should immediately notify their approved certifying organisation. Notification should include an assessment of the cause, extent, permanence and treatment of the contamination.
14. The approved certifying organisation should assess the contamination incident against its approved QM manual to determine the appropriate response.

Note: An approved certifying organisation may stipulate additional requirements and may set limits that are higher than those published in the National Standard for Organic and Biodynamic Produce.

15. When contamination by prohibited substances or materials is evident and cannot be adequately assessed from the operator's notification, it may be necessary for the approved certifying organisation to impose an interim suspension on the organic production system while the contamination incident is investigated.
16. Attachment A provides guidance on graduated sanctions available in response to an assessment or investigation of a contamination incident.

Background

17. The *Export Control (Organic Produce Certification) Order 2005* is the legal basis for the export of produce/goods labelled as organic or biodynamic.
18. The National Standard for Organic and Biodynamic Produce (national standard) details primary production and processing requirements for organic and biodynamic produce/goods for export.
19. Industry Advice Note 2015/04 was issued in October 2015 for a 6 month trial period. This notice reflects feedback and experience during the trial period.

ATTACHMENT A

Table 1 – Sanctions available in response to unnecessary intentional use of prohibited substances or materials, including genetically modified organisms and materials

CAUSE OF NON-COMPLIANCE	EXTENT OF NON-COMPLIANCE	OUTCOME OF SEVERITY ASSESSMENT/INVESTIGATION BY THE APPROVED CERTIFYING ORGANISATION		ACTIONS
Unnecessary intentional use of prohibited substances or materials, including the presence of genetically modified organisms and materials	**Organic Production Unit**	**Minor**	No persistent contamination, effective treatments applied	Suspend organic production system Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved Issue Letter of Warning regarding repetition
		Moderate	Some persistent or permanent contamination, effective treatments applied or available	Suspend organic production system Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved Issue Letter of Warning regarding repetition
		Major	Permanent contamination, effective treatments not available	Decertify organic production

CAUSE OF NON-COMPLIANCE	EXTENT OF NON-COMPLIANCE	OUTCOME OF SEVERITY ASSESSMENT/INVESTIGATION BY THE APPROVED CERTIFYING ORGANISATION		system ACTIONS
			Any repeat instance of unnecessary intentional contamination of the organic production unit	
	Off Production Unit Processes	Minor	No persistent contamination, effective treatments applied	Suspend organic production system Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved Issue Letter of Warning regarding repetition
		Moderate	Some persistent or permanent contamination, effective treatments applied or available	Suspend organic production system Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved Issue Letter of Warning regarding repetition
		Major	Permanent contamination, effective treatments not available	Decertify organic production system
			Any repeat instance of unnecessary contamination of the off production unit procedures	
	Organic Produce	Minor	**Contamination** level does not exceed the requirements of the Approved Certifying Organisation, relevant Australian legislation or standards or the relevant Importing Country	Issue organic produce certificate
		Major	**Contamination** level exceeds the requirements of the Approved Certifying Organisation, relevant Australian legislation or standards or the relevant Importing Country	Do not issue organic produce certificate Produce to be re-labelled

Table 2 – Sanctions available in response to negligent introduction of prohibited substances or materials, including genetically modified organisms and materials

CAUSE OF NON-COMPLIANCE	EXTENT OF NON-COMPLIANCE	OUTCOME OF SEVERITY ASSESSMENT/INVESTIGATION BY THE ORGANIC CERTIFYING ORGANISATION		ACTIONS
Negligent introduction of prohibited substances or materials, including the presence of genetically modified organisms and materials	**Organic Production Unit**	**Minor**	No persistent contamination, effective treatments applied	Issue Corrective Action Request (CAR) Issue Letter of Warning regarding repetition
		Moderate	Some persistent or permanent contamination, effective treatments applied or available	Suspend organic production unit only Issue Corrective Action Request (CAR)

			2nd repeat instance of negligent contamination of the organic production unit	Lift suspension when CAR is resolved Issue Letter of Warning regarding further repetition
		Major	Permanent contamination, effective treatments not available 3rd repeat instance of negligent contamination of the organic production unit	Decertify organic production system
		Minor	No persistent contamination, effective treatments applied	Issue Corrective Action Request (CAR) Issue Letter of Warning regarding repetition
	Off Production Unit Processes	Moderate	Some persistent or permanent contamination, effective treatments applied or available 2nd repeat instance of negligent contamination of the off production unit procedures	Suspend off production unit processes only Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved Issue Letter of Warning regarding further repetition
		Major	Permanent contamination, effective treatments not available 3rd repeat instance of negligent contamination of the off production unit procedures	Decertify organic production system
	Organic Produce	Minor	**Contamination** level does not exceed the requirements of the Approved Certifying Organisation, relevant Australian legislation or standards or the relevant Importing Country	Issue organic produce certificate
		Major	**Contamination** level exceeds the requirements of the Approved Certifying Organisation, relevant Australian legislation or standards or the relevant Importing Country	Do not issue organic produce certificate Produce to be re-labelled

Table 3 – Sanctions available in response to necessary use of, or accidental introduction of, prohibited substances or materials, including genetically modified organisms and materials

CAUSE OF NON-COMPLIANCE	EXTENT OF NON-COMPLIANCE	OUTCOME OF SEVERITY ASSESSMENT/INVESTIGATION BY THE ORGANIC CERTIFYING ORGANISATION		ACTIONS
Accidental introduction or necessary use of prohibited substances or materials, including the presence of genetically modified organisms or materials	**Organic Production Unit**	**Minor**	No persistent contamination, effective treatments applied	Issue Corrective Action Request (CAR)

CAUSE OF NON-COMPLIANCE	EXTENT OF NON-COMPLIANCE	OUTCOME OF SEVERITY ASSESSMENT/INVESTIGATION BY THE ORGANIC CERTIFYING ORGANISATION		ACTIONS
		Moderate	Some persistent or permanent contamination, effective treatments applied or available	Suspend organic production unit only Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved
		Major	Permanent contamination, effective treatments not available	Decertify organic production system
	Off Production Unit Processes	Minor	No persistent contamination, effective treatments applied	Issue Corrective Action Request (CAR)
		Moderate	Some persistent or permanent contamination, effective treatments applied or available	Suspend off production unit processes only Issue Corrective Action Request (CAR) Lift suspension when CAR is resolved
		Major	Permanent contamination, effective treatments not available	Decertify organic production system
	Organic Produce	Minor	Contamination level does not exceed the requirements of the Approved Certifying Organisation, relevant Australian legislation or standards or the relevant Importing Country	Issue organic produce certificate
		Major	Contamination level exceeds the requirements of the Approved Certifying Organisation, relevant Australian legislation or standards or the relevant Importing Country	Do not issue organic produce certificate Produce to be re-labelled

Glossary

Note: Unless specifically referenced below words in this guideline should be taken to have the same meaning as that provided in the National Standard for Organic and Biodynamic Produce

Unnecessary intentional use the deliberate use of prohibited substances or materials, including genetically modified organisms and materials, in a manner that is inconsistent with the National Standard for Organic and Biodynamic Produce and is not required under Commonwealth, State or Territory, Local or Statutory laws

Negligent introduction the introduction of prohibited substances or materials, including genetically modified organisms and materials, where the presence of those inputs could have been reasonably avoided through a level of care that someone of ordinary prudence would have exercised under the same circumstances

Accidental introduction the introduction of prohibited substances or materials, including genetically modified organisms and materials, where the presence of those inputs did not occur through deliberate action and count not have been reasonably avoided through a level of care that someone of ordinary prudence would have exercised under the same circumstances

Necessary intentional use the deliberate use of prohibited substances or materials, including genetically modified organisms and materials, in a manner that is inconsistent with the National Standard for Organic and Biodynamic Produce but is required under Commonwealth, State or Territory, Local or Statutory laws

Off production unit processes approved processes within an operator's supply chain that occur outside of the organic production unit

Organic production system all activities relating to an operator's approved production unit, off production unit processes and produce

Full suspension the suspension of all activities in an operator's organic production system

Partial suspension the suspension of some activities in an operator's organic production system

(2)

IN THE SUPREME COURT OF WESTERN AUSTRALIA
COMMERCIAL AND MANAGED CASES LIST

CIV 1561 of 2012

B E T W E E N:

STEPHEN WILLIAM MARSH Plaintiff

and

MICHAEL OWEN BAXTER Defendant

EXPERT REPORT OF PROFESSOR PATRICK RUDELSHEIM

Date of document:	2 October 2013
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Filed on behalf of:	The Defendant

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perseus

Roundup Ready® Canola

Expert Report

October 2, 2013 – Final version

Project BRD-13-001

Patrick L.J. RÜDELSHEIM
PERSEUS BVBA

Table of contents

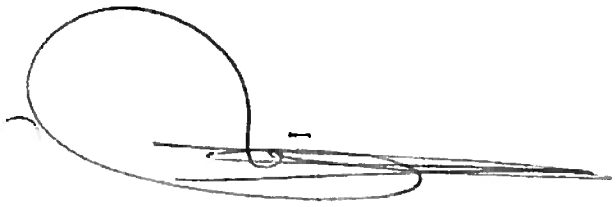
Abbreviations

ANZFA	Australia New Zealand Food Authority
APVMA	Australian Pesticides and Veterinary Medicines Authority
EIQ	Environmental Impact Quotient
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
FSANZ	Food Standards Australia New Zealand
GAT	glyphosate N-acetyltransferase
GOX	Glyphosate oxidoreductase
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology
RR	Roundup Ready®

1 Statement

In the framework of the case Stephen William Marsh vs. Michael Owen Baxter at the Supreme Court of Western Australia (CIV 1561 of 2012), I, Prof. Dr. Patrick Rüdelsheim, was asked to provide an expert report in support of specific questions relating to the nature and safety of Roundup Ready® ("RR") canola. The scope of the report is determined in relation to the list of matters to be addressed provided to me (Annex 1). My background and facts supporting my expertise in this matter are provided in Annex 2 to this report.

Conventional canola, the RR trait and genetically modified RR canola have been the subject of a broad range of publications. The report refers to a selection of reliable sources that were deemed relevant to support the statements. References to the sources have been included in the text where relevant or are added at the end of the report. This selection was made taking care not to omit any source known to the expert that would indicate any conflict with what is stated in the report.



Prof. Dr. Patrick Rüdelsheim
2 October 2013

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2 RR Canola

2.1 Glyphosate, the active ingredient of Roundup®

Proteins, large biological molecules consisting of one or more chains of amino acids, provide the basic structure of cells and tissues. More importantly, they make up all of the metabolic enzymes necessary for life. Whereas animals (including man) can only make a subset of amino acids, plants are capable of making a broader set of these essential building blocks. Because amino acids are needed for protein synthesis, which is required for plant growth and maintenance, the application of products that interfere with the amino acid synthesis results in plant death.

Glyphosate is an example of product that interferes with amino acid synthesis. In the early 1970s, it was discovered that glyphosate, a simple amino acid analogue, could selectively inhibit the activity of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase ("EPSPS"). This enzyme is only present in plants and microorganisms, such as bacteria and fungi, and is not present in animals and humans. In plants, EPSPS plays a key role in the biochemical pathway that results in the synthesis of the essential aromatic amino acids phenylalanine, tyrosine, and tryptophan. By inhibiting the activity of the EPSPS enzyme, the aromatic amino acid synthesis is shut off. Applying glyphosate to plants therefore results in EPSPS inhibition and subsequently plant death. Monsanto, the company which first produced glyphosate, began commercially marketing this herbicide in 1974 under the trade name Roundup®.

Glyphosate products, such as Roundup®, are broad-spectrum, non-selective, systemic herbicides. 'Broad-spectrum' and 'non-selective' indicates that it controls all plant types including grasses, perennials and woody plants. Treated plants are killed in days to weeks. 'Systemic' refers to the fact that when a plant is sprayed with Roundup®, the herbicide is absorbed through the leaves and the soft tissue of the stem and then transported throughout the plant. In contrast with herbicides that only operate at the contact surface, systemic herbicides will affect even plant parts that are difficult to reach (e.g. roots) and thereby provide a better weed control.

Given this broad-spectrum and non-selective effect, Roundup® was initially (and still is) marketed as a general weed control product e.g. to clear roadsides, pavements, etc. The high sensitivity of crop plants to glyphosate has limited its use as a pre-crop emergence herbicide in no-till management strategies[1], and as an herbicide and crop desiccant when applied shortly before crop harvest.

As a non-selective herbicide, Roundup® is promoted to have several attractive features, including:

- Given the high sensitivity of plants, quantities of the herbicide required for weed control are lower compared with other products. This leads to reduction in transport, exposure and application.
- Given the efficiency of the product, fewer applications are required resulting in reduction of operating costs and less herbicides introduced in the environment.
- The safety profile for human health and the environment is much better compared to that of other products used in crops.
- Glyphosate is readily degraded by natural mechanisms and none of the degradation products has a negative effect on health or the environment.

[1] No-till farming (also called zero tillage or direct planting or pasture cropping) is a way of growing crops from year to year without disturbing the soil through tillage. It is an agricultural technique, which increases the amount of water and organic matter (nutrients) in the soil and decreases erosion. It increases the amount and variety of life in and on the soil.

- There is no residual action, so other activities can be initiated shortly after treatment without risking a carry-over effect.

40 Years after the first introduction, glyphosate is probably the most widely used herbicide in the world.

2.2 Genetic modification for RR

The main agricultural interest is to control weeds during crop cultivation. Therefore, building on the attractive features of the non-selective use, options for selective use were explored. 'Selective' refers to the fact that upon application the desired plants (*i.c.* the crop plants) survive while the weed plants are affected.

In order to enable the selective use of Roundup® in crops, crop plants needed to be identified that were resistant to glyphosate. There are several mechanisms by which plants can tolerate exposure to an herbicide:

1) the plant produces a function which renders the herbicide ineffective;
2) the plant produces an altered target enzyme which is not affected by the herbicide; or
3) the plant produces physical or physiological barriers to uptake of the herbicide into the plant tissues and cells.

As yet, such mechanisms to protect against glyphosate have not been found crop plants. Although traditional mutagenesis and selection techniques could yield a mutant form of the target enzyme that is tolerant of the herbicide but retains its desirable enzymatic function, to date such an approach has failed to produce a useful level of tolerance in crop species.

In addition to searching for traits of interest in plants, advances in molecular research enabled scientists to unravel and steer the underlying genetic and biochemical determinants. Engineering resistance to glyphosate was one of the first applications in crops, which combined two major scientific breakthroughs:

1) The capability to genetically modify crop plants
   Following the discovery of naturally occurring mechanisms to introduce functional genetic information in plants, techniques were further refined to allow genetic modification of crop plants. Precise genetic information can now be introduced in plant cells of many species. It becomes part of the endogenous heritable material and provides additional traits.

