Roundup Ready® Canola

Expert Report

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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 x 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.

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[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 <u>in the field</u>, 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."*

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[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.

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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).

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- 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
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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 règlementation 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)