2) The knowledge of the mode of action of glyphosate and resistance mechanisms
   Detailed knowledge of how glyphosate operates and how natural resistance mechanism evolve led to the design of two successful strategies to produce glyphosate-tolerant plants:
   a) Introduction of an enzyme that inactivates glyphosate.
      Glyphosate oxidoreductase (GOX) and glyphosate N-acetyltransferase (GAT) were isolated from soil bacteria ubiquitous in nature. Both have the capacity to degrade glyphosate and thereby rendering it inactive. When it is introduced in plants, it will have no function unless the plant is treated with glyphosate. Upon glyphosate treatment, it will facilitate the breakdown of glyphosate and thereby limit the effect of the herbicide on the specific plant.
   b) Introduction of glyphosate-tolerant EPSPS
      A glyphosate-tolerant EPSPS gene ("CP4 EPSPS") was isolated from another soil bacterium. When it is expressed in transgenic plants, the CP4 EPSPS, which is insensitive to glyphosate, fulfils the aromatic amino acid needs of the plant even in the presence of glyphosate.

Depending on the crop, one or two of these functions have been introduced by genetic engineering. During genetic engineering, the newly introduced genes are inserted at different locations in the plant's own genetic information. As the expression of the inserted genes may differ depending on the exact location, each of these is separately identified as a specific transformation event. Table 1. provides an overview of glyphosate-tolerant products that have been developed in this way and have been approved for large-scale (commercial) release at least in 1 country. More and more products are offered that combine different genetically modified transformation events via classical breeding. This allows, for instance, to combine herbicide resistance with tolerance traits like insect protection. Such combined products, that include the RR trait, have been included in the table.

Table 1. Overview of transformation events with the RR trait introduced via genetic engineering (where available the OECD unique identifier has been provided; "x" indicates a combination between events produced via traditional breeding; events that harbour the RR trait have been underlined; the RR canola subject of this report is indicated in bold)

Crop	Scientific name	Genetically modified transformation events harbouring the RR trait
Sugar Beet	*Beta vulgaris L.*	KM-ØØØ71-4
Canola	*Brassica napus L.*	DP-Ø61Ø61-7 DP-Ø73496-4 MON89249-2 **MON-ØØØ73-7 (GT73, RT73)** MON-883Ø2-9 ACS-BNØØ5-8 x ACS-BNØØ3-6 x MON-ØØØ73-7
Soybean	*Glycine max L*	DP-356Ø43-5 DP-3Ø5423-1 x MON-Ø4Ø32-6 MON-87769-7 MON-877Ø1-2 x MON-89788-1 MON-877Ø5-6 MON-877Ø5-6 x MON-89788-1 MON-877Ø8-9 MON-877Ø8-9 x MON-89788-1 MON-89788-1 MON-Ø4Ø32-6 MST-FGØ72-3
Cotton	*Gossypium hirsutum L.*	BCS-GHØØ2-5 MONØ1445-2 MON-88913-8 MON-89383-1 BCS-GHØØ2-5 x ACS-GHØØ1-3 BCS-GHØØ2-5 × MON-15985-7 *MON-15985-7 x MONØ1445-2* MON-ØØ531-6 x MONØ1445-2 MON-15985-7 x MON-88913-8 BCS-GHØØ2-5 x ACS-GHØØ1-3 x MON-15985-7 BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS-GHØØ5-8 DAS-21Ø23-5 x DAS-24236-5 x MON-Ø1445-2 DAS-21Ø23-5 x DAS-24236-5 x MON-88913-8 SYN-IR1Ø2-7 x SYN-IR67B-1 x MON-88913-8
Alfalfa	*Medicago sativa L.*	MON-ØØ1Ø1-8 MON-ØØ163-7 MON-ØØ1Ø1-8 x MON-ØØ163-7
Potato	*Solanum tuberosum L*	RBMT21-129 RBMT21-350 *RBMT22-082*
Wheat	*Triticum aestivum L.*	MON71800
Maize	*Zea mays L.*	DP-Ø9814Ø-6 HCEM485 MON-87427-7 MON-88Ø17-3 MON-8Ø2ØØ-7 MON-ØØ6Ø3-6 MON-ØØ81Ø-6 MON-ØØØ21-9

Crop	Scientific name	Genetically modified transformation events harbouring the RR trait
		MON801 MON832 PH-MON-8Ø9-2 DAS-59122-7 x MON-88Ø17-3 DAS-59122-7 x MON-ØØ6Ø3-6 DAS-59122-7 x MON-ØØØ21-9 DAS-Ø15Ø7-1 x MON-88Ø17-3 DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 DAS-Ø15Ø7-1 x MON-ØØØ21-9 DP-Ø9814Ø-6 x DAS-59122-7 DP-Ø9814Ø-6 x DAS-Ø15Ø7-1 MON-8746Ø-4 x MON-ØØ6Ø3-6 MON-89Ø34-3 x MON-88Ø17-3 MON-89Ø34-3 x MON-ØØ6Ø3-6 MON-ØØ6Ø3-6 x ACS-ZM003-2 MON-ØØ6Ø3-6 x MON-ØØ81Ø-6 MON-ØØ81Ø-6 x MON-88Ø17-3 MON-ØØ863-5 x MON-ØØ6Ø3-6 MON-ØØØ21-9 x MON-ØØ81Ø-6 SYN-BTØ11-1 x MON-ØØØ21-9 SYN-E3272-5 x MON-ØØØ21-9 SYN-IR162-4 x MON-ØØØ21-9 SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 SYN-IR6Ø4-5 x MON-ØØØ21-9 DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 DAS-59122-7 x SYN-IR6Ø4-5 x MON-ØØØ21-9 DAS-Ø15Ø7-1 × DAS-59122-7 × MON-88Ø17-3 DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ6Ø3-6 DAS-Ø15Ø7-1 × SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 DP-Ø9814Ø-6 x DAS-Ø15Ø7-1 x DAS-59122-7 MON-87427-7 x MON-89Ø34-3 x MON-88Ø17-3 MON-87427-7 x MON-89Ø34-3 x MON-ØØ6Ø3-6 MON-8746Ø-4 x MON-89Ø34-3 x MON-88Ø17-3 MON-8746Ø-4 x MON-89Ø34-3 x MON-ØØ6Ø3-6 MON-89Ø34-3 x DAS- Ø15Ø7-1 x MON-88Ø17-3 MON-89Ø34-3 x DAS-59122-7 x MON-88Ø17-3 MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 MON-ØØ863-5 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 SYN-BTØ11-1 x DAS-59122-7 x MON-ØØØ21-9 SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9 SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9 SYN-E3272-5 x SYN-BTØ11-1 x MON-ØØØ21-9 SYN-E3272-5 x SYN-IR6Ø4-5 x MON-ØØØ21-9 SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9 DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 MON-89Ø34-3 x DAS- Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7 SYN-BTØ11-1 x DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x MON-ØØØ21-9 SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9 SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9 DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × SYN-IR6Ø4-5 x MON-ØØ6Ø3-6 SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-Ø53Ø7-1 x SYN-IR6Ø4-5 x SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 SYN-Ø53Ø7-1 x SYN-IR6Ø4-5 x SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 x SYN-IR162-4

The International Service for the Acquisition of Agri-Biotech Applications ("ISAAA") publishes yearly a brief on the Global Status of Commercialized Biotech/GM Crops. Since the first introduction of genetically modified crops in 1996 the cultivated surface has continued to expand, reaching 170.3 million hectares globally in 2012 (James, 2012). Of these, nearly 90% were planted with crops genetically modified to be tolerant to a specific herbicide.

As the resistance mechanisms are only introduced in the genetically modified plants, Roundup® can henceforth be applied as a selective herbicide after both crops and weeds have emerged, with little or no damage to the crop. In addition to advantages already indicated for non-selective use, this is expected to result in additional advantages:

- More options for integrated weed management
  Underlining the need to limit the effect of weeds on harvestable yield, modern integrated weed management schemes rely on a combination of techniques to achieve sustainable and cost-effective measures. An additional, efficient weed control product is an important asset in such management schemes.

- More flexibility, ease of use in weed management
  Most conventional herbicides are non-selective. In crop, they must be applied early in the season in anticipation of weed problems, long before it is revealed that weeds will be problematic. Similarly techniques of tillage and ploughing have been used as a preventive measure to avoid problems later in the season. Yet, these techniques have a devastating effect on soil erosion and quality. With a selective and effective herbicide, the farmer can postpone treatment until the first indications that the weed population will be problematic. Given the rapid response and good tolerance of the crop, late applications are possible.

- More flexibility in crop management
  Some products with a long residual activity may have an influence on subsequent land use. As glyphosate is readily degraded, already shortly after an application no effect on subsequent use will be expected. This allows even for replanting of another crop, in case the initially planted and treated RR crop fails. Also a second cropping can be envisaged more realistically.

Reviewing data from 15 years cultivation of genetically modified herbicide tolerance crops, Brookes & Barfoot (2013a and 2013b) confirm:

- A change in the profile of herbicides used.
  In general, a fairly broad range of, mostly selective (grass weed and broad-leaved weed), herbicides has been replaced by one or two broad-spectrum herbicides (mostly glyphosate) used in conjunction with one or two other (complementary) herbicides (e.g., 2,4-D).

- Aggregate reductions in both the volume of herbicides used (in terms of weight of active ingredient applied) and the associated field EIQ values[2], indicating net improvements to the environment.

- More cost effective (less expensive) and easier weed control for farmers.
  The magnitude of these impacts varies by country and year and is mainly due to prevailing costs of different herbicides used vs. conventional alternatives, the mix and amount of herbicides applied, the cost farmers pay for accessing the technology and levels of weed problems. In addition, some users of this technology have also derived higher yields from better weed control (relative to weed control obtained from conventional technology).

[2] The Environmental Impact Quotient (EIQ) developed at Cornell University effectively integrates the various environmental impacts of individual pesticides into a single "field value per hectare". The EIQ indicator provides an improved assessment of the impact of GM crops on the environment when compared with only examining changes in volume of active ingredient applied, because it draws on some of the key toxicity and environmental exposure data related to individual products, as applicable to impacts on farm workers, consumers and ecology.

The introduction of genetically modified herbicide resistance and the associated herbicide use has triggered concerns.

- Principal rejection

  Some reject any form of genetic engineering and consequentially oppose the introduction of genetically modified herbicide tolerant crops that represents the first large-scale and extremely successful deployment of this technology. In order to address this position, co-existence schemes have been suggested that allow the simultaneous use of different agricultural systems such as "conventional", "based on genetic modification", organic", or others. Although this may yield a workable environment, the author of this report wants to point out that in order to address the huge challenges that agriculture is facing, farmers should have access to the best techniques. They should be able to combine what is best for their fields and crops and ideally not be restricted by pre-defined management schemes that artificially impose limitations.

- Safety concerns

  Some feel that insufficient information is available to support safety of genetically modified organisms and therefore they prefer a delayed or slower introduction. Safety aspects will be discussed later in this report.

- Increased herbicide use

  Most countries strive for a reduction of the amount of chemicals used in agriculture. In consequence, it may be perceived contradictory to support the deployment of a trait that allows another herbicide use. The introduction of the RR trait enabled the use of Roundup® on crops impossible until then and surely this led to an increase in Roundup® consumption.

  There are two premises that guide this apparent contradiction:
  - Modern agriculture requires efficient weed management schemes in order to secure primary production.
  - Plant protection products have an important role in efficient weed management and the use of products with minimal side effects should be further encouraged.

  In this perspective, the genetically engineered herbicide tolerance traits do offer a very attractive alternative: the associated herbicide has a much better safety profile; in most cases its use results in a reduction of total herbicide use; and it allows more flexibility in weed management schemes.

- Development of resistant weeds

  Where RR crops have been widely grown, some incidence of weed resistance to glyphosate has occurred and has become an increasing problem in some regions. The International Survey of Herbicide Resistant Weeds[3] indicates that weeds have evolved resistance to 21 of the 25 known herbicide sites of action and to 148 different herbicides. 171 Reports relate to glyphosate resistance spontaneously developed in weeds, of which 16 reports indicating occurrence in 6 species in Australia. When targeted weeds become resistant, the herbicide may no longer be effective in controlling them.

  The development of resistance is a natural phenomenon and the selection of resistant weeds species can be attributed to how glyphosate was used. Because of its broad-spectrum post-emergence activity, it was often used as the sole method of weed control. This approach to weed control put tremendous selection pressure on weeds and as a result contributed to the evolution of weed populations predominated by resistant individual weeds.

[3] Database available at www.weedscience.org

As a result, growers of RR crops are increasingly being advised to include other herbicides (with different and complementary modes of action) in combination with glyphosate and in some cases to revert to ploughing in their integrated weed management systems. At the macro level, these changes have already begun to influence the mix, total amount, cost and overall profile of herbicides applied to RR crops. Compared with five years ago, the amount of herbicide active ingredient applied and number of herbicides used with RR crops in many regions has increased, and the associated environmental profile, as measured by the EIQ indicator, deteriorated. However, relative to the conventional alternative, the environmental profile of RR crop use has continued to offer important advantages and in most cases, provides an improved environmental profile compared with the conventional alternative (as measured by the EIQ indicator).

It should also be noted that many of the herbicides used in conventional production systems had significant resistance issues themselves in the mid-1990s. This was, for example, one of the reasons why RR soybean technology was rapidly adopted, as glyphosate provided good control of these weeds.

- Monopolies and farmer dependency
  There is concern over organizations gaining control of the food chain and agricultural production. If the same company develops the herbicide and the trait enabling the farmers to use the herbicide on crops, this could be seen as strengthening their market control. Farmers could then be 'forced' to buy the package herbicide and herbicide tolerance and thereby become more dependent on a single (multi-national) player.

  The market dynamics are difficult to picture, but farmers have never been forced to buy a specific product or package. James (2012) points out that the most compelling and credible testimony to biotech crops is that during the 17 year period 1996 to 2012, millions of farmers in ~30 countries worldwide, elected to make more than 100 million independent decisions to plant and replant an accumulated hectarage of more than 1.5 billion hectares – an area 50% larger than the total land mass of the US or China – and that there is one principal and overwhelming reason that underpins the trust and confidence of risk-averse farmers in biotechnology, namely genetically modified crops deliver substantial, and sustainable, socio-economic and environmental benefits.

  While in the case of RR, one company held the initial proprietary position, farmers retained the option to choose for varieties with other herbicide tolerances, introduced by genetic modification or not. They are free to use other herbicides and other weed management schemes. Obviously a farmer consciously opting for using Roundup® will look for a RR variety. As the proprietary position has lapsed, also other providers are offering glyphosate based herbicides as well as glyphosate tolerance traits in crops.

2.3 Genetically modified RR canola

Table 1 lists several RR canola events. To date, transformation event "MON-ØØØ73-7" (also known as GT73 or RT73) is the most advanced. Commercially developed in the early '90ies, it has been commercially deployed since. The RR canola used in Australia is derived by breeding from GT73. Event "MON-883Ø2-9" has not been fully deployed and the other events have been launched more recently.

GT73 is a transformant of the Canadian canola variety "Westar" in which both the CP4 EPSPS and the GOX genes were introduced. It was selected because of its overall crop performance and field

level resistance to glyphosate. The inserted genes are stably integrated and the event is phenotypically and genetically stable across generations and in various environments.

Once the genes responsible for the trait of interest are part of the plant's genetic information, inheritance will follow the natural Mendelian laws. The traits can be further transmitted to compatible species. Breeders use this feature to enter the trait in other varieties adapted for the local growing conditions. Starting with the Canadian 'Westar' variety, GT73 has now been transmitted to numerous varieties adapted for all canola-growing regions including those in Australia.

Along with the selection of the GT73 event, studies were conducted to assess and support its safety. Activities with genetically modified organisms being regulated in most countries, every field trial and commercial use has been subject to an expert assessment and regulatory approval. Table 2 provides a summary of the approvals at commercial level obtained so far.

Table 2. Summary of regulatory approvals at commercial level for GT73[4] (country, year of first approval and type of approval – based on GM Approval Database at www.ISAAA.org)

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic
Australia	2000	(2003)	2003
Canada	1994	1995	1995
China	2002	2002	
European Union	1997	2005	
Japan	2001	2003	2006
Mexico	1996		
New Zealand	2000		
Philippines	2003	2003	
South Korea	2003	2005	
United States of America	1995	1995	1999

In 2000, Food Standards Australia New Zealand (FSANZ), formerly Australia New Zealand Food Authority (ANZFA), amended Standard A18 - Food Produced Using Gene Technology of the Food Standards Code to include oil derived from RR canola GT73. In 2003, the Australian Gene Technology Regulator (OGTR) issued a licence[5] for the commercial release of RR canola GT73. In a subsequent communication OGTR confirmed that the RR canola can be used in the same manner as conventional canola, including the use as stockfeed. At the same time the Australian Pesticides and Veterinary Medicines Authority (APVMA), which is responsible for the registration of agricultural chemicals, concluded an extensive assessment of the herbicide and approved the use of it for weed control in RR canola crops.

It is of interest to note that the regulators flag that two important concerns have been identified and that these have been addressed:

- The potential for development of herbicide-resistant weeds, if glyphosate is used inappropriately

  The regulators indicate that the potential for the development of herbicide resistance in weeds was evaluated. As a result, the APVMA applied a number of conditions on the registration of the herbicide to ensure responsible management of the herbicide use on RR canola, and to minimise the risk of development of herbicide resistance.

[4] Based on GM Approval Database at www.ISAAA.org
[5] OGTR (2003) Licence for Dealings involving intentional release of a GMO into the environment DIR 020/2002 Issued 19 December 2003

- The possible economic and market impacts if RR canola spreads to adjoining farms.
  The regulators indicate that unwanted RR canola plants can be effectively removed with a range of approved herbicides and mechanical weed control methods. Using a mixture of weed control options is consistent with integrated weed management practice.

RR canola has been grown in Canada, the US and more recently Australia. Brookes & Barfoot (2013a and 2013b) estimate the environmental and economic impacts associated with changes in herbicide usage on different GM crops. The results for herbicide tolerant canola are provided in Table 3: in 2011, the use of genetically modified herbicide tolerant canola resulted in a 0.43 million kg reduction in the amount of herbicide active ingredient use (-6.4%), with an improvement in the environmental impact, as measured by the EIQ indicator of 18.9%.

Table 3. Summary of active ingredient usage and associated EIQ changes in the period 1996–2011 for genetically modified herbicide tolerant canola (based on Brooked & Barfoot 2013b)

Country	Change in active ingredient use (million kg)	Percent change in amount of active ingredient used	Percent change in EIQ indicator
United States of America	−2.5	−36.5	−47.3
Canada	−12.1	−17.2	−27.2
Australia	−0.1	−1.8	−1.1
Aggregate impact: all countries	−14.7	−17.3	−27.1

The fuel savings associated with making fewer spray runs in genetically modified crops (relative to conventional crops) and the switch to reduced tillage or no tillage farming systems facilitated by herbicide tolerant crops, have resulted in permanent savings in carbon dioxide emissions. For Canada, it was calculated that in 2011 the use of genetically modified herbicide tolerant canola resulted in a fuel saving of 66 million litres and 177 million kg of permanent carbon dioxide savings, which would be the equivalent of removing nearly 80000 family cars from the road for that year.

Also economical benefits have been realized. Table 4 presents different cases of the deployment of genetically modified herbicide tolerant canola. As pointed out before, the net gain is even higher as additional yield gains have been secured with more efficient weed control. In Australia, also other herbicide tolerance canola varieties are available for which the tolerance is not based on a genetic modification. In particular triazine tolerant canola and imidazolinone tolerant (also known as Clearfield) canola are popular. It is relative to the triazine form of canola that the main farm income benefits of RR canola has occurred.

Table 4. Summary of average farm level economic impacts in the period 1996–2011 for genetically modified herbicide tolerant canola (based on Brooked & Barfoot 2013b; average farm income benefit is calculated after deduction of cost of technology)

Country	Cost of technology ($/hectare)	Average farm income benefit ($/hectare)	Type of benefit
United States of America	12 – 33	59	Mostly yield gains[1] of +1% to +12%
Canada	18 – 32	49	Mostly yield gains[1] of +3% to +12%
Australia	32 – 41	61	Mostly yield gains[2] of +16% to +22%

[1] especially Invigor canola; [2] where replacing triazine tolerant canola

3 Safety aspects

3.1 Safety of glyphosate

Plant protection products, including herbicides such as glyphosate, are strictly regulated. No herbicides can be used for a specific purpose unless it is scientifically proven that this use:

- Doesn't harm people's health;
- Has no unacceptable effects on the environment;
- Is effective against the target organisms (i.c. weeds).

The comprehensive safety data package developed on glyphosate, initially for non-selective use and subsequently refined for use on specific RR crops, includes information on:

- Identity and physical/chemical properties
- Pharmacokinetics and metabolism
- Acute toxicity and irritation studies
- Genotoxicity studies
- Long-term toxicity and carcinogenicity studies
- Reproductive and developmental toxicity studies
- Toxicity to wildlife
- Persistence in the soil
- Water quality

In Australia, APVMA has primary regulatory responsibility for agricultural chemicals. Each submission to the APVMA is evaluated to ensure that the product is safe for people, animals and the environment, that it will not pose any unacceptable risk to Australia's international trade (e.g. by exceeding international residue limits) and that it will perform according to the label claims. If the APVMA is satisfied that the product meets these criteria, it may be registered for use in Australia with an APVMA approved label.

Glyphosate as a herbicide was developed in the 1970s and was registered for use in Australia by state and territory authorities not long afterwards. In the mid 1990s it was reassessed by the National Registration Authority (the precursor to APVMA) and granted registration following the consideration of relevant scientific information. Currently there are over 300 glyphosate products registered in Australia for use in croplands, industrial and commercial areas, aquatic areas, forests and plantations and in the home garden. In 2003, the APVMA has approved a variation of the registration for the glyphosate herbicide to enable its use on Roundup Ready® canola

Glyphosate has been reviewed by a number of international expert bodies and regulatory agencies since it was first registered. Amongst others, the European Standing Committee on Plant Health (2002) concluded after a thorough re-evaluation that plant protection products containing glyphosate fulfil the safety requirements laid down in the stringent European legislation.

Once a product is commercially released, new findings are regularly published that could indicate undesired side-effects. This has also been the case for glyphosate. In 2011, Greenpeace presented a summary report examining the environmental and health implications of the widespread and intensive use of the herbicide glyphosate in association with RR crops. The report signals alleged effects of glyphosate on human health, residues in food, presence in water, impacts on biodiversity, impacts on the soil-plant system and development of resistance in weeds. Part of the findings had already been addressed in the assessments by the regulators preceding the approvals of glyphosate. In other cases, new facts triggered a supplementary review. In few specific cases this has led to an adjustment

of the terms of use or call for specific vigilance. In no case did new findings so far result in a market suspension or interdiction of glyphosate.

One of the factors in the safety determination is the fate of the applied product and possible residues. In soil, the half-life of glyphosate (the time required for half of the compound to dissipate or degrade) varies, depending on conditions. The variability in rates of glyphosate degradation is believed to be due to the varying microbial activity and extent of soil-binding at the different sites. The authors of a comprehensive ecotoxicological assessment of glyphosate (Giesy *et al.*, 2000) concluded the following: "Field studies indicate that glyphosate typically dissipates rapidly from both simple ecosystems, such as agricultural, and more complex ecosystems, such as forestry, regardless of the diverse edaphic [soil] and climatic conditions." The authors also concluded that field studies conducted in agricultural and forest soils (13 studies, five countries, 47 different sites) indicated an average half-life of 32 days, a moderately rapid rate compared with degradation of other compounds. Furthermore, the detection of glyphosate residues in soil does not mean that these residues are bioavailable. Under normal conditions, they would be bound to the soil and not be available.

3.2 Safety of genetically modified RR canola

The development of genetically modified crops has spurred the establishment of regulatory frameworks with the intention to foster the development of genetically modified crops and to provide safe access of these crops to growers. While the implementation of regulatory programmes, legal frameworks and regulations may differ from country to country, the information that informs the risk assessments that underlie the safe deployment of transgenic crops share a common basis of globally accepted scientific elements.

In parallel with the selection and development of transformation event GT73, a safety data package was developed that includes information on:

- The transformation process and molecular/biochemical characterization of the product
- The gene products, CP4 EPSPS and GOX, their function and safety features
- Crop performance and level of tolerance to glyphosate under different environmental conditions
- Gene transfer/ Outcrossing of the trait to other canola varieties and other plants
- Weediness potential
- Secondary and non-target effects
- Impact of biodiversity
- Dietary exposure
- Nutritional data
- Toxicity and allergenicity

The data package was submitted to authorities. Based on publically available summaries, assessment reports and partial publication in literature (*e.g.* Canadian Food Inspection Agency, 1995; European Food Safety Authority, 2009; Mayers *et al.*, 2002), it can be concluded that the results established the food, feed and environmental safety of RR canola by demonstrating the safety of the CP4 EPSPS and GOX proteins to humans and animals, establishing equivalent nutritional composition and wholesomeness of RR canola compared to conventional canola varieties, and confirming that the potential impact of RR canola on the environment is no different than conventional canola varieties.

Both FSANZ's amendment of Standard A18 - Food Produced Using Gene Technology of the Food Standards Code and the OGTR's licence for the commercial release of RR canola GT73, were supported by a thorough risk assessment. The risk assessment considered information contained in the application (including information required by the Australian Act and the Regulations on the GMO,

the parent organism, and the proposed dealings and on potential impacts on human health and safety and the environment). The assessment also considered submissions received from expert groups and authorities consulted on the application as prescribed by the Act, invited advice from the public and the most current scientific knowledge.

ANZFA concluded that no potential public health and safety concerns had been identified in the safety assessment of food derived from this RR canola[6]. Based on the data submitted by the applicant, food derived from RR canola GT73, was regarded to be equivalent to food derived from conventional canola in respect of its composition, safety and end use. Similarly, following rigorous assessment (Office of Gene Technology Regulator, 2003), the Gene Technology Regulator considered that the risks posed by the proposed commercial release of RR canola to human health, safety and the environment are no greater than those posed by conventional (non-GM) canola.

Given the scope of this report, it is relevant to discuss residues of the genetically modified RR canola plants. As the RR canola behaves in the same way as conventional varieties, the distribution and behaviour of vegetative parts and seeds is equal to that known for routine for any canola cultivation. At the end of a cultivation cycle, two types of plant materials may remain in the field, namely vegetative material (remainder of roots, stems and leaves) and seeds:

- Vegetative material will predominantly degrade. Depending on the environmental condition some parts may produce new shoots, but these are routinely controlled by good agricultural practices. As long as decaying material is present it will be possible to identify via molecular tools that RR canola has been cultivated in that field. This is due to the sensitivity of molecular techniques and the relatively long persistence of the genetic information under optimal conditions. Nevertheless, this presence is not biologically significant. The residual material has lost its function, cannot be transferred and is not viable.

- Well-developed, fully mature canola seeds may remain viable for 25 years if dry seed is refrigerated in sealed containers. In the field, seeds can persist as part of the so-called "seed bank". Viability of seed lost during harvest is an important factor in determining the presence and amount of volunteer plants and populations in subsequent crops. Harvest losses can be substantial and the survival and persistence of this seed is greatly influenced by environment, seed dormancy as well as crop and field management. Most canola seeds, if left on or near the soil surface, will germinate and be killed by frost or cultivation or be eaten by rodents, birds and insects. High temperatures and low soil moisture availability experienced after harvest in Australia may provide conditions to induce secondary dormancy, which may contribute to higher persistence rates than under European or North-American conditions.

The residual presence of RR canola vegetative parts and seeds has been included in the risk assessment performed by the authorities. For instance OGTR (2003) indicates that:

> *"The emergence of volunteer plants subsequent to the cultivation of a crop, and their control or removal prior to the next season's planting, is an integral part of normal agricultural practice that is not in any way restricted or peculiar to either canola or GM crops. Therefore, adoption of Roundup Ready® canola will mean that farmers will need to make choices and potentially modify their farming practices. This may result in increased complexity in implementing alternative weed management strategies, as well as other economic considerations. It will not pose any greater risks to human health and safety or the environment than conventional canola. Therefore no risk management conditions are proposed in relation to weediness."*

[6] ANZFA (1999) Draft Risk Analysis Report (APPLICATION A363 Food produced from glyphosate-tolerant canola line GT73
http://www.foodstandards.gov.au/code/applications/documents/A363%20FA.pdf

4 Dispersal of RR canola material

4.1 Mechanisms of dispersal

As pointed out before, it was demonstrated that the behaviour and performance of RR canola GT73 is the same as that of conventional canola, and this is also true for mechanisms of dispersal. For canola dispersal can occur of vegetative material, pollen and seeds.

4.1.1 Dispersal of vegetative material

Vegetative material may be removed from the field accidentally, e.g. by heavy wind or agricultural activity, or intentionally. The vegetative material also contains seeds. In an early stage the seeds will be immature and not viable. They should be considered as vegetative material. When they are capable of germination, it should be considered as a dispersal of seeds.

4.1.2 Dispersal of pollen

Canola plants produce many flowers, each producing and releasing pollen as part of sexual reproduction. Under field conditions, canola has the ability to cross pollinate through physical contact between neighbouring plants and/or be insect pollinated. The pollen can also become airborne and although most pollen will travel less than 10 meters, potentially it can travel several kilometres downwind.

4.1.3 Dispersal of seeds

Seed movement can be an important factor in overall spatial (typically over shorter distances) and temporal (through survival in the seed bank for several years) gene movement. The main mechanisms for spatial seed dispersal include wind, humans (clothing, vehicles) and animals The following paragraph in OGTR's 2011 publication on 'the biology of *Brassica napus* L. (canola)' is particularly relevant in the context of this report:

> *"Widespread natural dispersal of canola seeds does not generally occur in the field. The small size of canola seeds and their high numbers on post harvest fields may facilitate some dispersal by wind. While pod shattering can disperse seeds over short distance, it is possible that windrows of canola plant material including seed could be blown into adjacent fields. The dispersal distance will depend on the wind strength, the amount of trash on the ground and the moisture content of the material. Although no data exists on wind dispersal of canola windrows, it is reasonable to expect, that seeds and pods of low moisture content, may be transported within the field or to adjacent fields during periods of unusually high winds."*

4.2 Impact of dispersed material

4.2.1 Vegetative material

The impact of dispersed vegetative material from RR canola will be negligible. Severed plant parts do not lead to regrowth or volunteers. Actually great care and human skills are required to regrow a new plant from a canola plant part. Rather it will decay and leave no residue in the field or on the plants. As

RR canola has been shown to be comparable to other conventional canola varieties and the dispersal of vegetative material has never caused any problem, this will not be different.

If the vegetative material were to be inadvertently consumed by animals either livestock or wild animals, no effect is expected. The feed safety of RR canola has been fully established and the product can safely be used as animal feed. Furthermore tests on different non-target organisms including quail and rainbow trout confirm that diverse species have no effect from consuming RR canola.

Dispersed vegetative material will decay and leave no residues. If the material had just been sprayed with glyphosate, then it may contain a minimal quantity of the herbicide and its breakdown products. These will also degrade rapidly. Overall no effect on the destination site is to be expected.

The genetically modified crops can be traced by molecular techniques. However, animals that have consumed a genetically modified crop retain no trace nor are modified in any way. Alexander *et al.* (2002) report that the rapid degradation of DNA following release from canola plant cells during ruminant digestion represents a considerable barrier to transfer of plant genetic information, genetically modified or not, to rumen bacteria or to ruminant animals. Similarly, studies have demonstrated that the CP4 EPSPS gene sequences could not be detected in muscle tissue of pigs (Jennings et al. 2003b), chickens (Jennings et al. 2003a) or in milk of dairy cows (Phipps et al. 2002) fed Roundup Ready® soybean.

The genetic modification present in the vegetative material cannot be transferred to other plant species. Also the likelihood for so-called horizontal gene transfer, *i.e.* transfer to unrelated species for which sexual compatibility hasn't been established, can be excluded.

4.2.2 Pollen

The presence of pollen *per se* doesn't have any impact, as it is not capable to produce any biological effect. Pollen of some species, including canola, are known to cause allergic reactions in part of the human population. This aspect has been addressed in the risk assessment and it was shown that the allergenic potential is not changed compared with pollen from conventional canola.

Pollen is also carried by and may be used as a source of nutrition of beneficial insects, e.g. pollinators like honeybees and bumblebees. On the basis of the characterization of the introduced proteins and the compositional analyses, no specific interactions of RR canola with non-target organisms are to be expected, beyond those that occur with other canola varieties. Also there have been no reports on alterations in the interactions with predatory or beneficial non-target organism.

When pollen is deposited on a receptive and compatible flower, fertilization can occur leading to seed production. Through pollen genetic information, including the RR trait introduced via genetic modification, can be transmitted. Yet in order to have an effective dispersal, all the following elements are required:

1) Production of viable pollen
   As the RR canola is fertile, it can be assumed that production of pollen is equivalent to that of conventional varieties.

2) Dispersal of viable pollen
   As no changes in the morphology have been observed, it must be assumed similar to conventional varieties. Pollen dispersal in canola occur through physical contact, pollinators and wind.

3) Deposition of viable pollen on flower of compatible species
Pollen viability varies with environmental conditions, particularly temperature and humidity. Under controlled conditions in the laboratory, canola pollen can remain viable for between 24 hours and one week. In Australia, canola crops flowers in spring when temperature increases and humidity declines; under these conditions, pollen viability may be reduced to 24 to 48 hours. In consequence, there is a limited window for effective dispersal.

Pollen as such is not capable of doing anything. It serves to pollinate the female organ of a receptive flower. Therefore, pollen needs to be deposited on another flower. Nothing will happen if this is a flower of a non-compatible species; the pollen will decay within hours. In order to have a successful dispersal, viable pollen must be deposited on the female organ of the flower of compatible species, e.g. another canola or a compatible *Brassica* related species.

4) Fertilisation of and seed development on compatible species
Once deposited, the pollen grain has to germinate and fertilize the distant plant. This process usually involved competition with other pollen grains that may be deposited at the same time. If the plant is located distantly, then it is likely that more competing pollen will be present. In addition the likelihood of a successful fertilization and seed development is largely influenced by the degree of relatedness between the plants. Canola is efficient in pollinating plants of its own species (e.g. other canola plants in a neighbouring field). Crosses with other members of the *Brassica* family are far less efficient and are rarely found under natural conditions.

5) Seed germination and plant establishment
The seeds need to mature, survive and germinate. This is most likely for crosses that have occurred between the RR canola and other canola varieties. For crosses with members of the *Brassica* family, each of these steps may proof to be a barrier for further propagation. Finally, the plant can establish and will carry the RR trait. A cross with a member of the Brassica family, usually leads to an intermediate hybrid plant, which can be recognized in the field.

One way to avoid this is to ensure that no receptive and compatible flowers occur at destination. This may not be possible if it concerns a receptive crop (e.g. a field of canola) or if the destination cannot be managed (e.g. a semi-managed zone like a roadside). If the destination is a field managed and planted with another crop, then by removing at least the canola plants, the farmer can significantly reduce the likelihood for a successful fertilization. The RR canola pollen has no impact on another crop like oats, wheat, barley, lupins, spelt or rye, conventional or organic as the pollen cannot fertilize the flower and cross-breeding is excluded.

Once the seed is mature, the impact will be comparable to what is described below. In stages before reaching maturity, no specific impact is expected.

The genetic material in pollen and in fertilized flowers can be traced using molecular techniques. It concerns however minimal quantities that can only be revealed using highly sensitive techniques. The demonstration of the presence of the genetic information, is not indicative of any effect; merely it reflects the physical presence.

4.2.3 Mature seeds

Dispersed mature seeds can be consumed by animals. Given the demonstration of safety for feed use of RR canola, this is not expected to cause any negative impact. Upon consumption, the animals may present a secondary step of dispersal. In an Australian study, Stanton *et al.* (2003) demonstrated that sheep fed canola seed as part of their diet excreted approximately 1 to 1.5% of the canola seed and a

portion of this was able to germinate. Germination rates of the excreted seed were highest (approximately 40%) on the first day after feeding of canola seed began, but then dropped by approximately an order of magnitude thereafter. The percentage of viable seed excreted daily was therefore in the order of 0.1% of daily intake. Sheep continued to excrete viable canola seed for 6 days after canola was removed from the diet. The results from the feeding study demonstrate that ingestion of canola seed by sheep reduces the viability of excreted seed, but that a small portion of seed remains viable.

Yet, most dispersed seeds will likely become part of seed bank. While a large portion will decay, survival over longer time is possible, leading to the presence of canola plants in subsequent seasons. The seeds as such will have no impact. They are dormant and have no active function. Exposed to the particular soil conditions and to attacks from diseases and pests, they have to rely on the protective capacity of their biological features. It is possible to encourage germination and degradation by agricultural techniques, e.g. by working the soil superficially.

When present in seed, the RR trait cannot be transferred to another crop like oats, wheat, barley, lupins, spelt or rye, conventional or organic.

As seeds of RR canola carry the genetically modified trait, it is possible to identify them specifically. When incorporated in soil, the soil matrix may need to be removed in order to allow detection. Again, demonstrating their presence has no biological relevance, but only indicates the presence of the genetic information.

4.2.4 Plants

Plants can establish either as a consequence of an intentional human act or as a result of seed germination. The seed can be either dispersed directly from the source field or can be produced at the new destination following a successful pollination of a receptive and compatible flower.

If this occurs in another crop, then good management practices pre-emergence and during the season should enable the farmer to eliminate the RR plants. In the risk assessment by OGTR for RR canola (2003), the possible economic and market impacts of RR canola spreading to adjoining farms was recognized. It was highlighted that unwanted RR canola plants can be effectively removed with a range of approved herbicides and mechanical weed control methods; and that using a mixture of weed control options is consistent with integrated weed management practice. This conclusion incorporated experience from Canada where the lack of awareness of this information led to growers being surprised when volunteers in paddocks neighbouring herbicide tolerant canola showed resistance to that herbicide, even though they could be readily controlled by the application of alternative herbicides. OGTR further notes that that the number of glyphosate tolerant canola volunteers appearing in neighbouring fields as a result of gene flow will be minimal compared to those occurring in the field following the harvest of the RR canola crop.

In any event, the farmer in the destination field can take actions to prevent the establishment of the RR canola plants, in principal similar to what is expected to be done for other canola. The only difference is that Roundup® cannot be used to eliminate the plants. In order to limit the impact and difficulties to control these plants, this must be done early in the season. In any event, the plants should be removed before flowering and seed set as this would potentially prolong the volunteer issue.

Even if the RR plants flower, no impact on another crop like oats, wheat, barley, lupins, spelt or rye, conventional or organic is expected.

Sources

- Alexander T.W., Sharma R., Okine E.K., Dixon W.T., Forster R.J., Stanford K. and McAllister T.A. (2002). Impact of feed processing and mixed ruminal culture on the fate of recombinant EPSP synthase and endogenous canola plant DNA. FEMS Microbiology Letters 214: 263-269.
- Brookes G. and Barfoot P. (2013a) The global income and production effects of genetically modified (GM) crops 1996–2011. GM Crops and Food: Biotechnology in Agriculture and the Food Chain 4:1, 74 - 83
- Brookes G. and Barfoot P. (2013b) Key environmental impacts of global genetically modified (GM) crop use 1996–2011. GM Crops and Food: Biotechnology in Agriculture and the Food Chain 4:2, 109 – 119
- Canadian Food Inspection Agency (1995) "Decision Document 1995-02: Determination of Environmental Safety of Monsanto Canada Inc.'s Roundup® Herbicide-Tolerant Brassica napus Canola Line GT73" of the http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd1995-02/eng/1303706149157/1303751841490#a14
- CERA (2012). GM Crop Database. Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Washington D.C. http://cera-gmc.org/index.php?action=gm_crop_database
- Duke S. O. and Powles S. B. (2009) Glyphosate-resistant crops and weeds: now and in the future. AgBioForum 12, 346–357
- European Food Safety Authority (2009) Scientific Opinion on applications (EFSA-GMO-RX-GT73 and EFSAGMO-RX-GT73) for renewal of the authorisation for continued marketing of existing (1) food and food ingredients produced from oilseed rape GT73; and of (2) feed materials, feed additives and food additives produced from oilseed rape GT73, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2009; 7(12):1417, 12p.
- European Standing Committee on Plant Health (2002) Review report for the active substance glyphosate - Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of glyphosate in Annex I of Directive 91/414/EEC. Document 6511/VI/99-final; 21 January 2002
- Giesy J.P., Dobson S. and Solomon KR. (2000) Ecotoxicological risk assessment for Roundup herbicide. Reviews of Environmental Contamination and Toxicology 167: 35-120.
- Greenpeace International (2011) Herbicide tolerance and GM crops – Why the world should be Ready to RoundUp glyphosate. Published by Greenpeace International, 44p.
- James C. (2012) Global Status of Commercialized Biotech/GM Crops: 2012. *ISAAA Brief* No. 44. ISAAA: Ithaca, NY.
- Jennings J.C., Albee L.D., Kolwyck D.C., Surber J.B., Taylor M.L., Hartnell G.F., Lirette R.P. and Glenn, K.C. (2003a). Attempts to detect transgenic and endogenous plant DNA and transgenic protein in muscle from broilers fed YieldGard Corn Borer Corn. Poultry Science 82:371-380.
- Jennings J.C., Kolwyck D.C., Kays S.B., Whetsell A.J., Surber J.B., Cromwell G.L., Lirette R.P. and Glenn K.C. (2003b). Determining whether transgenic and endogenous plant DNA and transgenic protein are detectable in muscle from swine fed Roundup Ready soybean meal. Journal of Animal Science 81: 1447-1455.
- Mayers P.R., Kearns P., McIntyre K.E. and Eastwood J.A. (2002) Case study: canola tolerant to Roundup herbicide. An assessment of its substantial equivalence compared to non-modified canola. Genetically modified crops: assessing safety. Atherton, K.T. (Ed) Taylor & Francis, London, UK p.138 - 163.
- OECD (1999) Consensus document on general information concerning the genes and their enzymes that confer tolerance to glyphosate herbicide. Series on Harmonization of Regulatory Oversight in Biotechnology No. 10 ENV/JM/MONO(99)9, 26 pages
- OECD (1999) Consensus document on the biology of Brassica crops (*Brassica spp*). Series on Harmonization of Regulatory Oversight in Biotechnology No. 54 ENV/JM/MONO(2012)41, 142 pages

- OECD (2012) Consensus document on the biology of *Brassica napus* L. (oilseed rape). Series on Harmonization of Regulatory Oversight in Biotechnology No. 7 OCDE/GD(97)63, 32 pages
- Office of Gene Technology Regulator (2003) Risk Assessment and Risk Management Plan (Final Version) Application for licence for dealings involving an intentional release into the environment DIR 020/2002 General Release of Roundup Ready® canola (*Brassica napus*) in Australia. Applicant: Monsanto Australia Ltd
- Office of Gene Technology Regulator (2011) The Biology of *Brassica napus* L., p. 76
- Phipps R.H., Beever D.E. and Humphries D.J. (2002). Detection of transgenic DNA in milk from cows receiving herbicide tolerant (CP4EPSPS) soyabean meal. Livestock Production Science 74: 269-273.
- Stanton R., Pratley J. and Hudson D. (2003). Sheep are potential vectors for the spread of canola (*Brassica napus*) seed. Australian Journal of Experimental Agriculture 43: 535-538.

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Annex 1 Matters to be addressed in the expert report

[1] RR canola is said to be resistant to the herbicide glyphosate. Please explain:

- The scientific reason why RR Canola is resistant to glyphosate?
- Whether there are other similar GM canola varieties, which are resistant to glyphosate?
- In what ways, if any, not referred to in your answer to the above questions, does RR canola and other glyphosate resistant GM canola varieties (hereafter referred to as GR canola') differ from non GM canola?
- Why other plants such as weeds are not resistant to glyphosate?
- Whether the active ingredient in glyphosate is harmful to mammals, fish, reptiles, birds and insects or to the soil?

[2] What are the benefits (if any) of the cultivation of GR canola including, but not limited to:

- Weed control;
- Soil conservation;
- Yields;
- The need for tillage.

[3] What are the disadvantages (if any) of the cultivation of GR canola?

[4] What are the risks (if any) associated with the cultivation of GR canola? In relation to each risk identified:

- Under what circumstances may the risk eventuate and with what consequences?
- How can the risk be controlled or managed?

[5] Is there a risk of cross-pollination between GR canola and other plants (including other varieties of canola)? If so:

- Under what circumstances may this risk eventuate and with what consequences?
- How can this risk be controlled or managed?

[6] Is there a risk that GR canola seed will be transferred from a farm on which it is cultivated to some other location, that such seeds will germinate and volunteer GR canola plants grow in the latter location? If so:

- Under what circumstances may this risk eventuate and with what consequences?
- How can this risk be controlled or managed?

[7] What evidence is there (if any) that GR canola plants, seeds or products are harmful to humans, animals or to the environment?

[8] What evidence is there (if any) that GR canola plants or seeds contain harmful or toxic substances?

[9] What evidence is there (if any) that, as a result of growing GR canola plants, harmful or toxic residues may accumulate in the soil?

[10] What evidence is there (if any) that, as the result of the growing of GR canola on a farm, sheep or cattle which graze upon the farm and consume the plant or its seeds will acquire harmful or toxic residues in their body or produce (meat, milk, cheese, eggs, wool etc)?

[11] In the event that sheep or cattle graze upon volunteer GR canola plants, which have

adventitiously grown on an organic farm, will:

- Any traces of the GM component of the GR canola be retained temporarily or permanently in the body of such animals?
- Scientific testing of the body of the animal or its produce reveal traces of the GM component of the GR canola?

[12] In the event that GR canola seeds adventitiously enter an organic farm, with the result that volunteer GR canola plants germinate and grow amongst organic cereal crops on the organic farm (where the organic farmer does not grow canola), is there a risk that the GM component of the GR canola, will pass to the cereal crop plant or seeds?

[13] In the event that GR canola seeds adventitiously enter an organic farm, with the result that volunteer GR canola plants germinate and grow, if the volunteer GM canola plants are removed (e.g., by hand) before forming seed pods, will:

- Any traces of the GM component of the GR canola plant pass into the soil?
- Any harmful or toxic residues remain in the soil?

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Annex 2 Curriculum of Prof. Dr. Patrick RÜDELSHEIM

Career

Prof. Dr. Rüdelsheim obtained his PhD in biology/botany at the University of Antwerp, Belgium.

He started his career in D.J. Vanderhave B.V., a Dutch Seed company where he was involved in the application of plant cell biology in classical breeding. In 1990, he joined Plant Genetic Systems N.V., Ghent, Belgium as Field Trial Supervisor. After being in charge of Product Development and Registration, he was appointed Director Regulatory Affairs and Member of the PGS Board. In 1996, following the acquisition of PGS by AgrEvo, he became Global Head of Biotechnology Regulatory Affairs for the AgrEvo group. In this function, he ensured the scientific argumentation for Product Safety and Quality as well as the compliance with all regulatory acquirements related to genetic engineering. After the creation of Aventis S.A. due to the merger of Hoechst and Rhône-Poulenc, Patrick Rüdelsheim became Global Head Regulatory Affairs BioScience of Aventis CropScience and following the acquisition of Aventis CropScience by Bayer in 2002, he was confirmed in that position for Bayer CropScience.

In 2003, he founded and became General Partner of Perseus BVBA, a service company focused on bio-safety and related regulatory requirements.

He is active in diverse associations (President 2008-2010 of the "International Society for Biosafety Research"; President 2011-2012 of the "European BioSafety Association", co-founder of the "Belgian Biosafety Professionals", member of the board of Bio.Be, member of the board and chairman of the "TaskForce Safety in Biotechnology" of the European Federation of Biotechnology, member of EuropaBio). In 2006 he was nominated biosafety expert by Belgium to the "Roster of Experts on Biosafety" of the "Cartagena Protocol on Biosafety" (Convention on Biodiversity).

He lectures at the University of Antwerp (Bioethics) and at the University of Ghent (Biosafety).

Publications

- Horemans S., Van Onckelen H.A., Rudelsheim P.L & J.A. De Greef. (1984) Study of parameters involved in the determination of IAA and ABA in plant materials. J. Exp. Bot., 35 : 1832-1845
- Van Onckelen H.A., Rudelsheim P.L., Hermans R., Horemans S., Messens E., Hernalsteens J.-P., Van Montagu M. & J.A. De Greef. (1984) Kinetics of endogenous cytokinin, IAA and ABA levels in relation to the growth and morphology of tobacco crown gall tissue. Plant & Cell Physiol., 25 (6) : 1017-1025.
- Van Onckelen H.A., Rudelsheim P.L., Inze D., Follin A., Messens E., Horemans S., Schell J., Van Montagu M. & J.A.De Greef. (1985) Tobacco plants transformed with the Agrobacterium T-DNA gene 1 contain high amounts of indol-3-acetamide.FEBS Letters, 181 (2) : 373-376.
- Caers M., Van Onckelen H.A., Rudelsheim P.L. & S. Horemans. (1985) Effect of heat stress on photosynthetic activity and chloroplast ultrastructure in correlation with endogenous cytokinin concentration in Maize seedlings. Plant & Cell Physiol. 26 : 47-52.
- Wyndaele R., Van Onckelen H.A., Christiansen J., Rudelsheim P.L., Hermans R. & J.A. De Greef. (1985) Dynamics of endogenous IAA and cytokinins during the growth cycle of soybean crown gall and untransformed callus. Plant & Cell Physiol., 26 (6) : 1147-1154.
- Van Onckelen H.A., Prinsen E., Inze D., Rudelsheim P.L., Van Lijsebettens M., Follin A., Schell J., Van Montagu M. & J.A.De Greef. (1986) Agrobacterium T-DNA gene 1 codes for tryptophan-2-monooxygenase activity in tobacco crown gall cells. FEBS Letters, 198 (2) : 357-360
- P. Rudelsheim, E. Prinsen, M. Van Lijsebettens, D. Inze, M. Van Montagu , J.A. De Greef & H.A. Van Onckelen. (1987) The effect of mutations in the T-DNA encoded auxin pathway on the endogenous phytohormone content in cloned *Nicotiana tabacum* crown gall tissues. Plant & Cell Physiol., 28(3), 86-174

- D. Inze, A. Follin, J. Velten, E. Prinsen, P. Rudelsheim, H.A. Van Onckelen, J. Schell & M. Van Montagu. (1987) The *Pseudomonas savastanoi* tryptophan-2-mono-oxygenase is biologically active in *Nicotiana tabacum*. Planta, 172, 555-562
- D. Inze, A. Follin, H. Van Onckelen, P. Rudelsheim, J.Schell And M. Van Montagu. (1987) Functional analysis of the T-DNA *onc* genes. In: "Molecular Biology of Plant Growth Control", UCLA Symposia on Molecular and Cellular Biology, New Series Vol.44, J.E.Fox and M.Jacobs Eds. New York, Alan R. Liss., p 181 -196
- P. Rudelsheim, M. De Loose ,D. Inze, M. Van Montagu, J.A.De Greef & H.A. Van Onckelen. (1987) Phytohormone-receptors from tobacco crown gall tissues. In: "Plant Hormone Receptors",D.Klaembt Ed., Springer-Verlag Heidelberg, 71-79
- P. Ulvskov, J. Marcussen, R. Rajacopal, E. Prinsen,P. Rudelsheim & H. Van Onckelen. (1987) Immunoaffinity purification of indole-3-acetamide using monoclonal antibodies. Plant & Cell Physiology, 28(5) 937-946
- P. Rudelsheim, D. Inze, J.P. Hernalsteens, R. Wyndaele, J.A. De Greef & H.A. Van Onckelen. (1987) Phytohormones in transformed plant cells. Med.Fac.Landbouww.Rijksuniv.Gent,52(4),1399-1407
- H. Van Onckelen, P. Rudelsheim, S. Beinsberger, D. Inze, M. Van Montagu & J. De Greef. (1988) Mutual interaction of plant specific and T-DNA controlled IAA metabolism in transformed tobacco tissue. In: "Physiol.and Bioch.of Auxins in Plants" M.Kutacek, R.S.Bandurski,J.Krekule (eds.),Academia Praha pp.379-387
- R. Wyndaele, J. Christiansen, R. Horseele, P. Rudelsheim & H.A. Van Onckelen. (1988) Endogenous IAA and cytokinin levels in transformed and habituated soybean cell lines. In:" Physiol. and Bioch. of Auxins in Plants", M.Kutacec, R.S.Bandurski,J.Krekule (eds.),Academia Praha, pp.415-420
- Wyndaele R., Christiansen J., Horseele R., Rudelsheim P. & Van Onckelen H. (1988) Functional correlation between endogenous phytohormone levels and hormone autotrophy of transformed and habituated soybean cell lines. Plant Cell Physiol.29(7), 1095- 1101.
- Rudelsheim P., Beinsberger S., Inze D., Christiansen J., Wyndaele R., De Greef J. & Van Onckelen H. (1988) T-DNA controlled and plant specific metabolism in Agrobacterium tumefaciens transformed Tobacco and Soybean tissues. Bull. Soc. bot. Fr.135, Actual. bot., 63-71.
- Prinsen E., Rüdelsheim P. & Van Onckelen H. (1991) Extraction, purification and analysis of endogenous indole-3-acetic acid and abscisic acid.- In: A laboratory guide for cellular and molecular plant biology / Negrutiu I. [edit.], e.a., Basel, Birkhäuser, 1991, p. 198-209
- Fredshavn, J.R., Poulsen, G.S., Huybrechts, I. & Rüdelsheim, P. (1995). Competitiveness of transgenic oilseed rape. Transgenic Res. 4: 142-8.
- Rüdelsheim P. (2008) CEN Workshop establishes an international Laboratory Biorisk Management Standard New BIOTECHNOLOGY Volume 25 (2-3), 117-118
- Johnson L, Anthony V, Alhassan WS and Rudelsheim P, eds. (2011). Agricultural Biotechnology in Africa: Stewardship Case Studies. Forum for Agricultural Research in Africa (FARA). Accra, Ghana. ISBN 978-9988-9373-4- 3
- Rüdelsheim P. (in press) Addressing Biosafety and Regulatory Issues Throughout the Product Life Cycle of a GM Crop. Collection of Biosafety Reviews

Conferences

- Presentation at the 1990 Kiawah Island, North Carolina Symposium "Biological Monitoring of Genetically Engineered Plants and Microbes"
- Cited in OECD environment monographs no. 91 Compendium of methods for monitoring organisms in the environment - Paris 1994
- Panel leader and rapporteur at the 3rd International Symposium on "The Biosafety Results of Field Tests of Genetically Modified Plants and Micro organisms" 1996, Monterey, California
- Vice-chair at the 1994 OECD "workshop on the commercialisation of agricultural products derived through modern biotechnology."
- Contribution at the Workshop on "Key biosafety aspects of genetically modified organisms" 1995, Braunschweig, Germany
- Contribution at the 1995 workshop of the Coordination Commission Risk Assessment Research (CCRO) on "Does the "Step-by-step" procedure perform as expected in the regulation of GMO trials?" The Netherlands
- Presentation at the 4th International Symposium on "The Biosafety Results of Field Tests of Genetically Modified Plants and Micro organisms" 1996, Tsukuba, Japan
- Presentation at the Brighton Crop Protection Conference (1997). European challenges for plant biotechnology. – Weeds 2:725-730.
- Contribution at the Advisory Committee on Releases to the Environment (ACRE) T25 Maize Hearing February 20th 2002.

- Presentation at the Workshop "Precautionary Principle", 2003, Brussels, Belgium
- Presentation "Deliberate release of GM plants: two decades of biosafety experience" at EBSA 2005 conference, Barcelona, Spain.
- Co-organizer of the "Workshop on the National Biosafety Framework of Romania - Current situation and next steps" 27 – 28 October 2005, Bucharest, Romania
- Organizer of the Seminar "Moving biological material into and out of Belgium: an update on requirements" on February 20, 2006, in Brussels, Belgium
- Co-organizer of the scientific inaugural meeting of the Belgian BioSafety Professionals on 28 March, 2006 in Brussels, Belgium.
- Co-organizer of the meeting of the Belgian BioSafety Professionals on "Standards for emergency plans for contained use of GMMOs" on 13 September 2006, in Ghent, Belgium.
- Co-organizer of the training workshop of the Belgian BioSafety Professionals on "Emergency plans for contained use of biological agents" on 13 March 2007, in Ghent, Belgium.
- Trainer at the workshop "Export, import and transport of GMOs from a practitioner point of view" at the 10th Annual Conference of the European Biosafety Association, 28 - 30 March 2007, Heidelberg/Germany
- Moderator of the session "Plant biotechnology use of plants as factories for the production of non-food products (pharmaceutical & industrial products)" at the 10th Annual Conference of the European Biosafety Association, 28 - 30 March 2007, Heidelberg/Germany
- Member of the Organizing Committee of the 13th European Congress on Biotechnology, on 17 - 19 September 2007, in Barcelona, Spain
- Co-organizer of the Belgian BioSafety Professionals Symposium on "Recent developments in decontamination technologies and practices Emergency plans for contained use of biological agents' on 11 December 2007, in Leuven, Belgium.
- Guest-lecturer on "From Transformation to market" at the IPBO Postgraduate Biosafety, 3 – 14 December, 2007 in Ghent, Belgium
- Presentation on "Food & Trade Issues in Europe" at the conference "Second Decade of Crop Biotechnology" on 16 - 17 January, 2008 in Washington D.C., USA.
- Member of the Organizing Committee of and Session Chairman at the 11th Annual Conference of the European Biosafety Association, 2 - 4 April 2008, Firenze/Italy
- Presentation on "Call GMO: How to prepare for and react on observations from the broad public?" at the conference "Workshop on Post Market Environmental Monitoring of Genetically Modified Plants: From Data to Conclusions - Next Steps towards Monitoring Practice" on April, 24-25, 2008, Berlin/Germany
- Presentation on "Drivers of GMO regulation" at the conference "EuroBio 2008" on October 7-9, 2008 Paris/France
- Member of the Symposium Committee of and Session Chairman at the 10th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO), 16 - 21 November 2008, Wellington/New Zealand
- Member of the Organizing Committee of and Session Chairman at the 12th Annual Conference of the European Biosafety Association, 15 - 17 June 2009, Stockholm/ Sweden
- Trainer at the workshop "Export, import and transport of GMOs from a practitioner point of view" at the 12th Annual Conference of the European Biosafety Association, 15 - 17 June 2009, Stockholm/Sweden
- Speaker at the BIOSAFENET Final Conference "How to strengthen the voice of biosafety research in the public debate on GM plants" 29 June 2009, Berlin/ Germany
- Trainer at the Workshop "Theoretical Approaches and their Practical Application in the Risk Assessment for the Deliberate Release of Genetically Modified Plants" of the International Centre for Genetic Engineering and Biotechnology (ICGEB), 12 – 16 October 2009 Ca' Tron di Roncade, Italy
- Presentation on "International Perspectives – Key Issues Affecting Adoption and Trade of GE Crops" at the 33rd Annual Meeting of the North American Plant Protection Organization (NAPPO) October 19 - 23, 2009, Chicago, USA
- Presentation on "Fermentatie en biokatalyse: het regulatoire kader geschetst" at the CINBIOS-workshop March 22, 2010, Mechelen, Belgium
- Presentation on "General Surveillance - Working with existing networks" at the Workshop on Post Market Environmental Monitoring of Genetically Modified Plants, May 3-4, 2010, Quedlinburg, Germany
- Chair of the Organizing Committee of and Session Chairman at the 13th Annual Conference of the European Biosafety Association, 22 - 23 June 2010, Ljubljana/Slovenia
- Trainer at the workshop "Emergency preparedness and contingency planning" at the 13th Annual Conference of the European Biosafety Association, 22 - 23 June 2010, Ljubljana/Slovenia

- Trainer at the Course "Introduction to Risk Analysis of Genetically Modified Organisms (GMO)"; on 3 – 7 October 2010 at the Kuwait Institute for Scientific Research, Kuwait.
- Member of the Symposium Committee of the 11th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO), 15 - 20 November 2010, Buenos Aires, Argentina
- Presentation on "Technical Specifications for GMO Detection for Seeds and Food Products " at the Second Regional Workshop on "Implementation of the Regional Platform for GMOs Detection Platform" of the FAO project TCP/RAB/3202 (D) on 24 - 27 January 2011, Beirut, Lebanon.
- Presentation and resource person at the "South Africa / Argentina Joint Regional Biosafety Workshop and Seminar "Biosafety of GM crops: Emerging issues and challenges in regulatory decision making", 7-11 March 2011, Pretoria, South Africa
- Chair of the Organizing Committee, Session Chairman and presenter at the 14th Annual Conference of the European Biosafety Association, 13 - 15 April 2011, Estoril, Portugal
- Presentation on "Introduction to the legal framework" at the Workshop "Biosafety for Plants and Plant Pathogens" of the Belgian Biosafety Professionals, 14 June 2011, Ghent, Belgium.
- Presentation on "PREM in Europe: What is Driving the Build-up of Requirements?" at the "Conference on Current Approaches to the Environmental Risk Assessment of Genetically Engineered Crops", 27 - 29 June, 2011, Hanoi, Vietnam
- Expert contribution in the workshop "Transgenes Going Wild? Risk Assessment of Transgene Introgression from Crops into Wild Relatives" 11 - 15 July 2011, at the Lorentz Center, Leiden, the Netherlands
- Presentation on "Les contraintes économiques provoquées par la réglementation des plantes transgéniques" at the "Colloque international: Biotechnologies Végétales, Environnement, Alimentation Et Santé : Quel Futur ?" 20 September 2011, Paris, France
- Chair of the "Chemical Disinfection Workshop" of the BVFPlatform and the Belgian Biosafety Professionals, 4 October 2011, Antwerp, Belgium.
- Presentation on "EBSA Programmes" at the "3rd Annual International Symposium - Biosecurity and Biosafety: Future Trends and Solutions", 12 - 14October, 2011, Milan, Italy
- Presentations on "EBSA and The Year of Building International Biosafety Communities" and "CEN WS 55 - Guidance document for CWA-15793 , CEN WS 53 - Biosafety Professional Competence document" at the Nordic Biosafety Network Meeting, 26 - 27 October, 2011 Riga, Latvia
- Main trainer at the FARA Course "Introduction to Biotechnology Stewardship" and "SABIMA Advanced Stewardship Trainer's Course"; on 28 November 2011, Accra, Ghana.
- Member of the International Organizing Committee of the "FIRST PAN-AFRICAN BIOTECHNOLOGY STEWARDSHIP CONFERENCE - Africa Managing Safe And High-Quality Biotech Crops" on 29 - 30 November 2011, Accra, Ghana.
- Presentation on "Biosafety organizations; the road ahead" at the BBP 2011 Symposium, 13 December 2011, Leuven, Belgium
- Scientific programme coordinator and trainer at the "Atelier International de Biosécurité en Laboratoire", 20 – 24 February 2012, Sfax, Tunisia
- Presentation on "Biosafety" at the 47th Seminaries of Occupational Health, 7 March 2012, Antwerp, Belgium
- Presentation on "Case study of incident with biological agents" at the National Meeting of Prevention Advisors, 13 March 2012, Affligem, Belgium
- Facilitator and rapporteur of the "Partners and Stakeholders' Meeting on Biosafety Capacity Development in Africa", 19 – 20 March 2012, Entebbe, Uganda
- Presentation on "Etats des lieux de la réglementation dans L'Union Européenne" at the Seminar "New Breeding Techniques" of the Union Français des Semenciers, 27 March 2012, Paris, France
- Co-organizer of the Workshop "Practical Biosecurity" by the Belgian Biosafety Professionals, May 3 2012, Antwerp, Belgium
- Participation in the 5th Workshop on Post Market Environmental Monitoring of Genetically Modified Plants: State of the Art, 10 – 11 May 2012, Berlin-Dahlem, Germany
- Presentation on "Biosafety organizations; the road ahead" at the 3rd Biosafety Symposium of the Italian Biosafety Platform, 16 May 2012, Firenze, Italy
- Chair of the Organizing Committee of the 15th Annual Conference of the European Biosafety Association, 12 - 13 June 2012, Manchester, UK
- Trainer at the workshop "Emergency preparedness and contingency planning" at the 15th Annual Conference of the European Biosafety Association, 11 June 2012, Manchester, UK
- Presentation on " Risk Assessment and Management: Capacity Building and Information sharing". at the "Strengthening Capacity for Implementation of the Biosafety Protocol in Africa" meeting 28-29 August 2012, Pretoria, South Africa

- Presentation (Poster) "Selecting existing monitoring networks for their utility in post market environmental monitoring of GMOs" at the 12th International Symposium on Biosafety of Genetically Modified Organisms, 16 – 20 September 2012, St Louis, USA
- Facilitator and rapporteur of the "Partners and Stakeholders' Meeting on Biosafety Capacity Development in Africa", 5 – 6 March 2013, Accra, Ghana
- Participant to the ERINHA BSL4-Workshop; 11 – 15 March 2013, Spiez, Switzerland
- Presentation on "Core elements of bio-incident management" at the meeting Bioincidents organised by the Belgian Biosafety Professionals, 7 May 2013, Liège, Belgium
- Presenter and main resource person at the workshop "Atelier sur les procédures standards règlementaires" organised by the by the National Biosafety Agency on 2 – 3 May 2013, Ouagadougou, Burkina Faso
- Chair of the Organizing Committee of the 16th Annual Conference of the European Biosafety Association, 17-18 June 2013, Basel, Switzerland
- Trainer at the pre-conference course "Emergency preparedness and response & incident and accident investigation" at the 16th Annual Conference of the European Biosafety Association, 17-18 June 2013, Basel, Switzerland
- Presentation and resource person at the "Strategic approaches in the Evaluation of the Science underpinning GMO Regulatory Decision-making" Biosafety Training Workshop organised by the International Centre for Genetic Engineering & Biotechnology in collaboration with the Italian Ministry of the Environment, 1-5 July 2013, Trieste, Italy
- Course director and faculty member at the 2013 Summer Course "Principles of Biorisk Management" at the University of Ghent, 9 – 13 September 2013, Ghent, Belgium

Projects

- Coordinator EC project BIOT-CT91-0298 "Safety assessment of the deliberate release of two model transgenic crop plants, oilseed rape and sugar beet"
- Contributor EC project BAP-0371/0384/0408/0423 "Study of gene dispersal from plants produced by recombinant DNA technology"
- Contributor EC project AIR3-CT94-2311 "Development of new methods for safety evaluation of transgenic food crops."
- Contributor EC project QLK1-1999-01182 "European network for safety assessment of genetically modified food crops"
- Contributor to the EU Workshop Precautionary Expertise for GM Crops (PEG), Quality of Life and Management of Living Resources - Key Action 111-13 Project no QLRT-2001-00034
- Performer of "EU-wide regulatory and stakeholder consultation on the integration of regulation for genetically modified organisms and clinical trial procedures" (EC contract n° 070402/2005/419827/MAR/B4)
- Performer of the Dutch COGEM project "Gg-gewassen met opbrengstverhogende/ handhavende eigenschappen zoals stresstoleranties"
- Contributor to the EU FP7 project "PEGASUS - Public Perception of Genetically modified Animals - Science, Utility and Society" (on-going)
- Consultant to FAO project TCP/RAB/3202 (D) "Strengthening capacities towards the establishment of a regional platform for the detection of genetically modified organisms"
- Performer of the Dutch COGEM project "Methodology for environmental risk assessments in medical and veterinary biotechnology"
- Performer of the Dutch COGEM project "Inventory gene therapy clinical trials in North-America"
- Contributor to the EU FP7 project "GRACE - GMO Risk Assessment and Communication of Evidence" (on-going)
- Performer of the project from the Belgian Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health on "Survey on the systems used for in vitro selection of GM plants intended for field research or commercial introduction".
- Contributor to the EFSA OC/EFSA/SAS/2012/02 project "Review of statistical methods and data requirements to support post market environmental monitoring of agro ecosystems" (on-going)
- Performer of the Dutch COGEM project "Allergens" (on-going)
- Contributor to the EU FP7 project "Nano3Bio – NanoBioEngineering of BioInspired BioPolymers" (on-going)

(3)

Expert Report by Dr. Christopher Preston, University of Adelaide
Re: Stephen William Marsh vs Michael Owen Baxter
Supreme Court of Western Australia – CIV 1561 of 2012

Prior to the preparation of this report I have been provided with a copy of the Code of Conduct for Expert Witnesses and certify this report complies with said code. In preparation of the report, I have responded to a set of questions put to me. I have relied on my own research both published and unpublished, my experience in the Australian agricultural sector and published research and reports from others.

1. **Please attach your curriculum vitae and provide a summary of your qualifications in agricultural science, plant science and research.**

I am an Associate Professor of Weed Management employed at the University of Adelaide. I have a Ph.D. in plant biochemistry in the course of which I investigated aspects of photosynthesis in salt-tolerant species. I spent 2.5 years working for the US Department of Energy on fundamental aspects of photosynthesis and the past 23 years working on herbicide resistant weeds at the University of Adelaide. I have published 96 peer reviewed research papers, as well as several book chapters.

In addition to my research and teaching activities, I sit on several industry committees including Chair of the Australian Glyphosate Sustainability Working Group, the National Integrated Weed Management Initiative and the Transgenic and Insect Management Strategies Committee Herbicide Technical Panel for the cotton industry. I also advise various agricultural companies, industry bodies and government agencies about herbicide resistance issues. I participate in the Herbicide Resistance Consultative Groups for Monsanto and Pioneer/Dupont and provide weed ecology and resistance management expertise to Monsanto's Institutional Biosafety Committee.

I have attached a brief CV.

2. **Please outline the details of any studies and research in which you have been involved in relation to the survival rates of volunteer canola plants in fields, on the roadside and in bush land in the agricultural areas of Australia:**
   i. **Where was such study or research conducted?**
   ii. **What methodology was employed in the conduct of the study or research?**
   iii. **What were the results of the study or research?**
   iv. **Were the results of the study or research published, and if so in what publication?**
   v. **Please provide your reasons for reaching the conclusions resulting from the study and research.**

I have designed and participated in research to address risk factors around canola volunteers in fields and on roadsides. This research has been conducted in South Australia, Victoria and New South Wales. Several pieces of research have been conducted. A study investigating persistence of canola in farmer's fields will be

addressed in the next section. In this section I will only address three studies examining canola on roadsides.

The first study was conducted in Victoria and South Australia in 2000-2002. In this study we collected seed pods from surviving canola plants growing along road sides. Pods were collected from up to 30 individual plants at individual locations separated by 400 km. For a total of 7 populations, DNA was separately extracted from one or more seed from each plant and a DNA fingerprinting technique called ISSR used to determine how many canola cultivars were present in each population. A set of canola cultivars grown in the region was provided by Mr Trent Potter, the SA canola breeder, to confirm that the technique was able to identify individual genotypes. The research also compared the genotype of the parent plant (by extracting DNA from the pod) with the progeny (DNA from seed inside the pod) to determine whether outcrossing was occurring in these roadside populations.

The results of this study were that small roadside canola populations (<5 individuals) shared a single genotype. Larger populations were composed of multiple genotypes (ranging from 2 to 5). The studies of parental and progeny DNA found no evidence of hybridization in the roadside populations.

Aspects of this research have been published in:

Baker, J., Hidayat, I. and Preston, C. 2007. Molecular tools for understanding distribution and spread of weed genotypes. Crop Protection 26, 198-206.

Baker, J. and Preston, C. 2004. Roadside canola in South Australia and Victoria: persistent or transient populations? In B.M. Sindel and S.B. Johnson eds. Proceedings of the 14th Australian Weeds Conference. Weed Society of New South Wales, Sydney, pp. 403-405.

I concluded from this research that canola populations on roadsides were the result of one or more spills from grain trucks rather than from persistent populations built up over time. The more complex populations were located near grain receival points where large numbers of grain trucks move, providing the opportunity for multiple spills. However, it was not possible to state whether the spills had occurred in a single year or over multiple years. I did conclude it was unlikely that the populations had persisted on the sites for many years, because if that were the case hybridisation between cultivars on roadsides would be expected. There was no evidence of this in the data collected.

The second study was conducted in 2009-2010. This study was conducted in Victoria. This study took advantage of the fact that only two grain receival sites were available for GM canola growers in western Victoria in the 2008 season. During early spring in 2009 a survey was conducted around Tatyoon and Lubeck in Victoria and leaf material collected from any canola plants growing on roadsides within 5 km of the grain receival points. The locations of the plants sampled were recorded using GPS. In total 50 samples were collected from 14 sites near Tatyoon and 51 samples collected from 17 sites near Lubeck. DNA was extracted from the leaf sample and tested for presence of the CP4 EPSPS using specific PCR primers. In 2010, the locations re-visited and leaf material collected from any canola plants occurring

within 50 m of the original locations. A total of 31 samples were collected at Tatyoon and 62 samples were collected at Lubeck. DNA was extracted from the leaf samples and tested for the presence of the C4 EPSPS using specific PCR primers.

In 2009, we identified GM canola at one location of the 14 sites near Tatyoon and at 5 locations of the 17 sites at Lubeck. In 2010, no sites at Tatyoon had GM canola present. At Lubeck, only one site that had GM canola present in 2009 had GM canola present in 2010. The remaining sites with GM canola present in 2009 had only non-GM canola present in 2010. At Lubeck, 4 of the sites that had no GM canola in 2009 had GM canola present in 2010. Across both sites, 14 of the 31 locations visited in 2009 had no canola present within 50 m in 2010.

This research is being prepared for publication and should be submitted by the end of 2013.

I concluded from this research that GM canola will be found on roadsides, particularly close to the grain receival points. Many of the locations where canola was present were on road bends, close to bridges and at intersections, areas where spills are more likely. I further concluded GM canola on road sides was not persisting in high numbers from year to year as most locations containing GM canola in one year had no GM canola the next year. Likewise, one location having only non-GM canola in 2009 had only GM canola in 2010. Therefore, a considerable portion of the canola on roadsides must be the result of spills from the previous year's harvest.

The third piece of research conducted was a survey of roadside canola populations across the canola-growing regions of Victoria and NSW in 2010. In this research, leaf samples were collected from canola volunteers growing on roadsides in spring 2010. A leaf was collected from a single plant at 292 locations. DNA was extracted from the leaf material and tested for the presence of the CP4 EPSPS using specific PCR primers.

The research was able to identify samples as GM canola in 49 samples out of the 292 tested. Therefore, across this area about 17% of the canola growing on roadsides was GM.

This research is being prepared for publication and should be submitted by the end of 2013.

I concluded from this research that GM canola present on roadsides was at a similar proportion to the area of the crop planted in the previous year. A market survey of 501 canola growers in NSW and Victoria in 2009 conducted by Hudson and Richards (2013) found 19% of the canola area planted by these growers was sown with Roundup Ready canola. Therefore, most canola growing on roadsides was likely to have arisen from spills from the previous year and a large population of canola was not persisting from year to year.

Hudson, D. and Richards, R. (2013) Evaluation of the agronomic, environmental, economic and co-existence impacts following the introduction of GM canola to Australia (2010-2012). Paper presented at GMCC-13, Lisbon 12-15 November 2013.

If large canola populations were to persist in roadside environments from year to year, then the amount of seed contributed by new seed spills would be considerably lower than the total amount of seed present in this environment. GM canola was first planted in NSW and Victoria over a very small area in 2008. Therefore, there would have been little opportunity for GM canola seed banks on road sides to build up to any size and nearly all of the seed present in seed banks would be from non-GM canola. Under such circumstances, the proportion of GM canola on roadsides in 2010 should have been much lower than the proportion of area planted to GM canola in 2009.

3. **Please describe the details of any studies and research in which you have been involved as to the survival of the canola seed bank in farmer managed paddocks in the agricultural areas of Australia:**
   i. **Where was such study or research conducted?**
   ii. **What methodology was employed in the conduct of the study or research?**
   iii. **What were the results of the study or research?**
   iv. **Were the results of the study or research published, and if so in what publication?**
   v. **Please provide your reasons for reaching the conclusions resulting from the study and research.**

From 2002 to 2005 research was conducted on commercial farms to examine the persistence of canola volunteers in commercial practice. Soil samples were collected from fields that had previously grown canola. The canola seed were removed from the soil by sieving and washing. Canola seed were identified visually. In 2005, seed was also tested for viability through a germination test.

This research determined that canola seed banks in the commercial fields decayed quickly after canola harvest and no viable seed remained after 2.5 years. There was an initial difference between minimum tillage (one pass prior to seeding) and no-till (direct drill with narrow points) systems in that higher seed banks were present in the minimum tillage system 6 months after harvest. However, this difference between tillage systems declined with time.

This research was published in:

Baker, J. and Preston, C. 2008. Canola (*Brassica napus* L.) seedbank declines rapidly in farmer-managed fields in South Australia. Australian Journal of Agricultural Research 59, 780-784.

I concluded from the research that volunteer canola would occur in cropped fields in the years after canola production, but that the seed bank would decay rapidly. The normal management practices adopted by the farmers in the area surveyed were effectively driving volunteer canola populations to extinction on their farms. We drew this conclusion from the rate of decline in populations between years and the fact that at 3.5 years no germinable canola seed remained.

4. **Please describe the studies and research in which you have been involved relating to the capacity of canola plants to cross pollinate with other plant varieties in Australia:**
   i. **Where was such study or research conducted?**
   ii. **What methodology was employed in the conduct of the study or research?**
   iii. **What were the results of the study or research?**
   iv. **Were the results of the study or research published, and if so in what publication?**
   v. **Please provide your reasons for reaching the conclusions resulting from the study and research.**

I have been involved in three trials investigating the capacity of canola to cross pollinate. One of the trials investigated the ability of canola to cross pollinate with wild radish under field conditions and was conducted in 1997-1999 in South Australia. The other two trials examined the ability of canola crops to cross pollinate and were conducted in 2000 in NSW, Victoria and South Australia and in 2008-2009 in NSW, Victoria and Western Australia.

For the wild radish trial, we grew test plots of canola (either susceptible or resistant to imidazolinone herbicides) with wild radish planted at 1 and 4 plants/m^2. Two wild radish populations were used: 1 susceptible to herbicides and 1 resistant to sulfonylurea herbicides. The susceptible wild radish was planted in the resistant canola plots and the resistant wild radish in the susceptible canola plots. At the end of the season, the wild radish was removed from the plots. Seed from the susceptible wild radish was kept and tested for resistance to herbicides. Seed from the susceptible canola plots was harvested and tested for resistance to herbicides. Any plants surviving the herbicide screen were further analysed through chromosome counts, RFLP analysis and morphologically to determine they were hybrids.

A total of 30,000 wild radish seedlings were screened and no hybrids identified. A total of 52 million canola seeds were screened, with 2 hybrids identified. These hybrids had 56 chromosomes, consistent with the hybrids being allohexaploids containing all canola and wild radish chromosomes. The hybrids were also intermediate in morphological characteristics between canola and wild radish and contained genetic material from both species. This work determined that hybrids between canola and wild radish would occur in the field, but at low frequencies. Where the hybrids occurred by crossing from wild radish to canola, it is most likely the seed would be harvested and removed.

This research was published in:

Rieger, M.A., Potter, T., Preston, C. and Powles, S.B. 2001. Hybridisation between *Brassica napus* L. and *Raphanus raphanistrum* L. under agronomic field conditions. Theoretical and Applied Genetics 103, 555-560.

Rieger, M.A., Preston, C., Potter, T. and Powles, S.B. 1999. Gene flow from transgenic canola to wild radish - a model system to determine the risks. In Lutman, P.J.W. ed. Gene Flow and Agriculture: Relevance for Transgenic Crops. British Crop Protection Council, Farnham UK, pp. 131-136.

I concluded from the research that viable hybrids between wild radish and canola were likely to occur in the field, but would occur at low frequencies. Where the canola carries a herbicide tolerance trait, the wild radish may become resistant to the herbicide through outcrossing. However, this is unlikely to become a major practical problem in the field, because it is likely resistance in wild radish would be selected by herbicide use faster in most cases than it would occur through gene flow.

A trial was conducted in 2000 in NSW, Victoria and South Australia to examine the potential of canola to cross-pollinate between crops. The research took advantage of the fact that imidazolinone-resistant canola (Clearfield canola) was sown commercially for the first time in 2000. Growers of Clearfield canola crops were identified and after crops had been windrowed, seed was collected from nearby non-Clearfield crops. The seed was collected from three different positions in each crop. Seed was sown, allowed to germinate and treated twice with a discriminating dose of a sulfonylurea herbicide.

A total of 63 non-Clearfield fields were visited. Herbicide resistant individuals were found in canola crops up to 3 km from the source crop. However, frequencies of resistance were low; below 0.2% in any collection. On a field basis, the level of resistant individuals averaged 0.009% of seed with a highest value of 0.07%.

This research was published in:

Rieger, M.A., Lamond, M., Preston, C., Powles, S.B. and Roush, R.T. 2002. Pollen-mediated movement of herbicide resistance between commercial canola fields. Science 296, 2386-2388.

My co-authors and I concluded from this research that co-existence of GM and non-GM canola should be possible in the Australian agricultural environment with delivery below market thresholds for adventitious presence, so long as a small buffer was in place between crops to limit mixing of seed at harvest. This conclusion was based on the low levels of herbicide tolerant canola present in the sink crops. My co-authors and I also concluded that sporadic low frequency gene movement was likely to occur and growers should manage the impact of this through effective management of canola volunteers.

In 2008 and 2009 we repeated the above trial using Roundup Ready canola crops as source crops. The methodology used was similar to the 2000 trial; except we used glyphosate herbicide to detect resistance and further confirmed resistance by PCR amplification of the CP4 EPSPS gene. This trial was conducted in NSW and Victoria in 2008 and Western Australia in 2009.

Samples were collected from a total of 121 non-GM canola crops located near 45 Roundup Ready crops. The frequency of herbicide resistant individuals ranged from 0 to 5.5% in any collection. High numbers were from samples collected close to the source GM crop (within 20 m). Resistance was detected up to 4.3 km from the source crop. On a field basis, resistance varied between 0 and 0.8% of canola seed. The amount of gene flow was higher in this trial than in the 2000 trial; averaging 0.05% in 2008 and 0.07% in 2009 compared with 0.009% in 2000.

This research has been submitted to Nature Biotechnology for review.

I concluded from this trial that even though the amount of gene flow was higher in 2008 and 2009, compared with 2000, that co-existence should still be practical in the Australian cropping system provided an appropriate buffer zone is in place. I came to this conclusion based on the evidence that the highest amount of resistance detected was still under the allowed adventitious presence limits (0.9%) for non-GM canola as stipulated by the European Union (EU). In addition, the research conducted in 2008 and 2009 showed there was a significantly higher frequency of gene flow to the windrow closest to the Roundup Ready crop than to elsewhere in the field. I concluded from this that the methodology used was likely to over-estimate the amount of GM canola present in non-GM fields.

5. **To what extent are the findings resulting from your studies and research as to the survival rates of volunteer canola plants and seeds on roadsides, in the field, and in bush land relevant to the survival rates of GM canola volunteers and seeds?**

The data from research I have been involved in concerning decay of canola seed banks in farmer fields is entirely relevant to the survival rates of canola seed in cropped fields in the Australian environment. The research on roadside canola is less relevant, but supportive of the fact that seed banks of canola decline rapidly with time. Adequate management of canola volunteers so that seed set is prevented should lead to extinction of the canola in less than 3.5 years. In our study above, the growers were implementing no additional practices to their normal weed control in order to limit the canola seed bank. Therefore, some canola plants were likely flowering each year and setting seed. Had these flowering canola plants been more rigorously controlled the growers may have been able to reduce their canola seed bank more quickly.

6. **Does GM canola have the capacity to cross pollinate with other varieties of canola? If so, what practices are followed in the agricultural areas of Australia to enable GM canola and non-GM canola to co-exist?**

The research I have been involved in discussed above has demonstrated that GM canola can cross pollinate with other varieties of canola. On a field basis, the rates of cross pollination are typically low, but can be as high as 0.8%. Cross pollination is more likely when crops are planted within 10 m and declines rapidly with distance.

The Roundup Ready Crop Management Plan recommends a minimum distance of 5 m between GM canola and other canola types to minimise adventitious presence.

Further under the Roundup Ready Crop Management Plan, if GM and non-GM canola are grown within 5 m of each other, growers are required to take action to reduce the impact of adventitious presence. These actions are to either slash and/or cultivate a 5 m band of the Roundup Ready crop prior to the onset of flowering or to deliver the first 5 m of the non-GM crop as GM canola.

7. **In Australia what tolerance is there for the presence of GM canola seeds in non-GM canola seed before delivery to the market?**

The Australian Oilseed Federation (AOF) produces oilseed delivery standards for Australia under the auspices of Grain Trade Australia, previously NACMA. The AOF canola delivery standard for non-GM canola CSO 1-a, states that under the standard:

"The adventitious presence of up to 0.9% of GM events approved by the Australian Government Office of the Gene Technology Regulator is permitted".

This value was set in order to meet international market requirements for non-GM canola. The value is consistent with the EU requirements for adventitious presence in canola seed.

8. **In Australia what tolerance is there for GM canola seed in non-GM canola seed in seed for sowing?**

The industry through the Australian Seeds Federation has established a standard for adventitious presence of approved GM canola events be below 0.5% in non-GM canola seed for sowing.

9. **Has scientific research or studies been conducted in Australia to determine the level of success in the management of the co-existence of GM canola and non-GM canola in keeping the GM canola within the permissible thresholds in non-GM canola crops? If so:**
   i. **Please identify the studies and research;**
   ii. **What conclusions did you reach as a result of the studies and research?**

In Australia, co-existence of GM and non-GM canola is an industry managed issue. It is managed through requirements in the Roundup Ready Crop Management Plan, Crop Declaration requirements for growers delivering canola, and testing of canola in the supply chain for adventitious presence.

The AOF has published three reports assessing co-existence practices covering the 2008/9 to 2010/11 seasons:

Market Choice in the Canola Industry: 2008/9 Final Stakeholders Report

Market Choice in the Canola Industry: 2009/10 Season Performance Report

Market Choice in the Canola Industry 2010/11 Season: Performance Report October 2011

These reports indicate no significant problems with co-existence of GM and non-GM canola in Australia in terms of delivery of specified products to markets.

Additionally, McCauley et al. (2012) published a paper that examined the introduction of GM canola into Western Australia:

McCauley, R., Davies, M., and Wyntje, A. (2012). The Step-wise Approach to Adoption of Genetically Modified (GM) Canola in Western Australia. AgBioForum, 15: 61-69.

This paper addressed the issues of adventitious presence and concluded:

> "There was effective segregation of non-GM canola from GM canola in 2009 and 2010. There was a coexistence-related event where an organic grower lost certification of a portion of his property due to the presence of GM plant material. This case highlights the need for realistic thresholds in biological systems to enable coexistence of different production systems."

From these surveys the conclusion I have drawn is that the arrangements for co-existence in the market place in Australia are currently working well for delivery of GM and non-GM canola to customers.

10. Were canola plant material and/or the volunteer canola plants which germinated on Eagle Rest scientifically capable of:

i. Infecting, poisoning or doing other damage to soil, crops, plants and sheep on Eagle Rest?

ii. Transmitting genetic material to soil, crops, plants and sheep at Eagle Rest?

Canola contains glucosinolates, which on enzymatic breakdown produce isothiocyanates. Isothiocyanates can be harmful to various organisms in the soil or to animals if large amounts of canola foliage are eaten. Glucosinolates occur in all memebers of the Brassicaceae plant family (contains canola, mustard, cabbage, radish, turnip and other crop and vegetable species as well as numerous agricultural weeds) studied and in 15 other plant families (Fahey et al. 2001). The type and content of glucosinolates present vary among plant species. Glucosinolate content is also affected by plant age.

Fahey, J. W., Zalcmann, A. T., and Talalay, P. (2001). The chemical diversity and distribution of glucosinolates and isothiocyanates among plants. Phytochemistry 56, 5-51.

Among *Brassica napus* crops, glucosinolate content is generally lower in oilseed crops, such as canola, than it is in leafy crops, such as rutabaga (Velasco et al. 2008). Within the *Brassica* genus, *B. napus* has lower glucosinolate content in leaves than other members, such as *B. oxyrhina* and *B. carinata* (Potter et al. 1999)

Velasco, P., Soengas, P., Vilar, M., Cartea, M. E., and del Rio, M. (2008). Comparison of glucosinolate profiles in leaf and seed tissues of different *Brassica napus* crops. Journal of the American Society for Horticultural Science, 133, 551-558.

Potter, M. J., Davies, K., & Rathjen, A. J. (1998). Suppressive impact of glucosinolates in *Brassica* vegetative tissues on root lesion nematode *Pratylenchus neglectus*. Journal of Chemical Ecology 24, 67-80.

With respect to Roundup Ready canola, research has demonstrated there is no significant difference between Roundup Ready canola and conventional canola in glucosinolate content of grain (Daun 1999; Nickson and Hammond 2002)

Nickson, T.E., and Hammond, B.G. (2002). Case Study: canola tolerant to Roundup® herbicide. In Atherib, K., ed. Genetically Modified Crops. Assessing Safety. Taylor & Francis, pp 138-163.

Daun, J. K. (1999). Comparison of the Quality of Genetically modified Canola Varieties with Other Canola Varieties Grown in Western Canada in 1996/97. In New Horizons for an old crop Proceedings of the 10th International Rapeseed Congress, The Regional Institute Ltd, Canberra, Australia.
http://www.regional.org.au/au/gcirc/4/223.htm

The OGTR assessment of Roundup Ready canola (OGTR 2003) included data on glucosinolate content of Roundup Ready canola seed and a conventional canola variety Westar. The assessment concluded:

"The levels of the naturally occurring toxicants of canola, erucic acid and glucosinolates, do not vary between GM and conventional canola"

OGTR (2003) General Release of Roundup Ready® canola (*Brassica napus*) in Australia. Risk Assessment and Risk Management Plan. Final Version. DIR020/2002.

As glucosinolates do not differ between Roundup Ready and conventional canola and are lower in canola than in some other species of the same family, I consider it unlikely that a small number of canola plants will have a major effect on soil organisms.

With respect to other components of Roundup Ready canola, the OGTR assessment of Roundup Ready canola concluded:

"Compositional analyses of Roundup Ready® canola show no significant differences to conventional canola as a result of the genetic modifications"

The lack of differences in composition between Roundup Ready canola and conventional canola (with the exception of the proteins introduced by the genetic modification) make it highly unlikely that Roundup Ready canola volunteers would damage soil, or poison crop plants or livestock to any greater extent than conventional canola.

Canola is not pathogenic, so it would not be able to infect other plants or animals. Roundup Ready canola is not more pathogenic than conventional canola.

It is very unlikely that genetic material will be transferred from the Roundup Ready canola to sheep on Eagle Rest. Free DNA is readily degraded in the acidic stomach of mammals. Alexander et al. (2002; 2004) examined the fate of the canola plant DNA and the CPE EPSPS gene in processing and digestion.

Alexander, T. W., Sharma, R., Okine, E. K., Dixon, W. T., Forster, R. J., Stanford, K., and McAllister, T. A. (2002). Impact of feed processing and mixed ruminal culture on the fate of recombinant EPSP synthase and endogenous canola plant DNA. FEMS Microbiology Letters, 214, 263-269.

Alexander, T. W., Sharma, R., Deng, M. Y., Whetsell, A. J., Jennings, J. C., Wang, Y., Okine, E., Damgaard, D. and McAllister, T. A. (2004). Use of quantitative real-time and conventional PCR to assess the stability of the *cp4 epsps* transgene from Roundup Ready® canola in the intestinal, ruminal, and fecal contents of sheep. Journal of biotechnology, 112, 255-266.

Their research showed that canola plant DNA was rapidly degraded in ruminal batch cultures once released from cells. Plant DNA could not be detected in the supernatant of the culture. Likewise the CP4 EPSPS gene was present as an intact gene for 0.5 minutes in simulated digestive fluid at pH 7, but not at all at pH 5.

Where measurements were made on the solid component of the ruminal cultures, Plant DNA could be detected for extended periods of time (Alexander et al. 2002; Sharma et al. 2004) depending on the digestibility of the food source. However, this plant DNA is still inside plant cells and is degraded rapidly once the cells are broken.

Sharma, R., Alexander, T. W., John, S. J., Forster, R. J., and McAllister, T. A. (2004). Relative stability of transgene DNA fragments from GM rapeseed in mixed ruminal cultures. British Journal of Nutrition, 91, 673-682.

Some research has concluded that plant DNA sequences and sequences from CP4 EPSPS can be detected in pig organs, but not in sheep (Sharma et al. 2006). However, only one fragment of the gene could be detected in organs, indicating the gene was no longer intact. Also the authors point out that examination of genomic libraries from the organs that tested positive for the CP4 EPSPS gene fragments could find no evidence that the DNA had become incorporated into the cellular genome.

Sharma, R., Damgaard, D., Alexander, T. W., Dugan, M. E., Aalhus, J. L., Stanford, K., and McAllister, T. A. (2006). Detection of transgenic and endogenous plant DNA in digesta and tissues of sheep and pigs fed Roundup Ready canola meal. Journal of Agricultural and Food Chemistry, 54, 1699-1709.

A similar study examining pigs fed Bt maize feed (Mazza et al. 2005) identified fragments of maize genes in all tissues tested except muscle and fragments of the Cry1Ab gene in several tissues.

Mazza R, Soave M, Morlacchini M, Piva G, Marocco A (2005) Assessing the transfer of genetically modified DNA from feed to animal tissues. Transgenic Res 14: 775–784

However, other research (Walsh et al. 2011; 2012) has failed to identify the presence of DNA fragments of transgenic Cry genes in pig organs, although Walsh et al. (2012) were able to detect small fragments of rubisco, a maize gene, in various organs.

Walsh, M.C., Buzoianu, S.G., Gardiner, G.E., Rea, M.C., Gelencsér, E, Jánosi, A., Epstein, M.M., Ross, P.R. and Lawlor, P.G. (2011) Fate of Transgenic DNA from Orally Administered Bt MON810 Maize and Effects on Immune Response and Growth in Pigs. PLoS ONE 6(11): e27177. doi:10.1371/journal.pone.0027177

Walsh, M.C., Buzoianu, S.G., Rea, M.C., O'Donovan, O., Gelencsér, E., Ujhelyi, G., Ross, R.P, Gardiner, G. P. and Lawlor, P.G. (2012). Effects of feeding Bt MON810 maize to pigs for 110 days on peripheral immune response and digestive fate of the cry1Ab gene and truncated Bt toxin. PloS ONE, 7(5): e36141. doi:10.1371/journal.pone.0036141

The various studies indicate that small pieces of plant DNA can occasionally be absorbed from the digestive system of monogastric species, such as pigs, and be detected by sensitive PCR tests. High copy number DNA sequences are more likely to be detected than single copy DNA sequences. There is currently no evidence that the pieces of DNA are integrated into the animal's genome.

Canola can cross pollinate and share genetic material with other canola crops, black, white and oriental mustard, radish vegetables and with *Brassica rapa* and *Brassica oleracea* vegetable crops, such as cauliflower, broccoli, Brussels sprouts, cabbage, swede and turnips (Salisbury 2002). If any of these crops are grown at Eagle Rest there is a probability that crossing between the volunteer canola and these crops would occur, provided they flowered at the same time as the volunteer canola.

Salisbury P.A. (2002). Gene flow between *Brassica napus* and other Brassicaceae species. Report PAS 0201, Institute of Land and Food Resources, University of Melbourne.

The greatest probability of out-crossing would occur to *Brassica napus* crops, followed by *Brassica rapa* and *Brassica juncea* crops. Out-crossing to the other species is possible, but has not been identified under field conditions.

Volunteer canola could also cross pollinate with several weed species if they were present at Eagle Rest. These weeds include: feral and volunteer versions of the species mentioned above, *Raphanus raphanistrum*, *Hirschfeldia incana*, *Sinapis arvensis*, *Brassica fruticulosa*, *Brassica tournefortii*, *Diplotaxis murialis*, *Diplotaxis tenuifolia* and *Rapistrum rugosum* (Rieger et al. 1999; Salisbury 2002). Crosses between canola and *Raphanus raphanistrum*, *Hirschfeldia incana* and *Sinapis arvensis* have been identified in field experiments at low frequencies.

Rieger MA, Preston C, Powles SB (1999) Risks of gene flow from transgenic herbicide-resistant canola (Brassica napus) to weedy relatives in southern Australian cropping systems. Aust J Agric Res 50: 115-128

Horizontal gene transfer is common among bacteria. Plasmids containing genes are frequently transferred from one bacterium to another, even when the bacteria are of different species. Several studies have identified the incorporation of transgenic material from plants into bacteria at low frequencies under artificial conditions (Nielsen et al. 2007; Simpson et al. 2007). However, these examples are restricted to specific circumstances where bacterial antibiotic resistance genes were being taken up

by bacteria containing a non-function version of the same gene and then being selected by the antibiotic.

Nielsen, K. M., Johnsen, P. J., Bensasson, D., and Daffonchio, D. (2007). Release and persistence of extracellular DNA in the environment. Environmental Biosafety Research, 6, 37-54.

Simpson, D.J., Fry, J.C., Rogers, H.J., and Day, M.J. (2007) Transformation of *Acinetobacter baylyi* in non-sterile soil using recombinant plant nuclear DNA. Environmental Biosafety Research, 6, 101-112.

Free DNA is typically present in the environment for short periods of time before it is degraded, reducing the potential for it to be incorporated by soil bacteria. The current evidence suggests bacterial antibiotic genes used as selectable markers in transgenic plants are the most likely genes to be acquired by soil bacteria. Roundup Ready canola does not contain any antibiotic genes.

In the case of the CP4 EPSPS and *gox* genes present in Roundup Ready canola, these were originally bacterial genes. These genes are abundant in the environment and there is no obvious selection pressure to drive the acquisition by bacteria of the plant versions. Even if a bacterium were to acquire one of these genes, there would be no advantage to it and it is extremely unlikely that any harm would ensue.

11. What if any practical measures could have been taken by Mr Marsh to remove or reduce the presence of GM canola volunteers on Eagle Rest.

My understanding from news reports is that cut mature canola plants from windrows were moved by wind onto the farm of Mr Marsh. Based on my experience in weed management my recommendations for action to minimise the potential for GM canola volunteers on the farm would have been to take the following steps:

1. Remove as many of the cut canola plants as possible from the fields and burn them in a suitable place or otherwise dispose of them. This would greatly reduce the amount of spilt seed remaining in the fields.
2. After harvest, avoid cultivating the fields over summer. This will keep any spilt seed on the surface, where it may fatally germinate after summer rain, or if plants do establish they can be removed. In the Australian environment, most of the loss of canola from the seed bank occurs in the first 6 months after harvest.
3. Scout the fields during the next winter to detect any canola plants and control or remove them to stop seed set. Canola is easily identified from a distance as a volunteer in early spring because of their distinctive flowers. Failure to stop volunteer canola plants setting seed at this time will replenish the seed bank and lead to a continuing problem.
4. Further monitoring in subsequent years should be undertaken to ensure all the canola is removed.

12. Are there any scientific tests capable of detecting the presence of particles or residues of GM canola plant material in the soil, sheep, plants or the

cereal grain seed grown on Eagle Rest (apart from any volunteer canola seed which may have been harvested with the cereal crops):

i. **If the answer is yes, please describe the relevant scientific tests;**
ii. **If the answer is no, are no such tests capable of detecting GM canola particles or residues?**

There are two types of tests that are commonly used to detect GM canola material in various circumstances. These are an ELISA (enzyme-linked immunosorbent assay) test that detects the CP4 EPSPS protein produced by the gene introduced into Roundup Ready canola or various PCR-based tests that detect the inserted genetic material.

The ELISA test uses an antibody to detect presence of the C4 EPSPS protein. It can be conducted in a laboratory setting or in the field using the so-called stick tests. Because it relies on detecting the C4 EPSPS protein, it is best conducted on grain samples or living leaf tissue. Once cells have been broken and the protein degraded, the ELISA test is unable to reliably detect the protein. The ELISA test typically has a quantification limit of 0.1%, although tests can be calibrated for lower sensitivity.

PCR-based methods employ the polymerase chain reaction to amplify DNA from the genome. The choice of primers to be used will depend on the material to be tested and the likelihood of similar sequences being present that might provide false positives. Typically primers are selected that will amplify part of the introduced gene or of regulatory sequences, such as the gene promoter or termination sequences. PCR requires a properly equipped laboratory, is time consuming and expensive. The theoretical quantification limit is 0.005%, but the practical detection limit is much higher than this value.

Variations on the PCR technique can be used to make the process quicker or more sensitive. The use of qPCR can increase the theoretical quantification limit to 0.001%. qPCR uses fluorescent probes to detect the amplified DNA after each cycle of amplification. Through this process the amount of sequence can be quantified. qPCR requires very specialised laboratory equipment and is more expensive than conventional PCR.

PCR-based tests can be used on any material from which DNA can be extracted. This includes plants, animals and soil. PCR does not require the tissue to be alive at the time of collection, as DNA can be extracted from dead and dried plant material. There are techniques in handling material that can enhance the probability of detection of the target DNA in a sample, for example through sieving large grain to concentrate smaller materials that would be more likely to contain canola seed or seed components.

However, there are limitations to PCR-based methods. PCR-based tests suffer from false positives, unless the amplified DNA is sequenced. Therefore, positive and negative controls need to be included. The choice of primers has to be done with care. If the primers amplify sequences from other organisms, soil bacteria for example, this will lead to false positives.

13. Is it practical to screen canola seed from cereal grain seed? If so:

i. By what means can the canola seed be screened out?

ii. Is such screening method commonly practical in farming?

During the harvesting operation, farmers typically harvest weed seed with their crop seed. There are price penalties for delivering grain with too much weed seed present. Therefore, farmers on occasions do remove weed seed from their harvested grain in order to meet delivery specifications.

Where the weed seed is a considerably different size to the grain, such as canola in cereals, a well set-up harvester will remove most of the small seeds from the harvested grain through the sieves. If further cleaning is required, the grain can be put through seed cleaning equipment that uses a combination of blowers and sieves to separate seeds by weight and size. If desired, further cleaning can be conducted with a gravity table. The gravity table cleans seed by density. Under normal circumstances, a gravity table would not be used to clean small seeds from cereal grain, because it would be unnecessary.

All of this equipment is used in commercial farming practice in Australia. However, the amount of seed cleaning that occurs varies depending on the market for the grain and the specification for delivery. Grain cleaning is a balance between the need to deliver grain to set specifications and the cost of the grain cleaning.

I Christopher Preston have made all inquiries which I believe are desirable and appropriate and that no matters of significance which I regard as relevant have, to my knowledge, been withheld from the Court.

Christopher Preston

4th December 2013

(4)

Golden year: Darren Moir's in a crop of canola on his farm near the Stirling Ranges on Western Australia's south coast. More than one-third WA's canola crop is GM, but the percentage of the entire canola crop made up biotech varieties has languished in recent years.

CROPPING

Genetically modified canola edges up

EMMA FIELD, The Weekly Times
July 11, 2017 10:00pm

THERE has been a small increase in the amount of genetically

Nationally GM canola is predicted to make up 21 per cent of the entire crop, based on Australian Oilseed Federation figures estimating 2.3 million hectares of canola was planted.

There has been a relatively rapid uptake of Roundup Ready varieties following the lifting of a moratorium on commercial GM crops in 2008 in Victoria and NSW and in 2010 in Western Australia.

RELATED COVERAGE: DRY START TO HIT NATIONAL CROP HARD

However in the past three years the growth in biotech canola as a percentage of the entire crop has slowed. In the past three years it has made up 20-21 per cent.

This year Monsanto predicts growers in the biggest canola growing state, Western Australia, have planted, 363,091ha, up 5 per cent on last year, and GM is tipped to make up 34 per cent of its canola crop.

There was a 22 per cent increase in Victoria's GM canola planting from last season to 56,000ha, however Roundup Ready varieties make up 14 per cent of the entire crop, while in NSW biotech varieties makes up 11 per cent of the canola crop.

Monsanto Australia marketing lead Keryn McLean said given the issues with seed production and shortages of hybrids GM canola the company was satisfied with the relatively modest increase in biotech plantings this year.

Earlier this year growers struggled to source hybrid canola seed after poor seed production last season and a spike in planned plantings.

Ms McLean said despite the shortage there was strong demand for GM canola from growers who were "seeing value in the weed control that Roundup Ready offers".

Australian Oilseeds Federation executive officer Nick Goddard said "resistant rye grass is not as bad (on the east coast) as it is in WA, so the need for Roundup Ready canola is lower".

Dookie agronomist Bruce Larcomb said in the past growers had issues marketing GM canola, but these have been overcome.

He said this season growers in his district has been hit by Roundup Ready hybrid seed shortages.

"This year, 30 per of (the cropping) area would have been hybrid canola but they couldn't get the seed so it's about 15 per cent," he said.